Federal Register
Vol. 69, No. 238
Monday, December 13, 2004

The Regulatory Plan

INTRODUCTION TO THE FALL 2004 REGULATORY PLAN

Federal regulation is a fundamental instrument of national policy. It is one of the three major tools — in addition to spending and taxing — used to implement policy. It is used to advance numerous public objectives, including homeland security, environmental protection, educational quality, food safety, transportation safety, health care quality, equal employment opportunity, energy security, immigration control, and consumer protection. The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) is responsible for overseeing and coordinating the Federal Government's regulatory policies.

The Regulatory Plan is published as part of the fall edition of the Unified Agenda of Federal Regulatory and Deregulatory Actions, and serves as a statement of the Administration's regulatory and deregulatory policies and priorities. The purpose of the Plan is to make the regulatory process more accessible to the public and to ensure that the planning and coordination necessary for a well-functioning regulatory process occurs. The Plan identifies regulatory priorities and contains information about the most significant regulatory actions that agencies expect to undertake in the coming year. An accessible regulatory process enables citizen centered service, which is a vital part of the President's Management Agenda.

Federal Regulatory Policy

The Bush Administration supports Federal regulations that are sensible and based on sound science, economics, and the law. Accordingly, the Administration is striving for a regulatory process that adopts new rules when markets fail to serve the public interest, simplifies and modifies existing rules to make them more effective or less costly or less intrusive, and rescinds outmoded rules whose benefits do not justify their costs. In pursuing this agenda, OIRA has adopted an approach based on the principles of regulatory analysis and policy espoused in Executive Order 12866, signed by President Clinton in 1993.

Effective regulatory policy is not uniformly pro-regulation or anti-regulation. It begins with the authority granted under the law. Within the discretion available to the regulating agency by its statutory authority, agencies apply a number of principles articulated in Executive Order 12866 (as well as other orders, such as Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' signed May 18, 2001, 66 FR 28355), in order to design regulations that achieve their ends in the most efficient way. This means bringing to bear on the policy problem sound economic principles, the highest quality information, and the best possible science. This is not always an easy task, as sometimes economic and scientific information may point in very different directions, and therefore designing regulations does not mean just the rote application of quantified data to reach policy decisions. In making regulatory decisions, we expect agencies to consider not only benefit and cost items that can be quantified and expressed in monetary units, but also other attributes and factors that cannot be integrated readily in a benefit-cost framework, such as fairness and privacy. However, effective regulation is the result

of the careful use of all available high-quality data, and the application of broad principles established by the President.

In pursuing this goal of establishing an effective, results-oriented regulatory system, the Bush Administration has increased the level of public involvement and transparency in its review and clearance of new and existing regulations.

For new rulemakings and programs, OIRA has enhanced the transparency of OMB's regulatory review process. OIRA's website now enables the public to find information on rules that are formally under review at OMB, have recently been cleared, or have been returned to agencies for reconsideration. OIRA has also increased the amount of information available on its website. In addition to information on meetings and correspondence, OIRA makes available communications from the OIRA Administrator to agencies, including ''prompt letters,'' ''return letters,'' and ''post clearance letters,'' as well as the Administrator's memorandum to the President's Management Council (September 20, 2001) on presidential review of agency rulemaking by OIRA.

For existing rulemakings, OIRA has initiated a modest series of calls for reform nominations in 2001, 2002, and 2004. In the draft 2001 annual Report to Congress on the Costs and Benefits of Federal Regulation, OMB asked for suggestions from the public about specific regulations that should be modified in order to increase net benefits to the public. We received suggestions regarding 71 regulations, 23 of which OMB designated as high priorities. After a similar call for reforms in the 2002 draft Report, OMB received recommendations on 316 distinct rules, guidance documents, and paperwork requirements from over 1,700 commenters. Of the 156 reform nominations that OMB determined were ripe for consideration by Cabinet-level agencies and the Environmental Protection Agency, agencies have decided to pursue 34 rules and 11 guidance documents for reform, are undecided about 26 rules and 4 guidance documents, and have decided not to pursue reform of 62 rules and 19 guidance documents at this time. Finally, in the 2004 draft Report, OMB requested public nominations of promising regulatory reforms relevant to the manufacturing sector. In particular, commenters were asked to suggest specific reforms to rules, guidance documents, or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty, and increasing flexibility. With the publication of the final 2004 Report, OMB will discuss the next steps in these regulatory reform initiatives and will work closely with the agencies to ensure a robust reform process. For further information, all of these Reports are available on OIRA's website at http://www.whitehouse.gov/omb/inforeg/regpol.html.

The Bush Administration has also moved aggressively to establish basic quality performance goals for all information disseminated by Federal agencies, including information disseminated in support of proposed and final regulations. The Federal agencies issued guidelines on October 1, 2002 under the Information Quality Act to ensure the ''quality, objectivity, utility, and integrity'' of all information disseminated by Federal agencies. Under these guidelines, Federal agencies are taking appropriate steps to incorporate the information quality performance standards into agency information dissemination practices, and developing pre-dissemination review procedures to substantiate the quality of information before it is disseminated. Under the agency information quality guidelines, ''affected persons'' can request that the agencies correct information if they believe that scientific, technical, economic, statistical or other information disseminated does not meet the agency and OMB standards. If the requestor is dissatisfied with the initial agency response to a correction request, an appeal opportunity is provided

by the agencies. To date, agencies have received and responded to approximately 30 complaints that appear to be stimulated by the Information Quality Law. Although we are still in the early phases of implementation, agencies are aware that ensuring the high quality of government information dissemination is a high priority of the Administration. Further information on OIRA's activities implementing the Information Quality Act is available on OIRA's website at http://www.whitehouse.gov/omb/inforeg/infopoltech.html.

As part of its efforts to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal agencies, OMB has proposed guidance to realize the benefits of meaningful peer review of the most important science disseminated by the Federal government. The Bulletin on Peer Review establishes minimum standards for when peer review is required and how intensive the peer review should be for different information. The Bulletin requires the most rigorous form of peer review for highly influential scientific assessments. Further information on peer review is available on OIRA's website at http://www.whitehouse.gov/omb/inforeg/infopoltech.html.

In addition, the Administration is currently increasing the impact of OMB's analytical perspective. The OIRA Administrator is using the ''prompt letter'' to agencies as a new way to suggest promising regulatory priorities, and highlight issues that may warrant regulatory attention. Though not meant to have legal authority, these prompt letters are designed to bring issues to the attention of agencies in a transparent manner that permits public scrutiny and debate. Prompt letters may highlight regulations that should be pursued, rescinded, revised, or further investigated. For example, OIRA's first set of prompts has suggested lifesaving opportunities at FDA, NHTSA, OSHA and EPA. In a letter to FDA, OIRA suggested that priority be given to completing a promising rulemaking (started in the previous Administration), to require that food labels report the trans-fatty acid content of foods. (Trans-fats are now recognized as a significant contributor to coronary heart disease.) FDA has now issued a final rule that will require the disclosure of trans-fat content in food labels. Similarly, OSHA has responded to an OIRA prompt letter by notifying each employer in the country of the lifesaving effects and cost-effectiveness of automatic defibrillators, a lifesaving technology designed to save lives during sudden cardiac arrest. A list of all of the prompt letters is available at OIRA's website at http://www.whitehouse.gov/omb/inforeg/prompt__letter.html.

In addition to increasing the level of public involvement and transparency in its review of regulations, the Bush Administration has sought to enhance the role of analysis in the development of effective regulations. On September 17, 2003, OMB issued revised guidance to agencies on regulatory analysis.[1] Key features of the revised guidance include more emphasis on cost-effectiveness, more careful evaluation of qualitative and intangible values, and a greater emphasis on considering the uncertainty inherent in estimates of impact. OIRA was very interested in updating the guidance in light of these and other innovations now commonplace in the research community. The 2004 Regulatory Plan continues OIRA's effort to ensure coordination across Federal agencies in pursuing analytically sound regulatory policies.

The Administration's 2004 Regulatory Priorities

With regard to Federal regulation, the Bush Administration's objective is quality, not quantity. Those rules that are adopted promise to be more effective, less intrusive, and more cost-effective in achieving national objectives while demonstrating greater durability in the face of political and legal attack. The Regulatory Plan is integral to enhancing the quality of

Federal regulations, and OMB seeks to ensure that the public is provided with the information needed to understand and comment on the Federal regulatory agenda. Accordingly, the 2004 Regulatory Plan highlights the following themes:

- Regulations that are particularly good examples of the Administration's ''smart'' regulation agenda to streamline regulations and reporting requirements, which is a key part of the President's economic plan.

- Regulations that are of particular concern to small businesses.

- Regulations that respond to public nominations submitted to OMB in 2001 or 2002.

Conclusion

Smarter regulatory policies, created through public participation, transparency, and cooperation across Federal agencies, are a key Administration objective. The following department and agency plans provide further information on regulatory priorities. All agencies' plans are a reflection of the Administration's Federal Regulatory Policy objectives, which aim at implementing an effective and results-oriented regulatory system.

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[1] See Circular A-4, ''Regulatory Analysis,'' published as part of OMB's 2003 Report to Congress on the Costs and Benefits of Federal Regulations. The report is available on OMB's website at: http://www.whitehouse.gov/omb/inforeg/2003__cost-ben__final__rpt.pdf

DEPARTMENT OF AGRICULTURE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
1	National Organic Program: Add Standards for the Organic Certification of Wild Captured Aquatic Animals (TM-01-08)	0581–AB97	Prerule Stage
2	Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Fish, Perishable Agricultural Commodities, and Peanuts (LS-03-04)	0581–AC26	Final Rule Stage
3	Revision of the Nursery Stock Regulations (Q.37)	0579–AB85	Prerule Stage
4	Foot-and-Mouth Disease; Payment of Indemnity	0579–AB34	Final Rule Stage
5	Chronic Wasting Disease in Elk and Deer; Interstate Movement Restrictions and Payment of Indemnity	0579–AB35	Final Rule Stage
6	Senior Farmers' Market Nutrition Program (SFMNP)	0584–AD35	Proposed Rule Stage
7	FSP: Discretionary Quality Control Provisions of Title IV of Public Law 107-171	0584–AD37	Proposed Rule Stage
8	Special Nutrition Programs: Fluid Milk Substitutions	0584–AD58	Proposed Rule Stage
9	Child and Adult Care Food Program: Improving Management and Program Integrity	0584–AC24	Final Rule Stage
10	Commodity Supplemental Food Program (CSFP): Plain Language, Program Accountability, and Program Flexibility	0584–AC84	Final Rule Stage
11	FSP: High Performance Bonuses	0584–AD29	Final Rule Stage
12	FSP: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD30	Final Rule Stage
13	FSP: Non-Discretionary Quality Control Provisions of Title IV of Public Law 107-171	0584–AD31	Final Rule Stage
14	FSP: Employment and Training Program Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD32	Final Rule Stage
15	Direct and Discretionary Certification in the School Meals Programs	0584–AD60	Final Rule Stage
16	Performance Standards for Pumped or Massaged Bacon	0583–AC49	Proposed Rule Stage
17	Egg Products Inspection Regulations	0583–AC58	Proposed Rule Stage
18	Food Standards; General Principles and Food Standards Modernization	0583–AC72	Proposed Rule Stage
19	Performance Standard for Chilling of Ready-To-Cook Poultry	0583–AC87	Proposed Rule Stage
20	Performance Standards for the Production of Processed Meat and Poultry Products	0583–AC46	Final Rule Stage
21	Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products	0583–AC60	Final Rule Stage
22	Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle	0583–AC88	Final Rule Stage
23	State Petitions for Inventoried Roadless Area Management	0596–AC10	Proposed Rule Stage
24	National Forest System Land Management Planning	0596–AB86	Final Rule Stage
25	Emergency Watershed Protection Program	0578–AA30	Final Rule Stage
26	Technical Service Provider Assistance	0578–AA35	Final Rule Stage
27	Conservation Security Program	0578–AA36	Final Rule Stage
28	Grassland Reserve	0578–AA38	Final Rule Stage
29	Confidentiality of Conservation Program Information	0578–AA40	Final Rule Stage

DEPARTMENT OF COMMERCE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
30	Designate Critical Habitat for 7 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in California	0648–AO04	Proposed Rule Stage
31	Designate Critical Habitat for 13 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington, Oregon and Idaho	0648–AQ77	Proposed Rule Stage
32	Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs—Crab Rationalization Program	0648–AS47	Proposed Rule Stage

DEPARTMENT OF COMMERCE (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
33	Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementation of Regulations	0648–AS83	Proposed Rule Stage
34	Listing Determinations for 27 Evolutionarily Significant Units (ESUs) of West Coast Salmon and Oncorhynchus Mykiss	0648–AR93	Final Rule Stage

DEPARTMENT OF EDUCATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
35	Reauthorization of the Individuals With Disabilities Education Act	1820–AB54	Prerule Stage

DEPARTMENT OF ENERGY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
36	Energy Efficiency Standards for Residential Furnaces and Boilers	1904–AA78	Proposed Rule Stage
37	Energy Efficiency Standards for Electric Distribution Transformers	1904–AB08	Proposed Rule Stage
38	Energy Efficiency Standards for Commercial Unitary Air Conditioners and Heat Pumps	1904–AB09	Proposed Rule Stage
39	Worker Safety and Health	1901–AA99	Proposed Rule Stage
40	Radiation Protection of the Public and the Environment	1901–AA38	Final Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
41	Food Labeling; Prominence of Calories	0910–AF22	Prerule Stage
42	Food Labeling; Serving Sizes of Products That Can Reasonably Be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes	0910–AF23	Prerule Stage
43	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Certain Biological Drugs, and Animal Drugs	0910–AA49	Proposed Rule Stage
44	Substances Prohibited From Use in Animal Food or Feed	0910–AF46	Proposed Rule Stage
45	Use of Materials Derived From Cattle In Human and Animal Medical Products	0910–AF54	Proposed Rule Stage
46	Requirements for Human and Animal Medical Products Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF55	Proposed Rule Stage
47	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products	0910–AA94	Final Rule Stage
48	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97	Final Rule Stage
49	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement	0910–AB28	Final Rule Stage
50	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)	0910–AB76	Final Rule Stage
51	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88	Final Rule Stage
52	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14	Final Rule Stage
53	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35	Final Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
54	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC39	Final Rule Stage
55	Registration of Food and Animal Feed Facilities	0910–AC40	Final Rule Stage
56	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41	Final Rule Stage
57	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol	0910–AF18	Final Rule Stage
58	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47	Final Rule Stage
59	Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF48	Final Rule Stage
60	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P)	0938–AG82	Proposed Rule Stage
61	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-P)	0938–AH17	Proposed Rule Stage
62	Hospice Care—Conditions of Participation (CMS-3844-P)	0938–AH27	Proposed Rule Stage
63	Organ Procurement Organization Conditions for Coverage (CMS-3064-P)	0938–AK81	Proposed Rule Stage
64	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26	Proposed Rule Stage
65	Revisions to the Oversight and Validation Program for Accrediting Organizations Approved for Deeming Authority (CMS-2255-P)	0938–AN62	Proposed Rule Stage
66	Medicare Advantage Program—Title II (CMS-4069-F)	0938–AN06	Final Rule Stage
67	Medicare Drug Benefit Effective Calendar Year 2006—Title I (CMS-4068-F)	0938–AN08	Final Rule Stage

DEPARTMENT OF HOMELAND SECURITY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
68	Homeland Security Information Sharing	1601–AA25	Proposed Rule Stage
69	Procedures for Handling Critical Infrastructure Information	1601–AA14	Final Rule Stage
70	Regulations Implementing the Support Antiterrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act)	1601–AA15	Final Rule Stage
71	Department of Homeland Security (DHS) Human Resources Management System	1601–AA21	Final Rule Stage
72	Commercial Fishing Industry Vessels (USCG-2003-16158)	1625–AA77	Proposed Rule Stage
73	Post Casualty Drug and Alcohol Testing (USCG-2001-8773)	1625–AA27	Final Rule Stage
74	United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT); Auth. To Collect Biometric Data From Addit'l Travelers and Expansion to 50 Most Highly Trafficked Land Border Ports	1650–AA00	Final Rule Stage
75	Establishing Procedures for Recertification of Schools Approved by the Student and Exchange Visitor Program (SEVP) to Enroll F or M Nonimmigrant Students	1653–AA42	Prerule Stage

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
76	Consolidated Plan Amendments (FR-4923)	2501–AD07	Proposed Rule Stage
77	Treble Damages for Failure To Engage in Loss Mitigation (FR-4553)	2501–AC66	Final Rule Stage
78	Housing Counseling Program (FR-4798)	2502–AH99	Proposed Rule Stage
79	Empowerment Zones: Resident Benefit and Economic Development Standards for Grants (FR-4853)	2506–AC16	Proposed Rule Stage

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
80	Capital Fund Program (FR-4880)	2577–AC50	Proposed Rule Stage
81	Operating Fund Allocation Formula (FR-4874)	2577–AC51	Proposed Rule Stage
82	Native American Housing Assistance and Self-Determination Act (NAHASDA): Revisions to the Indian Housing Block Grant Program Formula (FR-4938)	2577–AC57	Proposed Rule Stage
83	Project-Based Voucher Program (FR-4636)	2577–AC25	Final Rule Stage

DEPARTMENT OF THE INTERIOR

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
84	Valuation of Oil From Indian Leases	1010–AD00	Proposed Rule Stage
85	Grazing Administration—Exclusive of Alaska	1004–AD42	Final Rule Stage

DEPARTMENT OF JUSTICE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
86	Nondiscrimination on the Basis of Disability in Public Accommodations and Commercial Facilities	1190–AA44	Prerule Stage
87	Nondiscrimination on the Basis of Disability in State and Local Government Services	1190–AA46	Prerule Stage

DEPARTMENT OF LABOR

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
88	Family and Medical Leave Act of 1993; Conform to the Supreme Court's Ragsdale Decision	1215–AB35	Proposed Rule Stage
89	Child Labor Regulations, Orders, and Statements of Interpretation (ESA/W-H)	1215–AA09	Final Rule Stage
90	Revision to the Department of Labor Benefit Regulations for Trade Adjustment Assistance for Workers Under the Trade Act of 1974, as Amended	1205–AB32	Proposed Rule Stage
91	Revision to the Department of Labor Regulations for Petitions and Determinations of Eligibility To Apply for Trade Adjustment Assistance for Workers and Issuance of Regulations for the Alternative TAA	1205–AB40	Proposed Rule Stage
92	Labor Certification Process for the Permanent Employment of Aliens in the United States	1205–AA66	Final Rule Stage
93	Rulemaking Relating to Termination of Abandoned Individual Account Plans	1210–AA97	Proposed Rule Stage
94	Amendment of Regulation Relating to Definition of Plan Assets—Participant Contributions	1210–AB02	Proposed Rule Stage
95	Regulations Implementing the Health Care Access, Portability, and Renewability Provisions of the Health Insurance Portability and Accountability Act of 1996	1210–AA54	Final Rule Stage
96	Prohibiting Discrimination Against Participants and Beneficiaries Based on Health Status	1210–AA77	Final Rule Stage
97	Asbestos Exposure Limit	1219–AB24	Proposed Rule Stage
98	Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners	1219–AB29	Final Rule Stage
99	Occupational Exposure to Crystalline Silica	1218–AB70	Prerule Stage
100	Occupational Exposure to Hexavalent Chromium (Preventing Occupational Illness: Chromium)	1218–AB45	Proposed Rule Stage

DEPARTMENT OF LABOR (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
101	Assigned Protection Factors: Amendments to the Final Rule on Respiratory Protection	1218–AA05	Final Rule Stage
102	Standards Improvement (Miscellaneous Changes) for General Industry, Marine Terminals, and Construction Standards (Phase II)	1218–AB81	Final Rule Stage
103	Uniformed Services Employment and Reemployment Rights Act Regulations	1293–AA09	Proposed Rule Stage

DEPARTMENT OF TRANSPORTATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
104	Aging Aircraft Program (Widespread Fatigue Damage)	2120–AI05	Proposed Rule Stage
105	Enhanced Airworthiness Program for Airplane Systems (EAPAS) and SFAR 88	2120–AI31	Proposed Rule Stage
106	Aging Aircraft Safety—Development of TC and STC Holder Data	2120–AI32	Proposed Rule Stage
107	Flight Simulation Device Qualification	2120–AH07	Final Rule Stage
108	Transport Airplane Fuel Tank Flammability Reduction	2120–AI23	Final Rule Stage
109	Unified Registration System	2126–AA22	Proposed Rule Stage
110	Hours of Service of Drivers; Supporting Documents	2126–AA76	Proposed Rule Stage
111	Tire Pressure Monitoring Systems	2127–AJ23	Proposed Rule Stage
112	Whistle Bans at Highway-Rail Grade Crossings	2130–AA71	Final Rule Stage

DEPARTMENT OF THE TREASURY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
113	Implementation of a Revised Basel Capital Accord (Basel II)	1557–AC91	Proposed Rule Stage

DEPARTMENT OF VETERANS AFFAIRS

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
114	Enrollment—Provision of Hospital and Outpatient Care to Veterans—Subpriorities of Priority Categories 7 and 8 and Enrollment Level Decision	2900–AL51	Final Rule Stage

ENVIRONMENTAL PROTECTION AGENCY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
115	Endocrine Disruptor Screening Program (EDSP); Chemical Selection Approach for Initial Round of Screening	2070–AD59	Prerule Stage
116	Notification of Chemical Exports Under TSCA Section 12(b)	2070–AJ01	Prerule Stage
117	Lead-Based Paint Activities; Voluntary Program for Renovation and Remodeling	2070–AJ03	Prerule Stage
118	Clean Air Fine Particle Implementation Rule	2060–AK74	Proposed Rule Stage
119	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Allowables Plantwide Applicability Limit (PAL), Aggregation, and Debottlenecking	2060–AL75	Proposed Rule Stage

ENVIRONMENTAL PROTECTION AGENCY (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
120	Pesticides; Data Requirements for Conventional Chemicals	2070–AC12	Proposed Rule Stage
121	Pesticides; Emergency Exemption Process Revisions	2070–AD36	Proposed Rule Stage
122	Acceptability of Research Using Human Subjects	2070–AD57	Proposed Rule Stage
123	Increase Metals Reclamation From F006 Waste Streams	2050–AE97	Proposed Rule Stage
124	Regulatory Amendments to the F019 Hazardous Waste Listing To Exclude Wastewater Treatment Sludges From Chemical Conversion Coating Process (Zinc Phosphating) of Automobile Bodies of Aluminum	2050–AG15	Proposed Rule Stage
125	Toxics Release Inventory Reporting Burden Reduction Rule	2025–AA14	Proposed Rule Stage
126	Clean Air Visibility Rule	2060–AJ31	Final Rule Stage
127	Clean Air Mercury Rule—Electric Utility Steam Generating Units	2060–AJ65	Final Rule Stage
128	Clean Air Ozone Implementation Rule (Part 1 and Part 2)	2060–AJ99	Final Rule Stage
129	Nonattainment Major New Source Review (NSR)	2060–AM59	Final Rule Stage
130	Test Rule; Testing of Certain High Production Volume (HPV) Chemicals	2070–AD16	Final Rule Stage
131	NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors (Phase I Final Replacement Standards and Phase II)	2050–AE01	Final Rule Stage
132	Hazardous Waste Manifest Regulation	2050–AE21	Final Rule Stage
133	Standardized Permit for RCRA Hazardous Waste Management Facilities	2050–AE44	Final Rule Stage
134	RCRA Burden Reduction Initiative	2050–AE50	Final Rule Stage
135	Recycling of Cathode Ray Tubes (CRTs): Changes to Hazardous Waste Regulations	2050–AE52	Final Rule Stage
136	Hazardous Waste Management System; Modification of the Hazardous Waste Program: Mercury-Containing Equipment	2050–AG21	Final Rule Stage
137	National Primary Drinking Water Regulations: Groundwater Rule	2040–AA97	Final Rule Stage
138	National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule	2040–AD37	Final Rule Stage
139	National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule	2040–AD38	Final Rule Stage
140	Minimizing Adverse Environmental Impact From Cooling Water Intake Structures at Existing Facilities Under Section 316(b) of the Clean Water Act, Phase 3	2040–AD70	Final Rule Stage
141	Cross-Media Electronic Reporting (ER) and Recordkeeping Rule (CROMERRR)	2025–AA07	Final Rule Stage

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
142	Coordination of Retiree Health Benefits With Medicare and State Health Benefits	3046–AA72	Final Rule Stage

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
143	Federal Records Management	3095–AB16	Proposed Rule Stage

PENSION BENEFIT GUARANTY CORPORATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
144	Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets	1212–AA55	Proposed Rule Stage
145	Transparency of Information Related to Plan Liabilities	1212–AB01	Proposed Rule Stage

SMALL BUSINESS ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
146	Small Business Lending Companies Regulations	3245–AE14	Proposed Rule Stage
147	Proposed Small Business Innovation Research (SBIR) Policy Directive	3245–AF21	Proposed Rule Stage
148	Small Business Technology Transfer Program Policy Directive	3245–AE96	Final Rule Stage
149	Small Business Government Contracting Programs	3245–AF12	Final Rule Stage

SOCIAL SECURITY ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
150	Privacy and Disclosure of Official Records and Information (711P)	0960–AE88	Proposed Rule Stage
151	Federal Salary Offset (Withholding a Portion of a Federal Employee's Salary To Collect a Delinquent Debt Owed to the Social Security Administration) (721P)	0960–AE89	Proposed Rule Stage
152	Exemption of Work Activity as a Basis for a Continuing Disability Review (Ticket to Work and Work Incentives Improvement Act of 1999) (725P)	0960–AE93	Proposed Rule Stage
153	Revised Medical Criteria for Evaluating Immune System Disorders (804P)	0960–AF33	Proposed Rule Stage
154	Amendments to the Ticket to Work and Self-Sufficiency Program (967P)	0960–AF89	Proposed Rule Stage
155	Elimination of Parent-to-Child Deeming for Individuals Who No Longer Meet the Definition of Spouse of the Natural or Adoptive Parent (793P)	0960–AF96	Proposed Rule Stage
156	Rules for Helping Blind and Disabled Individuals Achieve Self-Support (506P)	0960–AG00	Proposed Rule Stage
157	Medicare Prescription Drug Premium and Cost-Sharing (1024P)	0960–AG03	Proposed Rule Stage
158	Civil Monetary Penalties, Assessments, and Recommended Exclusions (2362P)	0960–AG08	Proposed Rule Stage
159	Representative Payment; Additional Protections for Persons With Representative Payees (2422P)	0960–AG09	Proposed Rule Stage
160	Issuance of Work Report Receipts, Payment of Trial Work Period Months After a Fraud Conviction and Changes to the Student Earned Income Exclusion (2502P)	0960–AG10	Proposed Rule Stage
161	Income Related Medicare Part B Premium Subsidy Reduction (2101P)	0960–AG11	Proposed Rule Stage
162	Denial of Title II Benefits to Persons Fleeing Prosecution, Custody, or Confinement, and to Persons Violating Probation or Parole (2222P)	0960–AG12	Proposed Rule Stage
163	Privacy and Disclosure of Official Records and Information; Availability of Information and Records to the Public (2562P)	0960–AG14	Proposed Rule Stage
164	Revised Medical Criteria for Evaluating Malignant Neoplastic Diseases (399F)	0960–AD67	Final Rule Stage
165	Elimination of Clothing From the Definitions of Income and In-Kind Support and Maintenance, Exclusions of One Automobile, and Household Goods and Personal Effects Under SSI From Resources (950F)	0960–AF84	Final Rule Stage
166	Continuation of Benefit Payments to Certain Individuals Who Are Participating in a Program of Vocational Rehabilitation Services, Employment Services, or Other Support Services (925F)	0960–AF86	Final Rule Stage
167	Administrative Review Process; Incorporation by Reference of Oral Findings of Fact and Rationale in Wholly Favorable Written Decisions (964I)	0960–AF92	Final Rule Stage
168	Expanded Authority for Cross-Program Recovery of Benefit Overpayments (2221F)	0960–AG06	Final Rule Stage

CONSUMER PRODUCT SAFETY COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
169	Flammability Standard for Upholstered Furniture	3041–AB35	Proposed Rule Stage
170	Proposed Standard To Address Open-Flame Ignition of Mattresses/Bedding	3041–AC02	Proposed Rule Stage

[FR Doc. 04–26308 Filed 12–10–04; 8:45 am]
BILLING CODE 6820–27–S

DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

USDA is a primary issuer of regulations within the Federal Government covering a broad range of issues. Within the rulemaking process is the department-wide effort to reduce burden on participants and program administrators alike by focusing on improving program outcomes, and particularly on achieving the performance measures specified in the USDA and agency Strategic Plans. Significant focus is being placed on efficiencies that can be achieved through eGov activities, the migration to efficient electronic services and capabilities, and the implementation of focused, efficient information collections necessary to support effective program management. Important areas of activity include the following:

- USDA will develop new regulations and review existing regulations to prevent the introduction or spread of pests and diseases into the United States. In addition, it will continue to work to minimize impediments to trade while protecting U.S. animal and plant resources.
- In the area of food safety, USDA will continue to develop science-based regulations that improve the safety of meat, poultry, and egg products in the least burdensome and most cost-effective manner. Regulations will be revised to address emerging food safety challenges, streamlined to remove excessively prescriptive regulations, and updated to be made consistent with hazard analysis and critical control point principles.
- As changes are made for the nutrition assistance programs, USDA will work to foster actions that will help improve diets and particularly to prevent and reduce overweight and obesity. In 2005, this will include implementing refinements to the nutrition assistance programs included in reauthorization statutes as well as additional changes that will promote healthful eating and physical activity, while also improving the efficiency and integrity of program operations.
- USDA will continue to finalize rulemaking related to implementing the Farm Security and Rural Investment Act of 2002 (Farm Bill). Some of the Farm Bill rules have already been issued in final including those for the Conservation Reserve Program and the Environmental Quality Incentives Program. Other programs, such as the Conservation Security Program and the Grasslands Reserve Program, were implemented with interim final rules on which the public has submitted comments. Our focus in 2005 will be to make clarifications and modifications in response to these comments and to promulgate these rules in final.

Reducing Paperwork Burden on Customers

USDA has made substantial progress in implementing the goal of the Paperwork Reduction Act of 1995 to reduce the burden of information collection on the public. To meet the requirements of the Government Paperwork Elimination Act (GPEA), agencies across USDA are providing electronic alternatives to their traditionally paper-based customer transactions. As a result, producers increasingly have the option to electronically file forms and all other documentation online. To facilitate the expansion of electronic government and promote compliance with GPEA, USDA implemented an electronic authentication capability that allows customers to ''sign-on'' once and conduct business with all USDA agencies. Underlying these efforts are ongoing analyses to identify and eliminate redundant data collections and streamline collection instructions. The end result of implementing these initiatives is better service to our customers enabling them to choose when and where to conduct business with USDA.

The Role of Regulations

The programs of USDA are diverse and far reaching, as are the regulations that attend their delivery. Regulations codify how USDA will conduct its business, including the specifics of access to, and eligibility for, USDA programs. Regulations also specify the responsibilities of State and local governments, private industry, businesses, and individuals that are necessary to comply with their provisions.

The diversity in purpose and outreach of our programs contributes significantly to USDA being near the top of the list of departments that produce the largest number of regulations annually. These regulations range from nutrition standards for the school lunch program, to natural resource and environmental measures governing national forest usage and soil conservation, to regulations protecting American agribusiness (the largest dollar value contributor to exports) from the ravages of domestic or foreign plant or animal pestilence, and they extend from farm to supermarket to ensure the safety, quality, and availability of the Nation's food supply.

Many regulations function in a dynamic environment, which requires their periodic modification. The factors determining various entitlement, eligibility, and administrative criteria often change from year to year. Therefore, many significant regulations must be revised annually to reflect changes in economic and market benchmarks.

Almost all legislation that affects USDA programs has accompanying regulatory needs, often with a significant impact. The Farm Security and Rural Investment Act of 2002, Public Law 107-171; the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108-265; and the Agricultural Risk Protection Act of 2000, Public Law 106-224, affect most agencies of USDA resulting in the modification, addition, or deletion of many programs. These statutes set in motion rulemakings that provide for improvements in market loss and conservation assistance, crop and livestock disease and pest protection, marketing enhancements, pollution control, research and development for biomass, and refinements to the nutrition assistance programs to help ensure the best practical outcomes for beneficiaries and the taxpayer.

Major Regulatory Priorities

This document represents summary information on prospective significant regulations as called for in Executive Order 12866. The following agencies are represented in this regulatory plan, along with a summary of their mission and key regulatory priorities for 2005:

Food and Nutrition Service

Mission: FNS increases food security and reduces hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthful diet, and nutrition education in a manner that supports American agriculture and inspires public confidence.

Priorities: In addition to responding to provisions of legislation authorizing and modifying Federal nutrition assistance programs, FNS' 2004 regulatory plan supports the broad goals and objectives in the Agency's strategic plan that include:

Improved

Nutrition of Children and Low-Income People. This goal represents FNS' efforts to improve nutrition by providing access to program benefits (Food Stamps, WIC food vouchers and nutrition services, school meals, commodities, and State administrative funds), nutrition education, and quality meals and other benefits. It includes three major objectives: 1) Improved food security, which reflects nutrition assistance benefits issued to program participants; 2) FNS program participants make healthy food choices, which represents our efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion; and 3) improved nutritional quality of meals, food packages, commodities, and other program benefits, which represents our efforts to ensure that program benefits meet the appropriate nutrition standards to effectively improve nutrition for program participants.

In support of this goal, FNS plans to finalize rules implementing provisions of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), as well as under other authorities, that will give States additional new flexibility to streamline complex rules, simplify program administration, support work, and improve access to benefits in the Food Stamp Program. FNS will also publish rules implementing provisions of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108-265) to improve access to the WIC and Child Nutrition Programs and to support and strengthen school and community-based efforts to promote healthful eating and physical activity.

Improved

Stewardship of Federal Funds. This goal represents FNS' ongoing commitment to maximize the accuracy of benefits issued, maximize the efficiency and effectiveness of program operations, and minimize participant and vendor fraud. It includes two major objectives: 1) Improved benefit accuracy and reduced fraud, which represents the Agency's effort to reduce participant and Agency errors and to control Food Stamp and WIC trafficking and participant, vendor, and administrative agency fraud; and 2) improved efficiency of program administration, which represents our efforts to streamline program operations and improve program structures as necessary to maximize their effectiveness.

In support of this goal, FNS plans to finalize rules implementing provisions of Public Law 107-171 that give States substantial new flexibility to streamline some of the Food Stamp Program's complex rules, making it easier to administer and less error-prone. In addition, FNS will finalize rules that will simplify funding for the Food Stamp Employment and Training Program, and propose rules to enhance retailer sanctions and to streamline the sanction process. FNS will also publish rules implementing provisions of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108-265) to promote the accuracy of the certification process in the school meals programs, to improve WIC vendor management, and to ensure the effectiveness of WIC infant formula rebates in reducing program costs.

Food Safety and Inspection Service

Mission: The Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat, poultry, and egg products in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged.

Priorities: FSIS is committed to developing and issuing science-based regulations intended to ensure that meat, poultry, and egg products are wholesome and not adulterated or misbranded. FSIS continues to review its existing authorities and regulations to ensure that emerging food safety challenges are adequately addressed, to streamline excessively prescriptive regulations, and to revise or remove regulations that are inconsistent with the Agency's hazard analysis and critical control point regulations.

In addition to undertaking regulatory amendments based on the results of its review activities, FSIS has been developing regulations for emergency use. Such regulations are an outcome of the Agency's proactive, risk-based policy toward emerging and exotic threats to the safety of the Nation's meat, poultry, and egg product supply.

Following are some of the Agency's recent and planned initiatives:

In February 2001, FSIS proposed a rule to establish food safety performance standards for all processed ready-to-eat (RTE) meat and poultry products and for partially heat-treated meat and poultry products that are not ready-to-eat. The proposal contained provisions addressing post-lethality contamination of RTE products with Listeria monocytogenes. In June 2003, FSIS published an interim final rule requiring establishments that produce RTE products to apply verified control measures to prevent such product contamination. The Agency is planning further action with respect to other elements of the 2001 proposal.

In January 2004, FSIS issued a series of interim final rules to prevent the bovine spongiform encephalopathy (BSE) agent from entering the human food supply. FSIS issued the interim final rules in response to the confirmation of BSE in an imported cow in Washington State. The cow was imported from Alberta, Canada. The interim final rules: 1) Prohibit material that scientific studies demonstrate contain the BSE agent in cattle infected with BSE for use as human food; 2) prohibit the slaughter of non-ambulatory disabled cattle for human food; 3) prohibit the use of air-injection stunning devices on cattle; and 4) establish additional requirements for beef meat produced using advanced meat recovery (AMR) systems to ensure that high risk tissues are not incorporated into beef AMR product. In addition, in January 2004, FSIS issued a Federal Register Notice announcing that it would no longer pass and apply the mark of inspection to carcasses selected for BSE testing by USDA's Animal and Plant Health Inspection Service (APHIS) until the sample is determined to be negative. In July 2004, FSIS, APHIS, and the Food and Drug Administration issued an Advance Notice of Proposed Rulemaking (ANPRM) to solicit comments on additional actions that could be implemented by the U.S. government to prevent animal and human exposure to the BSE agent. The comment period for the ANPRM closed on September 14, 2004.

FSIS will propose removing from the poultry products inspection regulations the requirement for ready-to-cook poultry products to be chilled to 40 °F or below within certain time periods according to the weight of the dressed carcasses.

FSIS has proposed a rule clarifying requirements for meat produced using advanced recovery systems by replacing the compliance program parameters in the current regulations with non-compliance criteria for bone solids, bone marrow, and neural tissue. Establishments would have to have process control procedures in place before labeling or using the product derived by use of such systems.

In addition, FSIS is planning to propose requirements for federally inspected egg product plants to develop and implement HACCP systems and

sanitation standard operating procedures. The Agency will be proposing pathogen reduction performance standards for egg products. Further, the Agency will be proposing to remove requirements for approval by FSIS of egg-product plant drawings, specifications, and equipment prior to use, and to end the system for pre-marketing approval of labels for egg products.

FSIS will also propose to remove provisions that prescribe the substances and amounts of such substances that must be used to produce pumped or massaged bacon. FSIS will propose to replace these prescriptive provisions with an upper limit for nitrite and a performance standard that establishments producing pumped or massaged bacon would be required to meet.

FSIS has proposed requirements for the nutrition labeling of ground or chopped meat and poultry products and single-ingredient products. This proposed rule would require nutrition labeling, on the label or at the point-of-purchase, for the major cuts of single-ingredient, raw products and would require nutrition information on the label of ground or chopped products.

In addition, FSIS is developing a proposed rule with the Food and Drug Administration (FDA). FSIS and FDA are proposing to establish a set of general principles for food standards. The proposed general principles will establish the criteria that the agencies will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule. These proposed general principles are the agencies' first step in instituting a process to modernize their standards of identity (and any accompanying standards of quality and fill of container) and standards of composition.

Small business concerns: Nearly all FSIS regulations affect small businesses in some way because the majority of FSIS-inspected establishments and other FSIS-regulated entities are small businesses. FSIS makes available to small and very small establishments technical materials and guidance on how to comply with FSIS regulations. The Agency's post-September 11, 2001, security guidance materials were prepared especially for the benefit of small firms involved in the production, transportation, and distribution of meat, poultry, and egg products.

Animal and Plant Health Inspection Service

Mission: The mission of the Animal and Plant Health Inspection Service (APHIS) is to protect the health and value of American agricultural and natural resources. APHIS conducts programs to prevent the introduction of exotic pests and diseases into the United States and conducts surveillance, monitoring, control, and eradication programs for pests and diseases in this country. These activities enhance agricultural productivity and competitiveness and contribute to the national economy and the public health.

Priorities: APHIS continues to work on regulatory initiatives to ensure that a comprehensive framework is in place to address the threats posed to animal and plant resources. One important animal health initiative is a herd certification program for chronic wasting disease, a neurological disease of deer and elk. APHIS is also proceeding with rulemaking to improve its provisions for providing indemnity for animals and materials should an outbreak of foot-and-mouth disease occur in the United States. On the plant side, APHIS is planning to revise the regulations for the introduction of organisms and products altered or produced through genetic engineering to reflect new consolidated authorities under the Plant Protection Act. The Agency is also considering revisions to its nursery stock regulations to reduce the risk posed by imported plants, roots, seeds, bulbs, and other propagative materials. APHIS is also continuing to work with the Centers for Disease Control and Prevention to implement and amend, as necessary, regulations for the possession, use, and transfer of biological agents and toxins that could pose a severe disease or pest risk to animals and plants or their products.

In addition, recognizing the need to minimize impediments to trade while providing necessary protection to animal and plant resources, APHIS is developing a proposal to streamline the process for approving new fruits and vegetables for importation. The Agency is also continuing to work on amending its regulations concerning bovine spongiform encephalopathy (BSE) to provide for the importation of certain animals and products that present low risk, particularly from countries such as Canada, where effective measures have been in place to prevent the spread of the disease.

APHIS documents published in the **Federal Register** and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

Agricultural Marketing Service

Mission: The Agricultural Marketing Service (AMS) facilitates the marketing of agricultural products in domestic and international markets, while ensuring fair trading practices and promoting a competitive and efficient marketplace to the benefit of producers, traders, and consumers of U.S. food and fiber products.

Priorities: (1) As mandated by the 2002 Farm Bill, AMS is establishing a mandatory country of origin program for beef, lamb, pork, fish, perishable agricultural commodities, and peanuts. Under current Federal laws and regulations, country of origin labeling is not universally required for these commodities. In particular, labeling of U.S. origin is not mandatory, and labeling of imported products at the consumer level is not required in all cases. Thus, consumers desiring to purchase products based on country of origin are not fully able to do so. A proposed rule was published October 30, 2003, based on interim voluntary guidelines also required by the 2002 Farm Bill (that were issued on October 8, 2002), and related input from listening sessions held throughout the country during 2003. On October 5, 2004, the Agricultural Marketing Service published an interim final rule with request for comments for the labeling of fish and shellfish covered commodities that will become effective on April 4, 2005. A final regulatory action for all covered commodities will be issued by June 30, 2006.

(2) On April 12, 2003, Congress amended the Organic Foods Production Act (OFPA) to authorize certification of wild seafood. In response to this, AMS plans to propose regulations to amend the National Organic Program (NOP) regulations to add practice standards for organic certification of wild-caught and aquatic farm raised species. Under the OFPA, an organic certification program must be established for producers and handlers of agricultural products that have been produced using organic methods. The NOP has been reviewing organic certification of fish including wild-caught and aquaculture operations in response to a FY 2000 congressional mandate to develop regulations for the certification of seafood. The NOP has engaged in public meetings and workshops and conducted public comment proceedings on this subject.

AMS Program Rulemaking Pages: All of AMS' rules, as published in the **Federal Register**, are available on the Internet at http://www.ams.usda.gov/rulemaking. This site also includes commenting instructions and addresses, links to news releases and background material, and comments received on various rules.

Farm Service Agency

Mission: The mission of the Farm Service Agency is to stabilize farm income, help farmers conserve land and water resources, provide credit to new or disadvantaged farmers and ranchers, and help farm operations recover from the effects of disaster.

Priorities: The Farm Service's immediate priorities are to: (1) Implement the disaster assistance programs required by the Emergency Supplemental Appropriations for Hurricane Disaster Assistance Act, 2005 (H.R. 4837) and (2) implement the tobacco buyout program required by the Fair and Equitable Tobacco Reform Act of 2004 (Pub. L. 108-357). The disaster programs will provide assistance to agricultural producers in areas that were affected by the unusual number and severity of hurricanes in 2003 and 2004 for losses of crops, livestock, trees, dairy production, and sugarcane. The tobacco buyout program will end the 70-year-old tobacco quota and price support program. Quota holders and producers will be compensated for the value of their lost quota through a program financed by assessments on manufacturers and importers of tobacco products.

Forest Service

Mission: The mission of the Forest Service is to sustain the health, productivity, and diversity of the Nation's forests and rangelands to meet the needs of present and future generations. This includes protecting and managing National Forest System lands; providing technical and financial assistance to States, communities, and private forest landowners; and developing and providing scientific and technical assistance and scientific exchanges in support of international forest and range conservation.

Priorities: The Forest Service's priorities for fall 2004 are to publish final regulations at 36 CFR part 219, subpart A, to establish a framework for National Forest System land management planning and to seek comments on a proposed rule to replace the existing regulations at 36 CFR part 294, subpart B, with a petitioning process that would provide Governors an opportunity to seek establishment of management requirements for National Forest System inventoried roadless areas within their State.

The final planning rule reaffirms an emphasis on sustainability to provide for multiple uses over time and reaffirms an adaptive cycle of land management planning, including detailed project planning, plan implementation, monitoring, evaluation, and plan amendment or revision. This final rule is based on the principle that plans provide a framework for subsequent detailed project analysis and that analysis and disclosure are continuous throughout the adaptive planning cycle. A proposed rule was published in the **Federal Register** on December 6, 2002 (67 FR 72770).

The proposed State petitions for inventoried roadless area management rule emphasizes a commitment to collaborate and cooperate with States on the long-term strategy for the management of inventoried roadless areas on National Forest System lands. The petition process allows for the recognition of local situations and resolution of unique resource management challenges within a specific State. A proposed rule was published in the **Federal Register** on July 16, 2004 (69 FR 42636). The comment period originally ended on September 14, 2004, but was extended to November 15, 2004 (69 FR 54600).

Natural Resources Conservation Service

Mission: The Natural Resources Conservation Service (NRCS) mission is to provide leadership in a partnership effort to help people conserve, maintain, and improve our natural resources and environment.

Priorities: NRCS' priority for FY 2005 will be to finalize the rules related to the conservation provisions of the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), in response to public comments received pursuant to the promulgation of interim final rules for those programs. NRCS believes that these clarifications and modifications will ensure efficient and responsive delivery of conservation programs to landowners and land users and help further the agency mission to help people conserve, maintain, and improve our natural resources and the environment.

A non-Farm Bill priority for NRCS remains updating the 1981 Emergency Watershed Protection Program rule. New rulemaking will implement necessary efficiencies and make the EWP policies and rule more consistent. It will also ensure the Agency quickly meets the needs of landowners and sponsors adversely impacted by natural disasters and assists these communities in their recovery efforts.

NRCS remains committed to compliance with the Government Paperwork Elimination Act and the Freedom to E-File Act, which require Government agencies in general and NRCS in particular to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. NRCS is designing its program forms to allow the public to conduct business with NRCS electronically.

The NRCS plans to publish the following proposed or final rules during FY 2005:

1. Final Rule for the Technical Service Provider Assistance (TSP)
2. Final Rule for the Conservation Security Program (CSP)
3. Final Rule for Grassland Reserve Program (GRP)
4. Interim Final Rule for Confidentiality to provide the regulatory framework for existing statutory mandate and NRCS policy guidance.
5. Final Rule for the Emergency Watersheds Program (EWP)

The rulemaking for CSP, TSP, GRP, EWP, CIG, and Appeals are minor changes to existing interim final rules, and efforts will focus on making these rules final.

USDA—Agricultural Marketing Service (AMS)

PRERULE STAGE

1. NATIONAL ORGANIC PROGRAM: ADD STANDARDS FOR THE ORGANIC CERTIFICATION OF WILD CAPTURED AQUATIC ANIMALS (TM–01–08)

Priority:

Other Significant

Legal Authority:

7 USC 6501 through 6522

CFR Citation:

7 CFR 205

Legal Deadline:

None

Abstract:

The Agricultural Marketing Service (AMS) is revising regulations pertaining to labeling of agricultural products as organically produced and handled (7 CFR part 205). The term ''aquatic animal'' will be incorporated in the definition of livestock to establish production and handling standards for operations that capture aquatic animals from the wild. AMS has defined ''aquatic animal'' as any finfish or shellfish used for human consumption, whether taken from regulated but free roaming marine and fresh water populations (wild captured) or propagated and raised in a controlled or selected environment (aquaculture). Production standards for operations producing aquatic animals will incorporate requirements for livestock origin, feed ration, health care, living conditions, and recordkeeping. Handling standards for such operations will address prevention of commingling of organically produced commodities and prevention of contact between organically produced and prohibited substances.

Statement of Need:

This amendment to the National Organic Program is intended to facilitate interstate commerce and marketing of fresh and processed aquatic animals that are organically produced and to assure consumers that such products meet consistent, uniform standards. Also, this amendment will establish national standards for the production and handling of organically-produced aquatic animals and products, including a national list of substances approved and prohibited for use in organic production and handling.

Summary of Legal Basis:

This amendment is proposed under the Organic Foods Production Act of 1990 (OFPA). OFPA includes fish for food in its definition of livestock. Additionally, on April 12, 2003, Congress amended OFPA section 2107 (7 U.S.C. 6506) to authorize certification of wild seafood.

Alternatives:

AMS is fulfilling a congressional mandate to proceed with rulemaking for the establishment of national standards for the organic production and handling of aquatic animals.

Other options are to do nothing or to propose regulations prohibiting the labeling of aquatic animals as organically produced. Neither alternative is viable inasmuch as Congress has amended OFPA to authorize certification of wild seafood and is expecting the USDA to engage in rulemaking to establish standards for the production, handling, and labeling of organic aquatic animals.

Anticipated Cost and Benefits:

Potential benefits to consumers include more information on organic aquatic animals and protection from false and misleading organic claims. This proposal will address the problem of existing certifying agents using different standards. This proposal will also resolve the issue of whether aquatic animals can be labeled as organically produced.

The costs of this proposed regulation are the direct costs to comply with the specific standards. USDA-accredited certifying agents potentially will incur additional costs of accreditation should they opt to certify producers and handlers of aquatic animals. New applicants for accreditation to certify producers and handlers of aquatic animals under the National Organic Program will incur fees for accreditation. Producers and handlers of organically produced and handled aquatic animals will incur costs for certification levied by USDA-accredited certifying agents. USDA would not levy any fees on the certified operations. Producers and handlers will face numerous provisions that will regulate their production and handling methods. Retailers would not be directly regulated but would be subject to the same requirements for organic animals and products as they are currently for other foods under the NOP. AMS believes this action will have a minimal impact on retailers. Certified handlers will have to comply with requirements regarding the approved use of labels. The USDA, States operating State programs, and certifying agents will incur costs for enforcement of these new organic standards. Certifying agents, producers, and handlers would incur costs for reporting and recordkeeping. Certifying agents will be required to file reports and documents with the USDA and to maintain records regarding their accreditation and the certification of their clients. Certified operations will be required to develop and annually update an organic system plan and to maintain records regarding their certification and the administration of their operation.

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Federal, Local, State, Tribal

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USDA—AMS

FINAL RULE STAGE

2. MANDATORY COUNTRY OF ORIGIN LABELING OF BEEF, PORK, LAMB, FISH, PERISHABLE AGRICULTURAL COMMODITIES, AND PEANUTS (LS–03–04)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

7 USC 1621 through 1627, Agricultural Marketing Act of 1946

CFR Citation:

7 CFR 60

Legal Deadline:

Final, Statutory, September 30, 2004.

Abstract:

The Farm Security and Rural Investment Act of 2002 (Farm Bill) (Pub. L. 107-171) and the 2002 Supplemental Appropriations Act (2002 Appropriations) (Pub. L. 107-206) amended the Agricultural Marketing Act of 1946 (Act) (7 U.S.C. 1621 et seq.) to require retailers to notify their customers of the country of origin of covered commodities beginning September 30, 2004. Covered commodities include muscle cuts of

beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities; and peanuts. The FY 2004 Consolidated Appropriations bill (2004 Appropriations) (Pub. L. 108-199) delayed the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006. This final rule contains definitions, the requirements for consumer notification and product marking, and the recordkeeping responsibilities of both retailers and suppliers.

Statement of Need:

Under current Federal laws and regulations, country of origin labeling is not universally required for the covered commodities. In particular, labeling of U.S. origin is not mandatory, and labeling of imported products at the consumer level is required only in certain circumstances. This intent of the law is to provide consumers with additional information on which to base their purchasing decisions.

Summary of Legal Basis:

Section 10816 of Public Law 107-171 amended the Agricultural Marketing Act of 1946 to require retailers to inform consumers of the country of origin for covered commodities beginning September 30, 2004, and requires USDA to promulgate requirements for the mandatory labeling program no later than September 30, 2004.

Alternatives:

Various methods are being considered by which the objectives of this law could be accomplished. The proposed rule specifically invites comment on several alternatives including alternative definitions for ''processed food item,'' alternative labeling of mixed origin, and alternatives to using ''slaughtered'' on the label. The proposed rule published October 30, 2003, provided for a 60-day comment period which closed on December 29, 2003. A notice extending the comment period was published December 22, 2003. The notice extended the comment period to February 27, 2004.

Anticipated Cost and Benefits:

USDA has examined the economic impact of the proposed rule as required by Executive Order 12866. The estimated benefits associated with this rule are likely to be negligible. The estimated first-year incremental cost for growers, producers, processors, wholesalers, and retailers ranges from $582 million to $3.9 billion. The estimated cost to the U.S. economy in higher food prices and reduced food production in the tenth year after implementation of the rule ranges from $138 million to $596 million. AMS has invited further comment on start up costs and maintenance costs for the first year and beyond for firms directly affected by the proposed rule.

Risks:

AMS has not identified any risks at this time.

Timetable:

Action	Date	FR Cite
NPRM	10/30/03	68 FR 61944
NPRM Comment Period End	12/29/03	
Interim Final Rule	10/05/04	69 FR 59708
Interim Final Rule Comment Period End	01/03/05	
Interim Final Rule Effective	04/04/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

The U.S. Department of Agriculture issued an interim final rule with request for comments for the labeling of fish and shellfish covered commodities that will become effective on April 4, 2005. A final regulatory action for all covered commodities will be issued by June 30, 2006.

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USDA—Animal and Plant Health Inspection Service (APHIS)

PRERULE STAGE

3. REVISION OF THE NURSERY STOCK REGULATIONS (Q.37)

Priority:

Other Significant

Legal Authority:

7 USC 450; 7 USC 7701 to 7772; 21 USC 136 to 136a

CFR Citation:

7 CFR 319

Legal Deadline:

None

Abstract:

This action will solicit public comment on whether and how we should amend the regulations that govern the importation of nursery stock, also known as plants for planting. Under the current regulations, all plants for planting are allowed to enter the United States if they are accompanied by a phytosanitary certificate and if they are inspected and found to be free of plant pests, unless their importation is specifically prohibited or further restricted by the regulations. We are considering several possible changes to this approach, including establishing a category in the regulations for plants for planting that would be excluded from importation pending risk evaluation and approval; developing ongoing programs to reduce the risk of entry and establishment of quarantine pests via imported plants for planting; combining existing regulations governing the importation of plants for planting into one subpart; and reevaluating the risks posed by importation of plants for planting whose importation is currently prohibited. We are also considering how to best collect data on current imports of plants for planting so we can accurately ascertain the volume, type, and origin of such plants entering the United States. We are soliciting public comment on these issues to help us determine what changes we should propose to improve our regulations and which of these changes should be assigned the highest priority for implementation.

Statement of Need:

APHIS typically relies on inspection at a Federal plant inspection station or

port of entry to mitigate the risks of pest introduction associated with the importation of plants for planting. Importation of plants for planting is further restricted or prohibited only if there is specific evidence that such importation could introduce a quarantine pest into the United States. Most of the taxa of plants for planting currently being imported have not been thoroughly studied to determine whether their importation presents a risk of introducing a quarantined pest into the United States. The volume and the number of types of plants for planting have increased dramatically in recent years, and there are several problems associated with gathering data on what plants for planting are being imported and on the risks such importation presents. In addition, quarantined pests that enter the United States via the importation of plants for planting pose a particularly high risk of becoming established within the United States. Given these circumstances, APHIS needs to consider various ways in which the regulations governing plants for planting might be revised in order to address the risk of pest introduction via the importation of plants for planting. This ANPRM solicits public comment on several measures we are considering.

Summary of Legal Basis:

The Secretary of Agriculture may prohibit or restrict the importation or entry of any plant if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States of a plant pest or noxious weed (7 U.S.C. 7712).

Alternatives:

APHIS has identified two alternatives to the approach we are considering in this advance notice of proposed rulemaking. The first is to maintain the status quo; this alternative was rejected because, given our limited resources and the risks of pest introduction posed by the rapid increase in the importation of plants for planting, we do not believe that this approach would allow us to address the potential risks posed by quarantine pests in a timely manner. The second is to prohibit the importation of all nursery stock pending risk evaluation, approval, and notice-and-comment rulemaking, similar to APHIS's approach to regulating imported fruits and vegetables; this approach was rejected because, in the absence of additional resources for conducting risk evaluation and rulemaking, this approach would lead to a major interruption in international trade and would have significant economic effects on both U.S. importers and U.S. consumers of plants for planting.

Anticipated Cost and Benefits:

This action is currently in the advance notice of proposed rulemaking stage; we are gathering information to guide us in deciding what actions to take. In the absence of specific proposed measures, we cannot determine specific costs and benefits. However, the costs associated with plant pests that are introduced to the United States via imported nursery stock are expected to increase in the absence of some action to revise the nursery stock regulations to allow us to better address pest risks.

Risks:

In the absence of some action to revise the nursery stock regulations to allow us to better address pest risks, increased introductions of plant pests via imported nursery stock are likely, causing extensive damage to both agricultural and natural plant resources.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Additional Information:

APHIS documents published in the Federal Register and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—APHIS

FINAL RULE STAGE

4. FOOT–AND–MOUTH DISEASE; PAYMENT OF INDEMNITY

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8317

CFR Citation:

9 CFR 53

Legal Deadline:

None

Abstract:

This rule would amend the regulations for the cooperative control and eradication of foot-and-mouth disease (FMD) and other serious diseases, including both cooperative programs and extraordinary emergencies. The purpose of this rule is to remove possible sources of delay in eradicating foot-and-mouth disease, should an occurrence of that disease occur in this country, so that eligible claimants will be fully compensated while at the same time protecting the U.S. livestock population from the further spread of this highly contagious disease.

Statement of Need:

APHIS has reviewed these regulations to determine their sufficiency, should an occurrence of foot-and-mouth disease occur in the United States. This review was prompted, in part, by a series of outbreaks of foot-and-mouth disease that occurred in the United Kingdom and elsewhere around the world. Based on this review, APHIS has determined that changes to the regulations are needed with regard to the valuation of animals and materials, as well as the payment of an indemnity to those persons who suffer loss of property as a result of foot-and-mouth disease.

Summary of Legal Basis:

The Secretary of Agriculture, either independently or in cooperation with other Federal agencies, States or political subdivisions of States, national governments of foreign countries, local governments of foreign countries, domestic or international organizations, domestic or international associations, Indian tribes, and other persons, may carry out operations and measures to detect, control, or eradicate any pest or

disease of livestock that threatens the livestock of the United States, including the payment of claims arising out of the destruction of any animal, article, or means of conveyance, if necessary to prevent the dissemination of the pest or disease of livestock (7 U.S.C. 8306, 8308, 8310, and 8315).

Alternatives:

The rule comprises several regulatory changes, each of which is intended to facilitate the control and eradication of foot-and-mouth disease, should an outbreak of this disease occur in the United States. Reasonable alternatives to the rule would be to not make any changes at all and rely on the current regulations as applied to cooperative programs and extraordinary emergencies.

Anticipated Cost and Benefits:

The rule is expected to affect livestock operations and Federal and State government agencies. The vast majority of livestock operations are small entities. The potential costs and benefits would depend upon the characteristics of the outbreak and mitigation strategy. The proposed changes would strengthen programs for the control and eradication of FMD by broadening USDA's options. The changes would also lessen the chances that FMD's eradication would be delayed.

Risks:

The changes contained in the rule would be particularly important in removing sources of delay in achieving FMD eradication, should an outbreak of foot-and-mouth disease occur in the United States. An effective response in the early stages of such an outbreak greatly reduces the risk of the disease's wider dissemination.

Timetable:

Action	Date	FR Cite
NPRM	05/01/02	67 FR 21934
NPRM Comment Period Extended	06/28/02	67 FR 43566
NPRM Comment Period End	07/01/02	
NPRM Comment Period End	07/31/02	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

APHIS documents published in the Federal Register and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—APHIS

5. CHRONIC WASTING DISEASE IN ELK AND DEER; INTERSTATE MOVEMENT RESTRICTIONS AND PAYMENT OF INDEMNITY

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8316

CFR Citation:

9 CFR 55; 9 CFR 81

Legal Deadline:

None

Abstract:

This rulemaking would establish requirements for the interstate movement of farmed elk and deer and provide indemnity for the depopulation of farmed elk and deer that have been infected with, or exposed to, chronic wasting disease (CWD).

Statement of Need:

CWD has been confirmed in free-ranging deer and elk in a limited number of counties in northeastern Colorado and southeastern Wyoming and has also been diagnosed in farmed elk herds in South Dakota, Nebraska, Oklahoma, Montana, and Colorado. This project includes an interim rule to establish indemnity for voluntary depopulation of CWD-affected herds, followed by rulemaking to establish a voluntary certification program and interstate movement restrictions on captive elk and deer. APHIS believes that establishing restrictions on the interstate movement of infected and exposed farmed elk and deer, coupled with the payment of some level of indemnity for infected and exposed animals, will encourage producers who are not yet engaging in surveillance activities to begin doing so. To date, the level of support from States and the farmed cervid industry for such a program has been high. Without a Federal program in place to depopulate infected and exposed animals, the movement of infected animals into new herds and States with no known infection will continue or may even accelerate. APHIS needs to take action to document the prevalence of the disease and to prevent its further spread.

Summary of Legal Basis:

The Secretary of Agriculture, either independently or in cooperation with other Federal agencies, States or political subdivisions of States, national governments of foreign countries, local governments of foreign countries, domestic or international organizations, domestic or international associations, Indian tribes, and other persons, may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock of the United States, including the payment of claims arising out of the destruction of any animal, article, or means of conveyance, if necessary to prevent the dissemination of the pest or disease of livestock (7 U.S.C. 8305 to 8306, 8308, 8310, and 8315).

Alternatives:

APHIS has identified two additional alternatives to our selected action. The first—to maintain the status quo—was rejected because it would not address the animal disease risks associated with CWD. The second option would have been to provide financial and technical assistance to the cervid industry for continuation and expansion of a variety of herd management practices to reduce or eliminate CWD. Although this option may be less costly than the option chosen by APHIS, this option was not selected because it would not advance CWD eradication as quickly or effectively as the chosen option. However, APHIS will continue to work with industry to develop voluntary herd management practices to preserve and increase the reduction in CWD levels that the proposed program is expected to achieve.

Anticipated Cost and Benefits:

The presence of CWD in elk and deer causes significant economic and market

losses to U.S. producers. Recently, Canada has begun to require, as a condition for importing U.S. elk into Canada, that the animals be accompanied by a certificate stating that the herd of origin is not located in Colorado or Wyoming, and CWD has never been diagnosed in the herd of origin. The Republic of Korea recently suspended the importation of deer and elk and their products from the United States and Canada. Fear of CWD can severely affect the domestic prices for deer and elk, as it is more difficult for producers to sell cervid that are associated with any hint of exposure to the disease.

Risks:

Aggressive action in controlling this disease now will decrease the chance of having to deal with a much larger, widespread, and costly problem later, such as the situation with bovine spongiform encephalopathy (''mad cow disease'') in Europe. Although there is currently no evidence that CWD is linked to disease in humans, or in domestic animals other than deer and elk, a theoretical risk of such a link exists.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/08/02	67 FR 5925
Interim Final Rule Comment Period End	04/09/02	
NPRM	12/24/03	68 FR 74513
NPRM Comment Period End	02/23/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State

Additional Information:

APHIS documents published in the Federal Register and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—Food and Nutrition Service (FNS)

PROPOSED RULE STAGE

6. SENIOR FARMERS' MARKET NUTRITION PROGRAM (SFMNP)

Priority:

Other Significant

Legal Authority:

PL 107–171, sec 4306

CFR Citation:

7 CFR 249

Legal Deadline:

None

Abstract:

This proposed rule will implement the provision of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171) that gives the Department the authority to promulgate regulations for the operation and administration of the SFMNP. The purposes of the SFMNP are to provide fresh, nutritious, unprepared locally grown fruits, vegetables, and herbs from farmers' markets, roadside stands, and community supported agriculture programs to low-income seniors and to increase the consumption of agricultural commodities by expanding, developing, and/or aiding in the development of domestic farmers' markets, roadside stands, and community supported agriculture programs. (02-012)

Statement of Need:

The SFMNP has been administered since fiscal year 2001 as a competitive grant program in which State agencies, interested in receiving a grant to operate the program, submitted an application for SFMNP grant funds to USDA's Food and Nutrition Service. Such grants were reviewed and ranked against a set of explicit criteria, and SFMNP grants were then awarded to those State agencies whose applications received the highest scores. Public Law 107-171 authorized funding for the SFMNP through FY 2007 and also gave the Department the authority to promulgate regulations for the future operation and administration of the SFMNP. This legislative action establishes the SFMNP as a permanent nutrition assistance program and eliminates the need for State agencies to participate in an annual competition for program funds. Therefore, this proposed rulemaking converts the SFMNP from a competitive grant program to a permanent FNS-administered nutrition assistance program.

Summary of Legal Basis:

Public Law 107-171 (section 4306) authorized funding for the SFMNP through FY 2007 and also gave the Department the authority to promulgate regulations for the future operation and administration of the SFMNP.

Alternatives:

USDA considered a variety of alternatives when constructing the regulation for the SFMNP. Primarily, the proposed regulation is modeled after the WIC Farmers' Market Nutrition Program and the Senior Farmers' Market Nutrition Pilot Programs. Consistency lends to administrative ease among the State agencies, localities, and USDA, as well as provides continuity to beneficiaries and farmers who have been operating the pilot programs since 2001. Nevertheless, USDA addressed seven specific alternatives: Type of grant structure, eligible grantees and recipients, the use of community-supported agriculture programs, provision of administrative funding, eligibility requirements, verification procedures, and benefit levels. Each of these alternatives is explored in detail in the preamble to the proposed rulemaking.

Anticipated Cost and Benefits:

The funding level for the SFMNP is expected to remain stable through FY 2007. Therefore, the Department does not anticipate significant changes to the costs/benefits of the SFMNP as a result of the publication of this proposed rule.

Risks:

The proposed rule carries a 90-day comment period, during which interested parties may submit comments on any and all provisions contained in the rulemaking. Once the

comment period has expired, all comments received will be carefully considered in the development of the final rule. Opportunities for training on and discussion of the SFMNP regulations (in both their proposed and final forms) will be offered to State agencies and other entities with a vested interest in the operation and administration of the SFMNP.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	
NPRM Comment Period End	05/00/05	
Final Action	09/00/05	
Final Action Effective	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

URL For More Information:

www.fns.usda.gov

URL For Public Comments:

www.fns.usda.gov/wic

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RIN: 0584–AD35

USDA—FNS

7. FSP: DISCRETIONARY QUALITY CONTROL PROVISIONS OF TITLE IV OF PUBLIC LAW 107–171

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

7 CFR 271; 7 CFR 273; 7 CFR 275; 7 CFR 277

Legal Deadline:

None

Abstract:

This proposed rule will implement several quality control changes to the Food Stamp Act required by sections 4118 and 4119 of title IV of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171). The provisions in this rule affect the following areas: 1) The elimination of enhanced funding; 2) revisions to the time frames for completing individual case reviews; 3) extending the time frames in the procedures for households that refuse to cooperate with QC reviews; 4) procedures for adjusting liability determinations following appeal decisions; and 5) conforming and technical changes. (02-015)

Statement of Need:

The rule is needed to implement several food stamp quality control provisions of Public Law 107-171 the Farm Security and Rural Investment Act of 2002. Elimination of enhanced funding is required by the Act. The Act also requires the Department to propose rules for adjusting liability determinations following appeals decisions. The remaining changes are either conforming changes resulting from the required changes or policy changes already in effect but not updated in the regulations.

Summary of Legal Basis:

The legal basis for this rule is Public Law 107-171 the Farm Security and Rural Investment Act of 2002.

Alternatives:

This rule deals in part with changes required by title IV of Public Law 107-171 the Farm Security and Rural Investment Act of 2002. The Department has no discretion in eliminating enhanced funding for fiscal years 2003 and beyond. The provision addressing results of appeals is required to be regulated by Public Law 107-171. The remaining changes amend existing regulations and are required to make technical changes resulting from these changes or to update policy consistent with current requirements.

Anticipated Cost and Benefits:

The provisions of this rule are not anticipated to have any impact on benefit levels. The provisions of this rule are anticipated to reduce administrative costs.

Risks:

The FSP provides nutrition assistance to millions of Americans nationwide. The quality control system measures the accuracy of States providing food stamp benefits to the program recipients. This rule is intended to implement some of the quality control provisions of title IV of Public Law 107-171 the Farm Security and Rural Investment Act of 2002. The provisions of this rule will eliminate enhanced funding for low payment error rates. It will revise the system for determining State agency liabilities and sanctions for high payment error rates following appeal decisions.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	
NPRM Comment Period Ends	05/00/05	
Final Action	05/00/06	
Final Action Effective	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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Related RIN: Split from 0584–AD31

RIN: 0584–AD37

USDA—FNS

8. ● SPECIAL NUTRITION PROGRAMS: FLUID MILK SUBSTITUTIONS

Priority:

Other Significant

Legal Authority:

PL 108–265, sec 102

CFR Citation:

7 CFR 210; 7 CFR 220

Legal Deadline:

None

Abstract:

Currently, by regulation, schools must make substitutions for fluid milk for students with a disability when the

request is authorized by a licensed physician and may make substitutions for students with medical or other dietary needs if requested by recognized medical authority. These regulatory provisions were included in Public Law 108-265 which amended the Richard B. Russell National School Lunch Act. Public Law 108-265 also amended the current law to allow schools to substitute non-dairy beverages nutritionally equivalent (as established by the Secretary) to fluid milk for medical or other special dietary needs at the request of a parent/guardian. In response to Public Law 108-265, the National School Lunch Program and School Breakfast Program regulations will be revised to add these requirements.

(04-016)

Statement of Need:

The changes made to the Richard B. Russell National School Lunch Act concerning substitutions for fluid milk are intended to assist children with an intolerance to or a cultural or other restriction concerning the consumption of milk. This regulation allows schools to make substitutions at the request of a parent or guardian which assists families that are unable to obtain a doctor's statement. However, the Secretary must develop criteria to limit the substitutions for milk to nutritionally equivalent beverages. The determination of nutritionally equivalent beverages will require careful research and consultation.

Summary of Legal Basis:

These changes are being made in response to provisions in Public Law 108-265.

Alternatives:

USDA will be working with other Federal agencies to develop criteria for nutritionally equivalent substitutes for fluid milk as well as conducting research. USDA is issuing a proposed rule on this provision in order to solicit public comments prior to any final decisionmaking.

Anticipated Cost and Benefits:

Schools may incur additional costs in obtaining and offering substitute beverages. However, a significant benefit is to children who cannot consume milk and who will now have a nutritionally equivalent beverage to milk.

Risks:

USDA must be diligent in making any determinations of nutritional equivalency to milk.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

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RIN: 0584–AD58

USDA—FNS

FINAL RULE STAGE

9. CHILD AND ADULT CARE FOOD PROGRAM: IMPROVING MANAGEMENT AND PROGRAM INTEGRITY

Priority:

Other Significant

Legal Authority:

42 USC 1766; PL 103–448; PL 104–193; PL 105–336

CFR Citation:

7 CFR 226

Legal Deadline:

None

Abstract:

This rule amends the Child and Adult Care Food Program (CACFP) regulations. The changes in this rule result from the findings of State and Federal program reviews and from audits and investigations conducted by the Office of Inspector General. This rule revises: State agency criteria for approving and renewing institution applications; program training and other operating requirements for child care institutions and facilities; and State- and institution-level monitoring requirements. This rule also includes changes that are required by the Healthy Meals for Healthy Americans Act of 1994 (Pub. L. 103-448), the Personal Responsibility and Work Opportunities Reconciliation Act of 1996 (Pub. L. 104-193), and the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Pub. L. 105-336).

The changes are designed to improve program operations and monitoring at the State and institution levels and, where possible, to streamline and simplify program requirements for State agencies and institutions. (95-024)

Statement of Need:

In recent years, State and Federal program reviews have found numerous cases of mismanagement, abuse, and in some instances, fraud by child care institutions and facilities in the CACFP. These reviews revealed weaknesses in management controls over program operations and examples of regulatory noncompliance by institutions, including failure to pay facilities or failure to pay them in a timely manner; improper use of program funds for non-program expenditures; and improper meal reimbursements due to incorrect meal counts or to miscategorized or incomplete income eligibility statements. In addition, audits and investigations conducted by the Office of Inspector General (OIG) have raised serious concerns regarding the adequacy of financial and administrative controls in CACFP. Based on its findings, OIG recommended changes to CACFP review requirements and management controls.

Summary of Legal Basis:

Some of the changes proposed in the rule are discretionary changes being made in response to deficiencies found in program reviews and OIG audits. Other changes codify statutory changes made by the Healthy Meals for Healthy Americans Act of 1994 (Pub. L. 103-448), the Personal Responsibility and Work Opportunities Reconciliation Act of 1996 (Pub. L. 104-193), and the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Pub. L. 105-336).

Alternatives:

In developing the proposal, the Agency considered various alternatives to minimize burden on State agencies and

institutions while ensuring effective program operation. Key areas in which alternatives were considered include State agency reviews of institutions and sponsoring organization oversight of day care homes.

Anticipated Cost and Benefits:

This rule contains changes designed to improve management and financial integrity in the CACFP. When implemented, these changes would affect all entities in CACFP, from USDA to participating children and children's households. These changes will primarily affect the procedures used by State agencies in reviewing applications submitted by, and monitoring the performance of, institutions which are participating or wish to participate in the CACFP. Those changes which would affect institutions and facilities will not, in the aggregate, have a significant economic impact.

Data on CACFP integrity is limited, despite numerous OIG reports on individual institutions and facilities that have been deficient in CACFP management. While program reviews and OIG reports clearly illustrate that there are weaknesses in parts of the program regulations and that there have been weaknesses in oversight, neither program reviews, OIG reports, nor any other data sources illustrate the prevalence and magnitude of CACFP fraud and abuse. This lack of information precludes USDA from estimating the amount of money lost due to fraud and abuse or the reduction in fraud and abuse the changes in this rule will realize.

Risks:

Continuing to operate the CACFP under existing provisions of the regulations that do not sufficiently protect against fraud and abuse in CACFP puts the program at significant risk. This rule includes changes designed to strengthen current program regulations to reduce the risk associated with the program.

Timetable:

Action	Date	FR Cite
NPRM	09/12/00	65 FR 55103
NPRM Comment Period End	12/11/00	
Interim Final Rule	09/01/04	69 FR 53502
Interim Final Rule Effective	10/01/04	
Interim Final Rule Comment Period End	09/01/05	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

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USDA—FNS

10. COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP): PLAIN LANGUAGE, PROGRAM ACCOUNTABILITY, AND PROGRAM FLEXIBILITY

Priority:

Other Significant

Legal Authority:

PL 101–624; PL 104–127

CFR Citation:

7 CFR 247

Legal Deadline:

None

Abstract:

This rule will rewrite regulations pertaining to the Commodity Supplemental Food Program (7 CFR part 247) in ''plain language.'' It will also amend regulatory provisions in this part to increase program accountability, impose more rigorous performance measures on State and local agencies, increase flexibility for program operators, and incorporate legislative provisions that have been implemented through program policy. (99-005)

Statement of Need:

This rule is necessary to amend regulatory provisions in 7 CFR part 247 to increase program accountability, impose more rigorous performance measures on State and local agencies, increase flexibility for program operators and incorporate legislative provisions that have been implemented through program policy.

Summary of Legal Basis:

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. The rule meets these requirements. This rule also incorporates legislative amendments found in sections 1771(d) and 1771(e) of the Food, Agriculture, Conservation, and Trade Act of 1990; section 402(b) of the Federal Agriculture Improvement and Reform Act of 1996; section 4201(b) of the Farm Security and Rural Investment Act of 2002; and the Single Audit Act Amendments of 1996.

Alternatives:

No alternatives available.

Anticipated Cost and Benefits:

Changes in the rule reduce the burden imposed on State and local agencies while ensuring program accountability and are generally insignificant to the costs or overall operations of the program.

Risks:

There are no risks involved with this proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	10/31/03	68 FR 62164
NPRM Comment Period End	12/30/03	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State, Tribal

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RIN: 0584–AC84

USDA—FNS

11. FSP: HIGH PERFORMANCE BONUSES

Priority:

Other Significant

Legal Authority:

PL 107–171

CFR Citation:

7 CFR 272; 7 CFR 275

Legal Deadline:

None

Abstract:

This action will finalize amendments to the FSP regulations originally proposed on December 17, 2003, titled FSP High Performance Bonuses. These amendments were provided for in the Farm Security and Rural Investment Act of 2002 for States that demonstrate high or improved performance in administration of the Food Stamp Program. This action will finalize the measurement criteria for fiscal year 2005 and beyond. (02-006)

Statement of Need:

This rule is mandated by Public Law 107-171 to implement the performance measures used to award high performance bonuses for fiscal years 2005 and beyond.

Summary of Legal Basis:

The legal basis for this rule is Public Law 107-171.

Alternatives:

This rule is mandated by law. Therefore, there are no alternatives.

Anticipated Cost and Benefits:

Undetermined

Risks:

The law mandates that we publish the performance measures for the high performance bonuses for FY 2005 and beyond.

Timetable:

Action	Date	FR Cite
NPRM	12/17/03	68 FR 70193
NPRM Comment Period End	02/17/04	
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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RIN: 0584–AD29

USDA—FNS

12. FSP: ELIGIBILITY AND CERTIFICATION PROVISIONS OF THE FARM SECURITY AND RURAL INVESTMENT ACT OF 2002

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 107–171, secs 4101 to 4109, 4114, 4115, and 4401

CFR Citation:

7 CFR 273

Legal Deadline:

None

Abstract:

This rulemaking proposes to amend Food Stamp Program regulations to implement 11 provisions of the Farm Security and Rural Investment Act of 2002 that establish new eligibility and certification requirements for the receipt of food stamps.

Statement of Need:

The rule is needed to implement the food stamp certification and eligibility provisions of Public Law 107-171, the Farm Security and Rural Investment Act of 2002.

Summary of Legal Basis:

The legal basis for this rule is Public Law 107-171, the Farm Security and Rural Investment Act of 2002.

Alternatives:

This proposed rule deals with changes required by Public Law 107-171, the Farm Security and Rural Investment Act of 2002. The Department has limited discretion in implementing provisions of that law. Most of the provisions in this rule are effective October 1, 2002, and must be implemented by State agencies prior to publication of this rule.

Anticipated Cost and Benefits:

The provisions of this rule will simplify State administration of the Food Stamp Program, increase eligibility for the program among certain groups, increase access to the program among low-income families and individuals, and increase benefit levels. The provisions of Public Law 107-171 implemented by this rule will have a 5-year cost of approximately $1.9 billion.

Risks:

The FSP provides nutrition assistance to millions of Americans nationwide—working families, eligible non-citizens, and elderly and disabled individuals. Many low-income families don't earn enough money and many elderly and disabled individuals don't receive enough in retirement or disability benefits to meet all of their expenses and purchase healthy and nutritious meals. The FSP serves a vital role in helping these families and individuals achieve and maintain self-sufficiency and purchase a nutritious diet. This rule is intended to implement the certification and eligibility provisions of Public Law 107-171, the Farm Security and Rural Investment Act of 2002. It will simplify State administration of the Food Stamp Program, increase eligibility for the program among certain groups, increase access to the program among low-income families and individuals, and increase benefit levels. The provisions of this rule will increase benefits by approximately $1.95 billion over 5 years. When fully effective in FY 2006, the provisions of this rule will add approximately 415,000 new participants.

Timetable:

Action	Date	FR Cite
NPRM	04/16/04	69 FR 20724
NPRM Comment Period End	06/15/04	
Final Action	10/00/05	
Final Action Effective	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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RIN: 0584–AD30

USDA—FNS

13. FSP: NON–DISCRETIONARY QUALITY CONTROL PROVISIONS OF TITLE IV OF PUBLIC LAW 107–171

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

7 CFR 273; 7 CFR 275

Legal Deadline:

None

Abstract:

This final rule implements several quality control changes to the Food Stamp Act required by sections 4118 and 4119 of title IV of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171). The provisions in this rule affect the following areas: 1) Timeframes for completing quality control reviews; 2) timeframes for completing the arbitration process; 3) timeframes for determining final error rates; 4) the threshold for potential sanctions and time period for sanctions; 5) the calculation of State error rates; 6) the formula for determining States' liability amounts; 7) sanction notification and method of payment; and 8) corrective action plans. (02-014)

Statement of Need:

The rule is needed to implement the food stamp quality control provisions of Public Law 107-171, the Farm Security and Rural Investment Act of 2002.

Summary of Legal Basis:

The legal basis for this rule is Public Law 107-171, the Farm Security and Rural Investment Act of 2002.

Alternatives:

This interim rule deals with changes required by Public Law 107-171, the Farm Security and Rural Investment Act of 2002. The Department has no discretion in implementing these provisions of that law. The provisions in this rule are effective for the fiscal year 2003 quality control review period and must be implemented by FNS and State agencies during fiscal year 2003.

Anticipated Cost and Benefits:

The provisions of this rule are not anticipated to have any impact on benefit levels or administrative costs.

Risks:

The FSP provides nutrition assistance to millions of Americans nationwide. The quality control system measures the accuracy of States providing food stamp benefits to the program recipients. This rule is intended to implement the quality control provisions of Public Law 107-701, the Farm Security and Rural Investment Act of 2002. It will significantly revise the system for determining State agency liabilities and sanctions for high payment error rates.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/16/03	68 FR 59519
Interim Final Rule Effective	12/15/03	
Interim Final Rule Comment Period End	01/14/04	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State

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USDA—FNS

14. FSP: EMPLOYMENT AND TRAINING PROGRAM PROVISIONS OF THE FARM SECURITY AND RURAL INVESTMENT ACT OF 2002

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 107–171

CFR Citation:

7 CFR 273.7

Legal Deadline:

None

Abstract:

This final rule implements revisions to the Food Stamp Employment and Training (E&T) Program funding requirements. (02-009)

Statement of Need:

This rule is necessary to implement statutory revisions to E&T Program funding provisions.

Summary of Legal Basis:

All provisions of this proposed rule are mandated by Public Law 107-171.

Alternatives:

The alternative is not to revise current funding rules. This is not practical. The current rules have been superseded by changes brought about by Public Law 107-171. These changes were effective on May 13, 2002, the date of enactment of Public Law 107-171.

Anticipated Cost and Benefits:

None.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/19/04	69 FR 12981
NPRM Comment Period End	05/18/04	
Final Action	12/00/04	
Final Action Effective	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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USDA—FNS

15. ● DIRECT AND DISCRETIONARY CERTIFICATION IN THE SCHOOL MEALS PROGRAMS

Priority:

Other Significant

Legal Authority:

PL 108–265, sec 104

CFR Citation:

7 CFR 245

Legal Deadline:

None

Abstract:

Currently a school food authority may ''directly certify'' any child as eligible for free or reduced-price school meals, without further application, by directly communicating with the appropriate State or local agency to obtain documentation of the child's status as a member of a food stamp household or a family receiving TANF.

In response to Public Law 108-265, which amended the Richard B. Russell National School Lunch Act, 7 CFR 245, Determining Eligibility for Free and Reduced Price Meals and Free Milk in Schools, will be revised to require that school food authorities ''directly certify'' as eligible for free school meals, without further application, any child who is a member of a food stamp household. In order to carry out this requirement, the law also requires that each State agency enter into an agreement with the State food stamp agency to establish procedures under which children who are members of food stamp households will be directly certified and amends the Food Stamp Act to require State food stamp agencies to enter into the required agreements and cooperate in carrying out direct certification. The direct certification requirements are phased-in. For School Year 2006-2007, school districts with an enrollment of 25,000 students or more in the preceding year must comply. For School Year 2007-2008, school districts with an enrollment of 10,000 students or more in the preceding year must comply. For subsequent school years, all districts must comply. Until mandatory ''direct certification'' for children in food stamp households is fully implemented, the existing permissive authority is retained. In addition, this rule adds (to existing authority with regard to children in TANF families) permissive authority for school food authorities to directly certify homeless children, children served by programs under the Runaway and Homeless Youth Act, and migrant children. (04-018)

Statement of Need:

The changes made to the Richard B. Russell National School Lunch Act concerning direct verification are intended to improve program access, reduce paperwork, and improve the accuracy of the delivery of free meal benefits. This regulation will implement the statutory changes and provide State agencies and local educational agencies with the policies and procedures to conduct mandatory and discretionary direct certification.

Summary of Legal Basis:

These changes are being made in response to provisions in Public Law 108-265.

Alternatives:

FNS will be working closely with State agencies to implement the changes made by this regulation and will be developing extensive guidance materials in conjunction with our cooperators.

Anticipated Cost and Benefits:

This regulation will reduce paperwork, target benefits more precisely, and will improve program access of eligible school children.

Risks:

This regulation may require adjustments to existing computer systems to more readily share information between schools, food stamp offices, and other agencies.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

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USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

16. PERFORMANCE STANDARDS FOR PUMPED OR MASSAGED BACON

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq

CFR Citation:

9 CFR 424.22(b)

Legal Deadline:

None

Abstract:

FSIS is proposing to revise the regulatory provisions concerning the production and testing of pumped or massaged bacon (9 CFR 424.22(b)). FSIS is proposing to remove provisions that prescribe the substances and amounts of such substances that must be used to produce pumped or massaged bacon. FSIS is proposing to replace these provisions with an upper limit for nitrite and a performance standard that establishments producing pumped or massaged bacon must meet. To meet the proposed performance standard, the process used to produce pumped or massaged bacon would be required to limit the presence of nitrosamines when the product is cooked.

Statement of Need:

FSIS is proposing to replace restrictive provisions concerning the processing of pumped or massaged bacon with an upper limit for nitrite and a performance standard. The proposed performance standard concerns limiting the presence of volatile nitrosamines in pumped or massaged bacon. These proposed changes are necessary to make the regulations concerning pumped or massaged bacon consistent

with those governing Hazard Analysis and Critical Control Point (HACCP) systems.

Summary of Legal Basis:

Under the Federal Meat Inspection Act (21 U.S.C. 601 to 695), a meat or meat food product is adulterated ''if it bears or contains any poisonous or deleterious substance that may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health'' (21 U.S.C. 601(m)(1)). Volatile nitrosamines are deleterious because they are carcinogenic, and though not added directly to pumped or massaged bacon, they may be produced when the pumped or massaged bacon is fried. Processors can control the levels of nitrosamines that may be present when the product is fried by controlling the levels of ingoing nitrite and ingoing curing accelerators that are used in the production of pumped or massaged bacon. In 1978, USDA stated that nitrosamines present at confirmable levels in pumped bacon after preparation for eating were deemed to adulterate the product. FSIS still maintains that pumped bacon with confirmable levels of nitrosamines after preparation for eating is adulterated. Under this proposed rule, processors meeting the performance standard would control the levels of nitrosamines in the finished product by complying with a performance standard.

Alternatives:

No action; performance standards for all types of bacon (not just pumped or massaged bacon, as proposed).

Anticipated Cost and Benefits:

Because FSIS is proposing to convert existing regulations to a performance standard and is not proposing any new requirements for establishments producing pumped or massaged bacon, FSIS does not anticipate that this proposed rule would result in any significant costs or benefits. Pumped or massaged bacon processing establishments whose HACCP plans do not currently address nitrosamines as hazards reasonably likely to occur may incur some costs. Also, establishments that choose to test their products for nitrosamines after this rule becomes effective may incur some costs. Because this rule provides establishments the flexibility to develop new procedures for producing bacon, this rule may result in profits to processors who develop cheaper means of producing product or who develop a pumped or massaged bacon product with wide consumer appeal.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

17. EGG PRODUCTS INSPECTION REGULATIONS

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 1031 to 1056

CFR Citation:

9 CFR 590.570; 9 CFR 590.575; 9 CFR 590.146; 9 CFR 590.10; 9 CFR 590.411; 9 CFR 590.502; 9 CFR 590.504; 9 CFR 590.580; 9 CFR 591; . . .

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) is proposing to require egg products plants and plants pasteurizing shell eggs to develop and implement Hazard Analysis and Critical Control Points (HACCP) systems and Sanitation Standard Operating Procedures (SOPs). FSIS also is proposing pathogen reduction performance standards that would be applicable to egg products and pasteurized shell eggs. Plants would be expected to develop HACCP systems that ensure products meet the pathogen reduction performance standards. Finally, FSIS is proposing to amend the Federal egg products inspection regulations by removing current requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment prior to their use in official plants. The Agency also plans to eliminate the prior label approval system for egg products. This proposal will not encompass shell egg packers. In the near future, FSIS will initiate non-regulatory outreach efforts for shell egg packers that will provide information intended to help them to safely process shell eggs intended for human consumption or further processing.

The actions being proposed are part of FSIS' regulatory reform effort to improve FSIS' egg products food safety regulations, better define the roles of Government and the regulated industry, encourage innovations that will improve food safety, remove unnecessary regulatory burdens on inspected egg products plants, and make the egg products regulations as consistent as possible with the Agency's meat and poultry products regulations. FSIS is also taking these actions in light of changing inspection priorities and recent findings of Salmonella in pasteurized egg products.

Statement of Need:

FSIS is proposing to require egg products plants and plants pasteurizing shell eggs to develop and implement HACCP systems and sanitation SOPs. FSIS also is proposing pathogen reduction performance standards that would be applicable to pasteurized shell eggs and egg products. Plants would be expected to develop HACCP systems that ensure that these products meet the lethality required by the pathogen reduction performance standards. In addition, FSIS is proposing to amend the Federal egg products inspection regulations by removing current requirements for approval by FSIS of egg product plant drawings, specifications, and equipment prior to their use in official plants. Finally, the Agency plans to eliminate the pre-marketing label approval system for egg products but

to require safe-handling labels on all shell eggs.

The actions being proposed are part of FSIS' regulatory reform effort to improve FSIS' shell egg and egg products food safety regulations, better define the roles of Government and the regulated industry, encourage innovations that will improve food safety, remove unnecessary regulatory burdens on inspected egg products plants, and make the egg products regulations as consistent as possible with the Agency's meat and poultry products regulations. FSIS also is taking these actions in light of changing inspection priorities and recent findings of Salmonella in pasteurized egg products.

This proposal is directly related to FSIS' PR/HACCP initiative.

Summary of Legal Basis:

This proposed rule is authorized under the Egg Products Inspection Act (21 U.S.C. 1031 to 1056). It is not the result of any specific mandate by the Congress or a Federal court.

Alternatives:

A team of FSIS economists and food technologists is conducting a cost-benefit analysis to evaluate the potential economic impacts of several alternatives on the public, egg products industry, and FSIS. These alternatives include: (1) Taking no regulatory action; (2) requiring all inspected egg products plants to develop, adopt, and implement written sanitation SOPs and HACCP plans; and (3) converting to a lethality-based pathogen reduction performance standard many of the current highly prescriptive egg products processing requirements. The team will consider the effects of a uniform, across-the-board standard for all egg products; a performance standard based on the relative risk of different classes of egg products; and a performance standard based on the relative risks to public health of different production processes.

Anticipated Cost and Benefits:

FSIS is analyzing the potential costs of this proposed rulemaking to industry, FSIS and other Federal agencies, State and local governments, small entities, and foreign countries. The expected costs to industry will depend on a number of factors. These costs include the required lethality, or level of pathogen reduction, and the cost of HACCP plan and sanitation SOP development, implementation, and associated employee training. The pathogen reduction costs will depend on the amount of reduction sought and in what classes of product, product formulations, or processes.

Relative enforcement costs to FSIS and Food and Drug Administration may change because the two agencies share responsibility for inspection and oversight of the egg industry and a common farm-to-table approach for shell egg and egg products food safety. Other Federal agencies and local governments are not likely to be affected.

FSIS has cooperative agreements with four States and the Commonwealth of Puerto Rico under which they provide inspection services to egg processing plants under Federal jurisdiction. FSIS reimburses the States for staffing costs and expenses for full-time State inspectors. HACCP implementation may result in a reduction of staffing resource requirements in the States and a corresponding reduction of the Federal reimbursement. As a result, some States may decide to stop providing inspection services and convert to Federal inspection of egg products plants.

Egg and egg product inspection systems of foreign countries wishing to export eggs and egg products to the U.S. must be equivalent to the U.S. system. FSIS will consult with these countries, as needed, if and when this proposal becomes effective.

This proposal is not likely to have a significant impact on small entities. The entities that would be directly affected by this proposal would be the approximately 75 federally inspected egg products plants, most of which are small businesses, according to Small Business Administration criteria. If necessary, FSIS will develop compliance guides to assist these small firms in implementing the proposed requirements.

Potential benefits associated with this rulemaking include: Improvements in human health due to pathogen reduction; improved utilization of FSIS inspection program resources; and cost savings resulting from the flexibility of egg products plants in achieving a lethality-based pathogen reduction performance standard. Once specific alternatives are identified, economic analysis will identify the quantitative and qualitative benefits associated with each.

Human health benefits from this rulemaking are likely to be small because of the low level of (chiefly post-processing) contamination of pasteurized egg products. In light of recent scientific studies that raise questions about the efficacy of current regulations, however, it is likely that measurable reductions will be achieved in the risk of foodborne illness.

Risks:

FSIS believes that this regulatory action may result in a further reduction in the risks associated with egg products. The development of a lethality-based pathogen reduction performance standard for egg products, replacing command-and-control regulations, will remove unnecessary regulatory obstacles to, and provide incentives for, innovation to improve the safety of egg products.

To assess the potential risk-reduction impacts of this rulemaking on the public, an intra-Agency group of scientific and technical experts is conducting a risk management analysis. The group has been charged with identifying the lethality requirement sufficient to ensure the safety of egg products and the alternative methods for implementing the requirement. The egg products processing and distribution module of the Salmonella enteritidis Risk Assessment, made public June 12, 1998, will be appropriately modified to evaluate the risk associated with the regulatory alternatives.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State

Federalism:

Undetermined

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USDA—FSIS

18. FOOD STANDARDS; GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq; 21 USC 451 et seq; 21 USC 321 et seq

CFR Citation:

9 CFR 410; 21 CFR 130

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are proposing to modernize their food standards. The agencies are proposing a set of general principles for food standards. The adherence to these principles will result in standards that will better promote honesty and fair dealing in the interest of consumers, protect the public, allow for technological advances in food production, are consistent with international food standards, and are clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards. The proposed general principles will establish the criteria that the agencies will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule.

Statement of Need:

This rule is necessary to modernize FDA and FSIS food standards, so that they are consistent with the agencies' authorizing statutes, allow for technological advances in food production, are consistent with international food standards to the extent feasible, and are clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards.

Summary of Legal Basis:

Under 21 U.S.C. 341, FDA has authority to fix and establish standards of identity, standards of quality, or standards of fill of container for food products regulated by FDA, when such regulations will promote honesty and fair dealing in the interest of consumers. Similarly, under 21 U.S.C. 607(c) and 457(b), FSIS has authority to establish meat and poultry product standards of identity or composition whenever such regulations are necessary for the protection of the public. The proposed rule will ensure that FDA and FSIS food standards are consistent with the authorizing statutes.

Alternatives:

In addition to the option chosen, the Agencies considered the following options: 1) No action; 2) removing all food standards from the regulations and treating all foods as nonstandardized foods; 3) using Agency resources to review and revise food standards rather than relying on external petitions; and 4) requesting external industry groups to review, revise, and administer the food standards (private certification).

Anticipated Cost and Benefits:

Establishing general principles for food standards ensures that FSIS and FDA use a consistent and systematic approach when assessing standards. These principles would also apprise external parties of the framework FDA and FSIS intend to use when assessing standards, thereby reducing the costs for external parties to petition the agencies to change standards. An additional benefit is that establishing the set of principles specified in this proposed rule ensures that FDA and FSIS assess standards with respect to their ability to reduce consumers' search costs, while also reducing the likelihood that standards will impose unnecessary costs, or reduce competition and thereby increase prices.

FSIS and FDA expect the costs associated with this rule to be small and the benefits to be relatively substantial. Therefore, the Agencies believe that the benefits of establishing the proposed principles outweigh the costs.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

19. PERFORMANCE STANDARD FOR CHILLING OF READY–TO–COOK POULTRY

Priority:

Other Significant

Legal Authority:

21 USC 451 to 470

CFR Citation:

9 CFR 381.66

Legal Deadline:

None

Abstract:

FSIS is proposing a performance standard for the chilling of ready-to-cook poultry products that is intended to ensure the control of microorganisms on the products from a point after evisceration until the products are frozen, further processed, or packaged for shipment from the processing plant. The current specific time and temperature requirements for chilling poultry carcasses of various weights would be retained as alternative requirements that poultry processors could choose to meet. FSIS is taking this action to provide poultry processors with greater flexibility in achieving the purposes of the poultry chilling requirements whilst complying with the Agency's Hazard Analysis and Critical Control Point (HACCP) and other regulations. This proposal responds to petitions from industry trade associations.

Statement of Need:

This proposed rule addresses Federal regulations that are inconsistent with the PR/HACCP regulations because they restrict the ability of poultry processors to choose appropriate and effective measures to eliminate, reduce, or control biological hazards identified in their hazard analyses. The regulations also complicate efforts by establishments to comply with the terms of the January 9, 2001, final rule

further restricting the amount of water that may be retained in raw meat or poultry products after post-evisceration processing; some establishments may have to use chilling procedures that result in higher levels of retained water in carcasses than may be necessary to achieve the same food safety objective. For example, establishments that operate automated chillers may have to subject poultry carcasses to higher agitation rates or longer dwell times in the chillers. Also, as discussed above, the time/temperature chilling regulations for poultry are inconsistent with the PR/HACCP regulations, the retained water regulations, and the meat inspection regulations.

Summary of Legal Basis:

This regulatory action is authorized under the Poultry Products Inspection Act (21 U.S.C. 451 to 470).

Alternatives:

FSIS evaluated five regulatory alternatives: (1) Taking no regulatory action; (2) replacing the command-and-control requirements with a performance standard; (3) requiring meatpackers, as well as poultry processors, to comply with such a performance standard; (4) requiring all establishments that prepare raw meat or poultry products or handle, transport, or receive the products in transportation to comply with a performance standard; or (5) removing the command-and-control requirements from the poultry products inspection regulations. The Agency chose the second alternative but would make the existing requirements a ''safe harbor.''

Anticipated Cost and Benefits:

Poultry processors would gain the flexibility to choose the best processing techniques and procedures for achieving production efficiencies, meeting HACCP food safety objectives, and preventing economic adulteration of raw product with retained water in amounts greater than those which are unavoidable for food-safety purposes. They would be able to operate with a wider range of chilling temperatures consistent with the requirements of the PR/HACCP regulations. The poultry products industry could achieve energy efficiencies resulting in annual savings of as much as $2.8 million. The industry could also reduce carcass ''dwell times'' in immersion chillers and thereby reduce the amount of water absorbed and retained by the carcasses. The reduction in dwell time might enable some establishments, particularly those currently operating at the throughput capacity of their chillers, to increase production by installing additional evisceration lines.

Poultry establishments would therefore be able to operate more efficiently to provide consumers with product that is not adulterated. FSIS also would gain some flexibility by being able to reallocate some inspection resources from measuring the temperature of chilled birds to such activities as HACCP system verification.

This proposed rule would directly impose no new costs on the regulated industry. It would relieve burdens arising from the disparate impacts of the current regulations on the meat and poultry industries.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

FINAL RULE STAGE

20. PERFORMANCE STANDARDS FOR THE PRODUCTION OF PROCESSED MEAT AND POULTRY PRODUCTS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 451 et seq; 21 USC 601 et seq

CFR Citation:

9 CFR 301; 9 CFR 303; 9 CFR 317; 9 CFR 318; 9 CFR 319; 9 CFR 320; 9 CFR 325; 9 CFR 331; 9 CFR 381; 9 CFR 417; 9 CFR 430; CFR 431

Legal Deadline:

None

Abstract:

FSIS has proposed to establish pathogen reduction performance standards for all ready-to-eat (RTE) and partially heat-treated meat and poultry products. The performance standards spell out the objective level of pathogen reduction that establishments must meet during their operations in order to produce safe products but allow the use of customized, plant-specific processing procedures other than those prescribed in the earlier regulations. Along with HACCP, food safety performance standards will give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls, while providing objective, measurable standards that can be verified by Agency inspectional oversight. This set of performance standards will include and be consistent with standards already in place for certain ready-to-eat meat and poultry products.

Statement of Need:

The Food Safety and Inspection Service (FSIS) has proposed to amend the Federal meat and poultry inspection regulations by establishing food safety performance standards for all ready-to-eat and all partially heat-treated meat and poultry products. The proposed performance standards set forth both levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve during their operations in order to produce unadulterated products but allow the use of customized, plant-specific processing procedures. The proposed performance standards apply to ready-to-eat meat and poultry products, categorized as follows: Dried products (e.g., beef or poultry jerky); salt-cured products (e.g., country ham); fermented products (e.g., salami and Lebanon bologna); cooked and otherwise processed products (e.g., beef and chicken burritos, corned beef, pastrami, poultry rolls, and turkey franks); and thermally processed, commercially sterile products (e.g.,

canned spaghetti with meat balls and canned corned beef hash).

Although FSIS routinely samples and tests some ready-to-eat products for the presence of pathogens prior to distribution, there are no specific regulatory pathogen reduction requirements for most of these products. The proposed performance standards will help ensure the safety of these products; give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls; and provide objective, measurable standards that can be verified by Agency oversight.

The proposal also contained provisions addressing Listeria monocytogenes in RTE products. An Interim Final Rule on this subject was published June 6, 2003 (68 FR 34208).

FSIS also has proposed to eliminate its regulations that require that both ready-to-eat and not-ready-to-eat pork and products containing pork be treated to destroy trichinae (Trichinella spiralis). These requirements are inconsistent with HACCP, and some will be unnecessary if FSIS makes final the proposed performance standards for ready-to-eat meat and poultry products.

Summary of Legal Basis:

Under the Federal Meat Inspection Act (21 U.S.C. 601 to 695) and the Poultry Product Inspection Act (21 U.S.C. 451 to 470), FSIS issues regulations governing the production of meat and poultry products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and poultry products are safe, not adulterated, and properly marked, labeled, and packaged.

Alternatives:

As an alternative to all of the proposed requirements, FSIS considered taking no action. As alternatives to the proposed performance standard requirements, FSIS considered end-product testing and requiring ''use-by'' date labeling on ready-to-eat products.

Anticipated Cost and Benefits:

Benefits are expected to result from less contaminated products entering commercial food distribution channels as a result of improved sanitation and process controls and in-plant verification. FSIS believes that the benefits of the rule would exceed the total costs of implementing its provisions.

The main provisions of the proposed rule are: Lethality performance standards for Salmonella and E. coli 0157:H7 and stabilization performance standards for C. perfringens that firms must meet when producing RTE meat and poultry products. Most of the costs of these requirements would be associated with one-time process performance validation in the first year of implementation of the rule and with revision of HACCP plans. Total industry-wide costs are estimated to be $7.1 million. Benefits are expected to result from the entry into commercial food distribution channels of product with lower levels of contamination resulting from improved in-plant process verification and sanitation.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	02/27/01	66 FR 12590
NPRM Comment Period End	05/29/01	
NPRM Comment Period Extended	07/03/01	66 FR 35112
NPRM Comment Period End	09/10/01	
Interim Final Rule	06/06/03	68 FR 34208
Interim Final Rule Effective	10/06/03	
Interim Final Rule Comment Period End	12/08/04	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 0583–AC46

USDA—FSIS

21. NUTRITION LABELING OF SINGLE–INGREDIENT PRODUCTS AND GROUND OR CHOPPED MEAT AND POULTRY PRODUCTS

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq; 21 USC 451 et seq

CFR Citation:

9 CFR 317; 9 CFR 381

Legal Deadline:

None

Abstract:

FSIS has proposed to amend the Federal meat and poultry products inspection regulations to require nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, unless an exemption applies. FSIS also proposed to require nutrition information on the label of ground or chopped meat and poultry products, unless an exemption applies. The requirements for ground or chopped products will be consistent with those for multi-ingredient products.

FSIS also proposed to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the regulatory criteria to be labeled ''low fat,'' a lean percentage claim may be included on the label or in labeling, as long as a statement of the fat percentage also is displayed on the label or in labeling.

Statement of Need:

The Agency will require that nutrition information be provided for the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, because during the most recent surveys of retailers, the Agency did not find significant participation in the voluntary nutrition labeling program for single-ingredient, raw meat and poultry products. Without the nutrition information for the major cuts of single-ingredient, raw meat and poultry products that would be provided if significant participation in the voluntary nutrition labeling program existed, FSIS has concluded that these products would be misbranded.

Because consumers cannot easily estimate the level of fat in ground or chopped meat and poultry products and because producers are able to

formulate precisely the fat content of ground or chopped products, FSIS has concluded that ground or chopped meat and poultry products that do not bear nutrition information on their labels would also be misbranded.

Finally, FSIS will amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the criteria to be labeled ''low fat,'' a lean percentage claim may be included on the product, as long as a statement of the fat percentage is also displayed on the label or in labeling. FSIS will include these provisions in the final nutrition labeling regulations because many consumers have become accustomed to this labeling on ground beef products and because this labeling provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products.

Summary of Legal Basis:

This action is authorized under the Federal Meat Inspection Act (21 U.S.C. 601 to 695) and the Poultry Products Inspection Act (21 U.S.C. 451 to 470).

Alternatives:

No action; nutrition labels required on all single-ingredient, raw products (major cuts and non-major cuts) and all ground or chopped products; nutrition labels required on all major cuts of single-ingredient, raw products (but not non-major cuts) and all ground or chopped products; nutrition information at the point-of-purchase required for all single-ingredient, raw products (major and non-major cuts) and for all ground or chopped products.

Anticipated Cost and Benefits:

Costs will include the equipment for making labels, labor, and materials used for labels for ground or chopped products. The cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products should not be significant, because retail establishments would have the option of providing nutrition information through point-of-purchase materials.

Benefits of the nutrition labeling rule would result from consumers modifying their diets in response to new nutrition information concerning ground or chopped products and the major cuts of single-ingredient, raw products. Reductions in consumption of fat and cholesterol are associated with reduced incidence of cancer and coronary heart disease. FSIS has concluded that the quantitative benefits will exceed the quantitative costs of the rule.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/18/01	66 FR 4970
NPRM Comment Period End	04/18/01	
Extension of Comment Period	04/20/01	66 FR 20213
NPRM Comment Period End	07/17/01	
Final Action	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

22. PROHIBITION OF THE USE OF SPECIFIED RISK MATERIALS FOR HUMAN FOOD AND REQUIREMENTS FOR THE DISPOSITION OF NON–AMBULATORY DISABLED CATTLE

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

21 USC 601 et seq

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

On January 12, 2004, the Food Safety and Inspection Service (FSIS) issued an interim final rule to amend the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as ''specified risk materials'' (SRMs). The Agency declared that SRMs are inedible and prohibited their use for human food. In addition, as a result of the interim final rule, FSIS now requires that all non-ambulatory disabled cattle presented for slaughter be condemned. The Agency also requires that federally inspected establishments that slaughter cattle and federally inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS took this action in response to the diagnosis on December 23, 2003, by the U.S. Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington. This action is intended to minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. Infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease.

Statement of Need:

FSIS issued an interim final rule to amend the meat inspection regulations to add provisions to prevent meat and meat products that may contain the BSE agent from entering commerce.

BSE is a chronic, degenerative, neurological disorder of cattle. Worldwide, there have been more than 185,000 cases since the disease was first diagnosed in 1986 in Great Britain. Recent laboratory and epidemiological research indicate that there is a causal association between BSE and variant Creutzfeldt-Jakob Disease (vCJD), a slow degenerative disease that affects the central nervous system of humans. Both BSE and vCJD are always fatal.

USDA policy in regard to BSE has been to be proactive and preventive. The regulations: (1) Prohibit certain materials that have been shown to

contain the BSE agent in BSE-infected cattle to be used for human food or in the production of human food; (2) prescribe handling, storage, and transportation requirements for such materials; (3) prohibit slaughter procedures that may cause potentially infective tissues to migrate to edible tissues; (4) prescribe requirements for the slaughtering and processing of cattle whose materials are most likely to contain the BSE agent if the animal is infected with BSE; and (5) prescribe requirements for the sanitation or disposal of plant equipment that may be contaminated with the BSE agent.

Summary of Legal Basis:

Under the Federal Meat Inspection Act (21 U.S.C. 601 to 695), FSIS issues regulations governing the production of meat and meat food products. The regulations, along with FSIS inspection programs, are designed to ensure that meat food products are safe, not adulterated, and properly marked, labeled, and packaged.

Alternatives:

As an alternative to the interim final rule, FSIS considered taking no action. FSIS rejected this option because, as previously mentioned, USDA policy in regard to BSE has been to be proactive and preventive.

Anticipated Cost and Benefits:

This interim final rule could result in costs to the regulated industry. FSIS expects to minimize the costs by targeting the regulations to apply to those cattle whose materials are most likely to contain the BSE agent if the animal is infected with BSE. Banning certain materials, such as brain and spinal cord, for use as human food may require additional staff and time to remove such materials. Materials prohibited for use as human food could not be sold domestically or exported. Companies may be required to find new ways to handle and dispose of these materials, which would impose additional costs. Prohibiting the use of bovine vertebral column as a source material in AMRS could result in a decrease in product yield and may require companies that use these systems to produce boneless beef and beef products to find other uses for bovine vertebral column. Establishments whose equipment may have been contaminated with the BSE agent may have costs associated with sanitation or disposal of plant equipment.

FSIS may incur costs to increase inspection and compliance activities to ensure that the measures taken to prevent meat and meat food products that may contain the BSE agent from entering commerce are effective. Producers may receive lower prices from processors, and some of their stock may be condemned outright. The price consumers pay for meat may rise or fall depending on how the discovery of BSE in the U.S. affects consumer demand for beef.

The main benefit of this proposed rule is the prevention of vCJD in the United States. There have been over 100 definite and probable cases of vCJD detected worldwide since the disease was first identified in 1986 in the United Kingdom. While vCJD is still considered a rare condition, the extent or occurrence of a vCJD epidemic in the United Kingdom cannot be determined because of the long incubation period (up to 25 years). Thus, the interim final rule could have widespread public health benefits if it serves to prevent a vCJD epidemic from developing in the U.S. Even if vCJD remains a rare condition, this proposed rule will still have public health benefits because of the severity of the symptoms associated with vCJD and the fact that vCJD is always fatal.

This interim final rule may benefit the meat industry by helping to restore confidence in the domestic meat supply. This may limit losses to meat slaughter and processing operations in the long run.

Risks:

Although vCJD is a rare condition, the symptoms are severe, and it is always fatal. This interim final rule is intended to reduce the risk of humans developing vCJD in the U.S. in the event BSE is detected in native cattle. The measures implemented by FSIS are intended to minimize human exposure to materials from cattle that could potentially contain the BSE agent. In April 1998, USDA entered into a cooperative agreement with Harvard University's School of Public Health to conduct a risk analysis to assess the potential pathways for entry into U.S. cattle and the U.S. food supply, to evaluate existing regulations and policies, and to identify any additional measures that could be taken to protect human and animal health. FSIS used the findings of the risk assessment to inform its decision to prohibit certain bovine materials for human food.

Unlike bacterial and viral pathogens that may be found in or on meat food products, the BSE agent cannot be destroyed by conventional methods, such as cooking or irradiation. Also, although it is rare, vCJD, the human disease associated with exposure to the BSE agent, is generally more severe than the human illnesses associated with exposure to bacterial and viral pathogens. Thus, additional measures to reduce the risk of human exposure to the BSE agent are necessary to protect public health.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/12/04	69 FR 1862
Interim Final Rule Comment Period End	04/12/04	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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USDA—Forest Service (FS)

PROPOSED RULE STAGE

23. STATE PETITIONS FOR INVENTORIED ROADLESS AREA MANAGEMENT

Priority:

Other Significant

Legal Authority:

16 USC 472; 16 USC 529; 16 USC 551; 16 USC 1608; 16 USC 1613; 23 USC 201; 23 USC 205

CFR Citation:

36 CFR 294 subpart B

Legal Deadline:

None

Abstract:

On January 12, 2001, the Forest Service published the Roadless Area Conservation final rule (the ''roadless rule'') in the Federal Register establishing prohibitions on road construction, road reconstruction, and timber harvesting in inventoried roadless areas at 36 CFR part 294, subpart B (66 FR 3244). Since publication, the roadless rule has been challenged by nine lawsuits filed in six judicial districts and in four Federal circuits. On July 14, 2003, the U.S. District Court for the District of Wyoming issued a permanent injunction order enjoining the Department from implementing the roadless rule. That ruling has been appealed.

Due to the continued legal uncertainty of providing protection for roadless areas through the application of the roadless rule, the Agency is proposing to amend the roadless rule by replacing the prohibitions of the January 2001 rule with a procedural rule that would set out an administrative process for State Governors to petition the Secretary of Agriculture to establish or adjust management direction for roadless areas within their State. Such petitions would be evaluated and, if agreed to, addressed by the Secretary in subsequent rulemaking on a State-by-State basis.

Statement of Need:

The Department of Agriculture is committed to conserving and managing roadless values and considers inventoried roadless areas an important component of the National Forest System. The 2001 roadless rule has been the subject of nine lawsuits in Federal district courts in Idaho, Utah, North Dakota, Wyoming, Alaska, and the District of Columbia. On July 14, 2003, the U.S. District Court for the District of Wyoming found the 2001 roadless rule to be unlawful and ordered that the rule be permanently enjoined. That ruling has been appealed to the Tenth Circuit by intervenors. Due to the continued legal uncertainty surrounding the 2001 roadless rule, the Forest Service published a proposed rule on July 16, 2004, that would replace it with a petitioning process that would provide Governors an opportunity to seek establishment of management requirements for inventoried roadless areas within their State. This opportunity for State petitions would be available for 18 months following the effective date of the final rule. It is anticipated that this timeframe will be sufficient for States to collaborate effectively with local governments, Indian Tribes, stakeholders, and other interested parties to develop proposals that consider a full range of public input. A State petition would be evaluated and, if accepted by the Secretary of Agriculture, the Forest Service would initiate subsequent State-specific rulemaking for the management of inventoried roadless areas in cooperation with the State involved in the petitioning process and in consultation with stakeholders and experts. The Department believes that revising 36 CFR part 294 to replace the existing rule with a State petitioning process that would allow State-specific consideration of the needs of these areas is an appropriate solution to address the challenges of inventoried roadless area management. On September 9, 2004, in response to several written requests, the Forest Service extended the public comment period on the proposed rule until November 15, 2004. The Department will issue a final rule after thorough evaluation and consideration of public comments.

Summary of Legal Basis:

There is no aspect of this action that is required by statute or court order. On January 12, 2001, the Department of Agriculture promulgated a regulation to provide for the conservation and management of inventoried roadless areas within the National Forest System under the principles of the Multiple-Use Sustained-Yield Act of 1960. The existing Roadless Area Conservation Rule has been the subject of nine lawsuits and on July 14, 2003, was permanently enjoined and set aside by the U.S. District Court for the District of Wyoming. That ruling has been appealed to the Tenth Circuit by intervenors. This proposal is to replace the 2001 enjoined rule.

Alternatives:

Until promulgation of the 2001 roadless rule, the Forest Service managed inventoried roadless areas based on management requirements in individual land management plans. These plans have been developed for each unit of the National Forest System through a public notice and comment process, building on years of scientific findings and extensive public involvement. These plans typically identify and recommend inventoried roadless areas that would be appropriate to be designated as wilderness by the Congress and provide guidance on activities and uses in these areas. This is the current management situation with the 2001 roadless rule permanently enjoined. An alternative to the proposed rule would be for the management of these areas to revert to the management requirements in individual land management plans and not to allow Governors to petition the Secretary to adjust the management for these areas within their States (no action alternative).

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of this proposed rule have been developed by comparing selected effects if 58.5 million acres of inventoried roadless areas are managed following the prohibitions for road construction and timber management activities in the 2001 roadless rule or if these same areas are managed in accordance with the existing management requirements contained in individual land management plans. Approximately 25 percent of the total acres of inventoried roadless areas are in the State of Alaska. About 72 percent of the total is in the 11 Western States of Montana, Idaho, Wyoming, Washington, Utah, Oregon, New Mexico, Nevada, Colorado, California, and Arizona. The remaining 3 percent is scattered among 27 other States. While it is currently unknown which States may choose to submit a petition for State-specific rulemaking, the Forest Service assumes that all 38 States and the Commonwealth of Puerto Rico will do so in the first year after the rule is final. The costs to the Forest Service and the Department to evaluate and make a decision on a single petition are estimated to range from $75,000 to $150,000. Costs could range from $25,000 to $100,000 for an individual State submitting a petition. Total costs to the 38 States and the Commonwealth of Puerto Rico for 39 petitions would range from $975,000 to $3,900,000, therefore; and total costs to the Government would range from $2,925,000 to $5,850,000. Total costs of the rule are therefore estimated to range from $3,900,000 to $9,750,000. This proposed rule is expected to provide a variety of potential beneficial effects, which include the conservation of inventoried roadless areas; the protection of human health and safety; the reduction of hazardous fuels and restoration of essential wildlife habitats; the assurance of reasonable access to public and private property or facilities;

and the improvement of collaboration and partnerships with States.

Risks:

There are no risks addressed by this proposed rule. The conservation and management requirements of inventoried roadless areas on National Forest System lands have been developed through the land management planning process directed by the National Forest Management Act of 1976, and these management requirements are and have been consistent with all applicable Federal statutes, regulations, and policies. The controversy surrounding the management of these lands concerns the level of development activities that should be allowed on them. These areas were originally identified because they met the criteria for potential wilderness, and they are evaluated for their wilderness potential in the land management planning process. Certain developmental activities such as road construction, road reconstruction, or timber management, if allowed, may affect the future evaluation and consideration of these areas as potential wilderness.

Timetable:

Action	Date	FR Cite
NPRM	07/16/04	69 FR 42636
NPRM Comment Period End	09/14/04	
NPRM Comment Period Extended	09/09/04	69 FR 54600
NPRM Comment Period End	11/15/04	
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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USDA—FS

FINAL RULE STAGE

24. NATIONAL FOREST SYSTEM LAND MANAGEMENT PLANNING

Priority:

Other Significant

Legal Authority:

16 USC et seq; 5 USC 301

CFR Citation:

36 CFR 219 subpart A

Legal Deadline:

None

Abstract:

The Forest Service is adopting a final rule that revises the National Forest System Land and Resource Management Planning Rule adopted November 9, 2000. The proposed rule was published December 6, 2002 (67 FR 72770). The proposed changes are a result of a review conducted by Forest Service personnel at the direction of the Office of the Secretary.

The final rule also responds to internal review and comments received after the proposed rule was published on December 6, 2002. This rule is intended to improve upon the 2000 rule by providing a planning process that is more readily understood, is within the Agency's capability to implement, is within anticipated budgets and staffing levels, and recognizes the programmatic nature of planning.

Statement of Need:

The President's environmental program includes natural resource planning for all units of the National Forest System. In support of that effort, the Forest Service is adopting a final rule at 36 CFR part 219, subpart A, to revise the land management planning rule, published on November 9, 2000, governing how future changes in land management planning direction will be made and how those changes will be documented. The proposed rule was published in the Federal Register on December 6, 2002, for a 90-day public comment period. The comment period was extended 30 days to April 7, 2003. The proposed rule continued to support the major principles of the 2000 rule, which are the underlying concepts of sustainability, monitoring and evaluation, collaboration, and use of science. The proposed rule, however, improved the clarity of the 2000 rule, characterized planning as a continuous process, offered two options to provide for diversity of plant and animal communities, and provided for plan analysis to be categorically excluded from National Environmental Policy Act (NEPA) documentation. The Agency received over 195,000 comments on the proposed rule. Consideration of these comments will lead to a final rule that better enables the Forest Service to be good land stewards by providing the clean air and water and wildlife protection the public expects. This goal would be accomplished by shifting from a complex, cumbersome, and expensive up front planning process, to a streamlined process that better involves the public, and shifts resources to land management and continual monitoring and evaluation.

Summary of Legal Basis:

The Forest and Rangeland Renewable Resources Planning Act of 1974 (88 Stat. 476 et seq.), as amended by the National Forest Management Act of 1976 (NFMA) (90 Stat. 2949 et seq.), requires the Secretary to promulgate regulations under the principles of the Multiple-Use Sustained-Yield Act of 1960 that set out the process for the development and revision of land management plans (16 U.S.C. 1604(g)).

Alternatives:

The Forest Service considered and compared the final planning rule to both the 1982 and the 2000 planning regulations. Land management plans prepared under the 1982 rule were difficult to prepare, took 5 to 7 years to complete, and required detailed analytical requirements that were of limited use due to the high degree of uncertainty of the projections. The 2000 planning rule requires a number of detailed analytical requirements, lacks clarity regarding many of these requirements, is not flexible enough, and lacks recognition of the limits of agency budgets and personnel needed to implement it.

Anticipated Cost and Benefits:

Estimates of the anticipated costs and benefits focused on key activities in land and resource management planning for which costs could be estimated under the 1982, 2000, and final planning rules. Based on costs that can be quantified, this final rule is estimated to result in a savings, compared to the expected costs under the 1982 rule and compared to the 2000 rule.

In addition to the anticipated cost savings, numerous intangible benefits are expected to result from the final rule. The overall goal of the final rule is to develop a planning framework that fosters stewardship of the National Forest System lands and improves the likelihood of contributing toward the ecological, social, and economic components of sustainability. Better decisions provide sustained goods, services, and values without impairment of the health of the land. These improvements will be based on better collaboration with the public, improved monitoring and evaluation, integration of science, and a more flexible process that reduces the burden on both the public and the Agency. A planning process that addresses public concerns and leads to improved health of the public lands has value beyond the cost savings estimated in the analysis.

Risks:

The final planning rule will help to reduce the risks of natural resource management on National Forest System lands by strengthening the Forest Service's ability to respond quickly and effectively to a variety of continually changing issues, such as the development of new scientific information, new listing of species, the effects of wildfire, changes in demographics or the economy, and unforeseen effects of plan implementation activities. The final planning rule allows for a more flexible approach to planning and reducing risks by providing for a continual and adaptive planning cycle involving on-the-ground project proposal, analysis, and implementation; monitoring and evaluation; and plan adjustment. The final planning rule would allow flexible implementation of projects to avoid and reduce risks; for example, projects to implement the Agency's hazardous fuels reduction program.

Timetable:

Action	Date	FR Cite
NPRM	12/06/02	67 FR 72770
NPRM Comment Period End	03/24/03	
Final Action	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—Natural Resources Conservation Service (NRCS)

FINAL RULE STAGE

25. EMERGENCY WATERSHED PROTECTION PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 81–516; 33 USC 701; PL 95–334; PL 104–127; 16 USC 2203

CFR Citation:

7 CFR 624

Legal Deadline:

None

Abstract:

A revision is necessary to incorporate changes in the program, which have resulted from the passage of the 1996 Farm Bill; to fulfill a desire to make the program more responsive and efficient; and to respond to concerns of the public and the Agency. The rule is being reorganized and several items added.

Statement of Need:

The Emergency Watershed Protection (EWP) Program alleviates threats to life and property that remain in the Nation's watersheds in the aftermath of natural disasters such as floods, hurricanes, tornadoes, and wildfires. The EWP Program is administered by the USDA NRCS, which provides technical and financial assistance to local sponsoring authorities to preserve life and property threatened by disaster-caused erosion and flooding. Funding is provided through congressional emergency appropriations. Threats that the EWP Program addresses are termed ''watershed impairments.'' These include debris-clogged stream channels, undermined and unstable stream banks, jeopardized water control structures and public infrastructure, and damaged upland sites stripped of protective vegetation by fire or drought. If these watershed impairments are not addressed, they would pose a serious threat of injury, loss of life, or devastating property damage should a subsequent event occur.

NRCS' final rule action is to codify existing EWP Program implementation and institute programmatic changes that allow:

1.The repair of enduring conservation practices;

2.Limits repeated site repairs;

3.Allows additional easement purchases;

4.Addresses environmental justice issues; and

5.Limits treatments on federal lands.

To implement the final rule action, NRCS would incorporate changes in Program administration and in project execution dealing with traditional watershed impairments. It would expand the Program by providing to the list of watershed impairments EWP currently addresses:

1.Floodplain sediment deposition removal;

2.Upland wind-borne debris removal; and

3.Repair damaged structural conservation practices.

The purpose and need for the NRCS final rule action are to provide administrative transparency that ensures that the public is fully informed of program operations. Program delivery improvements are designed to enable NRCS field and State office personnel to pro EW assistance more effectively and efficiently. The improvements would more fully, equitably, and consistently meet the needs of people requiring emergency assistance. Program improvements are designed to address environmental, economic, and social concerns and values.

Summary of Legal Basis:

The regulation for EWP, 7 CFR 624, was first promulgated in 1973. The EWP Program was authorized by section 216 of the Flood Control Act of 1950 (Pub. L. 81-516) by amending the Flood Control Act of 1944 (Pub. L. 78-534).

The EWP Manual documents NRCS policy governing EWP; the National EWP Handbook provides field procedures. NRCS staff administers EWP in the field when sponsors request assistance with disaster damage. NRCS staff completes Disaster Survey Reports (DSRs) describing the watershed impairments at a particular site, their eligibility for repairs, the cost and benefits of appropriate conservation measures, the social impacts, and the environmental and technical soundness of the measures. The NRCS EWP implementing documents, manual, and handbook (including the DSR) will be revised to reflect any program changes in the EWP regulation. This means of assessing that net social benefits exceed net social costs on each individual DSR site assures that NRCS complies with the expectations of public process.

Section 382 of the Federal Agricultural Improvement and Reform Act of 1996, the 1996 Farm Bill, authorizes the acquisition of floodplain easements on flood prone lands as an alternative to traditional eligible EWP recovery practices. The floodplain easement acquisition component is fully voluntary and complements the traditional recovery practices to provide a more permanent solution to repetitive disaster assistance payments. This achieves greater environmental and societal benefits where the situation warrants and the affected landowner is willing to participate in the easement approach.

Alternatives:

Prioritized Watershed Planning and Management.

Anticipated Cost and Benefits:

Same under each option since Congress and Administration establish the appropriation. EWP is funded through emergency supplemental appropriations.

Risks:

Program delivery improvements through the promulgation of regulation are designed to enable NRCS field and State office personnel with EWP Program responsibility to provide EWP assistance more effectively and efficiently when and where it is needed. The improvements would more fully, equitably, and consistently meet the needs of people requiring emergency assistance. Program defensibility improvements are designed to address environmental, economic, and social concerns and values.

Timetable:

Action	Date	FR Cite
NPRM	11/19/03	68 FR 65202
NPRM Comment Period End	01/20/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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USDA—NRCS

26. TECHNICAL SERVICE PROVIDER ASSISTANCE

Priority:

Other Significant

Legal Authority:

16 USC 3842

CFR Citation:

7 CFR 652

Legal Deadline:

None

Abstract:

Third Party Vendor assistance will allow producers to obtain technical services from the department or entities by a certification process. This process will distinguish between certification of an individual working under his or her own auspices and that of an organization such as a corporation or a public agency which has individuals working on its behalf. Certification of an individual means the individual has the requisite education and technical expertise to perform the technical services. Certification of an entity or public agency means that the organization may receive payment for the services provided by individuals working under its auspices, but the work must be performed or warranted by certified individuals and the organization must assume the liability for the quality of work performed.

Statement of Need:

In 1994, the Department of Agriculture reorganized and transferred increased responsibilities for administration of conservation programs to the Natural Resources Conservation Service (NRCS) to provide technical and financial assistance to producers to improve the natural resource conditions on their land. The Federal Agricultural Improvement and Reform Act of 1996 (the 1996 Farm Bill), Public Law 104—127, created several new conservation programs for which the Secretary of Agriculture delegated administrative responsibility to NRCS.

Through the implementation of its conservation programs, NRCS utilizes its technical expertise to provide producers with information to help them make land management decisions. When a producer applies to participate in a conservation program, NRCS helps the producer evaluate the resource conditions on their land to determine the most appropriate way to meet the producer's conservation objectives. Through its conservation planning process, NRCS helps the producer develop a conservation plan and, depending upon the availability of funds, the Department provides financial assistance to the producer to implement identified conservation practices or systems. The Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), Public Law 107—171, expanded the availability of financial and technical assistance funds for the implementation of conservation programs. At the time of enactment, the Congressional Budget Office estimated that the 2002 Farm Bill represented a $17 billion increase in the level of funding for conservation programs.

The current staffing levels of NRCS are insufficient to adequately meet the increased need for technical assistance under the conservation programs authorized or reauthorized by the 2002 Farm Bill. Section 2701 of the 2002 Farm Bill amended section 1242 of the Food Security Act of 1985 (Food Security Act), as amended, to require the Secretary of Agriculture to provide technical assistance er the Food Security Act conservation programs to a producer eligible for that assistance ''directly ... or at the option of the producer, through a payment ... to the producer for an approved third party, if available.'' The Secretary of Agriculture delegated authority to implement section 1242 to NRCS.

Section 1242 of the Food Security Act greatly expanded the availability of technical assistance to producers by

encouraging other potential providers of technical assistance to assist in the delivery of technical services. To ensure that high quality technical services are available to all producers, section 1242 requires the Secretary of Agriculture to establish, by regulation, a system for ''approving individuals and entities to provide technical assistance to carry out programs under the [Farm Bill] ... and establishing the amounts and methods for payments for that assistance.''

NRCS published an interim final rule on November 21, 2002, that established a certification process under which NRCS evaluated and approved individuals, entities, and public agencies as eligible to provide conservation technical services for certain conservation programs. The interim final rule also established the criteria by which NRCS will evaluate all potential providers of technical assistance.

On March 24, 2003, NRCS published an amendment to the interim final rule, establishing the process for determining payment levels for technical service provider assistance. In addition the amendment set forth the policy regarding subcontracting by technical service providers in the course of their delivery of technical services. The amendment also clarified the process for certification and amended the definition of technical service provider. The March 24, 2003, amendment had a 90-day comment period. NRCS received 15 comments from seven entities to this amendment.

On July 9, 2003, NRCS published a second amendment to the interim final rule, establishing a limited exception to tification and payment requirements when the Department is partnering with State, local, or tribal governments to carry out its duties to provide technical services. The July 9, 2003, amendment had a 30-day comment period. NRCS received 25 comments from 11 entities to this second amendment.

The final rule will establish the regulatory framework for technical service provider assistance for FY 2005 and thereafter, and will provide response to public comment.

Summary of Legal Basis:

Section 2701 of the 2002 Farm Bill amended section 1242 of the Food Security Act of 1985 (Food Security Act), as amended, to require the Secretary of Agriculture to provide technical assistance under the Food Security Act conservation programs to a producer eligible for that assistance ''directly ... or at the option of the producer, through a payment ... to the producer for an approved third party, if available.'' The Secretary of Agriculture delegated authority to implement section 1242 to NRCS.Section 1242 of the Food Security Act greatly expanded the availability of technical assistance to producers by encouraging other potential providers of technical assistance to assist in the delivery of technical services. To ensure that high quality technical services are available to all producers, section 1242 requires the Secretary of Agriculture to establish, by regulation, a system for ''approving individuals and entities to provide technical assistance to carry out programs under the [Farm Bill] ... and establishing the amounts and methods for payments for that assistance.''

Alternatives:

Secretary of Agriculture is required by statute to provide conservation program participants the ability to acquire qualified third-party technical assistance. Alternative is to not implement statute as required.

Anticipated Cost and Benefits:

$153 million benefits and annual costs of $77 million, of which only an estimated $28 million annually is cost associated with this rule.

Risks:

USDA conservation program participants will not be able to obtain the technical assistance needed to implement conservation practices and the associated benefits to the Nation's natural resource base.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/21/02	67 FR 70119
Interim Final Rule Comment Period End	02/19/03	
Interim Final Rule Effective	03/01/03	
Interim Final Rule	03/24/03	68 FR 14131
Interim Final Rule Comment Period End	06/23/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Federalism:

This action may have federalism implications as defined in EO 13132.

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USDA—NRCS

27. CONSERVATION SECURITY PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

16 USC 3838

CFR Citation:

7 CFR 1470

Legal Deadline:

None

Abstract:

Under the Conservation Security Program (CSP) NRCS is authorized to provide financial and technical assistance to owners and operators of agricultural operations to promote conservation and improvement of the quality of soil, water, air, energy, plant and animal life, and other conservation purposes.

Statement of Need:

USDA intends that CSP will recognize those farmers and ranchers, the land stewards, who meet the highest standards of conservation and environmental management. By managing all of the natural resources on their farms and ranches in a sustainable fashion to these high standards, stewards of the land benefit themselves, their communities, and society as a whole. CSP can be an important tool for those stewards and others who strive towards the highest standards of conservation and environmental management. CSP helps sustain the economic well-being of those farmers and ranchers who reach this pinnacle of good land stewardship and enhance the ongoing production of clean water and clean air on their farms

and ranches, which are valuable commodities to all Americans.

The fundamental philosophy and intent of CSP is to support ongoing conservation stewardship of working agricultural lands by providing payments and assistance to producers to maintain and enhance the condition of the resources. To implement the Secretary's vision, the program will reward owners and operators of agricultural lands for their conservation stewardship efforts and assist them with the implementation and maintenance of additional conservation measures that can improve the natural resource conditions of their agricultural operations. CSP particularly targets producers and activities that can provide the greatest additional benefits for the resource concerns identified in this rule and in CSP signup announcements. NRCS is additionally encouraging those who do not meet the sign-up requirements for CSP to initiate a review of the natural resource conditions on their land and begin or continue moving toward achieving the minimum conservation requirements to enter CSP at a later signup. Other USDA programs may be available for technical or financial assistance to help them achieve their resource management goals.

Summary of Legal Basis:

The Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171, May 13, 2002) (the Act) amended the Food Security Act of 1985 (16 U.S.C. 3801 et seq.) to authorize the Conservation Security Program (CSP). The program is administered by USDA's Natural Resources Conservation Service (NRCS). The CSP is a voluntary program that provides financial and technical assistance to producers who advance the conservation and improvement of soil, water, air, energy, plant, and animal life and other conservation purposes on tribal and private working lands. Such lands include cropland, grassland, prairie land, improved pasture, and range land, as well as forested land and other non-cropped areas that are an incidental part of the agriculture operation.

As originally enacted, the Conservation Security Program was an entitlement program where many producers would have received payments if they were eligible. Subsequent to the enactment of the 2002 Act, the Omnibus Bill of 2003 amended the Act to limit CSP's total expenditures to a total of $3.77 billion over 11 years (fiscal year 2003 through fiscal year 2013). When developing the regulations to implement CSP, USDA confronted several challenges. The greatest challenge, however, was to design a new conservation entitlement program with a cap on its total expenditures over multiple years. Statute did not provide direction as to how the Secretary should implement a broad entitlement program with the statutory fiscal constraints.The limits imposed by the budget cap greatly reduce the potential scope of the program. For example, USDA's Economic Research Service (ERS) estimates that over 1.8 million farms and ranches may be eligible for CSP, using the land eligibility criteria found in the authorizing legislation. If all of these agricultural operations were enrolled, the cost of the program would exceed the $3.77 billion cap potentially in the first sign-up. In contract, NRCS estimates that the budget cap would allow less than 50,000 total agricultural operations to participate over the life of the program. Estimates derived from a variety of analyses indicate that the average Tier III contract, based on nationally averaged data, could be near $15,000 per year. If contracts were an average of 7 years in duration, the statutory funding could support an estimated 30,000 Tier III contracts. The average Tier I and Tier II contracts could be near $7,000 annually. If contracts were to average 5 years in duration, the statutory funding could support an estimated 90,000 Tier I and II contracts.

Furthermore, NRCS expects that a large number of producers will seek participation in CSP and ask for assistance to determine their potential eligibility for the program. Thus, the statutory cap on technical assistance of 15 percent becomes another limiting factor for implementing CSP. By law, NRCS cannot incur technical assistance costs for NRCS employees or approved technical assistance providers in excess of 15 percent of the available funds.

Alternatives:

NRCS Preferred Approach:

1. Limit sign-ups: Conduct periodic CSP sign-ups.

2. Eligibility: Criteria should be sufficiently rigorous to ensure that participants are committed to conservation stewardship. Additionally, eligibility criteria should ensure that the most pressing resource concerns are addressed.

3. Contracts requirements should be sufficiently rigorous to ensure that participants undertake and maintain high levels of stewardship.

4. Prioritize funding to ensure that those producers with the highest commitment to conservation are funded first.

5. Structure payments to ensure that environmental benefits will be achieved.

Alternative Approaches:

1. Prioritize funding based on environmental considerations (e.g., high priority watersheds) with consideration given to past historical conservation.

2. Apportion the limited budget according to a formula of some kind, for example by discounting each participant's contract payments equally (i.e., prorate payments).

3. Close signup once available funds are exhausted (i.e., first come, first served).

4. Limit the number of tiers of participation offered.

5. Only allow historic stewards to participate—only those who have already completed the highest conservation achievement would be funded.

Anticipated Cost and Benefits:

NRCS developed a simulation model to analyze CSP benefits and costs. The model assesses producer participation and the overall benefits and costs to society associated with that participation. The model is based on a series of composite farms, replicating the process of calculating the CSP participation decision. Given farm-level estimates of participation, enrolled acreage, payments, and costs, the model estimates on-site and environmental (off-site) benefits, net economic costs, Government costs, Government-to-producer transfer payments, net benefit to society, and the benefit-cost ratio.

The model calculates the overall CSP payment by calculating several payment components individually, and then by summing the results of: The base payment, cost-sharing for installation of new structural practices and adoption of new land management practices, cost-sharing for maintenance of existing structural and land management practices, and enhancement payments. The Net Present Value (NPV) of each payment is determined by a payment rate per acre, the number of acres to which the payment applies, contract years in which the payment is made (i.e., whether the payment is made on a one-time or annual basis), discounted to the

present using a 7 percent annual discount rate. Payments for structural and land management practices were calculated using a methodology similar to that used for the Environmental Quality Incentives Program (EQIP) Benefit/Cost Analysis, Final Report, May 29, 2003.

Although the analysis provides estimates of the social net benefits of each alternative examined, its primary value is to illustrate the relative order of the identified alternatives, rather than provide accurate estimates of the costs and benefits. NRCS based its estimates on a number of assumptions because of substantial data gaps. There is, for example, no available information on the benefits associated with major program elements, such as enhancement activities above and beyond the non-degradation level. Instead, the RIA used estimates generated from experience with EQIP, CRP, and other USDA conservation programs. NRCS also assumes that producers would enroll in CSP if the program provided any positive net benefit to them (i.e., even as small as $1). This assumption does not take into consideration producers' cash flow constraints, which along with other factors could affect participation. Since the analysis does not have information on the behavioral response of producers to the incentives provided by CSP, the benefits analysis provided in the RIA is largely a hypothetical construct and does not reflect the benefits of the proposed program and the identified alternatives. NRCS intends to refine the analysis for the final rule.

Risks:

By issuing the proposed rule, NRCS builds upon the public input it received during the comment period associated with its ANPRM and is obtaining additional public comment on the implementation of a new, innovative conservation program. The proposed rule provides the public an opportunity to participate in the NRCS formation of program policies and procedures prior to NRCS publishing a final rule for the program.

Timetable:

Action	Date	FR Cite
NPRM	01/02/04	69 FR 193
NPRM Comment Period End	03/02/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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USDA—NRCS

28. GRASSLAND RESERVE

Priority:

Other Significant

Legal Authority:

PL 107–171; 16 USC 3838

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

Under Grassland Reserve Program (GRP) the Department enters into easement or rental agreements with owners of grazing land to protect and restore such lands. The Department will designate payment for cost share to restore the functions and values of grasslands.

Statement of Need:

Historically, grassland and shrublands occupied approximately one billion acres, about half the landmass of the 48 contiguous United States (Richard Conner, Texas A&M, June 2001). Roughly 50 percent of these lands have been converted to cropland, urban land, and other land uses. Privately owned grasslands (pastureland and rangeland) cover approximately 526 million acres in this country (1997 National Resource Inventory (NRI)). Grasslands provide both ecological and economic benefits to local residents and society in general. Grassland importance lies not only in the immense area covered but also in the diversity of benefits they produce. These lands provide water for urban and rural uses, livestock products, flood protection, wildlife habitat, and carbon sequestration. These lands also provide aesthetic value in the form of open space and are vital links in the enhancement of rural social stability and economic vigor, as well as being part of the Nation's history.

Grassland loss through conversion to other land uses such as cropland, parcels for home sites, invasion of woody or non-native species, and urban development threatens grassland resources. About 24 million acres of grasslands and shrublands were converted to cropland or non-agriculture uses between 1992 through 1997 (1997 National Resource Inventory).

In the 2002 Farm Bill amendments to the Food Security Act of 1985 (the 1985 Act), Congress authorized the establishment of GRP. GRP is a voluntary program to assist landowners and agriculture operators in restoring and protecting grassland and land that contains forbs and shrublands. The 2002 Farm Bill provided that $254 million would be made available through FY 2007 to enroll no more than 2 million restored or improved grasslands. The statute requires that 40 percent of the program funds be used for 10-year, 15-year, and 20-year rental agreements, and 60 percent of the funds be used for 30-year rental agreements and easements.

The Secretry of Agriculture delegated the authority to administer GRP on behalf of the Commodity Credit Corporation, to the Chief, Natural Resources Conservation Service (NRCS) and the Administrator, Farm Service Agency (FSA). These agency leaders are Vice Presidents of the CCC. NRCS has the lead responsibility on technical issues and easement administration, and FSA has the lead responsibility for rental agreement administration and financial activities. The Secretary also delegated authority to the Forest Service to hold easements at the option of the landowner on properties adjacent to USDA Forest Service properties. At the State level, the NRCS State Conservationist and the FSA State Executive Director will determine how best to utilize the human resources of both agencies to deliver the program and implement National policies in an efficient manner.

Summary of Legal Basis:

The Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) amended chapter 2, subtitle D of title XII of the Food Security Act of 1985, to add subchapter C authorizing the Grassland Reserve Program (GRP), 16 U.S.C. 3838n to 3838q. The purpose of this program is to assist landowners and others in restoring and protecting

eligible grassland and certain other lands through rental agreements and easements. CCC published an interim final rule on May 21, 2004 (60 FR 29173), and requested public comment. This final rule responds to comments received from the public comment period and sets forth how the Secretary of Agriculture (the Secretary), using the funds, facilities, and authorities of the Commodity Credit Corporation (CCC), will implement GRP to meet the statutory objectives of the program.

Alternatives:

Continue implementation under current interim final rule.

Anticipated Cost and Benefits:

$254 million through FY 2007.

Risks:

Grasslands are being lost through urban expansion, cropland conversion, or encroachment of invasive species. The Grassland Reserve Program assists farmers and ranchers in the restoration and conservation of the Nation's grasslands.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/21/04	69 FR 29173
Interim Final Rule Comment Period End	07/20/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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USDA—NRCS

29. CONFIDENTIALITY OF CONSERVATION PROGRAM INFORMATION

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

5 USC 552(b)(3)

CFR Citation:

7 CFR 609

Legal Deadline:

None

Abstract:

Section 1244 of the Food Security Act of 1985, as amended by the Farm Security and Rural Investment Act of 2002, prohibits the release and disclosure of proprietary information unless certain exceptions apply. Once implemented, the regulations will ensure program participant confidence that proprietary information will not be released and disclosed and will ensure that the public benefits provided by the conservation programs will not be undermined.

Statement of Need:

The Natural Resources Conservation Service (NRCS) implements several conservation programs, including its conservation technical assistance activities under the Soil Conservation and Domestic Allotment Act and many of the technical and financial assistance activities under subtitle D of the Food Security Act of 1985. Through the implementation of these conservation programs, NRCS utilizes its technical expertise to provide owners, operators, and producers with information to help them make land management decisions. When an owner, operator, or producer applies for financial assistance under a conservation program, NRCS evaluates the resource conditions on their land in relation to natural resource program priorities.

Program participants provide NRCS with detailed information about the condition of their land and their agricultural operations to help ensure that they obtain the best technical assistance available and that their investment, augmented with NRCS financial assistance, is well-targeted. Program participants consider much of the information provided to NRCS as proprietary and might be reluctant to work with NRCS if such information could be disclosed as public information under the Freedom of Information Act (FOIA).

The voluntary adoption of conservation practices on agricultural land reaps great public benefits in soil loss reduction, water quality improvement, water conservation, wildlife habitat development, and wetland restoration. The Farm Security and Rural Investment Act of 2002 (the 2002 Act) greatly expanded the funding available to implement NRCS conservation programs. The 2002 Act also included a provision to protect information about program participants and their agricultural operations to help ensure that agricultural producers would continue to participate voluntarily in the expanded availability of conservation programs. Otherwise, the public availability of program participant information could undermine the successful voluntary adoption of conservation practices that provide so many public benefits.

Summary of Legal Basis:

Section 1244 of the Food Security Act of 1985, as amended by the Farm Security and Rural Investment Act of 2002, prohibits the release and disclosure of such information unless certain exceptions apply.

Section 1244 of the Food Security Act of 1985, as amended, balances the public right to information to ensure an open Government and an informed citizenry while protecting the privacy rights of program participants from opening up their proprietary information to competitors or to the wider public. First, section 1244 provides that the provision is pursuant to section 552a ... . Of title 5 of the United States Code. Section 552a... is part of FOIA and provides for additional protection from disclosure of documentation. Thus, section 1244 provides protection from disclosure or release of information that otherwise would be subject to release under FOIA.

In particular, information provided by program participants may not be subject to release to the public based upon either the Privacy Act or an exemption from release under FOIA. Under Exemption 4 of FOIA, program participants may receive protection from disclosure of commercial or financial information voluntarily provided to the government. However, disclosure under exemption 4 is discretionary, and current executive orders provide that, whenever possible, Federal agencies should exercise their discretion to release the information. Section 1244 removes this discretion of the Federal agency. Even if information could be released under Exemption 4 of FOIA or under the Privacy Act, section 1244 requires that NRCS not disclose or release the information.

While protecting program participants from having their proprietary information considered public information, section 1244 ensures that the public maintains its ability to

obtain payment information regarding conservation program participants.

Alternatives:

The Secretary of Agriculture is required to maintain the confidentiality of proprietary information provided by conservation program participants. Alternative is to not implement statute as required or not to obtain proprietary information from program participants. Either alternative is unacceptable.

Anticipated Cost and Benefits:

Undetermined at this time.

Risks:

Without regulatory framework, USDA employees are at risk for prosecution for releasing information that is required to be withheld from disclosure. Such disclosure has financial penalties.

Timetable:

Action	Date	FR Cite
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State

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BILLING CODE 3410–90–S

DEPARTMENT OF COMMERCE (DOC)

Statement of Regulatory and Deregulatory Priorities

Enhancing long-term economic growth is a central focus of the President's policies and priorities. The mission of the Department of Commerce is to promote job creation, economic growth, technological competitiveness, sustainable development, and improved living standards for all Americans by working in partnership with businesses, universities, communities, and workers to:

- Build for the future and promote U.S. economic competitivenessin the global marketplace by strengthening and safeguarding the Nation's economic infrastructure;
- Keep America competitive with cutting-edge science and technology and an unrivaled information base; and
- Provide effective management and stewardship of our Nation's resources and assets to ensure sustainable economic opportunities.

The DOC mission statement, containing our three strategic themes, provides the vehicle for understanding the Department's aims, how they interlock, and how they are to be implemented through our programs. This statement was developed with the intent that it serve as both a statement of departmental philosophy and as the guiding force behind the Department's programs.

The importance that this mission statement and these strategic themes have for the Nation is amplified by the vision they pursue for America's communities, businesses, and families. Commerce is the smallest Cabinet agency, yet our presence is felt, and our contributions are found, in every State.

The DOC touches Americans, daily, in many ways—we make possible the weather reports that all of us hear every morning; we facilitate the technology that all of us use in the workplace and in the home each day; we support the development, gathering, and transmitting of information essential to competitive business; we make possible the diversity of companies and goods found in America's (and the world's) marketplace; and we support environmental and economic health for the communities in which Americans live.

The DOC has a clear and powerful vision for itself, for its role in the Federal Government, and for its roles supporting the American people, now and in the future. We confront the intersection of trade promotion, civilian technology, economic development, sustainable development, and economic analysis, and we want to provide leadership in these areas for the Nation.

We work to provide programs and services that serve our country's businesses, communities, and families, as initiated and supported by the President and the Congress. We are dedicated to making these programs and services as effective as possible, while ensuring that they are being delivered in the most cost-effective ways. We seek to function in close concert with other agencies having complementary responsibilities so that our collective impact can be most powerful. We seek to meet the needs of our customers quickly and efficiently, with programs, information, and services they require and deserve.

As a permanent part of the Federal Government, but serving an Administration and Congress that can vary with election results, we seek to serve the unchanging needs of the Nation, according to the priorities of the President and the Congress. The President's priorities for the Department range from issues concerning the economy to the environment. For example, the President directs the Department to promote electronic commerce activities; encourage open and free trade; represent American business interests abroad; and assist small businesses to expand and create jobs. We are able to address these priorities effectively by functioning in accordance with the legislation that undergirds our programs and by working closely with the President and the committees in Congress, which have programmatic and financial oversight for our programs.

The DOC also promotes and expedites American exports, helps nurture business contacts abroad, protects U.S. firms from unfair foreign competition, and makes how-to-export information accessible to small and mid-sized companies throughout the Nation, thereby ensuring that U.S. market opportunities span the globe.

The DOC encourages development in every community, clearing the way for private-sector growth by building and rebuilding economically deprived and distressed communities. We promote minority entrepreneurship to establish businesses that frequently anchor neighborhoods and create new job opportunities. We work with the private sector to enhance competitive assets.

As the Nation looks to revitalize its industries and communities, the DOC works as a partner with private entities to build America with an eye on the future. Through technology, research and development, and innovation, we are making sure America continues to prosper in the short-term, while also helping industries prepare for long-term success.

The DOC's considerable information capacities help businesses understand clearly where our national and world economies are going and take advantage of that knowledge by planning the road ahead. Armed with the Department's economic and demographic statistics, businesses can undertake the new ventures, investments, and expansions that make our economy grow.

The DOC has instituted programs and policies that lead to cutting-edge, competitive, and better paying jobs. We work every day to boost exports, to deregulate business, to help smaller manufacturers battle foreign competition, to advance the technologies critical to our future prosperity, to invest in our communities, and to fuse economic and environmental goals.

The DOC is American business' surest ally in job creation, serving as a vital resource base, a tireless advocate, and its Cabinet-level voice.

The Regulatory Plan directly tracks these policy and program priorities, only a few of which involve regulation of the private sector by the Department.

Responding to the Administration's Regulatory Philosophy and Principles

The vast majority of the Department's programs and activities do not involve regulation. Of the Department's 12 primary operating units, only two—the Bureau of Industry and Security (BIS) and the National Oceanic and Atmospheric Administration (NOAA)—plan significant preregulatory or regulatory actions for this Regulatory Plan year. Of all the significant actions planned by the Department, NOAA plans to complete five actions that rise to the level of ''most important'' of the Department's ''significant regulatory actions''. They are (1) Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs - Crab Rationalization Program; (2) Designate Critical Habitat for 7 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in California; (3) Designate Critical Habitat for 13 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington and Oregon;

(4) Listing Determinations for 27 Evolutionarily Significant Units (ESUs) of West Coast Salmon and Oncorhynchus Mykiss; and (5) Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementing Regulations. Further information on these actions are provided below.

Though not principally a regulatory agency, the DOC has long been a leader in advocating and using market-oriented regulatory approaches in lieu of traditional command-and-control regulations when such approaches offer a better alternative. All regulations are designed and implemented to maximize societal benefits while placing the smallest possible burden on those being regulated.

The DOC is also refocusing on its regulatory mission by taking into account, among other things, the President's regulatory principles. To the extent permitted by law, all preregulatory and regulatory activities and decisions adhere to the Administration's statement of regulatory philosophy and principles, as set forth in section 1 of Executive Order 12866. Moreover, we have made bold and dramatic changes, never being satisfied with the status quo. We have emphasized, initiated, and expanded programs that work in partnership with the American people to secure the Nation's economic future. At the same time we have downsized, cut regulations, closed offices, and eliminated programs and jobs that are not part of our core mission. The bottom line is that, after much thought and debate, we have made many hard choices needed to make this Department ''state of the art.''

The Secretary has prohibited the issuance of any regulation that discriminates on the basis of race, religion, gender, or any other suspect category and requires that all regulations be written so as to be understandable to those affected by them. The Secretary also requires that the Department afford the public the maximum possible opportunity to participate in departmental rulemakings, even where public participation is not required by law.

National Oceanic and Atmospheric Administration

The National Oceanic and Atmospheric Administration (NOAA) establishes and administers Federal policy for the conservation and management of the Nation's oceanic, coastal, and atmospheric resources. It provides a variety of essential environmental services vital to public safety and to the Nation's economy, such as weather forecasts and storm warnings. It is a source of objective information on the state of the environment. NOAA plays the lead role in achieving the departmental goal of promoting stewardship by providing assessments of the global environment.

Recognizing that economic growth must go hand-in-hand with environmental stewardship, the Department, through NOAA, conducts programs designed to provide a better understanding of the connections between environmental health, economics, and national security. Commerce's emphasis on ''sustainable fisheries'' is saving fisheries and confronting short-term economic dislocation, while boosting long-term economic growth. The Department is where business and environmental interests intersect, and the classic debate on the use of natural resources is transformed into a ''win-win'' situation for the environment and the economy.

Three of NOAA's major components, the National Marine Fisheries Services (NMFS), the National Ocean Service (NOS), and the National Environmental Satellite, Data, and Information Service (NESDIS), exercise regulatory authority.

NMFS oversees the management and conservation of the Nation's marine fisheries, protects marine mammals, and promotes economic development of the U.S. fishing industry. NOS assists the coastal states in their management of land and ocean resources in their coastal zones, including estuarine research reserves; manages the Nation's national marine sanctuaries; monitors marine pollution; and directs the national program for deep-seabed minerals and ocean thermal energy. NESDIS administers the civilian weather satellite program and licenses private organizations to operate commercial land-remote sensing satellite systems.

The Administration is committed to an environmental strategy that promotes sustainable economic development and rejects the false choice between environmental goals and economic growth. The intent is to have the Government's economic decisions guided by a comprehensive understanding of the environment. The Department, through NOAA, has a unique role in promoting stewardship of the global environment through effective management of the Nation's marine and coastal resources and in monitoring and predicting changes in the Earth's environment, thus linking trade, development, and technology with environmental issues. NOAA has the primary Federal responsibility for providing sound scientific observations, assessments, and forecasts of environmental phenomena on which resource management and other societal decisions can be made.

In the environmental stewardship area, NOAA's goals include: rebuilding U.S. fisheries by refocusing policies and fishery management planning on increased scientific information; increasing the populations of depleted, threatened, or endangered species of marine mammals by implementing recovery plans that provide for their recovery while still allowing for economic and recreational opportunities; promoting healthy coastal ecosystems by ensuring that economic development is managed in ways that maintain biodiversity and long-term productivity for sustained use; and modernizing navigation and positioning services. In the environmental assessment and prediction area, goals include: modernizing the National Weather Service; implementing reliable seasonal and interannual climate forecasts to guide economic planning; providing science-based policy advice on options to deal with very long-term (decadal to centennial) changes in the environment; and advancing and improving short-term warning and forecast services for the entire environment.

Magnuson-Stevens Act Rulemakings

Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) rulemakings concern the conservation and management of fishery resources in the U.S. 3-to-200-mile Exclusive Economic Zone (EEZ). Among the several hundred rulemakings that NOAA plans to issue in the Regulatory Plan year, a number of the preregulatory and regulatory actions will be significant. The exact number of such rulemakings is unknown, since they are usually initiated by the actions of eight regional Fishery Management Councils (FMCs) that are responsible for preparing fishery management plans (FMPs) and FMP amendments, and for drafting implementing regulations for each managed fishery. Once a rulemaking is triggered by an FMC, the Magnuson-Stevens Act places stringent deadlines upon NMFS by which it must exercise its rulemaking responsibilities.

While most of these rulemakings will be minor, involving only the opening or closing of a fishery under an existing

FMP, five actions are of particular significance. In the first action entitled ''Amendments 18 and 19 to the to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs in the Bering Sea and the Aleutian Islands - Crab Rationalization Program,'' NMFS proposes to rationalize the Bering Sea and Aleutian Islands crab fisheries in the United States Exclusive Economic Zone off Alaska by amending the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs. The goal of rationalization is to end the race for fish and solve the problems of overcapacity while providing for a balanced distribution of benefits and improving fisheries management and resource conservation. In the second and third actions entitled ''Designate Critical Habitat for 7 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in California''' and ''Designate Critical Habitat for 13 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington and Oregon,'' NMFS would designate critical habitat for 20 Pacific salmon and O. mykiss Evolutionarily Significant Units (ECUS) listed under the Endangered Species Act of 1973. The geographic areas proposed for designation include lakes, riverine, and estuarian habitat in Washington, Oregon, Idaho, and California. In addition, in the action entitled Listing Determinations for 27 ESUs of West Coast Salmon and Oncorhynchus Mykiss, NMFS proposes to list ESUs as endangered or threatened, and also to delist ESUs as necessary. Finally, in the action entitled Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementation of Regulations, NOAA would designate the Northwest Hawaiian Islands as a national marine sanctuary and propose implementing regulations that best reflect the goals and objectives of the proposed sanctuary.

The Magnuson-Stevens Act, which is the primary legal authority for Federal regulation to conserve and manage fishery resources, establishes eight regional FMCs, responsible for preparing FMPs and FMP amendments. NMFS issues regulations to implement FMPs and FMP amendments. FMPs address a variety of fishery matters, including depressed stocks, overfished stocks, gear conflicts, and foreign fishing. One of the problems that FMPs may address is preventing overcapitalization (preventing excess fishing capacity) of fisheries. This may be resolved by limiting access to those dependent on the fishery in the past and/or by allocating the resource through individual transferable quotas, which can be sold on the open market to other participants or those wishing access. Quotas set on sound scientific information, whether as a total fishing limit for a species in a fishery or as a share assigned to each vessel participant, enable stressed stocks to rebuild. Other measures include staggering fishing seasons or limiting gear types to avoid gear conflicts on the fishing grounds, and establishing seasonal and area closures to protect fishery stocks.

The FMCs provide a forum for public debate and, using the best scientific information available, make the judgments needed to determine optimum yield on a fishery-by-fishery basis. Optional management measures are examined and selected in accordance with the national standards set forth in the Magnuson-Stevens Act. This process, including the selection of the preferred management measures, constitutes the development, in simplified form, of an FMP. The FMP, together with draft implementing regulations and supporting documentation, is submitted to NMFS for review against the national standards set forth in the Magnuson-Stevens Act, in other provisions of the Act, and other applicable laws. The same process applies to amending an existing approved FMP.

TheMagnuson-Stevens Act contains ten national standards against which fishery management measures are judged. NMFS has supplemented the standards with guidelines interpreting each standard, and has updated and added to those guidelines. One of the national standards requires that management measures, where practicable, minimize costs and avoid unnecessary duplication. Under the guidelines, NMFS will not approve management measures submitted by an FMC unless the fishery is in need of management. Together, the standards and the guidelines correspond to many of the Administration's principles of regulation as set forth in section 1(b) of Executive Order 12866. One of the national standards establishes a qualitative equivalent to the Executive Order's ''net benefits'' requirement—one of the focuses of the Administration's statement of regulatory philosophy as stated in section 1(a) of the Executive order.

Bureau of Industry and Security

The Bureau of Industry and Security (BIS) promotes U.S. national and economic security and foreign policy interests by managing and enforcing the Department's security-related trade and competitiveness programs. BIS plays a key role in challenging issues involving national security and nonproliferation, export growth, and high technology. The Bureau's continuing major challenge is combating the proliferation of weapons of mass destruction while furthering the growth of U.S. exports, which are critical to maintaining our leadership in an increasingly competitive global economy. BIS strives to be the leading innovator in transforming U.S. strategic trade policy and programs to adapt to the changing world.

Major Programs and Activities

The Export Administration Regulations (EAR) provide for export controls on dual use goods and technology (primarily commercial goods that have potential military applications) not only to fight proliferation, but also to pursue other national security, short supply, and foreign policy goals (such as combating terrorism). Simplifying and updating these controls in light of the end of the Cold War has been a major accomplishment of BIS.

BIS is also responsible for:

- Enforcing the export control and antiboycott provisionsof the Export Administration Act (EAA), as well as other statutes such as the Fastener Quality Act. The EAA is enforced through a variety of administrative, civil, and criminal sanctions.
- Analyzing and protecting the defense industrial and technologybase, pursuant to the Defense Production Act and other laws. As the Defense Department increases its reliance on dual-use high technology goods as part of its cost-cutting efforts, ensuring that we remain competitive in those sectors and subsectors is critical to our national security.
- Helping Ukraine, Kazakstan, Belarus, Russia, and othernewly emerging countries develop effective export control systems. The effectiveness of U.S. export controls can be severely undercut if ''rogue states'' or terrorists gain access to sensitive goods and technology from other supplier countries.
- Working with former defense plants in the Newly IndependentStates to help make a successful transition to profitable and peaceful civilian endeavors. This involves helping remove unnecessary obstacles to trade and investment and identifying

opportunities for joint ventures with U.S. companies.

- Assisting U.S. defense enterprises to meet the challenge of the reduction in defense spending by converting to civilian production and by developing export markets. This work assists in maintaining our defense industrial base as well as preserving jobs for U.S. workers.

DOC—National Oceanic and Atmospheric Administration (NOAA)

PROPOSED RULE STAGE

30. DESIGNATE CRITICAL HABITAT FOR 7 EVOLUTIONARILY SIGNIFICANT UNITS (ESUS) OF PACIFIC SALMON AND STEELHEAD IN CALIFORNIA

Priority:

Other Significant

Legal Authority:

16 USC 1533

CFR Citation:

50 CFR 226

Legal Deadline:

NPRM, Judicial, November 30, 2004.

Final, Judicial, June 15, 2005.

Abstract:

This action would designate critical habitat for 7 Pacific salmon and O. mykiss Evolutionarily Significant Units (ESUs) listed under the Endangered Species Act of 1973. The geographic area proposed for designation include riverine and estuarine habitat in California.

Statement of Need:

On February 16, 2000, NMFS published final critical habitat designations for 19 ESUs, thereby completing designations for all 25 ESUs listed at the time. In considering the economic impact of the February 16, 2000, action, NMFS determined that the critical habitat designations would impose very little or no additional requirements on Federal agencies beyond those already associated with the listing of the species themselves. The National Association of Homebuilders (NAHB) challenged the designations in District Court in Washington, D.C. as having inadequately considered the economic impacts of the critical habitat designations (National Association of Homebuilders v. Evans, 2002 WL 1205743 No. 00-CV-2799 (D.D.C.)). As a result of a district court's approval of a consent decree, the 19 critical habitat designations were vacated. A subsequent complaint from a group of fishing and environmental organizations regarding our failure to designate critical habitat led to a court approved agreement (July 13, 2004) to designate critical habitat for any listed ESUs under the Northwest Region's responsibility by September 30, 2004, and for any listed ESUs under the Southwest Region's responsibility by November 30, 2004. Final critical habitat designations for all of these ESUs are due on June 15, 2005.

Summary of Legal Basis:

Sections 4(a)(3)(A) and 4(b)(6)(C)(ii) of the Endangered Species Act (ESA) require the Secretary to designate critical habitat concurrently with making a determination that a species is threatened or endangered. Section 4(b)(6)(C)(ii) requires that a final regulation designating critical habitat be published concurrently with the final regulation listing the species as threatened or endangered unless such habitat is not then determinable, in which case, the Secretary may extend the one-year period for finalizing critical habitat by one additional year. The court approved agreement mentioned in the first paragraph requires final critical habitat designations by June 15, 2005, concurrently with the deadline for final listing determinations on the 26 ESUs that were proposed for revised listing determinations and the one additional ESU that was proposed for listing.

Section 4(b)(2) requires that critical habitat designation be based on the best scientific data available after taking economic impacts, impacts on national security, and any other relevant impact of specifying any particular area as critical habitat into account. The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless failure to designate such area as critical habitat will result in the extinction of the species concerned.

Alternatives:

Critical habitat designation is a requirement under the ESA. Alternatives can be considered during the section 4(b)(2) analysis when NMFS weighs the benefits of excluding some critical habitat with the benefits of specifying it as critical habitat. NMFS ranked different critical habitat areas as high, medium, or low value in terms of the benefits that can be expected to accrue to the salmon ESUs. One alternative is to include all habitat that has been identified as critical in the critical habitat designation. Another alternative is to exclude all the low value areas from the designation. A third alternative is to exclude a combination of all low value areas and some medium value areas.

Anticipated Cost and Benefits:

NMFS has conducted an economic analysis on the proposal to designate critical habitat for the ESUs in the Region. The net economic impacts of ESA section 7 associated with the areas proposed for designation are estimated to be approximately $88,980,000. The benefits to Pacific salmon cannot be monetized easily, but critical habitat designation should contribute to the health of the species.

Risks:

The principal benefit of designating critical habitat is that Federal activities that may affect such habitat are subject to consultation pursuant to section 7 of the ESA. Such consultation requires every Federal agency to insure that any action it authorizes, funds or carries out is not likely to result in the destruction or adverse modification of critical habitat. This complements the section 7 provision that Federal agencies insure that their action is not likely to jeopardize the continued existence of a listed species. Another benefit is that the designation of critical habitat can serve to educate the public regarding the potential conservation value of an area. This may focus and contribute to conservation efforts by clearly delineating areas of high conservation value for certain species.

Timetable:

Action	Date	FR Cite
NPRM	12/19/00	65 FR 79328
NPRM Comment Period End	02/20/01	
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

None

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Related RIN: Related to 0648–AQ77

RIN: 0648–AO04

DOC—NOAA

31. DESIGNATE CRITICAL HABITAT FOR 13 EVOLUTIONARILY SIGNIFICANT UNITS (ESUS) OF PACIFIC SALMON AND STEELHEAD IN WASHINGTON, OREGON AND IDAHO

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

16 USC 1533

CFR Citation:

50 CFR 226; 50 CFR 424

Legal Deadline:

NPRM, Judicial, September 30, 2004.

Final, Judicial, June 15, 2005.

Abstract:

This action would designate critical habitat for 13 Pacific salmon and O. mykiss Evolutionarily Significant Units (ESUs) listed under the Endangered Species Act of 1973. The geographic areas proposed for designation include lakes, riverine, and estuarine habitat in Washington, Oregon, and Idaho, and marine nearshore habitat in Washington.

Statement of Need:

On February 16, 2000, NMFS published final critical habitat designations for 19 ESUs, thereby completing designations for all 25 ESUs listed at the time. In considering the economic impact of the February 16, 2000, action, NMFS determined that the critical habitat designations would impose very little or no additional requirements on Federal agencies beyond those already associated with the listing of the species themselves. The National Association of Homebuilders (NAHB) challenged the designations in District Court in Washington, D.C. as having inadequately considered the economic impacts of the critical habitat designations (National Association of Homebuilders v. Evans, 2002 WL 1205743 No. 00-CV-2799 (D.D.C.)). As a result of a district court's approval of a consent decree, the 19 critical habitat designations were vacated. A subsequent complaint from a group of fishing and environmental organizations regarding our failure to designate critical habitat led to a court approved agreement (July 13, 2004) to designate critical habitat for any listed ESUs under the Northwest Region's responsibility by September 30, 2004, and for any listed ESUs under the Southwest Region's responsibility by November 30, 2004. Final critical habitat designations for all of these ESUs are due on June 15, 2005.

Summary of Legal Basis:

Sections 4(a)(3)(A) and 4(b)(6)(C)(ii) of the Endangered Species Act (ESA) require the Secretary to designate critical habitat concurrently with making a determination that a species is threatened or endangered. Section 4(b)(6)(C)(ii) requires that a final regulation designating critical habitat be published concurrently with the final regulation listing the species as threatened or endangered unless such habitat is not then determinable, in which case, the Secretary may extend the one-year period for finalizing critical habitat by one additional year. The court approved agreement mentioned in the first paragraph requires final critical habitat designations by June 15, 2005, concurrently with the deadline for final listing determinations on the 26 ESUs that were proposed for revised listing determinations and the one additional ESU that was proposed for listing.

Section 4(b)(2) requires that critical habitat designation be based on the best scientific data available after taking economic impacts, impacts on national security, and any other relevant impact of specifying any particular area as critical habitat into account. The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless failure to designate such area as critical habitat will result in the extinction of the species concerned.

Alternatives:

Critical habitat designation is a requirement under the ESA. Alternatives can be considered during the section 4(b)(2) analysis when NMFS weighs the benefits of excluding some critical habitat with the benefits of specifying it as critical habitat. NMFS has ranked different critical habitat areas as high, medium, or low value in terms of the benefits that can be expected to accrue to the salmon ESUs. One alternative is to include all habitat that has been identified as critical in the critical habitat designation. Another alternative is to exclude all the low value areas from the designation. A third alternative is to exclude a combination of all low value areas and some medium value areas.

Anticipated Cost and Benefits:

NMFS has conducted an economic analysis on the proposal to designate critical habitat for the ESUs in the Northwest Region. The net economic impacts of ESA section 7 associated with the areas proposed for designation are estimated to be approximately $223,950,127. The benefits to Pacific salmon cannot be monetized easily, but critical habitat designation should contribute to the health of the species.

Risks:

The principal benefit of designating critical habitat is that Federal activities that may affect such habitat are subject to consultation pursuant to section 7 of the ESA. Such consultation requires every Federal agency to insure that any action it authorizes, funds or carries out is not likely to result in the destruction or adverse modification of critical habitat. This complements the section 7 provision that Federal agencies insure that their action is not likely to jeopardize the continued existence of a listed species. Another benefit is that the designation of critical habitat can serve to educate the public regarding the potential conservation value of an area. This may focus and contribute to conservation efforts by clearly delineating areas of high conservation value for certain species.

Timetable:

Action	Date	FR Cite
ANPRM	09/29/03	68 FR 55926
ANPRM Comment Period End	11/13/03	
NPRM	11/00/04	
NPRM Comment Period End	02/00/05	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State, Tribal

Agency Contact:

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RIN: 0648–AQ77

DOC—NOAA

32. • AMENDMENTS 18 AND 19 TO THE FISHERY MANAGEMENT PLAN FOR BERING SEA/ALEUTIAN ISLANDS KING AND TANNER CRABS—CRAB RATIONALIZATION PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

16 USC 1801

CFR Citation:

50 CFR 679; 50 CFR 680

Legal Deadline:

Other, Statutory, January 1, 2005, Secretary approval of statutorily mandated FMP Amendment.

Abstract:

This action would rationalize the Bering Sea and Aleutian Islands crab fisheries in the United States Exclusive Economic Zone off Alaska by amending the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs. The goal of rationalization is to end the race for fish and solve the problems of overcapacity while providing for a balanced distribution of benefits and improving fisheries management and resource conservation.

Statement of Need:

This action would amend the regulations to implement Amendments 18 and 19 of the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs in Waters off Alaska. The U.S. Congress amended the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens) to require the Secretary of Commerce to approve the Crab Rationalization Program (Program) by January 1, 2005. Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (FMP) constitute this program. The regulations in this action are needed to implement this program. This rule is necessary to increase resource conservation, improve economic efficiency, and to address social concerns. This action is intended to promote the goals and objectives of the Magnuson-Stevens Act, the FMP, and other applicable laws.

Summary of Legal Basis:

In January 2004, the U.S. Congress amended section 313 of the Magnuson-Stevens Act through the Consolidated Appropriations Act of 2004 (Pub. L. No. 108-199, section 801), by adding paragraph (j). As amended, section 313(j)(1) requires the Secretary to approve and implement, by January 1, 2005, the Voluntary Three-pie Cooperative Program (Program) as it was approved by the North Pacific Fishery Management Council (Council) between June 2002 and April 2003, and all trailing amendments including those reported to Congress on May 6, 2003.

At this time, NMFS has not determined that the FMP amendments that this rule would implement are consistent with the national standards of the Magnuson-Stevens Act and other applicable laws. NMFS, in making that determination, will take into account the data, views, and comments received during the comment period.

Alternatives:

The Environmental Impact Statement (EIS) presents four alternative programs for management of the BSAI crab fisheries, namely, Status Quo/No Action (Alternative 1); a Voluntary Three-pie Cooperative Program (Alternative 2); an Individual Fisherman's Quota (IFQ) Program (Alternative 3); and a Cooperative Program (alternative 4). These alternatives constitute the suite of ''significant alternatives,'' under this action, for Regulatory Flexibility Act purposes. Please refer to EIS and Regulatory Impact Review (RIR) for more details.

Anticipated Cost and Benefits:

It is probable that producers will experience a net benefit as a result of implementing quota and cooperative features of the Program. The fishing industry operating in the BSAI crab fishery may see an economic increase from the implementation of the Program by lengthening the interval of time that crab are supplied to the market. Other rationalized fisheries have been observed to generate higher market prices by allowing for a longer interval of time during a year to supply product to the marketplace. In addition, it is likely that the costs to crab fishing and processing operations will be substantially reduced as a result of the quota and cooperative features of the Program. The BSAI crab fisheries are among the most highly overcapitalized fisheries in the Alaska region. Participation in the current short and inefficient open access fishing season has resulted in a greater number of fishing vessels, higher vessel operating costs, a greater number of crew, and costly redundancies in processing capacity compared with what will be required as a result of the quota and cooperative elements of the Program.

It is unknown how this regulation would affect consumers. There is the potential that consumers will benefit from less seasonal crab supplies. It is probable that a less rapidly paced fishery may result in improved product quality at harvest. Handling damage from the compressed seasons, symptomatic of the present managed open access crab fisheries may be significantly reduced by longer seasons under the quota fisheries, where vessels have expanded choices of how often and what times of year to fish.

Due to the lack of data on fixed and variable costs for both the BSAI crab fishery and processing operations, and inadequate data on market prices by crab product quality and product form, it is not possible to estimate the magnitude of the qualitative changes to the industry or nation from the Program. After the Program is implemented, the official record of quota market transactions and a mandatory economic data collection program will allow for detailed quantitative estimates of benefits and costs.

Risks:

The Program is a limited access system that balances the interests of several groups who depend on these fisheries. The Program addresses conservation and management issues associated with the current derby fishery and would reduce bycatch and associated discard mortality. The Program also would increase the safety of crab fishermen by ending the race for fish. Share allocations to harvesters and processors, together with incentives to participate in fishery cooperatives, would increase efficiencies, provide economic stability, and facilitate

compensated reduction of excess capacities in the harvesting and processing sectors. Community interests would be protected by Community Development Quota (CDQ) allocations and regional landing and processing requirements, as well as by several community protection measures.

Timetable:

Action	Date	FR Cite
Notice	09/01/04	69 FR 53359
NPRM	10/29/04	69 FR 63200
NPRM Comment Period End	12/13/04	
Final Action	02/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State

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DOC—NOAA

33. ● NORTHWEST HAWAIIAN ISLANDS NATIONAL MARINE SANCTUARY; DESIGNATION AND IMPLEMENTATION OF REGULATIONS

Priority:

Other Significant

Legal Authority:

PL 106–513; 16 USC 1431 et seq

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The National Marine Sanctuaries Program, together with state and federal partners and other stakeholders, designate the Northwest Hawaiian Islands as a national marine sanctuary and implement regulations that best reflects the goals and objectives of the proposed sanctuary.

Statement of Need:

By designating the Northwest Hawaiian Islands (NWHI) as a national marine sanctuary, the National Marine Sanctuary Program (NMSP), together with state and federal partners and other stakeholders, hope to catalyze the collaborative development of an ecosystem approach to address management issues. The NWHI are among the few, large-scale, intact, predator-dominated coral reef ecosystems left in the world. Significant Native Hawaiian cultural and maritime historical resources are found throughout the region. These vast and remote coral reef ecosystems support a distinctive assemblage of marine mammals, fish, sea turtles, birds, and invertebrates, including species that are endemic, rare, threatened, or endangered. Unfortunately, coral reef systems like the NWHI are in a state of decline as direct or indirect result of human activities.

Fishing is one of many human activities that may have direct and indirect effects on the health and integrity of coral reef ecosystems. Some of the direct impacts of fishing on coral reef ecosystems include depletion of fish stocks and habitat degradation. Examples of indirect effects include shifts in community structure and predatory-prey relationships. Historically, fisheries management approaches have been conducted through a single species approach. While this fishery management approach can provide valuable information, it does not consider the broader impacts of the activity on an ecosystem. The NMSP and the National Oceanic and Atmospheric Administration (NOAA) as a whole are working toward an ecosystem approach to resource management. This form of management is adaptive, is geographically specified, takes account of ecosystem knowledge and uncertainties, considers multiple external influences, and strives to balance diverse social objectives. Fishing in the NWHI must be carefully considered and evaluated in the context of an ecosystem approach to management in order to achieve a healthy, functional, and resilient ecosystem.

Summary of Legal Basis:

The NMSP of NOAA is in the process of designating the Northwest Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve) as a national marine sanctuary as directed by the National Marine Sanctuaries Amendments Act (NMSAA) of 2000 and Executive Orders 13178 and 13196, and in accordance with the National Marine Sanctuaries Act (NMSA). The Reserve was established in 2000 by EO 13178 with the principal purpose of long-term conservation and protection of the coral reef ecosystem and related marine resources and species of the Northwest Hawaiian Islands (NWHI) in their natural character. The sanctuary designation process is described in Section 304 of the NMSA and requires the preparation of an environmental impact statement.

Alternatives:

The NMSP is considering seven alternatives. The first alternative (Status Quo/No Action Alternative) maintains the NWHI Research and EO provisions as is. It assumes a sanctuary will not be designated. This places caps on all fishing activities that were active at the time the EO was issued, and prohibits the development of new or inactive fisheries. This alternative makes provisions for several types of commercial and recreational fishing including bottomfishing/pelagic trolling, commercial trolling, sustenance fishing, and Native Hawaiian cultural and subsistence use. The second alternative mirrors the provisions of EO 13178 and 13196 but assumes those provisions will become regulations promulgated under the NMSA. In addition, this alternative provides straight-line boundaries, as opposed to fathom boundaries, to define Reserve/Sanctuary Preservation Areas to aid in user compliance and enforcement. Fishing regulations would be promulgated that would prohibit precious coral and crustacean harvest, but provide for bottomfish/pelagic trolling, commercial pelagic trolling, various forms of recreational fishing, and Native Hawaiian cultural and subsistence uses. The third alternative was developed by the Western Pacific Fishery Management Council and assumes that the Reserve would be designated as a national marine sanctuary, with fishing regulations promulgated under the NMSA. However, fishing activities would be managed in accordance with existing fishery management plans for those fishing activities currently practiced. This alternative also suggests that future harvest of precious corals and crustaceans would be managed under previously developed FMPs. However, in a Federal Register notice, NOAA issues a zero-harvest guideline and

cited the EO as a reason to continue closure of the crustacean fishery.

The fourth alternative establishes a sanctuary with fishing regulations that would protect the highest ecosystem values while allowing compatible fishing activities in areas where they are likely to have less impact on the ecosystem. It prohibits precious coral and crustacean harvest, and pelagic longlining, but provides for commercial bottomfish/pelagic trolling, commercial pelagic trolling, various forms of recreational fishing, and Native Hawaiian cultural and subsistence uses through a permitting process. The fifth alternative is an iteration of the fourth alternative and prohibits the same fishing activities. It also provides for bottomfish/pelagic trolling, commercial pelagic trolling, various forms of recreational fishing and Native Hawaiian cultural subsistence uses. The sixth alternative was developed by the Reserve Advisory Council and is similar to alternative 2 but would close bottomfish/pelagic trolling within 1 year of sanctuary designation. It also calls for a zoning system to limit commercial and recreational pelagic fishing to minimize interactions with protected wildlife. The seventh alternative closes immediately the entire area to all extractive use, except for research or education.

Anticipated Cost and Benefits:

There are currently nine active commercial bottomfishermen in the NWHI, five in the Mau zone and four in the Ho'omalu zone. Total reported 2003 gross revenue for the nine NWHI fishermen was just under $1.3 million with $611 thousand for the Mau zone and $674 thousand for the Ho'omalu zone. Total costs for 2003 were estimated at $974 thousand for the nine NWHI fishermen. The first alternative (Status Quo/No Action Alternative) would result in a 28 percent reduction in pounds landed for bottomfish/pelagic trolling catch, and 13 percent reduction for pelagic species compared to pre-EO levels based on full implementation of the EO. The second alternative would result in a 28 percent reduction in pounds landed for bottomfish/ pelagic trolling catch, and 13 percent reduction in the pelagic catch associated with bottomfishing, as compared to pre-EO levels. The third alternative would result in a 0 percent reduction in pounds landed. The fourth alternative would reduce commercial bottomfish catch by 24 percent and pelagic landings by 13 percent. The fifth alternative would reduce bottomfish catch by 62 percent and pelagic catch by 10 percent due to the phase-out of bottomfishing for the Ho'omalu zone. The sixth alternative contemplates the complete phase-out of this industry within one year and would impact the industry by 100 percent. The seventh alternative would close the entire region to extractive use and would impact the industry by 100 percent.

Risks:

The establishment of the NWHI as a national marine sanctuary would protect one of the world's most productive and biologically rich ecosystems on Earth. The NWHI are among the few, large-scale, intact, predator-dominated coral reef ecosystems left in the world. Significant Native Hawaiian cultural and maritime historical resources are found throughout the region. These vast and remote coral reef ecosystems support a distinctive assemblage of marine mammals, fish, sea turtles, birds, and invertebrate, including species that are endemic, rare, threatened, or endangered. Federally protected species include the endangered Hawaiian monk seal. Roughly one-quarter of the 7,000 species found in the NWHI are believed to be endemic to the Hawaiian Island chain, found nowhere else on Earth.

Almost all of the alternatives would continue to allow some level of human activity in the area, including fishing. Research, monitoring and education activities would also be allowed pursuant to a permit system. There would, therefore, be risks to human safety associated with fishing and other vessels operating in remote areas of the Hawaiian Islands. At times, vessels could be exposed to potentially serious weather and sea conditions that could result in loss of life or injury as well as loss of property. In addition, risks to the environment could result from vessel groundings, lost fishing gear and other equipment, fuel spills, unauthorized discharges including sewage, etc. Depending on location, any of these incidents could harm or destroy fragile coral reefs or marine life.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

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DOC—NOAA

FINAL RULE STAGE

34. LISTING DETERMINATIONS FOR 27 EVOLUTIONARILY SIGNIFICANT UNITS (ESUS) OF WEST COAST SALMON AND ONCORHYNCHUS MYKISS

Priority:

Other Significant

Legal Authority:

16 USC 1533

CFR Citation:

50 CFR 223; 50 CFR 224

Legal Deadline:

NPRM, Judicial, March 31, 2004.

NMFS has requested an extension to the court-ordered deadline, but no decision has been made as of 4/23/2004.

Abstract:

NMFS has completed status reviews for 26 West Coast salmon and O. mykiss (inclusive of anadromous steelhead and co-occurring resident rainbow trout) Evolutionarily Significant Units (ESUs) previously listed as threatened and endangered species under the ESA, as well as one ESU that was designated as a candidate species. Following a September 2001 U.S. District Court ruling that rejected how NMFS treats hatchery populations in its listing determinations, the agency received several petitions seeking to delist, or to redefine and list several ESUs on the basis of the Court's ruling. In response to these petitions NMFS initiated status

reviews for 16 ESUs, and elected to conduct status reviews for an additional 11 ESUs. Based on these reviews, NMFS is taking this action to list ESUs as endangered or threatened, and also to delist ESUs as necessary.

Statement of Need:

In September 2001, the U.S. District Court in Eugene, Oregon, in Alsea Valley Alliance v. Evans (161 F. Supp. 2d 1154, D. Oreg. 2001; Alsea decision), set aside NMFS' 1998 ESA listing of Oregon Coast coho salmon (63 FR 42587; 08/10/1998). The Court ruled that the ESA does not allow NMFS to list a subset of an ESU, and that NMFS had improperly excluded stocks from the listing once it had decided that certain hatchery stocks were part of the ESU. Although the Court's ruling affected only one ESU, the interpretive issue raised by the ruling called into question nearly all of NMFS' Pacific salmonid listing determinations. The Court struck down the 1998 final rule listing Oregon coast coho as a threatened species, thus removing the ESU from the protections of the ESA. The Court remanded the case to NMFS for reconsideration consistent with the Alsea decision. NMFS did not contest the Court's ruling and informed the Court it would comply. In November 2001, intervenors appealed the Court's ruling to the U.S. Ninth Circuit Court of Appeals. Pending resolution of the appeal, the Ninth Circuit stayed the District Court's remand order and invalidation of the 1998 listing. While the stay was in place, the Oregon Coast coho ESU was again afforded the protections of the ESA (Alsea Valley Alliance v. Evans, 9th Circuit appeal, No. 01-36071, December 14, 2001). On February 24, 2004, the Appeals Court dismissed the appeal, and dissolved its stay of the District Courts' ruling in Alsea.

Following the District Court's ruling in the Alsea case, NMFS received several petitions (summarized below) addressing 17 listed salmonid ESUs, including five steelhead ESUs. These petitions cited the Alsea ruling and focused on NMFS' past practice of excluding certain ESU hatchery stocks from listing protection. Various litigants have also challenged the failure to list resident populations included in threatened and endangered steelhead ESUs. The anadromous form of O. mykiss is presently under NMFS' jurisdiction, while the resident freshwater forms, usually called ''rainbow'' or ''redband'' trout, are under FWS jurisdiction. In Environmental Defense Center et al. v. Evans et al. (EDC v. Evans, SACV-00-1212-AHS (EEA)), the plaintiffs argue that NMFS failed to include resident populations in the endangered listing of the Southern California steelhead ESU (62 FR 43937; August 18, 1997). In Modesto Irrigation District et al. v. Evans et al. (MID v. Evans, CIV-F-02-6553 OWW DLB (E.D.Cal)), the plaintiffs seek to invalidate NMFS' 1997 threatened listing of the Central Valley California steelhead ESU (63 FR 13347; March 19, 1998) for failing to list hatchery and resident populations identified as part of the ESU. This same factual situation is found in all listed steelhead ESUs; the listings do not include hatchery and/or resident populations considered to be part of the ESUs. For the proposed listing determinations detailed in this rule to be compliant with the Court's ruling in the Alsea case, all populations or stocks (natural, hatchery, resident, etc.) included in an ESU must be listed if it is determined that the ESU is threatened or endangered under the ESA.

Although the ESA section 4(d) regulations for threatened salmonids have proven effective at appropriately protecting threatened salmonid ESUs and permitting certain activities, several of the limits described therein are redundant, outdated, or are located disjunctly in the Code of Federal Regulations (CFR). The resulting complexity of the existing 4(d) regulations unnecessarily increases the administrative and regulatory burden of managing protective regulations for threatened ESUs, and does not effectively convey to the public the specific ESUs for which certain activities may be exempted from the take prohibitions under 4(d). As part of this proposed rulemaking, NMFS proposes to clarify the existing section 4(d) regulations for threatened salmonids so that they can be more efficiently and effectively accessed and interpreted by all affected parties.

Summary of Legal Basis:

Following the ruling in the Alsea case, NMFS received several petitions seeking to delist, or to redefine and list, ESUs of Pacific salmon and steelhead. The petitioners made reference to the Alsea decision in arguing for NMFS to reconsider the listing status for certain ESUs. Between September 2001 and April 2002, NMFS received eight separate petitions addressing a total of 17 listed salmon and steelhead ESUs. The ESA requires that, as a consequence of accepting the above petitions, NMFS promptly commence a review of the species' status and make a finding within 12 months after receiving the petition, whether the petitioned action is warranted (ESA section 4(b)(3)). There are 16 ESUs for which NMFS has statutory deadlines for the completion of ESA status reviews and listing determinations: seven chinook ESUs (the Upper Willamette River, Lower Columbia River, Upper Columbia River spring-run, Puget Sound, Snake River fall-run, and Snake River spring/summer-run chinook ESUs); three coho ESUs (the Central California Coast, Southern Oregon/Northern California Coast, and Oregon Coast coho ESUs); two chum ESUs (the Columbia River and Hood Canal summer-run chum salmon ESUs); and five steelhead ESUs (the Upper Willamette River, Lower Columbia River, Middle Columbia River, Upper Columbia River, and Snake River Basin steelhead ESUs).

Alternatives:

NMFS is required to use the best available scientific and commercial information in making its listing determinations under the ESA. Listing determinations are not subject to National Environmental Policy Act analysis, and they are exempt from economic considerations. This rule would clarify the existing section 4(d) regulations, and thus, NMFS is not evaluating new alternatives.

Anticipated Cost and Benefits:

This action would largely preserve the existing regulatory regime. Currently, hatchery fish are not listed, so their take is not prohibited. The provisions in this action would allow hatchery fish to continue to be available for harvest by not prohibiting their take. Currently, for the two species listed as endangered, all take is prohibited by section 9(a) of the ESA. The provisions in this action would maintain take prohibitions but with the greater flexibility allowed by a section 4(d) rule. Currently, the species listed as threatened are covered under a mix of 4(d) rules with varying degrees of flexibility. This rule would consolidate all of the species under one rule and apply the set of prohibitions and exceptions NMFS has found most flexible. For one species, Columbia River Coho, this rule would impose take prohibitions where none previously existed. NMFS has concluded that this revision will not have significant impacts on small entities. Since take of hatchery fish will not be prohibited, fisheries will be largely unaffected. Landowners will not

be affected because the range of the newly listed coho ESU overlaps that of already-listed species whose take is already prohibited.

Risks:

NMFS' Pacific Salmonid Biological Review Team (BRT) (an expert panel of scientists from several federal agencies including NMFS, FWS, and the U.S. Geological Survey) reviewed the viability and extinction risk of naturally spawning populations in the 27 ESUs that are the subject of this proposed rule (NMFS, 2003b). The BRT evaluated the risk of extinction based on the performance of the naturally spawning populations in each of the ESUs under the assumption that present conditions will continue into the future. The BRT did not explicitly consider artificial propagation in its evaluations. The BRT assessed ESU-level extinction risk (as indicated by the viability of the naturally spawning populations) at two levels: first, at the simpler population level; then, at the overall ESU level. The BRT used criteria for 'Viable Salmonid Populations' (VSP; McElhany et al., 2000) to guide its risk assessments. The VSP criteria were developed to provide a consistent and logical reference for making viability determinations and are based on are view and synthesis of the conservation biology and salmon literature. Individual populations were evaluated according to the four VSP criteria: Abundance, growth rate/productivity, spatial structure, and diversity. These four parameters are universal indicators of species viability, and individually and collectively function as reasonable predictors of extinction risk. After reviewing all relevant biological information for the populations in a particular ESU, the BRT ascribed an ESU-level risk score for each of the four VSP criteria.

Timetable:

Action	Date	FR Cite
NPRM	06/14/04	69 FR 33102
NPRM Comment Period End	09/13/04	
NPRM	08/31/04	69 FR 53031
NPRM Comment Period Extended to	10/20/04	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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DEPARTMENT OF DEFENSE (DOD)

Statement of Regulatory Priorities

Background

The Department of Defense (DoD) is the largest Federal department consisting of 3 military departments (Army, Navy, and Air Force), 9 unified combatant commands, 16 Defense agencies, and 11 DoD field activities. It has over 1,400,000 military personnel and 675,000 civilians assigned as of July 31, 2004, and over 200 large and medium installations in the continental United States, U. S. territories, and foreign countries. The overall size, composition, and dispersion of the Department of Defense, coupled with an innovative regulatory program, presents a challenge to the management of the Defense regulatory efforts under Executive Order 12866 ''Regulatory Planning and Review'' of September 30, 1993.

Because of its diversified nature, DoD is affected by the regulations issued by regulatory agencies such as the Departments of Energy, Health and Human Services, Housing and Urban Development, Labor, Transportation, and the Environmental Protection Agency. In order to develop the best possible regulations that embody the principles and objectives embedded in Executive Order 12866, there must be coordination of proposed regulations among the regulating agencies and the affected Defense components. Coordinating the proposed regulations in advance throughout an organization as large as DoD is straightforward, yet a formidable undertaking.

DoD is not a regulatory agency but occasionally issues regulations that have an impact on the public. These regulations, while small in number compared to the regulating agencies, can be significant as defined in Executive Order 12866. In addition, some of DoD's regulations may affect the regulatory agencies. DoD, as an integral part of its program, not only receives coordinating actions from the regulating agencies, but coordinates with the agencies that are impacted by its regulations as well.

The regulatory program within DoD fully incorporates the provisions of the President's priorities and objectives under Executive Order 12866. Promulgating and implementing the regulatory program throughout DoD presents a unique challenge to the management of our regulatory efforts.

Coordination

Interagency

DoD annually receives regulatory plans from those agencies that impact the operation of the Department through the issuance of regulations. A system for coordinating the review process is in place, regulations are reviewed, and comments are forwarded to the Office of Management and Budget. The system is working in the Department, and the feedback from the Defense components is most encouraging, since they are able to see and comment on regulations from the other agencies before they are required to comply with them. The coordination process in DoD continues to work as outlined in Executive Order 12866.

Internal

Through regulatory program points of contact in the Department, we have established a system that provides information from the Administrator of the Office of Information and Regulatory Affairs (OIRA) to the personnel responsible for the development and implementation of DoD regulations. Conversely, the system can provide feedback from DoD regulatory personnel to the Administrator, OIRA. DoD continues to refine its internal procedures, and this ongoing effort to improve coordination and communication practices is well received and supported within the Department.

Overall Priorities

The Department of Defense needs to function at a reasonable cost, while ensuring that it does not impose ineffective and unnecessarily burdensome regulations on the public. The rulemaking process should be responsive, efficient, cost-effective, and both fair and perceived as fair. This is being done in the Department while it must react to the contradictory pressures of providing more services with fewer resources. The Department of Defense, as a matter of overall priority for its regulatory program, adheres to the general principles set forth in Executive Order 12866 as amplified below.

Problem Identification

Congress typically passes legislation to authorize or require an agency to issue regulations and often is quite specific about the problem identified for correction. Therefore, DoD does not generally initiate regulations as a part of its mission.

Conflicting Regulations

Since DoD seldom issues significant regulations, the probability of developing conflicting regulations is low. Conversely, DoD is affected to a great degree by the regulating agencies. From that perspective, DoD is in a position to advise the regulatory agencies of conflicts that appear to exist using the coordination processes that exist in the DoD and other Federal agency regulatory programs. It is a priority in the Department to communicate with other agencies and the affected public to identify and proactively pursue regulatory problems that occur as a result of conflicting regulations both within and outside the Department.

Alternatives

DoD will identify feasible alternatives that will obtain the desired regulatory objectives. Where possible, the Department encourages the use of incentives to include financial, quality of life, and others to achieve the desired regulatory results.

Risk Assessment

Assessing and managing risk is a high priority in the DoD regulatory program. The Department is committed to risk prioritization and an ''anticipatory'' approach to regulatory planning, which focuses attention on the identification of future risk. Predicting future regulatory risk is exceedingly difficult due to rapid introduction of new technologies, side effects of Government intervention, and changing societal concerns. These difficulties can be mitigated to a manageable degree through the incorporation of risk prioritization and anticipatory regulatory planning into DoD's decisionmaking process, which results in an improved regulatory process and increases the customer's understanding of risk.

Cost-Effectiveness

One of the highest priority objectives of DoD is to obtain the desired regulatory objective by the most cost-effective method available. This may or may not be through the regulatory process. When a regulation is required, DoD considers incentives for innovation to achieve desired results, consistency in the application of the regulation, predictability of the activity outcome (achieving the expected results), and the costs for regulation development, enforcement, and compliance. These will include costs to the public, Government, and regulated entities, using the best available data or parametric analysis methods, in the cost-benefit analysis and the decisionmaking process.

Cost-Benefit

Conducting cost-benefit analyses on regulation alternatives is a priority in the Department of Defense so as to ensure that the potential benefits to society outweigh the costs. Evaluations of these alternatives are done quantitatively or qualitatively or both, depending on the nature of the problem being solved and the type of information and data available on the subject. DoD is committed to considering the most important alternative approaches to the problem being solved and providing the reasoning for selecting the proposed regulatory change over the other alternatives.

Information-Based Decisions

The Defense Department uses the latest technology to provide access to the most current technical, scientific, and demographic information in a timely manner through the worldwide communications capabilities that are available on the Internet. Realizing that increased public participation in the rulemaking process improves the quality and acceptability of regulations, DoD is committed to exploring the use of information technology (IT) in rule development and implementation. IT provides the public with easier and more meaningful access to the processing of regulations. Furthermore, the Department endeavors to increase the use of automation in the Notice and Comment rulemaking process in an effort to reduce time pressures and increase public access in the regulatory process. Notable progress has been made in the Defense acquisition regulations area toward achieving the Administration's E-government initiative of making it simpler for citizens to receive high-quality service from the Federal Government, inform citizens, and allow access to the development of rules.

Performance-Based Regulations

Where appropriate, DoD is incorporating performance-based standards that allow the regulated parties to achieve the regulatory objective in the most cost-effective manner.

Outreach Initiatives

DoD endeavors to obtain the views of appropriate State, local, and tribal officials and the public in implementing measures to enhance public awareness and participation both in developing and implementing regulatory efforts. Historically, this has included such activities as receiving comments from the public, holding hearings, and conducting focus groups. This reaching out to organizations and individuals that are affected by or involved in a particular regulatory action remains a significant regulatory priority of the Department and, we feel, results in much better regulations.

The Department is actively engaged in addressing the requirements of the Government Paperwork Elimination Act (GPEA) in implementing electronic government and in achieving IT accessibility for individuals with disabilities. This is consistent with the Administration's strategy of advancing E-government as expressed in ''The President's Management Agenda.'' The Department is actively participating in the eRulemaking Initiative to develop a Governmentwide docket management system that will provide the framework for wider citizen input and improve regulatory policies and outcomes by cultivating public participation in Federal decisionmaking.

Coordination

DoD has enthusiastically embraced the coordination process between and among other Federal agencies in the development of new and revised regulations. Annually, DoD receives regulatory plans from key regulatory agencies and has established a systematic approach to providing the plans to the appropriate policy officials within the Department. Feedback from the DoD components indicates that this communication among the Federal agencies is a major step forward in improving regulations and the regulatory process, as well as in improving Government operations.

Minimize Burden

In the regulatory process, there are more complaints concerning burden than anything else. In DoD, much of the burden is in the acquisition area. Over the years, acquisition regulations have grown and become burdensome principally because of legislative action. But, in coordination with Congress, the Office of Federal Procurement Policy, and the public, DoD is initiating significant reforms in acquisition so as to effect major reductions in the regulatory burden on personnel in Government and the private sector. DoD has implemented a multi-year strategy for reducing the paperwork burden imposed on the public. This plan shows that DoD has met and will exceed the goals set forth in the Paperwork Reduction Act. It is the goal of the Department of Defense to impose upon the public the smallest burden viable, as infrequently as possible, and for no longer than absolutely necessary.

Plain Language

Ensuring that regulations are simple and easy to understand is a high regulatory priority in the Department of Defense. All too often, the regulations are complicated, difficult to understand, and subject to misinterpretation, all of which can result in the costly process of litigation. The objective in the development of regulations is to write them in clear, concise language that is simple and easy to understand.

DoD recognizes that it has a responsibility for drafting clearly written rules that are reader-oriented and easily understood. Rules will be written for the customer using natural expressions and simple words. Stilted jargon and complex construction will be avoided. Clearly written rules will tell our customers what to do and how to do it. DoD is committed to a more customer-oriented approach and uses plain language rules thereby improving compliance and reducing litigation.

In summary, the rulemaking process in DoD should produce a rule that: Addresses an identifiable problem, implements the law, incorporates the President's policies defined in Executive Order 12866, is in the public interest, is consistent with other rules and policies, is based on the best information available, is rationally justified, is cost-effective, can actually be implemented, is acceptable and enforceable, is easily understood, and stays in effect only as long as is necessary. Moreover, the proposed rule or the elimination of a rule should simply make sense.

Regulations Related to the Events of September 11, 2001

Defense Federal Acquisition Regulation Supplement (DFARS) Case 2003-D107, Firefighting Service Contracts, implements section 331 of the National Defense Authorization Act for Fiscal Year 2004. Section 331 provides authority for contractor performance of firefighting functions at military installations or facilities for periods of one year or less, if the functions would otherwise have to be performed by members of the Armed Forces who are not readily available by reason of a deployment. The interim rule was published in the **Federal Register** on June 25, 2004 (69 FR 35532).

Federal Acquisition Regulation (FAR) Case 2003-022, Special Emergency Procurement Authority, implements section 1443 of the Fiscal Year 2004

Consolidated Appropriations Act. Section 1443 provides continuing authorities for acquisitions of property and services by or for an executive agency that are to be used in support of a contingency operation or to facilitate defense against or recovery from terrorism or nuclear, biological, chemical, or radiological attack. The interim rule was published in the **Federal Register**on February 23, 2004 (69 FR 8312).

Suggestions From the Public for Reform—Status of DoD Items

The Army Corps of Engineers has not undertaken any rulemaking actions in response to the public nominations submitted to the Office of Management and Budget in 2001 or 2002. Those nominations were discussed in ''Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities'' and ''Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities.''

When the Army Corps of Engineers reissued the nationwide permits on January 15, 2002 (67 FR 2020), several changes were made to clarify and simplify the nationwide permit program. These changes increased flexibility in decisionmaking, while enhancing protection of the aquatic environment.

The changes to the regulatory definitions of ''fill material'' and ''discharge of fill material'' that were published in the May 9, 2002, **Federal Register** resulted from the public notice and comment process required by the Administrative Procedures Act. The revised definitions provide consistency between Army Corps of Engineers and U.S. Environmental Protection Agency (EPA) regulations governing discharges of fill material into waters of the United States and do not warrant the preparation of an Environmental Impact Statement.

In the January 15, 2003, issue of the **Federal Register** (68 FR 1991), the Army Corps of Engineers and EPA issued an Advance Notice of Proposed Rulemaking (ANPRM) to obtain early comment on issues related to the scope of waters subject to Clean Water Act jurisdiction in light of the Solid Waste Agency of Northern Cook County v. Army Corps of Engineers decision by the U.S. Supreme Court (531 U.S. 159 (2001)). In Appendix A of this ANPRM, there is a joint memorandum issued by the Corps and EPA that provides clarifying guidance regarding the U.S. Supreme Court's decision in this case. This joint memorandum supercedes the January 19, 2001, guidance document and addresses several legal issues concerning Clean Water Act jurisdiction that have arisen since this decision. In response to the ANPRM, approximately 150,000 comments were received. On December 16, 2003, the Corps and EPA announced that a new rule on Clean Water Act regulatory jurisdiction over isolated waters would not be issued.

The Army Corps of Engineers is continuing its efforts to update and clarify the 1987 ''Corps of Engineers Wetlands Delineation Manual'' (1987 Manual). This effort may also include the development of regional wetland delineation manuals. Any proposed changes to the 1987 Manual, or the issuance of regional wetland delineation manuals, will be subject to the public notice and comment procedures required by the Administrative Procedures Act.

Specific Priorities

For this regulatory plan, there are four specific DoD priorities, all of which reflect the established regulatory principles. In those areas where rulemaking or participation in the regulatory process is required, DoD has studied and developed policy and regulations that incorporate the provisions of the President's priorities and objectives under the Executive order.

DoD has focused its regulatory resources on the most serious environmental, health, and safety risks. Perhaps most significant is that each of the priorities described below promulgates regulations to offset the resource impacts of Federal decisions on the public or to improve the quality of public life, such as those regulations concerning civil functions of the U.S. Army Corps of Engineers, acquisition, installations and the environment, and the Defense personnel system.

U.S. Army Corps of Engineers, Directorate of Civil Works

Compensatory Mitigation in the Army Regulatory Program

Section 314 of the National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108-136) requires the Secretary of the Army, acting through the Chief of Engineers, to issue regulations that establish performance standards and criteria for the use of compensatory mitigation for wetland functions lost as a result of activities authorized by Department of the Army (DA) permits. The statute also requires the regulation to contain provisions for the application of equivalent standards and criteria to each type of compensatory mitigation. The statutory deadline for publishing the final regulation is November 24, 2005.

The proposed regulation will be developed by considering concepts in current Federal compensatory mitigation guidance documents and updating and modifying those concepts to improve compensatory mitigation decisionmaking and processes. We believe that the proposed regulation should take a watershed approach to compensatory mitigation for permitted impacts to wetlands, streams, and other aquatic resources. Although the statute refers only to wetlands, we believe that the regulation should be broader in scope and address compensatory mitigation requirements for impacts to other aquatic resources, such as streams, in addition to wetlands.

Army Regulatory Program's Compliance With the National Historic Preservation Act

In 1990, the Army Corps of Engineers published as appendix Cof 33 CFR part 325, a rule that governs compliance with the National Historic Preservation Act (NHPA) for the Army's Regulatory Program. Over the years, there have been substantial changes in policy, and the NHPA was amended in 1992, leading to the publication in December 2000 of new implementing regulations at 36 CFR part 800, issued by the Advisory Council on Historic Preservation. Those regulations were amended on July 6, 2004. The Advisory Council on Historic Preservation's regulations allow Federal agencies to utilize alternate procedures in lieu of the regulations at 36 CFR part 800. To solicit public comment on the appropriate mechanism for revising the Army Regulatory Program's process for considering effects to historic properties resulting from activities authorized by DA permits, the Army Corps of Engineers published an Advance Notice of Proposed Rulemaking to obtain the views of interested parties. After reviewing the comments received in response to the ANPRM, the Army Corps of Engineers may develop and propose, in fiscal year 2005, agency alternate procedures to comply with the requirements of section 106 of the National Historic Preservation Act.

Defense Procurement and Acquisition

The Department continues its efforts to reengineer its acquisition system to

achieve its vision of an acquisition system that is recognized as being the smartest, most efficient, most responsive buyer of best value goods and services, which meet the warfighter's needs from a globally competitive base. To achieve this vision, the Department will focus in the acquisition regulations during this next year on implementing and institutionalizing initiatives that may include additional changes to existing and recently modified regulations to ensure that we are achieving the outcomes we desire (continuous process improvement).

The Department of Defense continuously reviews its supplement to the Federal Acquisition Regulation (FAR) and continues to lead Government efforts to simplify the following acquisition processes:

- Transform the Defense Federal Acquisition Regulation Supplement(DFARS) to improve the efficiency and effectiveness of the acquisition process, while allowing the acquisition workforce flexibility to innovate. The transformed DFARS will contain only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal operating procedures of DoD or a significant cost or administrative impact on contractors or offerors.
- Provide uniform treatment of contractor personnel whoprovide support in theater to a force deployed outside the United States in contingency operations, humanitarian or peacekeeping operations, and other major military operations or training exercises designated by the Combatant Commander.
- Implement new Free Trade Agreements and revise the FARand DFARS subparts on trade agreements, to make terminology consistent with our international agreements.
- Finalize the rewrite of FAR part 27, Patents, Data andCopyrights, to clarify, streamline, and update guidance and clauses on patents, data, and copyrights.
- Provide guidance on acceptability of photocopies of powersof attorney for bid bonds and allow treatment of questions regarding the authenticity and enforceability of the power of attorney at the time of bid opening as a matter of responsibility.
- Review various FAR cost principles to determine whethercertain FAR cost principles are still relevant in today's business environment, whether they place an unnecessary administrative burden on contractors and the Government, and whether they can be streamlined or simplified.
- Revise policy on the applicability of cost accountingstandards. The goal of this initiative is to modify and streamline the applicability of Federal cost accounting standards.
- Phase in requirements for contractors to affix radio frequencyidentification (RFID) tags to items delivered under DoD contracts. This practice will improve visibility of DoD assets in the supply chain, increase the accuracy of shipment and receipt data, and reduce the amount of time it takes to deliver material to the warfighter.
- Consider FAR and DFARS changes to facilitate timely contractcloseout.
- Implement Earned Value Management in the FAR.
- Revise the FAR part 45, Government Property, to organizeand streamline the management of Government property.

Defense Installations and the Environment

The Department is committed to reducing the total ownership costs of the military infrastructure while providing the Nation with military installations that efficiently support the warfighter in: Achieving military dominance, ensuring superior living and working conditions, and enhancing the safety of the force and the quality of the environment. DoD has focused its regulatory priorities on explosives safety, human health, and the environment. These regulations provide means for the Department to provide information about restoration activities at Federal facilities and to take public advice on the restoration activities.

Restoration Advisory Boards

The requirement for the establishment of Restoration Advisory Boards (RABs) is grounded in section 324(a) of Public Law 104-106, which requires the Secretary of Defense to ''prescribe regulations regarding the establishment, characteristics, composition, and funding of restoration advisory boards.'' Section 324(a) also stated that DoD's issuance of regulations shall not be a precondition to the establishment of RABs (amended section 2705(d)(2)(B)). In August 1996, the Department proposed and requested public comments on regulations regarding the characteristics, composition, funding, and establishment of RABs. These regulations were not finalized.

As a consequence of litigation in 2001, the Department substantially revised the regulations and shared a draft of the RAB Rule with RAB community members as part of the Department's outreach to affected members of the public. On March 26, 2003, OMB reviewed the Draft Proposed RAB Rule and agreed that it is not a ''significant regulatory action'' under Executive Order 12866. DoD has incorporated all appropriate community members' comments and provided a revised Draft Proposed RAB Rule to OMB for interagency review prior to publication in the **Federal Register.**

Because the applicability of the Federal Advisory Committee Act (FACA) to RABs was unclear, DoD sought a statutory clarification. Section 317 of the fiscal year 2004 National Defense Authorization Act provides that FACA does not apply to RABs. The revised Draft Proposed RAB Rule reflects this clarification.

Munitions Response Site Prioritization Protocol

Section 2710(b)(1) of title 10, United States Code, directs the Secretary of Defense to develop, in consultation with representatives of the States and Indian tribes, a proposed protocol for assigning to each defense site a relative priority for munitions response activities. Section 2710 provides for public notice and comment on the proposed protocol and requires that the proposed protocol be available for public comment on or before November 30, 2002. DoD is directed to issue a final protocol to be applied to defense sites listed in the Department's munitions response site inventory.

The Department met with State and tribal representatives and also representatives of other Federal agencies during preparation of the proposed rule published on August 22, 2003. The Department reviewed and incorporated comments from the 16 sets of comments received during the public comment period, which ended on November 19, 2003. The draft final rule is under review within the Department, which plans to publish the final rule in fiscal year 2005.

Most of the changes pertain to clarification of terms and definitions based on comments received or new statutory definitions promulgated in the National Defense Authorization Act for Fiscal Year 2004 and codified at 10 U.S.C. section 101. The most significant change to the proposed rule pertains to

the module that evaluates health hazards associated with munitions constituents and other chemical constituents. The Department also revised the rule to clarify that current landowners may participate in the application of the rule at Formerly Used Defense Sites and that the quality assurance panel that reviews each priority score will consist only of Department personnel.

National Security Personnel System

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108-136, November 24, 2003) provided the Department of Defense (DoD) the authority to establish a more flexible civilian personnel management system. The National Security Personnel System (NSPS) will allow the Department to be a more competitive and progressive employer at a time when the country's national security demands a highly responsive system of civilian personnel management.

NSPS will establish new rules for how DoD civilians are hired, assigned, compensated, promoted, and disciplined. NSPS will also address the Department's labor relations and appeals processes. This will all be within the framework of merit principles, veterans' preference, and employees' rights to organize and bargain collectively. The goal of NSPS is to strengthen DoD's ability to accomplish its mission in an ever-changing defense environment.

In April 2004, the Department established a DoD Program Executive Office, National Security Personnel System (PEO-NSPS) to manage, oversee, and coordinate the development, design, and implementation of NSPS throughout the Department. This includes drafting (with OPM) regulations establishing NSPS.

Human Resources Management System

Section 9902(a) of Public Law 108-136 authorizes the Secretary of Defense and the Director of the Office of Personnel Management (OPM) to issue jointly prescribed regulations to establish a human resources management system for the Department of Defense. These regulations will provide for new rules and flexibilities in the areas of:

- Position classification and pay
- Performance management (including a pay for performancesystem, as required in section 9902(b)(6)(I) of Public Law 108-136)
- Hiring, assignment, and reduction in force

Labor Management Relations System

Section 9902(m) of Public Law 108-136 authorizes the Secretary of Defense and the Director, OPM, to establish a new labor management relations system for the Department and to allow for a collaborative, issue-based approach to labor management relations. Regulations developed jointly with OPM will provide a new framework for labor relations in DoD, with the goal of streamlined processes to allow for quicker and more efficient resolution of labor relations issues, while preserving collective bargaining rights for DoD employees.

Employee Appeals

Section 9902(h) of Public Law 108-136 provide the Secretary of Defense with authority to establish an appeals process in conjunction with NSPS to provide employees fair treatment in decisions relating to their employment. The new appeals will be designed to streamline appeals procedures while ensuring that employees are afforded the protections of due process, as required by law.

NSPS Design Process and Timeline

The design of NSPS (which will result in regulations to be issued in the **Federal Register**) includes an extensive outreach effort to gather input and feedback from a variety of stakeholder groups, including DoD labor unions, employees, supervisors, managers, military commanders, and external groups such as veteran service organizations, (non-union) employee interest groups, and ''good-government'' groups. DoD working groups, comprised of DoD and OPM human resources experts, line managers, and system practitioners (e.g., legal, EEO) met in the late summer 2004 to identify and craft NSPS design options. In addition, DoD and OPM have met several times with DoD labor union representatives to gather input and discuss potential system designs.

Once NSPS design options are decided upon by DoD and OPM senior leadership, proposed regulations establishing and governing NSPS will be published via the **Federal Register** for public comment. The Department plans to issue proposed NSPS regulations in December 2004, Statutory procedures for collaborating with employee representatives on the content of the regulations are provided in sections 9902(f) and 9902(m)(3).

BILLING CODE 5001–06–S

DEPARTMENT OF EDUCATION (ED)

Statement of Regulatory and Deregulatory Priorities

General

We support States, local communities, institutions of higher education, and others to improve education nationwide. Our roles include providing leadership and financial assistance for education to agencies, institutions, and individuals in situations in which there is a national interest; monitoring and enforcing Federal civil rights laws in programs and activities that receive Federal financial assistance; and supporting research, evaluation, and dissemination of findings to improve the quality of education.

The 4,300 employees of our Department help to realize the educational promise of America. We administer programs, grants, and loans that touch nearly every American at one point in their lives—approximately 14,000 public school districts, nearly 54 million students attending 93,000 elementary and secondary schools, and almost 22 million postsecondary students.

To connect our customers to a ''one-stop-shopping'' center for information about our programs and initiatives, we instituted 1-800-USA-LEARN (1-800-872-5327). We also set up 1-800-4FED-AID (1-800-433-3243) for information on student aid, and we provide an online library of information on education legislation, research, statistics, and promising programs at the following Internet address: http://www.ed.gov

More than 763,225 people take advantage of these resources every week. In addition, our Office of Internal Communications established for the summer a Visitors Center at our headquarters. From Memorial Day to Labor Day, the center was staffed by employee volunteers who were trained to engage the public and respond to their inquiries. Some 1,000 visitors stopped by to give their views on education, learn about the No Child Left Behind Act and other Federal education legislation, and find out about resources and materials that we offer. We gave young children a special ''Visitors Center Activity Book,'' and talked with adults about our online resources.

We have forged effective partnerships with customers and others to develop policies, regulations, guidance, technical assistance, and approaches to compliance. We have a record of successful communication and shared policy development with affected persons and groups, including parents, students, educators, representatives of State, local, and tribal governments, neighborhood groups, schools, colleges, special education and rehabilitation service providers, professional associations, advocacy organizations, businesses, and labor organizations.

In particular, we continue to seek greater and more useful customer participation in our rulemaking activities through the use of consensual rulemaking and new technology. If we determine that the development of regulations is absolutely necessary, we seek customer participation at all stages—in advance of formal rulemaking, during rulemaking, and after rulemaking is completed in anticipation of further improvements through statutory or regulatory changes. We have expanded our outreach efforts through the use of satellite broadcasts, electronic bulletin boards, and teleconferencing. For example, we invite comments on all proposed regulations through the Internet.

We are continuing our efforts to streamline information collections, reduce burden on information providers involved in our programs, and make information maintained by us easily available to the public. To the extent permitted by statute, we will revise regulations to eliminate barriers that inhibit coordination across programs (such as by creating common definitions). This should help reduce the frequency of reports and eliminate unnecessary data requirements.

We currently have in place four Internet-based software applications: e-Application, e-Reports, e-Reader, and e-Administration. These enable applicants, grantees, and grant teams to file, review, and process applications and performance reports and to make administrative changes online. These applications were implemented in pilot phases between FY 2000 and 2003, and the program participation in these initiatives continues to grow each year. In addition, we are participating in the Governmentwide Grants.gov Find and Apply portal, which is a one-stop shopping site allowing grant applicants to find and apply for funding opportunities from agencies across the Federal government.

New Initiatives

We have recently implemented an Enterprise-Wide Risk Management initiative. The goal of this initiative is to mitigate concentrations of risk (including the risk of improper or erroneous payments) within our portfolio of grants, loans, and other operations by focusing human, financial, and technical resources to achieve targeted results. We have begun to identify a number of entities that have concentrations of risk (e.g., incomplete audits, qualified audit reports, and more that $1 million of funds at risk of reverting to Treasury), and we will be taking positive steps to partner with these entities to mitigate the risks.

We are also focusing on strategic management of human capital. Efforts are being taken to reduce the number of vacancies and the time it takes to fill those vacancies, clarify expectations of results, and enhance the performance appraisal process to promote differentiating among performance levels and to provide clear and effective feedback. We are also focused on strengthening and developing leadership talent by analyzing the critical skill needs of the organization, providing training based on identified leadership competencies, and implementing an executive leadership development program that will contribute to the depth and breadth of leaders at the Department.

Among our other new undertakings, the Secretary announced the Teacher-to-Teacher Initiative through which some of the Nation's best teachers and educational experts will have the opportunity to share with their colleagues classroom practices that have been successful in raising student performance and closing the achievement gap. The initiative includes ongoing workshops for teachers, teacher and principal roundtables, a national teacher summit, a ''Toolkit for Teachers'' containing resource materials, a weekly e-mail update entitled ''Teacher E-Bytes,'' and ''American Stars of Teaching,'' which focuses attention on effective teachers who are making a real difference in their students' lives.

No Child Left Behind

The No Child Left Behind Act of 2001, which reauthorized the Elementary and Secondary Education Act of 1965, increases accountability for States, school districts, and schools; provides greater choice for parents and students, particularly those attending low-performing schools; provides more flexibility for States and local educational agencies in the use of Federal education dollars; and places a stronger emphasis on reading, especially for our youngest children.

Each State, Puerto Rico, and the District of Columbia has submitted an accountability plan, which the Department approved. Each submitting jurisdiction has used its respective plan to hold schools and school districts accountable in school years 2002-03 and 2003-04 for all their students, including students in specific subgroups such as students with disabilities and limited English proficient (LEP) students.

With respect to students with disabilities and LEP students, in particular, the Department recently initiated regulatory actions to address unique issues. We issued final regulations that permit a State to (1) develop alternate achievement standards for students with the most significant cognitive disabilities and (2) include those students' proficient and advanced scores in adequate yearly progress (AYP) determinations, subject to a cap of one percent. We also published proposed regulations to permit a State to (1) exempt LEP students new to schools in the United States from one administration of the State's reading assessment and (2) include, for up to 2 years, former LEP students in the LEP subgroup for making AYP determinations.

We shall continue to focus on helping States place a highly qualified teacher in every classroom; identifying schools and districts in need of improvement and making sure they are getting the assistance they need to get back on track; expanding the opportunities for eligible students to receive tutoring and other supplemental services; and helping districts create capacity in order to make public school choice available to all eligible students who wish to transfer schools.

We shall also begin to peer review the new State content and student achievement standards and aligned assessment systems required by the No Child Left Behind Act. These must be in place by the 2005-06 school year.

Principles for Regulating

Our Principles for Regulating determine when and how we will regulate. Through consistent application of the following principles, we have eliminated unnecessary regulations and identified situations in which major programs could be implemented without any regulations or with only limited regulations.

We will regulate only if regulating improves the quality and equality of services to our customers, learners of all ages. We will regulate only if absolutely necessary and then in the most flexible, most equitable, and least burdensome way possible.

Whether to regulate:

- When essential to promote quality and equality of opportunity in education.
- When a demonstrated problem cannot be resolved without regulation.
- When necessary to provide legally binding interpretation to resolve ambiguity.
- Not if entities or situations to be regulated are so diverse that a uniform approach does more harm than good.

How to regulate:

- Regulate no more than necessary.
- Minimize burden and promote multiple approaches to meeting statutory requirements.
- Encourage federally funded activities to be integrated with State and local reform activities.
- Ensure that benefits justify costs of regulation.
- Establish performance objectives rather than specify compliance behavior.
- Encourage flexibility so institutional forces and incentives achieve desired results.

Regulatory and Deregulatory Priorities for the Next Year

Reauthorization of the Individuals With Disabilities Education Act (IDEA), parts C and D, and anticipated amendments to parts A and B, will make changes considered to be necessary to improve the implementation of the education of children with disabilities program (including pre-school services) and the early intervention program for infants and toddlers with disabilities under parts B and C and the effectiveness of national discretionary grants, contracts, and cooperative agreements in improving the education of children with disabilities under part D. The Secretary solicited public comment on the reauthorization of IDEA using the underlying framework of the President's principles of education reform to ensure that no child is left behind.

Reauthorization of the Higher Education Act of 1965 (HEA) will make changes considered necessary to the grant, loan, and work assistance programs authorized under title IV of the HEA in order to improve educational quality, expand access, and ensure affordability in postsecondary education. This reauthorization will seek to balance the reduction of burdensome requirements, especially on students, with the need to adequately safeguard taxpayers' funds. It would also make changes considered necessary to improve the implementation of the teacher quality enhancement programs under title II of the HEA, the institutional assistance programs under titles III and V of the HEA, the international and foreign language studies programs under title VI of the HEA, and the graduate education and postsecondary education improvement programs under title VII of the HEA.

ED—Office of Special Education and Rehabilitative Services (OSERS)

PRERULE STAGE

35. REAUTHORIZATION OF THE INDIVIDUALS WITH DISABILITIES EDUCATION ACT (SECTION 610 REVIEW)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

20 USC 1400 to 1487

CFR Citation:

34 CFR ch III

Legal Deadline:

None

Abstract:

These regulations would implement changes made by the anticipated reauthorization of the Individuals With Disabilities Education Act. This action is a notice that, if regulations are necessary, ED would review the regulations in 34 CFR chapter III under section 610 of the Regulatory Flexibility Act (5 U.S.C. 610). The purpose of this review would be to determine if these regulations should be continued without change, or should be amended or rescinded, to minimize any significant economic impact upon a substantial number of small entities. We would request comments on the continued need for the regulations; the complexity of the regulations; the extent to which they overlap, duplicate, or conflict with other Federal, State, or local government regulations; and the degree to which technology, economic

conditions, or other relevant factors have changed since the regulations were promulgated.

Statement of Need:

These regulations may be necessary to implement new legislation. ED would also complete its review of these regulations under section 610(c) of the Regulatory Flexibility Act. In developing any regulations, the Department would seek to reduce regulatory burden and increase flexibility to the maximum extent possible.

Summary of Legal Basis:

New legislation.

Alternatives:

In addition to implementing the anticipated reauthorization of the Individuals With Disabilities Education Act, the purpose of this review would be to determine whether there are appropriate alternatives.

Anticipated Cost and Benefits:

Existing regulatory provisions may be eliminated or improved as a result of this review.

Risks:

These regulations would not address a risk to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
Notice	01/10/02	67 FR 1411
ANPRM	02/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

URL For Public Comments:

www.regulations.gov

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RIN: 1820–AB54

BILLING CODE 4000–01–S

DEPARTMENT OF ENERGY (DOE)

Statement of Regulatory and Deregulatory Priorities

The Department makes vital contributions to the Nation's welfare through its extraordinary scientific and technical capabilities in energy research, environmental remediation, and national security. The Department's mission is to:

- Foster a secure and reliable energy system that is environmentallyand economically sustainable;
- Provide responsible stewardship of the Nation'snuclear weapons;
- Clean up the Department'sfacilities;
- Lead in the physical sciences and advance the biological,environmental and computational sciences; and,
- Provide premiere instruments of science for the Nation'sresearch enterprise.

The Department of Energy's regulatory plan reflects the Department's continuing commitment to enhance safety, cut costs, reduce regulatory burden, and increase responsiveness to the public. While not primarily a major Federal regulatory agency, the Department's regulatory activities are essential to achieving its critical mission and to implementing major initiatives in the President's National Energy Plan.

Energy Efficiency Program for Consumer Products and Commercial Equipment

The Department's priorities for its rulemaking activities related to energy efficiency standards and determinations, which have been established with significant input from the public, are reflected in the rulemaking schedules set forth in **The Regulatory Plan** and the **Unified Agenda of Federal Regulatory and Deregulatory Actions**.

During the coming year, the Department expects to revise the energy efficiency standards for residential furnaces and boilers; electric distribution transformers; and for commercial unitary air conditioners and heat pumps. Additional information and timetables for these actions can be found below. In addition, the Department will continue working on the analyses required to revise the standards for packaged terminal air conditioners and heat pumps, oil- and gas-fired commercial packaged boilers, tankless gas-fired instantaneous water heaters, 3-phased air conditioners and heat pumps, and single package vertical air conditioners and heat pumps.

The Department plans to publish final rules concerning test procedures for residential central air conditioners and heat pumps and electric distribution transformers. Information and timetables concerning these actions can be found in the Department's regulatory agenda, which appears elsewhere in this issue of the **Federal Register**.

Nuclear Safety Regulations

The Department is committed to openness and public participation as it addresses one of its greatest challenges—managing the environment, health, and safety risks posed by its nuclear activities. A key element in the management of these risks is to establish the Department's expectations and requirements relative to nuclear safety and to hold its contractors accountable for safety performance. The 1988 Price-Anderson Amendments Act revisions to the Atomic Energy Act of 1954 (AEA) provide for the imposition of civil and criminal penalties for violations of DOE nuclear safety requirements. As a result, new nuclear safety requirements were initiated with the publication of four notices of proposed rulemaking for review and comment in 1991. The Department's nuclear safety procedural regulations (10 CFR part 820) were published as a final rule in 1993. The Department's substantive nuclear safety requirements (10 CFR parts 830 and 835) were finalized in 2001 and 1998, respectively. The remaining action, 10 CFR part 834, Radiation Protection and the Environment, is scheduled for publication by the end of 2006. In addition, the Department will be proposing in November 2004 to add a new part, 10 CFR 851, Worker Safety and Health, that would establish basic requirements to ensure workers are protected from safety and health hazards at DOE facilities.

DOE—Energy Efficiency and Renewable Energy (EE)

PROPOSED RULE STAGE

36. ENERGY EFFICIENCY STANDARDS FOR RESIDENTIAL FURNACES AND BOILERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6295

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 1994.

Abstract:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and generally requires DOE to undertake two subsequent rulemakings, at specified times, to determine whether the extant standard for a covered product should be amended.

This is the initial review of the statutory standards for residential furnaces and boilers.

Statement of Need:

Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle costs. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

EPCA establishes initial energy efficiency standard levels for most types of major residential appliances and certain commercial equipment. EPCA generally requires DOE to undertake rulemakings, at specified times, to determine whether the standard for a covered product should be made more stringent.

Alternatives:

The statute requires the Department to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of the alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternatives in

the appliance standards development process. For example, under this process, the Department will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The specific costs and benefits of this rulemaking have not been established because the final standard levels have not been determined. Nevertheless, existing appliance standards are projected to save 23 quadrillion Btus of energy from 1993 to 2015, resulting in estimated consumer savings of $1.7 billion per year in 2000 and estimated annual emission reductions of 107 million tons of carbon dioxide and 280 thousand tons of nitrogen oxides in that year. Under the existing standards, the discounted energy savings for consumers are 2.5 times greater than the upfront price premium paid for the appliance.

Risks:

Without appliance standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions such as CO2 and NOx. Establishing standards that are too stringent could result in excessive increases in the cost of the product and possible reductions in product utility. It might also place an undue burden on manufacturers that could result in loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
ANPRM	09/08/93	58 FR 47326
Framework Workshop	07/17/01	
Venting Workshop	05/08/02	
ANPRM	07/29/04	69 FR 45419
DOE Review of Technical Support Documents	09/00/05	
NPRM	09/00/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local, State

Additional Information:

The timetable for this action reflects program priorities, which were established with significant input from the public.

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RIN: 1904–AA78

DOE—EE

37. ENERGY EFFICIENCY STANDARDS FOR ELECTRIC DISTRIBUTION TRANSFORMERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6317

CFR Citation:

10 CFR 430

Legal Deadline:

None

Abstract:

The Energy Policy and Conservation Act, as amended, (EPCA) establishes initial energy efficiency standard levels for certain types of major residential appliances and certain types of commercial equipment. EPCA contains no energy efficiency standards for distribution transformers. This rulemaking will determine whether it is appropriate to establish such standards.

Statement of Need:

Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

EPCA establishes initial energy efficiency standard levels for certain types of major residential appliances and certain types of commercial equipment and generally requires DOE to undertake rulemakings, at specified times, to establish the standards for those covered products without statutory standards.

Alternatives:

The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The specific costs and benefits for this rulemaking have not been established because the final standard levels have not been determined. Nevertheless, existing appliance standards are projected to save 23 quadrillion Btus of energy from 1993 to 2015, resulting in estimated consumer savings of $1.7 billion per year in the year 2000 and estimated annual emission reductions of 107 million tons of carbon dioxide and 280 thousand tons of nitrogen oxides in the year 2000. Under the existing standards, the discounted energy savings for consumers are 2.5 times greater than the up-front price premium paid for the appliance.

Risks:

Without appliance efficiency standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions of carbon dioxide and nitrogen oxides. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may place an undue burden on manufacturers that could result in a loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
Determination Notice	10/22/97	62 FR 54809
ANPRM	07/29/04	69 FR 45375
DOE Review of Technical Support Documents	09/00/05	
NPRM	09/00/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

The timetable for this action reflects program priorities, which were established with significant input from the public.

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RIN: 1904–AB08

DOE—EE

38. ENERGY EFFICIENCY STANDARDS FOR COMMERCIAL UNITARY AIR CONDITIONERS AND HEAT PUMPS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6293

CFR Citation:

10 CFR 431

Legal Deadline:

None

Abstract:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for certain types of major residential appliances and certain types of commercial equipment. EPCA requires DOE to amend the standards for products whenever ASHRAE amends its standards.

Statement of Need:

Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

EPCA establishes initial energy efficiency standard levels for certain types of major residential appliances and certain types of commercial equipment and requires DOE to amend the standard for this product when ASHRAE amends its standards, as recently occurred. DOE can establish a more stringent standard than the ASHRAE standard, if DOE determines by clear and convincing evidence that such higher standard is technologically feasible and economically justified and would result in additional energy conservation.

Alternatives:

The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The specific costs and benefits for this rulemaking have not been established because the final standard levels have not been determined.

Risks:

Without energy efficiency standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing energy efficiency reduces atmospheric emissions of carbon dioxide and nitrogen oxides. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may place an undue burden on manufacturers that could result in a loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
Screening Workshop	10/01/01	66 FR 43123
ANPRM	07/29/04	69 FR 45459
DOE Review of Technical Support Documents	09/00/05	
NPRM	09/00/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

The timetable for this action reflects program priorities, which were established with significant input from the public.

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RIN: 1904–AB09

DOE—Departmental and Others (ENDEP)

PROPOSED RULE STAGE

39. WORKER SAFETY AND HEALTH

Priority:

Other Significant

Legal Authority:

42 USC 2011; 42 USC 5801 to 5911; 42 USC 7101 to 7352

CFR Citation:

10 CFR 851

Legal Deadline:

Final, Statutory, December 2, 2003.

Abstract:

This action would add a new 10 CFR 851 regulation to DOE's regulations establishing a body of rules setting forth basic requirements to ensure workers are protected from safety and health hazards at DOE facilities.

Statement of Need:

The purpose of this rule is to ensure that the Department's obligation to protect the safety and health of its workers is fulfilled and to provide, if needed, a basis for the imposition of civil penalties consistent with section 3173 of the Bob Stump National Defense Authorization Act of 2003. This action is consistent with the Department's commitment to the issuance of safety and health requirements using notice and comment rulemaking.

Summary of Legal Basis:

Under the Atomic Energy Act of 1954 (AEA), as amended, the Department of Energy has the authority to regulate activities at facilities under its jurisdiction. On December 2, 2002, section 3173 of the National Defense Authorization Act amended the AEA to add section 234C (codified as 42 U.S.C. 2282c). Section 234C requires the Department to promulgate regulations for industrial and construction safety and health at DOE contractor facilities for contractors covered by an agreement of indemnification. The regulation must provide a level of protection to workers at such facilities that is substantially equivalent to the level of protection currently being provided to workers. Section 234C also makes DOE contractors that violate the safety and health regulations subject to civil penalties or a reduction of fees and other payments under its contract with DOE.

Alternatives:

None

Anticipated Cost and Benefits:

The incremental costs of the proposed rules should be minimal because contractors are currently bound by comparable contractual obligations.

Risks:

The proposed rule would allow DOE to assess penalties as directed by Congress for noncompliance. Therefore, contractors will be put at risk if they violate the safety and health requirements of the rule. The proposed rule may also reduce the injuries and illnesses of workers due to increased emphasis on complaint programs.

Timetable:

Action	Date	FR Cite
NPRM	12/08/03	68 FR 68276
NPRM Comment Period End	02/06/04	
NPRM Suspension	02/27/04	69 FR 9277
Supplemental NPRM	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

A Notice of Suspension was issued on 02/27/2004 to allow time for the Department to consult with the Defense Nuclear Facilities Safety Board (DNFSB) in order to resolve its concerns.

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DOE—ENDEP

FINAL RULE STAGE

40. RADIATION PROTECTION OF THE PUBLIC AND THE ENVIRONMENT

Priority:

Other Significant

Legal Authority:

42 USC 2201; 42 USC 7191

CFR Citation:

10 CFR 834

Legal Deadline:

None

Abstract:

This action would add a new 10 CFR 834 to DOE's regulations establishing a body of rules setting forth the basic requirements for ensuring radiation protection of the public and environment in connection with DOE nuclear activities. These requirements stem from the Department's ongoing effort to strengthen the protection of health, safety, and the environment from the nuclear and chemical hazards posed by these DOE activities. Major elements of the proposal include a dose limitation system for protection of the public; requirements for liquid discharges; reporting and monitoring requirements; and residual radioactive material requirements.

Statement of Need:

The purpose of this rule is to ensure that the Department's obligation to protect health and safety is fulfilled and to provide, if needed, a basis for the imposition of civil and criminal penalties consistent with the Price-Anderson Amendments Act of 1988. This action is consistent with the Department's commitment to the issuance of nuclear safety requirements using notice and comment rulemaking.

Summary of Legal Basis:

Under the Atomic Energy Act of 1954, as amended, the Department of Energy has the authority to regulate activities at facilities under its jurisdiction. The Department is committed to honoring its obligation to ensure the health and safety of the public and workers affected by its operations and the protection of the environs around its facilities.

Alternatives:

The Department could continue to impose nuclear safety requirements through directives made applicable to DOE contractors through the terms of their contracts.

Anticipated Cost and Benefits:

The incremental costs of the proposed rules should be minimal because contractors are currently bound by comparable contractual obligations. Full compliance by contractors with nuclear safety standards will result in substantial societal benefits.

Risks:

This rulemaking should reduce the risk of nuclear safety problems by clarifying safety requirements applicable to DOE contractors and improving compliance.

Timetable:

Action	Date	FR Cite
NPRM	03/25/93	58 FR 16268
Second NPRM	08/31/95	60 FR 45381
Conform to Related EPA Regulation	09/00/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Additional Information:

The Environmental Protection Agency (EPA) is considering revising the Federal Guidance for Radiation Protection of the Public. This Presidential-level guidance would refine the radiation protection and dose limitation framework for the public, and may include numerical Radiation Protection Goals (i.e., dose limits). Because it is DOE's policy to be consistent with Federal radiation protection policy, the Department is adjusting the schedule for part 834 in anticipation of revised Federal Guidance and will issue the rule following EPA action on the guidance. This will allow DOE to be consistent with the most current Presidential-level guidance upon its release.

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RIN: 1901–AA38

BILLING CODE 6450–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

The Department of Health and Human Services (HHS) is responsible for a broad range of programs designed to protect and promote the health and the social and economic well being of the American public. These programs especially affect some of the Nation's most vulnerable populations, including children, the elderly, and persons with disabilities. And, in one way or another, HHS' activities touch the lives of virtually every person in our country, citizens and non-citizens alike.

HHS' programs and activities include: Medicare, Medicaid, support for public health preparedness, biomedical research, substance abuse and mental health treatment, assurance of safe and effective drugs and other medical products, food safety, financial assistance to low income families, Head Start, services to older Americans, and direct health services delivery. These programs and services are essential to the well being of tens of millions of Americans across our country—people of every age, in every location, and in every walk of life.

To improve the administration and conduct of these programs and activities, Secretary Thompson has made it clear that the Department must develop and issue regulations in a culture of responsiveness, where listening and responding to those we serve and those we regulate is the cornerstone. From health promotion and disease prevention to public health preparedness to food safety, the Secretary is committed to widening communication with consumers, beneficiaries, and all regulated entities. Furthermore, the Secretary wishes to ensure that all HHS regulations are readily understandable, are clear and concise, and grounded both in pertinent law and common sense.

FY 2005 Regulatory Themes

The Secretary has adopted four overarching regulatory themes for FY 2005:

- modernizing Medicare;
- improving the Nation's ability to prepare for and/or respond to public health emergencies and disasters;
- reducing medical errors and enhancing patient safety; and
- protecting America's consumers.

Most of the Department's regulatory priorities for this fiscal year will fall under these themes (see the listing below). It should be noted, however, that the Secretary's overall priorities go beyond these categories and include, for example, increasing the percentage of the Nation's children and adults with access to regular health care; motivating American adults to gain the benefits of physical activity; enhancing the capacity and productivity of the Nation's health-science research enterprise; and supporting efforts to increase the independence of low-income families, the disabled, and older Americans.

Modernizing Medicare

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, improvement and Modernization Act of 2003 (MMA). This landmark legislation provides seniors and people living with disabilities with a prescription drug benefit, more choices, and better benefits under Medicare, and many other administrative and programmatic changes, the result of which is the most significant improvement to senior health care in nearly 40 years. Secretary Thompson announced in July 2003 proposed regulations to implement the prescription drug benefit, as well as new health plan choices, improved health care for rural America, and improved preventive care benefits. Bringing these proposals to completion is among the Secretary's highest priorities. The prescription drug benefit will allow all Medicare beneficiaries to enroll in drug coverage through a prescription drug plan or Medicare health plan, with Medicare paying for 75 percent of the premium. Additional benefits for Medicare beneficiaries with limited means will cover, on average, 95 percent of their drug costs. The new benefits also will provide new protections for retirees who currently receive drug coverage through their employers or unions. All the new Medicare benefits are voluntary, as seniors can choose to keep their existing traditional coverage.

Also, the following regulatory actions, supported by older statutory authority, will also effect important improvements in Medicare:

- a final rule to establish national and local coverage-determination appeals processes; standardized appeals processes will allow beneficiaries to challenge coverage policies that could otherwise prevent legitimate claim payments;
- two regulatory proposals to establish clearer performance standards under Medicare for Organ Procurement Organizations, and a new mechanism for reapproval of Organ Transplant centers; and
- a proposed rule under which current requirements for Medicare reimbursement for services to persons with End Stage Renal Disease would be completely overhauled and simplified.

Improving the Department's Ability to Respond to Emergencies and Disasters

HHS is responsible for directing and coordinating the medical and public health response to terrorism, natural disasters, major accidents, and other events that can result in mass casualties. Timely and well-focused responses to such events are key to limiting death and injury. The Department and its partners must be able to react quickly, and tailor responses to the specific emergency without being encumbered by counter-productive activities.

Regulations in the Plan designed to help ensure that HHS has appropriate authority and flexibility to address emergencies and disasters include:

- three final rules to improve readiness to respond to threats of food-related bioterrorism, by:
- requiring prior notification to the Food and Drug Administration (FDA) of all food importation to the United States,
- requiring owners or operators of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register the facility with the FDA; and
- requiring the maintenance of food-handling records identifying the immediate source from which a wholesale food facility received a food shipment as well as the shipment's immediate subsequent recipient, assisting FDA in addressing credible threats of serious adverse health consequences;
- a proposed rule reorganizing current FDA regulations requiring registration of drug establishments, enabling the agency to quickly identify firms that manufacture a specific product or ingredient that may be needed during a national emergency; and
- a proposed rule providing for an exception from the general requirement for informed consent in the use of investigational devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist threat or other public health emergency.

Reducing Medical Errors and Enhancing Patient Safety

Medical errors and other patient safety risks have been the subject of many recent studies and reports. The Secretary has directed that actions be taken to reduce these risks. Regulatory actions included in the Plan under this theme include:

- a final rule requiring that drug product labels contain a toll-free number for use in reporting adverse events associated with the use of that product;
- a final rule requiring improvements in the format and content requirements of the ''professional'' labeling of drug products, enabling health care practitioners to prescribe drugs more safely;
- a final rule requiring that blood establishments follow written procedures (often called ''lookback'') for appropriate action when it is determined that blood or blood components are at increased risk for transmitting hepatitis C virus infection.

Protecting America's Consumers

Consumer health and safety is a major concern for the public and the Secretary. Consumers are inundated each year with an availability of new products and ingredients. Every year, tens of thousands of Americans become sick and some die from foodborne pathogens, and the size of vulnerable populations (e.g., the elderly and those with compromised immune systems) is growing. The Secretary is especially interested in actions that enhance safety associated with the production of food, or provide better nutrition information to American consumers.

Regulations under this theme include:

- a final rule to standardize the manufacturing and packaging of dietary supplements;
- a final rule to strengthen safety requirements for the storage and distribution of eggs;
- a group of actions to further strengthen existing safeguards that protect consumers against the agent that causes bovine spongiform encephalopathy (''mad cow disease'), and
- two advance notices of proposed rulemaking that request information from the public regarding better labeling of the caloric content of food products.

Public Comments and Reactions

The Secretary welcomes comments not only on specific regulations as they are published in the **Federal Register**, but also on the overarching themes he has established. Such comments, as well as suggestions for regulatory improvements and initiatives, should be sent to Secretary Tommy G. Thompson, c/o Ann C. Agnew, Executive Secretary to the Department, Room 603, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

REGULATIONS BY THEME

(parentheses contain RIN numbers)

Modernizing Medicare

Medicare Prescription Drug Benefit—MMA Title I (0938-AN08)

Medicare Advantage Program—MMA Title II (0938-AN06)

Revisions to the Review and Approval of National Accreditation Organizations for Deeming Authority (0939-AN62)

Organ Procurement Organizations: Conditions for Coverage (0938-AK81)

End Stage Renal Disease: Conditions for Coverage (0938-AG82)

Requirements for Approval of Transplant Centers To Perform Transplants (0938-AHI7)

Improving the Nations Ability to Respond to Emergencies and Disasters

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act (0910-AC41)

Registration of Food and Animal Facilities (0910-AC40)

Establishment and Maintenance of Records To Identify Immediate Previous Source and Immediate Subsequent Recipient of Foods (0910-AC39)

Exception From General Requirements for Informed Consent; Request for Comments and Information (0910-AC25)

Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics (0910- AA49)

Reducing Medical Errors and Enhancing Patient Safety

Toll-Free Number for Reporting Adverse Events on Labeling For Human Drugs (0910-AC35)

Revised Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products (0910-AA94)

CGMPs for Blood and Blood Components: Notification of Cosignees and Transfusion Recipients Receiving Blood Components at Increase Risk of Transmitting Hepatitis C Virus (Lookback)

Current Good Tissue Practice for Manufacturers of Human Cells, Tissues and Cellular and Tissue-Based Products (0910-AB28)

Protecting America's Consumers

Use of Materials Derived From Cattle In Human and Animal Medical Products (0910-AF54)

Requirements for Human and Animal Medical Products Manufactured From, Processed With, or Otherwise Containing, Material From Cattle (0910-AF55)

Use of Materials Derived From Cattle in Human Food and Cosmetics (0910-AF47)

Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle (0910-AF48)

Substances Prohibited From Use in Animal Food or Feed (0910- AF-46)

Food Labeling; Prominence of Calories (0910- AF22)

Food Labeling; Serving Sizes (0910-AF23)

Use of Ozone-Depleting Substances: Removal of Essential-Use Designation; Albuterol (0910-AF18)

Control of Salmonella Enteritidis in Shell Eggs During Production And Retail (0910-AC14)

Current Good Manufacturing Practices for Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (0910-AB88)

HHS—Food and Drug Administration (FDA)

PRERULE STAGE

41. FOOD LABELING; PROMINENCE OF CALORIES

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 321; 21 USC 343; 21 USC 371

CFR Citation:

21 CFR 101.9

Legal Deadline:

None

Abstract:

In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM will request comments on ways to give more prominence to ''calories'' on the food label.

Statement of Need:

The Nation is currently facing a major long-term public health crisis. This trend toward overweight and obesity has accelerated during the past decade and is well documented by numerous scientific analyses. In 1999-2000, 64 percent of U.S. adults were overweight, increased from 56 percent when surveyed in 1988-1994; 30 percent of adults were obese, increased from 23 percent in the earlier survey. Among children age 6 through 19 years, 15 percent were overweight, compared with 10 percent to 11 percent in the earlier survey. Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers. The total economic cost of obesity in the United States is up to $117 billion per year, including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures. Fundamentally, overweight and obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity).

Summary of Legal Basis:

Section 403(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 USC 343) provides that certain foods under FDA's jurisdiction bear nutrition information that provides for, among other things, the total calories served from any source and the total number of calories derived from total fat in each serving size or other unit of measure. This ANPRM is soliciting recommendations on ways to give more prominence to caloric information on the food label.

Alternatives:

Possible alternatives to this advance notice of proposed rulemaking are: 1) do not amend certain provisions of the nutrition labeling regulations to give more prominence to calories on the food label; or 2) rely on industry to voluntarily give more prominence to ''calories'' on the food label.

Anticipated Cost and Benefits:

If rulemaking results from this ANPRM, the rule would generate costs because it would require firms to reformulate food labels. Benefits of any rulemaking resulting from this ANPRM, depends on how consumers and producers respond to any changes in calorie labeling.

Risks:

Attention to caloric intake is a key element of weight control since weight loss and weight management are dependent on caloric balance. Increasing the prominence of caloric information on food labels is one way to provide consumers with information about their caloric intake.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0910–AF22

HHS—FDA

42. FOOD LABELING; SERVING SIZES OF PRODUCTS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION; UPDATING OF REFERENCE AMOUNTS CUSTOMARILY CONSUMED; APPROACHES FOR RECOMMENDING SMALLER PORTION SIZES

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

21 USC 321; 21 USC 343; 21 USC 371

CFR Citation:

21 CFR 101.9(b); 21 CFR 101.12

Legal Deadline:

None

Abstract:

In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM will request comments on changes to the agency's nutrition labeling regulations on serving size and comments on allowance of truthful, nonmisleading, and useful approaches for promoting consumption of smaller portion sizes.

Statement of Need:

The Nation is currently facing a major long-term public health crisis. This trend toward overweight and obesity has accelerated during the past decade and is well documented by numerous scientific analyses. In 1999-2000, 64 percent of U.S. adults were overweight, increased from 56 percent when surveyed in 1988-1994; 30 percent of adults were obese, increased from 23 percent in the earlier survey. Among children age 6 through 19 years, 15 percent were overweight, compared with 10 percent to 11 percent in the earlier survey. Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers. The total economic cost of obesity in the United States is up to $117 billion per year, including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures. Fundamentally, overweight and obesity represents an imbalance between

energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity).

Summary of Legal Basis:

Section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 USC 343 (q)(1)(A)(i)) provides that certain foods under FDA's jurisdiction bear nutrition information based on a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure appropriate to the food. This ANPRM is soliciting recommendations on ways to amend certain provisions of its nutrition labeling regulations concerning serving size

Alternatives:

Possible alternatives to this advance notice of proposed rulemaking are: (1) do not amend certain serving size provisions of the nutrition labeling regulations, particularly on packaged products that can be readily consumed at one eating occasion, but that indicate they represent more than one serving; or (2) rely on industry to voluntarily revise their labels to clarify that, particularly for packaged products that can be readily consumed at one eating occasion, that there is more than one serving in the package.

Anticipated Cost and Benefits:

If rulemaking results from this ANPRM, the rule would generate costs because it would require firms to relabel some food products, in addition to potential reformulation and testing costs. Benefits of any rulemaking resulting from this ANPRM, depends on how consumers and producers respond to any changes in labeling serving sizes or portion sizes.

Risks:

Attention to serving size is a key element of weight control since weight loss and weight management are dependent on the amount of food consumed at one eating occasion. Clarifying how serving size is presented on food labels is one way to provide consumers with information about their caloric intake.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0910–AF23

HHS—FDA

PROPOSED RULE STAGE

43. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, CERTAIN BIOLOGICAL DRUGS, AND ANIMAL DRUGS

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271

CFR Citation:

21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514; 21 CFR 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271

Legal Deadline:

None

Abstract:

The proposed rule would reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. The proposed rule would require that this information be submitted via the Internet into the FDA registration and listing database, instead of the current requirement to submit the information to FDA on paper forms. The proposed rule would also require that the NDC number appear on drug labels. In addition, FDA would assign the NDC number to newly listed drugs and take other steps to minimize the use of inaccurate NDC numbers on drug labels.

Statement of Need:

FDA relies on establishment registration and drug listing for administering its postmarketing surveillance programs, such as identifying firms that manufacture a specific product or ingredient when that product or ingredient is in short supply or needed for a national emergency, for example, during a bioterrorism threat. FDA also uses registration and listing information for administering other programs such as assessing user fees. FDA is taking this action to improve its establishment registration and drug listing system and to utilize the latest technology in the collection of this information. In addition, improving the accuracy of and requiring NDC numbers on drug labels would help promote the Department's bar code, medication errors, and electronic prescribing initiatives.

Summary of Legal Basis:

The agency has broad authority under sections 301(p), 502(o), 510, and 701(a) of the act and sections 351 and 361 of the Public Health Service Act (PHS Act) to regulate certain establishments with respect to their submission of registration and listing information. Failure to register in accordance with section 510 of the act is a prohibited act under section 301(p) of the act. Failure to comply with section 510 of the act renders drugs misbranded under section 502(o) of the act.

Alternatives:

The alternatives to this rulemaking include not updating the registration and listing regulations and not requiring the electronic submission of registration and listing information. FDA originally published the registration regulations in 1963 and the listing regulations in 1973. The registration and listing paper forms that are currently mailed to FDA have been in use since that time. For the reasons stated above, and as a result of the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative.

Anticipated Cost and Benefits:

FDA estimates that the costs to industry resulting from the proposed rule would include annually recurring and one-time costs. The recurring costs would include, among other things, measures taken by registrants to protect the integrity of FDA's registration and listing database (such as the use of a unique electronic identifier). The one-time costs would include, among other things, additional time required to enter registration and listing data into FDA's database. In addition, certain registrants would need to convert their labeling to an electronically searchable format the first time they electronically list these products. The specific cost to FDA of developing, administering, and maintaining the Electronic Drug Registration and Listing System (EDRLS) is being calculated. EDRLS will not be ready for use until the rule is finalized.

FDA believes that electronic registration and listing will be less costly to industry in the long run than the current requirements. The proposed rule would require less establishment and product information from many registrants and savings would result from not having to process paper copies of the registration and listing forms. The electronic registration and listing process would also enable registrants to receive on-screen feedback if the information submitted is not complete, reducing errors and the time and cost of communicating back and forth with FDA. Information search and retrieval time will also be reduced for FDA, allowing for quicker agency response time.

The proposal would make the regulations more user-friendly and would make the registration and listing process easier by incorporating the use of the Internet to submit all information. The proposal would improve the ability to identify and catalogue marketed drugs by helping to eliminate inaccurate NDC numbers on drug labels.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

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RIN: 0910–AA49

HHS—FDA

44. • SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 321; 21 USC 342; 21 USC 343; 21 USC 349; 21 USC 371

CFR Citation:

21 CFR 589.2001

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE which resulted in this rulemaking.

Statement of Need:

In December 2003, the U.S. Department of Agriculture (USDA) announced a positive case of BSE in a dairy cow in Washington State. Subsequent epidemiological investigations confirmed that the infected cow was born and most likely became infected in Alberta, Canada, prior to Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants. This case followed the identification of BSE in a single cow in Alberta, Canada, in May 2003.

In response to the identification of these BSE cases in North America, FDA is proposing to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. This measure will further strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle.

BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSEs). TSE's are fatal, progressively degenerative central nervous system diseases of man and other animals. TSE's include, among other diseases, BSE in cattle, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease (CJD) in humans. There is no known treatment for these diseases, and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for BSE that can be used to test for the disease in live animals.

In the Federal Register of July 14, 2004 (69 FR 42288), FDA and USDA jointly published an advance notice of proposed rulemaking (ANPRM) to inform the public about the recommendations made by a team of international BSE experts (IRT) convened by the Secretary of Agriculture in January 2004 and to request comments on a number of issues related to possible regulatory measures. Among other recommendations, the IRT recommended that: 1) all specified risk materials (SRMs) be excluded from all animal feed including pet food; 2) cross contamination be prevented throughout thfeed chain; and 3) the use of all mammalian and poultry protein in ruminant feed be prohibited. FDA intends to consider all information received in response to the ANPRM prior to making a determination as to what measures are needed to further strengthen animal feed safeguards.

Summary of Legal Basis:

The agency is proposing these regulations under sections 402 and 701 of the Federal Food, Drug, and Cosmetics Act.

Alternatives:

FDA has considered four other measures that are not included in the proposed rule. These measures include: 1) a requirement that those facilities handling both prohibited materials and ruminant feeds use dedicated facilities or equipment for each; 2) a ban on the

use of poultry litter in ruminant feeds; 3) a ban on the use of blood and blood products in ruminant feeds; and 4) a ban on the use of what is commonly referred to as plate waste in ruminant feeds.

Anticipated Cost and Benefits:

The proposed regulation may be expected to require the expenditure of over $100 million in any one year by the private sector and may have a significant impact on a substantial number of small entities. The estimated total annualized costs of the rule are the sum of the costs of prohibiting the list of cattle origin materials identified in the proposed rule.

The benefit of the proposed rule includes the elimination of much of the remaining risk of spreading BSE in U.S. cattle. Assuming the hypothetical import of five infected cattle, FDA believes that the proposed rule would effectively remove about 95 percent of the remaining risk of human exposure to BSE infected material. The U.S. economy may also benefit from increased exports to the extent that the rule persuades foreign governments to import U.S. beef products. While we are unable to quantify these benefits, they are potentially large, given the significant loss of exports resulting from the discovery of an infected cow in Washington State.

Risks:

BSE is an incurable disease that can affect cattle and certain other mammals that ingest infective material from BSE infected cattle. In 1996, a newly recognized form of the human disease, Creutzfeldt-Jakob disease (CJD), referred to as variant CJD (vCJD), was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the agent that causes BSE. The discovery of a BSE positive dairy cow in Washington State in December 2003, caused the Agency to review its policies for the prevention of the spread of BSE within the United States. The need for regulatory action in this case is related to the inability of the market and existing regulations to ensure that the risk of BSE exposure through animal feed is minimized to the extent possible, given that BSE could potentially have an enormous adverse impact on both animal and human health.

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AF46

HHS—FDA

45. • USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN AND ANIMAL MEDICAL PRODUCTS

Priority:

Other Significant

Legal Authority:

Not Yet Determined

CFR Citation:

21 CFR 116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500; 21 CFR 600.16; 21 CFR 895; 21 CFR 1271.465; 21 CFR 1271.470

Legal Deadline:

None

Abstract:

The regulation would prohibit the use of certain cattle material in the manufacture of human medical products and animal drugs. The rule would prohibit the same cattle material that is prohibited in the previous FDA IFR that applies to foods and cosmetics. These include certain high risk tissues (e.g., brain, skull, eyes, spinal cord, trigeminal ganglia, parts of the vertebral column, and dorsal root ganglia) from cattle 30 months and older, tonsils and the distal ileum as well as the rest of the small intestine of cattle of any age, mechanically separated beef, material from nonambulatory disabled cattle, and material from cattle not inspected and passed for human consumption. The prohibitions would apply only to materials derived from animals slaughtered after the effective dates of the rules.

Statement of Need:

FDA is taking this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

Summary of Legal Basis:

Undetermined.

Alternatives:

There were several alternatives considered to the rule. These same alternatives, plus any new ones presented in comments, will be considered for the final.

- No new regulation.
- Prohibit the use of prohibited cattle materials in human medical products and animal drugs and require access to existing records relevant to determine compliance.
- Prohibit the use of prohibited cattle materials in human medical products and animal drugs and require establishment, maintenance, and access to records demonstrating that prohibited cattle materials are not used in human food and cosmetics.

Anticipated Cost and Benefits:

FDA expects minimal costs of compliance as this rule reflects current practices of most affected manufacturers. The costs of this rule are the costs to industry of assuring that prohibited materials are not used in the manufacture of medical products. By reducing exposure to potentially infective materials, this rule will provide an additional safeguard against a case of vCJD occurring in humans if cattle infected with BSE are used in the manufacture or processing of medical products.

Risks:

The benefits of the rule will be the value of the public and health benefits.

The public and animal health benefit is the reduction in the risk of the human and ruminant illness associated with exposure to the agent that causes BSE.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0910–AF54

HHS—FDA

46. • REQUIREMENTS FOR HUMAN AND ANIMAL MEDICAL PRODUCTS MANUFACTURED FROM, PROCESSED WITH, OR OTHERWISE CONTAINING MATERIAL FROM CATTLE

Priority:

Other Significant

Legal Authority:

Not Yet Determined

CFR Citation:

21 CFR 116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500; 21 CFR 600.16; 21 CFR 895; 21 CFR 1271.465; 21 CFR 1271.470

Legal Deadline:

None

Abstract:

This is a companion rulemaking to FDA's rule entitled ''Use of Materials Derived From Cattle in Human and Animal Medical Products,'' to be published in the same issue of the Federal Register. The rule would propose recordkeeping requirements for human and animal medical products that contain cattle material. Manufacturers and sponsors of such products would have to establish and maintain records to demonstrate that prohibited materials were not used in their manufacture.

Statement of Need:

FDA is proposing recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human medical products and animal drugs that contain or are manufactured with cattle material to ensure that these products do not contain prohibited cattle materials. Prohibited cattle materials are materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

FDA is proposing additional restrictions for higher risk human medical products and for ruminant drugs to address the greater disease risk posed by these products should they contain any infectious material from a BSE-positive animal.

Summary of Legal Basis:

Undetermined.

Alternatives:

Alternatives were not specifically considered in the proposed rule with regard to recordkeeping requirements because it was a companion rulemaking to the interim final rule prohibiting the use of certain cattle material in human medical products and animal drugs. Recordkeeping alternatives were considered in the interim final rule. Those same alternatives, plus any new ones presented in comments, will be considered for the final rule.

There were several alternatives considered to the proposed additional restrictions. These same alternatives, plus any new ones presented in comments, will be considered for the final.

- No additional restrictions.
- Prohibit the use in higher risk human medical products of listed neural tissues from cattle 12 months and older and all cattle material from countries listed by APHIS as having unacceptable risk or incidence of BSE, and prohibit the use in ruminant drugs of those materials that are prohibited in ruminant feed.

Anticipated Cost and Benefits:

FDA believes this rule reflects current practices of most affected manufacturers. The costs of this rule are the costs to industry of assuring that prohibited materials are not used in the manufacture of medical products and of conforming with additional restrictions on the use of cattle material in certain medical products (implantable, etc.). In addition, affected manufacturers will incur costs associated with establishing and maintaining records to demonstrate compliance. By reducing exposure to potentially infective materials, this rule will provide an additional safeguard against a case of vCJD occurring in humans if cattle infected with BSE are used in the manufacture or processing of medical products.

Risks:

The benefits of finalizing the proposed rule with respect to its recordkeeping requirements are derived from the benefits of the interim final rule, which are the value of the public and animal health benefits. The benefits of finalizing the proposed rule with respect to its additional requirements are also the value of the public and animal health benefits. The public and animal health benefit is the reduction in the risk of the human or animal illness associated with exposure to the agent that causes BSE.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Federalism:

Undetermined

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HHS—FDA

FINAL RULE STAGE

47. REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation:

21 CFR 201

Legal Deadline:

None

Abstract:

This regulation is one component of the Secretary's initiative to reduce medical errors. The regulation would amend the regulations governing the format and content of professional labeling for human prescription drugs (including biological products that are regulated as drugs), 21 CFR 201.56 and 201.57. The regulation would require that such labeling include a section containing highlights of prescribing information, and a section containing a table of contents of prescribing information; reorder currently required information and make minor changes to its content, and establish minimum graphical requirements.

Statement of Need:

The current format and content requirements in sections 201.56 and 201.57 were established in 1979 to help ensure that labeling includes adequate information to enable health care practitioners to prescribe drugs safely and effectively. However, various developments in recent years, such as increasing product liability and technological advances in drug product development, have contributed to an increase in the amount, detail, and complexity of labeling information. This has made it harder for practitioners to find specific information and to discern the most critical information in labeling.

FDA took numerous steps to evaluate the usefulness of labeling for practitioners and to determine whether, and how, its format and content can be improved. The agency conducted focus groups and a national survey of office-based physicians to ascertain how labeling is used by health care practitioners, what labeling information is most important to practitioners, and how labeling should be revised to improve its usefulness to practitioners.

Based on the concerns cited by practitioners in the focus groups and physician survey, FDA developed and tested two prototypes of revised labeling formats designed to facilitate access to important labeling information. Based on this testing, FDA developed a third revised prototype that it made available to the public for comment. Ten written comments were received on the prototype. FDA also presented the revised prototype at an informal public meeting held on October 30, 1995. At the public meeting, the agency also presented the background research and provided a forum for oral feedback from invited panelists and members of the audience. The panelists generally supported the prototype.

The proposed rule, published in 2000, described format and content requirements for prescription drug labeling that incorporate information and ideas gathered during this process. The agency has received several comments on the proposal and the comment period was extended until June 22, 2001.

Summary of Legal Basis:

The agency has broad authority under sections 201, 301, 501, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321, 331, 351, 352, 353, 355, and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262) to help ensure that prescription drugs (including biological products that are regulated as drugs) are safe and effective for their intended uses. A major part of FDA's efforts regarding the safe and effective use of drug products involves FDA's review, approval, and monitoring of drug labeling. Under section 502(f)(1) of the Act, a drug is misbranded unless its labeling bears ''adequate directions for use'' or it is exempted from this requirement by regulation. Under section 201.100 (21 CFR 201.100), a prescription drug is exempted from the requirement in section 502(f)(1) of the Act only if, among other things, it contains the information required, in the format specified, by sections 201.56 and 201.57.

Under section 502(a) of the Act, a drug product is misbranded if its labeling is false or misleading in any particular. Under section 505(d) and 505(e) of the Act, FDA must refuse to approve an application and may withdraw the approval of an application if the labeling for the drug is false or misleading in any particular. Section 201(n) of the Act provides that in determining whether the labeling of a drug is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences which may result from use of the drug product under the conditions of use prescribed in the labeling or under customary usual conditions of use.

These statutory provisions, combined with section 701(a) of the Act and section 351 of the Public Health Service Act, clearly authorize FDA to promulgate a final regulation designed to help ensure that practitioners prescribing drugs (including biological products) will receive information essential to their safe and effective use in a format that makes the information easier to access, read, and use.

Alternatives:

The alternatives to the final rule include not amending the content and format requirements in sections 201.56 and 201.57 at all, or amending them to a lesser extent. The agency has determined that although drug product labeling, as currently designed, is useful to physicians, many find it difficult to locate specific information in labeling, and some of the most frequently consulted and most important information is obscured by other information. In addition, the agency's research showed that physicians strongly support the concept of including a highlights section of the most important prescribing information, a table of contents and numbering system that permits specific

information to be easily located, and other requirements, such as the requirement for a minimum type size. Thus, the agency believes that the requirements in the final rule will greatly facilitate health care practitioners' access and use of prescription drug and biological product labeling information.

Anticipated Cost and Benefits:

The purpose of this rule is to make it easier for health care practitioners to access, read and use information in prescription drug labeling, thereby increasing the extent to which they rely on labeling to obtain information. FDA believes the revisions to the content and format of labeling will enhance the safe and effective use of prescription drug products, and in turn, reduce the number of adverse reactions resulting from medication errors due to misunderstood or wrongly applied drug information. The new requirements are important to the success of other initiatives aimed at improving patient care and decreasing the likelihood of medication errors. For example, revised labeling will facilitate initiatives to process, review and archive labeling electronically and provide a mechanism to facilitate the development of electronic prescribing systems.

The potential costs associated with the final rule include the cost of redesigning labeling for previously approved products to which the proposed rule would apply and submitting the new labeling to FDA for approval. In addition, one-time and ongoing incremental costs would be associated with printing the longer labeling that would result from additional required sections. These costs would be minimized by applying the amended requirements only to newer products and by staggering the implementation date for previously approved products.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/22/00	65 FR 81082
NPRM Comment Period End	03/22/01	
NPRM Comment Period Reopened	03/30/01	
NPRM Comment Period Reopening End	06/22/01	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AA94

HHS—FDA

48. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

CFR Citation:

21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 320; 21 CFR 600; 21 CFR 601; 21 CFR 606

Legal Deadline:

None

Abstract:

This regulation is one component of the Secretary's initiative to reduce medical errors. The final rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Statement of Need:

FDA currently has safety reporting requirements in section 21 CFR 312.32 for sponsors of investigational drugs for human use. FDA also has safety reporting requirements in sections 21 CFR 310.305, 314.80, 314.98 and 600.80 and 600.81 for applicants, manufacturers, packers, and distributors of approved human drug and biological products. FDA has undertaken a major effort to clarify and revise these regulations to improve the management of risks associated with the use of these products. For this purpose, the agency is proposing to implement certain definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to provide more effective and efficient safety reporting to regulatory authorities worldwide. Currently, the United States, European Union, and Japan require submission of safety information for marketed drug and biological products using different reporting formats and different reporting intervals.

Summary of Legal Basis:

The agency has broad authority under sections 505 and 701 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262) to monitor the safety of drug and biological products for human use.

Alternatives:

The alternatives to the proposal include not amending our existing safety reporting requirements. This alternative would be inconsistent with FDA's efforts to harmonize its safety reporting requirements with international initiatives and with its mission to protect public health.

Anticipated Cost and Benefits:

Manufacturers of human drug and biological products currently have limited incentives to invest capital and resources in standardized global safety reporting systems because individual firms acting alone cannot attain the economic gains of harmonization. This final rule would harmonize FDA's

safety reporting requirements with certain international initiatives, thereby providing the incentive for manufacturers to modify their safety reporting systems. Initial investments made by manufacturers to comply with the rule are likely to ultimately result in substantial savings to them over time.

The impact on industry includes costs associated with revised safety reporting and recordkeeping requirements. The benefits of the proposed rule are public health benefits and savings to the affected industries. The expected public health benefits would result from the improved timeliness and quality of the safety reports and analyses, making it possible for health care practitioners and consumers to expedite corrective actions and make more informed decisions about treatments. Savings to the affected industry would accrue from more efficient allocation of resources resulting from international harmonization of the safety reporting requirements.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Comment Review End	04/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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HHS—FDA

49. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE–BASED PRODUCT ESTABLISHMENTS; INSPECTION AND ENFORCEMENT

Priority:

Other Significant

Legal Authority:

42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation:

21 CFR 16; 21 CFR 1270; 21 CFR 1271

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program. FDA is also issuing regulations pertaining to labeling, reporting, inspections, and enforcement.

Statement of Need:

Donor screening and testing, although crucial, are not sufficient to prevent the transmission of disease through HCT/Ps. Each step in the manufacturing process needs to be controlled. Errors in labeling and testing records, failure to adequately clean work areas, and faulty packaging are examples of improper practices that could lead to a product capable of transmitting disease to a recipient. The agency is concerned about the spread of communicable disease through the use of such products. CGTP requirements are a fundamental component of FDA's risk-based approach to regulating HCT/Ps.

Summary of Legal Basis:

The Public Health Service Act (42 U.S.C. 264) authorizes FDA to promulgate regulations to prevent the spread of communicable diseases. HCT/Ps may transmit communicable diseases. The CGTP regulations are essential to the prevention of communicable disease transmission.

Alternatives:

An alternative to the proposed approach would be to continue with the use of voluntary industry standards. Reliance on industry's voluntary standards for good tissue practice, rather than establishing regulatory requirements, would not ensure uniform or consistent compliance and would preclude the agency's ability to effectively monitor HCT/Ps to ensure public health and safety.

Anticipated Cost and Benefits:

FDA has estimated that this rule would impose a total annualized cost of about $8 million for the entire industry. The primary beneficiaries of the proposed CGTP would be the patients who receive HCT/Ps. Benefits to patients would result from the reduced risk of communicable disease by avoiding product contamination through CGTP.

Risks:

FDA believes that the risks posed by requiring CGTP are minimal. In contrast, failure to reduce the risk of transmission of communicable disease through the use of HCT/Ps would jeopardize the public health.

Timetable:

Action	Date	FR Cite
NPRM	01/08/01	66 FR 1508
NPRM Comment Period End	05/08/01	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

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RIN: 0910–AB28

HHS—FDA

50. CGMPS FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION (LOOKBACK)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 21 USC 372; 21 USC 372; 21 USC 381; 42 USC 263

CFR Citation:

21 CFR 606; 21 CFR 610

Legal Deadline:

None

Abstract:

This rulemaking is one of a number of actions being taken to amend the biologics regulations to remove, revise, or update the regulations applicable to blood, blood components, and blood derivatives. These actions are based on FDA's comprehensive review of the biologics regulations and on reports by the U.S. House of Representatives Committee on Government Reform and Oversight's, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. In this rulemaking, FDA will amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested reactive for evidence of HCV. The HIV lookback regulations will be amended for consistency.

Statement of Need:

In the Federal Register of June 22, 1999 (64 FR 33309), FDA announced the availability of guidance, which updated previous guidance, providing recommendations for donor screening and further testing for antibodies to HCV, notification of consignees, transfusion recipient tracing and notification, and counseling by physicians regarding transfusion with blood components at increased risk for transmitting HCV (these activities are often called ''lookback''). FDA believes that regulations should be established consistent with the recommendations, to assure that there is clear enforcement authority in case deficiencies in an establishment's lookback program are found and to provide clear instructions for continuing lookback activities.

Summary of Legal Basis:

The Public Health Service Act (42 U.S.C. 201 et seq.) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) authorize FDA to regulate biological products and to ensure that the products are safe, pure, potent, and effective. The Public Health Service Act also contains authority under which FDA can promulgate regulations to prevent the spread of communicable diseases. This rulemaking would assure that appropriate action is taken when blood has been collected which may potentially be capable of transmitting HCV; that persons who have been transfused with such blood components are notified so that they receive proper counseling and treatment; and that infected donors are notified. These regulations will therefore help prevent the further transmission of HCV.

Alternatives:

FDA has considered permitting continued voluntary compliance with the recommendations that have already been issued. However, lookback will remain appropriate for the foreseeable future, and FDA believes that the procedures should be clearly established in the regulations.

Anticipated Cost and Benefits:

FDA is in the process of analyzing the costs related to the rulemaking. Monetary burdens will be associated with the tracing of previous donations of donors, quarantining in-date products, identifying the recipients of previous blood donations, and notifying these recipients, as appropriate. FDA believes that these costs will be more than balanced by the public health benefits, including benefits related to the notification of past transfusion recipients who may be unaware that they may be infected with HCV.

Risks:

FDA believes that there are minimum risks posed by requiring that appropriate lookback procedures for HCV be prepared and followed.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69377
NPRM Comment Period End	02/14/01	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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Related RIN: Related to 0910–AB26

RIN: 0910–AB76

HHS—FDA

51. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

CFR Citation:

21 CFR 111

Legal Deadline:

None

Abstract:

The Food and Drug Administration proposed in the Federal Register of March 13, 2003 (68 FR 12158), current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, or holding dietary ingredients of dietary supplements, they do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. FDA also proposed to require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding, e.g., which have the identity and provide the quantity of dietary ingredients declared in labeling.

Statement of Need:

FDA intends to publish a final rule to establish CGMP for dietary supplements and dietary ingredients for several reasons. First, FDA is concerned that some firms may not be taking appropriate steps during the manufacture of dietary supplements and dietary ingredients to ensure that products are not adulterated as a result of manufacturing, packing, or holding. There have been cases of misidentified ingredients harming consumers using dietary supplements. FDA is also aware of products that contain potentially harmful contaminants because of apparently inadequate manufacturing controls and quality control procedures. The agency believes that a system of CGMPs is the most effective and efficient way to ensure that these products will not be adulterated during manufacturing, packing, or holding.

Summary of Legal Basis:

If CGMP regulations were adopted by FDA, failure to manufacture, pack, or hold dietary supplements or dietary ingredients under CGMP regulations would render the dietary supplement or dietary ingredients adulterated under section 402(g) of the Act.

Alternatives:

The two principal alternatives to comprehensive CGMPs are end product testing and Hazard Analysis Critical Control Points (HACCP). The agency asked whether different approaches may be better able to address the needs of the broad spectrum of firms that conduct one or more distinct operations, such as the manufacture of finished products, or solely the distribution and sale of finished products at the wholesale or retail level.

Anticipated Cost and Benefits:

The costs of the regulation will include the value of resources devoted to increased sanitation, process monitoring and controls, testing, and written records. The benefits of the proposed regulation are to improve both product safety and quality. We estimate that the proposed regulation will reduce the number of sporadic human illnesses and rare catastrophic illnesses from contaminated products. The current quality of these products is highly variable, and consumers lack information about the potential hazards and variable quality of these products. The product quality benefits occur because there will be fewer product recalls and more uniform products will reduce consumer search for preferred quality products. The proposed rule will have a significant impact on a substantial number of small businesses, so it will be significant under the Regulatory Flexibility Act. We anticipate that small businesses will bear a proportionately larger cost than large businesses.

Risks:

Any potential for consumers to be provided adulterated (e.g., contaminated with industrial chemicals, pesticides, microbial pathogens, or dangerous misidentified ingredients or toxic components of ingredients) products must be considered a very serious risk because of the possibility that such contamination could be widespread, affecting whole segments of the population, causing some severe long-term effects and even loss of life. Dietary supplements are used by a large segment of the American public. Moreover, they are often used by segments of the population that are particularly vulnerable to adulterated products, such as the elderly, young children, pregnant and nursing women, and persons who may have serious illnesses or are taking medications that may adversely interact with dietary supplements. FDA has adopted or proposed manufacturing controls for a number of foods and commodities that present potential health hazards to consumers if not processed properly, including seafood, juice products, and fruits and vegetables, and it is appropriate that FDA consider whether manufacturing controls are necessary to assure consumers that dietary supplements are not adulterated during the manufacturing, packing, or holding process.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0910–AB88

HHS—FDA

52. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; . . .

CFR Citation:

21 CFR 16; 21 CFR 116; 21 CFR 118

Legal Deadline:

None

Abstract:

In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of salmonella enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010.

The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

In accordance with discussions at the public meetings, FDA intends to publish a proposed rule to require that shell eggs be produced under a plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

FDA intends to discuss in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at certain retail establishments. In addition, the agency plans to consider whether it should require provisions for certain retail establishments that serve populations most at risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

Statement of Need:

FDA is proposing regulations as part of the farm-to-table safety system for eggs outlined by the President's Council on Food Safety in its Egg Safety Action Plan. FDA intends to propose these regulations because of the continued reports of outbreaks of foodborne illness and death caused by SE that are associated with the consumption of shell eggs. The agency believes these regulations can have significant effect in reducing the risk of illness from SE-contaminated eggs and will contribute significantly to the interim public health goal of the Egg Safety Action Plan of a 50 percent reduction in egg-related SE illness by 2005.

Summary of Legal Basis:

FDA's legal basis for the proposed rule derives in part from sections 402(a)(4), and 701(a) of the Federal Food, Drug and Cosmetic Act (the Act) ((21 U.S.C. 342(a)(4) and 371(a)). Under section 402(a)(4) of the Act, a food is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the Act, FDA is authorized to issue regulations for the efficient enforcement of the Act. FDA also intends to rely on section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Scientific reports in published literature and data gathered from existing voluntary egg quality assurance programs indicate that measures designed to prevent SE from entering a poultry house (e.g., rodent/pest control, use of chicks from SE-monitored breeders, and biosecurity programs) can be very effective in reducing SE-contamination of eggs and related foodborne illness.

Alternatives:

There are several alternatives that the agency intends to consider in the proposed rule. The principal alternatives include: (1) no new regulatory action; (2) alternative testing requirements; (3) alternative on-farm prevention measures; (4) alternative retail requirements; and (5) HACCP.

Anticipated Cost and Benefits:

The benefits from the proposed regulation to control Salmonella Enteritidis in shell eggs on the farm derive from better farming practices. Improved practices reduce contamination and generate benefits measured as the value of the human illnesses prevented. FDA has produced preliminary estimates of costs and benefits for a number of options. The mitigations considered include on-farm rodent control, changes in retail food preparation practices, diversion of eggs from infected flocks to pasteurization, record keeping, refrigeration, and feed testing. The actual costs and benefits of the proposed rule will depend upon the set of mitigations chosen and the set of entities covered by the proposed rule.

Risks:

Any potential for contamination of eggs with SE and its subsequent survival or growth must be considered a very serious risk because of the possibility that such contamination, survival, and growth could cause widespread foodborne illness, including some severe long-term effects and even loss of life. FDA made a decision to publish a proposed rule that would include SE prevention measures, based on a considerable body of evidence, literature, and expertise in this area. In addition, this decision was also based on the USDA risk assessment on SE in shell eggs and egg products and the identified public health benefits associated with controlling SE in eggs at the farm and retail levels.

Timetable:

Action	Date	FR Cite
NPRM	09/22/04	69 FR 56824
Final Action	09/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 0910–AC14

HHS—FDA

53. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Priority:

Other Significant

Legal Authority:

21 USC 355b

CFR Citation:

21 CFR 201; 21 CFR 208; 21 CFR 209

Legal Deadline:

Final, Statutory, January 4, 2003.

Abstract:

To require the labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

Statement of Need:

Consumers may not be aware of FDA's adverse event reporting program under Medwatch. This requirement will promote FDA's mission to protect the public health by informing consumers of FDA's Medwatch system.

Summary of Legal Basis:

Section 17 of the Best Pharmaceuticals for Children Act (BPCA) requires a final rule to issue within one year of the date of its enactment on January 4, 2002.

Alternatives:

This rule is required by section 17 of the BPCA. FDA has considered alternatives within the scope of the statutory requirements, in particular, ways to reach the broadest consumer audience and to minimize costs to the pharmacy profession.

Anticipated Cost and Benefits:

Anticipated costs are to drug manufacturers and authorized dispensers of drug products, including pharmacies. The BPCA contains a provision requiring the Secretary to seek to minimize the cost to the pharmacy profession. Anticipated benefits are to obtain information about adverse events from consumers, which may inform FDA of trends in reported adverse events and result in a review of the safety and/or effectiveness of particular drug products on the market.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/22/04	69 FR 21778
NPRM Comment Period End	07/21/04	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

54. ESTABLISHMENT AND MAINTENANCE OF RECORDS PURSUANT TO THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

PL 107–188, sec 306

CFR Citation:

21 CFR 1

Legal Deadline:

None

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. The Act authorizes regulations that require the establishment and maintenance of records, for not longer than two years, that would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. Section 306 of the Act also added section 414(a) and amended section 704(a) of FFDCA to permit FDA to inspect these records and other information if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law on June 12, 2002. The regulations will implement section 306 of the Bioterrorism Act.

Summary of Legal Basis:

Section 306 of the Bioterrorism Act amended the FFDCA by adding section 414(b), which authorizes the Secretary to establish by regulation requirements for the creation and maintenance of records. That section of the Bioterrorism Act also added section 414(a) and amended section 704(a) of the FFDCA to permit FDA to inspect records and other information under certain circumstances. In addition, section 306 of the Bioterrorism Act also amends section 301 of the Federal Food, Drug, and Cosmetic Act by making the failure to establish or maintain any record required by the new regulations, or refusal to permit access to those records or other information as required by the new regulations, a prohibited act.

Alternatives:

None.

Anticipated Cost and Benefits:

The records provisions will be classified as significant under Executive Order 12866 (having an annual effect on the economy of over $100 million). The recordkeeping provisions would impose a substantial cost on industry. A first estimate is that the proposed provisions will cost the food industry approximately $235 million in the first year, approximately $510 million in the second year, and approximately $220 million every year there after.

The provisions will improve substantially FDA's ability to respond to outbreaks from deliberate and accidental contamination of food. FDA will use data collected by the Center for Disease Control and Prevention (CDC) and FDA on past outbreaks to estimate the benefit of improved documentation in standard tracing investigations. Of the 1,344 food-borne illness outbreaks CDC identified in 1999, only 368 (27 percent) had a confirmed etiology. A host of factors contribute to the inability to identify the cause of an outbreak, but many investigations are hampered by the lack of adequate records identifying the chain of custody of foods. While it is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring, FDA uses data collected by the agency on past outbreaks to estimate the benefit of the recordkeeping provisions on standard traceback investigations. Specifically, we estimate the number of illnesses averted from faster tracebacks and higher traceback completion rates that will result from improved recordkeeping practices.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism would advance the development, organization, and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the ability to address credible threats of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	05/09/03	68 FR 25188
NPRM Comment Period End	07/08/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

URL For More Information:

www.fda.gov/oc/bioterrorism/bioact.html

URL For Public Comments:

www.fda.gov/ohrms/dockets/02n0277/02n0277.htm

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RIN: 0910–AC39

HHS—FDA

55. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

PL 107–188, sec 305

CFR Citation:

21 CFR 1

Legal Deadline:

Final, Statutory, December 12, 2003.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 305, directs the Secretary, through FDA, to issue a final regulation establishing registration requirements by December 12, 2003. The statute is self-implementing on this date if FDA does not issue a final regulation that is effective by December 12, 2003.

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism and other foodborne illness emergencies. Section 415 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), directs the Secretary to require facilities engaged in manufacturing, processing, packing, or holding of food for consumption in the United States to be registered with the Secretary. Section 415 directs the Secretary to promulgate final regulations implementing the requirements by December 12, 2003. The owner, operator, or agent in charge of the facility must submit the registration. Foreign facilities must include the name of the United States agent for the facility. The registration must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. If the Secretary determines it is necessary through guidance, the registration must include the general food category (as identified under 21 CFR 170.3) of foods manufactured, processed, packed, or held at the facility. The registrant is required to notify the Secretary of changes to the information contained in the registration in a timely manner. Under the interim final rule (IFR) published on October 10, 2003 (68 FR 58894), upon receipt of the completed registration form, FDA will notify the registrant of receipt of the registration and assign a unique registration number to the facility. Section 415 requires the Secretary to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, ''facility'' includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from the registration requirement are farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the

consumer, and fishing vessels (except those engaged in processing as defined in 21 CFR 123.3(k)). Foreign facilities required to register include only those from which food is exported to the United States without further processing or packaging outside the United States. The Bioterrorism Act provides that if food from an unregistered foreign facility is offered for import into the United States, the food will be held at the port of entry or at a secure facility, until the foreign facility has registered. On April 14, 2004, FDA issued a notice reopening for 30 days, on a limited range of issues, the comment period on the IFR. FDA took this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in order to ensure that those commenting on the IFR had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the registration system.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was signed into law on June 12, 2002. This regulation is required by the Bioterrorism Act and is needed to implement the new statutory provision.

Summary of Legal Basis:

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) amends the FFDCA by adding section 415, which directs the Secretary to establish by regulation requirements for the registration of food and animal feed facilities. Section 305 amends section 301 of the FFDCA by making the failure to register in accordance with section 415 a prohibited act. Section 305 also amends section 801 of the FFDCA by requiring that food from an unregistered foreign facility that is offered for import into the United States be held at the port of entry or at a secure facility until the foreign facility has registered.

Alternatives:

None, based on clear statutory directive to establish the regulation.

Anticipated Cost and Benefits:

Costs: Requiring registration for domestic and foreign facilities that manufacture, process, pack, or hold food will create costs for facilities to register and for FDA to set up and administer a database of firms. Industry costs are primarily a function of the number of firms affected and the amount of labor needed to register those facilities. Foreign facilities are required to hire U.S. agents. FDA estimates that 216,721 domestic establishments and 205,405 foreign establishments covered by the statute and IFR will bear a cost of approximately $23 million and $306 million, respectively, in the first year. Annual costs will include new registration updates and fees for United States agents. For domestic facilities annual costs will be $6.9 million. For foreign facilities annual costs will be $228.8 million. FDA's costs will include labor hours, hardware, software, and mailing costs for creating and administering a database. The costs to the agency for setting up the database and registering the first year registrants are estimated to be $13.2 million. This includes four FDA FTEs, contractor development of the database, hardware, software, industry outreach, and a firewall. The costs for maintaining the database and adding new establishments are estimated to be $8 million in the second year. Total first year costs will be $342.2 million and second year costs will be $243.7 million. In the IFR, FDA requested comment on certain issues relating to the costs of the U.S. Agent requirement.

Benefits: These provisions will improve FDA's ability to respond to outbreaks from accidental and deliberate contamination of food and deter deliberate contamination. It is not possible to directly estimate the benefits of averting a terrorist attack, as FDA does not know the probability of an attack occurring or the reduction in risk resulting from registration. Instead, in order to estimate the benefits of averting foodborne emergencies, the IFR evaluates the costs of some severe foodborne illness outbreaks.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism will advance the development, organization, and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. This will improve the ability to address credible bioterrorist threats to food for humans or animals, and other food-related public health emergencies.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5377
Interim Final Rule	10/10/03	68 FR 58894
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19766
Interim Final Rule Comment Period Reopened End	05/14/04	
Final Rule	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

56. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 107–188, sec 307

CFR Citation:

21 CFR 1.276 et seq

Legal Deadline:

Final, Statutory, December 12, 2003.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notice requirements for all imported food by December 12, 2003. If FDA fails

to issue final regulations by this date, the statute is self-executing on this date, and requires FDA to receive prior notice of not less than eight hours, nor more than five days until final regulations are issued.

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. Section 801(m) requires notification to FDA prior to the entry of imported food. The required prior notice would provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law on June 12, 2002. The regulations implement section 307 of the Bioterrorism Act.

Summary of Legal Basis:

Section 307 of the Bioterrorism Act amended the FFDCA by adding section 801(m), which authorizes the Secretary through FDA to establish by regulation requirements for the notification to FDA prior to the entry of imported food. In addition, section 307 of the Bioterrorism Act also amends section 301 of the FFDCA by making the offering of a food for import or the importing of a food without prior notification, as required by the new regulations, a prohibited act.

Alternatives:

None, based on clear statutory directive to establish regulations.

Anticipated Cost and Benefits:

The prior notification provision is an economically significant regulatory action. For the calendar year 2002, there were approximately 5.2 million human and animal food line items imported into U.S. commerce by airplane, train, vessel, and truck.

This final rule will require that FDA be notified prior to the arrival of the food. This rule may cause changes in current business practices for some importers, most likely those persons importing fresh produce and seafood. Costs will include the costs of preparing the prior notice, and the costs associated with delayed entry of fresh produce and seafood.

FDA costs will include the labor hours, hardware, and software costs to develop a stand-alone technology system to handle prior notice entries.

Having prior notice of imported food will help deter deliberate and accidental contamination of food shipments. Knowledge of when, where, and how imported food will enter the United States will help mitigate the effects of any potential food contamination issues.

It is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring. However, we can look at some outbreaks attributed to imported foods to estimate the benefits of having prior notice.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism and other public health threats would advance the development, organization and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the FDA's ability to address bioterrorism events and public-health threats associated with imported food.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5428
Interim Final Rule	10/10/03	68 FR 58974
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19763
Interim Final Rule Comment Period Reopened End	07/13/04	
Final Rule	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—FDA

57. USE OF OZONE–DEPLETING SUBSTANCES: REMOVAL OF ESSENTIAL USE DESIGNATION; ALBUTEROL

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 402; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 343; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 42 USC 7671 et seq

CFR Citation:

21 CFR 2.125

Legal Deadline:

None

Abstract:

Under the Clean Air Act, the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services, in consultation with the

Environmental Protection Agency, is required to determine whether an FDA-regulated product that releases an ozone-depleting substance (ODS) is essential. The two agencies have tentatively determined that the two currently marketed non-ODS metered-dose inhalers (MDIs) will be satisfactory alternatives to albuterol MDIs that contain ODS, and have proposed to remove the essential use designations for albuterol MDIs. If the essential use designation is removed, albuterol MDIs that contain an ODS could not be marketed after a suitable transition period. The proposed rule specifically asked for comments on which phase-out period length will best ensure a smooth transition and minimize any adverse affects on the public health.

Statement of Need:

Chlorofluorocarbons (CFCs) are organic compounds that contain carbon, chlorine, and fluorine atoms. CFCs were first used commercially in the early 1930's and were later found to be useful as propellants in self-pressurized aerosol products, such as MDIs. CFCs are very stable in the troposphere—the lowest part of the atmosphere. They move to the stratosphere, a region that begins about 10-16 kilometers (km) (6-10 miles) above Earth's surface and extends up to about 50 km (31 miles) altitude. Within the stratosphere there is a zone about 15-40 km (10-25 miles) above the Earth's surfaces in which ozone is relatively highly concentrated. The zone in the stratosphere is generally called the ozone layer. Once in the stratosphere, CFCs are broken down by strong ultraviolet light, where they release chlorine atoms that then deplete stratospheric ozone. Depletion of stratospheric ozone by CFCs and other ODS will lead to higher UVB levels, which in turn will cause increased skin cancers and cataracts and potential damage to some marine organisms, plants, and plastics.

The link between CFCs and the depletion of stratospheric ozone was discovered in the mid-1970's. Since 1978, the U.S. government has pursued a consistent policy of limiting the production and use of ODS, including CFCs.

Summary of Legal Basis:

The Clean Air Act and EPA's implementing regulations contain general prohibitions on the use and manufacture of ODS, such as CFCs. Exceptions to these bans are provided for specific medical products that FDA, in consultation with EPA, has found to be essential. FDA's essential use determinations have been contained in 21 CFR section 2.125.

FDA published a new 21 CFR section 2.125 in the Federal Register on July 24, 2002 (67 FR 48370), (corrected in the Federal Registers of July 30, 2002 (67 FR 49396), and September 17, 2002 (67 FR 58678)). Section 2.125 provides criteria for determining when a use is essential and when a use is no longer essential. The procedures to determine when a use is no longer essential were implemented to better carry out responsibilities under both the Clean Air Act and the Montreal Protocol on Substances that Deplete the Ozone Layer, (September 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st sess., 26 I.L.M. 1541 (1987)).

Fran Du Melle, Executive Vice President of the American Lung Association, submitted a citizen petition on behalf of the U.S. Stakeholders Group on MDI Transition on January 29, 2003 (Docket No. 03P-0029/CP1). The petition requested that FDA initiate rulemaking to remove the essential use designation of albuterol MDIs. After evaluating the petition, comments submitted in response to the petition, and other information, FDA has tentatively determined that albuterol MDIs meet the criteria in section 2.125, and proposed a rule to remove other essential-use designations.

Alternatives:

In the proposed rule, FDA specifically requested comments on the best effective date for any final rule to remove the essential use status of albuterol MDIs. FDA is considering which dates will allow manufacturers to obtain the capacity to produce adequate numbers of non-ODS albuterol MDIs. FDA is also considering which dates might minimize any financial burden on patients who would have to switch to non-ODS albuterol MDIs.

Anticipated Cost and Benefits:

The expected benefit from this rulemaking, as part of an overall policy to eliminate production and use of ODSs, is the preservation of the Earth's stratospheric ozone.

Currently there are generic versions of ODS albuterol MDIs, while there are no generic non-ODS albuterol MDIs. This rulemaking could force patients to switch from lower-priced generic versions of ODS albuterol MDIs to higher-priced non-ODS albuterol MDIs.

Risks:

FDA is concerned about the possibility that some patients might stop using needed drugs because the prices of non-ODS albuterol MDIs might be higher than those of ODS albuterol MDIs.

Timetable:

Action	Date	FR Cite
NPRM	06/16/04	69 FR 33602
NPRM Comment Period End	08/16/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

58. • USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

Priority:

Other Significant

Legal Authority:

21 USC 342; 21 USC 361; 21 USC 371

CFR Citation:

21 CFR 189.5; 21 CFR 700.27

Legal Deadline:

None

Abstract:

On July 14, 2004, FDA issued an interim final rule, effective immediately, to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food,

including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. After reviewing comments received to the interim final rule, FDA will finalize the prohibitions on certain cattle material.

Statement of Need:

FDA is taking this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

Summary of Legal Basis:

FDA's legal basis for the IFR derived from the adulteration provisions in sections 402(a)(2)(C), 402(a)(3), 402(a)(4), 402(a)(5), 601(c), and under section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 342(a)(2)(C), 342(a)(3), 342(a)(4), 342(a)(5), 361(c), and 371(a)). Under section 402(a)(3) of the Act, a food is deemed adulterated ''if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' Because of the discovery of a BSE positive cow in the United States and the possibility of disease transmission to humans from exposure to material from infected cattle, BSE risk materials are unfit for food. Furthermore, some cattle are not inspected and passed because they have died before slaughter. Material from these cattle is adulterated under section 402(a)(5). The failure to ensure that food or cosmetics are prepared, packed, or held under conditions in which BSE risk materials do not contaminate the food or cosmetics constitutes an insanitary condition whereby the food or cosmetics may have been rendered injurious to health and thus renders the food or cosmetics adulterated under section 402(a)(4) or 601(c).

We are also relying on the food additive provision in section 402(a)(2)(C). Because neither a food additive regulation nor an exemption is an effect for BSE risk materials intended for use in human food, such materials, with the exception of dietary ingredients in dietary supplements, are adulterated under section 402(a)(2)(C) of the act and their presence in food renders the food adulterated. Finally, requiring measures to prevent food and cosmetics from being adulterated allows for efficient enforcement of the act under section 701(a). Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is BSE risk material. Therefore, the records access requirement is also necessary for the efficient enforcement of this rule.

Alternatives:

There were several alternatives considered to the interim final rule. These same alternatives, plus any new ones presented in comments, will be considered for the final.

- No new regulation.
- Prohibit the use of prohibited cattle materials in human food and cosmetics and require access to existing records relevant to determine compliance.
- Prohibit the use of prohibited cattle materials in human food and cosmetics and require establishment, maintenance, and access to records demonstrating that prohibited cattle materials are not used in human food and cosmetics.

Anticipated Cost and Benefits:

We expect the social cost of the final rule, which we approximate by multiplying the difference in ingredient prices by the preregulation quantity of ingredients, will be borne by producers and consumers of affected products. If demand is inelastic compared with supply, consumers will bear most of the social cost. If supply is inelastic compared with demand, producers will bear most of the social cost. The ready availability of alternatives for the prohibited ingredients, and the small number of products currently using them, implies that the social costs of this rule will likely be small for foods. The social costs for cosmetics will be greater. We estimate that the cost of ingredient switching for cosmetics will range from a lower bound of $0 to an upper bound of $18 million. The benefit of the final rule is that its requirements will-by reducing exposure to potentially infective materials-provide a safeguard against a case of vCJD occurring in humans if cattle infected with BSE enter the human food or cosmetic supply.

Risks:

The benefits of the final rule will be the value of the public health benefits. The public health benefit is the reduction in the risk of the human illness associated with consumption of the agent that causes BSE. The Harvard-Tuskegee risk assessment has stated that a ban on specified risk materials, including cattle brains, spinal cord and vertebral column, from inclusion in human and animal food would reduce the very few potential BSE cases in cattle by a further 88 percent and potential human exposure to infectivity in meat and meat products by a further 95 percent.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Comment Period End	10/12/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0910–AF47

HHS—FDA

59. ● RECORDKEEPING REQUIREMENTS FOR HUMAN FOOD AND COSMETICS MANUFACTURED FROM, PROCESSED WITH, OR OTHERWISE CONTAINING MATERIAL FROM CATTLE

Priority:

Other Significant

Legal Authority:

21 USC 342; 21 USC 361; 21 USC 371; 21 USC 381

CFR Citation:

21 CFR 189.5; 21 CFR 700.27

Legal Deadline:

None

Abstract:

On July 14, 2004, FDA proposed to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics.'' FDA intends to finalize this proposal after reviewing any comments received.

Statement of Need:

FDA proposed recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human food and cosmetics that contain cattle material to ensure that these products do not contain prohibited cattle materials. Prohibited cattle materials are materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

Summary of Legal Basis:

Because the rule is a companion rulemaking to the interim final rule prohibiting the use of certain cattle material in human food and cosmetics, we issued the proposed rule under the authorities cited in the interim final rule (21 U.S.C. sections 342(a)(2)(C), 342(a)(3), 342(a)(4), 342(a)(5), 361(c), and 371(a)) as well as sections 801(a) and 701(b) of the Federal Food, Drug, and Cosmetic Act (the Act). Without records documenting the absence of BSE risk materials in source materials, manufacturers and processors of human food and cosmetics cannot know whether they are adulterating their products by including BSE risk materials in their products. Therefore, a failure of manufacturers and processors to establish and maintain such records results in human food and cosmetics being prepared under unsanitary conditions whereby they may have been rendered injurious to health. Furthermore, without adequate records, FDA cannot know whether manufacturers and processors of human food and cosmetics have complied with the prohibitions against use of BSE risk materials. Therefore, the recordkeeping requirements are necessary for the efficient enforcement of the interim final rule.

We are also issuing the provisions of this proposed rule related to records regarding imported human food and cosmetics under sections 801(a) and 701(b) of the Act. Section 801(a) (21 U.S.C. 381(a)) provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) (21 U.S.C. 371(b)) authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801. This proposed rule sets out requirements for imported human food and cosmetics to ensure that only products that fully comply with the requirements of the interim final rule are admitted into the United States.

Alternatives:

Alternatives were not specifically considered in the proposed rule because it was a companion rulemaking to the interim final rule prohibiting the use of certain cattle material in human food and cosmetics. Recordkeeping alternatives were considered in the interim final rule. Those same alternatives, plus any new ones presented in comments, will be considered for the final rule.

Anticipated Cost and Benefits:

If the proposal is finalized, we expect that the costs will be to setup and then to maintain a recordkeeping system to document all cattle-derived ingredients, except tallow derivatives, used in FDA-regulated food and cosmetics. The setup costs are about $1 million, and the annual costs of maintaining the recordkeeping system are about $200,000. The benefit of the rule is that its requirements will—by requiring records that the provisions of the interim final rule have been followed—provide an additional safeguard against a case of vCJD occurring in humans.

Risks:

The benefits of finalizing the proposed rule are derived from the benefits of the interim final rule, which are the value of the public health benefits. The public health benefit is the reduction in the risk of the human illness associated with consumption of the agent that causes BSE. The Harvard-Tuskegee risk assessment has stated that a ban on specified risk materials, including cattle brains, spinal cord and vertebral column, from inclusion in human and animal food would reduce the very few potential BSE cases in cattle by a further 88 percent and potential human exposure to infectivity in meat and meat products by a further 95 percent.

Timetable:

Action	Date	FR Cite
NPRM	07/14/04	69 FR 42275
NPRM Comment Period End	08/13/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AF48

HHS—Centers for Medicare & Medicaid Services (CMS)

PROPOSED RULE STAGE

60. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P) (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

42 USC 1395rr

CFR Citation:

42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412; 42 CFR 488; 42 CFR 489; 42 CFR 494; 42 CFR 413; 42 CFR 414

Legal Deadline:

None

Abstract:

This proposed rule would revise the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

Statement of Need:

This proposed rule is a complete overhaul of the current ESRD conditions for coverage to reduce unnecessary process and procedural requirements and focus on the patient and the results and quality of the care furnished to the patient. The proposed conditions for ESRD facilities would include, among other things, new infection control guidelines; updated water quality standards; new fire safety standards; as well as patient assessment, care planning, quality improvement, and electronic data reporting provisions that reflect the current advances in dialysis technology and standard care practices. The ESRD conditions were last published in their entirety in 1976.

Summary of Legal Basis:

Section 1881 (42 U.S.C. 1395rr) of the Social Security Act (the Act) authorizes benefits for individuals who have been determined to have end stage renal disease as provided in section 226 (A). Section 1881(b) of the Act authorizes payments on behalf of such individuals to providers of services and renal dialysis facilities ''which meet requirements as the Secretary shall by regulation prescribe.'' ESRD conditions for coverage may be revised as needed under the Secretary's rulemaking authority in section 1881.

Alternatives:

Retain the current conditions. CMS has undertaken various quality improvement initiatives, e.g., the Dialysis Facility Compare Web site and the CMS Clinical Performance Measures Project that have improved beneficiaries' quality of care. These initiatives, however, lack the potential impact of an overall regulatory change.

Anticipated Cost and Benefits:

We anticipate a minimal cost for each dialysis facility in the initial year of implementation and in subsequent years. These costs are thought to be a small percent of dialysis facilities' expenses.

Risks:

Failure to update would result in outdated ESRD conditions for coverage that are over 26 years old and do not reflect current medical practices or scientific advances in the field.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

61. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–P)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh

CFR Citation:

42 CFR 482

Legal Deadline:

None

Abstract:

This proposed rule would establish conditions of participation for Medicare-covered transplants.

Statement of Need:

CMS is proposing new requirements for transplant centers to address several issues. First, although currently there are initial requirements hospitals must meet to become Medicare-approved to perform transplants, there are no requirements for reapproval. Thus, once a transplant center has received initial approval, CMS has no mechanism to remove the center's approval if its performance declines. Second, current outcome measures for initial approval are not risk adjusted and do not reflect the significant improvements in patient survival that have occurred in the years since the Medicare requirements were

put into place. Finally, current requirements for Medicare approval are difficult for transplant centers to locate and use, as they have been published in a variety of different documents, including the Federal Register, the Coverage Issues Manual, and Medicare Coverage Policy Decision Memoranda. Therefore, it is intended that the transplant requirements: (1) ensure that transplants are performed safely and effectively by establishing requirements for approval and re-approval and a process for oversight and enforcement activities; (2) establish risk-adjusted outcome measures that reflect improvements in patient and graft survival and ongoing changes in transplantation technology; and, (3) codify requirements for all transplant center types in one regulation.

Summary of Legal Basis:

The Medicare statute contains specific authority for prescribing the health and safety requirements for facilities to furnish ESRD care to beneficiaries, including renal transplant centers, under section 1181(b)(1) of the Social Security Act. Section 1102 of the Act authorizes the Secretary to publish rules and regulations ''necessary for the efficient administration of the functions with which the Secretary is charged under the Act.'' Section 1871 (a) of the Act authorizes the Secretary to ''prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.''

Alternatives:

CMS has considered various alternatives in developing outcome and process performance measures for transplant centers. CMS will propose requirements for initial and reapproval and will solicit public comments to identify additional alternatives.

Anticipated Cost and Benefits:

CMS estimates the economic impact of this rule to be $300,148 annually. While 867 transplant centers may be affected by the requirements in this proposed rule to a greater or lesser degree, the majority of the centers most likely have already put into practice the majority of the proposed process requirements. For the most part, the proposed requirements merely reflect advances in transplantation technology, as well as standard care practices. Furthermore, although the proposed rule would require a large amount of data to be submitted to the Organ Procurement and Transplantation Network (OPTN), transplant centers already submit these data to the OPTN.

In 2002, 12,795 donors (deceased and living) were recovered in the U.S. and 24,851 transplants (deceased and living donors) were performed; yet 80,792 patients were waiting for a transplant at the end of 2002. Given the scarcity of donated organs compared to the number of patients on waiting lists and the critical need to use limited resources efficiently, the proposed requirements for transplant centers would establish quality and procedural standards that ensure transplants are performed in a safe and effective manner both to protect transplant recipients and living donors and to improve graft survival, thus reducing the need for costly retransplantation following a failed original transplant.

Organ donation and transplantation is a priority for the Secretary as evidenced by the Secretary's Donation Initiative (Initiative); launch of the Initiative was one of the Secretary's first actions. The proposed rule will include requirements to guard against medical errors that endanger living donors and transplant recipients, including the transplantation of organs of the wrong blood type.

Risks:

Failure to publish the proposed requirements would result in the continued Medicare approval of transplant centers that may not perform organ transplants safely and effectively with the best possible outcomes for Medicare beneficiaries and other patients.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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HHS—CMS

62. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS–3844–P)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh

CFR Citation:

42 CFR 418

Legal Deadline:

None

Abstract:

This proposed rule is a regulatory reform initiative that would revise existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

Statement of Need:

This rule proposes to completely revise and reorganize the existing Conditions of Participation (CoPs) for Medicare participating hospice providers published in 1983. The proposed rule is a regulatory reform initiative that would revise the existing CoPs that hospices must meet to participate in

the Medicare and Medicaid programs. The proposed requirements focus on the care delivered to patients and patients' families by hospices and the outcomes of that care. The proposed requirements continue to reflect an interdisciplinary view of patient care and allow hospices flexibility in meeting quality standards. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of health care furnished through the Medicare and Medicaid programs. This proposed rule codifies hospice requirements in the Balanced Budget Act of 1997 and the Medicare Modernization Act of 2003, sections 408 and 946.

Summary of Legal Basis:

Section 1861(dd) of the Social Security Act (the Act) provides the statutory qualifications and requirements that a hospice must meet to receive payment for hospice care given to Medicare beneficiaries who elect the hospice benefit under the Medicare and Medicaid programs. This section gives the Secretary broad authority to establish standards for hospices. Under this authority, the Secretary established CoPs for hospices at 42 CFR 418, et seq.

In addition, section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which he is charged under the Act. This section of the Act gives the Secretary broad authority to establish requirements for hospices that are necessary for the efficient administration of the Medicare program.

Alternatives:

Rely on the current CoPs: This is not a reasonable option because the current CoPs are not patient-focused but rather problem-focused, an approach that has inherent limits. Trying to ensure quality through the enforcement of prescriptive health and safety standards, rather than trying to improve quality of care for all patients, adversely affects agency improvement efforts and does not stimulate broad-based quality of care initiatives. On the other hand, revising the current CoPs would take advantage of continuing advances in health care delivery.

Increase prescriptive requirements relative to patient rights, drugs and durable medical equipment, and personnel qualifications. CMS decided not to pursue this approach because the additional burden that would be placed on hospices would outweigh any potential benefits.

Exclude the revisions to the comprehensive assessment and interdisciplinary group requirements: Since these areas represent two of the most frequently cited deficiencies noted during hospice surveys and have a great impact on patient care, CMS decided that these sections did, in fact, need to be strengthened.

Anticipated Cost and Benefits:

While we anticipate a minimal annual cost per hospice to comply with the requirements in this rule, we expect a positive reaction from all affected entities including beneficiaries, associations, and providers. This rule is highly anticipated by the hospice industry since the standards have not been updated since 1990.

Risks:

Overall, this rule is a ''good news rule'' for which we expect a positive reaction from all affected entities including beneficiaries, associations, providers, and Congress. Beneficiaries—we expect that beneficiaries will be pleased with the strong focus on patient's rights, patient education, and patient safety throughout the proposed rule. Associations—the National Hospice and Palliative Care Organization and the National Association for Home Care have been requesting the promulgation of new regulations for several years and has actively worked with us in sharing information. Hospice providers—hospices may have mixed feelings about the proposed regulations. We are proposing to bring the regulations in line with current standards of practice and are proposing to substantially decrease provider burden in many areas of the proposed rule such as in nurse staffing and dietary counseling. However, we are also proposing to increase the focus on patient assessment, quality assessment, and performance improvement that may require an additional level of effort. We believe that the patient safety and quality care benefits should outweigh these concerns. In response to requests from hospice and nursing facility associations, we have clarified the relationship between hospices and nursing facilities through a proposed new condition. Nurse practitioners (NPs)—we are proposing to allow NPs to see, treat, and write orders for patients, as defined by the plan of care. Congress—we do not expect that these proposed regulations would be opposed in their overall approach to patient care.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Federalism:

Undetermined

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RIN: 0938–AH27

HHS—CMS

63. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–P)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Not Yet Determined

CFR Citation:

Not Yet Determined

Legal Deadline:

Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

Abstract:

This rule would establish conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from

Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from 2 years to 4 years and to promulgate new performance standards for OPOs.

Statement of Need:

As required by the Organ Procurement Organization Certification Act of 2000 and Section 219 of the Consolidated Appropriations Act, 2001, this proposed rule sets forth multiple new outcome and process performance measures for OPOs, as well as a new appeals process for OPOs to appeal a decertification based on substantive and procedural grounds.

Summary of Legal Basis:

Section 1138(b) of the Social Security Act (the Act) provides the statutory qualifications and requirements that an OPO must meet to receive payment for organ procurement costs associated with procuring organs for hospitals under the Medicare and Medicaid programs. This section gives the Secretary broad authority to establish performance-related standards for OPOs. Under this authority, the Secretary established conditions for coverage for OPOs at 42 CFR 486.301, et seq. Section 1138(b) of the Act specifies that an OPO must be certified or re-certified by the Secretary as meeting the standards to be a qualified OPO as described in section 371(b) of the Public Health Service (PHS) Act. The PHS Act requirements were established by the National Organ Transplant Act of 1984 and include provisions for OPO board membership, staffing, agreements with hospitals, and membership in the OPTN. The Organ Procurement Organization Certification Act of 2000 (42 U.S.C. section 273(b)(1)(D)) amended section 371(b) of the PHS Act to require CMS to promulgate multiple new outcome and process performance measures for OPOs and develop a new process for OPOs to appeal a decertification based on substantive and procedural grounds.

In addition, section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. This section of the Act gives the Secretary broad authority to establish requirements for OPOs that are necessary for the efficient administration of the Medicare program.

Alternatives:

CMS has considered various alternatives in developing outcome and process performance measures. CMS will propose measures based on donor potential and other related factors in OPO service areas and CMS will solicit public comments to identify additional alternatives.

Anticipated Cost and Benefits:

CMS believes the provisions contained in this proposed rule would have little or no economic impact on hospitals and would not have a substantial economic impact on a significant number of OPOs.

It is expected that improved OPO performance would result from the rule and would increase organ donation and transplantation, thereby decreasing deaths of patients waiting for organs. Increasing organ donation and transplantation is a priority for the Secretary as evidenced by the Secretary's Donation Initiative (Initiative); launch of the Initiative was one of the Secretary's first actions.

In addition, the proposed rule would include requirements to guard against medical errors that can lead to transplantation of organs of the wrong blood type or transmission of infectious disease to transplant recipients.

Risks:

Failure to publish the rule may decrease organ donation and transplantation, thereby increasing deaths of patients waiting for organs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/01	66 FR 67109
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0938–AK81

HHS—CMS

64. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS–2130–P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

PL 106–554, (BIPA 2000 of the Children's Health Act)

CFR Citation:

42 CFR 101; 42 CFR 418; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline:

None

Abstract:

This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Statement of Need:

In recent years, media, Government, and consumer reports of deaths and injuries occurring due to the use of restraint or seclusion have heightened concern about these mechanisms as interventions. Concern about use is nothing new; however, the appropriate use of restraint and seclusion has been debated and regulated in various health care settings for many years. Researchers have examined the use of restraint and seclusion, related injuries and deaths, and potential alternatives to address safety and care concerns while posing less inherent risk to the

individual. Patient advocates have lobbied for reduced and more highly regulated use. Health care facilities and professionals have examined mechanisms for reduction, and some have implemented training programs to promote safe application and use. Reports of injuries and deaths, however, have brought concerns about care and safety to the forefront. The issue has gained national attention, with a call for regulation across health care settings.

Several highly publicized newspaper articles and Federal reports are the impetus for this regulation. The CHA established a significant collaboration of several important children's health bills. CMS has responsibility for part H, which established certain requirements related to the rights of residents of certain facilities receiving Federal funds. SAMHSA intends to publish a notice of proposed rulemaking to implement part I, which sets forth requirements related to the rights of residents of certain nonmedical, community-based facilities for children and youth. The CHA establishes for certain facilities common definitions, staff training standards, reporting requirements, and strict enforcement criteria.

Summary of Legal Basis:

The Children's Health Act of 2000 (Pub. L. 106-310), section 3207, part H.

Alternatives:

No other regulatory alternatives were considered. Nevertheless, current regulations exist, in some form, for hospitals and residential treatment facilities, while nursing homes and ICFs/MR use survey guidelines. The CHA's intent is to develop consistency in requirements across all Federally-funded patient or residential care facilities. The statutory language required that regulations be promulgated within one year of its enactment. This proposed rule is currently two years behind its mandated time of publication.

Anticipated Cost and Benefits:

The anticipated benefits include enhanced patient safety and better consumer protections. Increases in staff education and training are expected to lead to treatment alternatives and decreases in the use of restraint and seclusion as a means of intervention, which then leads to less traumatic experiences for both beneficiaries and staff. The regulation creates a change in facility practices and policies on the use of restraint or seclusion as a treatment mechanism. The regulation will create standard criteria for patient or residential care facilities that receive Federal funds, which will establish an industrywide effect on beneficiaries who are receiving services within these Federal facilities. The regulation creates consistent criteria for staff training, and defining and reporting on restraint or seclusion.

The anticipated cost is based on regulations that will affect more than 32,350 Medicare and Medicaid funded facilities. At this time, however, the extent of potential facilities affected is unattainable until comments are received from other HHS agencies. It is estimated that the cost will be roughly $500 million per a year for Federal Medicaid, and $2.5 billion to $3 billion for all payers. The proposed rule will specifically solicit comments on actual staff training and reporting costs, and it is assumed this cost will decrease since the majority of facilities currently have training and reporting requirements.

Risks:

The risk in implementing the regulation -

1. Increase in cost for facilities in staff training; however, facilities that currently use restraint or seclusion as a form of intervention have some general staff training requirements. The CHA will only expand the content of this training.

2. Increase possibility of facilities having their Federal funding status placed in jeopardy due to noncompliance with regulations. Industry may raise concern that the CHA's enforcement aspect is too harsh. For nursing homes, argument may occur that the CHA's enforcement goes against the intent of the Congress and its OBRA '87 language to devise other alternative sanctions besides termination from the Medicare or Medicaid programs.

3. Concern from facilities that currently do not have any regulations governing the use of restraints or seclusion (for example, nursing homes, hospice inpatient facilities, critical access hospitals; however nursing homes have requirements in their survey guidance materials).

The risk in not implementing the regulation -

1. Continued unregulated use of restraint and seclusion in certain Federally funded facilities.

2. Continued under reporting of deaths as a result of restraint or seclusion, or deaths that occur within 24 hours after an individual has been restrained or in seclusion, or where it is reasonable to assume that the individual's death was caused by being placed in restraints or in seclusion.

3. Barrage of continued concerns from advocacy groups and Congress to publish this regulation, as well as requests from facilities for guidance.

4. Lack of protection for special needs populations, such as children, adolescents, persons with mental illness, developmental disabilities, or co-occurring mental retardation who are disproportionately affected by the usage of restraint or seclusion as a common form of intervention.

5. Lack of direction to organizations, advocacy groups, and more than 32,350 facilities for developing common definition.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0938–AL26

HHS—CMS

65. • REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

Social Security Act, sec 1864; Social Security Act, sec 1865; Social Security Act, sec 1875

CFR Citation:

42 CFR 488.1 to 488.9

Legal Deadline:

None

Abstract:

This rule is in response to the recommendations in the GAO Report, ''CMS Needs Additional Aurthority to Adequately Oversee Patient Safety in Hospitals'' (GAO-04-850). With resepct to the oversight and validation of hospital accreditation programs, a rate if disparity calculation is specified in Federal regulations at 42 CFR, section 488.8. This rule proposes to consider additional alternative measures to assess the performance of the accreditation organizations.

Statement of Need:

In the Department's official response to the recommendations in the GAO Report dealing with accredited hospitals, (GAO-04-850, ''CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals''), the Administrator committed to proposing that this regulatory initiative be added to the Department's regulatory plan for fiscal year 2005. With respect to the oversight and validation of hospital accreditation programs, a rate of disparity calculation is specified in Federal regulations at 42 CFR section 488.8. The agency agreed that it is quite appropriate to reexamine the rule and to consider additional or alternative measures to assess the performance of the accreditation organizations. CMS has already begun to examine this issue as part of the agency's hospital quality improvement activities. CMS is working to refine existing measures and develop new ones. It will be necessary to undertake rulemaking to revise the formula for calculating the rate of disparity measure, as well as to validate the threshold for acceptable performance or reasonable assurance. The notice and comment procedures inherent in the rulemaking process will provide an appropriate forum for this discussion of this significant public policy and will allow all of the stakeholders to participate. It will also provide for exposure to new perspectives and may yield innovative approaches to these problems. In addition, CMS will explore regulatory strategies to address the long-standing JCAHO performance issues with respect to the Life Safety Code.

Summary of Legal Basis:

Sections 1864, 1865, and 1875 of the Social Security Act.

Alternatives:

None. There are no alternative authorities that would permit this regulation to be issued as an interim final rule or final rule.

Anticipated Cost and Benefits:

None. There are no alternative authorities that would permit this regulation to be issued as an interim final rule or final rule.

Risks:

Risks include higher expenditures for the survey and certification program in conducting validation surveys of accredited providers and in other improvements to the measures and analyses used to evaluate the performance of accrediting organizations for inclusion in the annual report to Congress. Unless these additional costs are addressed through the appropriation and budget processes, reallocation of existing resources could reduce the oversight of other categories of providers and endanger the health and safety of program beneficiaries.

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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HHS—CMS

FINAL RULE STAGE

66. MEDICARE ADVANTAGE PROGRAM—TITLE II (CMS–4069–F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL108–173, MMA

CFR Citation:

42 CFR 417; 42 CFR 422

Legal Deadline:

None

Abstract:

This final rule implements title II of the Medicare Modernization Act establishing the Medicare Advantage program that will replace the existing Medicare+Choice program. Medicare Advantage offers improved managed care plans with coordinated care and competitive bidding, to promote greater efficiency and responsiveness to Medicare beneficiaries.

Statement of Need:

Implementation of the Medicare Advantage (MA) Program is required by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The MA program replaces the Medicare+Choice (M+C) program established under part C of title XVIII of the Social Security Act. The primary goal of the MA program is to expand health plan choices available to Medicare beneficiaries in areas that previously had no private plans and in areas with few competing plans. Beneficiary choice should be enhanced by the introduction of new types of plans, including specialized MA plans, and regional plans that are structured as preferred provider organizations. The MA program becomes effective January 1, 2006.

Summary of Legal Basis:

Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).

Alternatives:

None.

Anticipated Cost and Benefits:

In general, the MA program will have a positive impact on beneficiaries.

Transfer payments from the Federal Government will go towards the provision of additional benefits to enrollees of health plans and reduced out-of-pocket costs, including reduced part B and part D premiums for these enrollees. The law will result in increased revenue for participating private plans for the provision of the basic Medicare benefit and the provision of additional benefits. This is expected to help improve the availability of health plan choices for beneficiaries.

Risks:

Risks include not publishing the final regulation in time to allow prospective local and regional MA plans to participate in the MA program. Prospective MA plans need to apply to become an MA plan and prepare bids in the spring of 2005. This is a particular concern for MA organizations considering offering new types of plans, such as MA regional PPOs and specialized MA plans. If plans choose not to participate due to a delay in publishing the final regulation, there may be the risk of low participation in the MA program for 2006 and beneficiaries will continue to have little choice or only the choice of fee-for-service in many parts of the country. Because expanded choice of plans for beneficiaries is the cornerstone of the MMA legislation, this is a big risk.

Timetable:

Action	Date	FR Cite
NPRM	08/03/04	69 FR 46866
NPRM Comment Period End	10/04/04	
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0938–AN06

HHS—CMS

67. MEDICARE DRUG BENEFIT EFFECTIVE CALENDAR YEAR 2006—TITLE I (CMS–4068–F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 108–173, MMA

CFR Citation:

42 CFR 417; 42 CFR 423

Legal Deadline:

None

Abstract:

This final rule implements title I of the Medicare Modernization Act, which establishes a new voluntary outpatient prescription drug benefit under a new Medicare part D, beginning January 1, 2006. Coverage for the drug benefit will be provided by private prescription drug plans (PDPs) that offer drug only coverage, or through Medicare Advantage plans or preferred provider plans (PPOs) that will offer prescription drug and non-drug coverage. Plans will offer a standard drug benefit but have the flexibility to vary the drug benefit within actuarial equivalency parameters. Assistance with premiums and cost sharing will be provided to eligible low-income beneficiaries.

Statement of Need:

Implementation of the Medicare Prescription Drug Benefit is required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006.

Summary of Legal Basis:

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).

Alternatives:

None.

Anticipated Cost and Benefits:

The Prescription Drug benefit will have a positive impact on beneficiaries. All Medicare beneficiaries will have access to a voluntary drug benefit. A typical beneficiary—not eligible for additional low-income benefits—with no coverage today will see their total spending on drugs drop by 53 percent. In addition, it is estimated that nearly 11 million beneficiaries with limited means will participate in the low-income subsidy, receiving substantial additional help from Medicare. Beneficiaries will see lower drug costs as a result of price negotiation and coordination of health services by the prescription drug plans and Medicare Advantage plans.

Risks:

Risks include not publishing the final regulation in time to allow prospective prescription drug plans (PDPs) to participate. Prospective PDPs need to apply to become a Medicare PDP and prepare bids in the spring of 2005. This is a particular concern since this is a brand new program and benefit. If plans choose not to participate due to a delay in publishing the final regulation, there is the risk of low participation in the part D program for 2006 and beneficiaries will be without the drug benefit. Because the drug benefit is the cornerstone of the MMA legislation, this is a big risk.

Timetable:

Action	Date	FR Cite
NPRM	08/03/04	69 FR 46632
NPRM Comment Period End	10/04/04	
Notice	07/30/04	69 FR 45822
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

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Related RIN: Related to 0938–AN07

RIN: 0938–AN08

BILLING CODE 4150–24–S

DEPARTMENT OF HOMELAND SECURITY (DHS)

Statement of Regulatory Priorities

The attack on our homeland of September 11, 2001, was an assault on the ideas that make our Nation great. We were reminded that the values we hold dear must not be taken for granted. From these tragic events, a stronger union has emerged. Our citizens, and those of countries around the world, renewed their commitment to this Nation and the values for which it stands. In January 2003, the United States Government established the Department of Homeland Security (the Department or DHS), the Nation's 15th and newest Cabinet department, consolidating 22 previously disparate agencies and 180,000 employees under one unified organization. By rapidly and efficiently setting up the needed infrastructure, the Department was able to remain focused on its overriding and urgent mission: securing the American homeland and protecting the American people. Our Department quickly developed the high-level strategic thinking embodied in our strategic management initiatives and plans. Our Mission Statement is our guiding principle: We are charged to lead the unified national effort to secure America. We will prevent and deter terrorist attacks and protect against and respond to threats and hazards to the Nation. We will ensure safe and secure borders, welcome lawful immigrants and visitors, and promote the free flow of commerce.

DHS' Strategic Plan supports the President's *National Strategy for Protecting Homeland Security*. Our Strategic Plan governs the development of DHS' strategies, programs and projects, and ultimately is reflected in the Department's budget and regulatory agenda. DHS' Strategic Plan is posted on the Department's Web site: http://www.dhs.gov/dhspublic/interapp/editorial/editorial__0413.xml.

The Strategic Plan reflects the determination of our Nation to prevail against terror, to protect our homeland and to create a better world in the process. The Department strives for organizational excellence and uses a centralized and unified approach in managing its regulatory resources. Each regulatory project is linked to the Department's Strategic Plan and departmental goals and objectives. Senior Department leadership reviews each regulatory project, including the Unified Agenda, to ensure that the project fosters and supports the Department's Strategic Goals outlined in DHS' Strategic Plan. DHS' Strategic Goals are:

AWARENESS—Identify and understand threats, assess vulnerabilities, determine potential impacts, and disseminate timely information to our homeland security partners and the American public.

PREVENTION—Detect, deter, and mitigate threats to our homeland.

PROTECTION—Safeguard our people and their freedoms, critical infrastructure, property, and the economy of our Nation from acts of terrorism, natural disasters, or other emergencies.

RESPONSE—Lead, manage, and coordinate the national response to acts of terrorism, natural disasters, or other emergencies.

RECOVERY—Lead national, State, local, and private sector efforts to restore services and rebuild communities after acts of terrorism, natural disasters, or other emergencies.

SERVICE—Serve the public effectively by facilitating lawful trade, travel, and immigration.

ORGANIZATIONAL EXCELLENCE—Value our most important resource, our people. Create a culture that promotes a common identity, innovation, mutual respect, accountability, and teamwork to achieve efficiency, effectiveness, and operational synergies.

The Department ensures that all of its regulatory initiatives are aligned with its guiding principles to: protect civil rights and civil liberties, integrate our actions, build coalitions and partnerships, develop human resources, innovate, and be accountable to the American public. The Department values public involvement in the development of its regulatory plan, Unified Agenda, and regulations.

Last year, the Department partnered with two agencies leading the Federal electronic docket management initiative: the Environmental Protection Agency (EPA) and the Department of Transportation (DOT). Both agencies agreed to host selected DHS regulations on their docket management Web sites. The Department chose four significant regulations to pilot these docketing systems: Human Resources Management System Regulations and ''US-VISIT'' are on the EPA's EDocket; DHS Supplement to the Federal Acquisition Regulations and the regulations to Support Antiterrorism by Fostering Effective Technologies Act (SAFETY ACT) are hosted on the DOT Docket Management System (DMS). By using these two docketing systems, DHS provided optimal access to the public to review and comment on these regulatory proposals. In fact, the Human Resources Management System Regulations received nearly 4,000 public comments. Our ability to use existing electronic docketing systems has maximized departmental resources and significantly enhanced the regulatory process. The Department has decided that, since the U.S. Coast Guard and the Transportation Security Administration are legacy DOT agencies and that members of the public that ordinarily participate in their rulemaking process are accustomed to using DOT's DMS, those two agencies will remain on DOT's DMS until full migration to the Federal docketing management system. The remaining Department Headquarters and organizational elements have joined EPA's Federal EDocket system and members of the public can expect to see these elements using EPA's Federal EDocket system for those regulations listed in the Unified Agenda. The EPA Federal EDocket Web site is http://www.epa.gov/feddocket. The DOT DMS Web site for the U.S. Coast Guard and the Transportation Security Administration regulations is dms.dot.gov. The public may also provide public comments to DHS' regulations through www.regulations.gov. We strongly encourage public participation in DHS' upcoming regulatory initiatives.

Office of the Secretary

DHS is managed by Tom Ridge, the Secretary of the Department of Homeland Security; Admiral James Loy, the Deputy Secretary; five Under Secretaries (Asa Hutchinson, Under Secretary for the Directorate of Border and Transportation Security; Michael Brown, Under Secretary for Emergency Preparedness and Response; Janet Hale, Under Secretary for Management; General Frank Libutti, Under Secretary for Information Analysis and Infrastructure Protection; and Charles McQueary, Under Secretary for Science and Technology) and by those persons leading the independent organizational elements who report directly to the Secretary and the Deputy Secretary (Admiral Thomas Collins, Commandant of the U.S. Coast Guard; Eduardo Aguirre, Jr., Director of the U.S. Citizenship and Immigration Services agency are two independent elements with rulemaking authority). Joe Whitley, the General Counsel to the Department, manages the Department's regulatory plan and Unified Agenda.

The Office of the Secretary's regulatory plan includes regulations sponsored by the Department's Under Secretaries with the exception of the Under Secretary for Emergency Preparedness and Response (EP&R). The Under Secretary for EP&R is also the head of the Federal Emergency Management Agency (FEMA) and so the EP&R regulatory plan is the same as FEMA's. The U.S. Coast Guard and the U.S. Citizenship and Immigration Services are two independent organizational elements that exercise their statutory authorities, in part, through regulation. Their regulatory plans are discussed separately below. The Bureau of Customs and Border Protection, the Bureau of Immigration and Customs Enforcement, and the Transportation Security Administration's regulatory plans will also be discussed separately.

During fiscal year 2005, the Office of the Secretary expects to complete work on a regulatory program to implement the United States Visitor and Immigrant Status Indicator Technology (US-VISIT) program. US-VISIT is an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities, and authenticates aliens' travel documents through comparison of biometrics. US-VISIT will enhance national security while facilitating legitimate travel and trade through our borders. This regulatory program supports the Department's Strategic Goals of awareness, prevention, and protection by securing our borders against terrorists who intend to harm the United States.

The Department expects to finalize the interim rule on Procedures for Handling Critical Infrastructure Information (CII). This rulemaking establishes uniform procedures for the receipt, care, and storage of CII voluntarily submitted to the Federal Government. The procedures apply to all Federal agencies that receive, care for, or store CII voluntarily submitted to the Federal Government. It supports the Department's Strategic Goals of awareness, prevention, protection, and response by identifying and assessing the vulnerability of critical infrastructure and key assets.

The Department and the Office of Personnel Management expect to finalize their proposed regulations to establish a new human resources management system within DHS, as authorized by the Homeland Security Act of 2002. The affected subsystems include the systems governing basic pay, classification, performance management, labor relations, adverse actions, and employee appeals. This regulatory initiative supports DHS' Strategic Goal of organizational excellence by valuing our most important resource, our people. It is expected that the regulation will assist the Department by providing a coherent human resources management mechanism that maximizes efficiencies, effectiveness, and operational synergies promoting the Department's Strategic Goal of organizational excellence.

The Department also intends to finalize its interim rule on the SAFETY ACT. The SAFETY ACT regulation implements the Support Anti-Terrorism by Fostering Effective Technology Act found at subtitle G of the Homeland Security Act of 2002 (Homeland Security Act). DHS published an interim final rule with request for comments implementing the SAFETY ACT provision. This rule provides critical incentives for the development and deployment of antiterrorism technologies by providing liability protections for sellers of ''qualified antiterrorism technologies'' and others.

The Department intends to publish implementing regulations under section 892 of the Homeland Security Act addressing sharing sensitive homeland security information (SHSI). The regulations will propose procedures for the identification, sharing, and safeguarding of homeland security information that is sensitive but unclassified. These procedures will apply to all agencies of the Federal Government and may apply to State and local governments and first responders. This regulatory initiative supports DHS' Strategic Goals of awareness, prevention, protection, response and recovery by providing a comprehensive and unified mechanism of sharing sensitive homeland security information at Federal, State, and local levels.

U.S. Coast Guard

The U.S. Coast Guard (USCG) is a military, multi-mission, and maritime agency. Its statutory responsibilities include ensuring marine safety and security, preserving maritime mobility, protecting the marine environment, enforcing U.S. laws and international treaties, and performing search and rescue. The Coast Guard's Strategic Goals are aligned with the Department's Strategic Goals. In performing its duties, the Coast Guard has established certain priorities for its regulatory program and has identified which of its five strategic goals—maritime safety, protection of natural resources, maritime security, maritime mobility, and national defense—the project supports.

The Coast Guard continues to use plain language in its notices and rulemaking documents to promote better understanding of regulations and increased public participation in its rulemakings. The Coast Guard encourages early public involvement in this process and has particular concern for the impacts its rules have on small businesses. It has supported the e-rulemaking initiative, and, on the first day of **Federal Register** publication of each rulemaking project, the public can submit comments electronically and view agency documents and public comments on the Department of Transportation's Document Management System, which is available online at The Coast Guard endeavors to reduce the paperwork burden it places on the public and strives to issue only necessary regulations that are tailored to impose the least burden on society. The 60 rulemaking projects described in the Unified Agenda, and both of the rules appearing on The Regulatory Plan support our strategic goals and reflect the Department's and the Coast Guard's regulatory policies.

As part of its response to the terrorist attacks of September 11, 2001, after conducting public workshops and meetings, the Coast Guard, on July 1, 2003, issued six separate, but complementary, maritime security temporary interim rules designed to implement Maritime Transportation Security Act of 2002 (MTSA) mandates regarding maritime facilities, vessels, and ports and to require automatic identification equipment on certain vessels. Under authority of MTSA, the Coast Guard superceded these temporary interim rules with final rules that were published on October 22, 2003 (68 FR 60448). Also in response to 9/11, Coast Guard Captains of the Port have issued rules establishing security zones around nuclear power plants, airports, cruise ships, liquefied natural gas vessels, and maritime facilities.

Its post-September 11, 2001 emphasis on maritime security and national defense has not prevented the Coast Guard from carrying out its other regulatory responsibilities. Coast Guard Headquarters has issued many rules or proposed rules that are not security-related, as indicated by the wide range of topics covered in its 60 rulemaking projects in the final-rule, long-term actions, or proposed-rule stages in the Unified Agenda. Of particular interest to the Coast Guard are the two rules appearing in The Regulatory Plan: Post

Casualty Drug and Alcohol Testing and Commercial Fishing Industry Vessels. These rules promote the Department's Strategic Goals of protection by providing regulatory measures aimed at protecting the marine environment, living marine resources, and maritime safety.

The Coast Guard, through the rulemaking projects identified in The Regulatory Plan and the Unified Agenda, plans to continue to meet its multi-mission, regulatory obligations as reflected in its strategic and policy goals and the goals of the President's Six Point Plan for Economic Growth by streamlining its regulations.

U.S. Citizenship and Immigration Services

The U.S. Citizenship and Immigration Services' (USCIS) mission is to restore public confidence in the integrity of America's immigration services by making certain that those immigrant applicants meeting our statutory and regulatory requirements, such as those provided by the Immigration and Nationalization Act and its implementing regulations, duly receive all rights and benefits granted by law. USCIS will ensure that it issues benefits only to eligible individuals.

Strengthening Immigration Services

USCIS' key regulatory initiatives that govern nonimmigrant classes and admission requirements focus on eliminating the backlog of processing pending applications and petitions. Promulgation of these rules will help in streamlining processing procedures and the paperwork burden thereby improving customer service. These regulations are the Removal of the Standardized Request for Evidence Processing Timeframe; Petitions for Employment Based Immigrants; Removal of Limitations on the Validity Period for Certain Employment Authorization Documents; and Affidavits of Support on Behalf of Immigrants. Together, these rules will amend various USCIS regulatory provisions to: (1) remove fixed regulatory timeframes for responses to requests for evidence or notices of intent to deny; (2) remove fixed validity periods for employment authorization documents; (3) modify the evidentiary requirements for employment-based petitions to focus on evidence establishing the bona fides of the U.S employer and the validity of the job offered; and (4) clarify the standards for adjudication of Affidavits of Support that petitioning relatives must file to establish that the beneficiary will not become a public charge. These regulatory projects foster the President's SixPoint Plan for economic growth by streamlining regulatory requirements and are aligned with the Department's Strategic Goal of service and organizational excellence. These proposed rules will give USCIS the flexibility to set more appropriate timeframes for evidence requests and document validity periods as well as to clarify the standards for adjudication of various benefit applications and petitions, thereby enabling USCIS to reduce its backlog and benefit processing times.

An additional key regulatory initiative is the streamlining of the nonimmigrant regulations codified in 8 CFR part 214, which have grown in size and complexity during the past 15 years as Congress has added at least 10 new nonimmigrant classes and expanded the requirements and restrictions on many of the existing classes. This regulatory initiative provides for a comprehensive reorganization, streamlining, and rewriting of 8 CFR part 214 in plain language. This regulation is titled Restructuring the Nonimmigrant Regulations and furthers the President's Six Point Plan for economic growth.

There are a number of other planned regulatory actions focused on improving benefit processing and adjudication services, preventing fraudulent claims, and ensuring that USCIS issues ben efits only to eligible individuals. These and other planned rulemakings are delineated in USCIS' agenda. These proposed rules will amend various UCSIS regulatory provisions to: (1) clarify the procedures for individuals to seek review of adverse decisions issued by USCIS and the standards for adjudication of such requests; (2) allow USCIS to precertify certain U.S. employers' ability to pay an alien or that the job offered by the U.S. employer is a specialty occupation; (3) extend the time period within which an employer may file a petition for an alien with extraordinary ability or who is an athlete or entertainer; (4) modify USCIS' procedures to ensure that all background checks are completed on individual aliens before USCIS issues evidence of alien registration; and (5) standardize adjudication of all requests for waiver of fees.

By clarifying the standards for adjudication of various benefit applications and petitions, extending the timeframes for filing of petitions, and eliminating the need for certain employers to reestablish that they have met certain requirements for filing a petition every time a new petition is filed, USCIS is able to streamline its adjudication process, thus reducing its backlog through faster adjudication, and ultimately decreasing benefit processing times. USCIS believes that these regulatory initiatives will improve the processing of applications and petitions by streamlining the processes and thereby helping to alleviate the backlog. USCIS further believes that these initiatives have appropriate safeguards to prevent fraud and abuse. These regulatory activities foster many of the Department's Strategic Goals: awareness, prevention, protection, and organizational excellence by placing USCIS in a better position to safeguard against any risk that may be posed by unlawful applicants to national security or public safety by ensuring that documents are issued after the completion of required background and security checks. This initiative also fosters the President's Six Point Plan for Economic Growth.

Emergency Preparedness and Response / Federal Emergency Management Administration

The mission of the Federal Emergency Management Agency (FEMA) is: ''To lead the Nation to prepare for, mitigate the effects of, respond to, and recover from major disasters and emergencies, both natural and man-made, including acts of terrorism.'' FEMA is charged with developing and maintaining an integrated, nationwide operational capability to respond to and recover from disasters and emergencies, regardless of their cause, in partnership with other Federal agencies, State and local governments, volunteer organizations, and the private sector. FEMA coordinates and implements the Federal response to disasters declared by the President. FEMA also has the responsibility to ensure effective emergency preparedness. The agency is led by the Under Secretary for Emergency Preparedness and Response, Under Secretary Michael Brown.

The 9/11 Heroes Stamp Act of 2001 directed the U.S. Postal Service to issue a postal stamp and distribute the proceeds through FEMA to the families of emergency relief personnel killed or permanently disabled while serving in the line of duty in connection with the terrorist attacks of September 11, 2001. RIN 1660-AA34, Assistance Program Under the 9/11 Heroes Stamp Act of 2001, establishes the mechanism through which FEMA will distribute these funds. This regulation fosters the Department's Strategic Goal of recovery by assisting the families of emergency

relief personnel who served in the line of duty on 9/11 to rebuild their lives. RIN 1660-AA07, National Urban Search and Rescue Response System, would standardize the financing, administration, and operation of the National Urban Search and Rescue Response System; a cooperative effort of FEMA, participating State emergency management agencies, and local public safety agencies across the country.

Directorate of Border and Transportation Security

The Directorate of Border and Transportation Security (BTS) is comprised of the law enforcement agencies (with the exception of the U.S. Coast Guard and the U.S. Secret Service), three of which are contributors to The Regulatory Plan; the Bureau of Customs and Border Protection, led by Robert Bonner; the Bureau of Immigration and Customs Enforcement, headed by Michael Garcia; and the Transportation Security Administration, headed by Admiral David Stone.

Bureau of Customs and Border Protection

On November 25, 2002, the President signed the Homeland Security Act of 2002 (Homeland Security Act) establishing the Department of Homeland Security. Under section 403(1) of the Homeland Security Act, the United States Customs Service, including functions of the Secretary of the Treasury relating thereto, transferred to the Secretary of Homeland Security. As part of the DHS reorganization, the Customs Service inspection and trade functions were combined with the immigration and agricultural inspection functions and the Border Patrol and transferred into the Bureau of Customs and Border Protection (CBP). It is noted that certain regulatory authority of the United States Customs Service relating to customs revenue functions was retained by the Department of the Treasury (see the Department of the Treasury regulatory plan).

CBP is the Federal agency principally responsible for the security of our Nation's borders, both at and between the ports of entry and at official crossings into the United States. CBP must accomplish its border security and enforcement mission without stifling the flow of legitimate trade and travel. The primary mission of CBP is its homeland security mission, that is, to prevent terrorists and terrorist weapons from entering the United States. An important aspect of this priority mission involves improving security at our borders and ports of entry, but it also means extending our zone of security beyond our physical borders.

CBP is also responsible for administering laws concerning the importation into the United States of goods and enforcing the laws concerning the entry of persons into the United States. This responsibility includes regulating and facilitating international trade; collecting import duties; enforcing U.S. trade, immigration and other laws of the United States at our borders; inspecting imports, overseeing the activities of persons and businesses engaged in importing; enforcing the laws concerning smuggling and trafficking in contraband; apprehending individuals attempting to enter the United States illegally; protecting our agriculture and economic interests from harmful pests and diseases; servicing all people, vehicles, and cargo entering the United States; maintaining export controls; and protecting American businesses from theft of their intellectual property.

In carrying out its priority mission, CBP's goal is to facilitate the processing of legitimate trade and people efficiently without compromising security. During the past fiscal year, consistent with its primary mission of homeland security, CBP issued a final rule that increases advance data regarding incoming conveyances and goods. In accordance with the Trade Act of 2002, this final rule requires operators of sea vessels, aircraft, trucks, and trains to transmit advance information electronically to CBP pertaining to cargo before the cargo is either brought into or sent from the United States on those conveyances.

During fiscal year 2005, CBP plans to enhance homeland security further by issuing several other regulatory documents that will require advance information. CBP plans to finalize the following interim final rules: Passenger and Crew Manifests Required for Passenger Flights in Foreign Air Transportation to the United States (Passenger and Crew Manifests rule) and Passenger Name Record Information Required for Passengers on Flights in Foreign Air Transportation To or From the United States (Passenger Name Record Information rule). The Passenger and Crew Manifests rule requires that each air carrier, foreign and domestic, operating a passenger flight in foreign air transportation to the United States electronically transmit to CBP in advance of arrival a passenger and crew manifest that contains certain specified information. The Passenger Name Record Information rule requires that each air carrier must provide CBP with electronic access to Passenger Name Record information contained in the carrier's automated reservation system and/or departure control system that sets forth the identity and travel plans of any passengers on flights in foreign air transportation either to or from the United States. Both of these rules foster DHS' Strategic Goals of awareness and prevention.

In addition to its plans to continue issuing regulations to enhance border security, CBP, during fiscal year 2005, expects to continue to issue regulatory documents that will facilitate legitimate trade and implement trade benefit programs. Discussion of CBP regulations regarding the customs revenue function is contained in the regulatory plan of the Department of the Treasury. Also, CBP expects to issue regulatory projects reflecting CBP's responsibility for the immigration inspection function.

Bureau of Immigration and Customs Enforcement

The Bureau of Immigration and Customs Enforcement (ICE), the largest investigative arm of the Department, is responsible for identifying and preventing security vulnerabilities to the Nation's border, economic, transportation, and infrastructure. Its mission is to prevent acts of terrorism by targeting the people, money, and materials that support terrorist and criminal activities. Established to combat the criminal and national security threats emergent in a post 9/11 environment, ICE combines a new investigative approach with new resources to provide unparalleled investigation, interdiction and security services to the public and our law enforcement partners in the Federal and local sectors.

ICE will be pursuing rulemaking to implement major components of the President's and the Department's Strategic Goals. ICE will continue to promulgate regulations focused on addressing control issues for over 500,000 international students attending colleges and universities in the United States and a similar number of exchange visitors entering the United States through the Department of State's (DOS) ''J'' visa program. This regulatory action will foster the Department's Strategic Goals of awareness and prevention.

In an effort to streamline the removal process of persons who no longer have immigration status, ICE will promulgate a rule that requires aliens who become subject to a final order of removal to surrender themselves to the ICE within 30 days thereafter. This rule provides

that aliens who are given notice of the mandatory duty to surrender and later fail to comply with the surrender obligation will be denied all discretionary immigration benefits for the remainder of their presence in the United States and for 10 years after their departure. This action enhances the integrity of the removal process by shifting the burden upon termination of removal proceedings—eliminating the requirement that ICE seek out those subject to final removal orders—and instead requiring that such persons present themselves for removal. The surrender requirement will apply to aliens who receive notice of the obligation in the course of their immigration proceedings or concurrently with the final order of removal. This regulatory initiative promotes the Department's Strategic Goals of awareness and prevention.

Concurrently, ICE has launched an initiative to address the fact that large numbers of aliens who already have final removal orders have not departed the United States. Such aliens, termed absconders, are the subject of the ICE subregulatory Absconder Apprehension Initiative (AAI), which is designed to enhance the ability of ICE to apprehend absconders. In AAI, the agency has begun reviewing the files of absconders to enter appropriate records into the National Crime Information Center (NCIC) database so that they may be apprehended when encountered by Federal, State, or local law enforcement officials. This effort supplements efforts being undertaken by ICE to use recent resource enhancements to apprehend those absconders whom ICE can locate.

Transportation Security Administration

In response to the September 11, 2001, terrorist attacks in the United States, and with the potential for future attacks in this country, Congress enacted the Aviation and Transportation Security Act (ATSA), Public Law 107-71, 115 Stat. 597 on November 19, 2001. ATSA established the Transportation Security Administration (TSA) to protect the transportation system——a complex ''system of systems'' comprised of aircraft, ships, and rail and motor vehicles; airports, seaports, and transshipment facilities; roads, railways, bridges, and pipelines; and supporting infrastructures——and ensure the freedom of movement for people and commerce. Initially, TSA was created as an agency within the Department of Transportation (DOT). As of March 1, 2003, the Homeland Security Act transferred TSA from DOT to the Department.

Much of TSA's initial efforts focused on meeting congressionally mandated aviation-security objectives. We have made significant progress and will continue to fulfill our obligations in the aviation sector. However, we have expanded our efforts to address threats across all modes of transportation and to provide world-class security and customer service to travelers and shippers. As we work to meet the immediate needs of the transportation sector, we continue to develop and implement the strategies, through its people, processes, and technology that enable us to perform our daily activities while ultimately preparing us for the future.

TSA's Strategic Goals are aligned with the Department's Strategic Goals. In fiscal year 2005, TSA will emphasize regulatory efforts to implement transportation security enhancements responsive to Presidential leadership, DHS priorities, Congressional mandates, and public input, particularly the recommendations of the ''National Commission on Terrorist Attacks Upon the United States'' (the 9/11 Commission Report). In defining appropriate security enhancements, TSA will continue testing concepts, such as Registered Traveler, Secure Flight, and the Transportation Worker Identification Credential, to demonstrate feasibility and obtain public input prior to national implementation and rulemaking. These regulatory initiatives promote DHS' Strategic Goals of awareness, prevention, and protection by providing important information on certain persons using or are employed on our transportation systems. TSA is partnering with other DHS organizational elements, such as the Bureau of Immigration and Customs Enforcement, and the U.S. Coast Guard, and with other Federal, State, and local agencies, to achieve common objectives and assure a uniform and appropriate standard of transportation security for the benefit of the American public.

TSA is broadening targeted security screening of persons to include land transportation elements, foster development of methods to enhance screening of cargo in surface transport, and will publish a notice of proposed rulemaking to enhance air cargo security. These regulatory projects will increase our ability to identify and deter threats to our homeland, furthering DHS' Strategic Goals of awareness, prevention, and protection. In appropriate instances, TSA will seek authority to levy fees to offset all or a portion of the cost of certain security enhancements, such as certain background checks, and will propose a revised formula for computing the Aviation Security Infrastructure Fee (ASIF).

TSA will act to assure that sensitive security information (SSI) concerning all modes of transportation is collected when necessary, handled appropriately, shared among appropriate persons, and protected from improper disclosure or use. TSA will also take steps to assure that requirements directly affecting the security of the U.S. air transportation industry will be applied wherever the security of U.S. personnel or assets is at stake, and that industry personnel in identified critical transportation activities receive appropriate security training. Also, TSA will codify security requirements applicable to designated airports in the National Capitol Area. These regulatory initiatives promote DHS' Strategic Goals of awareness, prevention, protection, response, and organizational excellence by applying the appropriate measures to collect and disseminate SSI, and providing appropriate security training to industry personnel.

DHS—Office of the Secretary (OS)

PROPOSED RULE STAGE

68. ● HOMELAND SECURITY INFORMATION SHARING

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 107–296; 116 Stat 2135; 6 USC 301

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This proposed regulation will establish procedures for sharing, identifying and safeguarding, processing and handling, Homeland Security Information between agencies and appropriate State and local personnel.

Statement of Need:

This proposed rule will implement section 892 of the Homeland Security Act (HSA) addressing sharing sensitive homeland security information. The regulations will propose procedures for the identification, sharing, and safeguarding of homeland security information. These proposed procedures will apply to all agencies of the Federal Government, State and local governments, and first responders. The Department will seek comment on proposed procedures to facilitate more robust, effective, and timely sharing of homeland security information among agencies of the Federal Government and between the Federal Government and State and local personnel engaged in homeland security activities. Section 892 of the HSA provides explicit statutory authority to realize the objectives of the President's National Homeland Security Strategy and the recommendations of the 9/11 Commission Report by mandating clear procedures to establish the extent of sharing for homeland security information and govern how the actual sharing of the information will be accomplished. These regulations will assist the Federal Government, State and local governments, and first responders to effectively defend against and respond to potential terrorist attacks.

Summary of Legal Basis:

This regulation is needed to assist the Department of Homeland Security in meeting its statutory obligation under the Homeland Security Act to share sensitive homeland security information.

Alternatives:

The Department of Homeland Security believes that there is no alternative to sharing sensitive homeland security information. The statute mandates the sharing and the 9/11 Commission recommends its sharing.

Anticipated Cost and Benefits:

The Department of Homeland Security is still considering the costs associated with the identification, protection, storing, and sharing of homeland security information. We do not have a determination at this point. The benefits of sharing homeland security information is to provide Federal agencies, State and local governments, and first responders better information so that they may detect and prevent terrorists attacks.

Risks:

This regulatory project will complement other DHS initiatives designed to detect, deter and prevent terrorist attacks.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

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DHS—OS

FINAL RULE STAGE

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69. PROCEDURES FOR HANDLING CRITICAL INFRASTRUCTURE INFORMATION

Priority:

Other Significant

Legal Authority:

PL 107–296, 116 Stat 2135; 5 USC ch 1, sec 301; Section 214 of The Homeland Security Act of 2002

CFR Citation:

6 CFR 29

Legal Deadline:

None

Abstract:

This notice of proposed rulemaking establishes the procedures necessary to fulfill the provisions of section 214(e) of the Critical Infrastructure Information (CII) Act of 2002. This regulation establishes uniform procedures for the receipt, care, and storage of CII voluntarily submitted to the Federal Government. These procedures apply to all Federal agencies that receive, care for, or store CII voluntarily submitted to the Federal Government pursuant to the CII Act of 2002 (6 U.S.C. 214). In addition, these procedures apply to United States Government contractors, to foreign, State, and local governments, and Government authorities, pursuant to their express agreements.

Statement of Need:

This final rule will establish procedures to implement section 214 of the Homeland Security Act of 2002 regarding the receipt, care, and storage of critical infrastructure information voluntarily submitted to the Department of Homeland Security. The protection of critical infrastructure reduces the vulnerability of the United States to acts of terrorism. The purpose of the regulation is to encourage private sector entities to share information pertaining their particular and unique vulnerabilities, as well as those that may be systemic and sector wide. As part of its responsibilities under the Homeland Security Act of 2002, this information will be analyzed by the Department of Homeland Security to develop a more thorough understanding of the critical infrastructure vulnerabilities of the Nation. By offering an opportunity for protection from disclosure under the Freedom of Information Act that qualifies under section 214, the Department will assure private sector entities that their information will be safeguarded from abuse by competitors or the open market.

Summary of Legal Basis:

This regulation is needed to finalize the interim final rule that implements section 214 of the Homeland Security Act by establishing uniform procedures for the receipt, care, and storage of critical infrastructure Information.

Alternatives:

The Department of Homeland Security believes that there is no alternative to protecting critical infrastructure information. Section 214 of the Homeland Security Act instructs DHS to establish uniform procedures for the receipt, care, and storage of critical infrastructure information that is voluntarily submitted to the Government.

Anticipated Cost and Benefits:

The Department of Homeland Security had considered the costs and benefits in the interim final rule. The interim rule affects entities in the private sector that have critical infrastructure information that they wish to share

with DHS. The interim rule requires that when DHS receives, validates, and shares CII, DHS and the receiving parties, whether they be other Federal agencies or State or local governments with whom DHS has signed agreements detailing the procedures on how protected CII must be safeguarded, must take appropriate action to safeguard its contents and to destroy it when it is no longer needed. The interim rule does not require the use of safes or enhanced security equipment or the use of a crosscut shredder. Rather, the interim rule requires only that an affected entity or person restrict disclosure of, and access to, the protected information to those with a need to know, and destroy such information when it is no longer needed. Under the rule, a locked drawer or cabinet is an acceptable means of complying with the requirement to secure Protected Critical Infrastructure Information, and a normal paper shredder or manual destruction are acceptable means of destroying protected CII.

Risks:

This regulatory project will complement other DHS initiatives designed to detect, deter, and prevent terrorist attacks.

Timetable:

Action	Date	FR Cite
NPRM	04/15/03	68 FR 18524
Interim Final Rule	02/20/04	69 FR 8073
Interim Final Rule Comment Period End	05/20/04	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Federalism:

This action may have federalism implications as defined in EO 13132.

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DHS—OS

70. REGULATIONS IMPLEMENTING THE SUPPORT ANTITERRORISM BY FOSTERING EFFECTIVE TECHNOLOGIES ACT OF 2002 (THE SAFETY ACT)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

Not Yet Determined

CFR Citation:

6 CFR 25

Legal Deadline:

None

Abstract:

This interim rule implements subtitle G of title VIII of the Homeland Security Act of 2002—the Support of Antiterrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act). As discussed in the SAFETY Act, through regulations promulgated by the Department of Homeland Security (the Department), it provides critical incentives for the development and deployment of antiterrorism technologies by providing liability protections for sellers of ''qualified antiterrorism technologies'' and others.

Statement of Need:

This regulation implements the SAFETY Act. The Department believes the current development of antiterrorism technologies has been slowed due to the potential liability risks associated with their development and eventual deployment. In a fully functioning insurance market, technology developers would be able to insure themselves against excessive liability risk; however, the terrorism risk insurance market appears to be in disequilibrium. The attacks of September 11 fundamentally changed the landscape of terrorism insurance. Congress, in the findings of the Terrorism Risk Insurance Act of 2003 (TRIA), concluded that temporary financial assistance in the insurance market is needed to ''allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses.'' TRIA section 101(b)(2). This interim rulemaking addresses a similar concern, to the extent that potential technology developers are unable to efficiently insure against large losses due to an ongoing reassessment of terrorism issues in insurance markets. Even after a temporary insurance market adjustment, purely private terrorism risk insurance markets may exhibit negative externalities. Because the risk pool of any single insurer may not be large enough to efficiently spread and therefore insure against the risk of damages from a terrorist attack, and because the potential for excessive liability may render any terrorism insurance prohibitively expensive, society may suffer from less than optimal technological protection against terrorist attacks. The measures set forth in the interim rule are designed to meet this goal; they provide certain liability protection from lawsuits and consequently will increase the likelihood that businesses will pursue important technologies that may not be pursued without this protection.

Summary of Legal Basis:

On July 11, 2003, a notice of proposed rulemaking was published entitled ''Regulations Implementing the Support Antiterrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act)'' in the Federal Register (68 FR 41420). No public hearing was requested and none was held. The interim rule was published in October 2003. The Department finds that the need to foster antiterrorism technology by instituting liability protection measures, as soon as found practicable, furnishes good cause for this interim rule to take effect immediately under both the Administrative Procedure Act, 5 U.S.C. 552(d)(3), and section 808 of the Congressional Review Act. The Department believes the current development of antiterrorism technologies has been slowed due to the potential liability risks associated with their development and eventual deployment. In a fully functioning insurance market, technology developers would be able to insure themselves against excessive liability risk; however, the terrorism risk insurance market appears to be in disequilibrium. The attacks of September 11 fundamentally changed the landscape of terrorism insurance. Congress, in its statement of findings and purpose in TRIA, concluded that temporary financial assistance in the insurance market is needed to ''allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses.'' TRIA section 101(b)(2).

Alternatives:

The Department considered public comments received on the interim rule

and will determine whether possible supplemental regulations are needed as we gain experience with implementing the Act.

Anticipated Cost and Benefits:

Costs and Benefits to Technology Development Firms

Since the interim rulemaking puts in place an additional voluntary option for technology developers, the expected direct net benefits to firms of the interim rulemaking will be positive; companies presumably will not choose to pursue the designation of ''antiterrorism technology'' unless they believe it to be a profitable endeavor. The Department cannot predict with certainty the number of applicants for this program. An additional source of uncertainty is the reaction of the insurance market to this designation. As mentioned above, insurance markets appear currently to be adjusting their strategy for terrorism risk, so little market information exists that would inform this estimate. The Department invited comments on these issues.

If a firm chooses to invest effort in pursuing SAFETY Act liability protection, the direct costs to that firm will be the time and money required to submit the required paperwork and other information to the Department. Only companies that choose to request this protection will incur costs. Please see the accompanying PRA analysis for an estimate of these costs.

The direct benefits to firms include lower potential losses from liability for terrorist attacks, and as a consequence a lower burden from liability insurance for this type of technology. In this assessment, we were careful to only consider benefits and costs specifically due to the implementation of the interim rule and not costs that would have been incurred by companies absent any interim rulemaking. The SAFETY Act requires the sellers of the technology to obtain liability insurance ''of such types and in such amounts'' certified by the Secretary. The entire cost of insurance is not a cost specifically imposed by the interim rulemaking, as companies in the course of good business practice routinely purchase insurance absent Federal requirements to do so. Any difference in the amount or price of insurance purchased as a result of the SAFETY Act would be a cost or benefit of this interim rule for firms.

The wording of the SAFETY Act clearly states that sellers are not required to obtain liability insurance beyond the maximum amount of liability insurance reasonably available from private liability sources on the world market at prices and terms that will not unreasonably distort the sales price of the seller's antiterrorism technologies. We tentatively concluded, however, that this interim rulemaking will impact both the prices and terms of liability insurance relative to the amount of insurance coverage absent the SAFETY Act. The probable effect of the interim rule is to lower the quantity of liability coverage needed in order for a firm to protect itself from terrorism liability risks, which would be considered a benefit of this interim rule to firms. The change will most likely be a shift back in demand that leads to a movement along the supply curve for technology firms already in this market; they probably will buy less liability coverage. This will have the effect of lowering the price per unit of coverage in this market.

The Department also expects, however, that the interim rulemaking will lead to greater market entry, which will generate surplus for both technology firms and insurers. Again, this market is still in development, and the Department solicits comments on exactly how to predict the effect of this interim rulemaking on technology development.

Costs and Benefits to Insurers

The Department has little information on the future structure of the terrorism risk insurance market, and how this interim rulemaking affects that structure we continue to consider this matter. As stated above, this type of intervention could serve to lower the demand for insurance in the current market, thus the static effect on the profitability of insurers is negative. The benefits of the lower insurance burden to technology firms would be considered a cost to insurers; the static changes to insurance coverage would cause a transfer from insurers to technology firms. On the other hand, this type of intervention should serve to increase the surplus of insurers by making some types of insurance products possible that would have been prohibitive to customers or impossible for insurers to design in the absence of this interim rulemaking.

Costs and Benefits to the Public

The benefits to the public of the interim rulemaking were very difficult to put in dollar value terms since its ultimate objective is the development of new technologies that will help prevent or limit the damage from terrorist attacks. It is not possible to even determine whether these technologies could help prevent large or small scale attacks, as the SAFETY Act applies to a vast range of technologies, including products, services, software, and other forms of intellectual property that could have a widespread impact. In qualitative terms, the SAFETY Act removes a great deal of the risk and uncertainty associated with product liability and in the process creates a powerful incentive that will help fuel the development of critically needed antiterrorism technologies. Additionally, we expect the SAFETY Act to reduce the research and development costs of these technologies.

The tradeoff, however, may be that a greater number of technologies may be developed and qualify for this program that have a lower average effectiveness against terrorist attacks than technologies currently on the market, or technologies that would be developed in the absence of the interim rulemaking. In the absence of this rulemaking, strong liability discouragement implies that the fewer products that are deployed in support of antiterrorist efforts may be especially effective, since profit maximizing firms will always choose to develop the technologies with the highest demand first. It is the tentative conclusion of the Department that liability discouragement in this market is too strong or prohibitive, for the reasons mentioned above. The Department tentatively concludes that this interim rule will have positive net benefits to the public, since it serves to strike a better balance between consumer protection and technological development. The Department welcomes comments informing this tradeoff argument, and public input on whether this interim rulemaking does strike the correct balance.

Risks:

The United States remains at risk to terrorist attacks. It is in the public's interest to have this interim rule effective immediately because its aim is to foster the development and deployment of antiterrorism technologies. Additionally, this interim rule will clarify to the greatest extent possible the application of the liability protections created by the SAFETY Act, thus providing an instant incentive for prospective applicants to apply for its protections and for others to begin exploring new measures that will prevent or reduce acts of terrorism. The interim rule will also provide the Department with sufficient program

flexibility to address the specific circumstances of each particular request for SAFETY Act coverage. The application process is interactive. Those persons availing themselves of the protections afforded in this interim rule will also be interacting with the Department in the application process. Furthermore, the Department will continue to consider comments on this interim rule. Since the use of the liability protections afforded in this interim rulemaking is voluntary, there are no mandatory costs or burdens associated with the immediate implementation of this rule.

By having these provisions in place, the Department may begin processing applications for the liability protections and thus provide qualified sellers of antiterrorism technologies valuable incentives to develop and sell such technologies, as well as incentives for others to deploy such technologies. The purpose of those technologies is to detect, deter, mitigate, or assist in the recovery from a catastrophic act of terrorism. Thus, the Department finds that it is not only impracticable to delay an effective date of implementation, but it is also in the public's interest to make the interim rule effective upon publication in the Federal Register.

Timetable:

Action	Date	FR Cite
NPRM	07/11/03	68 FR 41419
NPRM Comment Period End	08/11/03	
Interim Final Rule	10/16/03	68 FR 59683
Interim Final Rule Comment Period End	12/15/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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DHS—OS

71. DEPARTMENT OF HOMELAND SECURITY (DHS) HUMAN RESOURCES MANAGEMENT SYSTEM

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

PL 107–296, Homeland Security Act

CFR Citation:

5 CFR 970

Legal Deadline:

None

Abstract:

The Department of Homeland Security and the Office of Personnel Management are issuing final regulations to establish a new human resources management system within DHS, as authorized by the Homeland Security Act of 2002. The affected subsystems include those governing basic pay, classification, performance management, labor relations, adverse actions, and employee appeals. These changes are designed to ensure the Department's human resources management system aligns with its critical mission requirements without compromising the statutorily protected civil service rights of its employees.

Statement of Need:

DHS and OPM have determined that the Department needs to establish a new human resources management system, one that is flexible and contemporary. The system is being designed to assure that the Department will be able to attract, retain, and reward a workforce that is able to meet the critical mission entrusted to the Department.

Summary of Legal Basis:

This rule is authorized by the Homeland Security Act of 2002, Public Law 107-296—specifically, 5 U.S.C. 9701(a).

Alternatives:

DHS and OPM could have elected not to change the current human resources management system. However, the current system does not satisfy the needs of the Department. For example, the current system rewards longevity of service, requires time-consuming bargaining procedures that could detract from the Department's ability to act expeditiously to enhance security, and results in lengthy delays for resolving issues relating to individual employees.

Within the framework of the new regulations, OM and DHS have considered many alternatives to specific regulatory requirements that were suggested by employee representatives and individuals who commented on the proposed rule and participated in the rulemaking process. An analysis of each alternative considered appears in the preamble to the regulation.

Anticipated Cost and Benefits:

DHS estimates that the overall costs associated with implementing the new DHS HR system will be approximately $130 million through fiscal year 2007. Costs will not equal or exceed $100 million in any one year.

Risks:

This description should include, if applicable, ''how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency'' (section 4(c)(1)(D) of E.O. 12866). The risk addressed is that the Department will be hampered in its efforts to implement needed security measures because, for example, it will not be able to attract and retain high-performing individuals or will not be able to take actions expeditiously. DHS is unable to quantify this risk or the extent to which the regulation will reduce it; however, it appears likely that the rule will contribute significantly to enhancing homeland security.

Timetable:

Action	Date	FR Cite
NPRM	02/20/04	69 FR 8030
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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Related RIN: Related to 3206–AK31

RIN: 1601–AA21

DHS—U.S. Coast Guard (USCG)

PROPOSED RULE STAGE

72. COMMERCIAL FISHING INDUSTRY VESSELS (USCG–2003–16158)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

46 USC 4502(a) to 4502(d)

CFR Citation:

46 CFR 28

Legal Deadline:

None

Abstract:

This rulemaking would add new and clarify existing rules for commercial fishing vessels in 46 CFR part 28. It would also establish rules on stability and watertight integrity for fishing vessels under 79 feet in length and institute regulations for the carriage of immersion suits in seasonally cold waters. To improve crew preparedness in case of an emergency, this project would also add requirements such as mandatory logging of already required drills, providing evidence of training, and ensuring that personnel required to be trained are current in their training. The project would amend 46 CFR part 28 to clarify and improve the consistency of the regulatory language so to aid in vessels compliance with the existing rules. This rulemaking supports the Coast Guard's strategic goals of maritime safety and protection of natural resources.

Statement of Need:

Commercial fishing remains one of the most dangerous industries in America. The Commercial Fishing Industry Vessel Safety Act of 1988 (the Act, codified in 46 U.S.C., chapter 45) mandated regulations intended to improve the safety of vessels operating in that industry. The Coast Guard first issued rules under the Act in 1991. This rulemaking would complete our earlier, incomplete efforts to require fishing vessels to carry immersion suits for their workers and to incorporate stability features in their design. We would also require vessels to document certain training and drill measures, require the use of high water alarms in some spaces, and revise or clarify some existing requirements, all to reflect industry and Coast Guard experience since passage of the Act.

Summary of Legal Basis:

46 U.S.C. 4502, as delegated by the Secretary of DHS to the Coast Guard.

Alternatives:

Regulatory alternatives considered and rejected: (a) maintain regulatory status quo; (b) full Coast Guard licensing of commercial fishermen and full Coast Guard inspection of commercial fishing; (c) adopt training-based certificate program for operators and crew. Nonregulatory alternatives considered: continue voluntary compliance with Coast Guard 1986 guidelines.

Anticipated Cost and Benefits:

The bulk of the costs are expected to come from the stability and watertight integrity requirements as well as the requirement for carrying immersion suits in seasonally cold waters. Exempting existing vessels from the stability and watertight regulations would reduce the costs considerably. The benefits of this rule would be calculated by isolating the specific marine-casualty cases over a suitable time that could have been prevented or mitigated by the rule. Cases will be retrieved from a Coast Guard database. After each casualty has been looked at individually to establish a causal link between the regulation in question and the correlating benefit, damages to vessels, lives lost, and injuries will be quantified and given dollar values.

Risks:

Commercial fishing continues to rank at or near the top of the most hazardous occupations in the United States. Coast Guard data indicate that regulations adopted under the 1988 Act have had a significant impact in reducing industry casualties, but that impact has leveled off. Studies suggest that this rulemaking, by targeting significant remaining problem areas, could have an additional significant impact on casualty reduction.

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Tribal

Agency Contact:

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DHS—USCG

FINAL RULE STAGE

73. POST CASUALTY DRUG AND ALCOHOL TESTING (USCG–2001–8773)

Priority:

Other Significant

Legal Authority:

PL 105–383, sec 304

CFR Citation:

46 CFR 4

Legal Deadline:

None

Abstract:

This project will revise the requirements for chemical testing following a serious marine incident. The revision will establish procedures to ensure that alcohol testing be conducted within two hours of a serious marine incident, as required by the Coast Guard Authorization Act of 1998. The rule will also make additional minor procedural changes to the part. This rule supports the Coast Guard strategic goal of maritime safety.

Statement of Need:

The Coast Guard proposes changing the alcohol testing requirements for commercial vessels following a serious marine incident. The 1998 Coast Guard Authorization Act requires the Coast Guard to establish procedures ensuring alcohol testing is conducted within two hours of a serious marine casualty. The Coast Guard proposes to establish requirements for testing within the statutory time limits, to expand the existing requirements for commercial vessels to have alcohol-testing devices on board, and to authorize use of a wider variety of testing devices. This rulemaking would also make additional minor procedural changes to part 4, including a time limit for conducting drug testing following a serious marine incident. This action is required to

comply with the 1998 Coast Guard Authorization Act.

Summary of Legal Basis:

In 1998, Congress passed Public Law 105-383, which revised title 46, U.S. Code, by adding a new section 2303a, Post Serious Marine Casualty Alcohol Testing (hereafter section 2303a). Section 2303a requires the Coast Guard to establish procedures ensuring that after a serious marine casualty occurs, required alcohol testing is conducted no later than two hours after the casualty occurred. If the alcohol testing cannot be conducted within that timeframe because of safety concerns directly related to the casualty, section 2303a requires the alcohol testing to be conducted as soon thereafter as the safety concerns have been adequately addressed to permit such testing. However, section 2303a prohibits us from requiring alcohol testing to be conducted more than eight hours after the casualty occurs.

Alternatives:

We would use the standard rulemaking process to develop regulations for serious marine incident alcohol testing. Nonregulatory alternatives such as Navigation and Vessel Inspection Circulars and Marine Safety Manual have been considered and may be used for the development of policy and directives to provide the maritime industry and our field offices guidelines for implementation of the regulation. Nonregulatory alternatives cannot be substituted for the standards being proposed with this rule.

Anticipated Cost and Benefits:

A cost analysis was prepared and published with the notice of proposed rulemaking on February 28, 2003 (67 FR 9622). The benefits of this action will be to ensure that alcohol tests are conducted after serious marine incidents so that the public will be informed whether or not alcohol use contributed to the incident. This action will also deter improper alcohol use by commercial vessel personnel.

Risks:

Under current regulations, the risk of not obtaining a valid alcohol test after a serious marine incident is high because specific time frames are not given. This action will significantly reduce the risk of not obtaining a valid test.

Timetable:

Action	Date	FR Cite
NPRM	02/28/03	68 FR 9622
NPRM Comment Period End	06/30/03	
Notice of Public Meeting; Reopening of Comment Period	08/25/03	68 FR 50992
NPRM; Reopening of Comment Period	10/21/03	68 FR 60073
Comment Period End	11/20/03	
Final Rule	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

Additional Information:

Transferred from RIN 2115-AG07

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 1625–AA27

DHS—Directorate of Border and Transportation Security (BTS)

FINAL RULE STAGE

74. • UNITED STATES VISITOR AND IMMIGRANT STATUS INDICATOR TECHNOLOGY PROGRAM (US–VISIT); AUTH. TO COLLECT BIOMETRIC DATA FROM ADDIT'L TRAVELERS AND EXPANSION TO 50 MOST HIGHLY TRAFFICKED LAND BORDER PORTS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

8 USC 1365a; . . .

CFR Citation:

8 CFR 215; 8 CFR 235; 8 CFR 252

Legal Deadline:

Other, Statutory, September 30, 2004, Publication deadline to meet representations made to Congress.

Abstract:

This interim rule was signed by the Secretary on August 26, 2004, and published in the Federal Register on August 31, 2004. This interim rule expands US-VISIT to the 50 most highly trafficked land border ports of entry in the United States. This interim rule also will require persons entering the United States without visas under the Visa Waiver Program (VWP) to provide biometric, biographic, and other information required under US-VISIT.

Statement of Need:

On January 5, 2004, the Department established the United States Visitor and Immigrant Status Technology Program (US-VISIT), an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. The US-VISIT Program is integral to strengthening the security of the United States. US-VISIT requires aliens seeking to be admitted to the United States pursuant to nonimmigrant visas to provide fingerprints, photographs, or other biometric identifiers upon arrival in, or departure from, the United States at designated ports of entry and departure.

This interim rule is necessary to safeguard the public safety by expanding the US-VISIT program to the 50 most highly trafficked land border ports of entry in the United States. Further, this interim rule authorizes the Department to obtain biometric information from persons traveling without visas under the VWP. Enrolling VWP travelers in US-VISIT will allow the Department to conduct biometric-based checks at time of a VWP traveler's application for admission into the United States and thus greatly reduces the risk that the VWP traveler's identity could subsequently be used by another traveler seeking to enter the United States.

Summary of Legal Basis:

The Department established US-VISIT in accordance with several statutory mandates that collectively require the Department to create an integrated, automated entry and exit system (entry-exit system) that records the arrival and departure of aliens; verifies the

identities of aliens; and authenticates travel documents presented by such aliens through the comparison of biometric identifiers. Aliens subject to US-VISIT requirements may be required to provide fingerprints, photographs, or other biometric identifiers upon arrival in, or departure from, the United States. The statutory mandates which authorize the Department to establish US-VISIT include, but are not limited to, section 2(a) of the Immigration and Naturalization Service Data Management Improvement Act of 2000 (DMIA), Public Law 106-215; section 205 of the Visa Waiver Permanent Program Act of 2000 (VWPPA), Public Law 106-396; section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107-56; and section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act) Public Law 107-173.

Under DMIA (8 U.S.C. section 1365a(d)), the Department is required to implement US-VISIT at the 50 most highly trafficked land border ports of entry no later than December 31, 2004. This interim rule allows the Department to meet that statutory deadline.

Alternatives:

The Department will continue to consider public comments and determine whether possible supplemental regulations are needed as we gain experience with implementing this program.

Anticipated Cost and Benefits:

The anticipated benefits of this rule include: (1) improving identification of travelers who may present threats to public safety and the national security of the United States through use of biometric identifiers; (2) enhancing the government's ability to match an alien's fingerprints and photographs to other law enforcement or intelligence data associated with identical biometrics; (3) improving the ability of the United States to identify individuals who may be inadmissible to the United States; (4) improving cooperation across international, Federal, State, and local agencies through better access to data on foreign nationals who may pose a threat to the United States; (5) improving facilitation of legitimate travel and commerce by improving the timeliness and accuracy of the determination of a traveler's immigration status and admissibility; (6) enhancing enforcement of immigration laws, contributing to the increased integrity of the system of immigration in the United States, including the collection of more complete arrival and departure information on VWP travelers and aliens who seek to enter the United States through a land border port of entry; (7) reducing fraud, undetected impostors, and identity theft; and, (8) increasing integrity within the VWP program, through better data collection, tracking, and identification, allowing better compliance monitoring through increased and more accurate data.

The costs associated with implementation of this interim rule for travelers not otherwise exempt from US-VISIT requirements include an increase of approximately 15 seconds in inspection processing time per applicant over the current average inspection time of one minute, whether at a land, air, or sea port-of-entry. No significant difference is anticipated in the processing of an alien traveling with a visa as compared to a traveler without a visa under VWP.

The Department anticipates that, by December 31, 2005, when US-VISIT is required to be implemed at all land border ports of entry in the United States, approximately 3.2 million nonimmigrant applicants for Form I-94 issuance could be affected at the designated land ports-of-entry. The Department, when conducting a cost-benefit analysis for the January 5, 2004, interim rule, estimated that the time required to obtain the biometric information required under US-VISIT was approximately 15 seconds per person. Since the implementation of US-VISIT at air and sea ports on January 5, 2004, the Department has not received reports of average processing times greater than 15 seconds nor any significant delays for travelers resulting from the collection of biometric information under US-VISIT. The limited 15 second processing time was not expected to cause significant delays for travelers at air or sea ports because persons not required to provide biometrics (e.g. U.S. citizens, lawful permanent residents, and visa-exempt non-immigrants) generally are routed through different inspection lines, thereby easing any impact of the biometric collection process. Because the same biometric information will be obtained at land border ports of entry, through a similar secondary inspection process, DHS does not anticipate any increase in the 15 second processing time or any significant delay for travelers at land border ports of entry in the United Stated.

In addition, over time, the efficiency with which the process is employed will increase, and the process can be expected to improve further.

The additional costs to the Government and the public to implement the requirements of this rule are approximately $155 million for all 50 ports during fiscal year 2004, or approximately $3.1 million at each of the ports. These expenditures are required to upgrade the information technology hardware (i.e. desktop hardware and peripherals, upgrading local and wide area networks) at the affected ports.

Risks:

The United States remains at risk to terrorist attacks. Since its implementation in January 2004, US-VISIT has proven that the use of biometrics to check identity and background is a highly effective law enforcement tool. US-VISIT has already prevented 196 criminal aliens from entering the United States, even though the program is currently operating on a limited basis. Expanding the classes of aliens subject to US-VISIT to VWP aliens immediately should result in additional aliens being identified on ''lookout'' lists being prevented admission or arrested as fugitives or wanted criminals. Further, expanding the program to include the major land border ports-of-entry should result in even more ''hits.'' Accordingly, expanding both the classes of aliens subject to US-VISIT, as well as the location of ports where US-VISIT will be implemented, will have a considerable and positive effect on national security. Any delay in the implementation of this interim rule to allow for public comment may increase the opportunity for aliens who may otherwise not be admissible to the United States, due to suspected terrorist affiliations or criminal records, to enter the United States using false identifies, and false, fraudulent, or stolen passports or other travel documents.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/31/04	69 FR 53318
Interim Final Rule Effective	09/30/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Public Compliance Cost:

; Yearly Recurring Cost: $155000000; Base Year for Dollar Estimates: 2004

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Related RIN: Related to 1651–AA54

RIN: 1650–AA00

DHS—Bureau of Immigration and Customs Enforcement (BICE)

PRERULE STAGE

75. ● ESTABLISHING PROCEDURES FOR RECERTIFICATION OF SCHOOLS APPROVED BY THE STUDENT AND EXCHANGE VISITOR PROGRAM (SEVP) TO ENROLL F OR M NONIMMIGRANT STUDENTS

Priority:

Other Significant

Legal Authority:

PL 107–173, sec 502; 8 USC 1356(m); PL 107–56

CFR Citation:

8 CFR 103; 8 CFR 214

Legal Deadline:

Final, Statutory, October 2004, Schools become eligible for recertification as early as October 1, 2004.

The Uniting and Strengthening America by Providing Appropriate Controls Required to Intercept and Obstruct Terrorism Act (USA PARTRIOT Act), Public Law 107-56, mandated that SEVIS be completely implemented before January 1, 2003. Both Directive No. 2 and the Border Security Act require DHS to conduct periodic reviews of all schools within two years of the initial approval of their SEVP certification, and every two years thereafter. In order to meet this mandate.

Abstract:

This interim rule amends DHS regulations governing recertification of schools approved by the Student and Exchange Visitor Program (SEVP) for attendance by F or M nonimmigrant students. It sets the fee amount for recertification at a flat nonrefundable rate of $580 dollars, adds a provision to allow a school to voluntarily withdraw from its certification, and clarifies procedures for school operation with regard to nonimmigrant students during the review process and following withdrawal of certification.

On October 30, 2001, the President issued Homeland Security Directive No. 2, requiring periodic reviews of all institutions certified to receive nonimmigrant students. The Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107-173, enacted May 14, 2002, also requires a periodic review of approved schools every two years. This rule is being promulgated consistent with these mandates.

Statement of Need:

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act), Public Law 107-56, mandated that SEVIS be fully implemented prior to January 1, 2003. Both Directive 2, and the Border Security Act require DHS to conduct periodic reviews of all schools within two years of their initial SEVP certification and every two years thereafter. In order to meet this mandate and because the periodic review of all approved schools is important to safeguarding against abuse of American openness to foreign students by foreign terrorists, this rule must be effective immediately. Vital national security concerns that underpin Directive No. 2, the USA PATRIOT Act, and the Border Security Act might be placed at risk by observing the requirements of 5 U.S.C. 533(b) and (d). Additionally, the provision for the recertification fee has been in 8 CFR 124.3(h)(3) since September 25, 2002.

Summary of Legal Basis:

On October 30, 2001, the President issued Homeland Security Directive No. 2 (Directive 2) requiring DHS to conduct periodic reviews of all institutions approved to accept nonimmigrant students. More recently, section 502 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107-173, enacted May 14, 2002, required DHS to review all schools approved for attendance by F or M nonimmigrant students within two years of the passage of the Border Security Act. Further, it mandates that DHS recertify the approval of all schools every two years thereafter. 8 U.S.C. 1356(m) requires the recovery of the full cost of providing adjudication services for immigration-related benefits. Because certification allows schools to have their foreign students admitted to the United States as nonimmigrants under certain visa categories, certification constitutes a benefit under title 8 and is subject to the 1356(m) requirement. The requirement for recertification and the intent to charge a fee was established in 67 FR 60107 (September 25, 2002). At that time, it was anticipated that the cost of recertification would be comparable to the cost of initial certification.

Alternatives:

None

Anticipated Cost and Benefits:

8 U.S.C. 1356(m) requires the recovery of the full cost of providing adjudication services for immigration-related benefits. Because certification allows schools to have their foreign students admitted to the United States as nonimmigrants under certain visa categories, certification constitutes a benefit under title 8 and is subject to the 1356(m) requirement.

The requirement for recertification and the intent to charge a fee was established in 67 FR 60107 (September 25, 2002). At that time, it was anticipated that the cost of recertification would be comparable to the cost of initial certification.

Combined with a fee collected from nonimmigrant F and M students and J exchange visitors, the fees in this rule are intended to meet costs of SEVP.

Risks:

Timely implementation of this rule is critical to continued fulfillment of the SEVP mission.

Timetable:

Action	Date	FR Cite
ANPRM	01/00/05	
NPRM	06/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Additional Information:

ICE No. 2329-04

Agency Contact:

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BILLING CODE 4410–10–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The regulatory plan for the Department of Housing and Urban Development for fiscal year (FY) 2005 highlights the priority regulations and policy initiatives directed toward the achievement of HUD's traditional goals of increasing the supply of affordable housing (rental and homeownership), ensuring equal opportunity for housing, and promoting jobs and economic development, as well as its more recent goal of restoring the public's trust in HUD. These goals are embodied in HUD's mission and its strategic goals for FY 2005.

Under the leadership of Secretary Alphonso Jackson, HUD approaches the new fiscal year with a renewed sense of commitment to its mission and goals and greater accountability for its performance. Reflecting HUD's role as the primary Federal agency responsible for addressing America's housing needs and improving and developing the nation's communities, the Secretary's regulatory plan is designed to implement HUD's broad, but focused, strategic goals and objectives. HUD's strategic goals and objectives are to:

1. Increase homeownership opportunities;
2. Promote decent, affordable housing;
3. Strengthen communities;
4. Ensure equal opportunity in housing;
5. Embrace high standards of ethics, management, and accountability; and
6. Promote participation of faith-based and community organizations.

Under the leadership of Secretary Jackson, HUD's regulatory plan for FY 2005 builds upon the successes of the previous fiscal year through regulations that are designed to expand homeownership opportunities, promote decent, affordable housing, particularly for the most vulnerable Americans, and strengthen America's communities.

Priority: Expanding Homeownership through Educating Potential First-time Homebuyers

Helping more low- and moderate-income Americans become homeowners is a national priority. Under the leadership of Secretary Jackson, the Department is committed to helping everyone, especially first-time homebuyers and minority families, take advantage of new opportunities to own their own homes. The reasons for this priority are clear. Homeownership benefits individual families by helping them build economic security, and it fosters healthy, vibrant communities. Owning a home is good for families and provides a sense of security that allows families to build wealth. Homeownership is also good for communities. Homeowners work to maintain the value of their investment, which translates into a greater concern for neighborhoods and surrounding communities. A family that owns its home is more likely to upgrade the property, to take pride in its neighborhood, and to feel invested in the community. When citizens become homeowners, they become stakeholders as well. By increasing the ranks of stakeholders, communities not only enjoy increased stability, but also benefit from a new spirit of revitalization.

Regulatory Action: Housing Counseling

In order to expand homeownership, the Department is working to ensure that those who purchase a home are better able to avoid circumstances that might result in foreclosure. An educated homebuyer is the best defense against abusive lending practices, known as predatory lending, that have too often been used by unscrupulous lenders. One of the best ways to avoid future problems and promote homeownership is to educate families about the process and responsibilities of homeownership. Housing counseling services can also help low- and moderate-income renters improve their access to affordable housing by increasing their abilities to budget for needed home expenses and regular rent payments, enhancing their housing conditions, and helping them to avoid rental delinquency. These counseling services have proven to be extremely important in helping families purchase a home and keep it in times of financial stress. With appropriate advice, families coping with financial difficulties are more likely to survive tough times with their homes intact. As a result, HUD is pursuing rulemaking to codify the key provisions of its housing counseling program. Housing counseling services include assisting eligible homebuyers to seek out and purchase homes; helping renters locate and qualify for assisted rental units; helping eligible homebuyers obtain affordable housing; assisting homeowners to avoid foreclosures; assisting renters to avoid evictions; helping the homeless find temporary or permanent shelter; reporting fair housing or discrimination complaints or both; and addressing other housing problems.

Priority: Expanding Homeownership by Helping Existing Homeowners Keep Their Homes

HUD is continuing its efforts to assist first-time homeowners maintain their homeownership status. Among the ways HUD is advancing this goal is through foreclosure prevention activities and better monitoring of appraisals. In particular, the requirement imposed on Federal Housing Administration (FHA) lenders to engage in loss mitigation has proven a successful strategy for assisting homeowners keep their homes and will be strengthened.

Regulatory Action: Treble Damages For Failure to Engage in Loss Mitigation

The HUD appropriations act for fiscal year 1999 amended the National Housing Act (NHA) to add a triple penalty for failure to engage in appropriate loss mitigation to the existing civil money penalty system. Section 230(a) of title II of the NHA, as amended, makes it mandatory for the mortgagee, upon the default of a single-family mortgage, to engage in loss mitigation actions, including, but not limited to, special forbearance, loan modification, and deeds in lieu of foreclosure, for the purpose of providing alternatives to foreclosure. On April 14, 2004, HUD published a proposed rule that would amend HUD's civil money penalty regulations to reflect HUD's authorization to impose treble damages on a mortgagee for any mortgage for which the mortgagee had a duty but failed to engage in appropriate loss mitigation actions. The proposed rule followed publication of an advanced notice of proposed rulemaking (ANPRM) and took into consideration public comments on the ANPRM. HUD intends to give priority to making this rule final.

Priority: Promote Decent Affordable Housing

While seeking to expand homeownership opportunities, HUD recognizes that homeownership may not be practical for all families. To help these families obtain safe, decent, and affordable housing, HUD's regulatory plan will strengthen its current rental assistance programs. HUD will focus on improving the physical quality of public and assisted housing and on improving housing agencies' utilization of assistance.

Regulatory Action: Public Housing Operating Fund Program

On October 21, 1998, the Congress enacted the Quality Housing and Work Responsibility Act of 1998 (QHWRA), which made sweeping changes to HUD's public and assisted housing programs. Section 519 of QHWRA amended section 9 of the United States Housing Act of 1937 to establish an operating fund for the purpose of making assistance available to public housing agencies (PHAs) for the operation and management of public housing. On March 29, 2001, HUD published an interim rule, developed through negotiated rulemaking, implementing the operating fund.

Since that time, HUD, as directed by Congress, contracted with the Harvard University Graduate School of Design to conduct a study of the cost incurred in operating a well run public housing agency (the Harvard Cost Study). The Harvard University Graduate School of Design performed extensive research on the issue of calculating the expense level of well managed public housing and conducted a number of public meetings to allow for an exchange of thoughts and expectations with PHAs. The Harvard University Graduate School of Design issued its final report on June 6, 2003.

On March 10, 2004, HUD announced the establishment of its Negotiated Rulemaking Committee on the Operating Fund. The goal of the committee was to provide advice and recommendations for a rule for effectuating changes to the Operating Fund Program in response to the Harvard Cost Study. The committee held four meetings to complete its work. Operating by consensus decisionmaking and under its approved charter and protocols, the committee developed a rule, the goal of which is to improve and clarify the current regulations governing the Operating Fund Program. The rule also takes into consideration the recommendations contained in the Harvard Cost Study.

Regulatory Action: Project-Based Voucher Program

The Project-Based Voucher Program replaces the former Project-Based Certificate Program and provides PHAs with flexibility in administering the program that will assist PHAs in increasing housing opportunities. The Project-Based Program was authorized by law in 1998, as part of the statutory merger of the certificate and voucher tenant-based programs. In 2000, the Congress substantially revised the project-based voucher law. The statutory revisions of 2000 made a number of changes to the program including permitting a PHA to pay project-based assistance for a term of up to 10 years, permitting a PHA to provide project-based assistance for existing housing that does not need rehabilitation, as well as for newly constructed or rehabilitated housing, and allowing a family to move from a project-based voucher unit after one year and transfer to the PHA's tenant-based voucher program. Initial guidance on the new law was provided to PHAs and residents in January 2001. On March 18, 2004, HUD published a proposed rule that would begin the process of providing the more permanent regulatory framework for this new program. HUD intends to give priority to making this rule final.

Regulatory Action: Public Housing Capital Fund Program

QHWRA also amended section 9 of the United States Housing Act of 1937 to establish a capital fund for the purpose of making assistance available to PHAs for the development, financing, and modernization of public housing. This proposed rule would establish the full regulatory framework for the capital fund program. This proposed rule would combine several legacy programs. Many of the requirements of these programs are redundant, overlapping, and in need of updating. In addition, new components, such as capital fund financing, capital-fund-only assistance, and homeownership, need program guidance. HUD is embarking on a comprehensive review of the legacy programs to streamline, shorten, and combine the requirements into a single regulation.

Regulatory Action: Revisions to Indian Housing Block Grant Program

HUD's policy to promote the general welfare by meeting the national goal of providing decent, safe, and affordable housing extends to the nation's over 562 federally recognized Indian tribes. HUD's tribal partners are diverse. They are located on Indian reservations, in Alaska Native villages, and in other traditional Indian areas. In addressing tribal housing issues, HUD is committed to the principle of government-to-government relations with federally recognized Indian tribes. In this regard, HUD established a negotiated rulemaking committee to develop several revisions to the Indian Housing Block Grant Program allocation formula authorized under section 302 of the Native American Housing Assistance and Self-Determination Act of 1996. The first meeting of the committee took place in April 2003. Overall, the committee met a total of seven times, with the final meeting held in January 2004. Based on the committee's agreement to operate by consensus rulemaking and under its approved charter and protocols, the committee undertook a comprehensive review of the Indian Housing Block Grant (IHBG) formula. The committee identified certain areas of the IHBG formula that required clarification, were outdated, or were not operating as intended by the original negotiated rulemaking committee. This proposed rule reflects the consensus decisions as reached by the committee during the negotiated rulemaking process on the best way to address these issues.

Priority: Strengthen Communities

HUD is committed to preserving America's cities as vibrant hubs of commerce and making communities better places to live, work, and raise a family. Toward this end, many State and local governments depend upon HUD and its system of grants to support community development projects, revive troubled neighborhoods, and spark urban renewal. HUD is committed to helping communities address development priorities through local decisionmaking. HUD will also move to ensure that its community development partners have greater flexibility to address locally determined priorities and maintain long-term prosperity.

Regulatory Action: Streamlining the Consolidated Plan

In fiscal year 2002, the President's Management Agenda directed HUD to work with local stakeholders to streamline the consolidated plan, making it more results-oriented and useful to communities in assessing their own progress toward addressing the problems of low-income areas. To launch this activity, HUD held several focus group sessions with grantees and other stakeholders in 2002 to discuss ways to streamline the consolidated plan and improve performance measurement. HUD also convened a national planning meeting to introduce the concept of the Consolidated Plan Improvement Initiative to a national audience that included public interest groups, grantees, and other stakeholders. At this meeting, six working groups were established to assess alternative planning requirements, review performance measures, and identify communities that would be willing to test pilots of alternative planning procedures.

This proposed rule resulted from an extensive consultation process that involved stakeholders representing the

interests of State and local governments and low-income persons. The proposed rule builds on the existing framework that established the consolidated plan as a collaborative process whereby a community establishes a unified plan of community development actions. That framework gives States and local governments the flexibility to use existing plans and strategies to help citizens understand the jurisdiction's priority needs and assess the jurisdiction's progress toward meeting identified goals and objectives through measurable indicators.

Regulatory Action: Empowerment Zone Resident Benefit and Economic Development

In December 1998, HUD designated 15 new urban Empowerment Zones (EZs). The 1998 designation is referred to as Round II. These designees are able to use tax-incentive packages to open new businesses, provide thousands of new jobs, rehabilitate and build new housing, and change lives for the better in urban and rural areas throughout the Nation. This EZ initiative offers communities opportunities and resources to overcome seemingly insurmountable problems by providing incentives for new business, affordable housing, and jobs. HUD believes that the opportunity to prosper through tax incentives is a major shift in the paradigm of how government creates the atmosphere to stimulate economic revitalization.

This regulation would ensure that Round II EZs assure that a certain level of the benefits resulting from the use of and the expenditure of associated grant funds will accrue to persons who reside within the EZ. Accordingly, this regulation would require an implementation plan submitted for HUD approval by EZs to describe their planned use of HUD EZ grants funds to meet one of three standards of resident benefit: a principal benefit standard, a proportional benefit standard, or an exception criterion for determining the amount of HUD EZ grant funds that may be used to fund a particular project or activity described in an implementation plan. This rule would also provide more specific direction on the restriction contained in the statutory language appropriating the funds that the HUD EZ grant funds be used ''in conjunction with economic development activities'' and sets standards for applying the restriction to individual activities that may be assisted through the use of the funds.

The Priority Regulations that Comprise HUD's FY 2005 Regulatory Plan

A more detailed description of the priority regulations that comprise HUD's FY 2005 regulatory plan follows.

HUD—Office of the Secretary (HUDSEC)

PROPOSED RULE STAGE

76. CONSOLIDATED PLAN AMENDMENTS (FR–4923)

Priority:

Other Significant

Legal Authority:

42 USC 3535(d); 42 USC 3601 to 3619; 42 USC 5301 to 5315; 42 USC 12701 to 12711; 42 USC 12741 to 12756; 42 USC 12901 to 12912; . . .

CFR Citation:

24 CFR 91

Legal Deadline:

None

Abstract:

This rule would amend the consolidated plan regulations to make clarifying and streamlining changes that are expected to make the consolidated plan more results-oriented and useful to communities in assessing their own progress toward addressing the problems of low-income areas. The proposed rule would eliminate some obsolete and redundant provisions and make other changes that would conform the consolidated plan regulations with HUD's public housing regulations that govern the Public Housing Agency Plan.

Statement of Need:

This rule resulted from an extensive consultation process that involved stakeholders representing the interests of State and local governments and low-income persons. The general view of the involved stakeholders was that the consolidated plan should be a concise, action-oriented management tool that would be more understandable to the public and more useful to decisionmakers in the community.

Summary of Legal Basis:

The Consolidated Plan incorporates the planning activities of the Comprehensive Housing Affordability Strategy (CHAS), enacted by the Cranston-Gonzalez National Affordable Housing Act of 1990 and the document submission requirements for four formula grant programs: Community Development Block Grant, HOME, Emergency Shelter Grant, and Housing Opportunities for Persons with AIDS (HOPWA).

Alternatives:

This action is a rule of general applicability and future effect that does not fall into any of the rulemaking exceptions.

Anticipated Cost and Benefits:

This rule is based on an extensive consultation process that involved numerous stakeholders representing the interests of State and local governments and low-income persons. Anticipated changes benefit State and local governments by providing a streamlined reporting process that is more internally consistent and conforms to recent statutory changes. At the same time, this rule should have minimal impact on State and local governments.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HUD—HUDSEC

FINAL RULE STAGE

77. TREBLE DAMAGES FOR FAILURE TO ENGAGE IN LOSS MITIGATION (FR–4553)

Priority:

Other Significant

Legal Authority:

12 USC 1715u; 12 USC 1735f–14; 12 USC 1701q–1; 12 USC 1703; 1735f–15; 15 USC 1717a; 28 USC 2641 note; 12 USC 1709; 12 USC 1710; 12 USC 1715b; 42 USC 3535(d)

CFR Citation:

24 CFR 30; 24 CFR 203

Legal Deadline:

None

Abstract:

This rule will implement a statutory triple penalty for failure to engage in loss mitigation to the existing penalty system, and will also describe the process for assessing treble damages when a mortgagee fails to engage in loss mitigation activities with cooperative and qualified mortgagors. The rule will amend 24 CFR parts 30 and 203 to set out the maximum penalty amounts for those servicing mortgagees that fail to engage in loss mitigation. Mortgagees that fail to engage in loss mitigation may be subject to penalties of three times the amount of any mortgage insurance benefits claimed by the mortgagee. In assessing loss mitigation performance, this rule will rank mortgagees into four tiers, with tier 1 representing the highest loss mitigation performance, and tier 4 the lowest (i.e., a systematic failure to engage in loss mitigation). This rule will focus primarily on the tier 4 performers.

Statement of Need:

This rule implements a law authorizing HUD to assess civil money penalties for specific types of mortgage lender violations, including failure to engage in loss mitigation. The law also directs HUD to implement regulations as it determines necessary to implement the civil money penalty provisions. This rule is necessary to encourage certain lenders that rarely engage in loss mitigation activities to do so. Failure to engage in loss mitigation leads to additional claims on FHA's insurance funds. Greater emphasis by certain lenders on loss mitigation will act to reduce those claims and enhance the health of the funds.

Summary of Legal Basis:

Section 230 of the National Housing Act (NHA), (12 U.S.C. 1715u), requires mortgage lenders utilizing FHA-insured financing to engage in loss mitigation actions upon the default of any insured mortgage. Section 536(b)(1)(I) of the NHA (12 U.S.C. 1735f-14(b)(1)(I)) includes failure to engage in loss mitigation among the activities for which HUD may assess civil penalties. Section 536(a) of the NHA (12 U.S.C. 1735f-14(a)) provides that in the case of failure to engage in loss mitigation, the penalty may be tripled. Section 536(h) of the NHA (12 U.S.C. 1735f-14(h)) provides that HUD shall issue regulations to implement these provisions as it determines is appropriate.

Alternatives:

This action is a rule of general applicability and future effect that does not fall into any of the rulemaking exceptions. Therefore, rulemaking is the only available procedure to implement these provisions.

Anticipated Cost and Benefits:

This rule authorizes the imposition of a penalty on those lenders that have poor records in the area of loss mitigation. The announcement of the availability of treble damages as an enforcement tool should encourage lenders to engage in loss mitigation activities upon default by mortgagors, with adherence to statutorily required loss mitigation activities the rule is expected to help safeguard the insurance fund in the form of reduced claims on the insurance fund and hence reduced payouts.

Risks:

This rule imposes no risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
ANPRM	12/06/00	65 FR 76520
ANPRM Comment Period End	02/05/01	
NPRM	04/14/04	69 FR 19906
NPRM Comment Period End	06/14/04	
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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HUD—Office of Housing (OH)

PROPOSED RULE STAGE

78. HOUSING COUNSELING PROGRAM (FR–4798)

Priority:

Other Significant

Legal Authority:

12 USC 1701; 42 USC 3535(d)

CFR Citation:

24 CFR 214

Legal Deadline:

None

Abstract:

This rule would establish regulations for the Department's Housing Counseling program, as authorized by the Housing and Urban Development Act of 1968, and for which, the past several years, notices of funding availability are issued on an annual basis. Establishment of regulations would assist homeowners and tenants in improving their housing conditions and in meeting the responsibilities of homeownership and tenancy. This rule would adopt, without substantive change, the housing counseling program requirements with which grantees and Housing Counseling agencies are already familiar.

Statement of Need:

Establishment of regulations would reflect the permanency and importance of this program.

Summary of Legal Basis:

Section 106(a) of the Housing and Urban Development Act of 1968 defines housing counseling services as ''counseling and advice to tenants and homeowners with respect to property maintenance, financial management and such other matters as may be appropriate to assist them in improving

their housing conditions and in meeting the responsibilities of homeownership.'' Under section 106, HUD may provide counseling directly, or may enter into contracts with, or make grants to, and provide other types of assistance to eligible private or public organizations with special competence and knowledge in providing housing counseling to low- and moderate-income families for the purposes of providing counseling and advice to tenants and homeowners. Current law at 12 U.S.C. 1701x extends eligibility of housing counseling services for virtually all defaulting homeowners and tenants. In addition, section 255(d)(2)(B) of the National Housing Act, which authorizes mortgage insurance of home equity conversion mortgages (HECM) for elderly homeowners, requires that a HECM must be executed by a mortgagor who received ''adequate counseling by a third party (other than the lender).'' Certain other HUD housing programs may require participation in the Housing Counseling program.

Alternatives:

Under the current program, grantees and HUD-approved counseling agencies must refer to notices of funding availability and HUD handbooks for specific program procedures. The practice of consulting numerous sources for program information presents confusion especially when presented with termination of HUD-approved status and other related actions. Since the program has been funded annually to date, regulations are the appropriate vehicle to establish program requirements.

Anticipated Cost and Benefits:

This rule will benefit tenants, homeowners, potential homebuyers, and the homeless. Housing counseling assists eligible homebuyers to seek out and purchase homes, helps renters locate and qualify for assisted rental units, helps eligible homebuyers to obtain affordable housing and avoid foreclosures, and helps the homeless to find temporary or permanent shelter. The program will not add additional costs to housing counseling agencies or those who seek housing counseling services.

Risks:

This rule poses no risk to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HUD—Office of Community Planning and Development (CPD)

PROPOSED RULE STAGE

79. EMPOWERMENT ZONES: RESIDENT BENEFIT AND ECONOMIC DEVELOPMENT STANDARDS FOR GRANTS (FR–4853)

Priority:

Other Significant

Legal Authority:

26 USC 1391; 42 USC 3535(d)

CFR Citation:

24 CFR 598

Legal Deadline:

None

Abstract:

This rule proposes to establish review standards for determining whether grant funds provided to Empowerment Zones will provide a sufficient level of benefit to residents and also be used in conjunction with economic development activities consistent with the strategic plan for each Empowerment Zone (EZ).

Statement of Need:

HUD has determined that it is appropriate to require a level of resident benefit from the use of funds appropriated by Congress for Round II EZs (HUD EZ Grant Funds). EZ residents are intended to be among the principal beneficiaries of the EZ program and requiring that HUD EZ Grant Funds provide a direct benefit to EZ residents is consistent with promoting such a result. In addition, HUD EZ Grant Funds have generally been accompanied by the explicit requirement that the funds be used ''in conjunction with economic development activities consistent with the strategic plan for each EZ.'' A number of questions have arisen about whether particular planned activities would fall within this statutory restriction. This rule proposes the standards that are to be used for determining whether an activity proposed for assistance will meet that requirement.

Summary of Legal Basis:

The strategic plan for an EZ required under 26 U.S.C. 1391 must address, among other issues, the extent to which poor persons and families will be empowered to become economically self-sufficient. The statutes appropriating HUD EZ Grant Funds generally require the funds to be used in conjunction with economic development activities.

Alternatives:

The changes made by this rule would modify regulatory requirements and, therefore, must also be promulgated through regulation. Nonregulatory alternatives (such as through HUD notice or handbook) would not be binding upon HUD program participants.

Anticipated Cost and Benefits:

The requirements proposed by this rule would not impact the costs of using HUD EZ Grant Funds, but would only provide direction for the use of such funds consistent with the purposes of EZ designation. The benefits of having this direction is that it provides more certainty for planning and executing activities that will promote the purposes of the authorizing legislation.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local

Agency Contact:

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Office of Community Planning and Development
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RIN: 2506–AC16

HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

80. CAPITAL FUND PROGRAM (FR–4880)

Priority:

Other Significant

Legal Authority:

42 USC 1437g; 42 USC 1437z–7; 42 USC 3535(d)

CFR Citation:

24 CFR 905

Legal Deadline:

None

Abstract:

This rule will implement the regulatory framework for the Capital Fund Program for the capital and management improvement needs of public housing agencies that will govern the use of the assistance made available from the Capital Fund formula. The new rule at part 905 will replace and remove several other rules that currently govern a PHA's use of HUD assistance including part 941 (Public Housing Development) and part 968 (Public Housing Modernization). This rule will continue and expand the streamlining of procedures and requirements initiated under the Comprehensive Grant and Comprehensive Improvement programs that are included in part 968.

Statement of Need:

Assistance under the Capital Fund Program is the primary, regular source of funding made available by HUD to a PHA for its capital activities, including modernization and development of public housing. This rule will implement the requirements for the use of assistance made available under the Capital Fund program. The regulations will provide the appropriate notice of the legal framework for the program, and clear and uniform guidance for program operation.

Summary of Legal Basis:

Sections 518, 519, and 539 of the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105-276, approved October 21, 1998) (referred to as QHWRA), amending sections 9 and 5, and adding section 35(g) of the U.S. Housing Act of 1937.

Alternatives:

The QHWRA required a formula system to be established to govern funding of PHAs' public housing capital needs. Guidance for administration of these funds necessitates a permanent legal framework rather than informal and sporadic HUD notices.

Anticipated Cost and Benefits:

The costs of the program as administered with one fund from which a PHA will fund all of its capital needs is the same as under existing provisions. The benefits of having one funding mechanism for all such needs, and the provision of additional flexibility to PHAs to manage their physical assets provides increased benefits to the PHAs. Likewise, uniform program administration of these funds will provide increased benefits to the PHAs.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

William Thorson
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Department of Housing and Urban Development
Office of Public and Indian Housing
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RIN: 2577–AC50

HUD—PIH

81. OPERATING FUND ALLOCATION FORMULA (FR–4874)

Priority:

Economically Significant

Legal Authority:

42 USC 1437g; 42 USC 3535(d)

CFR Citation:

24 CFR 990

Legal Deadline:

None

Abstract:

This rule will revise the formula system for allocating funds to public housing agencies (PHAs) for their operation and management of public housing. The current formula system was developed pursuant to section 519 of the Quality Housing and Work Responsibility Act of 1998 (title V of Public Law 105-276, approved October 21, 1998, 112 Stat. 2551). That statute amended section 9 of the United States Housing Act of 1937 to require development of a new formula that would change the method of determining the payment of operating subsidies to PHAs.

Statement of Need:

Section 519 of the Quality Housing and Work Responsibility Act requires HUD to develop this rule to govern funding of PHAs' operating and management needs.

Summary of Legal Basis:

The Consolidated Appropriations Act of 2004 requires that HUD develop the rule to govern funding of PHA's operating and management needs.

Alternatives:

The Consolidated Appropriations Act of 2004 requires rulemaking.

Anticipated Cost and Benefits:

The costs of the program as administered with one fund from which a public housing agency (PHA) will fund all of its operating and management needs will be the same as under existing provisions. The benefits of having one funding mechanism for all such needs provides increased benefits to the PHAs. Likewise, uniform program administration of these funds will provide increased benefits to the PHAs.

The costs of the program as administered with one fund from which a PHA will fund all of its operating and management needs will

be the same as under existing provisions. The benefits of having one funding mechanism for all such needs provides increased benefits to the PHAs. Likewise, uniform program administration of these funds will provide increased benefits to the PHAs.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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RIN: 2577–AC51

HUD—PIH

82. NATIVE AMERICAN HOUSING ASSISTANCE AND SELF–DETERMINATION ACT (NAHASDA): REVISIONS TO THE INDIAN HOUSING BLOCK GRANT PROGRAM FORMULA (FR–4938)

Priority:

Other Significant

Legal Authority:

25 USC 4101 et seq; 42 USC 3535(d)

CFR Citation:

24 CFR 1000

Legal Deadline:

None

Abstract:

This rule would make several revisions to the Indian Housing Block Grant (IHBG) Program allocation formula authorized under section 302 of the Native American Housing Assistance and Self-Determination Act of 1996. Through the IHBG Program, HUD provides Federal housing assistance for Indian tribes in a manner that recognizes the right of Indian self-determination and tribal self-government. HUD negotiated the rule with active tribal participation and using the procedures of the Negotiated Rulemaking Act of 1990. The proposed regulatory changes reflect the consensus decisions reached by HUD and the tribal representatives on ways to improve and clarify the current regulations governing the IHBG Program formula.

Statement of Need:

The regulations for the IHBG program at 24 CFR 1000.306 provide that the IHBG allocation formula shall be reviewed within five years after issuance. This five-year period closed in 2003, which prompted HUD to establish a negotiated rulemaking committee for the purposes of reviewing and recommending possible changes to the allocation formula. The committee identified certain areas of the allocation formula that required clarification, were outdated, or were not operating as originally intended. The final rule reflects the consensus decisions reached by HUD and the Indian tribes on the best ways to address the necessary changes to the IHBG Program allocation formula.

Summary of Legal Basis:

Section 301 of NAHASDA requires that the Secretary of HUD use an allocation formula to make fiscal year block grants to Indian tribes under the IHBG program.

Alternatives:

Section 302 of NAHASDA required that the allocation formula for the IHBG Program be established by regulation. Accordingly, the revisions to the allocation formula must also be codified in HUD's regulations.

Anticipated Cost and Benefits:

The changes to the allocation formula made by the final rule will not impact the costs of the IHBG Program. The benefits of having the changes to the formula developed through negotiated rulemaking is that it allows Indian tribes directly affected to have a say in how the allocation formula will operate, and consequently to help foster constructive, creative and acceptable solutions to difficult problems.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Office of Public and Indian Housing
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RIN: 2577–AC57

HUD—PIH

FINAL RULE STAGE

83. PROJECT–BASED VOUCHER PROGRAM (FR–4636)

Priority:

Other Significant

Legal Authority:

42 USC 1437f(o); 42 USC 3535(d)

CFR Citation:

24 CFR 983

Legal Deadline:

None

Abstract:

The Project-Based Voucher Program replaces the Project-Based Certificate Program that was in existence for many years. Under the Project-Based Voucher Program, HUD pays rental assistance for eligible families to live in specific housing developments or units. A public housing agency (PHA) that administers a tenant-based housing choice voucher program may ''project-base'' up to 20 percent of voucher units funded by HUD. The Project-Based Program was authorized by law in 1998, as part of the statutory merger of the certificate and voucher tenant-based programs. In 2000, the Congress substantially revised the project-based voucher law. The law made a number of changes including permitting a PHA to pay project-based assistance for a

term of up to 10 years, permitting a PHA to provide project-based assistance for existing housing that does not need rehabilitation, as well as for newly constructed or rehabilitated housing, and allowing a family to move from a project-based voucher unit after one year and transfer to the PHA's tenant-based voucher program.

Statement of Need:

This rule will implement the requirements for the new Section 8 Project-Based Voucher program. The regulations will provide the appropriate notice of the legal framework for the program, and clear and uniform guidance for program operation for PHAs and the residents that the PHAs serve.

Summary of Legal Basis:

The statute is not self-implementing. Regulations are needed to present the legal framework for the program. The Secretary is authorized under the U.S. Housing Act of 1937 and the Department of Housing and Urban Development Act to prescribe such rules and regulations as may be necessary to effectively administer Department programs.

Alternatives:

This is a new program that provides assistance for housing and replaces a previous HUD program. Effective and fair administration of the program necessitates a permanent legal framework rather than informal and sporadic HUD notices.

Anticipated Cost and Benefits:

The new law and the regulations to be implemented by HUD provide additional flexibility to PHAs to manage their project-based voucher programs, and also provide more housing choices to the individuals and families served by the PHA.

Risks:

The rule poses no threat to public safety, health or the environment.

Timetable:

Action	Date	FR Cite
Notice	01/16/01	66 FR 3605
NPRM	03/18/04	69 FR 12950
NPRM Comment Period End	05/17/04	
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Agency Contact:

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RIN: 2577–AC25

BILLING CODE 4210–01–S

DEPARTMENT OF THE INTERIOR (DOI)

Statement of Regulatory Priorities

The Department of the Interior (DOI) is the principal Federal steward of our nation's public lands and resources, including many of our cultural treasures. We serve as trustee to Native Americans and Alaska natives and also are responsible for relations with the island territories under United States jurisdiction. We manage more than 500 million acres of Federal lands, including 388 park units, 545 wildlife refuges, 24,000 miles of trails, and approximately 1.7 billion acres submerged in offshore waters. The Department protects natural, historic and cultural resources, recovers endangered species, manages water projects, manages forests and fights wildland fires, leases public lands for coal, oil and gas production to meet the Nation's energy needs, educates children in Indian schools and provides recreational opportunities for almost 300 million visitors annually in our national parks. To fulfill these responsibilities, the Department generates scientific information relating to land and resource management.

The Department is committed to achieving its stewardship objectives in partnership with States, communities, landowners, and others through consultation, cooperation, and communication.

We will review and update the Department's regulations and policies to ensure that they are effective, efficient, and promote accountability. Special emphasis will be given to regulations and policies that:

- Adopt performance-based approaches focusing on achieving results in the most cost-effective and timely manner;
- Incorporate the best available science, and utilize peer review where appropriate;
- Promote partnerships with States, other groups, and individuals;
- Provide incentives for private landowners to achieve conservation goals; and
- Minimize regulatory and procedural burdens, promoting fairness, transparency, and accountability by agency regulators while maintaining performance goals.

Major Regulatory Areas

Among the Department's bureaus and offices, the Office of Surface Mining Reclamation and Enforcement (OSM) has a significant concentration of regulatory responsibilities. OSM, in partnership with the States and Indian tribes, establishes and enforces environmental standards for coal mining and reclamation operations. In addition, OSM administers the abandoned mine land reclamation program, which is funded by a fee assessed on each ton of coal produced. Money from these fees is placed in a fund that, subject to appropriation, is used to reclaim lands and waters impacted by historic mining activities conducted before the enactment of the Surface Mining Control and Reclamation Act of 1977. The collection of the fee for reclamation purposes was originally scheduled to expire in 1992 but was extended by the Energy Policy Act of 1992 to September 30, 2004; language in the Department's FY 2005 appropriation would further extend it for an as yet to be determined period.

Other DOI bureaus rely on regulations to implement legislatively mandated programs that focus on the management of natural resources and public or trust lands. Some of these regulatory activities include:

- Management of migratory birds and preservation of certain marine mammals and endangered species;
- Management of dedicated lands, such as national parks, wildlife refuges, and American Indian trust lands;
- Management of public lands open to multiple use;
- Leasing and oversight of development of Federal energy, minerals, and renewable resources;
- Management of revenues from American Indian and Federal minerals;
- Fulfillment of trust and other responsibilities pertaining to American Indian tribes;
- Natural resource damage assessments; and
- Management of financial and nonfinancial assistance programs.

Regulatory Policy

How DOI Regulatory Procedures Relate to the Administration's Regulatory Policies

Within the requirements and guidance in Executive Orders 12866, 12630, and 13132, DOI's regulatory programs seek to:

- Fulfill all legal requirements as specified by statutes or court orders;
- Perform essential functions that cannot be handled by non-Federal entities;
- Minimize regulatory costs to society while maximizing societal benefits; and
- Operate programs openly, efficiently, and in cooperation with Federal and non-Federal entities.

DOI bureaus have taken the initiative in working with other Federal agencies, non-Federal government agencies, and public entities to make our regulations easier to comply with and understand. Regulatory improvement is a continuing process that requires the participation of all affected parties. We strive to include all affected entities in the decisionmaking process and to issue rules efficiently. To better manage and review the regulatory process, we have revised our internal rulemaking and information quality guidance. Our regulatory process ensures that bureaus share ideas on how to reduce regulatory burdens while meeting the requirements of the laws they enforce and improving their stewardship of the environment and resources under their purview. Results have included:

- Increased bureau awareness of and responsiveness to the needs of small businesses and better compliance with the Small Business Regulatory Enforcement Fairness Act (SBREFA);
- A Departmentwide effort to evaluate the economic effects of planned rules and regulations;
- Issuance of guidance in the Departmental Manual to ensure the use of plain language;
- Issuance of new guidance in the Departmental Manual to ensure that Departmental National Environmental Policy Act reforms that streamline decisionmaking and enhance citizen participation are institutionalized; and
- In the Natural Resources Damage Assessment Program, de-emphasizing actions stemming from litigation while increasing outreach to involved parties and stressing cooperation and restoration of affected sites.
- A Departmentwide effort to streamline decisionmaking pertaining to fuels reduction projects under the Healthy Forests Initiative; and
- Joint counterpart pesticide regulations for EPA/FWS endangered species consultations that will allow the agencies to work together to complete the consultations (25,000 backlog) in

as timely a manner as possible and as efficiently as possible.

Implementing the President's National Energy Policy

The President's National Energy Policy promotes ''dependable, affordable, and environmentally sound production and distribution of energy for the future.'' The Department of the Interior plays a vital role in implementing the President's energy policy goals. The lands and facilities managed by the Department account for nearly 30 percent of all the energy produced in the United States.

The Department is taking over 100 actions to implement the President's energy policy, including several regulatory actions. The Department has diligently completed regulatory tasks assigned to it by the NEP, including the Bureau of Land Management's rule that provides a comprehensive set of regulations for managing oil and gas leases in the National Petroleum Reserve B Alaska, and the Minerals Management Service's rule that provides an incentive for development of deep gas resources offshore in order to encourage drilling of these high-risk wells and help tap into an important new source of natural gas supply. The Office of Surface Mining is developing regulations that will create a stable regulatory environment in order to encourage the development of better mining and reclamation practices that will reduce environmental damages associated with coal operations, while maintaining coal production. OSM anticipates that Congress will reauthorize the Abandoned Mine Land Fee. However, OSM is making contingency rulemaking plans should Congress decide otherwise. These and other regulatory actions within the Department are designed to streamline permitting processes and encourage environmentally sound energy production.

Encouraging Responsible Management of the Nation's Resources

The Department's mission includes protecting and providing access to our Nation's natural and cultural heritage and honoring our trust responsibilities to tribes. We are committed to this mission and to applying laws and regulations fairly and effectively. The Department's priorities include protecting public health and safety, restoring and maintaining public lands, ameliorating land and resource-management problems on public lands, and ensuring accountability and compliance with Federal laws and regulations.

Consistent with the President's Executive Order on Cooperative Conservation, the Department is continuing to work together with State and local governments, landowners, conservation groups, and the business community to conserve species and habitat. Building on successful approaches such as habitat conservation plans, safe harbor agreements, and candidate conservation agreements, the Department is reviewing its policies and regulations to identify opportunities to streamline the regulatory process where possible, consistent with protection of wildlife, and to enhance incentive-based programs to encourage landowners and others to implement voluntary conservation measures. For example, the Fish and Wildlife Service has issued guidance to promote the establishment of conservation banks as a tool to offset adverse impacts to species listed under the Endangered Species Act and restore habitat.

The Department is improving incentives through administrative flexibility under the Endangered Species Act. Released for public comment in September 2003 are proposed rule changes intended to provide greater clarity of what is allowable under incidental take permits and provide greater private landowner protections under safe harbor agreements. The first improvements of procedures relate to enhancement of survival permits (actions intended to improve survival or habitat of a species) and will refine and clarify the application requirements. The second, which relates to the issuing of safe harbor permits, will make the process easier to understand and will provide participating landowners greater certainty. Comments have been received and are being reviewed. Final rules on both will follow sometime before the end of the year.

The Department is also developing a uniform code of scientific conduct and policy on research. The Code describes ethical conduct for all Department employees who are engaged in conducting scientific activities on behalf of the Department. The primary reason for developing the Code is to implement a Federal policy on research misconduct as required by the Office of Management and Budget. The policy applies to all Federal agencies and federally funded research, whether conducted in-house or by partners at universities or in non-governmental organizations. This policy meets the expectations of the Secretary regarding the conduct of scientific activities with honesty, integrity, and accuracy; to make decisions based on the best science available; and is consistent with professional codes of conduct of other organizations.

In 2002, Secretaries Norton and Veneman signed an historic agreement with 17 western governors, county commissioners and other affected parties on a plan to make communities safer from wildfires through coordinating Federal, State and local action. Under the 10-year Comprehensive Strategy Implementation Plan, Federal wildfire agencies, affected States, counties, and local governments agreed to the same goals, implementation outcomes, performance measures and tasks that need to be accomplished by specific deadlines. The plan covers all phases of the fire program, including fire preparedness, suppression and prevention, hazardous fuels management, restoration of burned areas, community assistance and monitoring of progress.

In 2002, the President announced the Healthy Forests Initiative, in which he directed Federal agencies to develop administrative and legislative tools to restore forests and woodlands to more healthy, natural conditions and to assist in executing core components of the National Fire Plan. The Healthy Forests Initiative is providing public land managers the tools to undertake commonsense management of our forests and woodlands. The initiative focuses on reducing the risk of catastrophic fire by thinning dense undergrowth and brush in priority locations that are collaboratively selected by Federal, State, tribal, and local officials and communities. In 2005, the Department will continue to implement the administrative and legislative ''tools'' provided for under the Healthy Forests Initiative and the Healthy Forests Restoration Act.

The National Park Service has completed an Environmental Assessment to provide for Temporary Winter Use Plan that provides for continued snowmobile and snowcoach use in Yellowstone and Grand Teton National Parks and John D. Rockefeller, Jr. Memorial Parkway for up to the next three winter seasons. This EA will allow the NPS to engage in longer-term studies and to monitor the impacts of new technology snowmobiles in the parks, as well as the effects of road grooming in the winter on bison migration in Yellowstone. The EA will continue to require the use of cleaner, quieter

snowmobiles and set caps on the numbers of machines allowed in the parks each day. The parks are working to provide a more stable winter use plan to help gateway communities develop a winter economic plan. The interim plan and longer-term studies are both intended to satisfy the problems raised by the Federal District Courts in Wyoming and the District of Columbia, respectively, that have vacated the plans previously completed by the NPS in 2001 and 2003.

The Bureau of Land Management is working on a grazing administration rule that would ensure grazing decision rules conform with the Administrative Procedure Act, compliance with recent court decisions regarding conservation use permits, require BLM to consider social and economic factors when considering changes to grazing use, and offer other improvements to grazing activities on public lands.

On September 20, 2004, the U.S. Oceans Commission issued its report, which included over 200 recommendations. The Interior Department will play an active role in developing the Administration's initial response (the President has 90 days to respond), given the significant ocean and coastal related activities of many of Interior's agencies. In 2005, it is expected that significant time will be devoted to policy, regulatory, and legislative activities likely to occur as a result of the issuance of the report.

Minimizing Regulatory Burdens

We are using the regulatory process to ease the burdens on various entities throughout the country while improving results. For instance, the Endangered Species Act (ESA) allows for the delisting of threatened and endangered species if they no longer need the protection of the ESA. We have identified approximately 40 species for which delisting or downlisting (reclassification from endangered to threatened) may be appropriate. The eastern gray wolf has been delisted and an ESA section 10(j) rule for S tates with approved management plans will be ready in December.

The Federal Power Act authorizes the Department to include in hydropower licenses issued by the Federal Energy Regulatory Commission conditions and prescriptions necessary to protect Federal and tribal lands and resources and to provide fishways when navigable waterways or Federal reservations are used for hydropower generation. Over the past year, the Department has worked extensively with the Federal Energy Regulatory Commission (FERC), along with the Departments of Commerce and Agriculture, to establish a new integrated licensing process that will reduce both the time and cost of obtaining a FERC hydropower license. In July 2003 FERC issued its new rules. On September 9, DOI published a proposed rule on FERC licensing. The public review process will enable the public and the license applicant to comment on the Department's preliminary conditions and prescriptions, and to provide information to assist the Department in its formulation of modified conditions and prescriptions. The information obtained through this process will help the Department in refining and developing its conditions and prescriptions, which an applicant may appeal using the proposed appeals process to obtain an expeditious policy level review. These proposed processes are designed to coincide with and complement the Commission's overall licensing process.

Encouraging Public Participation and Involvement in the Regulatory Process

The Department is encouraging increased public participation in the regulatory process to improve results by ensuring that regulatory policies take into account the knowledge and ideas of our customers, regulated community, and other interested participants. The Department is reaching out to communities to seek public input on a variety of regulatory issues. For example, every year FWS establishes migratory bird hunting seasons in partnership with ''flyway councils,'' which are made up of State fish and wildlife agencies. As the process evolves each year, FWS holds a series of public meetings to give other interested parties, including hunters and other groups, opportunities to participate in establishing the upcoming season's regulations.

Similarly, the Bureau of Land Management (BLM) uses Resource Advisory Councils (RACs) made up of affected parties to help prepare land management plans and regulations that it issues under the Rangeland Reform Act.

In addition, the Department has recently completed a review of its NEPA compliance program and proposed new procedures aimed at improving public participation and reducing excess paperwork and redundancy of effort in the field. This has led to concrete reform measures. On March 8, 2004, the Department published its final revised procedures in the **Federal Register**. The reforms cover a number of areas. They include: Consensus-based management, public participation, community-based training, use of integrated analysis, adaptive management, and tiered and transferred analysis. Each of these concepts is aimed at ensuring the field staff have the tools to tailor their approach to the NEPA process to local needs and interests. Along with the departmental manual changes, policy guidance was distributed to bureaus earlier this year on how to implement the major reforms.

We encourage public consultation during the regulatory process. For example:

- OSM is continuing its outreach to interested groups to improve the substance and quality of rules and, to the greatest extent possible, achieve consensus on regulatory issues;
- The Bureau of Indian Affairs has finalized its roads program rule that was developed using the negotiated rulemaking process, which has resulted in a rule that better serves the diverse needs of the Native American community, reflecting the importance of the roads program to the individual tribes and the varying needs of the tribal governments;
- The Golden Gate National Recreation Area, a unit of the National Park System, has engaged in negotiated rulemaking to resolve an issue regarding walking dogs off-leash in the park. Existing NPS regulations require all dogs to be on a leash while in Golden Gate NRA, and the park has asked interested parties on both sides of the issue to come to the table to help draft a proposed rule. The effort has identified over 20 area organizations that will likely participate in the negotiated rulemaking process.

Regulatory Actions Related to the Events of September 11, 2001

The Bureau of Reclamation is responsible for protecting 348 reservoirs and more than 500 Federal dams, 58 hydroelectric plants, and over 8 million acres of Federal property. Public Law 107-69 granted Reclamation law enforcement authority for its lands. Reclamation finalized an interim rule published in April 2002 for one year that implements this authority. It has since been extended through 2005.

Rules of Particular Interest to Small Businesses

The National Park Service snowmobiling rule for Yellowstone and Grand Teton National Parks and the

John D. Rockefeller Memorial Parkway is of great interest to small businesses in the area of the parks, in particular those who rent snowmobiles. An initial Regulatory Flexibility Analysis points toward economic benefits to businesses in gateway communities, with some costs incurred by non-snowmobile users of the parks.

The Fish and Wildlife Service is making critical habitat designations more site-specific and is using the ESA section 4(b) exclusion process to reduce regulatory costs on small businesses.

The Future of DOI

Interior has developed a new Departmentwide strategic plan in response to Congressional, OMB and other appraisals indicating that Interior's ten separate strategic planning documents are too long and lack the appropriate agency-level focus. The process of developing the new strategic plan provides the Secretary with an opportunity to:

- Incorporate key Administration and Secretarial priorities into Interior's goals and performance measures;
- Consult with key interested constituents on the future direction of the Department; and
- Make Interior programs more ''results-oriented'' and accountable to citizens.

Interior also is using the single Strategic Plan as the basis for preparing a single Departmentwide Annual Performance Plan beginning with the plan for FY 2004. The Interior bureaus will continue to prepare internal plans to support their budget initiatives and to meet management excellence and accountability needs. However, we plan to submit only Departmentwide strategic and annual plans to the Congress.

Bureaus and Offices Within DOI

The following brief descriptions summarize the regulatory functions of DOI's major regulatory bureaus and offices.

Bureau of Indian Affairs

The Bureau of Indian Affairs (BIA) is responsible for managing trust responsibilities to the Indian tribes and encouraging tribal governments to assume responsibility for BIA programs.

The Bureau's rulemaking and policy development processes are designed to foster public and tribal awareness of the standards and procedures that directly affect them. The processes also encourage the public and the tribes to participate in developing these standards and procedures. The goals of BIA regulatory policies are to: (a)?Ensure consistent policies within BIA that result in uniform interactions with the tribal governments, (b) facilitate tribal involvement in managing, planning, and evaluating BIA programs and services, and (c) ensure continued protection of tribal treaties and statutory rights.

Under the No Child Left Behind Act of 2001, the Secretary of the Interior established a negotiated rulemaking committee to develop proposed rules to implement several sections of the Act relating to the Bureau of Indian Affairs-funded school system. The committee is comprised only of representatives of tribes and tribally operated schools and the Federal Government. The tribal representative membership reflects the proportionate share of students from tribes served by the Bureau-funded school system. This committee has negotiated rules to implement portions of the No Child Left Behind Act affecting the definition of ''Adequate Yearly Progress,'' attendance boundaries for Bureau-funded schools, funding for Bureau-funded schools, rights of students in the Bureau-funded school system, and grants under the Tribally Controlled Schools Act. The proposed rule was published in the Federal Register on February 25, 2004. The Bureau and the negotiated rulemaking committee have reviewed the comments on the proposed rule and their recommendations are being incorporated into the final rule that is now under preparation.

Bureau of Land Management

The BLM manages about 262 million acres of land surface and about 700 million acres of Federal mineral estate. These lands consist of extensive grasslands, forests, mountains, arctic tundra, and deserts. Resources on the lands include energy and minerals, timber, forage, wild horse and burro populations, habitat for fish and wildlife species, wilderness areas and archaeological and cultural sites. The BLM manages these lands and resources for multiple purposes and the sustained yield of renewable resources. Primary statutes under which the Agency must operate include: the Federal Land Management and Policy Act of 1976; the General Mining Act of 1872; the Mineral Leasing Act of 1920, as amended; the Recreation and Public Purposes Act; the Taylor Grazing Act; the Wilderness Act; and the Wild Free-Roaming Horses and Burros Act.

The Regulatory Program mirrors statutory responsibilities and Agency objectives including the following:

- Providing for a wide variety of public uses while maintaining the long-term health and diversity of the land while preserving significant natural, cultural, and historic resource values;
- Understanding the arid, semi-arid, arctic, and other ecosystems we manage and our commitment to using the best scientific and technical information to make resource management decisions;
- Understanding the needs of the public that use the BLM-managed lands and providing them with quality service;
- Committing to recover a fair return for using publicly owned resources and avoiding the creation of long-term liabilities for American taxpayers; and
- Resolving problems and implementing decisions in cooperation with other agencies, States, tribal governments, and the public.

The Regulatory Program contains its own objectives. These include preparing regulations that:

- Are the product of communication, coordination, and consultation with all affected members of the public;
- Are easy for the public to understand, especially those who would be most affected by them; and
- Are subject to periodic review to determine whether the rules are outdated, whether they require updating to reflect statutory and policy changes and whether they are achieving desired results.

The BLM's regulatory priorities include:

- Completing oil and gas leasing and operations regulations to make the program more efficiently serve the regulated public;
- Completing updating and consolidating the regulations on locating, filing, and maintaining mining claims and mill and tunnel sites, to remove unnecessary and outdated provisions, reorder the regulations more logically, and make them easier to read and understand; and
- Revising the regulations on administrative rights-of-way on the public lands to increase cost recovery to levels that properly compensate BLM for our administrative and monitoring costs, and to raise the cap on strict liability for right-of-way

holders to a reasonable level for costs associated with environmental cleanup.

Most of BLM's regulations affect small business because many business entities that operate on public lands meet the definition of a small business established by the Small Business Administration (SBA). BLM's regulations do not specifically target small businesses. BLM strives to ensure that our regulations do not unduly burden entities whether or not they are considered small businesses.

BLM's mining and grazing projects likely generate the greatest concern to small businesses because most livestock operators and mining companies are also considered small businesses, as classified by SBA.

The final grazing rule that BLM intends to publish before the end of the calendar year will amend grazing regulations that BLM promulgated on February 22, 1995 (59 FR 29206). The final rule will not substantively change the existing rules. When published, the rule will rely on the regulatory flexibility analysis prepared by BLM for the 1995 final rule. At that time, we determined that the 1995 rule should not have a significant impact on a substantial number of small entities.

The proposed minerals cost recovery rule will increase many fees and impose several new fees to cover BLM's costs of processing certain documents related to its mineral programs. The proposed rule will affect a large number of small entities since nearly all of them will face fee increases for activities on public lands. However, we have concluded that the effects will not be significant. The BLM completed a threshold analysis, which is available for public review at www.blm.gov/nhp/news/regulatory/index.htm.

Minerals Management Service

The Minerals Management Service (MMS) has two major responsibilities. The first is timely and accurate collection, distribution, accounting for, and auditing of revenues owed by holders of Federal onshore, offshore, and Indian mineral leases in a manner that meets or exceeds Federal financial integrity requirements and recipient expectations. The second is management of the resources of the Outer Continental Shelf in a manner that provides for safety, protection of the environment, and conservation of natural resources. These responsibilities are carried out under the provisions of the Federal Oil and Gas Royalty Management Act, the Minerals Leasing Act, the Outer Continental Shelf Lands Act, the Indian Mineral Leasing Act, and other related statutes.

For the Minerals Revenue Management program (MRM), we issued a final Federal Oil Valuation Rule (1010-AD04), published in the **Federal Register** on May 5, 2004, at 69 FR 24959, with an effective date of August 1, 2004), which amends current regulations at 30 CFR part 206. These amendments primarily affect which published market prices are most appropriate to value crude oil not sold at arm's-length and what transportation deductions should be allowed. MRM issued another final rule (1010-AC30, published in the **Federal Register** on September 13, 2004, at 69 FR 55076, with an effective date of September 13, 2004), which implements certain provisions in the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996. These regulations explain how lessees and their designees can obtain accounting and auditing relief for production from Federal oil and gas leases and units and communitization agreements that qualify as marginal properties.

We also plan to continue our review of existing regulations and to issue rules to refine the Minerals Revenue Management (MRM) regulations in chapter II of 30 CFR.? MRM is in the process of issuing regulations to: (1) revise its oil valuation regulations for Indian leases; (2) revise gas valuation regulations for Federal leases; and (3) codify provisions in the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSM) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA) to ''strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal as an essential source of energy.''

The principal regulatory provisions contained in title V of SMCRA set minimum requirements for obtaining a permit for surface coal mining operations, set standards for those operations, require land reclamation once mining ends, and require rules and enforcement procedures to ensure that the standards are met. Under SMCRA, OSM is the primary enforcer of SMCRA's provisions until the States achieve ''primacy;'' that is, until they demonstrate that their regulatory programs meet all the specifications in SMCRA and have regulations consistent with those issued by OSM.

When a primacy State takes over the permitting, inspection, and enforcement activities of the Federal Government, OSM then changes its role from regulating mining activities directly to overseeing and evaluating State programs. Today, 24 of the 26 key coal-producing States have primacy. In return for assuming primacy, States are entitled to regulatory grants and to grants for reclaiming abandoned mine lands. In addition, under cooperative agreements, some primacy States have agreed to regulate mining on Federal lands within their borders. Thus, OSM regulates mining directly only in nonprimacy States, on Federal lands in States where no cooperative agreements are in effect, and on Indian lands.

SMCRA charges OSM with the responsibility of publishing rules as necessary to carry out the purposes of the Act. The fundamental mechanism for ensuring that the purposes of SMCRA are achieved is the basic policy and guidance established through OSM's permanent regulatory program and related rulemakings. This regulatory framework is developed, reviewed, and applied according to policy directives and legal requirements.

Litigation by the coal industry and environmental groups is responsible for some of the rules now being considered by OSM. Others are the result of efforts by OSM to address areas of concern that have arisen during the course of implementing OSM's regulatory program, and two are the result of legislation.

OSM has sought to develop an economical, safe, and environmentally sound program for the surface mining of coal by providing a stable, consistent regulatory, results-focused framework. At the same time, however, OSM has recognized the need (a) to respond to local conditions, (b) to provide flexibility to react to technological change, (c) to be sensitive to geographic diversity, and (d) to eliminate burdensome recordkeeping and reporting requirements that over time have proved unnecessary to ensure an effective regulatory program.

Major regulatory objectives regarding the mining of surface coal include:

- Regulatory certainty so that coal companies know what is expected of them and citizens know what is intended and how they can participate;

- Ensuring an affordable, reliable energy supply while protecting the environment.
- Continuing consultation, cooperation, and communication with interest groups during the rulemaking process in order to increase the quality of the rulemaking, and, to the greatest extent possible, reflect consensus on regulatory issues.

U.S. Fish and Wildlife Service

The mission of the U.S. Fish and Wildlife Service is working with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people. Four principal mission goals include:

- *The sustainability of fish and wildlife populations*. FWS conserves, protects, restores, and enhances fish, wildlife, and plant populations entrusted to its care. They carry out this mission goal through migratory bird conservation at home and abroad; native fisheries restoration; recovery and protection of threatened and endangered species; prevention and control of invasive species; and work with our international partners.
- *Habitat conservation through a network of lands and waters*. Cooperating with others, FWS strives to conserve an ecologically diverse network of lands and waters of various ownership that provide habitat for fish, wildlife, and plant resources. This mission goal emphasizes two kinds of strategic actions: (1) The development of formal agreements and plans with partners who provide habitat for multiple species, and (2) the actual conservation work necessary to protect, restore, and enhance those habitats vital to fish and wildlife populations. The FWS's habitat conservation strategy focuses on the interaction and balance of people, lands and waters, and fish and wildlife through an ecosystem approach.
- *Public use and enjoyment*. FWS provides opportunities to the public to enjoy, understand, and participate in the use and conservation of fish and wildlife resources. The Service directs activities on national wildlife refuges and national fish hatcheries that increase opportunities for public involvement with fish and wildlife resources. Such opportunities include hunting, fishing, wildlife observation and photography, and environmental education and interpretation, as well as hands-on experiences through volunteer conservation activities on Service lands.
- *Partnerships in natural resources*. FWS supports and strengthens partnerships with tribal, State, and local governments and others in their efforts to conserve and enjoy fish, wildlife, and plants and habitats, consistent with the President's Executive Order on Cooperative Conservation. FWS administers Federal grants to States and territories for restoration of fish and wildlife resources and has a continuing commitment to work with tribal governments. FWS also promotes partnerships with other Federal agencies where common goals can be developed.

The Service carries out these mission goals through several types of regulations. While carrying out its responsibility to protect the natural resources entrusted to our care, FWS works continually with foreign and State governments, affected industries and individuals, and other interested parties to minimize any burdens associated with its activities. In carrying out its assistance programs, the Service administers regulations to help interested parties obtain Federal assistance and then comply with applicable laws and Federal requirements.

Some Service regulations permit activities otherwise prohibited by law. These regulations allow possession, sale or trade, scientific research, and educational activities involving fish and wildlife and their parts or products. In general, these regulations supplement State regulations and cover activities that involve interstate or foreign commerce.

FWS enforces regulations that govern public access, use, and recreation on more than 545 national wildlife refuges and in national fish hatcheries. The Service authorizes only uses that are compatible with the purpose for which each area was established, are consistent with State and local laws where practical, and afford the public appropriate economic and recreational opportunity.

FWS administers regulations to manage migratory bird resources. Annually, the Service issues a regulation on migratory bird hunting seasons and bag limits that is developed in partnership with the States, tribal governments, and the Canadian Wildlife Service. These regulations are necessary to permit migratory bird hunting that would otherwise be prohibited by various international treaties.

Finally, FWS implements regulations under the Endangered Species Act (ESA) to fulfill its statutory obligation to identify and conserve species faced with extinction and to conserve certain mammals under the Marine Mammal Protection Act. The ESA dictates that the basis for determining endangered and threatened species must be limited to biological considerations. Regulations enhance the conservation of ESA-listed species and help other Federal agencies comply with the ESA. Under section 7 of the ESA, all Federal agencies must consult with the Service on actions that may jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of their critical habitats.

In designating critical habitat for listed species, the Service considers biological information and economic and other impacts of the designation. Areas may be excluded if the benefits of exclusion outweigh the benefits of inclusion, provided that such exclusion will not result in the extinction of the species. The Department is reviewing guidance for designation of critical habitat. The guidance will provide policy direction and a process for developing critical habitat designations

Section 4(f)(1) of the ESA directs the Secretary of the Interior to develop and implement plans (known as recovery plans) for the conservation and survival of endangered and threatened species. The Service has been coordinating with the National Marine Fisheries Service to revise the joint Recovery Planning Guidance for the recovery of endangered and threatened species under the ESA. The purpose of the proposed guidance is to achieve greater consistency in the implementation of the ESA while working with our partners. In addition, section 6 of the ESA pertains to cooperation with the States in the conservation of endangered and threatened species. The Department will also issue guidance to facilitate better coordination with the States and provide more opportunities for the States' direct involvement in managing endangered and threatened species.

National Park Service

The National Park Service is dedicated to conserving the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations. The Service also manages a great variety of national and international programs designed to help

extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.

There are 388 units in the National Park System, including national parks and monuments; scenic parkways, preserves, trails, riverways, seashores, lakeshores, and recreation areas; and historic sites associated with important movements, events, and personalities of the American past. The NPS develops and implements park management plans, and staffs the areas under its administration. It relates the natural values and historical significance of these areas to the public through talks, tours, films, exhibits, and other interpretive media. It operates campgrounds and other visitor facilities and provides, usually through concessions, lodging, food, and transportation services in many areas.

The NPS also administers the following programs: the State portion of the Land and Water Conservation Fund; Federal Lands to Parks; Nationwide outdoor recreation coordination and information, and State Comprehensive Outdoor Recreation Planning; Rivers, Trails and Conservation Assistance; National Trails System; Hydropower Recreation Assistance; National Register of Historic Places; National Historic Landmarks; National Natural Landmarks; American Battlefield Protection; National Maritime Heritage Grants; Native American Graves Protection and Repatriation; Tribal Heritage Preservation Grants; Technical Preservation Services; Historic American Buildings Survey; Historic American Engineering Record; Historic American Landscapes Survey; and Interagency Archeological Services.

The NPS's regulatory activities focus on management of the National Park System and management of the programs assigned to it by Congress (and listed in the previous paragraph). Park-related regulations are designed to protect park resources while encouraging appropriate uses of the parks, consistent with each park's mission. Those regulations help ensure safe and sustainable public use, access, and recreation in the parks. Program-related regulations establish the procedures and standards by which the NPS will implement its legislated program responsibilities regarding, for example, the National Register Program and the Native American Graves Protection and Repatriation Act. The NPS regulatory program develops and reviews regulations for consistency with statutory law, current Administration priorities, and Servicewide policies.

Bureau of Reclamation

The Bureau of Reclamation's mission is to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. To accomplish this mission, Reclamation applies management, engineering, and scientific skills that result in effective and environmentally sensitive solutions.

Reclamation projects provide for some or all of the following concurrent purposes: Irrigation water service, municipal and industrial water supply, hydroelectric power generation, water quality improvement, groundwater management, fish and wildlife enhancement, outdoor recreation, flood control, navigation, river regulation and control, system optimization, and related uses. Reclamation has increased security at its facilities and is implementing its law enforcement authorization received in November 2001.

Reclamation's regulatory program is designed to ensure that its mission is carried out expeditiously, efficiently, and with an emphasis on cooperative problemsolving.

Office of the Secretary, Natural Resource Damage Assessment and Restoration Program

The regulatory functions of the Natural Resource Damage Assessment and Restoration Program (Restoration Program) stem from requirements under section 301(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). Section 301(c) requires the development of natural resource damage assessment rules and the biennial review and revisions, as appropriate, of these rules. Rules have been promulgated for the optional use of natural resource trustees to assess compensation for damages to natural resources caused by hazardous substances. The Restoration Program is overseeing the study and possible promulgation of additional rules pursuant to section 301(c)(2) and the review and possible revision of the existing rule in compliance with section 301(c)(3).

DOI—Minerals Management Service (MMS)

PROPOSED RULE STAGE

84. VALUATION OF OIL FROM INDIAN LEASES

Priority:

Other Significant

Legal Authority:

25 USC 2101 et seq; 25 USC 396 et seq; 25 USC 396a et seq; 30 USC 1701 et seq

CFR Citation:

30 CFR 206

Legal Deadline:

None

Abstract:

This rule would modify the regulations that establish royalty value for oil produced from Indian leases and create a new form for collecting value and differential data. These changes would decrease reliance on oil posted prices and make Indian oil royalty valuation more consistent with the terms of Indian leases.

Statement of Need:

Current oil valuation regulations rely on posted prices and prices under arm's-length sales to value oil that is not sold at arm's-length. Over time, posted prices have become increasingly suspect as a fair measure of market value. This rulemaking would modify valuation regulations to place substantial reliance on the higher of crude oil spot prices, major portion prices, or gross proceeds, and eliminate any direct reliance on posted prices. This rulemaking would also add more certainty to valuation of oil produced from Indian leases.

Summary of Legal Basis:

The primary legal basis for this rulemaking is the Federal Oil and Gas Royalty Management Act of 1982, as amended, which defines the Secretary of the Interior's (1) authority to implement and maintain a royalty management system for oil and gas leases on Indian lands, and (2) trust responsibility to administer Indian oil and gas resources.

Alternatives:

We considered a range of valuation alternatives such as making minor adjustments to the current gross

proceeds valuation method, using futures prices, using index-based prices with fixed adjustments for production from specific geographic zones, relying on some type of field pricing other than posted prices, and taking oil in-kind. We chose the higher of the average of the high daily applicable spot prices for the month, major portion prices in the field or area, or gross proceeds received by the lessee or its affiliate. We chose spot prices as one of the three value measures because: (1) they represent actual trading activity in the market; (2) they mirror New York Mercantile Exchange futures prices; and (3) they permit use of an index price for the market center nearest the lease for oil most similar in quality to that of the lease production.

Anticipated Cost and Benefits:

We estimate compliance with this rulemaking would cost the oil industry approximately $5.4 million the first year and $4.9 million each year thereafter. These estimates include the up-front computer programming and other administrative costs associated with processing the new form. The monetary benefits of this rulemaking are an estimated $4.7 million increase in annual royalties collected on oil produced from Indian leases. Additional benefits include simplification and increased certainty of oil pricing, reduced audit efforts, and reduced valuation determinations and associated litigation.

Risks:

The risk of not modifying current oil valuation regulations is that Indian recipients may not receive royalties based on the highest price paid or offered for the major portion of oil produced—a common requirement in most Indian leases. These modifications ensure that the Department fulfills its trust responsibilities for administering Indian oil and gas leases under governing mineral leasing laws, treaties, and lease terms.

Timetable:

Action	Date	FR Cite
ANPRM	12/20/95	60 FR 65610
NPRM	02/12/98	63 FR 7089
NPRM Comment Period Extended	04/09/98	
NPRM Comment Period End	05/13/98	
Comment Period Extended to 03/20/2000	02/28/00	65 FR 10436
Supplemental NPRM	12/00/04	
Supplemental NPRM Comment Period End	02/00/05	
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

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Related RIN: Previously reported as 1010–AC24

RIN: 1010–AD00

DOI—Bureau of Land Management (BLM)

FINAL RULE STAGE

85. GRAZING ADMINISTRATION—EXCLUSIVE OF ALASKA

Priority:

Other Significant

Legal Authority:

43 USC 315; 43 USC 315a to 315r; 43 USC 1181d; 43 USC 1740

CFR Citation:

43 CFR 4100

Legal Deadline:

None

Abstract:

This rule will ensure that BLM documents its consideration of the social, cultural, environmental, and economic consequences of grazing changes; provide that changes in grazing use will be phased in under certain circumstances; allow BLM to share title with permittees and lessees to range improvements in certain circumstances; make clear how BLM will authorize grazing if a BLM decision affecting a grazing permit is stayed pending administratvive appeal; remove provisions in the present regulations concerning conservation use grazing permits; ensure adequate time for developing and successfully implementing an appropriate management action when BLM finds that rangelands do not meet standards and guidelines for rangeland health and that authorized grazing is a significant factor in not achieving one or more land health standards or not conforming with guidelines for grazing administration; and revise some administrative service charges.

Statement of Need:

This rulemaking is necessary to contribute to improving working relationships with permittees and lessees, protecting the health of the rangelands, and increasing administrative efficiency and effectiveness.

Summary of Legal Basis:

The primary laws that govern grazing on public land are the Taylor Grazing Act (TGA) of 1934, the Federal Land Policy and Management Act (FLPMA) of 1976, and the Public Rangelands Improvement Act (PRIA) of 1978.

TGA directs that occupation and use of the range be regulated to preserve the land and its resources from destruction or unnecessary injury, and to provide for the orderly use, improvement, and development of the range. FLPMA provides authority and direction for managing the public lands on the basis of multiple use and sustained yield and mandates land use planning principles and procedures for the public lands. PRIA defines rangeland as public lands on which there is domestic livestock grazing or which are determined to be suitable for livestock grazing, establishes a national policy to improve the condition of public rangelands so they will become as productive as feasible for all rangeland values, requires a national inventory pf public rangeland conditions and trends, and authorizes funding for range improvement projects.

Alternatives:

The draft environmental impact statement (DEIS) on the proposed rule considered two alternatives in addition to the rule as proposed. The first alternative to the proposed rule considered in the DEIS was to continue to operate under the existing regulations. The existing regulations contain provisions that have been found unlawful by the Federal Courts. They also do too little to promote cooperation between BLM and grazing

permittees and lessees. They are also ambiguous at times and hard to understand.

The DEIS also considered a modified alternative with different approaches to several provisions in the proposed rule. BLM would have more discretion in phasing in changes in grazing use, be limited to five consecutive years in approving nonuse, and have discretion to use range assessments or monitoring or both to determine whether grazing management is achieving standards and conforming with guidelines. The alternative would include a prohibition of failing to comply with weed seed-free forage requirements, but would not include the current prohibition of failing to comply with Federal or State laws pertaining to resources.

In the early stages of planning this rule, BLM considered additional provisions such as Reserve Common Allotments for grazers to use when their allotments are unavailable due to fire, drought, or other factors, and authorizing grazers to lock gates on public lands temporarily. These provisions were dropped due to public comment on the advance notice of proposed rulemaking.

Anticipated Cost and Benefits:

BLM anticipates the following benefits: Increased livestock production as a result of increased forage productivity or increased ability to maintain grazing when it might otherwise be reduced; increased managerial flexibility, resulting in increased livestock output; improved environmental conditions; and potential changes in recreation values.

The major categories of costs include: BLM administrative costs (including enforcement and monitoring costs); compliance costs for permittees and lessees; environmental costs if the rule results in worsened environmental conditions.

The benefits and costs are thoroughly discussed in the Benefit-Cost/Unfunded Mandates Act Analysis and Initial Regulatory Flexibility Act Analysis dated November 14, 2003, and available in the administrative record of the rule.

Risks:

As with any new rule, the public may at first misunderstand the changes in regulatory requirements. BLM will work with the public in implementing the rule and conduct outreach meetings to explain the rule as necessary.

There is also a risk that the monitoring requirements imposed by the rule may entail increased administrative costs and the need to reallocate administrative resources. We expect this risk to be minimized because of the thresholds in the regulations that must be crossed before monitoring is required.

Timetable:

Action	Date	FR Cite
ANPRM	03/03/03	68 FR 9964
NPRM	12/08/03	68 FR 68452
NPRM Comment Period End	03/02/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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BILLING CODE 4310–RK–S

DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The first and overriding priority of the Department of Justice is to prevent, detect, disrupt, and dismantle terrorism while preserving constitutional liberties. To fulfill this mission, the Department is devoting all the resources necessary and utilizing all legal authorities to eliminate terrorist networks, to prevent terrorist attacks, and to bring to justice those who kill Americans in the name of murderous ideologies. It is engaged in an aggressive arrest and detention campaign of lawbreakers with a single objective: To get terrorists off the street before they can harm more Americans. In addition to using investigative, prosecutorial, and other law enforcement activities, the Department is also using the regulatory process to enhance its ability to prevent future terrorist acts and safeguard our borders while ensuring that America remains a place of welcome to foreigners who come here to visit, work, or live peacefully. The Department also has wide-ranging responsibilities for criminal investigations, law enforcement, and prosecutions and, in certain specific areas, makes use of the regulatory process to better carry out the Department's law enforcement missions.

The Department of Justice's regulatory priorities focus in particular on a major regulatory initiative in the area of civil rights. Specifically, the Department is planning to revise its regulations implementing titles II and III of the Americans With Disabilities Act. However, in addition to this specific initiative, several other components of the Department carry out important responsibilities through the regulatory process. Although their regulatory efforts are not singled out for specific attention in this regulatory plan, those components carry out key roles in implementing the Department's anti-terrorism and law enforcement priorities.

Civil Rights

The Department is planning to revise its regulations implementing titles II and III of the ADA to amend the ADA Standards for Accessible Design (28 CFR part 36, appendix A) to be consistent with the revised ADA accessibility guidelines published by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) in final form on July 23, 2004. (The Access Board had issued the guidelines in proposed form in November 1999 and in final draft form in April 2002.) Title II of the ADA prohibits discrimination on the basis of disability by public entities, and title III prohibits such discrimination by places of public accommodation and requires accessible design and construction of places of public accommodation and commercial facilities. In implementing these provisions, the Department of Justice is required by statute to publish regulations that include design standards that are consistent with the guidelines developed by the Access Board. The Access Board was engaged in a multiyear effort to revise and amend its accessibility guidelines. The goals of this project were: 1) To address issues such as unique State and local facilities (e.g., prisons, courthouses), recreation facilities, play areas, and building elements specifically designed for children's use that were not addressed in the initial guidelines; 2) to promote greater consistency between the Federal accessibility requirements and the model codes; and 3) to provide greater consistency between the ADA guidelines and the guidelines that implement the Architectural Barriers Act. The Access Board issued guidelines that address all of these issues. Therefore, to comply with the ADA requirement that the ADA standards remain consistent with the Access Board's guidelines, the Department will propose to adopt revised ADA Standards for Accessible Design that are consistent with the revised ADA Accessibility Guidelines.

The Department also plans to review its regulations implementing title II and title III (28 CFR parts 35 and 36) to ensure that the requirements applicable to new construction and alterations under title II are consistent with those applicable under title III, to review and update the regulations to reflect the current state of law, and to ensure the Department's compliance with section 610 of the Small Business Regulatory Enforcement Fairness Act (SBREFA).

The Department is planning to adopt and interpret the Access Board's revised and amended guidelines in three steps. The first step of the rulemaking process is an advance notice of proposed rulemaking, published in the Federal Register on September 30, 2004, at 69 FR 58768, which the Department believes will simplify and clarify the preparation of the proposed rule to follow. In addition to giving notice of the proposed rule that will adopt revised ADA accessibility standards, the advance notice raises two sets of questions for public comment, and proposes a framework for the regulatory analysis that will accompany the proposed rule. One set of questions addresses interpretive matters related to adopting revised ADA accessibility standards, such as what should be the effective date of the revised standards and how best to apply the revised standards to existing facilities that have already complied with the current ADA standards. Another set of questions is directed to collecting data about the benefits and costs of applying the new standards to existing facilities. The second step of the rulemaking process will be a proposed rule proposing to adopt revised ADA accessibility standards consistent with the Access Board's revised and amended guidelines that will, in addition to revising the current ADA Standards for Accessible Design, supplement the standards with specifications for prisons, jails, court houses, legislative facilities, building elements designed for use by children, play areas, and recreation facilities. The proposed rule will also offer proposed answers to the interpretive questions raised in the advance notice and present an initial regulatory assessment; it will be followed by a final rule, the third step of the process. A separate part of the rulemaking process will be an advanced notice of proposed rulemaking seeking public comment on the section 610 review of the ADA regulations under SBREFA, with proposed and final rules to follow.

The Department's revised and supplemented regulations under the ADA will affect small businesses, small governmental jurisdictions, and other small organizations (together, small entities). The Access Board has prepared regulatory assessments (including cost impact analyses) to accompany its new guidelines, which estimate the annual compliance costs that will be incurred by covered entities with regard to construction of new facilities. These assessments include the effect on small entities and will apply to new construction under the Department's revised and supplemented regulations. With respect to existing facilities, the Department will prepare an additional regulatory assessment of the estimated annual cost of compliance with regard to existing facilities. In this process, the Department will give careful consideration to the cost effects on small entities, including the solicitation of comments specifically designed to obtain compliance data relating to small entities.

Other Department Initiatives

1. Immigration Matters

On March 1, 2003, pursuant to the Homeland Security Act of 2002 (HSA),

the responsibility for immigration enforcement and for providing immigration-related services and benefits such as naturalization and work authorization was transferred from the Justice Department's Immigration and Naturalization Service (INS) to the Department of Homeland Security (DHS). However, immigration judges and the Board of Immigration Appeals in the Executive Office for Immigration Review (EOIR)) remain part of the Department of Justice; the immigration judges adjudicate approximately 300,000 cases each year to determine whether the aliens should be ordered removed or should be granted some form of relief from removal. Accordingly, the Attorney General has a continuing role in the conduct of removal hearings, the granting of relief from removal, and the detention or release of aliens pending completion of removal proceedings. The Attorney General also is responsible for civil litigation and criminal prosecutions relating to the immigration laws.

In several pending rulemaking actions, the Department is working to revise and update the regulations relating to removal proceedings in order to improve the efficiency and effectiveness of the hearings in resolving issues relating to removal of aliens and the granting of relief from removal.

1. Criminal

Law Enforcement

In large part, the Department's criminal law enforcement components do not rely on the rulemaking process to carry out their assigned missions. The Federal Bureau of Investigation (FBI), for example, is responsible for protecting and defending the United States against terrorist and foreign intelligence threats, upholding and enforcing the criminal laws of the United States, and providing leadership and criminal justice services to Federal, State, municipal, and international agencies and partners. Only in very limited contexts does the FBI rely on rulemaking.[1] However, other components do make use of the rulemaking process in certain significant respects.

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of firearms and explosives. ATF's mission and regulations are designed to:

- Curb illegal traffic in, and criminal use of, firearms, and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence;
- Facilitate investigations of violations of Federal explosives laws and arson-for-profit schemes;
- Regulate the firearms and explosives industries, including systems for licenses and permits;
- Assure the collection of all National Firearms Act (NFA) firearms taxes and obtain a high level of voluntary compliance with all laws governing the firearms industry; and
- Assist the States in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes and alcohol in avoidance of Federal and State taxes.

ATF will continue, as a priority during fiscal year 2005, to seek modifications to its regulations governing commerce in explosives. ATF continues analysis of its regulations governing storage requirements for explosives, including fireworks explosive materials. ATF plans to issue final regulations implementing the provisions of the Safe Explosives Act, title XI, subtitle C, of Public Law 107-296, the Homeland Security Act of 2002 (enacted November 25, 2002).

The Drug Enforcement Administration (DEA) is responsible for controlling abuse of narcotics and dangerous drugs, while ensuring adequate supplies for legitimate medical purposes, by regulating the aggregate supply of those drugs. However, now, the growing combination of drug trafficking and terrorism serves to call us even more urgently to action. DEA accomplishes its objectives through coordination with State, local, and other Federal officials in drug enforcement activities, development and maintenance of drug intelligence systems, regulation of legitimate controlled substances, and enforcement coordination and intelligence-gathering activities with foreign government agencies. DEA continues to develop and enhance regulatory controls relating to the diversion control requirements for controlled substances, as well as the requirements of the Comprehensive Methamphetamine Control Act of 1996 and the Methamphetamine Anti-Proliferation Act of 2000, which regulate certain chemicals to prevent them from being diverted for the production of methamphetamine.

The Federal Bureau of Prisons issues regulations to enforce the Federal laws relating to its mission: To protect society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. During the next 12 months, in addition to other regulatory objectives aimed at accomplishing its mission, the Bureau will continue its ongoing efforts to: Reduce the introduction of contraband through various means (such as clarifying drug and alcohol surveillance testing programs); improve disciplinary procedures; and improve drug abuse treatment services.

Footnotes:

1. As one recent example, the FBI published a final rule in July 2004, amending regulations implementing the National Instant Criminal Background Check System (''NICS'') pursuant to the Brady Handgun Violence Prevention Act (''Brady Act''). This rule balanced the Brady Act's mandate that the Department protect legitimate privacy interests of law-abiding firearm transferees and the Department's obligation to enforce the Brady Act and the rest of the Gun Control Act and prevent prohibited persons from receiving firearms. Changes made by the final rule regarding the amount of time that the NICS retains information about approved firearm transfers in the system's chronological log of background check transactions (''Audit Log'') were required by section 617 of H.R. 2673, the Fiscal Year 2004 Consolidated Appropriations bill, which was signed into law on January 23, 2004.

DOJ—Civil Rights Division (CRT)

PRERULE STAGE

86. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN PUBLIC ACCOMMODATIONS AND COMMERCIAL FACILITIES (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509; 28 USC 510; 42 USC 12186(b)

CFR Citation:

28 CFR 36

Legal Deadline:

None

Abstract:

In 1991, the Department of Justice published regulations to implement title III of the Americans With Disabilities Act of 1990 (ADA). Those regulations include the ADA Standards for Accessible Design, which establish requirements for the design and construction of accessible facilities that are consistent with the ADA Accessibility Guidelines (ADAAG) published by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board). In the time since the regulations became effective, the Department of Justice and the Access Board have each gathered a great deal of information regarding the implementation of the Standards. The Access Board began the process of revising ADAAG a number of years ago. It published new ADAAG in final form on July 23, 2004, after having published guidelines in proposed form in November 1999 and in draft final form in April 2002. In order to maintain consistency between ADAAG and the ADA Standards, the Department is reviewing its title III regulations and expects to propose, in one or more stages, to adopt revised ADA Standards consistent with the final revised ADAAG and to make related revisions to the Department's title III regulations. In addition to maintaining consistency between ADAAG and the Standards, the purpose of this review and these revisions will be to more closely coordinate with voluntary standards; to clarify areas which, through inquiries and comments to the Department's technical assistance phone lines, have been shown to cause confusion; to reflect evolving technologies in areas affected by the Standards; and to comply with section 610 of the Regulatory Flexibility Act, which requires agencies once every 10 years to review rules that have a significant economic impact upon a substantial number of small entities.

The first step in adopting revised Standards is an advance notice of proposed rulemaking that was published in the Federal Register on September 30, 2004, at 69 FR 58768, issued under both title II and title III. The Department believes that the advance notice will simplify and clarify the preparation of the proposed rule to follow. In addition to giving notice that the proposed rule will adopt revised ADA accessibility standards, the advance notice raises questions for public comment and proposes a framework for the regulatory analysis that will accompany the proposed rule.

The adoption of revised ADAAG will also serve to address changes to the ADA Standards previously proposed in RIN 1190-AA26, RIN 1190-AA38, RIN 1190-AA47, and RIN 1190-AA50, all of which have now been withdrawn from the Unified Agenda. These changes will include technical specifications for facilities designed for use by children, accessibility standards for State and local government facilities, play areas, and recreation facilities, all of which had previously been published by the Access Board.

The timetable set forth below refers to the notice of proposed rulemaking that the Department will issue as the second step of the above described title III rulemaking. This notice of proposed rulemaking will be issued under both title II and title III. For purposes of the title III regulation, this notice will propose to adopt revised ADA Standards for Accessible Design consistent with the minimum guidelines of the revised ADAAG. The second stage will initiate the review of the regulation in accordance with the requirements of section 610 of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including title III. Section 306(c) of the ADA requires the Attorney General to promulgate regulations implementing title III that are consistent with the Access Board's ADA guidelines. Because this rule will adopt standards that are consistent with the minimum guidelines issued by the Access Board, this rule is required by statute. Similarly, the Department's review of its title III regulation is being undertaken to comply with the requirements of the Regulatory Flexibility Act, as amended by SBREFA.

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above under Legal Authority and Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation. Pursuant to SBREFA, the Department's title III regulation will consider whether alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Access Board has analyzed the effect of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they constitute a significant regulatory action for purposes of Executive Order 12866. The Access Board's determination will apply as well to the revised ADA standards published by the Department. The Department's proposed procedural amendments will not have a significant impact on small entities.

As part of its revised ADAAG, the Access Board made available in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Access Board's regulatory assessment will also apply to the Department's proposed adoption of revised ADAAG as ADA standards insofar as the standards apply to new construction and alteration. The Department will also prepare an additional regulatory assessment of the estimated annual cost of compliance with the revised standards with regard to existing facilities.

Risks:

Without the proposed changes to the Department's title III regulation, the ADA Standards will fail to be consistent with the ADAAG.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/04	69 FR 58768
ANPRM Comment Period End	01/28/05	
NPRM	07/00/05	
NPRM Comment Period End	10/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Additional Information:

RIN 1190-AA44, which will effect changes to 28 CFR 36 (the Department's regulation implementing title III of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190-AA46, which will effect changes to 28

CFR 35 (the Department's regulation implementing title II of the ADA).

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DOJ—CRT

87. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN STATE AND LOCAL GOVERNMENT SERVICES (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509 to 510; 42 USC 12134; PL 101–336

CFR Citation:

28 CFR 35

Legal Deadline:

None

Abstract:

On July 26, 1991, the Department published its final rule implementing title II of the Americans With Disabilities Act (ADA). On November 16, 1999, the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) issued its first comprehensive review of the ADA Accessibility Guidelines, which form the basis of the Department's ADA Standards for Accessible Design. The Access Board published an Availability of Draft Final Guidelines on April 2, 2002, and published the ADA Accessibility Guidelines in final form on July 23, 2004. The ADA (section 204(c)) requires the Department's standards to be consistent with the Access Board's guidelines. In order to maintain consistency between ADAAG and the Standards, the Department is reviewing its title II regulations and expects to propose, in one or more stages, to adopt revised standards consistent with new ADAAG. The Department will also, in one or more stages, review its title II regulations for purposes of section 610 of the Regulatory Flexibility Act and make related changes to its title II regulations.

In addition to the statutory requirement for the rule, the social and economic realities faced by Americans with disabilities dictate the need for the rule. Individuals with disabilities cannot participate in the social and economic activities of the Nation without being able to access the programs and services of State and local governments. Further, amending the Department's ADA regulations will improve the format and usability of the ADA Standards for Accessible Design; harmonize the differences between the ADA Standards and national consensus standards and model codes; update the ADA Standards to reflect technological developments that meet the needs of persons with disabilities; and coordinate future ADA Standards revisions with national standards and model code organizations. As a result, the overarching goal of improving access for persons with disabilities so that they can benefit from the goods, services, and activities provided to the public by covered entities will be met.

The first part of the rulemaking process is an advance notice of proposed rulemaking, published in the Federal Register on September 30, 2004, at 69 FR 58768, issued under both title II and title III. The Department believes the advance notice will simplify and clarify the preparation of the proposed rule to follow. In addition to giving notice of the proposed rule that will adopt revised ADA accessibility standards, the advance notice raises questions for public comment and proposes a framework for the regulatory analysis that will accompany the proposed rule.

The adoption of revised ADA Standards consistent with revised ADAAG will also serve to address changes to the ADA Standards previously proposed under RIN 1190-AA26, RIN 1190-AA38, RIN 1190-AA47, and RIN 1190-AA50, all of which have now been withdrawn from the Unified Agenda. These changes will include technical specifications for facilities designed for use by children, accessibility standards for State and local government facilities, play areas, and recreation facilities, all of which had previously been published by the Access Board.

The timetable set forth below refers to the notice of proposed rulemaking that the Department will issue as the second step of the above-described title II rulemaking. This notice of proposed rulemaking will be issued under both title II and title III. For purposes of the title II regulation alone, this notice will also propose to eliminate the Uniform Federal Accessibility Standards (UFAS) as an alternative to the ADA Standards for Accessible Design.

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including title II. Section 204(c) of the ADA requires the Attorney General to promulgate regulations implementing title II that are consistent with the Access Board's ADA guidelines. Because this rule will adopt standards that are consistent with the minimum guidelines issued by the Access Board, this rule is required by statute. Similarly, the Department's review of its title II regulations is being undertaken to comply with the requirements of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above under Legal Authority and Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation as described in the Statement of Need above. Pursuant to SBREFA, the Department's title II regulation will consider whether alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Administration is deeply committed to ensuring that the goals of the ADA are met. Promulgating this amendment to the Department's ADA regulations will ensure that entities subject to the ADA will have one comprehensive regulation to follow. Currently, entities subject to title II of the ADA (State and local governments) have a choice between following the Department's ADA Standards for title III, which were adopted for places of public accommodation and commercial facilities and which do not contain standards for common State and local government buildings (such as courthouses and prisons), or the Uniform Federal Accessibility Standards (UFAS). By developing one comprehensive standard, the Department will eliminate the confusion that arises when governments try to mesh two different standards. As a result, the overarching goal of improving access to persons with disabilities will be better served.

The Access Board has analyzed the effect of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they constitute a significant regulatory action for purposes of Executive Order 12866. The Access Board's determination will apply as well to the revised ADA Standards published by the Department. The Department's proposed procedural amendments will not have a significant impact on small entities.

As part of its revised ADAAG, the Access Board made available in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Access Board's regulatory assessment will also apply to the Department's proposed adoption of revised ADAAG as ADA standards insofar as the standards apply to new construction and alteration. The Department will also prepare an additional regulatory assessment of the estimated annual cost of compliance with the revised standards with regard to existing facilities.

The Access Board has made every effort to lessen the impact of its proposed guidelines on State and local governments but recognizes that the guidelines will have some federalism effects. These affects are discussed in the Access Board's regulatory assessment, which also applies to the Department's proposed rule.

Risks:

Without this amendment to the Department's ADA regulations, regulated entities will be subject to confusion and delay as they attempt to sort out the requirements of conflicting design standards. This amendment should eliminate the costs and risks associated with that process.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/04	69 FR 58768
ANPRM Comment Period End	01/28/05	
NPRM	07/00/05	
NPRM Comment Period End	10/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

RIN 1190-AA46, which will effect changes to 28 CFR 35 (the Department's regulation implementing title II of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190-AA44, which will effect changes to 28 CFR 36 (the Department's regulation implementing title III of the ADA). By adopting revised ADAAG, this rulemaking will, among other things, address changes to the ADA Standards previously proposed in RINs 1190-AA26, 1190-AA36, and 1190-AA38, which have been withdrawn and merged into this rulemaking. These changes include accessibility standards for State and local government facilities that had been previously published by the Access Board (RIN 1190-AA26) and the timing for the compliance of State and local governments with the curb-cut requirements of the title II regulation (RIN 1190-AA36). In order to consolidate regulatory actions implementing title II of the ADA, on February 15, 2000, RINs 1190-AA26 and 1190-AA38 were merged into this rulemaking and on March 5, 2002, RIN 1190-AA36 was merged into this rulemaking.

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DEPARTMENT OF LABOR (DOL)

DEPARTMENT OF LABOR (DOL)

2004 Regulatory Plan

Executive Summary: Protecting America's Workers

Since its creation in 1913, the Department of Labor has been guided by the idea that workers deserve safe and healthy workspaces, as well as protection of their wages and pensions. Protecting America's workers is a top priority of the Secretary of Labor. The Department works to enforce laws and regulations to ensure the health and safety of the American workforce. The vast majority of employers work hard to keep their employees and workplaces safe and secure. DOL also strives to provide employers with the knowledge and tools they need to carry out their legal obligations. The Secretary has made protecting workers through the coupling of compliance assistance and tough enforcement one of her top priorities. Her compliance assistance initiative is based on the proven success that comes when government, employers, unions and employees work together.

Compliance assistance works to prevent injuries. Educating and encouraging employers helps workers far more than enforcement alone, since no enforcement process can possibly identify every violation of the law, and fines and penalties can never fully redress losses of life, health, and economic well-being.

The Department is committed to aggressively enforcing the laws that protect employees, including the rights of workers returning to their jobs after military service. Workers also need information about protection of their health insurance and pension benefits. In addition, DOL has responsibilities beyond worker protection. The Department recognizes that workers need constant updating of skills to compete in a changing marketplace. DOL helps employers and workers bridge the gap between the requirements of new high-technology jobs and the skills of the workers who are needed to fill them.

The Secretary of Labor's Regulatory Plan for Accomplishing These Objectives

In general, DOL tries to help employees and employers meet their needs in a cooperative fashion. DOL will maintain health and safety standards and protect employees by working with the regulated community.

DOL considers the following proposals to be proactive, common sense approaches to the issues most clearly needing regulatory attention.

The Department's Regulatory Priorities

DOL has identified 16 high priority items for regulatory action. Six items address health and safety issues, which are central to DOL's mission and which represent a major focus of the Secretary. Two agencies, the Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA), are responsible for these initiatives.

MSHA administers the Federal Mine Safety and Health Act of 1977 (Mine Act). The agency is committed to ensuring safer and healthier workplaces for the nation's miners in a number of ways, and will continue to concentrate on improving existing health standards and addressing emerging health hazards in mining.

MSHA is considering lowering the existing permissible exposure limit (PEL) for asbestos at metal and nonmetal and coal mines, to reduce the risk of asbestos-related death and disease among miners. MSHA also is considering specifying criteria for the method used for sample analysis (RIN 1219-AB24). MSHA published an advance notice of proposed rulemaking (ANPRM) and conducted a series of public meetings in 2002 to allow early participation by interested parties in the rulemaking. MSHA is preparing a proposed rule that fully considers comments received in response to the ANPRM, testimony at the public meeting, current scientific evidence, and the experience of other agencies.

MSHA also continues its rulemaking on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (RIN 1219-AB29). A proposed rule was published in August 2003. MSHA will address several provisions in the final standard, including changing the diesel particulate matter surrogate from total carbon to elemental carbon for the interim and limit changing the interim limit concentration-based limit to a personal exposure limit (PEL) establishing the hierarchy of controls that MSHA applies to metal and nonmetal mines pursuant to its enforcement policy for exposure-based health standards, allowing Personal Protective Equipment (PPE), and addressing the diesel particulate matter control plan.

The Occupational Safety and Health Administration oversees a wide range of measures in the public and private sectors. OSHA is committed to establishing clear and sensible priorities, and to continuing to reduce occupational deaths, injuries, and illnesses.

OSHA's high-priority initiatives address health standards. The first, a revision to the Respiratory Protection Standard, will address Assigned Protection Factors for different types of respirators (RIN 1218-AA05). This action will improve respiratory protection for employees required to wear respirators and will make it easier for employers to choose the appropriate respirator for a given task. OSHA published an NPRM on June 6, 2003, and informal public hearings were held on January 28-30, 2004.

OSHA's second initiative in the area of health standards addresses worker exposures to crystalline silica (RIN 1218-AB70). This substance is one of the most widely found in workplaces and data indicate that exposure to it may cause silicosis, a debilitating respiratory disease, and perhaps cancer as well. OSHA has obtained input from small businesses about regulatory approaches through a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel, and the Panel report was submitted to the Assistant Secretary of OSHA on December 19, 2003. OSHA is currently preparing a risk assessment and plans to complete an external peer review of a draft assessment by February 2005. This rule was discussed in the 2002 OMB Report to Congress on the Costs and Benefits of Regulations.

OSHA's third health initiative addresses worker exposure to hexavalent chromium (RIN 1218-AB45). Approximately 380,000 workers are exposed to this substance in general industry, maritime, construction and agriculture. Exposure to hexavalent chromium is associated with lung cancer and dermatoses. OSHA has obtained input from small businesses about regulatory approaches through a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel, and the Panel report was submitted to the Assistant Secretary of OSHA on April 20, 2004. The proposed rule was published on October 4, 2004. This standard was discussed in OMB's 2002 Report to Congress on the Costs and Benefits of Regulation.

The fourth health initiative, OSHA's Standards Improvement Project, will streamline a number of health standards by removing language that is outdated, duplicative, unnecessary or inconsistent (RIN 1218-AB81). These changes will reduce the time and effort needed to

understand and comply with these standards. An NPRM was published October 31, 2002. A hearing was held in July 2003, and a final rule has been prepared.

Protection of pension and health benefits continues to be a priority of the Secretary of Labor. Consistent with the Secretary's priorities for FY 2005, the Employee Benefits Security Administration (EBSA) will focus on compliance assistance for pension and group health plans through issuance of guidance. Specific initiatives for group health plans include guidance on the application of the Health Insurance Portability and Accountability Act (HIPAA) access, portability and renewability provisions (RIN 1210-AA54); and the HIPAA nondiscrimination provisions of the Employee Retirement Income Security Act (ERISA) (RIN 1210-AA77). With respect to pension plans, the Department will focus on establishing a safe harbor under which employers will be treated as having made timely deposits of participant contributions in their 401(k) plan (RIN 1210-AB02). The Department also will focus on the development of guidance that will facilitate the payment of benefits from 401(k) and other defined contribution plans that have been abandoned by their sponsors (RIN 1210-AA97).

ERISA's requirements affect an estimated 730,000 private sector employee pension benefit plans (covering approximately 99 million participants); an estimated 2.5 million group health benefit plans (covering 131 million participants and dependents); and 3.4 million other welfare benefits plans (covering approximately 190 million participants).

The Secretary's emphasis on meeting the needs of the 21st century workforce is reflected in the plan of the Employment and Training Administration (ETA) to issue regulations reflecting recent changes to the Trade Adjustment Assistance (TAA) program, as enacted in the Trade Act of 2002. The regulations will be issued in two parts: regulations covering TAA program benefits (RIN 1205-AB32), and regulations covering petition filing, investigations and the new Alternative TAA Program for Older Workers (RIN 1205-AB40). The proposed rules would address the many new features of the TAA program: consolidation of the TAA and NAFTA-TAA programs; rapid response services for workers to facilitate more rapid reemployment; expanded eligibility; increased benefits, including health care insurance assistance; and Alternative TAA for Older Workers program. The new regulations will be written in plain English, making them easier to read and use.

In its second initiative, ETA proposes to re-engineer the permanent labor certification process (RIN 1205-AA66). ETA's goals are to make fundamental changes that will streamline the process, save resources, improve the effectiveness of the program, and better serve the Department of Labor's customers. This rule was discussed in the 2002 OMB Report to Congress on the Costs and Benefits of Regulations.

The Employment Standards Administration (ESA) has set forth two priority regulatory initiatives. ESA's first initiative updates the child labor rules issued under the Fair Labor Standards Act (FLSA) to address changes in the nature of the workplace and situations in which minors may operate certain kinds of machinery (RIN 1215-AA09). While young workers need employment experiences that will help them gain the skills needed to find and hold good jobs later in life, they also need to focus on obtaining a high-quality education, and the assurance that their work hours are reasonable will help them in doing so.

ESA's second initiative pertains to regulations issued under the Family and Medical Leave Act (FMLA) that were also discussed in OMB's 2001 and 2002 Reports to Congress on the Costs and Benefits of Regulations. Revisions will be proposed to the FMLA's implementing regulations to address issues raised by the decision of the U.S. Supreme Court in *Ragsdale v. Wolverine World Wide, Inc.,* 122 S. Ct. 1155 (2002), and the decisions of other courts.

Finally, the Secretary 's commitment to protecting the employment rights of service members as they return to the civilian workforce is reflected by the Veterans' Employment and Training Service's (VETS) initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA). USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA. Authoritative written guidance interpreting USERRA will ensure that our service members serve secure in the knowledge that they will be able to return to their jobs with the same pay, benefits, and status they would have attained had they not been away on military duty.

DOL—Employment Standards Administration (ESA)

PROPOSED RULE STAGE

88. FAMILY AND MEDICAL LEAVE ACT OF 1993; CONFORM TO THE SUPREME COURT'S RAGSDALE DECISION

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 2654

CFR Citation:

29 CFR 825

Legal Deadline:

None

Abstract:

The U.S. Supreme Court, in Ragsdale v. Wolverine World Wide, Inc., 122 S. Ct. 1155 (2002), invalidated regulatory provisions issued under the Family and Medical Leave Act (FMLA) pertaining to the effects of an employer's failure to timely designate leave that is taken by an employee as being covered by the FMLA. The Department intends to propose revisions to the FMLA regulations to address issues raised by this and other judicial decisions.

Statement of Need:

The FMLA requires covered employers to grant eligible employees up to 12 workweeks of unpaid, job-protected leave a year for specified family and medical reasons, and to maintain group health benefits during the leave as if the employees continued to work instead of taking leave. When an eligible employee returns from FMLA leave, the employer must restore the employee to the same or an equivalent job with equivalent pay, benefits, and other conditions of employment. FMLA makes it unlawful for an employer to interfere with, restrain, or deny the exercise of any right provided by the FMLA.

The FMLA regulations require employers to designate if an employee's use of leave is counting against the employee's FMLA leave entitlement,

and to notify the employee of that designation (29 CFR section 825.208). Section 825.700(a) of the regulations provides that if an employee takes paid or unpaid leave and the employer does not designate the leave as FMLA leave, the leave taken does not count against the employee's 12 weeks of FMLA leave entitlement.

On March 19, 2002, the U.S. Supreme Court issued its decision in Ragsdale v. Wolverine World Wide, Inc., 122 S. Ct. 1155 (2002). In that decision, the Court invalidated regulatory provisions pertaining to the effects of an employer's failure to timely designate leave that is taken by an employee as being covered by the FMLA. The Court ruled that 29 CFR section 825.700(a) was invalid absent evidence that the employer's failure to designate the leave as FMLA leave interfered with the employee's exercise of FMLA rights. This proposed rule is being prepared to address issues raised by this and other judicial decisions.

Summary of Legal Basis:

This rule is issued pursuant to section 404 of the Family and Medical Leave Act, 29 U.S.C. section 2654.

Alternatives:

After completing a review and analysis of the Supreme Court's decision in Ragsdale and other judicial decisions, regulatory alternatives will be developed for notice-and-comment rulemaking.

Anticipated Cost and Benefits:

The costs and benefits of this rulemaking action are not expected to exceed $100 million per year or otherwise trigger economic significance under Executive Order 12866.

Risks:

This rulemaking action does not directly affect risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	
NPRM Comment Period End	05/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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DOL—ESA

FINAL RULE STAGE

89. CHILD LABOR REGULATIONS, ORDERS, AND STATEMENTS OF INTERPRETATION (ESA/W–H)

Priority:

Other Significant

Legal Authority:

29 USC 203(l)

CFR Citation:

29 CFR 570

Legal Deadline:

None

Abstract:

Section 3(l) of the Fair Labor Standards Act requires the Secretary of Labor to issue regulations with respect to minors between 14 and 16 years of age ensuring that the periods and conditions of their employment do not interfere with their schooling, health, or well-being. The Secretary is also directed to designate occupations that are particularly hazardous for minors 16 and 17 years of age. Child Labor Regulation No. 3 sets forth the permissible industries and occupations in which 14- and 15-year-olds may be employed, and specifies the number of hours in a day and in a week, and time periods within a day, that such minors may be employed. The Department has invited public comment in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders, and whether changes are needed in some of the applicable hazardous occupation orders. Comment has also been solicited on whether revisions should be considered in the permissible hours and time-of-day standards for 14- and 15-year-olds. Comment has been sought on appropriate changes required to implement school-to-work transition programs. Additionally, Congress enacted Public Law 104-174 (August 6, 1996), which amended FLSA section 13(c) and requires changes in the regulations under Hazardous Occupation Order No. 12 regarding power-driven paper balers and compactors, to allow 16- and 17-year-olds to load, but not operate or unload, machines meeting applicable American National Standards Institute (ANSI) safety standards and certain other conditions. Congress also passed the Drive for Teen Employment Act, Public Law 105-334 (October 31, 1998), which prohibits minors under age 17 from driving automobiles and trucks on public roads on the job and sets criteria for 17-year-olds to drive such vehicles on public roads on the job.

Statement of Need:

Because of changes in the workplace and the introduction of new processes and technologies, the Department is undertaking a comprehensive review of the regulatory criteria applicable to child labor. Other factors necessitating a review of the child labor regulations are changes in places where young workers find employment opportunities, the existence of differing Federal and State standards, and the divergent views on how best to correlate school and work experiences.

Under the Fair Labor Standards Act, the Secretary of Labor is directed to provide by regulation or by order for the employment of youth between 14 and 16 years of age under periods and conditions which will not interfere with their schooling, health and well-being. The Secretary is also directed to designate occupations that are particularly hazardous for youth between the ages of 16 and 18 years or detrimental to their health or well-being. The Secretary has done so by specifying, in regulations, the permissible industries and occupations in which 14- and 15-year-olds may be employed, and the number of hours per day and week and the time periods within a day in which they may be employed. In addition, these regulations designate the occupations declared particularly hazardous for minors between 16 and 18 years of age or detrimental to their health or well-being.

Public comment has been invited in considering whether changes in

technology in the workplace and job content over the years require new hazardous occupation orders or necessitate revision to some of the existing hazardous orders. Comment has also been invited on whether revisions should be considered in the permissible hours and time-of-day standards for the employment of 14- and 15-year-olds, and whether revisions should be considered to facilitate school-to-work transition programs. When issuing the regulatory proposals (after review of public comments on the advance notice of proposed rulemaking), the Department's focus was on assuring healthy, safe and fair workplaces for young workers, and at the same time promoting job opportunities for young people and making regulatory standards less burdensome to the regulated community.

The Department will also be considering what additional revisions to the hazardous occupation orders will be undertaken to address recommendations of the National Institute for Occupational Safety and Health in its May 2002 report to the Department.

Summary of Legal Basis:

These regulations are issued under sections 3(l), 11, 12, and 13 of the Fair Labor Standards Act, 29 U.S.C. sections 203(l), 211, 212, and 213 which require the Secretary of Labor to issue regulations prescribing permissible time periods and conditions of employment for minors between 14 and 16 years old so as not to interfere with their schooling, health, or well-being, and to designate occupations that are particularly hazardous or detrimental to the health or well-being of minors under 18 years old.

Alternatives:

Regulatory alternatives developed based on recent legislation and the public comments responding to the advance notice of proposed rulemaking included specific proposed additions or modifications to the paper baler, teen driving, explosive materials, and roofing hazardous occupation orders, and proposed changes to the permissible cooking activities that 14- and 15-year-olds may perform in retail establishments.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of this regulatory action indicated that the rule was not economically significant. Benefits will include safer working environments and the avoidance of injuries with respect to young workers.

Risks:

The child labor regulations, by ensuring that permissible job opportunities for working youth are safe and healthy and not detrimental to their education as required by the statute, produce positive benefits by reducing health and productivity costs employers may otherwise incur from higher accident and injury rates to young and inexperienced workers. Given the limited nature of the changes in the proposed rule, a detailed assessment of the magnitude of risk was not prepared.

Timetable:

Action	Date	FR Cite
Final Rule	11/20/91	56 FR 58626
Final Rule Effective	12/20/91	
ANPRM	05/13/94	59 FR 25167
ANPRM Comment Period End	08/11/94	59 FR 40318
NPRM	11/30/99	64 FR 67130
NPRM Comment Period End	01/31/00	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1215–AA09

DOL—Employment and Training Administration (ETA)

PROPOSED RULE STAGE

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90. REVISION TO THE DEPARTMENT OF LABOR BENEFIT REGULATIONS FOR TRADE ADJUSTMENT ASSISTANCE FOR WORKERS UNDER THE TRADE ACT OF 1974, AS AMENDED

Priority:

Other Significant

Legal Authority:

19 USC 2320; Secretary's Order No. 3–81, 46 FR 31117

CFR Citation:

29 CFR 90; 20 CFR 617; 20 CFR 618; 20 CFR 665; 20 CFR 671; . . .

Legal Deadline:

None

Abstract:

The Trade Adjustment Assistance Reform Act of 2002, enacted on August 6, 2002, contains provisions amending title 2, chapter 2 of the Trade Act of 1974, entitled Adjustment Assistance for Workers. The amendments, effective 90 days from enactment (November 4, 2002), make additions to where and by whom a petition may be filed, expand eligibility to workers whose production has been shifted to certain foreign countries and to worker groups secondarily affected, and make substantive changes regarding trade adjustment assistance (TAA) program benefits.

It is the agency's intention to create a new 20 CFR part 618 to incorporate the amendments and write it in plain English, while amending the WIA regulations at 20 CFR parts 665 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of nine subparts: subpart A - General; subpart B—Petitions and Determinations of Eligibility to Apply for Trade Adjustment Assistance (and Alternative TAA); subpart C-—Delivery of Services throughout the One-Stop Delivery System; subpart D—Job Search Allowances; subpart E—Relocation Allowances; subpart F—Training Services; subpart G—Trade Readjustment Allowances (TRA); subpart H—Administration by Applicable State Agencies; and subpart I—Alternative Trade Adjustment Assistance for Older Workers. Because of the complexity of the subject matter and the States' needs for definitive instructions on providing TAA benefits, the rulemaking for part 618 is divided into two parts. This notice of proposed rulemaking covers the general provisions (subpart A) and TAA benefits portions (subpart C through subpart H) of the regulations. A separate notice of proposed rulemaking will cover the two remaining subparts (subpart B and subpart I).

Statement of Need:

The Trade Adjustment Assistance Reform Act of 2002, enacted August 6, 2002, repeals the North American Free Trade Agreement-Transitional Adjustment Assistance provisions for workers affected by the NAFTA Implementation Act and adds significant amendments to worker benefits under Trade Adjustment Assistance for Workers, as provided for in the Trade Act of 1974.

The 2002 Trade Act amends where and by whom a petition may be filed. Program benefits for TAA eligible recipients are expanded to include for the first time a health care tax credit, and eligible recipients now include secondarily affected workers impacted by foreign trade. Income support is extended by 26 weeks and by up to one year under certain conditions. Waivers of training requirements in order to receive income support are explicitly defined. Job search and relocation benefit amounts are increased. Within one year of enactment, the amendments offer an Alternative TAA for Older Workers program that targets older worker groups who are certified as TAA eligible and provides the option of a wage supplement instead of training, job search, and income support.

The Department is mandated to implement the amendments within 90 days from enactment (November 4, 2002), and it issued operating instructions in a guidance letter on October 10, 2002, and later published in the Federal Register (67 FR 69029-41). State agencies rely on the regulations to make determinations as to individual eligibility for TAA program benefits. TAA program regulations as written have been described as complicated to interpret. With the new TAA program benefit amendments contained in the Trade Act of 2002, it is imperative that the regulations be in an easy-to-read and understandable format.

Summary of Legal Basis:

These regulations are authorized by 19 U.S.C. 2320 due to the amendments to the Trade Act of 1974 by the Trade Adjustment Assistance Reform Act of 2002.

Alternatives:

The public will be afforded an opportunity to provide comments on the TAA program changes when the Department publishes the proposed rule in the Federal Register.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs of this regulatory action have not been determined at this time and will be determined at a later date.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

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DOL—ETA

91. • REVISION TO THE DEPARTMENT OF LABOR REGULATIONS FOR PETITIONS AND DETERMINATIONS OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE FOR WORKERS AND ISSUANCE OF REGULATIONS FOR THE ALTERNATIVE TAA

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

19 USC 2320; Secretary's Order No. 3–81, 46 FR 31117

CFR Citation:

29 CFR 90; 20 CFR 617; 20 CFR 618; 20 CFR 665; 20 CFR 671; . . .

Legal Deadline:

None

Abstract:

The Trade Adjustment Assistance Reform Act of 2002, enacted on August 6, 2002, contains provisions amending title 2, chapter 2 of the Trade Act of 1974, entitled Adjustment Assistance for Workers. The amendments, effective 90 days from enactment (November 4, 2002), make additions to where and by whom a petition may be filed, expand eligibility to workers whose production has been shifted to certain foreign countries and to worker groups secondarily affected, and make substantive changes regarding trade adjustment assistance (TAA) program benefits.

It is the agency's intention to create a new 20 CFR part 618 to incorporate the amendments and write it in plain English, while amending the WIA regulations at 20 CFR parts 665 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of nine subparts: subpart A—General; subpart B—Petitions and Determinations of Eligibility to Apply for Trade Adjustment Assistance (and Alternative TAA); subpart C—Delivery of Services throughout the One-Stop Delivery System; subpart D—Job Search Allowances; subpart E—Relocation Allowances; subpart F—Training Services; subpart G—Trade Readjustment Allowances (TRA); subpart H—Administration by Applicable State Agencies; and subpart I—Alternative Trade Adjustment Assistance (ATAA) for Older Workers. Because of the complexity of the subject matter and the States' needs for definitive instructions on providing TAA benefits, the rulemaking for part 618 is divided into two parts. This notice of proposed rulemaking covers the petitions and determinations (subpart B) and ATAA (subpart I) of the regulations. A separate notice of proposed rulemaking will cover the remaining subparts (subpart A and subparts C through H).

Statement of Need:

The Trade Adjustment Assistance Reform Act of 2002, enacted August 6, 2002, repeals the North American Free Trade Agreement-Transitional Adjustment Assistance provisions for workers affected by the NAFTA Implementation Act and adds significant amendments to worker benefits under Trade Adjustment Assistance for Workers, as provided for in the Trade Act of 1974.

The 2002 Trade Act amends where and by whom a petition may be filed. Program benefits for TAA eligible recipients are expanded to include for the first time a health care tax credit,

and eligible recipients now include secondarily affected workers impacted by foreign trade. Income support is extended by 26 weeks and by up to one year under certain conditions. Waivers of training requirements in order to receive income support are explicitly defined. Job search and relocation benefit amounts are increased. Within one year of enactment, the amendments offer an Alternative TAA for Older Workers program that targets older worker groups who are certified as TAA eligible and provides the option of a wage supplement instead of training, job search, and income support.

The Department is mandated to implement the amendments within 90 days from enactment (November 4, 2002), and it issued operating instructions in a guidance letter on October 10, 2002, and later published in the Federal Register (67 FR 69029-41). State agencies rely on the regulations to make determinations as to individual eligibility for TAA program benefits. TAA program regulations as written have been described as complicated to interpret. With the new TAA program benefit amendments contained in the Trade Act of 2002, it is imperative that the regulations be in an easy-to-read and understandable format.

Summary of Legal Basis:

These regulations are authorized by 19 U.S.C. 2320 due to the amendments to the Trade Act of 1974 by the Trade Adjustment Assistance Reform Act of 2002.

Alternatives:

The public will be afforded an opportunity to provide comments on the TAA program changes when the Department publishes the proposed rule in the Federal Register.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs of this regulatory action have not been determined at this time and will be determined at a later date.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State

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DOL—ETA

FINAL RULE STAGE

92. LABOR CERTIFICATION PROCESS FOR THE PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES

Priority:

Other Significant

Legal Authority:

29 USC 49 et seq; 8 USC 1182(a)(5)(A), 1189(p)(1)

CFR Citation:

20 CFR 656

Legal Deadline:

None

Abstract:

The Employment and Training Administration (ETA) is in the process of reengineering the permanent labor certification process. ETA's goals are to make fundamental changes and refinements that will streamline the process, save resources, improve the effectiveness of the program and better serve the Department of Labor's (DOL) customer.

Statement of Need:

The labor certification process has been described as being complicated, costly and time consuming. Due to the increases in the volume of applications received and a lack of adequate resources, it can take up to 2 years or more to complete processing an application. The process also requires substantial State and Federal resources to administer and is reportedly costly and burdensome to employers as well. Cuts in Federal funding for both the permanent labor certification program and the U.S. Employment Service have made it difficult for State and Federal administrators to keep up with the process. ETA, therefore, is taking steps to improve effectiveness of the various regulatory requirements and the application processing procedures, with a view to achieving savings in resources both for the Government and employers, without diminishing protections now afforded U.S. workers by the current regulatory and administrative requirements.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 212(a)(5)(A) of the Immigration and Nationality Act.

Alternatives:

Regulatory alternatives are now being developed by the Department. The public was afforded an opportunity to comment on the Department's plans for streamlining the permanent labor certification process in a notice of proposed rulemaking which was published in the Federal Register on May 6, 2002.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits have not been determined at this time. Preliminary estimates will be developed after a decision is made as to what regulatory amendments are necessary and after the implementing forms and automated systems to support a streamlined permanent labor certification process have been developed.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	05/06/02	67 FR 30465
NPRM Comment Period End	07/05/02	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, State

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DOL—Employee Benefits Security Administration (EBSA)

PROPOSED RULE STAGE

93. RULEMAKING RELATING TO TERMINATION OF ABANDONED INDIVIDUAL ACCOUNT PLANS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

29 USC 1135; 29 USC 1002(16)(A)

CFR Citation:

29 CFR 2591

Legal Deadline:

None

Abstract:

This rulemaking will establish a procedure and standards for distributing the benefits of individual account plans that have been abandoned by their sponsoring employers or plan administrators.

Statement of Need:

Thousands of individual account plans have, for a variety of reasons, been abandoned by their sponsors, creating problems for plan participants, administrators, financial institutions (e.g., banks, insurance companies, mutual funds), the courts and the Federal Government. At present, the potential liability and costs attendant to terminating such plans and distributing the assets inhibits financial institutions and others from taking on this responsibility. Due to ongoing administrative costs and other factors, the continued maintenance of such plans is often not in the interest of the participants and beneficiaries. This rulemaking will establish a procedure for a financial institution that holds the assets of such a plan to terminate the plan and distribute its assets to the participants and beneficiaries. The rulemaking will also include standards for determining when plans may be terminated pursuant to this procedure and for carrying out the functions necessary to distribute benefits and shut down plan operations.

Summary of Legal Basis:

Section 505 of ERISA provides that the Secretary may prescribe such regulations as the Secretary finds necessary and appropriate to carry out the provisions of title I of the Act. Section 403(d)(1) provides that, upon termination of such a plan, the assets shall be distributed generally in accordance with the provisions that apply to defined benefit plans, ''except as otherwise provided in regulations of the Secretary.'' ERISA section 3(16)(A) permits the Secretary to issue regulations designating an administrator for a plan where the plan document makes no designation and the plan sponsor cannot be identified.

Alternatives:

Alternatives will be considered following a determination of the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed, as appropriate, following a determination regarding the alternatives to be considered.

Risks:

Failure to provide guidance in this area will leave the retirement benefits of participants and beneficiaries in abandoned plans at risk of being significantly diminished by ongoing plan administrative expenses, rather than distributed to participants and beneficiaries in connection with a timely and orderly termination of the plan.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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RIN: 1210–AA97

DOL—EBSA

94. • AMENDMENT OF REGULATION RELATING TO DEFINITION OF PLAN ASSETS—PARTICIPANT CONTRIBUTIONS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 1135

CFR Citation:

29 CFR 2510.3–102

Legal Deadline:

None

Abstract:

This rulemaking will amend the regulation that defines when participant monies paid to or withheld by an employer for contribution to an employee benefit plan constitute ''plan assets'' for purposes of title I of ERISA and the related prohibited transaction provisions of the Internal Revenue Code. The regulation contains an amendment to the current regulation that will establish a safe harbor period of a specified number of business days during which certain monies that a participant pays to, or has withheld by, an employer for contribution to a plan would not constitute ''plan assets.''

Statement of Need:

This amendment of the participant contribution regulation would, upon adoption, establish a ''safe harbor'' period of a specified number of days during which certain monies that a participant pays to, or has withheld from wages, by an employer for contribution to an employee benefit plan, would constitute plan assets for purposes of title I of ERISA and the related prohibited transaction

provisions of the Internal Revenue Code. The amendment is needed to provide greater certainty to employers, participants and beneficiaries, service providers and others concerning when participant contributions to a plan constitute plan assets.

Summary of Legal Basis:

Section 505 of ERISA provides that the Secretary may prescribe such regulations as she finds necessary and appropriate to carry out the provisions of title I of the Act. Regulation 29 CFR 2510.3-102 provides that the assets of an employee benefit plan covered by title I of ERISA includes amounts (other than union dues) that a participant or beneficiary pays to an employer, or has withheld from wages by an employer, for contribution to the plan as of the earliest date on which such contributions can reasonably be segregated from the employer's general assets; the regulation also specifies the maximum time period for deposit of such contributions by the employer.

Alternatives:

Alternatives will be considered following a determination of the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed, as appropriate, following a determination regarding the alternatives to be considered.

Risks:

Failure to provide the safe harbor that would be afforded by the proposed amendment with regard to monies contributed to employee benefit plans would deprive employers, other plan fiduciaries, and service providers of the certainty they need to optimize compliance with the law. Also, any risk of loss or lost earnings resulting from permitting employers who would otherwise transmit contributions to the plan sooner than the time specified in the safe harbor should be minimal, while the benefits attendant to encouraging employers to review and modify their systems or practices to take advantage of the safe harbor may be significant.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Federalism:

Undetermined

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RIN: 1210–AB02

DOL—EBSA

FINAL RULE STAGE

95. REGULATIONS IMPLEMENTING THE HEALTH CARE ACCESS, PORTABILITY, AND RENEWABILITY PROVISIONS OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1171; 29 USC 1172; 29 USC 1191c

CFR Citation:

29 CFR 2590

Legal Deadline:

Other, Statutory, April 1, 1997, Interim Final Rule.

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended title I of ERISA by adding a new part 7, designed to improve health care access, portability and renewability. This rulemaking will provide regulatory guidance to implement these provisions.

Statement of Need:

In general, the health care portability provisions in part 7 of ERISA provide for increased portability and availability of group health coverage through limitations on the imposition of any preexisting condition exclusion and special enrollment rights in group health plans after loss of other health coverage or a life event. Plan sponsors, administrators and participants need guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Part 7 of ERISA specifies the portability and other requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 of ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Request for Information	10/25/99	64 FR 57520
Comment Period End	01/25/00	
Final Rule	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Federalism:

This action may have federalism implications as defined in EO 13132.

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RIN: 1210–AA54

DOL—EBSA

96. PROHIBITING DISCRIMINATION AGAINST PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1182; 29 USC 1191c; 29 USC 1194

CFR Citation:

29 CFR 2590.702

Legal Deadline:

None

Abstract:

Section 702 of the Employee Retirement Income Security Act of 1974, amended by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), establishes that a group health plan or a health insurance issuer may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. These provisions are also contained in the Internal Revenue Code under the jurisdiction of the Department of the Treasury, and the Public Health Service Act under the jurisdiction of the Department of Health and Human Services.

On April 8, 1997, the Department, in conjunction with the Departments of the Treasury and Health and Human Services (collectively, the Departments) published interim final regulations implementing the nondiscrimination provisions of HIPAA. These regulations can be found at 26 CFR 54.9802-1 (Treasury), 29 CFR 2590.702 (Labor), and 45 CFR 146.121 (HHS). That notice of rulemaking also solicited comments on the nondiscrimination provisions and indicated that the Departments intend to issue further regulations on the nondiscrimination rules. This rulemaking contains additional regulatory interim guidance under HIPAA's nondiscrimination provisions. In addition, the rulemaking contains proposed guidance on bona fide wellness programs.

Statement of Need:

Part 7 of ERISA provides that group health plans and health insurance issuers may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. Plan sponsors, administrators, and participants need additional guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Section 702 of ERISA specifies the respective nondiscrimination requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
NPRM	01/08/01	66 FR 1421
NPRM Comment Period End	04/09/01	
Second Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Comment Period End	04/09/01	
Final Rule	03/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

This item has been split off from RIN 1210-AA54.

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RIN: 1210–AA77

DOL—Mine Safety and Health Administration (MSHA)

PROPOSED RULE STAGE

97. ASBESTOS EXPOSURE LIMIT

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 56; 30 CFR 57; 30 CFR 71

Legal Deadline:

None

Abstract:

MSHA's permissible exposure limit (PEL) for asbestos applies to surface (30 CFR part 56) and underground (30 CFR part 57) metal and nonmetal mines and to surface coal mines and surface areas of underground coal mines (30 CFR part 71) and is over 20 years old. MSHA is considering rulemaking to lower the PEL in order to reduce the risk of miners developing asbestos-induced occupational disease. A report by the Office of the Inspector General (OIG) recommended that MSHA lower its existing permissible exposure limit for asbestos to a more protective level, and address take-home contamination from asbestos. It also recommended that MSHA use Transmission Electron Microscopy to analyze fiber samples that may contain asbestos.

Statement of Need:

Current scientific data indicate that the existing asbestos PEL is not sufficiently protective of miners' health. MSHA's asbestos regulations date to 1967 and are based on the Bureau of Mines (MSHA's predecessor) standard of 5 mppcf (million particles per cubic foot of air). In 1969, the Bureau proposed a 2 mppcf and 12 fibers/ml standard. This standard was promulgated in 1969. In 1970, the Bureau proposed to lower the standard to 5 fibers/ml, which was promulgated in 1974. MSHA issued its current standard of 2 fibers/ml in 1976 for coal mining (41 FR 10223) and 1978 for metal and nonmetal mining (43 FR 54064). During inspections, MSHA routinely takes samples, which are analyzed for compliance with its standard.

Other Federal agencies have addressed this issue by lowering their PEL for asbestos. For example, the Occupational Safety and Health

Administration, working in conjunction with the Environmental Protection Agency, enacted a revised asbestos standard in 1994 that lowered the permissible exposure limit to an 8-hour time-weighted average limit of 0.1 fiber per cubic centimeter of air and the excursion limit to 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes. These lowered limits reflected increased asbestos-related disease risk to asbestos-exposed workers.

Summary of Legal Basis:

Promulgation of this regulation is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

The Agency has increased sampling efforts in an attempt to determine current miners' exposure levels to asbestos, including taking samples at all existing vermiculite, taconite, talc, and other mines to determine whether asbestos is present and at what levels. In early 2000, MSHA began an intensive sampling effort at operations with potential asbestos exposure. These efforts continue. While sampling, MSHA staff discussed with miners and mine operators the potential hazards of asbestos and the types of preventive measures that could be implemented to reduce exposures. The course of action MSHA takes in addressing asbestos hazards to miners will, in part, be based on these sampling results.

Anticipated Cost and Benefits:

MSHA will develop a preliminary regulatory economic analysis to accompany any proposed rule that may be developed.

Risks:

Miners could be exposed to the hazards of asbestos during mine operations where the ore body contains asbestos. There is also potential for exposure at facilities in which installed asbestos-containing material is present. Overexposure to asbestos causes asbestosis, mesothelioma, and other forms of cancers.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/02	67 FR 15134
Notice of Public Meetings	03/29/02	
Notice of Change to Public Meetings	04/18/02	67 FR 19140
ANPRM Comment Period End	06/27/02	
NPRM	03/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

The Office of the Inspector General's ''Evaluation of MSHA's Handling of Inspections at the W.R. Grace & Company Mine in Libby, Montana,'' was issued in March 2001.

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RIN: 1219–AB24

DOL—MSHA

FINAL RULE STAGE

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98. DIESEL PARTICULATE MATTER EXPOSURE OF UNDERGROUND METAL AND NONMETAL MINERS

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 57

Legal Deadline:

None

Abstract:

On January 19, 2001, MSHA published a final rule addressing diesel particulate matter (DPM) exposure of underground metal and nonmetal miners (66 FR 5706). The final rule established new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines. The rule establishes an interim concentration limit of 400 micrograms of total carbon per cubic meter of air that became applicable July 20, 2002, and a final concentration limit of 160 micrograms to become applicable after January 19, 2006. Industry challenged the rule and organized labor intervened in the litigation. Settlement negotiations with the litigants have resulted in further regulatory actions on several requirements of the rule. One final rule has been published (67 FR 9180). This new rulemaking will address many of the remaining issues. MSHA issued an advance notice of proposed rulemaking (ANPRM) on September 25, 2002 (67 FR 60199) to obtain additional information and published a notice of proposed rulemaking (NPRM) in August 2003.

Statement of Need:

As a result of the first partial settlement with the litigants, MSHA published two documents in the Federal Register on July 5, 2001. One document delayed the effective date of 57.5066(b) regarding the tagging provisions of the maintenance standard; clarified the effective dates of certain provisions of the final rule; and gave correction amendments (66 FR 35518).

The second document was a proposed rule to clarify 57.5066(b)(1) and (b)(2) of the maintenance standards and to add a new paragraph (b)(3) to 57.5067 regarding the transfer of existing diesel equipment from one underground mine to another underground mine. The final rule on these issues was published February 27, 2002, and became effective March 29, 2002.

As a result of the second partial settlement agreement, MSHA proposed specific changes to the 2001 DPM final rule. On September 25, 2002, MSHA published an ANPRM. In response to commenters, MSHA proposed changes only to the interim DPM standard of 400 micrograms per cubic meter of air. In a separate rulemaking, the Agency will propose a rule to revise the final concentration limit of 160 micrograms per cubic meter of air. The scope of both rulemakings is limited to the settlement agreement. The current rulemaking addresses the following provisions:

57.5060(a) - Whether to change the existing DPM surrogate for the interim limit from total carbon to elemental carbon; and change the concentration limit to a comparable permissible exposure limit.

57.5060(c) - Whether to adapt to the interim limit the existing provision that allows mine operators to apply to the Secretary for additional time to come into compliance with the final concentration limit. MSHA also agreed

to propose to include consideration of economic feasibility, and to allow for annual renewals of such special extensions.

57.5060(d) — Whether to remove the existing provision permitting miners to engage in certain activities in concentrations exceeding the interim and final limits upon application and approval from the Secretary, since the Agency agreed to propose the current hierarchy of controls that MSHA applies in its existing metal and nonmetal exposure based health standards for abating violations.

57.5060(e) — Whether to remove the existing prohibition on the use of personal protective equipment.

57.5060(f) - Whether to remove the prohibition on the use of administrative controls.

57.5061(a) — Whether to change the reference from ''concentration'' to PEL.

57.5061(b) — Whether to change the reference from ''total carbon'' to ''elemental carbon.''

57.5061(c) - Whether to delete the references to ''area'' and ''occupational'' sampling for compliance.

57.5062 — Whether to revise the existing diesel control plan.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 101 and 103 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

This rulemaking would amend and improve health protection from that afforded by the existing standard.

Anticipated Cost and Benefits:

MSHA's preliminary economic analysis indicates that making the changes under consideration would result in a cost savings to the mining industry.

Risks:

Several epidemiological studies have found that exposure to diesel exhaust presents potential health risks to miners. These potential adverse health effects range from headaches and nausea to respiratory disease and cancer. In the confined space of the underground mining environment, occupational exposure to diesel exhaust may present a greater hazard due to ventilation limitations and the presence of other airborne contaminants, such as toxic mine dusts or mine gases. We believe that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate matter. Proceeding with rulemaking on the provisions discussed above will more effectively reduce miners' exposure to DPM.

Timetable:

Action	Date	FR Cite
ANPRM	09/25/02	67 FR 60199
ANPRM Comment Period End	11/25/02	
NPRM	08/14/03	68 FR 48668
NPRM Comment Period End	10/14/03	
Limited Reopening of the Comment Period	02/20/04	69 FR 7881
Limited Reopening of the Comment Period End	04/05/04	69 FR 7881
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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DOL—Occupational Safety and Health Administration (OSHA)

PRERULE STAGE

99. OCCUPATIONAL EXPOSURE TO CRYSTALLINE SILICA

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910; 29 CFR 1915; 29 CFR 1917; 29 CFR 1918; 29 CFR 1926

Legal Deadline:

None

Abstract:

Crystalline silica is a significant component of the earth's crust, and many workers in a wide range of industries are exposed to it, usually in the form of respirable quartz or, less frequently, cristobalite. Chronic silicosis is a uniquely occupational disease resulting from exposure of employees over long periods of time (10 years or more). Exposure to high levels of respirable crystalline silica causes acute or accelerated forms of silicosis that are ultimately fatal. The current OSHA permissible exposure limit (PEL) for general industry is based on a formula recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1971 (PEL=10mg/cubic meter/(% silica + 2), as respirable dust). The current PEL for construction and maritime (derived from ACGIH's 1962 Threshold Limit Value) is based on particle counting technology, which is considered obsolete. NIOSH and ACGIH recommend a 50ug/m3 exposure limit for respirable crystalline silica.

Both industry and worker groups have recognized that a comprehensive standard for crystalline silica is needed to provide for exposure monitoring, medical surveillance, and worker training. The American Society for Testing and Materials (ASTM) has published a recommended standard for addressing the hazards of crystalline silica. The Building Construction Trades Department of the AFL-CIO has also developed a recommended comprehensive program standard. These standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance.

Statement of Need:

Over two million workers are exposed to crystalline silica dust in general industry, construction and maritime industries. Industries that could be particularly affected by a standard for crystalline silica include: foundries, industries that have abrasive blasting operations, paint manufacture, glass and concrete product manufacture, brick making, china and pottery manufacture, manufacture of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing. The seriousness of the health hazards associated with silica exposure is demonstrated by the

fatalities and disabling illnesses that continue to occur; between 1990 and 1996, 200 to 300 deaths per year are known to have occurred where silicosis was identified on death certificates as an underlying or contributing cause of death. It is likely that many more cases have occurred where silicosis went undetected. In addition, the International Agency for Research on Cancer (IARC) has designated crystalline silica as a known human carcinogen. Exposure to crystalline silica has also been associated with an increased risk of developing tuberculosis and other nonmalignant respiratory diseases, as well as, renal and autoimmune respiratory diseases. Exposure studies and OSHA enforcement data indicate that some workers continue to be exposed to levels of crystalline silica far in excess of current exposure limits. Congress has included compensation of silicosis victims on Federal nuclear testing sites in the Energy Employees' Occupational Illness Compensation Program Act of 2000. There is a particular need for the Agency to modernize its exposure limits for construction and maritime, and to address some specific issues that will need to be resolved to propose a comprehensive standard.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of silicosis and other serious disease and that rulemaking is needed to substantially reduce the risk. In addition, the proposed rule will recognize that the PELs for construction and maritime are outdated and need to be revised to reflect current sampling and analytical technologies.

Alternatives:

Over the past several years, the Agency has attempted to address this problem through a variety of non-regulatory approaches, including initiation of a Special Emphasis Program on silica in October 1997, sponsorship with NIOSH and MSHA of the National Conference to Eliminate Silicosis, and dissemination of guidance information on its Web site. OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of crystalline silica. The Agency is currently evaluating several options for the scope of the rulemaking.

Anticipated Cost and Benefits:

The scope of the proposed rulemaking and estimates of the costs and benefits are still under development.

Risks:

A detailed risk analysis is under way.

Timetable:

Action	Date	FR Cite
Completed SBREFA Report	12/19/03	
Complete Peer Review of Risk Assessment	02/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 1218–AB70

DOL—OSHA

PROPOSED RULE STAGE

100. OCCUPATIONAL EXPOSURE TO HEXAVALENT CHROMIUM (PREVENTING OCCUPATIONAL ILLNESS: CHROMIUM)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910

Legal Deadline:

NPRM, Judicial, October 4, 2004.

Abstract:

In July 1993, the Occupational Safety and Health Administration (OSHA) was petitioned for an emergency temporary standard (ETS) to reduce the permissible exposure limit (PEL) for occupational exposures to hexavalent chromium (CrVI). The Oil, Chemical, and Atomic Workers International Unions (OCAW) and Public Citizen's Health Research Group (HRG) petitioned OSHA to promulgate an ETS to lower the PEL for CrVI compounds to 0.5 micrograms per cubic meter of air (ug/m3) as an eight-hour, time-weighted average (TWA). The current PEL in general industry is a ceiling value of 100 ug/m3, measured as CrVI and reported as chromic anhydride (CrO3). The amount of CrVI in the anhydride compound equates to a PEL of 52 ug/m3. The ceiling limit applies to all forms of CrVI, including chromic acid and chromates, lead chromate, and zinc chromate. The current PEL of CrVI in the construction industry is 100 ug/m3 as a TWA PEL, which also equates to a PEL of 52 ug/m3. After reviewing the petition, OSHA denied the request for an ETS and initiated a section 6(b)(5) rulemaking.

OSHA began collecting data and performing preliminary analyses relevant to occupational exposure to CrVI. However, in 1997, OSHA was sued by HRG OCAW for unreasonable delay in issuing a final CrVI standard. The 3rd Circuit, U.S. Court of Appeals ruled in OSHA's favor and the Agency continued its data collection and analytic efforts on CrVI. In 2002, OSHA was sued again by HRG and Paper, Allied-International, Chemical and Energy Workers Ineternational Union (PACE) for continued unreasonable delay in issuing a final CrVI standard. In August, 2002 OSHA published a Request for Information on CrVI to solicit additional information on key issues related to controlling exposures to CrVI and on December 4, 2002, OSHA announced its intent to proceed with developing a proposed standard. On December 24, 2002, the 3rd Circuit, U.S. Court of Appeals ruled in favor of HRG and ordered the Agency to proceed expeditiously with a CrVI standard.

Statement of Need:

Approximately 380,000 workers are exposed to CrVI in general industry, maritime, construction, and agriculture. Industries or work processes that could be particularly affected by a standard for CrVI include: Electroplating, welding, painting, chromate production, chromate pigment production, ferrochromium production, iron and steel production, chromium catalyst production, and chromium dioxide and sulfate production.

Exposure to CrVI has been shown to produce lung cancer, an often fatal disease, among workers exposed to CrVI compounds. The International Agency for Research on Cancer (IARC) classifies CrVI compounds as a Group 1 Carcinogen: Agents considered to be carcinogenic in humans. The Environmental Protection Agency (EPA) and the American Conference of Governmental Industrial Hygienists (ACGIH) have also designated CrVI compounds as known and confirmed human carcinogens, respectively. Similarly, the National Institute for Occupational Safety and Health (NIOSH) considers CrVI compounds to be potential occupational carcinogens. OSHA's current standards for CrVI compounds, adopted in 1971, were established to protect against nasal irritation. Therefore, there is a need to revise the current standard to protect workers from lung cancer.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of lung cancer and dermatoses and that rulemaking is needed to substantially reduce the risk.

Alternatives:

OSHA had considered non-regulatory approaches, including the dissemination of guidance on its web site. However, OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of CrVI and the Agency has been ordered by the U.S. Court of Appeals to move forward with a final rule.

Anticipated Cost and Benefits:

The proposed rulemaking includes estimates of the costs and benefits are being developed.

Risks:

A detailed risk analysis is included in the NPRM.

Timetable:

Action	Date	FR Cite
Request for Information	08/22/02	67 FR 54389
Comment Period End	11/20/02	
Initiate SBREFA Process	12/23/03	
SBREFA Report	04/20/04	
NPRM	10/04/04	69 FR 59305
NPRM Comment Period End	01/03/05	
Public Hearings	02/00/05	
Final Rule	01/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Undetermined

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RIN: 1218–AB45

DOL—OSHA

FINAL RULE STAGE

101. ASSIGNED PROTECTION FACTORS: AMENDMENTS TO THE FINAL RULE ON RESPIRATORY PROTECTION

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910.134

Legal Deadline:

None

Abstract:

In January 1998, OSHA published the final Respiratory Protection standard (29 CFR 1910.134), except for reserved provisions on assigned protection factors (APFs) and maximum use concentrations (MUCs). APFs are numbers that describe the effectiveness of the various classes of respirators in reducing employee exposure to airborne contaminants (including particulates, gases, vapors, biological agents, etc.). Employers, employees, and safety and health professionals use APFs to determine the type of respirator to protect the health of employees in various hazardous environments. Maximum use concentrations establish the maximum airborne concentration of a contaminant in which a respirator with a given APF may be used.

Currently, OSHA relies on the APFs developed by NIOSH in the 1980s unless OSHA has assigned a different APF in a substance-specific health standard. However, many employers follow the more recent APFs published in the industry consensus standard, ANSI Z88.2-1992. For some classes of respirators, the NIOSH and ANSI APFs vary greatly.

This rulemaking action will complete the 1998 standard, reduce compliance confusion among employers, and provide employees with consistent and appropriate respiratory protection. On June 6, 2003, OSHA published an NPRM on Assigned Protection Factors in the Federal Register at 68 FR 34036 containing a proposed APF table, and requesting public comment. The extended comment period ended October 2, 2003, and an informal public hearing was held January 28-30, 2004.

Statement of Need:

About five million employees wear respirators as part of their regular job duties. Due to inconsistencies between the APFs found in the current industry consensus standard (ANSI Z88.2-1992) and in the NIOSH Respirator Decision Logic, employers, employees, and safety and health professionals are often uncertain about what respirator to select to provide protection against hazardous air contaminants.

Summary of Legal Basis:

The legal basis for this proposed rule is the determination that assigned protection factors and maximum use concentrations are necessary to complete the final Respiratory Protection standard and provide the full protection under that standard.

Alternatives:

OSHA has considered allowing the current situation to continue. Accordingly, OSHA generally enforces NIOSH APFs, but many employers follow the more recent consensus standard APFs. However, allowing the situation to continue results in inconsistent enforcement, lack of guidance for employers, and the potential for inadequate employee protection.

Anticipated Cost and Benefits:

The estimated compliance costs for OSHA's proposed APF rule are $4.6 million. The APFs proposed in this rulemaking help to ensure that the benefits attributed to proper respiratory

protection under 29 CFR 1910.134 are achieved, as well as provide an additional degree of protection.

Risks:

The preamble to the final Respiratory Protection rule (63 FR 1270, Jan. 8, 1998) discusses the significance of the risks potentially associated with the use of respiratory protection. No independent finding of significant risk has been made for the APF rulemaking since it only addresses a single provision of the larger rule.

Timetable:

Action	Date	FR Cite
ANPRM	05/14/82	47 FR 20803
ANPRM Comment Period End	09/13/82	
NPRM	11/15/94	59 FR 58884
Final Rule	01/08/98	63 FR 1152
Final Rule Effective	04/08/98	
NPRM	06/06/03	68 FR 34036
NPRM Comment Period End	09/04/03	
NPRM Comment Period Extended	10/02/03	68 FR 53311
Public Hearing on 01/28/2004	11/12/03	68 FR 64036
Final Rule: Revocation of Respiratory Protection M. TB	12/31/03	68 FR 75767
Public Hearing	01/28/04	
Post–Hearing Comment and Brief Period Extended	03/30/04	69 FR 16510
Post–Hearing Comment Period End	04/29/04	
Post–Hearing Briefs End	05/29/04	
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State, Tribal

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RIN: 1218–AA05

DOL—OSHA

102. STANDARDS IMPROVEMENT (MISCELLANEOUS CHANGES) FOR GENERAL INDUSTRY, MARINE TERMINALS, AND CONSTRUCTION STANDARDS (PHASE II)

Priority:

Other Significant

Legal Authority:

29 USC 655(b)

CFR Citation:

29 CFR 1910, subpart Z; 29 CFR 1910.1001 to 1910.1052; 29 CFR 1910.142; 29 CFR 1910.178; 29 CFR 1910.219; 29 CFR 1910.261; 29 CFR 1910.265; 29 CFR 1910.410; 29 CFR 1917.92; 29 CFR 1926.1101; 29 CFR 1926.1127; 29 CFR 1926.1129; 29 CFR 1926.60; 29 CFR 1926.62

Legal Deadline:

None

Abstract:

The Occupational Safety and Health Administration (OSHA) proposed to remove or revise provisions in its health standards that are out of date, duplicative, unnecessary, or inconsistent. Where appropriate, the Agency is primarily changing that provision to reduce the burden imposed on the regulated community by these requirements. In this document, substantive changes standards will revise or eliminate duplicative, inconsistent, or unnecessary regulatory requirements without diminishing employee protections. Phase I of this Standards Improvement process was completed in June 1998 (63 FR 33450). OSHA plans to initiate Phase III of this project at a future date to address problems in various safety and health standards.

Statement of Need:

Some parts of OSHA's standards are out of date, duplicative, unnecessary, or inconsistent. The Agency needs to periodically review its standards and make needed corrections. This effort results in standards that are easier for employers and employees to follow and comply with, and thus enhances compliance and worker protection.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary finding that the OSHA standards need to be updated to bring them up to date, reduce inconsistency, and remove unneeded provisions.

Alternatives:

OSHA has considered updating each standard as problems are discovered, but has determined that it is better to make such changes to groups of standards so it is easier for the public to comment on like standards. OSHA has also considered the inclusion of safety standards that need to be updated. However, the Agency has decided to pursue a separate rulemaking for safety issues because the standards to be updated are of interest to different stakeholders.

Anticipated Cost and Benefits:

This revision of OSHA's standards is a deregulatory action. It will reduce employers' compliance obligations.

Risks:

The project does not address specific risks, but is intended to improve OSHA's standards by bringing them up to date and deleting unneeded provisions. The anticipated changes will have no negative effects on worker safety and health.

Timetable:

Action	Date	FR Cite
NPRM	10/31/02	67 FR 66493
NPRM Comment Period End	12/20/02	
NPRM Comment Period Extended	01/08/03	68 FR 1023
Second NPRM Comment Period End	01/30/03	
Public Hearing	07/08/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 1218–AB81

DOL—Office of the Assistant Secretary for Veterans' Employment and Training (ASVET)

PROPOSED RULE STAGE

103. UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT REGULATIONS

Priority:

Other Significant

Legal Authority:

38 USC 4331(a)

CFR Citation:

20 CFR 1002

Legal Deadline:

None

Abstract:

The Secretary's commitment to protecting the employment rights of servicemembers as they return to the civilian work force is reflected by the initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA) with regard to States, local governments and private employers. USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA, although the law dates back to 1994.

Statement of Need:

The Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA), 38 U.S.C. 4301-4333, provides employment and reemployment rights for members of the uniformed services, including veterans and members of the Reserve and National Guard. Under USERRA, eligible service members who leave their civilian jobs for military service are entitled to return to reemployment with their previous employers with the seniority, status and rate of pay they would have attained had they not been away on duty. USERRA also assures that they will not suffer discrimination in employment because of their military service or obligations.

Following the attacks of September 11, 2001, the President authorized a major mobilization of National Guard and Reserve forces that has continued into 2004. In the past three years, the Department has experienced a tremendous increase in the number of inquiries about USERRA from employers and members of the Guard and Reserve. The high volume of requests for technical assistance indicates that there is a significant need for consistent and authoritative USERRA guidance. USERRA regulations will provide the Department's interpretations of the law and procedures for enforcing the law.

Summary of Legal Basis:

USERRA authorizes the Secretary of Labor, in consultation with the Secretary of Defense, to issue regulations implementing USERRA with regard to States, local governments and private employers. 38 U.S.C. 4331(a).

Alternatives:

In lieu of regulations, the Department could choose to continue its compliance assistance efforts, and could issue interpretations of USERRA in the form of a USERRA Handbook, policy memoranda or other less formal means. These would not benefit from broad-based public input, nor would they receive the same level of deference as regulations. See United States v. Mead Corp., 533 U.S. 218, 230 (2001).

Timetable:

Action	Date	FR Cite
NPRM	09/20/04	69 FR 56266
NPRM Comment Period End	11/19/04	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Local, State

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BILLING CODE 4510–23–S

DEPARTMENT OF TRANSPORTATION (DOT)

Statement of Regulatory Priorities

The Department of Transportation (DOT) consists of nine operating administrations, the Bureau of Transportation Statistics, and the Office of the Secretary, each of which has statutory responsibility for a wide range of regulations. For example, DOT regulates safety in the aviation, motor carrier, railroad, mass transit, motor vehicle, commercial space, and pipeline transportation areas. DOT regulates aviation consumer and economic issues and provides financial assistance and writes the necessary implementing rules for programs involving highways, airports, mass transit, the maritime industry, railroads, and motor vehicle safety. It writes regulations carrying out such disparate statutes as the Americans with Disabilities Act and the Uniform Time Act. Finally, DOT has responsibility for developing policies that implement a wide range of regulations that govern internal programs such as acquisition and grants, access for the disabled, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, and the use of aircraft and vehicles.

The Department has adopted a regulatory philosophy that applies to all its rulemaking activities. This philosophy is articulated as follows: DOT regulations must be clear, simple, timely, fair, reasonable, and necessary. They will be issued only after an appropriate opportunity for public comment, which must provide an equal chance for all affected interests to participate, and after appropriate consultation with other governmental entities. The Department will fully consider the comments received. It will assess the risks addressed by the rules and their costs and benefits, including the cumulative effects. The Department will consider appropriate alternatives, including nonregulatory approaches. It will also make every effort to ensure that legislation does not impose unreasonable mandates.

An important initiative of Secretary Mineta's has been to increase the timeliness of DOT rulemaking actions and address the large number of old rulemakings. To implement this, the Secretary has required (1) regular meetings of senior DOT officials to ensure effective scheduling of rulemakings and timely decisions, (2) better tracking and coordination of rulemakings, (3) regular reporting, (4) early briefings of interested officials, (5) better training of staff, and (6) necessary resource allocations. The Department has achieved significant success as a result of this initiative with the number of old rulemakings as well as the average time to complete rulemakings decreasing. This is also allowing the Department to use its resources more effectively and efficiently.

The Department's regulatory policies and procedures provide a comprehensive internal management and review process for new and existing regulations and ensure that the Secretary and other appropriate appointed officials review and concur in all significant DOT rules. DOT continually seeks to improve its regulatory process. The Department's development of regulatory process and related training courses for its employees; creation of an electronic, Internet-accessible docket that can also be used to submit comments electronically; a ''list serve'' that allows the public to sign up for e-mail notification when the Department issues a rulemaking document; creation of an electronic rulemaking tracking and coordination system; the use of direct final rulemaking; and the use of regulatory negotiation are a few examples of this.

In addition, the Department continues to engage in a wide variety of activities to help cement the partnerships between its agencies and its customers that will produce good results for transportation programs and safety. The Department's agencies also have established a number of continuing partnership mechanisms in the form of rulemaking advisory committees.

The Department is also actively engaged in the review of existing rules to determine whether they need to be revised or revoked. These reviews are in accordance with section 610 of the Regulatory Flexibility Act, the Department's regulatory policies and procedures, and Executive Order 12866. This includes determining if the rules would be more understandable if they are written using a plain language approach. Appendix D to our Regulatory Agenda highlights our efforts in this area.

Over the next year, the Department will continue its efforts to use advances in technology to improve its rulemaking management process. For example, the Department created an effective tracking system for significant rulemakings to ensure that rules are either completed in a timely manner or that delays are identified and fixed. Through this tracking system, a monthly report is generated. To make its efforts more transparent, the Department has made this report Internet-accessible. By doing this, the Department is providing valuable information concerning our rulemaking activity and is providing information necessary for the public to evaluate the Department's progress in meeting its commitment to completing rulemakings in a timely manner.

The Department will continue to place great emphasis on the need to complete high quality rulemakings by involving senior Departmental officials in regular meetings to resolve issues expeditiously.

Office of the Secretary of Transportation (OST)

The Office of the Secretary (OST) oversees the regulatory process for the Department. OST implements the Department's regulatory policies and procedures and is responsible for ensuring the involvement of top management in regulatory decisionmaking. Through the General Counsel's office, OST is also responsible for ensuring that the Department complies with Executive Order 12866 and other legal and policy requirements affecting rulemaking, including new statutes and Executive orders. Although OST's principal role concerns the review of the Department's significant rulemakings, this office has the lead role in the substance of projects concerning aviation economic rules and those affecting the various elements of the Department.

OST provides guidance and training regarding compliance with regulatory requirements and process for use by personnel throughout the Department. OST also plays an instrumental part in the Department's efforts to improve our economic analyses, risk assessments, and regulatory flexibility analyses.

OST also leads and coordinates the Department's response to Administration and congressional proposals that concern the regulatory process. The General Counsel's Office works closely with representatives of other agencies, the Office of Management and Budget, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

During fiscal year 2005, OST expects to complete work on an NPRM that will propose accessibility requirements for vessels which involves complex issues

unlike those affecting land transportation. This NPRM will propose feasible requirements to make passenger vessels accessible to, and usable by, individuals with disabilities.

Federal Aviation Administration (FAA)

The FAA issues regulations to provide a safe, secure, and efficient global aviation system for civil aircraft. In an effort to make sure their rules are concise and easy to understand, the FAA reexamined the use of plain language in its regulations. The initial result of this review was revisions to 14 CFR part 11, which delineates the process for rulemaking changes. We have extended this initiative to include plain language revisions to our regulatory documents, advisory material, handbook guidance, and all reports and correspondence we prepare. Other actions include:

Supporting the FAA's Safety Agenda on Safer Skies. This agenda is based on a comprehensive review of the causes of aviation accidents and is designed to bring about an 80 percent reduction in fatal accidents. Projects related to controlled flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decisionmaking, and cabin safety are some of the focus areas identified that may result in rulemaking advisory and guidance materials.

Continuing to involve the aviation community early in the regulatory process. The Aviation Rulemaking Advisory Committee (ARAC) completed numerous reports and recommendations, leading to the publication of seven regulatory actions and issuance of several advisory circulars and other guidance materials. The FAA Aging Transport Nonstructural Systems Plan addresses concerns with potential safety issues associated with problems that may develop in transport category airplanes systems as a result of wear and degradation in service. One important component of the plan is use of the Aging Transport Nonstructural Systems Rulemaking Advisory Committee to provide a mechanism for public input to FAA activities. The FAA will continue to receive recommendations from the Committee in the form of regulations, guidance materials, and training requirements supporting enhanced airworthiness for airplane systems.

Continuing to harmonize the U.S. aviation regulations with those of other countries. The harmonization of the U.S. regulations with the European Joint Aviation Regulations is the FAA's most comprehensive long-term rulemaking effort. The differences worldwide in certification standards, practice and procedures, and operating rules must be identified and minimized to reduce the regulatory burden on the international aviation system. The differences between the FAA regulations and the requirements of other nations impose a heavy burden on U.S. aircraft manufacturers and operations. Harmonization and standardization should help the U.S. aerospace industry remain internationally competitive. While the overall effort to achieve this is global, it will be accomplished by many small, individual, nonsignificant rulemaking projects. The FAA has published 41 regulations based on recommendations of ARAC that will lead to harmonizing FAA regulations and Joint Aviation Requirements.

Continuing to recognize the needs of small entities by complying with the Small Business Regulatory Enforcement Fairness Act and addressing small entity concerns whenever appropriate in rulemaking documents. In response to the Act, the FAA has established a Small Entity Contact, a website on FAA's home page, a toll-free number, and an e-mail address for receipt of inquiries.

Ensuring that the congressional mandates for rulemaking deadlines established by the FAA Reauthorization Act of 1996 are met. One mandate is the issuance of a final rule 16 months after the close of the comment period on the proposed rule.

Top regulatory priorities for 2004-2005 include a final rule concerning flight simulation device requirements and several rulemaking projects known collectively as the FAA's Aging Airplane Program. The FAA developed the Aging Airplane Program to address structural and non-structural system safety issues that may arise as airplanes age and in response to:

- Airplanes being operated beyond their original designservice goals;
- The 1988 Aloha B737 accident; and
- The Aging Airplane Safety Act of 1991.

The rulemakings included in the Aging Airplane Program are:

- Enhanced Airworthiness Program for Aging Systems/FuelTank Safety;
- Development of Type Certificate and Supplemental TypeCertificate Holder Data for the Aging Aircraft Safety Program; and
- Widespread Fatigue Damage Program.

Other related rulemakings include withdrawal of a notice of proposed rulemaking on Corrosion Prevention and Control Program (69 FR 50350, August 16, 2004) and taking final action on the Aging Airplane Safety Interim Final Rule issued on December 6, 2002.

We recently performed a comprehensive review of our Aging Airplane Program and published for public comment an overview of our findings (69 FR 45936, July 30, 2004).

Federal Highway Administration (FHWA)

The FHWA will continue with ongoing regulatory initiatives in support of its surface transportation programs. The FHWA will continue to implement legislation in the least burdensome and restrictive way possible consistent with the FHWA's mission. The FHWA will continue to pursue regulatory reform in areas where project development can be streamlined or accelerated, duplicative requirements can be consolidated, recordkeeping requirements can be reduced or simplified, and the decisionmaking authority of our State and local partners can be increased.

Federal Motor Carrier Safety Administration (FMCSA)

FMCSA commenced operations on January 2, 2000, pursuant to the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Public Law 106-159), as codified at 49 U.S.C. section 113, to improve the administration of the Federal motor carrier safety program. The agency's primary mission is to reduce crashes, injuries, and fatalities involving large trucks and buses. DOT set a safety goal for all its surface transportation agencies to reduce the fatality rate by 41 percent during the period from 1996 to 2008. FMCSA has been working to achieve a goal of reducing the number of large truck- and bus-involved fatalities by 41 percent, or a reduction to no more than 1.65 commercial motor vehicle (CMV) fatalities per 100 million truck vehicle miles traveled by the end of 2008. Although any life lost in a traffic crash is too many, FMCSA will strive to meet and exceed this safety goal. For example, regulations relating to performance standards for vehicles, drivers, and motor carriers will help achieve this goal. In MCSIA, Congress put special emphasis on the importance of timely rulemaking as a way to achieve reductions in the number and severity of large truck-involved crashes. FMCSA continues to develop a more effective and efficient regulatory program to meet the expectations of

Congress, its stakeholders and partners, and the general public. To improve both the quality and timeliness of the agency's rulemakings, FMCSA established a rulemaking process for the development of its motor carrier safety regulations and updates it periodically.

In fiscal year 2004, FMCSA completed four final rules pursuant to the settlement agreement entered into by the parties and the court's order In re Citizens for Reliable and Safe Highways, et al., No. 02-1363 (D.C. Cir.) (February 21, 2003): Safety Performance History of New Drivers (69 FR 16684, 03/30/2004); Minimum Training Requirements for Longer Combination Vehicle (LCV) Operators and LCV Driver-Instructor Requirements (69 FR 16722, 03/30/2004); Minimum Training Requirements for Entry-Level Commercial Motor Vehicle Operators (69 FR 29384, 05/21/2004); and Hazardous Materials Safety Permits (69 FR 39350, 06/30/2004). FMCSA also published implementing procedures covering its obligations under the National Environmental Policy Act (69 FR 9680, 03/01/2004).

On September 30, Congress passed and the President signed HR 5183, an extension of the surface transportation program authorizations which addressed the Hours of Service (HOS) rule announced by FMCSA in April 2003. The action by Congress means the new hours-of-service rule stays in effect and will be enforced until September 30, 2005, or until such earlier time as FMCSA issues a revised rule addressing the concerns of the U.S. Court of Appeals for the District of Columbia Circuit stated in Public Citizen et al. v. FMCSA. FMCSA has issued an ANPRM on Electronic On-Board Recorders (EOBRs) under RIN 2126-AA89 as part of its efforts to meet the concerns of the Court.

As one of its priorities in fiscal year 2005, FMCSA has announced that it is holding a series of Public Listening Sessions as part of a Comprehensive Safety Analysis 2010 Initiative (CSA-2010). The listening sessions will be used to ask motor carriers, insurance and safety advocacy groups, traffic enforcement professionals, commercial drivers and the public for their views on the ideal ways to measure the safety of truck and bus operations (69 FR 51748, 08/20/2004). Based on the information from the listening sessions, FMCSA hopes to redesign and improve the way FMCSA conducts compliance and enforcement operations, and to help in its goal of decreasing CMV fatalities to no more than 1.65 per 100 million miles by the end of 2008.

Other FMCSA priorities in 2005 are a rulemaking that involves combining the medical certification with the commercial driver's license (the last remaining MCSIA initiative); rulemakings directed at strengthening our enforcement activities; and a number of rulemakings related to operational safety.

National Highway Traffic Safety Administration (NHTSA)

The statutory responsibilities of the National Highway Traffic Safety Administration (NHTSA) relating to motor vehicles include reducing the number of, and mitigating the effects of, motor vehicle crashes and related fatalities and injuries; providing safety performance information to aid prospective purchasers of vehicles, child restraints, and tires; and improving automotive fuel efficiency. NHTSA pursues policies that encourage the development of nonregulatory approaches when feasible in meeting its statutory mandates. It issues new standards and regulations or amendments to existing standards and regulations when appropriate. It ensures that regulatory alternatives reflect a careful assessment of the problem, consideration of international standards and harmonization objectives, and a comprehensive analysis of the benefits, costs, and other impacts associated with the proposed regulatory action. Finally, it considers alternatives consistent with the Administration's regulatory principles.

In the coming year, occupant protection in rear-end crashes will be improved as a result of a final rule to require more effective head restraints. Rear seat occupants, especially children, will be better protected in crashes because of a final rule to require rear center lap/shoulder belts. NHTSA will propose to alert vehicle owners by a new Tire Pressure Monitoring System in cars and light trucks when the vehicle's tires are significantly underinflated. The agency will take final action on this proposal before September 30, 2005.

In addition to numerous programs that focus on the safe performance of motor vehicles, the Agency is engaged in a variety of programs to improve driver and occupant behavior. These programs emphasize the human aspects of motor vehicle safety and recognize the important role of the States in this common pursuit. NHTSA has identified two high priority areas, safety belt use and impaired driving. In 2003, it released a report analyzing safety belt use problems and describing actions to address them. A separate report analyzed and described actions to address the problem of impaired driving. To address this problem, the Agency is focusing especially on three strategies — conducting highly visible, well publicized enforcement; supporting prosecutors who handle impaired driving cases and expanding the use of DWI/Drug Courts, which hold offenders accountable for receiving and completing treatment for alcohol abuse and dependency; and the adoption of alcohol screening and brief intervention by medical and health care professionals. Other behavioral efforts encourage child safety-seat use, combat excessive speed and aggressive driving, improve motorcycle, bicycle, and pedestrian safety, and provide consumer information to the public.

Federal Railroad Administration (FRA)

The Federal Railroad Administration (FRA) exercises regulatoryauthority over all areas of railroad safety. Fashioning regulations that have favorable benefit-to-cost ratios and that, where feasible, incorporate flexible performance standards, requires cooperative action by all affected parties. In order to foster an environment of collaborative rulemaking, FRA established the Railroad Safety Advisory Committee (RSAC). The purpose of the RSAC is to develop consensus recommendations for regulatory action on issues referred to it by FRA. Where consensus is achieved, and FRA believes the consensus recommendations serve the public interest, the resulting rule is very likely to be better understood, more widely accepted, more cost-beneficial, and more correctly applied. Where consensus cannot be achieved, however, FRA will fulfill its regulatory role without the benefit of the RSAC's recommendations. The RSAC has met regularly and currently has working groups actively addressing the following tasks: (1) The development of safety standards for locomotive crashworthiness; (2) the development of safety standards for locomotive working conditions, including occupational noise exposure; and (3) the development of accident survivability standards for locomotive event recorders. FRA is also completing a rulemaking based on the RSAC's recommendations entitled ''Performance Standards for Processor-Based Signal and Train Control Systems.'' Further, at FRA's request the RSAC is conducting a preliminary exploration of further opportunities for improvement of the safety of rail

passenger service that might lead to recommendations for public or private actions.

One of the top priorities of FRA for 2004-2005 is a final rule concerning whistle bans at highway-rail grade crossings.

Federal Transit Administration (FTA)

The Federal Transit Administration (FTA) provides financial assistance to State and local governments for mass transportation purposes. The regulatory activity of FTA focuses on establishing the terms and conditions of Federal financial assistance available under the Federal transit laws.

FTA's policy regarding regulations is to:

- Implement statutory authorities in ways that provide the maximum net benefits to society;
- Keep paperwork requirements to a minimum;
- Allow for as much local flexibility and discretion as is possible within the law;
- Ensure the most productive use of limited Federal resources;
- Protect the Federal interest in local investments; and
- Incorporate good management principles into the grant management process.

As mass transportation needs have changed over the years, so have the requirements for Federal financial assistance under the Federal transit laws and related statutes. FTA's regulatory priorities for 2004-2005 are to continue to amend existing regulations as necessary and appropriate, with an eye towards reauthorization of the Federal transit programs in the near future, which may require several significant rulemakings thereafter.

Maritime Administration (MARAD)

MARAD administers Federal laws and programs designed to promote and maintain a U.S. merchant marine capable of meeting the Nation's shipping needs for both national security and domestic and foreign commerce.

MARAD's regulatory objectives and priorities reflect the Agency's responsibility of ensuring the availability of adequate and efficient water transportation services for American shippers and consumers. To advance these objectives, MARAD issues regulations, which are principally administrative and interpretive in nature, when appropriate, in order to provide a net benefit to the U.S. maritime industry.

MARAD's regulatory priorities are to update existing regulations and to reduce unnecessary burden on the public.

Research and Special Programs Administration (RSPA)

The Research and Special Programs Administration (RSPA) has responsibility for rulemaking under two programs. Through the Associate Administrator for Hazardous Materials Safety, RSPA administers regulatory programs under Federal hazardous materials transportation law and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990. Through the Associate Administrator for Pipeline Safety, RSPA administers regulatory programs under the Federal pipeline safety laws and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990.

In the area of hazardous materials transportation, the regulatory priority is to clarify through rulemaking the applicability of regulations to the loading, unloading, and storage of hazardous materials incidental to their movement in commerce. Clarifying the applicability of the regulations will facilitate compliance with them and also clarify when other requirements of Federal, State, local, and tribal governments apply.

Bureau of Transportation Statistics (BTS)

The Bureau of Transportation Statistics (BTS) is responsible for collecting, compiling, analyzing, and making accessible information on the Nation's transportation systems; identifying needs for new information and analysis and implementing programs to meet those needs; and enhancing the quality and effectiveness of the Department's statistical programs through the development of guidelines, coordination with related information-gathering activities conducted by other Federal agencies, and promotion of improvements in data acquisition, archiving, dissemination, and use.

BTS's Office of Airline Information (OAI) collects airline financial and operating statistical data, covering both passenger and cargo traffic. This information gives the Government consistent and comprehensive economic and market data on individual airline operations and is used, for instance, in supporting policy initiatives, negotiating international bilateral aviation agreements, awarding international route authorities, and meeting international treaty obligations. The aviation, travel, and tourism communities value this information for a variety of purposes, such as conducting analyses of on-time performance, denied boardings, market trends, and economic analyses.

Saint Lawrence Seaway Development Corporation (SLSDC)

The Saint Lawrence Seaway Development Corporation (SLSDC) is a wholly owned Government corporation created by Congress in 1954. The primary operating service of the SLSDC is to ensure the safe transit of commercial and noncommercial vessels through the two U.S. locks and navigation channels of the Saint Lawrence Seaway System. The SLSDC works jointly with its Canadian counterpart to operate and maintain this deep draft waterway between the Great Lakes and the Atlantic Ocean. The SLSDC also works jointly with its Canadian counterpart on all matters related to rules and regulations, overall operations, vessel inspection, traffic control, navigation aids, safety, operating dates, and trade development programs.

The regulatory priority of the SLSDC is to provide its customers with the safest, most reliable, and most efficient Seaway System possible.

DOT—Federal Aviation Administration (FAA)

PROPOSED RULE STAGE

104. +AGING AIRCRAFT PROGRAM (WIDESPREAD FATIGUE DAMAGE)

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 41706; . . .

CFR Citation:

14 CFR 121; 14 CFR 129

Legal Deadline:

None

Abstract:

The FAA proposes to require incorporation of a program to preclude widespread fatigue damage into the FAA-approved maintenance program of

each operator of large transport category airplanes. This action is the result of concern for the continued operational safety of airplanes that are approaching or have exceeded their design service goal. This proposed rulemaking would require a limit of validity in flight cycles or hours of the structural maintenance program, where the operator must incorporate added inspections and/or modification/replacement actions into its maintenance program to allow continued operation.

Statement of Need:

History has shown that widespread fatigue damage is a significant safety risk for transport category airplanes. The Aloha B-737 accident in 1988 showed FAA and industry that WFD could be a problem that could lead to catastrophic failure of airplane structure. Numerous widespread fatigue damage incidents since then have confirmed that it is a threat common to all aging airplanes. Because widespread fatigue damage results from the interaction of many small cracks, existing inspection methods are inadequate to reliably detect and prevent it.

Summary of Legal Basis:

Section 44701, Title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

The FAA acknowledges the proposed rule may have a significant impact on a substantial number of small entities. We conclude the current proposal is the preferred alternative because it provides for a common WFD system for all operators who fly in the same airspace under the same operating environment.

We considered the following alternatives:

1.Exclude small entities

2.Extend the compliance deadline for small entities

3.Establish lesser technical requirements for small entities

4.Expand the requirements to cover more airplanes

Anticipated Cost and Benefits:

The cost of this proposal is $358.1 million. The benefits of this proposal consist of $654 million in accident prevention benefits and $74 million in detection benefits, for total benefits of $728 million.

Risks:

Because widespread fatigue damage problems will occur as airplanes operate beyond their initial operational limit, operators are likely to detect such problems over the 20-year forecast period. The FAA has assumed that there is a probability of widespread fatigue damage problems occurring for each fuselage type of five percent in each year. Under this assumption, there is a 35 percent chance that there will be zero WFD problems detected for a particular fuselage type over a 20-year period.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI05

DOT—FAA

105. +ENHANCED AIRWORTHINESS PROGRAM FOR AIRPLANE SYSTEMS (EAPAS) AND SFAR 88

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 1155; 49 USC 1372; 49 USC 40103; 49 USC 40119; 49 usc 40120; 49 USC 106(g); 49 USC 40103; 49 USC 40113; 49 USC 40119 to 40120; 49 USC 41706; 49 USC 4401; 49 USC 44111; 49 USC 44701 to 44705; 49 USC 44709 to 44713; 49 USC 44715 to 44717

CFR Citation:

14 CFR 1; 14 CFR 25; 14 CFR 91; 14 CFR 121; 14 CFR 125; 14 CFR 129; 14 CFR 1; 14 CFR 121; 14 CFR 129; 14 CFR 25; 14 CFR 91

Legal Deadline:

None

Abstract:

This rulemaking would change wiring system and fuel tank system requirements for transport category airplanes. It would organize and clarify design requirements for wire systems by moving existing regulatory references to wiring into a single section of the regulations specifically for wiring and adding new certification rules to address aging issues in wire systems. This rulemaking would require holders of type certificates for certain transport category airplanes to conduct analyses and make necessary changes to existing Instruction for Continued Airworthiness (ICA) to improve maintenance procedures for wire systems. It would require operators to incorporate those ICA for wiring into their maintenance or inspections programs. It would also clairfy requirements of certain existing operational rules for operators to incorporate ICA for fuel tank systems into their maintenance or inspection programs. The intent of this rule is to help ensure the continued safety of commercial airplanes by improving the design, installation, and maintenance of their electrical wiring systems as well as by aligning those requirements as closely as possible with the requirements for fuel tank system safety.

Statement of Need:

The proposal will address a continuing history of wire-related failures, resulting in smoke in the cabin/flight deck, fires, arcing etc. Current maintenance practices have not been adequate to address issues of aging and degradation in wiring. Wires have not been viewed as important systems on their own.

Summary of Legal Basis:

Section 44701, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

1. Require operators to clean and inspect each airplane every C-check or every three years, causing an additional

$192.5 million in cleaning and inspection costs, and an additional $104.0 million in downtime. This option would result in additional costs of $296.5 million with no commensurate increase in benefits.

2. Require electrical wiring interconnection systems training for four new groups of people (electrical/avionic engineers, individuals involved in engineering or planning work, flight deck crew, and cabin crew) in addition to maintenance workers. Training these individuals would require that operators develop additional courses. The total estimated additional cost of this alternative is approximately $381.1 million with no commensurate increase in benefits.

3. We also considered voluntary compliance with the intent of this proposal by the affected parties. Some in industry have suggested issuing advisory circulars to give guidance on changes that need to be made. However, previous voluntary safety assessments have been difficult to complete in a timely manner because they lack enforceability. Similarly, issuance of guidance material would depend on voluntary compliance, and would not be enforceable.

Anticipated Cost and Benefits:

Total costs are estimated at $474.3 million ($209.2 million in present value) over 25 years. Total benefits are estimated at $755.3 million ($340.7 million in present value) over 25 years.

Risks:

The FAA estimates there may be more than 1.2 fatal events caused by electrical wiring interconnection systems (EWIS) over a 25-year period. The Poisson distribution provides a measure for this risk. Based on a mean value of 1.2 fatal EWIS events, there is a 70 percent chance there will be 1 or more occurrences of a fatal EWIS event, a 34 percent chance there will be 2 or more fatal EWIS events; and a 12 percent chance of 3 or more occurrences of fatal EWIS events.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI31

DOT—FAA

106. +AGING AIRCRAFT SAFETY—DEVELOPMENT OF TC AND STC HOLDER DATA

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 44701; 49 USC 44702; 49 USC 44704

CFR Citation:

14 CFR 25

Legal Deadline:

None

Abstract:

This rulemaking would require type certificate holders and supplemental type certificate holders of certain transport category airplanes to develop data to support damage-tolerance-based inspections and procedures for their airplanes' baseline structure, including repairs, alterations and modifications to the baseline structure. It would also help ensure that maintenance of the airplanes age sensitive parts and components have been adequate and timely. These actions are needed to assure that 14 CFR part 121 certificate holders have the necessary data to comply with the damage tolerance requirements of the Aging Airplane Safety rule.

Statement of Need:

In several recent rules the FAA has adopted operational requirements without a corresponding requirement for design approval holders to develop and provide the necessary data and documents to support operator compliance. The difficulty encountered by operators in complying with these rules has convinced us that corresponding design approval holder requirements are necessary to enable operators to comply by the regulatory deadlines.

Summary of Legal Basis:

Section 44704, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

Issuance of guidance material would depend on voluntary compliance, and would not be enforceable.

Anticipated Cost and Benefits:

Not yet determined.

Risks:

Without a regulatory requirement imposed on design approval holders, operators would have to rely on voluntary compliance by design approval holders to provide data operators needed to comply with the regulatory requirement to develop damage tolerance programs required by the Aging Airplane Safety rule.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI32

DOT—FAA

FINAL RULE STAGE

107. +FLIGHT SIMULATION DEVICE QUALIFICATION (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 44701 to 44703; 49 USC 44707; 49 USC 44709; 49 USC 44711; 49 USC 45102 to 45103; 49 USC 45301 to 45302

CFR Citation:

14 CFR 1; 14 CFR 11; 14 CFR 60; 14 CFR 61; 14 CFR 63; 14 CFR 141; 14 CFR 142

Legal Deadline:

None

Abstract:

This action will amend the regulations establishing flight simulation device qualification requirements for all certificate holders in a new part. The basis of these requirements currently exists in different parts of the FAA's regulation and in advisory circulars. The proposed changes would consolidate and update flight simulation device requirements.

Statement of Need:

It is important to consolidate and update flight simulation device requirements to ensure that users of flight simulation devices receive the best possible training in devices that closely match the performance and handling characteristics of the aircraft being simulated.

Summary of Legal Basis:

Section 44701, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

The FAA chartered an Aviation Rulemaking Committee to develop alternative rule language to Notice No. 02-11.

Anticipated Cost and Benefits:

The FAA has placed a Draft Regulatory Evaluation of the NPRM in the docket.

Risks:

The purpose of this rulemaking is to ensure that users of flight simulation devices receive the best possible training in devices that closely match the performance and handling characteristics of the aircraft being simulated.

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 20284
NPRM Comment Period Extended	11/15/02	67 FR 69149
Notice of On–Line Public Forum	11/21/02	67 FR 70184
NPRM Comment Period End	12/24/02	
NPRM Extended Comment Period End	02/24/03	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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DOT—FAA

108. +TRANSPORT AIRPLANE FUEL TANK FLAMMABILITY REDUCTION

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 44701–44702; 49 USC 44704

CFR Citation:

14 CFR 25

Legal Deadline:

None

Abstract:

This rulemaking will require that flammability reduction means be incorporated into existing airplanes, newly manufactured airplanes, and new designs. It proposes new design standards for future and pending applications for type certification as well as new operating rules for retrofitting existing airplanes.

Statement of Need:

There have been four accidents caused by fuel tank explosions since 1989. Two occurred during flight and two others occurred on the ground. Terrorists caused one of the four. In the other three cases, no ignition source was identified as the cause of the explosion. In all four cases, however, investigators concluded that the center wing fuel tank in these airplanes contained flammable vapors when the fuel tanks exploded and the accidents occurred.

Summary of Legal Basis:

Section 44701, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

1. Require flammability reduction means on new production and new designs without requiring retrofit. The risk analysis for this option predicted an unacceptable high number of future accidents due to the high number of airplanes within the current fleet that would remain in service for many years.

2. Require inerting of all fuel tanks on existing airplanes in the fleet and new type designs.

3. Exclude all cargo operators.

4. Address unsafe condition through airworthiness directive.

5. Impose changes on operators as opposed to requiring OEMs to develop design changes.

Past experience on similar safety initiatives shows the OEMs do not consistently support these effors and places in undue burden on the operators.

Anticipated Cost and Benefits:

The FAA is conducting a regulatory evaluation using various combinations of the value of a human life, the timing of the next accidents, the passenger load on the next accident airplane, and the effectiveness of SFAR 88. We anticipate costs and benefits will vary based upon assumptions used in calculating these values. Using a value of 3 million per life, average airplane size, average time for the next accident, the costs could exceed $1 billion and quantitative benefits will be less than $1 billion.

Risks:

The FAA believes at least one and as many as five accidents will happen in the next 50 years.

Timetable:

Action	Date	FR Cite
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI23

DOT—Federal Motor Carrier Safety Administration (FMCSA)

PROPOSED RULE STAGE

109. +UNIFIED REGISTRATION SYSTEM

Priority:

Other Significant

Legal Authority:

PL 104–88; 109 Stat. 803, 888 (1995); 49 USC 13908

CFR Citation:

49 CFR 360, 365, 366, 368, 387, and 390

Legal Deadline:

Final, Statutory, January 1, 1998.

Abstract:

This action proposes replacing three current identification and registration systems—USDOT identification number system, registration/licensing system, and financial responsibility system—with a unified registration system. It will consolidate and simplify current Federal registration processes and increase public accessibility to data about interstate and foreign motor carriers, property brokers, and freight forwarders. In addition, the agency invites comments on how it might replace a fourth system—single-State registration system—in a manner consistent with conditions imposed by statute.

Statement of Need:

As a result of the ICC Termination Act of 1995 [Public Law 104-88, December 29, 1995, 109 Stat. 888] (ICCTA), Congress terminated the Interstate Commerce Commission and transferred its functions concerning licensing and financial responsibility requirements to the DOT. Congress mandated that the agency consider unifying the four current systems with a single, on-line Federal system.

Summary of Legal Basis:

The ICCTA created a new 49 U.S.C. 13908 directing ''[t]he Secretary, in cooperation with the States, and after notice and opportunity for public comment,'' . . . to ''issue regulations to replace the current DOT identification number system, the single State registration system under section 14504, the registration system contained in this chapter, and the financial responsibility information system under section 13906 with a single, on-line, Federal system.''

Alternatives:

FMCSA considered several alternatives to the proposal discussed here, in an effort to minimize the potential new filing burden on small entities. For instance, we considered exempting existing carriers from certain new filing requirements (via a grandfather clause), with the idea that it would minimize the compliance costs of this proposal. However, while reducing compliance costs (and thereby improving filing efficiency), it would also have reduced, not enhanced, the fairness of the motor carrier registration process relative to the status quo by placing higher burdens on new entrants than existing carriers. As such, it would have acted as a barrier to entry to small new entrants to the benefit of existing carriers.

Conversely, we also considered exempting new entrants from these requirements, but dismissed this on the grounds that it too would have reduced the fairness of the registration process. Additionally, either option would have reduced safety relative to the proposal discussed here. Exempting new entrants from various requirements would not have assisted small entities over larger ones, given that the composition of the new entrant carrier universe is similar to that of the overall existing population (namely, 80 percent have six or fewer power units).

The agency also considered removing the process agent designation filing requirement on the grounds that it was the most costly of the initiatives in this proposal. However, the agency dismissed this option because FMCSA division administrators felt that this particular filing requirement had the best potential to increase industry safety by improving the productivity of the agency's safety investigators (thereby allowing them to initiate additional compliance reviews). Additionally, the process agent designation filing requirement also enhances the fairness of the agency's registration process.

Anticipated Cost and Benefits:

The regulatory evaluation for the NPRM will be placed in the docket.

Risks:

FMCSA will decide if a risk assessment is necessary.

Timetable:

Action	Date	FR Cite
ANPRM	08/26/96	61 FR 43816

Action	Date	FR Cite
ANPRM Comment Period End	10/25/96	
NPRM	02/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

Docket No. FMCSA-97-2349.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2126–AA22

DOT—FMCSA

110. +HOURS OF SERVICE OF DRIVERS; SUPPORTING DOCUMENTS

Priority:

Other Significant

Legal Authority:

PL 103–311, sec 113; 108 Stat. 1673, 1676 (1994); 49 USC 504; 49 USC 14122, 31133, 31136, and 31502

CFR Citation:

49 CFR 385, 390, and 395

Legal Deadline:

Final, Statutory, February 1996.

Abstract:

This rulemaking would amend the hours-of-service recordkeeping requirements to clarify what supporting documents motor carriers must have to validate hours of service records. It will clarify: That the duty of motor carriers is to verify the accuracy of drivers' hours of service (HOS) and records of duty status (RODS) if including automatic on-board records; that the driver's duty is to collect and submit to the motor carrier all supporting documents with the RODS; that carriers are required to maintain supporting documents with the RODS; and that a supporting document based on a self-monitoring system is required to be the primary method for ensuring compliance with the HOS regulations. It would allow the use of electronic documents as a supplement to, and in certain instances in lieu of, paper supporting documents in recognition of developing technologies. It would clarify the definitions of ''supporting documents,'' ''employee,'' and ''driver,'' and the current requirement that each motor carrier use a self-monitoring system to verify HOS and RODS.

Statement of Need:

In order for the motor carriers to ensure that drivers are alert and not fatigued, carriers must maintain self-monitoring systems that compare records of duty status (RODS) to supporting documents. The Federal Highway Administration (FHWA) as part of its regulatory oversight to assist motor carriers in operating safely decided to adopt this practice of maintaining ''RODS supporting documents.'' On November 26, 1982, FHWA published a final rule which, in part, required motor carriers operating in interstate commerce to retain supporting documents, along with drivers' RODS, for at least six months from the date of receipt (47 FR 53383). 49 CFR 395.8(k). However, FHWA did not define the term ''supporting document'' in that final rule.

Summary of Legal Basis:

FMCSA is authorized, by 49 U.S.C. 504(c), to inspect and copy any record of a carrier, lessor, or association and to inspect the equipment of a carrier, or lessor, or other person controlling, controlled by, or under common control with a carrier, as long as these actions were made in furtherance of an investigation and regardless of whether or not the records were required to be maintained by FMCSA regultions or orders.

This rulemaking is required by sec. 113 (Driver's Record of Duty Status) of the Hazardous Materials Transportation Authorization Act of 1994, Pub. L. 103-311, August 26, 1994, 108 Stat. 1673, at 1676. Section 113 assumes the existence of FMCSA's more general authority to regulate the HOS of commercial motor vehicle drivers and related matters. That authority is conferred by the Motor Carrier Act of 1935, now codified at 49 U.S.C. 31502(b), and the Motor Carrier Safety Act of 1984, 49 U.S.C. 31136(a).

More specifically, sec. 113(b)(2) requires specifying the number and kind of supporting documents that must be retained by a motor carrier. Section 113(b)(3) requires a regulatory provision specifying how long a motor carrier must maintain HOS records. Section 113(b)(4) requires a provision authorizing motor carriers (individually or in groups), on a case-by-case basis, to use ''self-compliance systems'' that ensure driver compliance with the HOS rules and allow enforcement officers to audit those systems to validate compliance.

Alternatives:

Reducing the length of records retention would reduce costs, but only slightly. Short retention periods would restrict the investigator's ability to identify patterns that indicate unsafe practices. The SNPRM will solicit comments on alternatives the public may want to offer.

Anticipated Cost and Benefits:

The regulatory evaluation for the SNPRM will be placed in the docket.

Risks:

FMCSA will decide if a risk assessment is necessary.

Timetable:

Action	Date	FR Cite
NPRM	04/20/98	63 FR 19457
NPRM Comment Period End	06/19/98	
Supplemental NPRM	11/03/04	69 FR 63997
Supplemental NPRM Comment Period End	01/03/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

Docket No. FMCSA-98-3706.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

Agency Contact:

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Related RIN: Split from 2126–AA23

RIN: 2126–AA76

DOT—National Highway Traffic Safety Administration (NHTSA)

PROPOSED RULE STAGE

111. +TIRE PRESSURE MONITORING SYSTEMS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

49 USC 322; 49 USC 30111; 49 USC 30115; 49 USC 30117; . . .

CFR Citation:

49 CFR 571.138; 49 CFR 571.101

Legal Deadline:

None

Abstract:

The Transportation Recall Enhancement Accountability and Documentation (TREAD) Act required the Secretary of Transportation to initiate rulemaking to require a warning system in new motor vehicles to indicate to the operator when a tire is significantly under-inflated. The agency issued a final rule for tire pressure monitoring systems (TPMS)(establishing FMVSS No. 138) on June 5, 2002; however, the final rule establishing the standard was vacated by a decision issued by the U.S. Court of Appeals for the Second Circuit in August 2003.

The agency will take action in accordance with the Administrative Procedures Act to re-establish FMVSS No. 138, in a manner consistent with the court's decision, and also provide a new phase-in period.

Statement of Need:

The TPMS rulemaking is one of the rulemakings mandated by the Transportation Recall Enhancement Accountability and Documentation Act of 2000. To prevent vehicles from being driven on under-inflated tires, Congress mandated the installation of tire pressure monitoring systems that will warn drivers when one or more tires, up to a total of 4, are under-inflated. Under-inflation can lead to over-heating of the tires and sudden tire failures (blowouts and tread separations).

Summary of Legal Basis:

49 USC 322, 49 USC 30111, 49 USC 30115, 49 USC 30117, and 49 USC 30166 provide the legal basis.

Alternatives:

Potential alternatives to the TPMS rulemaking proposed by the agency include:

• No rulemaking to require that drivers be warned when a tire(s) is significantly under-inflated (NB: this alternative is not permitted under the TREAD Act); and

• Variations of the proposed TPMS performance requirements (especially the threshold level of under-inflation the triggers a warning to the driver) and test procedures.

Anticipated Cost and Benefits:

The agency estimates that the TPMS rule will prevent approximately 120 fatalities annually, and prevent or reduce in severity approximately 8,400 injuries. The TPMS rule will also provide economic benefits by reducing tire tread wear, improving vehicle fuel economy, and reducing property damage when collisions do occur.

The agency estimates the total net cost per vehicle for the TPMS to be between $26.00 and $100.00.

Risks:

There is a potential risk that some drivers might rely on TPMS and not check the pressure in their tires on a regular basis. To guard against that possibility, the agency has proposed requiring vehicle manufacturers to include in their vehicle owner's manuals a statement emphasizing the need for motorists to check tire pressure monthly, and explaining the consequences of not doing so.

Timetable:

Action	Date	FR Cite
NPRM	09/16/04	69 FR 55896
NPRM Comment Period End	11/15/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Federalism:

This action may have federalism implications as defined in EO 13132.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

Agency Contact:

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RIN: 2127–AJ23

DOT—Federal Railroad Administration (FRA)

FINAL RULE STAGE

112. +WHISTLE BANS AT HIGHWAY–RAIL GRADE CROSSINGS

Priority:

Other Significant

Legal Authority:

49 USC 20153

CFR Citation:

49 CFR 222

Legal Deadline:

Final, Statutory, November 2, 1996, subsequent enactment prohibited issuance prior to July 1, 2001.

Abstract:

This action would govern when train whistles at public grade crossings must be sounded. FRA has found that failing to use the locomotive horn can significantly increase the number of collisions with motorists using the crossing. This action is considered significant because of substantial public interest. This action is being taken

pursuant to statutory mandate. Pub. Law 103-440 requires the Secretary to prohibit local whistle bans, except where there is no significant risk of accidents, alternative safety measures are adequate, or where use of a horn as a warning is impractical. After publishing an NPRM, FRA participated in extensive public hearings to gather comments and issued an interim final rule to implement the statute.

Statement of Need:

This rule is required by Public Law 103-440. The Act requires the use of locomotive horns at every public highway-rail grade crossing but gives FRA the authority to make reasonable exceptions. Studies have shown that highway-rail grade crossing accidents increase 67 percent at gated crossings where whistle bans are in effect. Congress amended this law in 1996 to require that FRA take into account the interest of the communities with pre-existing restrictions on locomotive horns. In 2000, Congress prohibited FRA from issuing a rule before July 1, 2001.

Summary of Legal Basis:

Issuance of this rule is required by 49 USC 20153.

Alternatives:

There was no alternative to initiating this rulemaking, as it is required by statute. However, the rule would provide a list of supplementary measures that FRA has determined to be effective substitutes for the locomotive horn in the prevention of highway-rail grade crossing casualties. The rule would also allow for whistle bans if there are alternative safety measures that compensate for the lack of a locomotive horn.

Anticipated Cost and Benefits:

The problems considered by this rule are collisions and their associated casualties and property damage involving vehicles on public highways and trains at whistle-ban grade crossings.

The costs of this rulemaking will be incurred predominantly by communities. The most significant impacts from this rule will be on about 260 governmental jurisdictions whose communities have whistle bans in place. However, there are also costs to railroads and to the Federal Government. Approximately 640 small railroads would be minimally impacted by train horn sound level testing requirements contained in this rule. In adddition, some small businesses that operate along or near rail lines that currently have whistle bans in place could be moderately impacted.

Risks:

As a result of studies conducted on accident rates at crossings at which locomotive horns are banned, FRA has concluded that such crossings generally have a higher risk of accident than crossings at which horns are sounded. FRA has found that the risk of a collision was 67 percent greater at crossings equipped with automatic gates and flashing lights than at similarly equipped crossings across the nation without bans. Congress required that FRA issue a regulation requiring the sounding of locomotive horns at all public highway rail grade crossings. However, an exception to the requirement is permissible in circumstances in which there is not a significant risk of loss of life or serious personal injury, use of the locomotive horn is impractical, or supplementary safety measures fully compensate for the absence of the warning provided by the horn. Issuance of the rule would lower the increased collision risk associated with crossings at which no locomotive horns are sounded.

Timetable:

Action	Date	FR Cite
NPRM	01/13/00	65 FR 2230
NPRM Comment Period End	05/26/00	
Interim Final Rule	12/18/03	68 FR 70586
Interim Final Rule Comment Period End	04/19/04	
Final Rule	01/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State

Additional Information:

An Omnibus Bill at the end of the 106th Congress prohibited publication of a final rule before July 2001.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2130–AA71

BILLING CODE 4910–62–S

DEPARTMENT OF THE TREASURY (TREAS)

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are:

- To promote prosperous and stable American and world economies, including promoting domestic economic growth and maintaining our Nation's leadership in global economic issues, supervising national banks and thrift institutions, and helping to bring residents of distressed communities into the economic mainstream.
- To manage the Government's finances by protecting the revenue and collecting the correct amount of revenue under the Internal Revenue Code, overseeing customs revenue functions, financing the Federal Government and managing its fiscal operations, and producing our Nation's coins and currency.
- To safeguard our financial systems by enforcing laws relating to Federal Government securities and developing regulations to combat money laundering.

Consistent with these missions, most regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President. Unless circumstances require otherwise, it is the policy of the Department to issue a notice of proposed rulemaking and carefully consider public comments before adopting a final rule. Also, in particular cases, the Department invites interested parties to submit views on rulemaking projects while a proposed rule is being developed, and holds public hearings to discuss proposed rules.

In response to the events of September 11, 2001, the President signed the USA PATRIOT Act of 2001 into law on October 26, 2001. Since then, the Department of the Treasury has accorded the highest priority to developing and issuing regulations to implement the provisions in this historic legislation that target money laundering and terrorist financing. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Financial Crimes Enforcement Network (FinCEN).

On November 26, 2002, the President signed into law the Terrorism Risk Insurance Act of 2002. The purpose of this legislation is to address disruptions in the market for terrorism risk insurance. The new law established a temporary Federal reinsurance program under which the Federal Government will share the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers. Over the past two years, the Department of the Treasury has accorded the highest priority to developing and issuing regulations to implement the provisions of this Act. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Terrorism Risk Insurance Program Office.

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Order 12866, and to develop regulations that maximize aggregate net benefits to society while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Terrorism Risk Insurance Program Office

The Office of the Assistant Secretary for Financial Institutions is responsible for developing promulgating regulations implementing the Terrorism Risk Insurance Act of 2002 (TRIA). The Terrorism Risk Insurance Program Office, which is part of the Office of the Assistant Secretary for Financial Institutions, is responsible for operational implementation of the Act. The purposes of this legislation, which was enacted as a consequence of the events of September 11, 2001, are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections. TRIA established a temporary Federal program that provides a system of shared public and private compensation for insured losses resulting from certain types of terrorist acts.

Over the past year, the Office of the Assistant Secretary has continued the ongoing work of quickly implementing TRIA. The Office has issued formal regulations specifying claims procedures for property and casualty insurers who seek federal reimbursement under TRIA for their insured losses. The Office has also developed a claims processing capability and issued a final rule to implement the litigation management provisions of TRIA. During fiscal year 2005, the Office will refine regulations and procedures for filing claims under TRIA and develop regulations for recouping the Federal share of compensation to insurers through risk-spreading premiums.

Customs Revenue Functions

On November 25, 2002, the President signed the Homeland Security Act of 2002 (the Act), establishing the Department of Homeland Security (DHS). The Act transferred the United States Customs Service from the Department of the Treasury to the DHS, where it is now known as the Bureau of Customs and Border Protection (CBP). Notwithstanding the transfer of the Customs Service to DHS, the Act provides that the Secretary of the Treasury retains sole legal authority over the customs revenue functions. The Act also authorizes the Secretary of the Treasury to delegate any of the retained authority over customs revenue functions to the Secretary of Homeland Security. By Treasury Department Order No. 100-16, the Secretary of the Treasury delegated to the Secretary of Homeland Security authority to prescribe regulations pertaining to the customs revenue functions. This Order further provided that the Secretary of the Treasury retained the sole authority to approve any such regulations concerning import quotas or trade bans, user fees, marking, labeling, copyright and trademark enforcement, and the completion of entry or substance of entry summary including duty assessment and collection, classification, valuation, application of the U.S. Harmonized Schedules, eligibility or requirements for preferential trade programs, and the establishment of recordkeeping requirements relating thereto.

During fiscal year 2005, Treasury and CBP plan to finalize several interim regulations involving the customs revenue functions not delegated to DHS. Among these are the following interim regulations that implement the trade benefit provisions of the Trade Act of 2002:

- The Andean Trade Promotion and Drug Eradication Act
- The Caribbean Basin Economic Recovery Act
- The African Growth and Opportunity Act

CBP also plans to issue interim regulations this fiscal year to implement the preferential trade benefit provisions of the United States-Chile Free Trade

Agreement Implementation Act and the United States-Singapore Free Trade Agreement Implementation Act.

In addition, Treasury and CBP plan to finalize proposed regulations that will implement two provisions of the Tariff and Suspension Act of 2000. One rule will establish procedures for allowing the duty-free entry of prototypes that are to be used exclusively in product development, testing, evaluation or quality control. The other rule will allow merchandise that is purchased and invoiced as a single entity but shipped in an unassembled or disassembled condition in separate shipments due to the size or nature of the merchandise to be treated for entry purposes as a single transaction.

Treasury and CBP also plan to continue moving forward with amendments to improve its regulatory procedures began under the authority granted by the Customs Modernization provisions of the North American Free Trade Implementation Act (Customs Mod Act). These efforts, in accordance with the principles of Executive Order 12866, have involved and will continue to involve significant input from the importing public. CBP will also continue to test new programs to see if they work before proceeding with proposed rulemaking to permanently establish the programs.

Community Development Financial Institutions Fund

The Community Development Financial Institutions Fund (Fund) was established by the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4701 *et seq.*). The primary purpose of the Fund is to promote economic revitalization and community development through a variety of programs: the Community Development Financial Institutions (CDFI) Program, the Bank Enterprise Award (BEA) Program, and the New Markets Tax Credit (NMTC) Program.

In fiscal year 2005, the CDFI Program will comprise the Financial Assistance Component through which the Fund makes investments in and provides financial assistance to CDFIs, and the Technical Assistance Component through which the Fund provides technical assistance grants to CDFIs. In addition, the Fund administers the Native American CDFI Assistance (NACA) Component, through which the Fund provides technical assistance grants and financial assistance awards to promote the development of CDFIs that serve Native American, Alaska Native, and Native Hawaiian communities.

Through the BEA Program, the Fund provides financial incentives to encourage insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs.

In addition, the Fund administers the NMTC Program in coordination with Treasury's Office of Tax Policy and the Internal Revenue Service. The NMTC Program is intended to spur investments in businesses located in low-income communities. Through the NMTC Program, taxpayers are provided a credit against Federal income taxes for qualified investments made to acquire stock or other equity interests in designated Community Development Entities (CDEs). Substantially all of the proceeds of qualified investments must in turn be used by the CDE to make qualified investments in low-income communities.

The Fund's fiscal year 2005 regulatory priority will include developing guidance and/or regulations regarding aspects of the administration and operation of the NMTC Program.

Financial Crimes Enforcement Network

The regulations of the Financial Crimes Enforcement Network (FinCEN) constitute the core of Treasury's anti-money laundering initiatives and are an essential component of Treasury's anti-narcotics effort. FinCEN's regulations implement the Bank Secrecy Act (BSA), as amended in October 2001 by the USA PATRIOT Act. The BSA authorizes the Secretary of the Treasury to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, or regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures. FinCEN is working closely with the Treasury Offices of the General Counsel, Terrorism/Violent Crimes, and Financial Institutions to develop regulations to implement the amendments to the BSA made by the USA PATRIOT Act that target money laundering and terrorist financing.

FinCEN's regulatory priorities for fiscal year 2005 include the following projects, all of which are related to the events of September 11, 2001:

- *Due Diligence for Correspondent Accounts and Private Banking Accounts.* This final rule implements section 312 of the USA PATRIOT Act, which requires certain financial institutions to establish due diligence policies, procedures, and controls reasonably designed to detect and report money laundering through correspondent accounts and private baking accounts established or maintained for non-U.S. persons.
- *Anti-Money Laundering Programs.* These final and proposed rules implement section 352 of the USA PATRIOT Act, under which financial institutions must adopt anti-money laundering programs. FinCEN expects to finalize interim final rules issued in April 2002 for banks and other depository institutions, casinos, securities broker-dealers, futures commission merchants, mutual funds, operators of credit card systems, and money services businesses. FinCEN also expects to finalize rules proposed in September 2002 for insurance companies and unregistered investment companies, rules proposed in February 2003 for dealers in precious metals, stones, or jewels, and rules proposed in May 2003 for investment advisers and commodity trading advisers. FinCEN will issue a proposed rule for loan or finance companies (including pawnbrokers). Finally, FinCEN expects to determine whether to issue a series of proposed rules for other financial institutions—vehicles sellers; persons involved in real estate closings and settlements; and travel agencies—after reviewing comments received in response to a series of advance notices of proposed rulemaking.
- *Suspicious Activity Reporting.* FinCEN expects to finalize several rules proposed under 31 U.S.C. 5318(g) requiring insurance companies and mutual funds to report suspicious transactions.

Internal Revenue Service

The Internal Revenue Service, working with the Office of the Assistant Secretary (Tax Policy), promulgates regulations that interpret and implement the Internal Revenue Code and related tax statutes. The purpose of these regulations is to carry out the tax policy determined by Congress in a fair, impartial and reasonable manner, taking into account the intent of Congress, the realities of relevant transactions, the need for the Government to administer the rules and monitor compliance, and the overall integrity of the Federal tax system. The goal is to make the

regulations practical and as clear and simple as possible.

Most Internal Revenue Service regulations interpret tax statutes to resolve ambiguities or fill gaps in the tax statutes. This includes interpreting particular words, applying rules to broad classes of circumstances, and resolving apparent and potential conflicts between various statutory provisions.

During fiscal year 2005 the Internal Revenue Service will accord priority to the following regulatory projects:

- *Transfer Pricing Guidance Initiatives.* Treasury and the IRS anticipate issuing regulatory guidance under section 482 and other provisions of the Internal Revenue Code during fiscal year 2005 with respect to accounting for the economic value of intangible property in the context of cross-border related-party activities and transactions. The economic value of intangible property can be a significant factor in a variety of cross-border transactions, in addition to those in which intangibles are sold or licensed directly. The various guidance projects are being coordinated to ensure that consistent rules govern the treatment of intangibles in economically similar transactions, whether intangibles are transferred outright, transferred via a buy-in pursuant to a cost sharing arrangement, embedded into services performed, or transferred as part of an outbound incorporation or reorganization transfer. The projects include regulatory guidance regarding related-party cost sharing arrangements under section 482, regarding intercompany services under section 482, and regarding outbound transfers of intangibles in a reorganization under section 367(d).
- *Elimination or Reduction of Certain Type of Benefits in Qualified Plans.* Section 411(d)(6)(B) of the Internal Revenue Code generally prohibits an amendment to a tax-qualified retirement plan that has the effect of eliminating or reducing an early retirement benefit or a retirement-type subsidy, or eliminating an optional form of benefit, with respect to benefits attributable to service before the amendment. EGTRRA directed the Secretary to issue regulations providing that section 411(d)(6)(B) does not apply to any amendment that reduces or eliminates early retirement benefits or retirement-type subsidies that create significant burdens or complexities for the plan and plan participants unless such amendment adversely affects the rights of any participant in a more than de minimis manner. The IRS and Treasury issued proposed regulations that would implement this provision and provide additional guidance under section 411(d)(6) on March 24, 2004. The IRS and Treasury intend to finalize these regulations.
- *Application of the Repeal of the General Utilities Doctrine in the Context of Consolidated Returns.* On March 7, 2002, the IRS and Treasury issued temporary regulations (26 CFR 1.337(d)-2T) that disallow certain losses recognized by a member of a consolidated group on the disposition of stock of another member. These regulations ensure that the purposes of the *General Utilities* repeal, which generally requires a corporation to recognize gain or loss on a disposition of any asset, may not be circumvented through the use of the consolidated return regulations. During the coming fiscal year, the IRS and Treasury plan to reexamine these regulations.
- *Safe Harbor Methodology for Determining the Fair Market Value of Financial Instruments that are Marked to Market.* Section 475 of the Internal Revenue Code requires dealers in stocks, debt, certain derivative financial instruments, or other securities to mark their securities to market at the end of each tax year. That is, those dealers must compute their taxable income by including their securities in inventory at their fair market value or recognizing gain or loss as if their securities had been sold for their fair market value at the end of the tax year. Dealers and traders in commodities, and securities traders are not required to use mark-to-market accounting but may elect to do so. The IRS and Treasury are considering whether to publish proposed regulations that would allow dealers in securities (and perhaps dealers in commodities or traders in securities or commodities) to use a safe harbor method to satisfy the statutory requirement to determine the fair market value of items marked to market. As a first step in this process, the IRS and Treasury issued an advance notice of proposed rulemaking (ANPRM) on May 5, 2003, describing and explaining a possible framework for a safe harbor that might allow taxpayers to use as fair market value for section 475 purposes the value used on certain financial statements. That ANPRM stated certain broad principles that any safe harbor finally adopted might have to meet. The ANPRM also requested both general and specific comments concerning the adoption of a safe harbor based on financial statement conformity or some other principle. It also requested comments concerning the scope of any safe harbor, which taxpayers could use it, what financial statements would qualify, and what securities (or commodities) would be covered.
- *Capitalization of Interest and Carrying Charges Properly Allocable to Straddles.* Sections 1092 and 263(g) of the Internal Revenue Code were enacted in 1981 to address tax abuses employing straddles in commodity futures contracts, but the two sections are worded broadly enough to deal with other abusive straddles. Section 1092 limits loss recognition on one leg of a straddle if there is unrecognized gain with respect to one or more offsetting positions. Section 263(g) disallows a deduction for interest and carrying charges properly allocable to personal property that is part of a straddle.

The IRS and Treasury expect to issue final regulations clarifying the circumstances in which a taxpayer must capitalize interest and carrying charges incurred to purchase or carry personal property that is part of a straddle. The regulations are expected to address the definition of personal property for purposes of section 263(g), the types of expenses subject to capitalization, and the operation of the capitalization rules. In addition, the regulations will indicate when the debtor's position in a debt instrument will be treated as a position in personal property that may be part of a straddle. The regulations are also expected to clarify the application of the straddle anti-abuse rules to various financial instruments and straddle transactions.

- *Credit for Household and Dependent Care Services.* Section 21 of the Internal Revenue Code allows a credit for an amount equal to a percentage of employment-related expenses paid by an individual who maintains a household that includes a qualifying individual (usually a child under age 13). Section 21, originally enacted in 1976, has been amended repeatedly. The 2001 amendments increased the credit significantly. The regulations, currently found under section 1.44A of the Income Tax Regulations, have not been amended or updated since 1984. This regulation project will update the regulations to reflect the

statutory changes and will clarify issues relating to payments for certain services.

- *Deduction and Capitalization of Costs for Tangible Assets.* Section 162 of the Internal Revenue Code allows a current deduction for ordinary and necessary expenses paid or incurred in carrying on any trade or business. Under section 263(a), no immediate deduction is allowed for amounts paid out for new buildings or for permanent improvements or betterments made to increase the value of any property or estate. Such expenditures are capital expenditures that generally may be recovered only in future taxable years, as the property is used in the taxpayer's trade or business. It often is not clear whether an expenditure to repair, improve, or rehabilitate property is a deductible expense or is a capital expenditure. Although existing regulations provide that a deductible repair is an expenditure that does not materially add to the value of the property nor appreciably prolong its life, the IRS and Treasury believe that additional clarification is needed to reduce uncertainty and controversy in this area. In December 2003, the IRS and Treasury requested public comment on rules that might be provided to clarify the application of section 263(a) to repairs and improvements to tangible property. During fiscal year 2005, the IRS and Treasury intend to propose regulations in this area.
- *R&E Credit for Controlled Groups.* Section 41 of the Internal Revenue Code provides a credit for increasing research expenditures. The R&E Credit has been the subject of significant controversy between the IRS and taxpayers, particularly as it relates to the computation and allocation of the credit for members of a controlled group of corporations or a group of trades or businesses under common control. Section 41(f) generally provides that in determining the amount of the credit, all members of the same controlled group of corporations are treated as a single taxpayer. The IRS and Treasury issued proposed regulations in 2003 providing rules for the computation of the group research credit, and allocation of that credit among members of the controlled group. During fiscal year 2005, the IRS and Treasury intend to issue further guidance on this issue.
- *Partnership Equity for Services.* Like other businesses, partnerships frequently issue interests in partnership equity to service providers. Although there currently is some guidance on a partnership's issuance of a profits interest to a service provider, there is little guidance on the Federal income tax consequences (to the service provider and the partnership) on the issuance, in connection with the performance of services, of an interest in partnership capital or an option to acquire such an interest. More specifically, uncertainty exists as to whether the principles of section 83 of the Internal Revenue Code apply to the issuance of such interests and whether the partnership recognizes gain on the issuance of a capital interest to, or the exercise of an option by, a service provider. In this project, the IRS and Treasury will provide guidance on these and related issues.
- *Corporate Estimated Tax.* Section 6655 of the Internal Revenue Code sets forth the requirements for the payment of estimated income taxes by corporations. The existing regulations under section 6655 do not reflect significant changes to the tax law since 1984. The IRS and Treasury expect to issue proposed regulations that will reflect changes to the tax law since 1984 and that will provide clear rules for taxpayers to follow and the IRS to administer. Among other issues, the proposed regulations will address the alternative methods for computing quarterly installments of estimated tax and the treatment of certain items when computing quarterly installments of estimated tax.
- *Practice Before the Internal Revenue Service (Circular 230).* Section 330 of title 31 of the United States Code authorizes the Secretary of the Treasury to regulate the practice of representatives before the Treasury Department. The Secretary has published these regulations in Circular 230 (31 CFR part 10). In 2001, the IRS and Treasury issued proposed amendments to the regulations relating to practice before the IRS, which addressed general matters and proposed standards of practice for tax shelter opinions. In 2002, final regulations were issued incorporating only the non-tax shelter matters. In 2003, amendments to the standards of practice for tax shelter opinions were reproposed. Those reproposed regulations set forth best practices for tax advisors providing advice to taxpayers relating to Federal tax issues or submissions to the IRS and modified the standards for certain tax shelter opinions. The IRS and Treasury expect to finalize the reproposed regulations and to issue additional regulations regarding practice before the IRS.
- *Student FICA Exception.* Section 3121(b)(10) of the Internal Revenue Code provides that for purposes of the FICA, employment does not include services performed for a school, college or university by a student who is enrolled and regularly attending classes at the institution. Thus, compensation for services that come within this exception is not subject to FICA tax. As a result of some recent litigation, questions have arisen as to the scope of the exception. In particular, there is a need for additional guidance on who is a student and what constitutes a school, college or university for purposes of this exception. The IRS and Treasury issued proposed regulations that would clarify the application of section 3121(b)(10) on February 25, 2004. The IRS and Treasury intend to finalize these regulations.

Office of the Comptroller of the Currency

The Office of the Comptroller of the Currency (OCC) charters, regulates, and supervises national banks to ensure a safe, sound, and competitive national banking system that supports the citizens, communities, and economy of the United States. The substantive content of the OCC's regulations reflects four organizing principles that support this mission:

- The OCC's regulations help ensure safety and soundness by establishing standards that set the limits of acceptable conduct for national banks.
- The OCC's regulations promote competitiveness by facilitating a national bank's ability to develop new lines of business, subject to any safeguards that are necessary to ensure that the bank has the expertise to manage risk effectively and adapt its business practices to deal responsibly with its customers.
- Regulations can also affect national banks' ability to compete by contributing significantly to their costs. The OCC's goal is to improve efficiency and reduce burden by updating and streamlining its regulations and eliminating those that no longer contribute significantly to the fulfillment of its mission.
- The OCC's regulations help assure fair access to financial services for all Americans by removing unnecessary

impediments to the flow of credit to consumers and small businesses, by encouraging national banks' involvement in community development activities, and by implementing Federal laws designed to protect consumers of financial services.

The OCC's regulatory workload and plans are affected directly by statute. One statute requiring regulatory action is the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA). The OCC, together with the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (agencies), is conducting a review of its regulations, pursuant to the EGRPRA. This process will continue through 2006. To date, the agencies' review has included: (1) issuing three notices, published in the Federal Register, that solicit comment from the industries we regulate and the public on ways to reduce regulatory burden with respect to specific categories of regulations; and (2) conducting outreach meetings with bankers and consumer groups in cities across the country for the same purpose. The review process and outreach meetings have generated a number of helpful suggestions which we, along with the other agencies, are evaluating on an ongoing basis. When these processes for obtaining input are complete, the OCC expects to be able to determine whether revisions to any of its rules are appropriate in order to further the purposes of the EGRPRA and reduce burden. The agencies will further report to Congress on their conclusions at the end of the process, along with any suggestions for possible legislative changes.

Significant final rules issued during fiscal year 2004 include:

- *Rules, Policies, and Procedures for Corporate Activities; Bank Activities and Operations; Real Estate Lending and Appraisals (12 CFR Parts 3, 5, 6, 7, 9, 28, and 34).* The Office of the Comptroller of the Currency issued this rule revising 12 CFR parts 5 and 7 to implement new authority provided to national banks by sections 1204, 1205, and 1206 of the American Homeownership and Economic Opportunity Act of 2000. Section 1204 permits national banks to reorganize directly to be controlled by a holding company. Section 1205 increases the maximum term of service for national bank directors, permits the OCC to adopt regulations allowing for staggered terms for directors, and permits national banks to apply for permission to have more than 25 directors. Section 1206 permits national banks to merge with one or more of their nonbank affiliates, subject to OCC approval. The OCC also made other amendments to 12 CFR parts 5, 7, 9, and 34, as well as several technical corrections. The OCC published a final rule on December 17, 2003, at 68 FR 70122.
- *Rules, Policies, and Procedures for Corporate Activities; International Banking Activities (12 CFR Parts 5 and 28).* The Office of the Comptroller of the Currency issued this rule to amend its regulations pertaining to the foreign operations of national banks, and of Federal branches and agencies of foreign banks operating in the United States. The OCC clarified and revised a number of application procedures, including applicable standards for approval. The rule permits Federal branches and agencies to operate with one license in the United States, with a license issued only for the initial Federal branch or agency, rather than requiring each office of a foreign bank to have a separate license. It also permits a Federal branch to operate a loan production office as part of its branch license. In addition, the OCC implemented, through this regulation, a number of OCC interpretations regarding the capital equivalency deposit required of Federal branches and agencies. The OCC also revised several definitions. The OCC published a final rule on December 19, 2003, at 68 FR 70691.
- *Rules, Policies, and Procedures for Corporate Activities (12 CFR Part 5).* The Office of the Comptroller of the Currency issued this rule to require a national bank to receive OCC approval before changing the composition of all, or substantially all, of its assets (1) through sales or other dispositions, or (2) after having sold or disposed of all, or substantially all, of its assets through subsequent purchase, other acquisitions, or other expansion of its operations. The rule provides that, in the second case, the OCC will apply the same standards as it applies to the establishment of a de novo bank. The OCC published a final rule on August 16, 2004, at 69 FR 50293.
- *Reporting and Disclosure Requirements for National Banks With Securities Registered Under the Securities Exchange Act of 1934; Securities Offering Disclosure Rules (12 CFR Parts 11 and 16).* The Office of the Comptroller of the Currency issued this rule to revise its regulations to reflect amendments to the Securities Exchange Act of 1934 (Exchange Act) made by the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act). These amendments to the Exchange Act give the OCC the authority to administer and enforce a number of the Sarbanes-Oxley Act's new reporting, disclosure, and corporate governance requirements with respect to national banks that have a class of securities registered under the Exchange Act. The OCC also made conforming revisions to its rules that prescribe securities offering disclosure rules for national banks that issue securities that are not subject to the registration requirements of the Securities Act of 1933. The OCC published a final rule on December 9, 2003, at 68 FR 68489.
- *Bank Activities and Operations; Real Estate Lending and Appraisals (12 CFR Parts 7 and 34).* The Office of the Comptroller of the Currency issued this rule to add provisions to OCC regulations expressly addressing the applicability of certain types of state laws to national banks' deposit-taking and lending activities. In new 12 CFR 7.4007 (pertaining to deposit-taking) and 12 CFR 7.4008 (pertaining to non-real estate lending), and in revised 12 CFR 34.4 (pertaining to real estate lending), are listed particular types of state laws that are preempted by the rule. Each of these three sections also contains a list of types of state laws that generally are not preempted. In addition, in new 12 CFR 7.4007, 7.4008, and 7.4009 (pertaining to other Federally authorized activities), and in revised 12 CFR 34.4, the rule contains s general statement that state laws do not apply to national banks if they ''obstruct, impair, or condition'' the bank's ability to fully exercise its Federally authorized powers.

The rule operates to preempt, without the need for further analysis, only those types of State laws that are listed in 12 CFR 7.4007, 7.4008, and 34.4. These are State laws for which substantial precedent existed, prior to adoption of the preemption rule, recognizing the interference they pose to the ability of Federally chartered institutions to operate under uniform Federal standards. Thus, the rule preempts State laws that impermissibly affect national bank deposit taking and lending powers and that are listed in the regulation.

Other types of State laws—those not listed in the regulation—remain subject to case-by-case evaluation under the longstanding preemption standards that the U.S. Supreme Court has established. The rule also prohibits a national bank from making any consumer loan based predominately on the bank's realization of the foreclosure value of the borrower's collateral, without regard to the borrower's ability to repay the loan according to its terms. The OCC published a final rule on January 13, 2004, at 69 FR 1904.

- *Risk-Based Capital Guidelines; Capital Adequacy Guidelines; Capital Maintenance: Interim Capital Treatment of Consolidated Asset-Backed Commercial Paper Program Assets (12 CFR Part 3).* The Office of the Comptroller of the Currency, together with the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies), issued an interim rule with request for comment on October 1, 2003, at 68 FR 56530. The interim rule amended the banking agencies' risk-based capital standards by providing an interim treatment for assets in asset-backed commercial paper (ABCP) programs that are consolidated onto the balance sheets of sponsoring banks, bank holding companies, and thrifts (collectively, sponsoring banking organizations) as a result of a recently issued accounting interpretation, Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46). Specifically, the interim capital treatment allows sponsoring banking organizations to remove consolidated ABCP program assets from their risk-weighted asset base for the purpose of calculating their risk-based capital ratios. The interim rule was issued in conjunction with a joint agency notice of proposed rulemaking that would also require sponsoring banking organizations to hold risk-based capital against liquidity facilities provided to ABCP programs with an original maturity of one year or less, and a risk-based capital charge for early amortization risk associated with certain types of revolving securitizations. The agencies issued a final rule covering both documents on July 28, 2004, at 69 FR 44908.
- *Bank Activities and Operations (12 CFR Part 7).* The Office of the Comptroller of the Currency issued this rule to clarify the scope of its visitorial powers regulation at 12 CFR 7.4000. The rule identifies the scope of the activities of national banks for which the OCC's visitorial powers are exclusive under 12 U.S.C. 484, that is, the content and conduct of activities authorized for national banks under Federal law. The rule also clarifies that the ''vested in the courts of justice'' exception in 12 U.S.C. 484 pertains to the powers inherent in the judiciary and does not grant to state or other authorities any new right to exercise visitorial powers with respect to national banks. The OCC published a final rule on January 13, 2004, at 69 FR 1895.

The OCC's regulatory priorities for fiscal year 2005 include projects in the following areas:

The OCC plans to issue rules implementing the requirements of the Fair and Accurate Credit Transactions Act of 2003 as follows:

- *Proper Disposal of Consumer Information (12 CFR Parts 30 and 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) are planning to issue a joint rule to implement section 216 of the Fair and Accurate Credit Transactions Act of 2003. Section 216 requires the banking agencies, the National Credit Union Administration, the Securities and Exchange Commission, and the Federal Trade Commission to adopt consistent and comparable regulations, to the extent possible, requiring entities subject to their jurisdiction to properly dispose of consumer information as a means to reduce the risk of identity theft. The agencies issued a joint notice of proposed rulemaking on June 8, 2004, at 69 FR 31913.
- *Fair Credit Reporting Regulations; Use of Medical Information (12 CFR Part 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration (agencies) are planning to issue a joint rule to implement section 411 of the Fair and Accurate Credit Transactions Act of 2003. Section 411(a) requires the agencies to prescribe regulations that permit creditors to obtain or use medical information for certain credit eligibility purposes. Additionally, section 411(b) authorizes the agencies to issue rules to allow additional sharing of information determined by the agencies to be appropriate or necessary. The agencies issued a joint notice of proposed rulemaking on April 28, 2004, at 69 FR 23380.
- *Identity Theft Detection, Prevention, and Mitigation Program for Financial Institutions and Creditors (12 CFR Parts 30 and 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration, and Federal Trade Commission (agencies) are planning to issue a rule to establish guidelines and regulations to implement section 114 of the Fair and Accurate Credit Transactions Act of 2003. Section 114 requires the agencies to issue jointly guidelines for financial institutions and creditors identifying patterns, practices, and specific forms of activity that indicates the possible existence of identity theft. In addition, the agencies must issue regulations requiring each financial institution and creditor to establish reasonable policies and procedures to implement the guidelines. The regulations must contain a provision requiring a card issuer to notify the cardholder if the card issuer receives a notice of change of address for an existing account, and a short time later receives a request for an additional or replacement card.
- *Fair Credit; Affiliate Marketing Regulations (12 CFR Part 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration (agencies) are planning to issue a rule to implement the affiliate-sharing provisions of section 214 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act). The rule would implement the consumer notice and opt-out provisions of the FACT Act regarding the sharing of consumer information among affiliates for marketing purposes. The agencies issued a notice of proposed rulemaking on July 15, 2004, at 69 FR 42502.

The OCC plans to issue other rules as follows:

- *Recordkeeping Requirements for Bank Exceptions from Securities Broker or Dealer Registration (12 CFR To Be Determined).* The Office of the Comptroller of the Currency, Board of

Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision may issue a notice of proposed rulemaking (NPRM) that contains recordkeeping requirements that implement section 204 of the Gramm-Leach-Bliley Act (GLBA). Section 204 directs the Federal banking agencies to establish recordkeeping requirements for banks relying on exceptions to the definitions of ''broker'' and ''dealer'' contained in paragraphs (4) and (5) of section 3(a) of the Securities Exchange Act of 1934. Issuance of this NPRM is contingent on the completion of the Securities and Exchange Commission's rulemaking to implement the substantive provisions of the GLBA.

- *Community Reinvestment Act Regulation (12 CFR 25).* The Office of the Comptroller of the Currency plans to issue a notice of proposed rulemaking that would revise certain provisions of our rules implementing the Community Reinvestment Act (CRA). The OCC plans to take this action in response to public comments we received on our February 2004 CRA proposal (69 FR 5729). The proposal would address regulatory burden imposed on smaller national banks by revising the eligibility requirements for CRA evaluation under the lending, investment, and service tests. Specifically, the proposal would provide a simplified lending test and a flexible and streamlined community development test for small banks with an asset size between $250 million and $1 billion. Holding company affiliation would not be a factor in determining which CRA evaluation standards applied to a bank. The OCC estimates that this proposal would reduce burden and costs for national banks. In particular, banks with assets between $250 million and $1 billion would have reduced data reporting costs that include fixed costs (such as purchasing and updating CRA software and establishing and maintaining internal processes to collect and check data) and variable costs (*e.g.*, organizing data, monitoring data quality, and correcting data).
- *Electronic Filing and Disclosure of Beneficial Ownership Reports (12 CFR Part 11).* The Office of the Comptroller of the Currency plans to adopt a final rule based on the interim rule, issued on September 22, 2003 , at 68 FR 54981, to implement provisions enacted in the Sarbanes-Oxley Act of 2002 (Act). The Act made amendments to section 16(a) of the Securities Exchange Act of 1934, which requires the filing of beneficial ownership reports by officers, directors, and principal shareholders of issuers of securities. The OCC administers and enforces section 16(a) with respect to officers, directors, and principal shareholders of national banks. Effective July 30, 2003, the Act required that beneficial ownership reports be filed electronically and posted on the issuer's corporate Web site, if it has a Web site. The interim rule requires that beneficial ownership reports filed by officers, directors, and principal shareholders of national banks be filed electronically pursuant to the FDIConnect system and that the reports be placed on the Web site on national banks that have Web sites. The OCC may adopt a final rule.
- *Risk-Based Capital Guidelines: Implementation of New Basel Capital Accord (12 CFR Part 3).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) plan to issue a notice of proposed rulemaking based on the *International Convergence of Capital Measurement and Capital Standards: A Revised Framework*, the new capital adequacy framework commonly known as Basel II. The banking agencies published an advance notice of proposed rulemaking (ANPRM) on August 4, 2003, at 68 FR 45900 soliciting industry comments on a draft of the proposed framework for implementing the New Basel Capital Accord in the United States. In particular, the ANPRM described significant elements of the Advanced Internal Ratings-Based approach for credit risk and the Advanced Measurement Approaches for operational risk (together, the advanced approaches). The ANPRM specified criteria that a banking organization must meet to use the advanced approaches. Under the advanced approaches, a banking organization would use internal estimates of certain risk components as key inputs in the determination of their regulatory capital requirements. The OCC included this rulemaking project in part II of The Regulatory Plan.
- *Safety and Soundness Standards; Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (12 CFR Part 30).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration (agencies) are issuing an interpretation of section 501(b) of the Gramm-Leach-Bliley Act and the Interagency Guidelines Establishing Standards for Safeguarding Customer Information. This interpretation describes the agencies' expectations regarding the response programs, including customer notification procedures, that a financial institution should develop and implement to address the unauthorized access to or use of customer information that could result in substantial harm or inconvenience to a customer. A proposed interpretation was published for comment on August 12, 2003, at 68 FR 47954.

Office of Thrift Supervision

As the primary Federal regulator of the thrift industry, the Office of Thrift Supervision (OTS) has established regulatory objectives and priorities to supervise thrift institutions effectively and efficiently. These objectives include maintaining and enhancing the safety and soundness of the thrift industry; a flexible, responsive regulatory structure that enables savings associations to provide credit and other financial services to their communities, particularly housing mortgage credit; and a risk-focused, timely approach to supervision.

OTS and the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation (collectively, the banking agencies) continue to work together on regulations where the agencies share the responsibility to implement statutory requirements. The agencies are working to update capital standards to maintain, and, where necessary, improve consistency in the agencies' rules, including the *International Convergence of Capital Management and Capital Standards: A Revised Framework (Basel II).* The domestic implementation of the New Basel Capital Accord was introduced in 2003 with publication of an advanced notice of proposed rulemaking and draft supervisory guidance. It included an introduction to the advanced internal ratings-based (IRB) approach to credit risk, and included modifications to the current

U.S. domestic capital framework. The agencies plan to issue a proposed rule by mid-year. Possible changes to capital regulations for U.S. institutions not subject to the framework-based regulations will be considered and addressed in this same general time frame.

Also, OTS anticipates implementing sections of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act) as follows:

- *Proper Disposal of Consumer Information.* The banking agencies, along with the National Credit Union Administration (NCUA), the Securities and Exchange Commission (SEC), and the Federal Trade Commission (FTC), plan to issue a final rule implementing section 216 of the FACT Act by amending the Interagency Guidelines Establishing Standards for Safeguarding Customer Information to require each financial institution to develop, implement, and maintain appropriate measures to properly dispose of consumer information derived from consumer reports and to address the risks associated with identity theft as part of its information security program.
- *Fair Credit Reporting Affiliate Marketing Regulations.* The banking agencies and the NCUA also plan to issue a final rule implementing section 214 of the FACT Act, which amended the Fair Credit Reporting Act (FCRA) by prohibiting a person from using information received from an affiliate to make a solicitation for marketing purposes to a consumer, unless the consumer is given notice and an opportunity and simple method to opt out of the making of such solicitations.
- *Fair Credit Reporting Regulations (Medical Information):* The banking agencies and the NCUA also plan to publish a final rule implementing section 411 of the FACT Act, which amended the FCRA by (1) prohibiting creditors from obtaining or using medical information pertaining to a consumer in connection with any determination of the consumer's eligibility or continued eligibility for credit, and (2) creating limited exceptions to permit affiliates to share medical information with each other without becoming consumer reporting agencies.
- *Identity Theft Detection, Prevention, and Mitigation Program for Financial Institutions and Creditors.* The banking agencies, the NCUA, and the FTC also plan to issue a proposed rule implementing section 114 of the FACT Act, which requires the agencies to develop guidelines for use in identifying patterns, practices, and specific forms of activity that indicate the possible existence of identity theft. The agencies are also required to issue regulations requiring each financial institution and creditor to establish reasonable policies and procedures to implement such guidelines. The regulations must contain a provision requiring a card issuer to notify the cardholder if the card issuer receives a notice of change of address for an existing account, and a short time later receives a request for an additional or replacement card. Related to this matter, the agencies are also considering issuing an interpretation of section 501(b) of the Gramm-Leach-Bliley Act and the Interagency Guidelines Establishing Standards for Safeguarding Customer Information. This interpretation would describe the agencies' expectations regarding the response programs, including customer notification procedures, that a financial institution should develop and implement to address the unauthorized access to or use of customer information that could result in substantial harm or inconvenience to a customer. A proposed interpretation was published for comment on August 12, 2003 (68 FR 47954).

OTS, along with the other Federal banking agencies, plan to issue a final rule revising *Community Reinvestment Act (CRA)* rules to incorporate changes in the Standards for Defining Metropolitan and Micropolitan Statistical Areas, published by the U.S. Office of Management and Budget in December 2000; census tracts designated by the U.S. Bureau of the Census; and the Board of Governors of the Federal Reserve System's Regulation C, which implements the Home Mortgage Disclosure Act (HMDA).

OTS is also reviewing its CRA rules to ensure that they continue to encourage institutions to meet their statutory responsibilities while affording them greater flexibility. For example, OTS is reevaluating how the investment test works in today's environment, including considering making the investment test and the lending test mutually available opportunities; possibly revising the definition of ''community development'' under its CRA rules to encourage all savings associations to increase their community development activities in rural areas, with a particular focus on underserved nonmetropolitan areas; and encouraging institutions to perform community development activities in any areas affected by natural or other disasters or other major community disruptions.

OTS plans to issue a proposed rule describing the existing authority of federal savings associations to engage in various securities broker, dealer, and underwriting activities under the HOLA, and requiring a savings association to notify OTS when it begins to conduct certain securities activities. The proposed rule also updates the existing prohibition on the sale of debt and equity securities issued by a savings association or its affiliates at the offices of a savings association, and eliminates various obsolete OTS securities regulations.

Moreover, as part of its review of regulations under section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996, OTS plans to issue an interim final rule to reduce regulatory burden on savings associations by updating and revising various application and reporting requirements.

Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB) issues regulations to enforce the Federal laws relating to the manufacture and commerce of alcohol products, tobacco products, and the Federal excise tax on firearms and ammunition. TTB's mission and regulations are designed to:

- Regulate the alcohol and tobacco industries, including systems for licenses and permits;
- Assure the collection of all alcohol, tobacco, and firearms and ammunition taxes, and obtain a high level of voluntary compliance with all laws governing those industries;
- Suppress commercial bribery, consumer deception, and other prohibited practices in the alcoholic beverage industry; and
- Assist the States and other Federal agencies in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes in avoidance of State taxes.

In 2005, TTB will continue to pursue its multi-year program of modernizing its regulations in title 27 of the Code of Federal Regulations. This program involves updating and revising the regulations to be more clear, current,

and concise, with an emphasis on the application of plain language principles. TTB laid the groundwork for this program in 2002 when it started to recodify its regulations in order to present them in a more logical sequence. This continuing revision effort will make the TTB regulations more accessible and understandable for small businesses and the general public.

Bureau of the Public Debt

The Bureau of the Public Debt (BPD) administers the following regulations:

- Governing transactions in Government securities by Government securities brokers and dealers under the Government Securities Act of 1986 (GSA), as amended.
- Implementing Treasury's borrowing authority, including rules governing the sale and issue of savings bonds, marketable Treasury securities, and State and local Government securities.
- Setting out the terms and conditions by which Treasury may redeem (buy back) outstanding, unmatured marketable Treasury securities through debt buyback operations.
- Governing the acceptability and valuation of all collateral pledged to secure deposits of public monies and other financial interests of the Federal Government.

Treasury's GSA rules govern financial responsibility, the protection of customer funds and securities, recordkeeping, reporting, audit, and large position reporting for all government securities brokers and dealers, including financial institutions. During fiscal year 2005, BPD will give priority to expanding an exemption in the GSA regulations to include savings associations regulated by the Office of Thrift Supervision (OTS) that hold Government securities in a fiduciary and custodial capacity. The amendment would make savings associations regulated and examined by the OTS eligible for the exemption under the same conditions that currently apply to depository institutions regulated and examined by the other bank regulators.

The rules setting out the terms and conditions for the sale and issue of marketable book-entry Treasury bills, notes, and bonds are known as the Uniform Offering Circular. During fiscal year 2005, BPD will accord priority to issuing an amendment to the Uniform Offering Circular that would treat two parties in a merchant banking relationship as separate bidders rather than as a single bidder in Treasury marketable securities auctions.

Financial Management Service

The Financial Management Service (FMS) issues regulations to improve the quality of Government financial management and to administer its payments, collections, debt collection, and Governmentwide accounting programs.

During fiscal year 2005, FMS' regulatory priorities include ongoing initiatives in the following areas:

- *Payment of Federal Taxes and the Treasury Tax and Loan Program (TT&L)* (31 CFR Part 203): FMS is completing its revisions to this rule that governs the collection of corporate withholding taxes and the investment of the Government's excess operating funds. FMS is streamlining this rule and writing it in plain language.
- *Automated Clearing House (ACH)* (31 CFR Part 210): FMS will issue its annual update to this rule that establishes standards for Federal Government payments and collections via the ACH system. FMS will revise this rule in order to stay current with private industry rules and to facilitate the continued expansion of electronic commerce.

TREAS—Comptroller of the Currency (OCC)

PROPOSED RULE STAGE

113. IMPLEMENTATION OF A REVISED BASEL CAPITAL ACCORD (BASEL II)

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

12 USC 93a; 12 USC 3907

CFR Citation:

12 CFR 3

Legal Deadline:

None

Abstract:

As part of the OCC's ongoing efforts to develop and refine capital standards to ensure the safety and soundness of the national banking system and to implement statutory requirements, the OCC is amending various provisions of the capital rules for national banks. This change involves the implementation of the new Basel Capital Accord (Basel II) (formerly referred to as domestic capital framework). The OCC is conducting this rulemaking jointly with the other Federal banking agencies.

Statement of Need:

This rulemaking is necessary to implement an international initiative regarding the capital adequacy regulation of certain domestic financial institutions. Specifically, this rulemaking implements the ''International Convergence of Capital Measurement and Capital Standards'' (Basel II), which comprehensively revises the 1988 ''International Convergence of Capital Measurement and Capital Standards.'' This rulemaking will translate the lengthy and complicated text of Basel II into the standards and requirements that will govern the largest banks in the United States.

Summary of Legal Basis:

The OCC is implementing the Basel II capital framework for certain domestic financial institutions. This initiative is based on the OCC's general rulemaking authority in 12 U.S.C. 93a and its specific authority under 12 U.S.C. 3907. 12 U.S.C. 3907(a)(2) specifically authorizes the OCC to establish minimum capital levels for financial institutions that the OCC, in its discretion, deems necessary or appropriate.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Not yet determined.

Risks:

Not yet determined.

Timetable:

Action	Date	FR Cite
ANPRM	08/04/03	68 FR 45900
NPRM	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Related RIN: Split from 1557–AB14

RIN: 1557–AC91

BILLING CODE 4810–25–S

DEPARTMENT OF VETERANS AFFAIRS (VA)

Statement of Regulatory Priorities

The Department of Veterans Affairs (VA) administers benefit programs that recognize the important public obligations to those who served this Nation. VA's regulatory responsibility is almost solely confined to carrying out mandates of the laws enacted by Congress relating to programs for veterans and their beneficiaries. VA's major regulatory objective is to implement these laws with fairness, justice, and efficiency.

Most of the regulations issued by VA involve at least one of three VA components: The Veterans Benefits Administration, the Veterans Health Administration, and the National Cemetery Administration. The primary mission of the Veterans Benefits Administration is to provide high-quality and timely nonmedical benefits to eligible veterans and their beneficiaries. The primary mission of the Veterans Health Administration is to provide high-quality health care on a timely basis to eligible veterans through its system of medical centers, nursing homes, domiciliaries, and outpatient medical and dental facilities. The primary mission of the National Cemetery Administration is to bury eligible veterans, members of the Reserve components, and their dependents in VA National Cemeteries and to maintain those cemeteries as national shrines in perpetuity as a final tribute of a grateful Nation to honor the memory and service of those who served in the Armed Forces.

VA's regulatory priorities include a special project to undertake a comprehensive review and improvement of its existing regulations. The first portion of this project is devoted to reviewing, reorganizing, and rewriting the VA's compensation and pension regulations found in part 3 of 38 CFR. The goal of the Regulation Rewrite Project is to improve the clarity and logical consistency of these regulations in order to better inform veterans and their family members of their entitlements.

The Department of Veterans Affairs' 2004 regulatory plan contains one rulemaking action from the Veterans Health Administration. The Veterans Health Administration rulemaking is RIN 2900–AL51 ''Enrollment—Provision of Hospital and Outpatient Care to Veterans Subpriorities of Priority Categories 7 and 8 and Annual Enrollment Level Decision,'' which was published as an interim final rule on January 17, 2003. It amends the Department's medical regulations to protect the quality and improve the timeliness of care provided to all veterans by restricting new enrollments in higher enrollment-priority categories.

VA

FINAL RULE STAGE

114. ENROLLMENT—PROVISION OF HOSPITAL AND OUTPATIENT CARE TO VETERANS—SUBPRIORITIES OF PRIORITY CATEGORIES 7 AND 8 AND ENROLLMENT LEVEL DECISION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 104–262

CFR Citation:

38 CFR 17.36

Legal Deadline:

None

Abstract:

The Department of Veterans Affairs (VA) published in the Federal Register on January 17, 2003, an interim final rule amending VA's medical regulations at 38 CFR part 17 to establish additional subpriorities within enrollment priority categories 7 and 8 and to provide that, beginning January 17, 2003, VA will continue to treat all veterans currently enrolled in any category, and will treat new enrollees in categories 1 through 7. However, the interim final rule provided that VA will suspend the enrollment of additional veterans who are in the lowest statutory enrollment category (priority category 8). Based on the rationale set forth in the interim final rule, VA is adopting the provisions of the interim final rule as a final rule without change.

Statement of Need:

Public Law 104-262, the Veterans' Health Care Eligibility Reform Act of 1996, requires the Secretary of Veterans Affairs to make annual decisions concerning enrollment in VA's health care system in order to ensure that resources are available to provide medical services that are both timely and acceptable in quality. This document announces the enrollment decision to suspend the enrollment of additional veterans who are in the lowest statutory enrollment category (priority category 8). This also amends existing regulations to establish additional subpriorities within priority categories 7 and 8.

Summary of Legal Basis:

38 CFR 17.36(c) requires that the Secretary determine which categories of veterans are eligible to be enrolled and that the Secretary notify eligible enrollees of the determination by announcing it in the Federal Register.

Alternatives:

The Department had to consider placing additional enrollees on waiting lists and extending the waiting period for eligible enrollees seeking appointments for care as alternatives.

Anticipated Cost and Benefits:

By suspending enrollment of additional priority category 8 veterans, VA would avoid significant additional medical benefits costs and begin to bring demand in line with capacity, which will reduce the number of veterans on waiting lists. Without action to suspend new enrollment, the cost projection for FY 2003 is $23.455 billion. This is based on the projected average enrollment for FY 2003 of 6,991,405, together with the projected expenditures that would be needed to provide the medical benefits package to all enrollees. Suspending new enrollment would reduce enrollment in priority category 8 by 164,367 in FY 2003, which is expected to grow to over 520,000 by FY 2005.

Risks:

Without action to suspend new enrollment, patient safety and quality and access to care would be adversely affected.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/17/03	68 FR 2670
Interim Final Rule Effective	01/17/03	
Interim Final Rule Comment Period End	03/18/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For Public Comments:

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BILLING CODE 8320–01–S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Environmental Protection Agency

Statement of Priorities

OVERVIEW

The U.S. Environmental Protection Agency (EPA) is the leading Federal agency responsible for protecting human health and the environment. Since its creation in 1970, EPA has taken actions that have led to measurable improvements in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful chemicals and pesticides.

Specifically, EPA leads the nation's environmental science, research, education and assessment efforts by:

Developing and enforcing regulations: EPA works to develop and enforce regulations that implement environmental laws enacted by Congress. EPA is responsible for researching and setting national standards for a variety of environmental programs, and delegates to States and tribes the responsibility for issuing permits and for monitoring and enforcing compliance. Where national standards are not met, EPA can issue sanctions and take other steps to assist the states and tribes in reaching the desired levels of environmental quality.

Offering financial assistance: In recent years, between 40 and 50 percent of EPA's enacted budgets have provided direct support through grants to State environmental programs. EPA grants to States, non-profits and educational institutions support high-quality research that will improve the scientific basis for decisions on national environmental issues and help EPA achieve its goals.

- EPA provides research grants and graduate fellowships.
- The Agency supports environmental education projects that enhance the public's awareness, knowledge, and skills to make informed decisions that affect environmental quality.
- The Agency also offers information for State and local governments and small businesses on financing environmental services and projects.
- EPA also provides other financial assistance through programs as the Drinking Water State Revolving Fund, the Clean Water State Revolving Fund, and the Brownfields program.

Performing environmental research: At laboratories located throughout the nation, the Agency works to assess environmental conditions and to identify, understand, and solve current and future environmental problems; integrate the work of scientific partners such as nations, private sector organizations, academia and other agencies; and provide leadership in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.

Sponsoring voluntary partnerships and programs: The Agency works through its headquarters and regional offices with over 10,000 industries, businesses, non-profit organizations, and state and local governments, on over 40 voluntary pollution prevention programs and energy conservation efforts. Partners set voluntary pollution-management goals; examples include conserving water and energy, minimizing greenhouse gases, slashing toxic emissions, re-using solid waste, controlling indoor air pollution, and getting a handle on pesticide risks. In return, EPA provides incentives like vital public recognition and access to emerging information.

Furthering environmental education: EPA advances educational efforts to develop an environmentally conscious and responsible public, and to inspire personal responsibility in caring for the environment.

To view the Agency's complete strategic plan and annual report, go to http://www.epa.gov/ocfopage/plan/plan.htm.

FOCUSING ON A BETTER WAY

EPA is focusing on finding a better way of environmental protection, one that can accelerate environmental progress. The existing system has served the nation well . . . but today's challenges are more complex. New approaches are needed that can help achieve goals more quickly and cost-effectively. EPA is relying on four cornerstones to finding a better way - Collaborative problem-solving, market incentives, new technology, and a focus on results.

Collaborative problem-solving is a way of achieving more with our collective resources - bringing all available expertise and resources to bear in solving problems. For example, EPA is collaborating with States and other partners in an effort to improve the Great Lakes and scaling up its National Environmental Performance Track Program. Performance Track is the flagship EPA voluntary program that recognizes and rewards top-performing facilities representing all sizes of businesses from a variety of sectors. This program provides public recognition to these entities and offers regulatory, policy, and administrative incentives, such as a low priority for routine EPA inspections, extended on-site storage times for hazardous waste, and reduced reporting frequency under the Clean Air Act.

Incentives are the second cornerstone. Market-based approaches or other incentives can lead businesses, government agencies, and other organizations to do more than is required. These approaches provide a way to link environmental and economic interests so that doing more for the environment nets more for the bottom line. EPA is working to build more incentives into our programs and policies. For example, EPA is proposing to use market-based approaches to drastically reduce emissions of mercury, SOx and NOx.

Technology is the third cornerstone. To continue making progress, it is critical to harness the latest scientific, technological, and information capabilities for environmental gain. For example under our Technology for a Sustainable Environment (TSE) program, after a competition, we award grants to support fundamental and applied research related to pollution prevention in industrial processes and methodologies ultimately leading to a reduction in waste at the source. Under this program, as an alternative to organic or halogenated solvents, a CO2-based process was developed. The work was further supported with a Small Business Innovation Research grant and now a $400 million commercial facility is being built to exploit it.

Focus on results is the fourth cornerstone. EPA understands that traditional environmental strategies have sometimes gotten bogged down in process at the expense of real progress. One of the best examples is reducing dirty emissions from older diesel school buses. Recognizing diesel engines have long life spans - sometimes 30 years - and that many school systems would use current buses until they had ''run their course,'' EPA launched a nationwide campaign to retrofit older buses and provide our children with a much cleaner, healthier ride to school. Hundreds of communities now have retrofitting programs underway.

EPA believes these cornerstones will be the foundation to finding a better way to environmental progress.

Attention to Small Businesses

Helping small businesses improve environmental performance is a top priority for EPA. EPA offers a variety of services for small businesses, including a toll-free hotline, a semiannual newsletter, online expert systems, and for some sectors, compliance assistance centers that focus on the unique environmental management issues facing specific industries. EPA also maintains a Small Business Ombudsman, which provides a point of contact for small businesses and ensures compliance with the Small Business Paperwork Relief Act of 2002.

In FY 2004, EPA is focusing on implementing the Small Business Strategy. By better coordinating small business activities, EPA aims to improve its technical assistance and outreach efforts, minimize burdens to small businesses in its regulations, and simplify small businesses' participation in its voluntary programs.

A number of rules included in this Plan may be of particular interest to small businesses (and for a more extensive list of rules affecting small businesses, please see appendices B and C to the Regulatory Agenda which is available at epa.gov/regagenda.)

- Groundwater Rule (2040-AA97)
- Long Term 2 Enhanced Surface Water Treatment Rule (2040-AD37)
- Stage 2 Disinfection Byproducts Rule (2040-AD38)
- Minimizing Adverse Environmental Impacts from Cooling Water Intake Structures (316(b) Phase III) Rule (2040-AD70)
- Standardized Permit for RCRA Hazardous Waste Management Facilities Final Rule (2050-AE44)
- Office of Solid Waste Burden Reduction Project Final Rule (2050-AE51)
- Recycling of Cathode Ray Tubes and Mercury-Containing Equipment: Changes to Hazardous Waste Regulations Final Rule (2050-AE52)
- Increase Metals Reclamation from F006 Waste Streams Proposed Rule (2050-AE97)
- Standards and Practices for Conducting ''All Appropriate Inquiry'' Proposed Rule (2050-AF04)
- Control of Emissions from Spark-Ignition Engines and Fuel Systems from Marine Vessels and Small Equipment (2060-AM34)

HIGHLIGHTS OF EPA'S REGULATORY PLAN

Office of Air and Radiation

The principal regulatory priority of EPA's Office of Air and Radiation (OAR) for FY 2005 is to protect public health and the environment from the harmful effects of fine particulate matter and ozone, the two air pollutants that persist widely in the Nation's air in amounts that exceed Clean Air Act health standards. Exposure to these pollutants is associated with numerous harmful effects on human health, including respiratory problems, heart and lung disease, and premature death. These pollutants also degrade visibility in National parks and other scenic areas. In addition to ozone and particulate pollution, OAR is continuing to address toxic air pollution by implementing a toxics-control program under the Clean Air Act. OAR is also working to increase the effectiveness and efficiency of its permitting programs, which are the main mechanisms through which these protections are implemented. These efforts are described briefly below.

One of OAR's principal vehicles to mitigate particulate and ozone pollution is the Clean Air Interstate Rule, which will achieve large reductions in sulfur dioxide and nitrogen oxide emissions that cause particulate and ozone pollution. Emissions of sulfur dioxide and nitrogen oxide, especially from electric powerplants, can be transported on the wind over long distances from the Midwest to the east coast. Such emissions can be a major factor in the pollution problems of eastern cities. This program will achieve its reductions through use of a ''cap-and-trade'' system similar to the one that has proved so successful in EPA's Acid Rain program. OAR is also developing a separate rule to enhance scenic areas by reducing the particulate pollution that restricts visibility in those areas.

OAR is also developing a rulemaking addressing another category of emissions that cause particulate and ozone pollution: emissions from locomotives and smaller marine engines. This rule will enhance the overall mobile-source control program that has already set stringent standards for most categories of vehicles, engines, and their fuels.

Even though these Federal rules will go a long way toward reducing the ozone and particulate pollution in America's cities, they can't do the job alone. Additional State and local control programs under the Clean Air Act will need to be instituted or enhanced in many of the most polluted areas. To help and guide the States and local governments in these efforts, EPA is developing implementation rulemakings for both ozone and particulates that will provide technical help and policy guidance crucial to assuring that State and local efforts achieve their pollution-control goals.

OAR also continues to assess new scientific information that underlies the National Ambient Air Quality Standards (NAAQS), which are the centerpiece of the Clean Air Act and the foundation of OAR's program. In 2005, EPA expects to announce the results of the latest review of the particulate matter NAAQS in the form of a proposed rule to either revise or reaffirm the current standard.

EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990. EPA has largely completed implementing the ''Maximum Achievable Control Technology'' (MACT) program, which has the goal of controlling toxic air pollution from major emitters nationwide. Toxic air pollution is a term that covers a large number of industrial chemicals and other substances that have been shown to cause cancer, birth defects, and developmental problems in children. To date, EPA's air toxics program has focused primarily on reducing emissions from large industrial sources, such as petroleum refineries and chemical manufacturing plants, through technology-based standards. When fully implemented, the overall MACT program will reduce more than one million tons of toxic air emissions per year. The Electric Utility MACT regulation will address one of the most significant remaining sources of mercury in the United States. While working on these standards, OAR is beginning to evaluate those sources with standards already in place to determine if the remaining risk from those sources warrants additional regulation.

Since many air quality programs are administered through permitting programs, OAR continues to work toward improving these programs to increase efficiency and reduce regulatory burden. Currently, OAR is developing rulemakings to streamline and improve its New Source Review (NSR) permitting program. This effort will clarify the circumstances under which companies must obtain construction permits before building new facilities or significantly modifying existing facilities. These revisions will provide more regulatory certainty by clarifying compliance requirements, and will also make the program easier to

administer while maintaining its environmental benefits. In developing these NSR rule revisions, OAR is drawing upon many years of intense involvement with major stakeholders, who have helped shape a suite of reforms that are expected to both improve the environmental effectiveness of these programs and make them easier to comply with.

The annual report on the costs and benefits of regulations, entitled ''Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities,'' that is prepared by the Office of Management and Budget (OMB) and submitted to Congress each year, included several nominations for reform from the public. In FY2005, OAR expects to address through regulatory action one of the areas raised: New Source Review (Comments #16, 30, 77, 187, 188, 189, and 196). (For a copy of these comments, go to OMB's compilation of the comments at http://www.whitehouse.gov/omb/inforeg/key__comments.html.)

Office of Environmental Information

EPA's Office of Environmental Information (OEI) continues to ensure that EPA collects and provides access to high quality environmental information and data to our partners, stakeholders, and the public. In keeping with this mandate, one of OEI's top regulatory priorities will be the finalization of the electronic reporting provisions of the Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR). EPA is deferring any further action on the CROMERRR electronic record-keeping provisions until a later time. This final rule will address electronic reporting by companies regulated under all of EPA's programs: air, water, pesticides, toxic substances, wastes, and emergency response. CROMERRR would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, this rule would set the conditions for allowing electronic reporting under State, tribal, or local environmental programs that operate under EPA authorization.

CROMERRR is intended to make electronic reporting as simple, efficient, and cost-effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no obstacles to adopting new technologies as they emerge.

To ensure that authorized programs at the State, tribal, and local levels meet CROMERRR's goals, the rule would specify a set of criteria that these programs must satisfy as they initiate electronic reporting. The final rule would specify a process for certifying that these programs meet the criteria. EPA is on schedule to finalize CROMERRR by the first half of FY2005. In response to public comment, a decision was made to focus the final rule on electronic reporting only, and to defer coverage of electronic record keeping until a later time. Also in response to comments, EPA currently is exploring a streamlined process to review State programs for electronic reporting.

Another key regulatory priority that OEI is undertaking is the enactment of burden reduction for the Toxics Release Inventory (TRI) reporting community. The TRI program collects chemical release and other waste management data on over 650 chemicals from over 24,000 facilities across the U.S. each year. To provide TRI reporters with appropriate burden relief, TRI intends to propose two rulemakings to address both short-term and longer-term reporting requirement modifications while maintaining the practical utility of the TRI data. Specifically, OEI intends to propose the TRI Reporting Forms Modification rule to address noncontroversial modifications to the TRI reporting requirements (i.e., Form R). At the same time, OEI intends to continue parallel work on a second rulemaking to examine more significant reporting modifications with greater potential impact on reporting burden. The second rulemaking, the ''Toxics Release Inventory Reporting Burden Reduction Rule,'' focuses on exploring long-term reporting modifications.

OEI is assessing a number of burden reduction options for both rulemakings within the criteria of what is technically, practically and legally feasible in order to meet the goals and statutory obligations set forth for TRI reporting. Although the primary goal of both efforts is to reduce burden associated with TRI reporting, these rules will also maintain EPA's commitment to providing valuable information to the public.

In addition, EPA is committed to providing electronic means to its stakeholders to meet EPA's reporting requirements, specifically through the Central Data Exchange (CDX) system. CDX is an integrated system that provides electronic reporting services to more than 30,000 users for 16 data flows in six major EPA media programs, and is on track to provide electronic reporting services for all significant environmental data collections over the next two years. By enabling the regulated community to utilize CDX as a reporting tool, the TRI Program has seen a 49% increase in the number of reports submitted to EPA via the Internet for TRI Reporting Year 2003 when compared to Reporting Year 2002. To take advantage of CDX's paperless reporting feature, TRI reporters must use the EPA-provided TRI Made-Easy (TRI-ME) Software. This upward trend toward greater Internet reporting via CDX is great news for the TRI program. Money saved from processing more-costly hard-copy paper submissions to TRI can now be reinvested in helpful tools and automated data quality checks to assist facilities and in ways to provide greater electronic means of accessing TRI data.

CDX also promulgated a number of new data flows, including the Office of Water's Stormwater Electronic Notice of Intent (an electronic permit application), the Office of Solid Waste and Emergency Response's Risk Management Plan WebRC (electronic updates of emergency contact information), and the Office of Prevention, Pesticides, and Toxic Substances' Lead Request for Certification (payment transactions online).

CDX is EPA's point of presence on the Environmental Exchange Network, known as the ''Node.'' Using CDX, EPA has worked with States to provide the technical specifications and exchange protocols for the Network. CDX provides support services, including node building, security and authentication and help desk. OEI is working with the major programs to deploy their data flows as ''node'' exchanges, using XML and web services. These efforts are some examples of EPA's commitment to the collection and dissemination of the highest quality of environmental information.

Office of Prevention, Pesticides, and Toxic Substances

EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) plays an important role in protecting public health and the environment from potential risk from pesticides and chemicals. In addition to the daily

activities related to our licensing programs, OPPTS has identified several regulatory priorities for the coming year.

Evidence suggests that environmental exposure to man-made chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in human and wildlife populations. The Food Quality Protection Act directed EPA to develop a chemical screening program (the Endocrine Disruptor Screening Program, EDSP), using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. OPPTS is implementing recommendations from a scientific advisory committee, which was established to advise EPA on the EDSP, by developing and validating test systems for determining whether a chemical may have effects similar to those produced by naturally occurring hormones. As part of this program EPA is also designing a regulatory framework for procedures and processes to use when implementing the EDSP, and will develop an initial list of chemicals for which testing will be required. In early 2005, EPA anticipates publishing the final chemical selection approach for this initial list of chemicals, which was proposed in December 2002 for public comment.

In 2005, OPPTS will be revising its pesticide emergency exemption program, under which States and other Federal agencies may obtain permission to temporarily use a pesticide not in accordance with registration requirements under emergency conditions. In response to State concerns, EPA has already reduced the review time for emergency exemptions significantly. Other changes that EPA is considering have the potential for further streamlining the exemption program and allowing more flexibility in its applicability.

OPPTS will propose to update and revise data requirements for the registration of pesticide products in 40 CFR part 158. The regulations specify the data required as the basis for the Agency's pesticide risk assessment and licensing decisions. Although the Agency has kept pace with evolving scientific understanding of pesticide risks by requiring the submission of data on a case-by-case basis, the 1984 regulations have not been updated to reflect these data needs on a routine basis. The first in a series of proposals will address data requirements for conventional chemical pesticides for agricultural uses. Subsequent proposals are planned for antimicrobial, biochemical, microbial pesticides, and plant-incorporated protectants.

In 2006, OPPTS will begin implementing a program, mandated by section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), to review the registrations of all pesticides at least once each 15 years. The registration review program will replace the tolerance reassessment program (ending in 2006) and reregistration program (ending in 2008) currently underway. These two programs are both one-time reviews that evaluate and manage the risks posed by existing pesticides. The Agency intends to initiate registration review while it completes tolerance reassessment and reregistration. FIFRA 3(g) requires the Agency to establish procedural regulations for the registration review program. Promulgation of a procedural regulation is a very high priority for OPP, in order to achieve a smooth transition into the new registration review program.

EPA anticipates it will develop a policy or regulation concerning the use of human research to support Agency actions to protect public health and the environment. In developing a future policy or rule, EPA will consider the public comments received in response to the Advance Notice of Proposed Rulemaking issued in May 2003, and will also carefully consider advice from the National Academy of Sciences submitted to EPA in February 2004. The policy or rule would establish rigorous scientific and ethical standards that EPA would apply in its analysis of various types of research involving people exposed to toxicants to identify or quantify their effects. The Agency will particularly focus on ''third-party intentional dosing human studies,'' but recognizes that standards applicable to these studies may also be applicable to other types of studies. ''Third-party studies'' refers to research not conducted or supported by EPA or other federal agencies, and therefore not governed by the regulation for ''Protection of Human Subjects,'' widely referred to as the ''Common Rule'' (40 CFR part 26).

The Agency launched the HPV Initiative in April 1998 to collect or, where necessary, develop basic screening level hazard data necessary to provide critical information about the environmental fate and potential hazards associated with high production volume (HPV) chemicals. These chemicals are defined as organic chemicals manufactured (including imported) at or above 1 million pounds per year based on information submitted under the 1990 Inventory Update Rule established pursuant to the Toxic Substances Control Act (TSCA). Data collected and/or developed under the HPV Initiative will provide critical basic information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action. The HPV Initiative includes a voluntary component, the HPV Challenge Program, and rulemaking under TSCA. Under the voluntary HPV Challenge Program component, EPA received commitments from 401 companies individually or through consortia and the International Council of Chemical Associations (ICCA) to sponsor 2,222 of the estimated 2,800 HPV chemicals included in the HPV Initiative. OPPTS issued a status report for the HPV Challenge Program on December 1, 2004. The report, ''Status and Future Directions of the HPV Challenge Program,'' showcases the extensive voluntary participation by companies that have agreed to provide data to EPA on chemicals they manufacture or import, and outlines a preliminary strategy for how EPA will deal with chemicals that are not yet sponsored. More information about the report and the HPV Chemical Program is available at http://www.epa.gov/chemrtk/hpvstatr.htm.

In the spring of 2005, OPPTS expects to issue a final rulemaking under TSCA that will require testing for a number of the HPV chemicals that were not sponsored as part of the voluntary HPV Challenge Program.

Childhood lead poisoning is an ongoing problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline and various food sources, remaining lead-based paint in older houses continues to be a significant source of childhood lead poisoning. Section 402(c) of TSCA directs EPA to address renovation and remodeling activities in these older houses by first conducting a study of the extent to which persons engaged in various types of renovation and remodeling activities

are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 Subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others. Given the significant number of older houses affected, such a rule is likely to have a potentially significant economic impact. In an effort to minimize that impact, the Agency has worked with stakeholders to explore the development of non-regulatory approaches for reducing the potential creation of lead-based paint hazards from renovation or remodeling activities. The Agency will be pilot testing one such approach, the ''Lead Safety Partnership,'' beginning in the fall of 2004. The Lead Safety Partnership is a public/private initiative to encourage contractors to use Lead Safe Work Practices (LSWP) during renovation, repair, and painting. LSWP are a set of work methods that avoid making and spreading lead-contaminated dust. Such lead-based paint program activities are intended to insure that the individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under six years old.

In 2005, OPPT expects to assess the status of the pending implementation in the U.S. of the Rotterdam Convention on Prior Informed Consent (PIC), which includes export notification requirements related to a comment mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations. (See OMB's compilation of comments, summary no. 190, page 10, commenter no. 12 available at http://www.whitehouse.gov/omb/inforeg/key__comments.html.)

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Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) has a number of regulatory priorities aimed at improving environmental quality. Protection of public health and the environment and environmental stewardship are two key themes, as is reducing burden on the regulated community where environmental protections are maintained.

EPA will promote and protect air quality by reducing emissions of arsenic, beryllium, cadmium, chromium, dioxins and furans, hydrogen chloride, lead, manganese, and mercury, all of which cause adverse health effects. EPA plans to promulgate national emission standards for these hazardous air pollutants for hazardous waste combustors. This rule will also contain a final decision to the Cement Kiln Recycling Coalition petition of the Administrator to withdraw Agency policy and technical guidance concerning site-specific risk assessments for hazardous waste combustors and re-issue them as regulations, if EPA continues to believe that they are necessary. This rule also supports a reform nomination for site-specific risk assessments in the Resource Conservation and Recovery Act (RCRA) that was mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations.

To promote environmental stewardship, EPA is encouraging recycling. One of the largest hazardous waste streams amenable to recycling is the wastewater treatment sludges from electroplating operations (waste code F006). EPA is considering changes to the existing RCRA regulations to encourage safe recycling and waste management practices of wastewater treatment sludges from electroplating operations. These electroplating sludges are sufficiently high in metal(s) and sufficiently low in other toxic constituents.

EPA also seeks to remove unnecessary regulatory barriers to recycling of Cathode Ray Tubes. These tubes, which are found in televisions and computer monitors, contain lead to protect users from x-rays. To promote recycling, EPA will seek to streamline RCRA requirements for managing mercury-containing equipment.

To reduce burden on the regulated community, Agency efforts are underway to eliminate duplicative and non-essential paperwork burden imposed by RCRA reporting and recordkeeping requirements. This rule will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations. This rule also supports a reform nomination for burden reduction under RCRA that was mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations.

EPA also intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum. The current federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a RCRA hazardous waste. Yet, such sludges do not contain the constituents for which the F019 hazardous waste was originally listed (cyanide and chromium).

EPA also plans to streamline both the RCRA permit and hazardous waste manifest processes. The Agency is creating a standardized permit for RCRA facilities that generate hazardous waste and routinely manage the waste on-site in tanks, containers, and containment

buildings. This standardized permit process would allow facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process.

Likewise, the Agency plans to reduce paperwork burden by standardizing the Uniform Hazardous Waste Manifest, which is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of RCRA hazardous waste during its transportation. EPA plans to specify one format for the manifests that may be used in all states. EPA is working toward standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes.

Office of Water

EPA's Office of Water's primary goals are to ensure that drinking water is safe, restore and maintain oceans, watersheds, and their aquatic ecosystems to protect human health, support economic and recreational activities, and provide healthy habitat for fish, plants, and wildlife. In order to meet these goals, EPA has established a number of regulatory priorities for the coming year. They include rules affecting cooling water intakes and drinking water.

In November 2004, EPA issued a proposed rule to control the adverse environmental impacts associated with cooling water intakes. Many power plants and factories withdraw large volumes of water from rivers, lakes, or other water bodies to cool their production equipment. As required by the Clean Water Act (CWA), EPA must ensure that the location, design, construction and capacity of these cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. EPA's rulemaking may affect existing facilities that use cooling water intake structures, and whose intake flow levels exceed a minimum threshold to be determined by EPA during this rulemaking. EPA will accept comments on the proposed rule until March 24, 2005.

Finally, EPA is developing three rules to protect the safety of drinking water. First, EPA is developing a final Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). This rule would reduce risks from microbial pathogens, especially *Cryptosporidium*, in public water systems that use surface water sources. LT2ESWTR provisions would target systems where current standards do not provide sufficient protection, including both filtered systems with elevated source water pathogen levels and unfiltered systems. Second, EPA plans to finalize the Ground Water Rule, a rule that addresses fecal contamination in public water systems served by ground water sources. Finally, EPA is developing a final Stage 2 Disinfectants and Disinfection Byproducts Rule to control exposure to disinfection byproducts beyond the requirements of the Stage 1 Disinfectants and Disinfection Byproducts Rule. This rule will respond to new data the Agency has received on: disinfection byproduct occurrence; bladder, colon, and rectal cancer; and possible reproductive and developmental health effects.

EPA

PRERULE STAGE

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115. ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP); CHEMICAL SELECTION APPROACH FOR INITIAL ROUND OF SCREENING

Priority:

Other Significant

Legal Authority:

15 USC 2603 TSCA; 21 USC 346(a) FFDCA; 42 USC 300(a)(17) SDWA; 7 USC 136 FIFRA

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

EPA published a proposed policy statement in the Federal Register setting forth the Endocrine Disruptor Screening Program (EDSP) on December 28, 1998. In that FR Notice, the Agency described the major elements of the Program EPA had developed to comply with the requirements of FFDCA section 408(p) as amended by FQPA. One of those elements is Priority Setting which was defined as the collection, evaluation, and analysis of relevant information to determine the general order in which chemical substances and mixtures will be subjected to screening and testing. Under this current action, EPA is developing a priority setting approach to be used by the Agency to identify the initial list of chemicals for which EDSP Tier 1 testing will be required. On December 30, 2002, EPA published in the Federal Register for public comment a proposed chemical selection approach for this initial list of chemicals. The public comment period on this proposed approach was extended to April 1, 2003 in a Federal Register notice dated February 26, 2003. EPA has considered the comments and will issue a Federal Register notice setting forth its final approach. EPA will issue an additional Federal Register notice setting forth the draft initial list of chemicals it proposes for testing. This additional notice is expected to be published to allow sufficient time for review and comment prior to actual Tier 1 assay testing. Although this action is not a rulemaking, the Agency has included it in the Regulatory Agenda to help inform the public.

Statement of Need:

The Endocrine Disruptor Screening Program fulfills the statutory requirement to screen pesticide chemicals for their potential to disrupt the endocrine system and adversely affect human health.

Summary of Legal Basis:

The mandate to screen pesticide chemicals for estrogenic effects that may affect human health is section 408(p) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)). Discretionary authority to test contaminants in sources of drinking water is in the Safe Drinking Water Act as amended in 1996 (42 U.S.C. 300j-17). General authority to require testing of chemicals and pesticides is in TSCA (15 U.S.C. 2603) and FIFRA (7 U.S.C. 136) respectively.

Alternatives:

A federal role is mandated under cited authority. There is no alternative to the role of the Federal government on this issue to ensure that pesticides, commercial chemicals and contaminants are screened and tested for endocrine disruption potential. A limited amount of testing may be conducted voluntarily but this will fall far short of the systematic screening which is necessary to protect public health and the environment and ensure the public that all important substances have been adequately evaluated.

Anticipated Cost and Benefits:

None.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk

from exposure to chemicals operating through an endocrine mediated pathway. Preliminary studies show decreases on IQ tests and increases in aggression in children. Severe malformations of the genitals of boys has increased steadily over the last two decades and fertility has decreased in young males. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish, amphibians, alligators, and shellfish have been documented in the U.S., Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the U.S. to proceed on a two track strategy: research on the basic science regarding endocrine disruption and screening with validated assays to identify which chemicals are capable of interacting with the endocrine system. The combination of research and test data submitted in this program will enable EPA to take action to reduce risks.

Timetable:

Action	Date	FR Cite
Notice: Proposed Approach	12/30/02	67 FR 79611
Notice: Final Approach	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN No. 4727, EDocket No. OPPT-2004-0109; Split from RIN 2070-AD26.

URL For More Information:

http://www.epa.gov/scipoly/oscpendo/prioritysetting/index.htm

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RIN: 2070–AD59

EPA

116. NOTIFICATION OF CHEMICAL EXPORTS UNDER TSCA SECTION 12(B)

Priority:

Other Significant

Legal Authority:

15 USC 2611

CFR Citation:

40 CFR 707

Legal Deadline:

None

Abstract:

Section 12(b)(2) of the Toxic Substances Control Act (TSCA) states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which submission of data is required under section 4 or 5(b), or for which a rule, action or order has been proposed or promulgated under section 5, 6, or 7, shall notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance. Legislation is currently pending to address the implementation in the United States of the Rotterdam Convention on Prior Informed Consent (PIC), which itself includes export notification requirements. In order to address these concerns, and additional concerns expressed by other stakeholders, EPA has reported to OMB that as of August 2004, the PIC legislation is not yet in force. EPA further informed OMB that in 2005, the Agency will reassess the status of the legislation and, if appropriate, will initiate the rulemaking process for considering changes to the TSCA section 12(b) regulation, within the scope of existing statutory authority. This could include holding public meetings and/or issuing an ANPRM that invites interested parties to participate in developing amendments to the current TSCA section 12(b) regulations.

Statement of Need:

Industry has nominated the implementing regulations for reform consideration in the annual report on the costs and benefits of regulations, entitled ''Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities,'' that is prepared by the Office of Management and Budget (OMB) and submitted to Congress each year. (See OMB's compilation of comments, summary no. 190, pg 10, commenter no. 12 available at http://www.whitehouse.gov/omb/inforeg/key__comments.html.)

Summary of Legal Basis:

Section 12(b)(2) of the Toxic Substances Control Act (TSCA).

Alternatives:

To be determined.

Anticipated Cost and Benefits:

Minimal, but yet to be determined.

Risks:

None.

Timetable:

Action	Date	FR Cite
Notice	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN 4858.

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RIN: 2070–AJ01

EPA

117. LEAD–BASED PAINT ACTIVITIES; VOLUNTARY PROGRAM FOR RENOVATION AND REMODELING

Priority:

Other Significant

Legal Authority:

15 USC 2682 TSCA 4 402; PL 102–550 sec 402(c)(3)

CFR Citation:

40 CFR 745

Legal Deadline:

None

Abstract:

As an alternative to the regulatory program, EPA is working with stakeholders to develop a voluntary program for renovations and remodeling activities. The voluntary program would partner the Agency and national organizations together to promote an initiative which could provide incentives to participating contractors and property owners who incorporate lead safe work practices into their standard operating procedures. The Agency plans, in a Notice or ANPRM to be published in the winter of 2004, to introduce the voluntary program, discuss its component parts, and review how it will be evaluated.

Statement of Need:

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood, (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline, and food sources, remaining paint in older houses continues to be a significant source of childhood lead poisoning. These rules will help insure that individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under 6 years old.

Summary of Legal Basis:

TSCA section 402(c) directs EPA to address renovation and remodeling activities by first conducting a study of the extent to which persons engaged in various types of renovation and remodeling activities are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others.

Alternatives:

TSCA section 402(c) states that should the Administrator determine that any category of contractors engaged in renovation or remodeling does not require certification; the Administrator may publish an explanation of the basis for that determination. This voluntary program is one of the key alternatives considered to developing a more prescriptive regulatory program.

Anticipated Cost and Benefits:

EPA's quantitative cost estimates fall into four categories: Training Costs, Work Practice Costs, Clearance Testing Costs, and Administrative Costs. The estimates vary depending upon the option selected. In most cases we expect that requirements related to Clearance Testing and Work Practices will contribute the most to overall rule cost. The benefits analysis will not provide direct quantitative measures of each (or any) option. EPA does not have a complete risk assessment (with dose-response functions) that would permit direct quantitative estimates. We do have other data, such as estimated loadings of Pb generated by renovation work, number and type of renovation events, demographics of the exposed population, and the costs of various health effects previously linked to Pb exposure. With the available information we are able to utilize several qualitative approaches to frame the benefits associated with an effective renovation rule.

Risks:

Like the rules under consideration, this voluntary program is aimed at reducing the prevalence and severity of lead poisoning, particularly in children. The Agency has concluded that many R&R work activities can produce or release large quantities of lead and may be associated with elevated blood lead levels. These activities include, but are not limited to: sanding, cutting, window replacement, and demolition. Lead exposure of R&R workers appears to be less of a problem than that of building occupants (especially young children). Some workers (and homeowners) are occasionally exposed to high levels of lead. Any work activity that produces dust and debris may create a lead exposure problem.

Timetable:

Action	Date	FR Cite
Notice Announcing 1st Pilot	12/00/04	
Notice Announcing 2nd Pilot	05/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 3557.1; Split from RIN 2070-AC83.

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RIN: 2070–AJ03

EPA

PROPOSED RULE STAGE

118. CLEAN AIR FINE PARTICLE IMPLEMENTATION RULE

Priority:

Other Significant

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

42 USC 7410; 42 USC 7501 et seq

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

In 1997, EPA promulgated revised National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM-2.5). The rule described in this paragraph—the Implementation Rule for PM-2.5 NAAQS—will include requirements and guidance for State and local air pollution agencies to develop and submit State implementation plans (SIPs) designed to bring the areas into attainment with the 1997 standards. These SIP-development activities include conducting technical analyses to identify effective strategies for reducing emissions contributing to PM-2.5 levels, and adopting regulations as needed in order to attain the standards. Ambient air quality monitoring for 1999-2001 shows that areas exceeding the standards are located throughout the eastern half of the United States and in California. Estimates show that compliance with the standards will prevent thousands of premature deaths from heart and lung disease, tens of thousands of hospital admissions and emergency room visits, and millions of absences from school and work every year.

Statement of Need:

This rule is needed in order to provide guidance to State and local agencies in preparing State Implementation Plans (SIPs) designed to bring areas into attainment with the 1997 PM-2.5 standards. The implementation requirements for nonattainment areas are generally described in subpart 1 of section 172 of the Clean Air Act. This rule provides further interpretation of those requirements for the PM-2.5 standards.

Summary of Legal Basis:

42 USC 7410 and 42 USC 7501 et seq.

Alternatives:

Alternatives will be explored as the proposal is developed.

Anticipated Cost and Benefits:

This information will be provided as the proposal is developed.

Risks:

The risks addressed by this rule are those addressed by the 1997 NAAQS rule — i.e., the health and environmental risks associated with nonattainment of the NAAQS. These risks were summarized in detail in the analyses accompanying the 1997 NAAQS rule.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4752;

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RIN: 2060–AK74

EPA

119. PREVENTION OF SIGNIFICANT DETERIORATION (PSD) AND NONATTAINMENT NEW SOURCE REVIEW (NSR): ALLOWABLES PLANTWIDE APPLICABILITY LIMIT (PAL), AGGREGATION, AND DEBOTTLENECKING

Priority:

Other Significant

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 51.165; 40 CFR 51.166; 40 CFR 52.21

Legal Deadline:

None

Abstract:

These rules clarify when less than significant emissions increases from multiple activities at a single major stationary source must be considered together for the purposes of determining major new source review (NSR) applicability (aggregation). We are also changing in the way emissions from permitted emissions units upstream or downstream from those undergoing a physical change or change in the method of operation are considered when determining if a proposed project will result in a significant emissions increase (debottlenecking). The rules also provide an allowables plantwide applicability limit (PAL) option that is based on the allowable emissions from major stationary sources. A PAL is an optional approach that provides the owners or operators of major stationary sources with the ability to manage

facility-wide emissions without triggering major NSR. The added flexibility of a PAL allows sources to respond rapidly to market changes consistent with the goals of the NSR program. The regulations for aggregation and debottlenecking are intended to improve implementation of the program by articulating principles for determining major NSR applicability that were previously addressed through guidance only. The purpose of the allowables PAL rule is to encourage major stationary sources to install state-of-the-art controls in exchange for regulatory certainty and flexibility.

Statement of Need:

The current New Source Review program provides for emissions from multiple projects to be aggregated (aggregation) as one single project under certain circumstances. Similarly, when making a PSD applicability calculation, emissions from units whose effective capacity and potential to emit have been increased as a result of a modification to another unit (debottlenecked units), must be included in the initial PSD applicability calculations. Specific questions regarding the application of these two terms have been addressed on a case-by-case basis. By completing this rulemaking, regulated entities and regulatory agencies will be provided an additional level of certainty in addressing applicability issues. In December 2002 we promulgated NSR rules for a Plantwide Applicability Limit (PAL) based on actual emissions that applies to existing major stationary sources. In 2005, we will propose an allowables PAL based on a facility's allowable emissions mainly for greenfield sources. If a company commits to keep its facility emissions below Allowables PAL level, then these regulations will allow the plant owners to avoid the NSR permitting process when they make changes at individual units at the plant, as long as the total emissions from the facility will not increase. This would provide flexibility for sources to respond rapidly to market changes without compromising environmental protection.

Summary of Legal Basis:

42 USC 7411(a)(4)

Alternatives:

Alternatives will be developed as the rulemaking proceeds.

Anticipated Cost and Benefits:

Cost and benefit information will be developed as appropriate as the rulemaking proceeds.

Risks:

Risk information will be developed as appropriate as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4793;

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RIN: 2060–AL75

EPA

120. PESTICIDES; DATA REQUIREMENTS FOR CONVENTIONAL CHEMICALS

Priority:

Other Significant

Legal Authority:

7 USC 136(a) to 136(y)

CFR Citation:

40 CFR 158

Legal Deadline:

None

Abstract:

EPA will propose revisions to its data requirements for the registration of conventional pesticide products. In this action, the Agency will propose revisions to the data requirements that pertain to product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, nontarget terrestrial and aquatic organisms, nontarget plant protection, and environmental fate. The proposed data requirements will reflect current scientific knowledge and understanding. These revisions would improve the Agency's ability to make regulatory decisions about the human health and environmental effects of pesticide products to better protect wildlife, the environment, and people, including sensitive subpopulations. Coupled with revision of data requirements, EPA will propose to reformat the requirements and revise its general procedures and policies associated with data submission. By codifying existing data requirements which are currently applied on a case-by-case basis, the pesticide industry, along with other partners in the regulated community, would attain a better understanding and could better prepare for the pesticide registration process. EPA intends to propose a series of revisions to the data requirements, covering different data disciplines and product types.

Statement of Need:

Since the data requirements were first published in 1984, the information needed to support the registration of a pesticide has evolved along with the expanding knowledge base of pesticide chemical technology. Over the years, updated data requirements have been applied on a case-by-case basis to support individual registration applications or imposed by data call-in on registrants of similar products. The codified data requirements have not been revised to keep pace with the updated data requirements. EPA will also propose to reformat the data requirements and revise procedures and policies for data submission. The changes to be proposed are intended to provide stakeholders with a more transparent and improved clarity of the potential data requirements, more focused use patterns that reflect current practice, and a more efficient registration process.

Summary of Legal Basis:

The planned proposed rule is intended to describe data and information needed to support multiple pesticide mandates under two statutes, specifically the registration, reregistration, registration review,

experimental use permit programs under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the tolerance-setting program under the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA section 3(c) requires that applicants for registration provide the Agency a full description of tests made and the results that support the registration of a pesticide product, and requires the Agency to issue guidelines specifying the kinds of information needed to support registration. FIFRA section 3(g) requires the Agency to review every 15 years the registration of each pesticide, and determine that it continues to meet the registration standard. The data requirements established for registration will be the foundation of the Agency's registration review. FIFRA section 4 requires the Agency to reregister pesticides that were registered prior to 1984, and in so doing, to provide data and summaries of studies previously submitted to support registration. FIFRA section 5 authorizes the Agency to issue experimental use permits for which data may be required. FFDCA section 408 authorizes EPA to establish tolerances (or expemptions from tolerance) for pesticide residues in food, and prescribes generally the types of data that are to be submitted to support such tolerances.

Alternatives:

The Agency is required by its various statutory mandates to establish data requirements that support its regulatory decisions. It is incumbent on the Agency to reevaluate those data requirements in light of scientific advances, analytical improvements, and new technology, in order to provide a sound scientific basis for those decisions. Accordingly, EPA sees no alternative to the overall need to update and revise its data requirements periodically. As it does so, however, each individual data requirement is evaluated against current scientific standards, value and cost, and undergoes an extensive review, including external and public participation, to assess the continued need for the data. The Agency also considers whether alternative regulatory methods, such as restrictions on use, would obviate the need for data, and explores means of introducing flexibility and clarity to reduce burdens on the regulated community.

Anticipated Cost and Benefits:

Although estimates may change before the proposal is published, the following estimates are based on the current draft Economic Analysis. Using the currently codified requirements as the baseline for the impact analysis, the total annual impact of the proposed revisions to the pesticide industry is estimated to be about $50 million. Of this estimated total annual impact, about $29 million per year represents new data requirements that were imposed over the years but were not specified in the existing CFR. As they have been applied to an increasing number of registrations, these data requirements have become more regularly required and will be proposed for codification. In addition, about $22 million represents the cost of the proposed modified or expanded existing data requirements for certain tests and use patterns, and about $2 million represents the cost of proposed new data requirements for data that have not yet been routinely sought. The benefits are difficult to quantify but were an important part of the Agency consideration in developing the proposal. The following parties are expected to benefit: consumers and the general public; farmers and other workers; registrants; animal welfare concerns; scientific, environmental and health communities; State and local governments; EPA and other Federal agencies; and governments outside the United states.

Risks:

The revisions to the data requirements to be proposed, like the existing requirements in part 158, would require an applicant for pesticide registration to supply the Agency with information on the pesticide: composition, toxicity, potential human exposure, environmental properties and ecological effects, and efficacy in certain cases. This information is used to assess the human health and environmental risks associated with the product. The data that would be required by this regulation in its current form, and as expected to be proposed, form the foundation of EPA's risk assessment for pesticides, and provide a sound scientific basis for any licensing decisions that impose requirements that mitigate or reduce risks, and that ensure that pesticide residues in food meet the ''reasonable certainty of no harm'' risk standard of the FFDCA.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN 2687.

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

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RIN: 2070–AC12

EPA

121. PESTICIDES; EMERGENCY EXEMPTION PROCESS REVISIONS

Priority:

Other Significant

Legal Authority:

7 USC 136p; 7 USC 136w

CFR Citation:

40 CFR 166

Legal Deadline:

None

Abstract:

EPA will publish a Notice of Proposed Rulemaking in the Federal Register proposing several improvements to the pesticide emergency exemption process under section 18 of the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA). Two of these potential improvements are currently being tested through a limited pilot, and are based on recommendations from the States which are the primary applicants for emergency exemptions. EPA has established regulations under section 18 of FIFRA which allow a Federal or State agency to apply for an emergency exemption to allow an unregistered use of a pesticide for a limited time when such use is necessary to alleviate an emergency condition. The proposed revisions would streamline the application and review process, thereby reducing the burden to applicants and EPA, while allowing for quicker emergency response without compromising existing protections for human health and the environment.

Statement of Need:

In 1996, stakeholders, including States and Federal agencies, identified a number of issues related to improving the emergency exemption process. States and Federal agencies are the only applicants for emergency exemptions. Representatives of States have recommended modifications to the current process for application, review and approval of emergency exemptions. If adopted, the changes would reduce unnecessary burden to both applicants and EPA, and expedite decisions on applications (which is critical in emergency situations).

Summary of Legal Basis:

FIFRA section 18 authorizes EPA to temporarily exempt States from the requirements of registration to alleviate an emergency condition.

Alternatives:

EPA has analyzed several measures for streamlining or improving the emergency exemption process, and has received considerable comment, both formally and informally, from stakeholders, including specific recommendations from a group representing States' interests. Since the modifications would generally constitute regulatory relief, and are not expected to cause any adverse economic impact, options with varying cost do not apply.

Anticipated Cost and Benefits:

EPA has assessed the potential economic impacts of the proposed improvements and found that they would reduce burdens and costs to States and Federal agencies that apply for emergency exemptions, as well as reduced burden to EPA. The Agency estimates an annual cost reduction of $820,000 for applicants and $120,000 for EPA, for a total of $940,000. Indirect benefits may accrue to users of pesticides under emergency exemptions if changes result in faster review and approval, or greater availability of pesticides.

Risks:

In general, the measures being considered are primarily intended to reduce burdens for States and EPA and achieve efficiencies in the program. No impact on risk is anticipated.

Timetable:

Action	Date	FR Cite
Notice: Limited Pilot	04/24/03	68 FR 20145
NPRM	09/03/04	69 FR 53866
NPRM Comment Period End	11/02/04	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4216, EDocket No. OPP-2004-0038;

Sectors Affected:

9241 Administration of Environmental Quality Programs

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RIN: 2070–AD36

EPA

122. ACCEPTABILITY OF RESEARCH USING HUMAN SUBJECTS

Priority:

Other Significant

Legal Authority:

5 USC 301; 7 USC 136a; 7 USC 136w; 15 USC 2603; 21 USC 346a; 42 USC 300v–1(b); 42 USC 7601; 33 USC 1361; 42 USC 9615; 42 USC 11048; 42 USC 6912; 42 USC 300j–9

CFR Citation:

40 CFR 26 (Revision)

Legal Deadline:

None

Abstract:

EPA is evaluating its current policy with respect to the protection of human research subjects in testing. Current EPA regulations in 40 CFR part 26 apply to research conducted or supported by the Agency or ''otherwise subject to regulation.'' No action has been taken yet to give effect to the ''otherwise subject to regulation'' phrase. In addition, EPA has received the advice of the National Academy of Sciences (NAS) on several issues surrounding the acceptability and interpretation of third party studies involving deliberate dosing of human subjects for the purpose of defining or quantifying toxic endpoints and public comment on an ANPRM. EPA will seek public comment on issues related to Agency use of human research data in its regulatory decisionmaking. EPA believes the process being initiated will serve two important Agency goals: ensuring the availability of sound and appropriate scientific data in its decisions, and protection of the interests, rights and safety of human research subjects. EPA may issue one or more documents, which may include policy statements, rulemaking or requests for public comment.

Statement of Need:

In July 1998, the Agency stated that it had not used any human study data for final decisions under the FQPA. The Agency subsequently convened a special joint subcommittee of the FIFRA Scientific Advisory Panel and the EPA Science Advisory Board to advise on this policy. The subcommittee completed its report in September 2000 without reaching consensus on many issues. In December 2001 the Agency sought the advice of the National Academy of Sciences on remaining scientific and ethical issues.

At the same time, the Agency clarified its interim policy, committing, subject to certain exceptions, not to consider or rely on any third party studies involving intentional dosing of human subjects with toxicants for the purpose of defining or quantifying their effects until a final policy is in place, and clarifying that this interim policy applies across all Agency programs. In May 2003 the Agency published an Advance Notice of Proposed Rulemaking on the subject of the acceptability of human studies, posing an array of questions in response to which many comments and suggestions were received. The ANPRM also restated the Agency's intention to issue proposed rules for comment. In June 2003, the U.S. Court of Appeals vacated the December 2001 interim policy on the ground that it constituted an improperly promulgated ''rule.'' The court further stated that as a consequence the Agency's ''previous practice of considering third party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide,'' was reinstated ''until it is replaced by a lawfully promulgated regulation.'' In February 2004, the NAS released their report, making many recommendations now under review by the Agency. Some of the Academy's recommendations could only be implemented through rulemaking.

Summary of Legal Basis:

Rulemaking concerning human studies is authorized under a variety of provision of the different environmental statutes EPA administers. With respect to pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136), a licensing statute, requires applicants for registration to provide a ''full description of tests made and the results thereof'' and further authorizes EPA to call in data to maintain a registration under FIFRA sec. 3(c)(2)(B). FIFRA sec. 25(a) provides general rulemaking authority to implement these data requirements, and also to interpret FIFRA sec. 12(a)(2)(P), which makes it unlawful to conduct tests using human subjects unless the subjects volunteer for such tests and are fully informed. Section 408(e) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348) authorizes the Administrator to issue regulations establishing general procedures and requirements. The Clean Air Act (42 U.S.C. 7601(a)) gives EPA general rulemaking authority. The Clean Water Act (33 U.S.C. 1361) authorizes the Administrator to promulgate regulations. The Comprehensive Environmental Response, Compensation, and Liability Act (42. U.S.C. 9615) authorizes the President to establish regulations to implement the statute, this authorizes being delegated to the Administrator under Executive Order 12580. The Emergency Planning and Community Right-to-Know Act (42. U.S.C. 11048) contains a general rulemaking authority. The Resource Conservation and Recovery Act (42 U.S.C. 6912) specifically authorizes the Administrator to prescribe regulations to carry out the functions under the Act. The Safe Drinking Water Act (42 U.S.C. 300j-9) authorizes the Administrator to prescribe regulations that are necessary and appropriate to carry out EPA's functions under the Act. In addition, EPA has broad authority under 5 U.S.C. 301 and 42 U.S.C. 300v-1(b).

Alternatives:

Still to be identified.

Anticipated Cost and Benefits:

No analysis has been performed yet.

Risks:

No analysis has been performed yet.

Timetable:

Action	Date	FR Cite
ANPRM	05/07/03	68 FR 24410
Notice	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4610, EDocket No. OPP-2003-0132;

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

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RIN: 2070–AD57

EPA

123. INCREASE METALS RECLAMATION FROM F006 WASTE STREAMS

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

Not Yet Determined

CFR Citation:

40 CFR 261

Legal Deadline:

None

Abstract:

Many metal finishers and other industrial sectors generate an electroplating sludge as part of their production process that is amenable to recycling, i.e., the sludge contains economically recoverable amounts of metals such as copper, nickel, zinc, etc. Currently, these sludges (F006) are listed hazardous wastes subject to RCRA regulations. Many generators continue to send these sludges for treatment and disposal when they could be recycled. Similarly, generators currently sending their sludges for recycling receive no economic benefit for this practice. Since the mid-1990s, EPA has been working with industry and the States to create incentives for safe recycling and has promulgated rules to foster this practice. However, EPA is interested in exploring whether further regulatory changes are warranted.

EPA is currently evaluating several options that would provide regulatory relief to generators and handlers of F006. All options would reduce regulatory costs to generators and handlers relative to the current RCRA subtitle C regulatory program.

Statement of Need:

F006 represents one of the largest hazardous waste streams amenable to recycling. Currently, there is no differentiation in regulatory requirements between the land disposal and recycling of F006 electroplating sludges. This effort seeks to evaluate different regulatory options that would eliminate existing disincentives to the safe recycling of F006 with the ultimate objective of possibly proposing changes to the existing regulatory framework. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006, and increasing natural resource conservation by reducing emissions from landfills and surface waters.

Summary of Legal Basis:

RCRA sections 2002, 3001-3004, 42 U.S.C. 6912, 6921-6924. No aspect of this action is required by statute or court order.

Alternatives:

Regulatory options being examined would affect generators and possibly other handlers of F006, i.e., consolidators, commercial hazardous waste recyclers and mineral processing facilities. EPA is also considering various options for the minimum amount of recoverable metals contained in F006 electroplating sludges.

Anticipated Cost and Benefits:

This rule is designed to provide regulatory relief to generators and possibly other handlers of F006. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006 and increasing natural resource conservation by reducing emissions from landfills and surface waters.

Risks:

Options being evaluated would ensure that the risks posed from recycling F006 would not increase. These include risks from storage and management of the materials throughout the recycling process, as well risks from any non-recyclable constituents included in the F006.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN No. 4651

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RIN: 2050–AE97

EPA

124. REGULATORY AMENDMENTS TO THE F019 HAZARDOUS WASTE LISTING TO EXCLUDE WASTEWATER TREATMENT SLUDGES FROM CHEMICAL CONVERSION COATING PROCESS (ZINC PHOSPHATING) OF AUTOMOBILE BODIES OF ALUMINUM

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1006 et seq

CFR Citation:

40 CFR 261.31; 40 CFR 302.4

Legal Deadline:

None

Abstract:

Automobile manufacturers are adding aluminum or aluminized components to automobiles to reduce the weight of vehicles to increase fuel economy. When aluminum components are added to the automobile assembly process, the current Federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a hazardous waste under the Resource Conservation and Recovery Act. EPA intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum.

Statement of Need:

This action when finalized will reduce the burden on the automobile industry from treating sludges from the process of zinc phosphating of aluminum as hazardous wastes. The applicable listed hazardous waste (F019) was listed as such because it contains cyanide and chromium. The sludges from the zinc phosphating of aluminum do not contain any of these constituents.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Additional Information:

SAN No. 4834;

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RIN: 2050–AG15

EPA

125. TOXICS RELEASE INVENTORY REPORTING BURDEN REDUCTION RULE

Priority:

Other Significant

Legal Authority:

42 USC 11023 et seq

CFR Citation:

40 CFR 372

Legal Deadline:

None

Abstract:

The primary goal of this effort by EPA is to reduce burdens associated with Toxics Release Inventory (TRI) reporting while at the same time continuing to provide valuable information to the public consistent with the goals and statutory requirements of the TRI program.

Statement of Need:

EPA is looking to explore various options with the intention of identifying a specific burden reduction initiative that effectively lessens the burden on facilities but at the same time ensures that TRI continues to provide communities with the same high level of significant chemical release and other waste management information.

Summary of Legal Basis:

Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1990.

Alternatives:

Still under analysis.

Anticipated Cost and Benefits:

Still under analysis.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4896;

URL For More Information:

www.epa.gov/tri

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RIN: 2025–AA14

EPA

FINAL RULE STAGE

126. CLEAN AIR VISIBILITY RULE

Priority:

Economically Significant

Legal Authority:

42 USC 7410; 42 USC 7414; 42 USC 7421; 42 USC 7470 to 7479; 42 USC 7491; 42 USC 7492; 42 USC 7601; 42 USC 7602

CFR Citation:

40 CFR 51.308(e)(1); 40 CFR 51 app Y (New)

Legal Deadline:

NPRM, Judicial, April 15, 2004, Consent Decree: April 15, 2004.

Final, Judicial, April 15, 2005, Consent Decree: April 15, 2005.

Abstract:

To meet the Clean Air Act's requirements, EPA published the regional haze rule on July 1, 1999 (64 FR 35714). On May 24, 2002, the DC Circuit vacated certain provisions of the regional haze rule related to best available retrofit technology (BART). Because of this court decision, we need to propose and publish revised BART provisions in the regional haze rule. The purpose of this effort is to provide the appropriate changes to the BART requirements and guidelines, and to address additional issues related to reasonable progress goals for the visibility program. On July 20, 2001, we proposed guidelines intended to add further clarifications to the BART requirements in the regional haze rule. Since then, due to additional information that has come to light since that proposal, we have decided that a supplemental proposal is needed. The supplemental proposal was published on May 5, 2004.

Statement of Need:

This action is needed in response to the May 2002 ruling of the U.S. Court of Appeals for the D.C. Circuit (American Corn Growers et al. V. EPA,, 291 F.3d 1) vacating the Best Available Retrofit Technology (BART) provisions of the regional haze rule. The Clean Air Act requires that States to include BART in their visibility State Implementation Plans (SIPs). The Clean Air Act also requires that a State take steps to prevent emissions from sources located within its boundaries from interfering with a downwind State's ability to meet air quality standards, or interfering with measures to protect visibility.

Summary of Legal Basis:

Clean Air Act section 169A requires States to include BART in their visibility SIPs. Clean Air Act section 110(a)(2)(D) (42 USC 7410(a)(2)(D)) requires that each state's implementation plan include the ''good neighbor'' provisions of prohibiting sources in the State from emitting air pollutants in amounts that contribute significantly to nonattainment in a downwind state, or interfere with measures to protect visibility in a Class I areas. Section 110(a)(1) (42 USC 7410(a)(1)) requires States to submit implementation plans within a specified period of time after the promulgation of a new or revised national ambient air quality standard. In addition, EPA has authority under section 110(k)(5) (42 USC 7410(k)(5)) to require States to revise existing implementation plans whenever EPA finds that those plans are inadequate to comply with any requirement. Further, section 301(a)(1) (42 USC 7601(a)(1)) confers general authority upon the EPA Administrator. These provisions of the Clean Air Act confer authority on EPA to promulgate the present regulations.

Alternatives:

This entry comprises the action the Agency plans to take to implement the

BART provisions of the Clean Air Act. The major alternatives facing the Agency include: (1) How to structure the process for exempting individual emission sources from BART that is mandated by the court ruling, and (2) whether to include prescriptive control levels for visibility-impairing pollution from large electric generating units, and what control levels to prescribe.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis (RIA) for the proposed BART rule. Updated cost and benefit calculations will be made as development of the RIA proceeds for the final rulemaking.

Risks:

The risks addressed are the health and welfare impacts resulting from emissions that interfere with measures to protect visibility in Class I areas. These effects were outlined in detail in the Regulatory Impact Analysis for the proposed BART rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	07/20/01	66 FR 38108
Supplemental NPRM	05/05/04	69 FR 25184
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 4450;

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RIN: 2060–AJ31

EPA

127. CLEAN AIR MERCURY RULE—ELECTRIC UTILITY STEAM GENERATING UNITS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

42 USC 7412; 42 USC 7411

CFR Citation:

40 CFR 63; 40 CFR 60

Legal Deadline:

NPRM, Judicial, December 15, 2003.

Final, Judicial, March 15, 2005.

Abstract:

On January 30, 2004, the EPA proposed alternative approaches to regulating mercury emissions from coal-fired electric utility steam generating units and nickel emissions from oil-fired electric utility steam generating units.

Statement of Need:

Oil and coal-fired electric utility steam generating units were added (December 20, 2000) to the list of source categories to be regulated under section 112 of the Clean Air Act, as amended. On January 30, 2004, EPA proposed to remove oil- and coal-fired electric utility steam generating units from the list so that they could be regulated under section 111 of the Clean Air Act.

Summary of Legal Basis:

Sections 111 and 112 of the Clean Air Act, as amended.

Alternatives:

Alternative approaches to regulating electric utility steam generating units were proposed on January 30, 2004.

Anticipated Cost and Benefits:

It is anticipated that this rule will result in significant costs to the affected industry, including Federal, State, and local entities that own/operate electric utility steam generating units. These costs will be identified as the final rule is developed.

Risks:

Risk information will become available as the final rule is developed.

Timetable:

Action	Date	FR Cite
NPRM	01/30/04	69 FR 4754
Supplemental NPRM	03/16/04	69 FR 12298
Notice of Reopening Comment Period	05/05/04	69 FR 25052
NODA	11/00/04	
Final Action	03/15/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4571, EDocket No. OAR-2002-0056;

Sectors Affected:

221112 Fossil Fuel Electric Power Generation

URL For More Information:

www.epa.gov/ttn/atw/utility/utiltoxpg.html

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RIN: 2060–AJ65

EPA

128. CLEAN AIR OZONE IMPLEMENTATION RULE (PART 1 AND PART 2)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 7408; 42 USC 7410; 42 USC 7501 to 7511f; 42 USC 7601(a)(1)

CFR Citation:

40 CFR 51; 40 CFR 50; 40 CFR 81

Legal Deadline:

None

Abstract:

This rule would provide specific requirements for State and local air pollution control agencies and Tribes to prepare State Implementation Plans (SIPs) and Tribal Implementation Plans (TIPs) under the 8-hour national ambient air quality standard (NAAQS) for ozone, published by EPA on July 18, 1997. The Clean Air Act (CAA) requires EPA to set ambient air quality standards and requires States to submit SIPs to implement those standards. The 1997 standards were challenged in court, but in February 2001, the Supreme Court determined that EPA has authority to implement a revised ozone standard, but ruled that EPA must reconsider its implementation plan for moving from the 1-hour standard to the revised standard. The Supreme Court identified conflicts between different parts of the CAA related to implementation of a revised NAAQS, provided some direction to EPA for resolving the conflicts, and left it to EPA to develop a reasonable approach for implementation. Thus, this rulemaking must address the requirements of the CAA and the Supreme Court's ruling. This rule would provide detailed provisions to address the CAA requirements for SIPs and TIPs and would thus affect States and tribes. States with areas that are not attaining the 8-hour ozone NAAQS will have to develop—as part of their SIPs—emission limits and other requirements to attain the NAAQS within the timeframes set forth in the CAA. Tribal lands that are not attaining the 8-hour ozone standard may be affected, and could voluntarily submit a TIP, but would not be required to submit a TIP. In cases where a TIP is not submitted, EPA would have the responsibility for planning in those areas.

Statement of Need:

This action is needed in response to the U.S. Supreme Court's ruling in February 2001 (Whitman v. American Trucking Assoc., 121 S.Ct.903) that stated that EPA has the authority to implement a revised ozone NAAQS but that EPA could not ignore the provisions of subpart 2 when implementing the 8-hour NAAQS. The Supreme Court identified several portions of subpart 2 that are ill-fitted to the revised NAAQS but left it to EPA to develop a reasonable implementation approach. Consequently, EPA is developing a rule to implement the 8-hour ozone NAAQS under the provisions of subpart 2 of the CAA.

Summary of Legal Basis:

Title I of the Clean Air Act

Alternatives:

This entry comprises the action the Agency plans to take to implement the 8-hour ozone NAAQS. The major alternatives facing the Agency is whether the 8-hour O3 NAAQS should be implemented under the less prescriptive part of the Clean Air Act (title I, part D, subpart 1) or the more prescriptive part of the Act (subpart 2). Another major set of alternatives concern the kind of transition EPA should make from implementation of the current 1-hour ozone standard to the new 8-hr ozone standard.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis for the final ozone NAAQS, and has prepared a cost analysis for the proposed implementation rule. The benefits of the rule are those associated with attainment of the ozone NAAQS including significant improvements in premature mortality, chronic asthma, chronic and acute bronchitis, upper and lower respiratory symptoms, work days lost, decreased worker productivity, visibility in urban and suburban areas, and increases in yields of commercial forests currently exposed to elevated ozone levels.

Risks:

The risks addressed by this action are the likelihood of experiencing increased health and environmental effects associated with nonattainment of the National Ambient Air Quality Standard for ozone. These effects are briefly described above in the ''costs and benefits'' section, and they were outlined in detail in the Regulatory Impact Analysis for the ozone NAAQS rulemaking. The results are summarized in the Federal Register notice for that rulemaking (62 FR 38856, July 18, 1997).

Timetable:

Action	Date	FR Cite
NPRM	06/02/03	68 FR 32802
Final Action (Phase 1)	04/30/04	69 FR 23951
Final Action (Phase 2)	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State, Tribal

Additional Information:

SAN No. 4625;

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RIN: 2060–AJ99

EPA

129. ● NONATTAINMENT MAJOR NEW SOURCE REVIEW (NSR)

Priority:

Other Significant

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 51, app S

Legal Deadline:

None

Abstract:

This final action will promulgate changes to regulations that govern NSR permitting of major stationary sources in nonattainment areas where there is no approved SIP. Appendix S of 40 CFR part 51 contains the permitting program for major stationary sources in nonattainment areas in transition periods before approval of a SIP to implement part D of title I. This final action will revise appendix S to conform it to the changes made to regulations at 40 CFR 51.165 for SIP programs for nonattainment major NSR. (67 FR 80816; December 31, 2002)

Statement of Need:

In August 1992, EPA voluntarily initiated a comprehensive effort to reform the NSR process. This effort was

initiated to examine complaints from the regulated community that the current regulatory scheme is too complex, needlessly delays projects, and unduly restricts source flexibility. Currently there are no applicable statutory or judicial deadlines for the NSR reform rulemaking effort. The goal of this effort is to address industry's concerns without sacrificing the environmental benefits embodied in the present approach; that is, protecting and improving local air quality, and stimulating pollution prevention and advances in control technologies. In July 1993, the NSR Reform Subcommittee of the CAA Advisory Committee was formed. The Subcommittee's purpose is to provide independent advice and counsel to EPA on policy and technical issues associated with reforming the NSR rules. The Subcommittee was composed of representatives from industry, State/local air pollution control agencies, environmental organizations, EPA headquarters and regions, and other Federal agencies (National Park Service and Forest Service, Department of Energy, and the Office of Management and Budget).

Summary of Legal Basis:

Clean Air Act sections 165 and 173.

Alternatives:

The Subcommittee discussed numerous options for implementing NSR reform. However, EPA's primary focus has been to consider the specific recommendations developed by the Subcommittee and, where appropriate, use them in this rulemaking effort. In January 1996, EPA, as part of another regulatory streamlining measure, merged portions of a separate rulemaking to implement the 1990 CAA Amendments with the Reform effort. The combined package was proposed in the Federal Register on July 23, 1996. On July 24, 1998, EPA issued another Federal Register Notice seeking comment on two applicability provisions. On February 2-3, 1999, EPA convened a public meeting to listen to new stakeholder proposals for streamlining NSR applicability and control technology requirements. Stakeholder groups submitted written proposals during May and June 1999.

Anticipated Cost and Benefits:

From a cost perspective, the proposed rulemaking represents a decrease in applications and recordkeeping costs to industry of at least $13 million per year, as compared to the preexisting program, based primarily on the fact that fewer sources will need to apply for major source permits. In addition, the cost to State and local agencies will be reduced by approximately $1.4 million per year. The Federal Government should realize a savings of approximately $116,000 per year. Additional cost reductions, which are difficult to quantify, will be realized due to the streamlining effect of the rulemaking on the permitting process, for example, the opportunity costs for shorter time periods between permit application and project completion and reduced uncertainty in planning for future source growth.

Risks:

This is a procedural rule applicable to a wide variety of source categories. Moreover, it applies to criteria pollutants for which NAAQS have been established. This action is considered environmentally neutral. However, any potential risks are considered in the NAAQS rulemaking from a national perspective.

Timetable:

Action	Date	FR Cite
Final Action	11/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State

Additional Information:

SAN No. 3259.2; Split from RIN 2060-AE11. See also SAN 4390

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RIN: 2060–AM59

EPA

130. TEST RULE; TESTING OF CERTAIN HIGH PRODUCTION VOLUME (HPV) CHEMICALS

Priority:

Other Significant

Legal Authority:

15 USC 2603; 15 USC 2611 to 2612; 15 USC 2625 to 2626

CFR Citation:

40 CFR 790 to 799

Legal Deadline:

None

Abstract:

EPA is proposing test rules under section 4(a) of the Toxic Substances Control Act (TSCA) to require testing and recordkeeping requirements for certain high production volume (HPV) chemicals (i.e., chemicals which are manufactured (including imported) in the aggregate at more than 1 million pounds on an annual basis) that have not been sponsored under the voluntary HPV Challenge Program. Although varied based on specific data needs for the particular chemical, the data generally collected under these rules may include: Acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate. The first rule proposed testing for 37 HPV chemicals with substantial worker exposure. The number of chemicals included in the first final rule may be reduced based on new information on annual production volumes, worker exposure, and commitments to the voluntary HPV Challenge Program. Subsequent test rules will require similar screening level testing for other unsponsored HPV Challenge Program chemicals.

Statement of Need:

EPA has found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million pounds per year based on 1990 reporting for EPA's Inventory Update Rule (IUR), only 7 percent have a full set of publicly available internationally recognized basic health and environmental fate/effects screening test data. Of the over 2,800 HPV chemicals based on 1990 data, 43 percent have no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data are available. This lack of available hazard data compromises EPA's and others' ability to determine

whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's right to know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy. It is EPA's intent to close this knowledge gap. EPA believes that for most of the HPV chemicals, insufficient data are readily available to reasonably determine or predict the effects on health or the environment from the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that a program to collect and, where needed, develop basic screening level toxicity data is necessary and appropriate to provide information in order to assess the potential hazards/risks that may be posed by exposure to HPV chemicals. On April 21, 1998, a national initiative, known as the Chemical Right-To-Know Initiative, was announced in order to empower citizens with knowledge about the most widespread chemicals in commerce—chemicals that people may be exposed to in the places where they live, work, study, and play. A primary component of EPA's Chemical Right-To-Know (ChemRTK) initiative is the voluntary HPV Challenge Program, which was created in cooperation with industry, environmental groups, and other interested parties, and is designed to assemble basic screening level test data on the potential hazards of HPV chemicals while avoiding unnecessary or duplicative testing. Data needs which remain unmet in the voluntary HPV Challenge Program may be addressed through the international efforts or rulemaking.

Summary of Legal Basis:

These test rules will be issued under section 4(a)(1)(B) of TSCA. Section 2(b)(1) of TSCA states that it is the policy of the United States that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture (which is defined by statute to include import) and those who process such chemical substances and mixtures(.)'' To implement this policy, TSCA section 4(a) mandates that EPA require by rule that manufacturers and processors of chemical substances and mixtures conduct testing if the Administrator finds that: (1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment, (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture, (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necesssary to develop such data.

Alternatives:

The strategy and overall approach that EPA is using to address data collection needs for U.S. HPV chemicals includes a voluntary component (the HPV Challenge Program), certain international efforts, and these rulemakings under TSCA. The issuance of a rulemaking is often the Agency's final mechanism for obtaining this important information.

Anticipated Cost and Benefits:

The potential benefits of these test rules are substantial, as no one—whether in industry, government, or the public—can make reasoned risk management decisions in the absence of reliable health and environmental information. The cost of the baseline screening testing that would be imposed is estimated to be about $200,000 per chemical for a full set of tests. It is unlikely, however, for a chemical to need a full set of tests, which would only occur if none of the data in question already exists.

Risks:

Data collected and/or developed under these test rules, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action.

Timetable:

Action	Date	FR Cite
NPRM	12/26/00	65 FR 81658
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN 3990. See also the Regulatory Plan entry entitled Chemical Right-to-Know Initiative (RIN 2070-AD25; SAN 4176).

Sectors Affected:

325 Chemical Manufacturing; 32411 Petroleum Refineries

URL For More Information:

www.epa.gov/opptintr/chemtest/sect4rule.htm

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RIN: 2070–AD16

EPA

131. NESHAPS: STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR HAZARDOUS WASTE COMBUSTORS (PHASE I FINAL REPLACEMENT STANDARDS AND PHASE II)

Priority:

Other Significant

Legal Authority:

42 USC 6924 RCRA 3004; 42 USC 6925 RCRA 3005; 42 USC 7412 CAA 112; 42 USC 7414 CAA 114

CFR Citation:

40 CFR 63; 40 CFR 264; 40 CFR 265; 40 CFR 266; 40 CFR 270

Legal Deadline:

NPRM, Judicial, March 31, 2004, Consent decree for Phase 2 portion of rule.

Final, Judicial, June 14, 2005, Consent decree.

Abstract:

On September 30, 1999, EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn hazardous waste (referred to as the Phase I Rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the Phase I rule. On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow them time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 14, 2005. EPA will ultimately finalize the Phase I replacement standards. Also, EPA is developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as Phase II Sources because the standards were originally scheduled to be promulgated after Phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the Phase II sources by the same date as those for Phase I (June 14, 2005). EPA has developed options for calculating the emission standards that are considered to be consistent with both the statutory requirements and the opinion of the Court. EPA has proposed emission standards and compliance provisions for both the Phase I and Phase II sources.

Statement of Need:

Section 112 of the Clean Air Act requires that the EPA promulgate regulations requiring the control of hazardous air pollutants from major and certain area sources. The control of hazardous air pollutants is achieved through promulgation of emission standards under sections 112(d) and (f) and, in appropriate circumstances, work practice standards under section 112(h).

On September 30, 1999 EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn hazardous waste (referred to as the Phase I Rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the Phase I rule.

Summary of Legal Basis:

On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 14, 2005. EPA is working towards promulgation by this date. EPA is also developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as Phase II Sources because the standards were originally scheduled to be promulgated after Phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the Phase II sources by the same date as those for Phase I (June 14, 2005).

Alternatives:

EPA has developed several options for calculating the emission standards and has included these options in the April 20, 2004 proposal.

Anticipated Cost and Benefits:

Estimated costs and benefits for the proposed standards are summarized in the April 20, 2004 proposal.

Risks:

For the 1999 rule, we estimated the avoided incidence of mortality and morbidity associated with reductions in particulate matter (PM) emissions. Estimates of cases of mortality and morbidity avoided were made for children and the elderly, as well as the general population, using concentration-response functions derived from human epidemiological studies. Morbidity effects included respiratory and cardiovascular illnesses requiring hospitalization, as well as other illnesses not requiring hospitalization, such as acute and chronic bronchitis and acute upper and lower respiratory symptoms. For this rule, we are comparing characteristics of the sources covered by the 1999 rule to the sources covered by the replacement rule that are related to risk. These characteristics include emissions, stack characteristics, meteorology, and population. Based on the results of the statistical comparisons, we will infer whether the risks will be about the same, less than, or greater than the 1999 rule. Risk inferences for boilers and HCl production furnaces will be based on comparisons with incinerators for the 1999 rule. The risk estimates for the proposed standards are summarized in the April 20, 2004 proposal.

Timetable:

Action	Date	FR Cite
NPRM–CK	04/19/96	61 FR 17358
Final–Fasttrack	06/19/98	63 FR 33782
Final–CK	09/30/99	64 FR 52828
NODA	07/27/00	65 FR 39581
DF 1	07/03/01	66 FR 35087
NPRM–Phase1	07/03/01	66 FR 35126
Parallel Proposal	07/03/01	66 FR 35124
Direct Final Action	10/15/01	66 FR 52361
Final Compliance Exten.	12/06/01	66 FR 63313
Interim Final Action	02/13/02	67 FR 6792
Final HAP	02/14/02	67 FR 6968
NPRM–Phases 1&2	04/20/04	69 FR 21197
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN No. 3333, EDocket No. OAR-2004-0022; For information on the Phase I portion of this effort, see SAN 4418, RIN 2050-AE79.

Sectors Affected:

3335 -; 3343 Audio and Video Equipment Manufacturing; 3251 Basic Chemical Manufacturing; 3273 Cement and Concrete Product Manufacturing; 3271 Clay Product and Refractory Manufacturing; 3328 Coating, Engraving, Heat Treating and Allied

Activities; 3342 Communications Equipment Manufacturing; 3341 Computer and Peripheral Equipment Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 45431 Fuel Dealers; 3332 Industrial Machinery Manufacturing; 3274 Lime, Gypsum and Gypsum Product Manufacturing; 3327 Machine Shops, Turned Product, and Screw, Nut and Bolt Manufacturing; 3362 Motor Vehicle Body and Trailer Manufacturing; 3361 Motor Vehicle Manufacturing; 3363 Motor Vehicle Parts Manufacturing; 2123 Non-Metallic Mineral Mining and Quarrying; 3259 Other Chemical Product Manufacturing; 3329 Other Fabricated Metal Product Manufacturing; 3339 Other General Purpose Machinery Manufacturing; 3279 Other Nonmetallic Mineral Product Manufacturing; 3255 Paint, Coating, Adhesive, and Sealant Manufacturing; 3253 Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing; 3241 Petroleum and Coal Products Manufacturing; 4227 Petroleum and Petroleum Products Wholesalers; 3254 Pharmaceutical and Medicine Manufacturing; 3231 Printing and Related Support Activities; 5629 Remediation and Other Waste Management Services; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing; 3344 Semiconductor and Other Electronic Component Manufacturing; 22132 Sewage Treatment Facilities; 5622 Waste Treatment and Disposal

URL For More Information:

www.epa.gov/hwcmact/

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RIN: 2050–AE01

EPA

132. HAZARDOUS WASTE MANIFEST REGULATION

Priority:

Other Significant

Legal Authority:

42 USC 6922 RCRA 3002; 42 USC 6923 RCRA 3003; 42 USC 6924 RCRA 3004; 42 USC 6926 RCRA 3006; PL 105–277; Government Paperwork Elimination Act 17

CFR Citation:

40 CFR 260; 40 CFR 262; 40 CFR 263; 40 CFR 264; 40 CFR 265; 40 CFR 271

Legal Deadline:

None

Abstract:

The Uniform Hazardous Waste Manifest (Form 8700-22) is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of hazardous waste during its transportation. Waste handlers (e.g., generators and transporters) are required to use the manifest, and States may not require a different manifest in its place. However, the manifest has State blocks which allow States, at their option, to require the entry of additional specific information to serve their State's regulatory needs. Under the current regulations more than 20 states print the manifest form in accordance with the format specified in Federal regulations. However, the variability among State manifest programs associated with State optional blocks, different copy distribution schemes, and the manifest hierarchical acquisition scheme has drawn complaints from the regulated community. Variability among States' manifest programs and the manifest system's current reliance on paper result in significant paperwork and cost burden to waste handlers and States who choose to collect manifest information. The Agency intends to standardize further the manifest form elements, and to specify one format for the manifests that may be used in all States. In addition, the Agency intends to announce standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes. Finally, the Agency intends to pursue an optional approach that would use information technologies to conduct the manifest process electronically, thereby reducing paperwork burden, and improving the speed and accuracy of preparing, transmitting, and recordkeeping the manifest form. However, the Agency will bifurcate the manifest rule so that the form revisions may be expedited, while additional analysis on the e-manifest continues.

Statement of Need:

Since the adoption of the Uniform Manifest by EPA and the Department of Transportation (DOT) in 1984, the regulated community and authorized States have pressed EPA to adopt changes that would simplify and further reduce the variability among the hazardous waste manifest forms required and distributed by the States. In addition, the recent focus on electronic government has highlighted the potential advantages of an electronic manifest system in terms of reduced paperwork burdens and more timely waste tracking. This action responds to these needs with a truly universal set of manifest data elements and a manifest format that will be identical in all States, as well as standards that will allow the manifest data to be completed, signed, transmitted, and recorded electronically.

Summary of Legal Basis:

EPA's regulations implementing the manifest are based on section 3002(a)(5) of the RCRA statute, which requires that EPA include in its hazardous waste generator regulations requirements addressing the ''use of a manifest system and ony other reasonable means necessary'' to assure that all such hazardous waste is designated for and arrives at treatment, storage, or disposal facilities that have been permitted under RCRA subtitle C requirements. Secion 3003(a)(3) of the Act requires transporters of hazardous waste to comply with the manifest system, while section 3004(a)(2) requires compliance with the manifest system by treatment, storage, and disposal facilities. Moreover, according to section 1004(12) of the Act, the manifest is defined as the ''form used for identifying the quantity, composition, and the origin, routing, and destination of hazardous waste during its transportation from the point of generation to the point of disposal, treatment, or storage.'' The manifest also serves as the ''shipping paper'' meeting DOT requirements for the transportation of hazardous materials under the Federal Hazardous Materials laws and regulations.

EPA's current manifest regulations require generators to obtain manifest forms from the authorized States. The generator must complete the paper form by identifying the type and quantity of

hazardous waste in off-site shipments, as well as the identities of the transporters and waste receiving facilities that will manage the waste. The regulations require waste handlers to sign the manifest form by hand when they receive a waste shipment, and to retain copies of the signed manifests that document the chain of custody of a shipment, and any discrepancies.

EPA and DOT have authority to eliminate variability among State manifests, since DOT's hazardous materials laws generally call for uniformity in the use of hazardous materials shipping papers such as the manifest, and EPA must regulate transportation consistently with DOT. EPA and DOT consented in 1984 to the inclusion of several ''optional'' data fields, but our experience with the manifest system has demonstrated that the inclusion of optional fields introduces excessive variability and burden for waste handlers. EPA also has authority to automate the waste tracking functions of the manifest, since the Act states that EPA can employ any reasonable means necessary to track waste shipments under a manifest system. There is nothing in the statute that precludes EPA from establishing standards allowing electronic manifesting of shipments, as well as use of the traditional paper forms.

Alternatives:

The form revisions part of the rulemaking examines alternatives to the current system that allows authorized States to print and distribute slightly varying manifest forms (typically for a fee) to waste handlers generating or shipping waste in a particular State. This rule would establish a precise Federal specification for the manifest that would preclude variability in manifest forms, wherever they are used. This option was proposed in May 2001, and was supported by the great preponderance of commenters who submitted written comments to the docket.

The rule also examines alternative electronic formats for completing electronic manifests, and alternative methods for signing manifests electronically. Moreover, EPA has been examining in response to comments whether electronic manifest systems should be developed in a decentralized fashion by private companies in adherence with standards announced by EPA (the proposed approach), or developed and hosted centrally in a national system. We expect that additional stakeholder outreach will be necessary to determine the appropriate design and functionality of the e-manifest approach for the final rule. Therefore, the e-manifest part of the rulemaking has been separated from the form revisions part of the rule, so that final action on the form revisions will not be delayed by future outreach and analysis conducted in connection with the e-manifest.

Anticipated Cost and Benefits:

The baseline manifest system results in annual paperwork burdens of 4.6 million hours and annual costs of about $193 million. In developing the May 2001, proposed rule, EPA estimated that the proposed revisions to the hazardous waste manifest system (form changes and electronic manifest) would reduce the paperwork burdens imposed by the manifest by 765,000 to 1.24 million hours annually, and would reduce annual costs by $24 to $37 million. The rule should also eliminate much of the complexity that arises from having to obtain and comply with States' slightly varying manifest forms, and the burden and complexity of having to supply information to satisfy the current so-called ''optional'' State fields. The ability to complete and transmit manifest data electronically should improve the accuracy of manifest data, and the timeliness and effectiveness of waste shipment tracking.

Risks:

This rule addresses only administrative requirements for tracking waste shipments. The rule does not address risks posed by particular substances or waste management activities, and no risk assessments have been prepared to support this action.

Timetable:

Action	Date	FR Cite
NPRM	05/22/01	66 FR 28240
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 3147, EDocket No. RCRA-2001-0032; Because of significant issues identified during the public comment period on the electronic manifest part of the rule, this part of the rule has been separated from the form revisions part of the rule for purposes of publishing a final action. The form revisions part of the rule will be finalized first.

Sectors Affected:

325 Chemical Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 332 Fabricated Metal Product Manufacturing; 2122 Metal Ore Mining; 2111 Oil and Gas Extraction; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 3221 Pulp, Paper, and Paperboard Mills; 482 Rail Transportation; 484 Truck Transportation; 5621 Waste Collection; 5622 Waste Treatment and Disposal; 483 Water Transportation

URL For More Information:

http://www.epa.gov/epaoswer/hazwaste/gener/manifest/index.htm

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RIN: 2050–AE21

EPA

133. STANDARDIZED PERMIT FOR RCRA HAZARDOUS WASTE MANAGEMENT FACILITIES

Priority:

Other Significant

Legal Authority:

42 USC 6905; 42 USC 6912; 42 USC 6924; 42 USC 6925; 42 USC 6927; 42 USC 6974

CFR Citation:

40 CFR 124; 40 CFR 267; 40 CFR 270

Legal Deadline:

None

Abstract:

EPA has proposed creating a new type of general permit, called a standardized permit, for facilities that generate waste and routinely manage the waste on-site in tanks, containers, and containment buildings. Under the standardized permit, facility owners and operators would certify compliance with generic design and operating conditions set on a national basis. The permitting agency would review the certifications submitted by the facility owners and operators. The permitting agency would also be able to impose additional site-specific terms and conditions for corrective action or other purposes, as called for by RCRA. Ensuring compliance with the standardized permit's terms and conditions would occur during inspection of the facility after the permit has been issued. The standardized permit should streamline the permit process by allowing facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process. EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately $100 to $5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. The proposal raised issues for public comment on how all facilities receiving RCRA permits can satisfy RCRA corrective action requirements under appropriate alternative State cleanup programs and on financial assurance issues. The Agency is developing a final rule addressing this topic.

Statement of Need:

The Agency convened a special task force in 1994 to look at permitting activities throughout its different programs and to make specific recommendations to improve these permitting programs. This task force, known as the Permits Improvement Team (PIT), spent two years working with stakeholders from the Agency, State permitting agencies, industry, and the environmental community. The PIT stakeholders mentioned, among other things, that permitting activities should be commensurate with the complexity of the activity. The stakeholders felt that current Agency permitting programs were not flexible enough to allow streamlined procedures for routine permitting activities. Currently, facilities that store, treat, or dispose of hazardous waste must obtain site-specific ''individual'' permits prescribing conditions for each ''unit'' (e.g., tank, container area, etc.) in which hazardous waste is managed. Experience gained by the Agency and States over the past 15 years has shown that not all the waste management activities are at the same level of complexity. Some activities, such as thermal treatment or land disposal of hazardous wastes, are more complex than storage of hazardous waste. The Agency believes that thermal treatment and land disposal activities continue to warrant ''individual'' permits, prescribing unit-specific conditions. However, the Agency believes that some accommodation can be made for hazardous waste management practices in standardized units such as tanks, container storage areas, and containment buildings. In April 1996, the PIT tentatively recommended, among other things, that regulations be developed to allow ''standardized permits'' for on-site storage and non-thermal treatment of hazardous waste in tanks, containers, and containment buildings. On October 12, 2001, the Agency proposed revising the RCRA regulations to allow for this type of permit, and is preparing to finalize the rule.

Summary of Legal Basis:

Facilities that manage hazardous waste are required under RCRA to obtain a permit and carry out corrective action as necessary (see: RCRA sections 3004, 3005, 3008, and 3010). EPA has discretion under these statutory provisions to apply different permitting procedures to different types of facilities. No aspect of this streamlining action is required by court order.

Alternatives:

EPA considered several options regarding RCRA permits and corrective action alternatives. The Agency proposed to limit the scope of the rule to facilities that generate waste and manage it on-site, but asked for comment on whether to expand that scope to facilities that manage wastes generated off-site. The Agency also asked for comment on the option of allowing a facility's RCRA corrective action activities to be postponed if corrective action is being carried out under an approved State remedial program.

Anticipated Cost and Benefits:

The RCRA standardized permit is an optional rule designed to streamline the regulatory burden to EPA/States, as well as to private sector facilities covered by the rule, by reducing the amount of information collected, submitted, and reviewed for RCRA hazardous waste permit actions (i.e., new permit applications, permit modifications, and permit renewals). Because the rule proposed to streamline existing RCRA regulation, rather than add new RCRA regulation, implementation of the rule by the EPA and by States with EPA-authorized permitting programs is expected to result in economic benefits in the form of national cost savings from reducing both government and private sector resources required for the RCRA permit process. The national workload level of RCRA permit actions involving on-site hazardous waste storage and non-thermal treatment units has averaged 92 permit determinations per year over the 10-year period 1990-1999. Relative to this average annual workload, EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately $100 to $5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. On a national basis, the rule is expected to generate a minimum of $0.36 to $0.53 million in average annual paperwork cost savings, based on the scope of the proposed rule, which was limited to on-site waste management facilities. However, the final rule may expand the initial scope of eligible facilities, which could easily double or triple the national cost savings benefits (i.e., $1.1 to $1.6 million per year in cost savings).

Risks:

The purpose of this rule is to streamline existing RCRA permit application and issuance procedures to achieve national paperwork burden reduction. Because of the facts that facilities covered by this rule: (a) Are currently already required to obtain RCRA permits, and (b) are relatively simple to design, install/construct, operate, and clean-close, this rule is expected to have minimal incremental effects on existing levels of human health and environmental risk for these types of hazardous waste management facilities.

Timetable:

Action	Date	FR Cite
NPRM	10/12/01	66 FR 52192
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4028;

Sectors Affected:

3251 Basic Chemical Manufacturing; 332813 Electroplating, Plating, Polishing, Anodizing and Coloring; 32551 Paint and Coating Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32411 Petroleum Refineries; 325211 Plastics Material and Resin Manufacturing; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing

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RIN: 2050–AE44

EPA

134. RCRA BURDEN REDUCTION INITIATIVE

Priority:

Other Significant

Legal Authority:

42 USC 6907; 42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925; 42 USC 6926; 42 USC 6927; 42 USC 6930; 42 USC 6934; 42 USC 6935; 42 USC 6937; 42 USC 6938; 42 USC 6939; 42 USC 6944; 42 USC 6949(a); 42 USC 6974; PL 104–13

CFR Citation:

40 CFR 261.38; 40 CFR 264.16; 40 CFR 264.52; 40 CFR 264.56; 40 CFR 264.73; 40 CFR 264.98 et seq; 40 CFR 265.16; 40 CFR 265.52; 40 CFR 265.56; 40 CFR 265.73; 40 CFR 265.98 et seq; 40 CFR 266.103; 40 CFR 261.4; 40 CFR 268.7; 40 CFR 268.9

Legal Deadline:

None

Abstract:

EPA plans to reduce the burden imposed by the RCRA reporting and recordkeeping requirements to help meet the Federal Governmentwide goal established by the Paperwork Reduction Act (PRA).

In June 1999, EPA published a Notice of Data Availability (NODA) in the Federal Register (64 FR 32859) to seek comment on a number of burden reduction ideas to eliminate duplicative and nonessential paperwork. After reviewing the comments received on the NODA, EPA proposed (67 FR 2518, 1/17/02) to implement many of these ideas. EPA issued a notice (68 FR 61662; 10/29/03) seeking further input on a number of changes we proposed. EPA plans to finalize this burden reduction effort.

Statement of Need:

The Paperwork Reduction Act of 1995 establishes a Federal Governmentwide goal to reduce the paperwork and reporting burden it imposes. The RCRA Burden Reduction Initiative Proposed Rulemaking makes the regulatory changes necessary to meet this goal.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

Reducing recordkeeping and reporting will require changes in our regulations. There was no alternative to doing a rulemaking. The Agency sought opinions from the regulated community on various burden reduction possibilities.

Anticipated Cost and Benefits:

Our cost-benefit analysis showed a savings of $120 million and 929,000 hours for the final rule. The rule will have minimal impact on the protectiveness of the RCRA regulations. It will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations.

Risks:

The rule will have no risk impacts.

Timetable:

Action	Date	FR Cite
NODA 1	06/18/99	64 FR 32859
NPRM	01/17/02	67 FR 2518
NODA 2	10/29/03	68 FR 61662
Final Action	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4084; Applicable SIC codes: Chemicals and Allied Products (28), Primary Metal Industries (33), Fabricated Metals (34), Industrial Machinery and Equipment (35), Electrical Equipment (36), Transportation Equipment (37), Other Manufacturing, Transportation and Utilities (40-49), Wholesale Trade (50-51), Services (70-89) and Other SIC Groups

Sectors Affected:

325 Chemical Manufacturing; 334 Computer and Electronic Product Manufacturing; 332 Fabricated Metal Product Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 562 Waste Management and Remediation Services

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RIN: 2050–AE50

EPA

135. RECYCLING OF CATHODE RAY TUBES (CRTS): CHANGES TO HAZARDOUS WASTE REGULATIONS

Priority:

Other Significant

Legal Authority:

42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925

CFR Citation:

40 CFR 261; 40 CFR 273

Legal Deadline:

None

Abstract:

This action will ultimately revise the existing Federal hazardous waste regulations to encourage recycling and better management of Cathode Ray

Tubes (CRTs) by providing a conditional exclusion from the definition of solid waste for CRTs being recycled. A CRT is the display component of a television or computer monitor. A CRT is made largely of specialized glasses, some of which contain lead to protect the user from X-rays inside the CRT. Due to the lead, when they are disposed of or reclaimed, some CRTs are hazardous wastes under the Federal Resource Conservation and Recovery Act (RCRA) regulations.

Statement of Need:

This rule is needed to respond to recommendations of the Electronics Subcommittee of the CSI Council regarding CRT recycling. It is also needed to streamline RCRA requirements for these materials to encourage better management and recycling.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

EPA solicited comments on alternative management requirements, including notification and tracking, accumulation requirements, requirements for CRT glass processors, export requirements, and disposal requirements.

Anticipated Cost and Benefits:

EPA estimates that, if finalized, this action would result in annual savings of up to 3 million dollars to reduce administrative, transportation, and management costs compared to current regulations.

Risks:

The risks are undetermined.

Timetable:

Action	Date	FR Cite
NPRM	06/12/02	67 FR 40507
Final Action	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4092, EDocket No. RCRA-2004-0010 (CRTs) RCRA-2004-0012 (Mercury devices);

Sectors Affected:

334411 Electron Tube Manufacturing

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RIN: 2050–AE52

EPA

136. • HAZARDOUS WASTE MANAGEMENT SYSTEM; MODIFICATION OF THE HAZARDOUS WASTE PROGRAM: MERCURY–CONTAINING EQUIPMENT

Priority:

Other Significant

Legal Authority:

42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925

CFR Citation:

40 CFR 261; 40 CFR 273

Legal Deadline:

None

Abstract:

Mercury-containing equipment (MCE) consists of devices, items, or articles that contain varying amounts of elemental mercury that is integral to their functions, including several types of instruments that are used throughout the electric utility industry and other industries, municipalities, and households. Some commonly recognized devises are thermostats, barometers, manometers, and mercury switches, such as light switches in automobiles. This definition does not include mercury waste that is generated as a byproduct through the process of manufacturing or treatment. This action will add mercury-containing equipment to the federal list of universal wastes regulated under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. Handlers of universal wastes are subject to less stringent standards for storing, transporting, and collecting these wastes. EPA believes that regulating spent mercury-containing equipment as a universal waste will lead to better management of this equipment and will facilitate compliance with hazardous waste requirements.

Statement of Need:

This rule is needed to respond to a petition from the Utilities Solid Waste Activities Group regarding management of mercury-containing equipment. It is also needed to streamline RCRA requirements for these materials to encourage better management and recycling and to reduce management of mercury in the municipal waste system.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

EPA solicited comments on alternative management requirements and alternative approaches for meeting its goals with respect to mercury equipment management.

Anticipated Cost and Benefits:

EPA estimates that, if finalized, this action would result in annual savings of up to $270,000 to reduce administrative, transportation, and management costs compared to current regulations. In addition, this action would improve management of mercury wastes from small and large generators and increase collection of these materials for proper management.

Timetable:

Action	Date	FR Cite
Final Action	06/00/05	

Regulatory Flexibility Analysis Required:

DATA MISSING

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4092.1, EDocket No. RCRA-2004-0010 (CRTs) RCRA-2004-0012 (Mercury devices); Split from RIN 2050-AE52.

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RIN: 2050–AG21

EPA

137. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUNDWATER RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 300 g–1 SDWA 1412 (b)(8); 42 USC 300j–4 SDWA 1445

CFR Citation:

40 CFR 141; 40 CFR 142

Legal Deadline:

Other, Statutory, Not later than promulgation of the Stage 2 Disinfection Byproducts Rule (currently scheduled for July 2005).

Abstract:

EPA has proposed a targeted risk-based regulatory strategy for all public water systems served by groundwater. The proposed requirements provide a meaningful opportunity to reduce public health risk for a significant number of people served by groundwater sources from the exposure to waterborne pathogens from fecal contamination. The proposed strategy addresses risks through a multiple-barrier approach that relies on five major components: periodic sanitary surveys of groundwater systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a requirement for correction of significant deficiencies and fecal contamination through the following actions: eliminate the source of contamination, correct the significant deficiency, provide an alternative source water, or provide a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses; and compliance monitoring to insure disinfection treatment is reliably operated where it is used.

Statement of Need:

Public water systems (PWSs) that use groundwater as their sole source of water, as opposed to surface water PWSs, are not federally regulated as to treatment for microorganisms. There is data that indicates that a number of groundwater PWSs are contaminated with microorganisms of fecal origin that can and have caused illness.

Summary of Legal Basis:

Section 1412(b)(8) of the Safe Drinking Water Act requires that EPA develop regulations specifying the use of disinfectants for ground water systems as necessary and ''. . .(as part of the regulations) promulgate criteria. . .to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water.''

Alternatives:

EPA considered four regulatory alternatives in the development of the GWR proposal; the proposed regulatory alternative (multi-barrier option), the sanitary survey option, the sanitary survey and triggered monitoring option, and the across-the-board disinfection option. All options include the sanitary survey provision. The sanitary survey option would require the primacy agency to perform surveys every three to five years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring option adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multi-barrier option, which was proposed by EPA, adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive, results in a routine source water fecal indicator monitoring requirement. The multi-barrier option and the sanitary survey and triggered monitoring options are targeted regulatory approaches designed to identify wells that are fecally contaminated or are at a high risk for contamination. The across-the-board disinfection option would require all systems to install treatment instead of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

Anticipated Cost and Benefits:

EPA estimates the cost of the proposed GWR will be $183 million dollars per year (using a 3 percent discount rate). More than half of the estimated costs are for corrective actions which systems will be required to take to fix or prevent fecal contamination. The remainder of the costs are due to increased scope and frequency of sanitary surveys, hydrogeologic sensitivity assessments and source water monitoring. System costs are expected to be $162 million per year for implementation of the GWR. States are expected to incur costs of $21 million per year. Cost estimates do not include land acquisition, public notification or the potential cost of illness due to exposure to disinfection by-products. The total estimated value of these benefits is $205 million per year, $139 million from avoided illness and $66 million from avoided deaths. These benefits are monetized based on a cost of illness and a value of statistical life. These estimates do not include pain and suffering associated with viral and bacterial illness avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality.

Risks:

EPA estimates that currently over 200,000 illnesses and 18 deaths occur each year due to viral and bacterial contamination of public groundwater systems. Children, the elderly and the immunocompromised are particularly sensitive to the waterborne pathogens and account for between 20 and 30 percent of the illnesses and deaths. As proposed, the GWR is expected to reduce the total number of illnesses by 115,000 and the total number of deaths by 11 each year. The GWR in conjunction with the Surface Water Treatment Rule (SWTR), Total Coliform Rule (TCR) the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Filter Backwash Rule (FBR) and the Long Term Enhanced Surface Water Treatment Rules (LT1ESWTR and LT2ESWTR) will provide protections to the consumers of public water supply systems from waterborne pathogens.

Timetable:

Action	Date	FR Cite
NPRM	05/10/00	65 FR 30194
Final Action	05/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 2340; Statutory deadline for final rule: After August 6, 1999, but not later than the Administrator promulgates a Stage II rulemaking for disinfection byproducts (currently scheduled for July 2005).

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AA97

EPA

138. NATIONAL PRIMARY DRINKING WATER REGULATIONS: LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

42 USC 300f; 42 USC 300g–1; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

None

Abstract:

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will control risk from microbial pathogens, specifically cryptosporidium, in drinking water. It is being developed simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR), which will address risk caused by the use of disinfectants in drinking water. This rule could affect all public water systems that use surface water as a source. Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the LT2ESWTR, EPA has analyzed a significant body of new survey data on microbial pathogens in source and finished waters, as well as data on parameters which could serve as indicators of microbial risk. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, has provided a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was previously available. EPA has also used significant new data on the efficiency of treatment processes for the removal and inactivation of microorganisms, as well as new information on the pathogenicity of certain microbes, to determine effective regulatory requirements for controlling microbial risk. On March 30, 1999, EPA established a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an agreement in principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is to reduce health risks posed by Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoa which causes cryptosporidiosis, a severe gastrointestinal disease. While cryptosporidiosis is generally self limiting in healthy individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of Cryptosporidium in drinking water sources through the Information Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems have an unacceptably high risk for Cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for Cryptosporidium through monitoring and prescribe an appropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

Summary of Legal Basis:

Section 1412(b)(7)(A) of SDWA authorizes the Administrator to promulgate a national primary drinking water regulation that requires the use of a treatment technique in establishing a maximum contaminant level if the Administrator makes a finding that it is not feasible to ascertain the level of the contaminant. The MCLG for Cryptosporidium is zero and it is not feasible for public water systems to measure Cryptosporidium concentrations in treated water. Consequently, under Section 1412(b)(1)(A), the Administrator may establish a treatment technique for Cryptosporidium if this presents a meaningful opportunity for health risk reduction. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule concurrently with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

Alternatives:

EPA is considering various rule scenarios to reduce risk from Cryptosporidium. These scenarios include treatment requirements that would apply to all systems, such as requiring all conventional plants to achieve 2-log inactivation of Cryptosporidium. Alternative scenarios have involved assigning systems to bins based on mean Crypto source water concentrations. Additional treatment requirements would then depend on the bin to which a system was assigned. Issues associated with the binning approach include: amount of monitoring necessary to assign systems to bins, appropriate Crypto concentrations to demarcate bin boundaries, and appropriate level of additional treatment for a given bin.

EPA is exploring analyses that evaluate the impact of these issues on costs and benefits. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the LT2ESWTR, as proposed will have an annual cost of $73 to $111 million per year. The majority of people (approximately 67 percent) are served by public water systems that use a surface water or ground water under the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. EPA estimates that the proposed LT2ESWTR would prevent up to 1,020,000 cases of cryptsporidiosis annually with an economic benefit of up to $1.4 billion. In addition, EPA has recently identified UV light as a technology that can achieve high levels of Cryptosporidium inactivation at relatively low cost.

Risks:

Approximately 67 percent of consumers are served by drinking water systems that use surface water sources or ground water under the direct influence of surface water. Survey data indicate that Cryptosporidium is prevalent in drinking water sources and current levels of treatment may not be adequate to control highly resistant pathogens like Cryptosporidium. Cryptosporidiosis is a potentially fatal disease in people with weak immune systems, such as infants, the elderly, people with AIDS, and people taking immune suppressing drugs like cancer and transplant patients. By requiring additional treatment for those systems with the highest concentrations of Cryptosporidium in their source waters, EPA expects to significantly reduce current risk.

Timetable:

Action	Date	FR Cite
NPRM	08/11/03	68 FR 47639
Final Action	07/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN 4341.

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD37

EPA

139. NATIONAL PRIMARY DRINKING WATER REGULATIONS: STAGE 2 DISINFECTION BYPRODUCTS RULE

Priority:

Economically Significant

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

42 USC 300f; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

Final, Statutory, July 14, 2003.

Abstract:

This Regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that will be promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process, although the impacts may be limited to community water systems (CWSs) and non-transient non-community water systems (NTNCWSs). Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the Stage 2 DBPR, EPA analyzed a significant body of new survey data on source water quality parameters, treatment data and disinfection byproduct occurrence. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was previously available. EPA also used new information on the health effects of exposure to DBPs to determine effective regulatory requirements for controlling risk. On March 30, 1999, EPA reconvened a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an Agreement in Principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Stage 2 Disinfectants/Disinfection Byproducts Rule (DBPR) is to reduce potential health risks posed by disinfection byproducts (DBPs). Certain DBPs have been shown in laboratory tests to be carcinogens or to cause adverse reproductive and developmental health effects. In addition, epidemiology studies have indicated that exposure to chlorinated water may increase the risk of bladder cancer, miscarriage, and certain developmental defects. The Stage 2 DBPR is designed to reduce peak events in DBP exposure in order to mitigate these potential health risks.

Summary of Legal Basis:

Section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than July 14, 2003. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule concurrently with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes

it is important to finalize these rules together.

Alternatives:

EPA is considering various rule scenarios to achieve reductions in disinfection byproduct exposure. These alternatives include: decreasing the standard set in the Stage 1 DBPR (0.080 mg/L total trihalomethanes (TTHM) and 0.060 mg/L the sum of 5 haloacetic acids (HAA5)) by half and maintaining a running annual average compliance calculation; maintaining 80/60 TTHM/HAA5 standards but revising the compliance calculation to a stricter locational running annual average; setting the 80/60 TTHM/HAA5 standard as a never to be exceeded maximum; and revising the standard for bromate which is currently 0.010 mg/L. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the Stage 2 DBPR will have an annual economic impact of $59-65 million. Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants and potentially exposed to DBPs. Thus, a large number of people will benefit from the Stage 2 DBPR.

Risks:

Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Due to the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health. EPA estimates that the Stage 2 DBPR will decrease exposure to DBPs on average but more importantly, the rule will significantly reduce exposure to peak occurrences of DBPs.

Timetable:

Action	Date	FR Cite
NPRM	08/18/03	68 FR 49548
Final Action	07/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN 4342.

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD38

EPA

140. MINIMIZING ADVERSE ENVIRONMENTAL IMPACT FROM COOLING WATER INTAKE STRUCTURES AT EXISTING FACILITIES UNDER SECTION 316(B) OF THE CLEAN WATER ACT, PHASE 3

Priority:

Other Significant

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

33 USC 1311 CWA 301; 33 USC 1316 CWA 306; 33 USC 1326 CWA 316; 33 USC 1361 CWA 501

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 125

Legal Deadline:

NPRM, Judicial, November 1, 2004.

Final, Judicial, June 1, 2006.

Abstract:

This rulemaking will affect existing facilities that use cooling water intake structures, and whose intake flow levels exceed a minimum threshold to be determined by EPA during this rulemaking. The proposed rule addresses all existing facilities if they meet the proposed threshold levels, including those in the following industries: (1) Electricity generating facilities not covered by Phase 2 regulations; (2) pulp and paper manufacturing facilities; (3) chemicals and allied products manufacturing facilities; (4) petroleum and coal products manufacturing facilities; and (5) primary metals manufacturing facilities. EPA also proposed regulations for new offshore and coastal oil and gas extraction facilities, which EPA excluded from the Phase I rule for other, land-based facilities. Section 316(b) of the Clean Water Act provides that any standard established pursuant to sections 301 or 306 of the Clean Water Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. A primary purpose of this action is to minimize the impingement and entrainment of fish and other aquatic organisms by cooling water intake structures. Impingement occurs when fish and other aquatic life are trapped against cooling water intake structures. Entrainment occurs when aquatic organisms, eggs and larvae are drawn into a cooling system and then pumped back out, resulting in significant injury or mortality to the entrained organisms.

Statement of Need:

In the absence of national regulations, Permit Directors have regulated cooling water intake structures incompletely and inconsistently, especially with respect to the manufacturing sector. In some instances, permit issuance or reissuance has been significantly delayed or permit decisions from 20 or more years ago have not been reevaluated. Significant numbers of fish and other aquatic organisms may be cropped annually as a result of cooling water intake structures at a single large intake or through the cumulative impact at multiple small intakes on the same waterbody. By court order, EPA must propose and take final action on this regulation. This regulation may have substantial ecological benefits.

Summary of Legal Basis:

This action is required under an Amended Consent Decree in Riverkeeper Inc. et al. v. Whitman, 93 Civ. 0314 (AGS)(U.S. District Court, Southern District of New York, November 21, 2000).

Alternatives:

This analysis will cover various sizes and types of potentially regulated facilities. EPA is considering whether to regulate on a site-specific, waterbody category, or national basis. EPA is also considering several flow thresholds, below which the regulation would not apply and permits would continue to be issued on a case-by-case basis by Permit Directors using their best professional judgment.

Anticipated Cost and Benefits:

Costs are yet to be determined, but are not expected to exceed $100 million. While monetized use benefits are expected to be lower than monetized costs, a qualitative assessment of ecological benefits at several large facilities indicates the potential for additional benefits when intakes are controlled. Costs and benefits are generally expected to be smaller at facilities that use smaller amounts of cooling water.

Risks:

Cooling water intake structures may pose significant risks for aquatic ecosystems.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4543; Split from RIN 2040-AC34.

Sectors Affected:

312 Beverage and Tobacco Product Manufacturing; 325 Chemical Manufacturing; 61131 Colleges, Universities and Professional Schools; 334 Computer and Electronic Product Manufacturing; 211111 Crude Petroleum and Natural Gas Extraction; 22111 Electric Power Generation; 335 Electrical Equipment, Appliance and Component Manufacturing; 332 Fabricated Metal Product Manufacturing; 311 Food Manufacturing; 333 Machinery Manufacturing; 21 Mining; 211112 Natural Gas Liquid Extraction; 327 Nonmetallic Mineral Product Manufacturing; 322 Paper Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 22133 Steam and Air-Conditioning Supply; 313 Textile Mills; 336 Transportation Equipment Manufacturing; 321 Wood Product Manufacturing

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RIN: 2040–AD70

EPA

141. CROSS–MEDIA ELECTRONIC REPORTING (ER) AND RECORDKEEPING RULE (CROMERRR)

Priority:

Other Significant

Legal Authority:

PL 104–13; PL 105–277

CFR Citation:

40 CFR 3 (New); 40 CFR 9 (Revision)

Legal Deadline:

None

Abstract:

As proposed, the Cross-Media Electronic Reporting (ER) and Recordkeeping Rule (CROMERRR) was intended to provide a uniform legal framework for paperless electronic reporting and recordkeeping, including electronic signature/certification, across EPA's environmental compliance programs. Based on public comment, however, EPA now plans to focus on finalizing the electronic reporting components of proposed CROMERRR, and to defer further action on the electronic recordkeeping components until a later time. Under current plans, the final electronic reporting (ER) rule will address electronic reporting by companies regulated under all of EPA's programs: air, water, pesticides, toxic substances, wastes, and emergency response. The final rule would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, the rule would set the conditions for allowing electronic reporting under State, tribal or local environmental programs that operate under EPA authorization. The final ER rule is intended to make electronic reporting as simple, efficient, and cost-effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no obstacles to adopting new technologies as they emerge. To ensure that authorized programs at the State, tribal, and local levels meet EPA's electronic reporting goals, the final ER rule would specify a set of criteria that these programs must satisfy as they initiate electronic reporting. In response to public comments, EPA is also planning to include provisions for a streamlined process for EPA to review and approve authorized program revisions or modifications to allow electronic reporting.

Statement of Need:

EPA is required by the Government Paperwork Elimination Act (GPEA) of 1998 to make the option of electronic reporting and recordkeeping available, where practicable, to its regulated community by 2003. To meet this deadline and comply with GPEA, EPA believes that it needs to put a new legal framework in place for electronic reporting. A final ER rule would provide for this legal framework by: (1) Removing legal obstacles to electronic reporting posed by explicit references to paper and paper-based processes in EPA regulations; and (2) assuring that electronically submitted documents will have the same legal and evidentiary force as their paper counterparts, whether the submission is directly to EPA or under an EPA-authorized program.

Summary of Legal Basis:

Government Paperwork Elimination Act (GPEA) of 1998. GPEA requires Federal agencies to provide, where practicable, the option of electronic reporting and

recordkeeping to their regulated communities by 2003.

Alternatives:

One alternative to an EPA cross-media ER rule that applies to most compliance reports under 40 CFR would be individual rulemakings by each of the program offices. EPA's past experience with program-by-program ER rulemakings has demonstrated that such an approach would be more costly and take much longer to complete. EPA also considered the use of guidance instead of rulemaking, but rejected this alternative based principally on a concern that program enforceability depends greatly on the ability to mandate a certain level of functionality for systems that will be used to receive electronic reports and other electronic documents.

Anticipated Cost and Benefits:

EPA received a number of comments on the assumptions used to generate the cost and benefit estimates for the electronic reporting components of proposed CROMERRR; based on this feedback, EPA decided to develop a new analysis of the costs and benefits for the final ER rule. As a part of this effort, EPA has conducted extensive follow-up interviews with commenters, reevaluated existing sources of information, and conducted new market research on ER technologies. The results have led EPA to revise certain assumptions associated with the CROMERRR proposal that bear on the ER rule's costs and benefits to regulated entities and to Federal, State, and local governments. Proposed CROMERRR had assumed that the costs and benefits of electronic reporting under authorized programs could be attributed entirely to the rule. EPA has since learned that a significant number of electronic reporting systems already operate under such programs; correspondingly, the ER rule cannot take credit for the costs and benefits of electronic reporting in such cases, but only for the costs or benefits that result from changes that occur as a result of the rule. With respect to regulated entities, EPA has had to adjust a number of assumptions associated with electronic signature requirements, including those related to the number of registered signature-holders at each facility, and the availability of acceptable alternatives to Public Key Infrastructure-based electronic signature approaches in many instances. EPA is also refining its estimate of the number of potentially affected regulated entities. With respect to the Federal government, EPA has reconsidered the general costs and benefits of electronic reporting based on experience operating EPA's Central Data Exchange and other EPA systems, and based also on an in-depth analysis of business processes and associated costs for several major EPA programs implementing electronic reporting. Based on these and other revisions to our assumptions, EPA has developed preliminary new cost/benefit results. They indicate that regulated entities and State and local government agencies will incur modest net costs from the ER rule; EPA will experience modest net benefits. Qualitative benefits of electronic reporting were also identified, including: enhanced data quality, faster public access to submitted data, better tracking of compliance submissions, and opportunities for re-engineering current paper processes. Finally, comments on the CROMERRR also indicated the need for substantial reworking of the cost and benefit analyses with respect to the electronic recordkeeping components of the proposal. Given EPA's current focus on electronic reporting, EPA will defer additional economic analysis in this area until the Agency resumes work on electronic recordkeeping.

Risks:

The risks are undetermined.

Timetable:

Action	Date	FR Cite
NPRM	08/31/01	66 FR 46162
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 4270; Formerly listed as RIN 2020-AA41.

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RIN: 2025–AA07

BILLING CODE 6560–50–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

Statement of Regulatory and Deregulatory Priorities

The mission of the Equal Employment Opportunity Commission (EEOC, Commission, or Agency) is to ensure equality of opportunity in employment by vigorously enforcing six Federal statutes. These statutes are: Title VII of the Civil Rights Act of 1964, as amended (prohibits employment discrimination on the basis of race, color, sex, religion, or national origin); the Equal Pay Act of 1963, as amended; the Age Discrimination in Employment Act of 1967 (ADEA), as amended; title I of the Americans with Disabilities Act of 1990, as amended, and sections 501 and 505 of the Rehabilitation Act of 1973, as amended (disability); and the Government Employee Rights Act of 1991, which extends protections against employment discrimination to certain employees who were not previously covered.

The significant action of a regulatory nature now under consideration is amending regulations governing age discrimination in employment to exempt from the prohibitions of the Age Discrimination in Employment Act (ADEA) the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits. This rule will ensure that the application of the ADEA does not discourage employers from providing health benefits to their retirees. The Commission does not believe that the proposed exemption will have a significant impact on small business entities under the Regulatory Flexibility Act because it imposes no economic or reporting burdens on such firms.

Consistent with section 4(c) of Executive Order 12866, this statement was reviewed and approved by the Chair of the Agency. The statement has not been reviewed or approved by the other members of the Commission.

EEOC

FINAL RULE STAGE

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142. COORDINATION OF RETIREE HEALTH BENEFITS WITH MEDICARE AND STATE HEALTH BENEFITS

Priority:

Other Significant

Legal Authority:

29 USC 628

CFR Citation:

29 CFR 1625

Legal Deadline:

None

Abstract:

The Commission proposes to exempt from the prohibitions of the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 et seq. (ADEA or Act), the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits.

Statement of Need:

In August 2001, the Commission announced that it would consider the relationship between the ADEA and employer-sponsored retiree health benefit plans that alter, reduce, or eliminate benefits upon eligibility for Medicare or a comparable State-sponsored retiree health benefits program. There has been a decline in the number of employers providing retiree health benefits over the last 10 years. Various factors have contributed to this erosion, including the increased cost of health care coverage, an increased demand for such coverage as large numbers of workers near retirement age, and changes in the way accounting rules treat the long-term costs of providing retiree health benefits. Another factor has been employer concern about the potential application of the ADEA to employer-sponsored retiree health benefits. The Commission is proposing a narrowly drawn ADEA exemption that permits the practice of coordinating employer-provided retiree health coverage with eligibility for Medicare or a State-sponsored retiree health benefits program, so that the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees.

Summary of Legal Basis:

Pursuant to section 9 of the ADEA, the Commission is authorized to establish reasonable exemptions to and from any or all provisions of the Act as it may find necessary and proper in the public interest.

Alternatives:

The Commission considered various alternatives in developing this proposal. The Commission will consider all alternatives offered by the public commenters.

Anticipated Cost and Benefits:

The Commission recognizes that while employers are under no legal obligation to offer retiree health benefits, some employers choose to do so in order to maintain a competitive advantage in the marketplace, using these and other benefits to attract and retain the best talent available to work for their organizations. The proposed rule will ensure that the application of the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees who otherwise would have to obtain such coverage in the private individual marketplace at significant personal expense. The Commission believes that it is in the best interest of both employers and employees for the Commission to pursue a policy that permits employers to offer these benefits to the greatest extent possible. It is not anticipated that the proposal will result in increased costs.

Risks:

The proposed regulatory action will reduce the risks of liability for noncompliance with the statute by exempting certain employer practices from regulation. This proposal does not address risks to public safety or the environment.

Timetable:

Action	Date	FR Cite
NPRM	07/14/03	68 FR 41542
NPRM Comment Period End	09/12/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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RIN: 3046–AA72

BILLING CODE 6570–01–S

GENERAL SERVICES ADMINISTRATION (GSA)

Statement of Regulatory and Deregulatory Priorities

The General Services Administration (GSA) establishes Governmentwide policy for construction and operation of buildings, procurement and distribution of supplies, travel and transportation, acquisition, electronic commerce, management of advisory committees, and utilization and disposal of real and personal property.

GSA's fiscal year 2005 regulatory priority is to complete conversion of the Federal Property Management Regulations to the Federal Management Regulation (FMR).

GSA is writing the FMR so that its contents are consistent and sensible and limit the regulatory burden placed on Government officials and the public. GSA has adopted a question and answer, plain language format for its regulations to make them easier to read and understand. Non-regulatory guidance is being moved into other, less formal publications such as customer service guides.

As necessary, GSA will prepare its regulations so that they address national health and security concerns, particularly those created as a result of the events of September 11, 2001.

BILLING CODE 6840–34–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Statement of Regulatory Priorities

The National Aeronautics and Space Administration (NASA) was established by the National Aeronautics and Space Act of 1958 (the Act), 42 United States Code (U.S.C.) 2451 et seq., which laid the foundation for NASA's mission. The Act authorizes NASA, among other things, to conduct space activities devoted to peaceful purposes for the benefit of humankind; to preserve the leadership of the United States in aeronautics and space science and technology; and to expand knowledge of the Earth and space. To carry out this mission, NASA is authorized to conduct research for the solution of problems of flight within and outside the Earth's atmosphere; to develop, construct, test, and operate aeronautical and space vehicles for research purposes; to operate space transportation systems, including the Space Shuttle and the International Space Station; and to perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with human-tended, robotic, and expendable vehicles and arranges for the most effective utilization of the scientific and engineering resources of the United States with other nations engaged in aeronautical and space activities for peaceful purposes.

NASA's mission, as documented in its 2003 Strategic Plan, is to understand and protect our home planet, to explore the universe and search for life, and to inspire the generation of explorers as only NASA can.

Our mission is driven by science, exploration, and discovery, and it will be carried out with a firm commitment to fiscal responsibility. We will study climate change and the natural and human-induced hazards to Earth's ecosystem. We will help to counter the threat of international terrorism by developing technologies that can improve the security and safety of our air transportation system. We will lead the world into a new understanding of our planet, our solar system, and the universe around us, and in so doing, we will begin to understand whether life may have developed elsewhere in the cosmos.

The following are narrative descriptions of the most important regulations being planned for publication in the **Federal Register** during fiscal year (FY) 2005.

The Federal Acquisition Regulation (FAR), 48 CFR chapter 1, contains procurement regulations that apply to NASA and other Federal agencies. NASA implements and supplements FAR requirements through the NASA FAR Supplement (NFS), 48 CFR chapter 18. Major revisions are not expected in FY 2005, except to conform to FAR changes that are currently being promulgated in part 27, Patents, Data, and Copyrights; part 45, Government Property; and part 47, Transportation. In a continuing effort to keep the NFS current with NASA initiatives and Federal procurement policy, minor revisions to the NFS will be published.

To reduce the time and cost spent by the Agency and our industry partners in the procurement of basic and applied research under cooperative agreements, NASA is focusing on streamlining our processes. To go forward in this effort, policy and guidance associated with the generation and review of Cooperative Agreements Notices (CAN) is being considered. Additionally, changes necessary for implementing a common format for grant announcements and addressing other internal management practices will be made.

NASA is continuing consideration of revisions to the cross-waiver of liability regulation at 14 CFR part 1266. Specifically, NASA is considering implementation of the cross-waiver of liability provision of the intergovernmental agreement of the International Space Station and refinement and clarification of contractual cross-waivers in NASA agreements involving launch services.

BILLING CODE 7510–13–S

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)

Statement of Regulatory Priorities

Overview

The National Archives and Records Administration (NARA) issues regulations directed to other Federal agencies and to the public. Records management regulations directed to Federal agencies concern the proper management and disposition of Federal records. Through the Information Security Oversight Office (ISOO), NARA also issues Governmentwide regulations concerning information security classification and declassification programs. NARA regulations directed to the public address access to and use of our historically valuable holdings, including archives, donated historical materials, Nixon Presidential materials, and Presidential records. NARA also issues regulations relating to the National Historical Publications and Records Commission (NHPRC) grant programs.

NARA has four regulatory priorities for fiscal year 2005. The first, included in The Regulatory Plan, is to revise and update our records management regulations in 36 CFR ch. XII, subchapter B. We began work on this priority in fiscal year 2004 with a proposal for a new organizational framework for the records management regulations to make them easier to use. We will be issuing the revised regulations in stages. We are issuing certain priority revisions relating to records scheduling and disposition in advance of the overall subchapter B revision. This regulatory activity is part of a major NARA initiative to review and redesign our records management program that started in 2000.

The second priority is to complete the revision of our records center facility standards regulation in 36 CFR part 1228, subpart K. This regulation affects small businesses and is discussed in greater detail in the following section.

Our third priority regulatory action is reviewing and revising our records declassification regulation in 36 CFR part 1260 to reflect changes in the Executive Order governing declassification of national security classified information (E.O. 12958, as amended, Classified National Security Information). Our regulations in part 1260 establish procedures for the automatic declassification of records in NARA's legal custody and revise requirements for reclassification of information as provided for in the Executive Order. NARA serves the public and Federal agencies by specifying the declassification process we use.

Our fourth priority regulatory action is reviewing and updating our NHPRC grants program regulations in 36 CFR part 1206. The NHPRC grants program participates in the Grants.gov eGovernment Initiative, and our review will ensure that the regulations reflect that participation. The NHPRC makes grants to preserve and to deliver historical records for use by the American people. The Commission each year receives over 150 applications requesting over $15 million of which less than $10 million is available to award.

NARA does not have any planned regulatory actions that relate to the events of September 11, 2001.

Regulations of Particular Concern to Small Businesses

NARA's regulation specifying facility standards for records storage facilities that house Federal records (RIN 3095-AA81) has been identified as being of particular concern to small businesses. The current regulation went into effect in 2000 and was among the public reform nominations in the Office of Management and Budget's (OMB) 2003 Report to Congress on the Costs and Benefits of Regulations. OMB referred this regulation to NARA for evaluation. After reviewing the regulation and extensive discussions with the records center industry association to which many small business records centers belong, NARA issued a proposed rule on September 7, 2004, that will still ensure protection of Federal records while reducing the burden on records centers that are small businesses.

NARA

PROPOSED RULE STAGE

143. FEDERAL RECORDS MANAGEMENT

Priority:

Other Significant

Legal Authority:

44 USC 2104(a); 44 USC ch 21; 44 USC ch 29; 44 USC ch 33

CFR Citation:

36 CFR 1220 to 1238

Legal Deadline:

None

Abstract:

As part of its initiative to redesign Federal records management, NARA is revising its records management regulations in 36 CFR ch. XII, subchapter B to ensure that the regulations are appropriate, effective, and clear. During fiscal year 2005, we will publish several rules relating to the redesign.

Statement of Need:

NARA's records management program was developed in the 20th century in a paper environment. This program has not kept up with a Federal Government that creates and uses most of its records electronically. Today's Federal records environment requires different management strategies and techniques.

The revision of NARA's records disposition policies, processes, and tools is identified in our Strategic Plan as a key Strategy to meet the primary goal that ''essential evidence will be created, identified, appropriately scheduled, and managed for as long as needed'' Without effective records management, records needed to document citizens rights, actions for which Federal officials are responsible, and the historical experience of our Nation will be at risk of loss, deterioration, or destruction.

Summary of Legal Basis:

Under the Federal Records Act, the Archivist of the United States is responsible for: 1) providing guidance and assistance to Federal agencies to ensure adequate and proper documentation of the policies and transactions of the Federal Government and ensuring proper records disposition (44 U.S.C. 2904); 2) approving the disposition of Federal records (44 U.S.C. ch. 33); and 3) preserving and making available the Federal records of continuing value that have been transferred to the National Archives of the United States (44 U.S.C. ch. 21).

The Federal Records Act also makes the heads of Federal agencies responsible for making and preserving records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and is designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities (44 U.S.C. 3101). Agency heads must also

have an active, continuing records management program (44 U.S.C. 3102).

Alternatives:

None.

Anticipated Cost and Benefits:

The revision of NARA's records disposition policies and processes, of which this regulation review is a part, is intended to reduce the burden on agencies and NARA in the area of records disposition activities.

Risks:

None.

Timetable:

Action	Date	FR Cite
Begin Review	09/17/02	
ANPRM	03/15/04	69 FR 12100
ANPRM Comment Period End	05/14/04	
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

URL For More Information:

www.archives.gov/records__management/initiatives/strategic__directions.html

URL For Public Comments:

www.regulations.gov

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Related RIN: Related to 3095–AB05, Related to 3095–AB41, Related to 3095–AB43, Related to 3095–AB39

RIN: 3095–AB16

BILLING CODE 7515–01–S

OFFICE OF PERSONNEL MANAGEMENT (OPM)

Statement of Regulatory Priorities

The Office of Personnel Management (OPM) is the human resources and personnel manager for the President and the Federal Government. The primary focus of OPM's regulatory efforts in the coming year will continue to be the modernization and improvement of human resources management to support the President's goal of creating a Government that is citizen-centered, results-oriented and market-based. To this end, OPM's primary regulatory objective is to implement improvements to human resources management that will enable the Federal Government to recruit, manage, develop, and retain the high-quality, diverse workforce that departments and agencies require to carry out their respective missions.

The *President's Management Agenda* recognizes the critical role that human resources management must play in reforming Government by identifying the Strategic Management of Human Capital as the first of its five core Governmentwide initiatives. OPM is the managing partner on this Presidential initiative and has aggressively implemented a program to assist other agencies in achieving success in this area through aligning human resources management practices with agency missions and objectives. OPM will implement this initiative by way of collaboration, coordination, and regulation as necessary and appropriate during the coming year.

Department of Homeland Security

The Homeland Security Act of 2002 authorized the creation of the Department of Homeland Security (DHS) through the combination of components of 22 other departments and agencies. In addition, the Act granted the President flexibility in the management of the Department's human resources (HR). OPM has been working with DHS and stakeholders for 18 months to design a new HR system in the areas of pay, performance management, labor management relations, adverse actions and appeals, and to issue enabling regulations that are responsive to the critical needs of the Department. We anticipate that final joint DHS/OPM regulations establishing a new HR system will be issued in early fiscal year 2005.

National Security Personnel System

The 2004 National Defense Authorization Act (NDAA) authorizes the creation of a National Security Personnel System (NSPS) at the Department of Defense (DoD). OPM has collaborated extensively with DoD to identify the regulatory requirements needed to establish a flexible and contemporary human resources management system as called for in the statute. The NSPS must be fair and credible, adhere to merit principles, honor veterans' preference, protect against prohibited personnel practices, and include a performance management system that incorporates pay for performance. In addition, the Act permits the establishment of a new labor relations system and a new employee appeals process, and grants flexibilities in recruitment and assignment actions and in the adjustment of overall agency staff. The NSPS is vital to DoD's national security mission and will remain a regulatory priority for OPM in the year ahead.

Compensation Reform

OPM continues to study Governmentwide compensation reform and to gather information from stakeholders following the publication of OPM Director Kay Coles James' white paper on Federal compensation reform: ''A Fresh Start for Federal Pay: The Case for Modernization.'' In addition, because compensation reform is a necessary element of improving the management of human capital?a central goal of the *President's Management Agenda?*OPM anticipates making promulgation of compensation reform regulations a priority in 2005, including the final regulations necessary to implement the SES pay for performance system, which was authorized under NDAA. OPM will also proceed with promulgating regulations to implement the provisions of the Human Capital Performance Fund, which was authorized under NDAA as well.

e-Government

OPM has been designated as the managing partner on 5 of the 24 e-Government initiatives in the *President's Management Agenda*. Specifically, OPM is the managing partner for Recruitment One Stop, e-Clearance, e-Training, e-Payroll, and e-Enterprise HR Integration (e-EHRI). These initiatives will require promulgation of new or modified regulations. In addition, OPM has been designated the managing partner of the Human Resources Line of Business (HR LOB). The objective of HR LOB is to create a framework for a Governmentwide, modern, cost effective, standardized, and interoperable Human Resources (HR) solution that provides common core functionality and maximizes automation of processes to support the strategic management of human capital. The current suite of e-Government initiatives managed by OPM will be transitioned and integrated into the HR LOB. This initiative will also require promulgation of new or modified regulations in 2005.

No FEAR Regulations

In July 2003, the President delegated responsibility for promulgating regulations pursuant to title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 to OPM. The provisions of title II relate to reimbursement of the Treasury Department's judgment fund, notice and training for applicants and employees, and reporting requirements by agencies. Regulations concerning reimbursement of the judgment fund were promulgated on an interim final basis on January 22, 2004. In the coming year, working with the EEOC and Office of Special Counsel, OPM will promulgate regulations for the remaining provisions of title II of the Act.

Human Resources (HR) Flexibilities

In 2003, OPM issued interim regulations to implement five new HR authorities enacted in the Chief Human Capital Officers Act (CHCO Act, title XIII of the Homeland Security Act). These included Voluntary Separation Incentive Program regulations that provided agencies with Governmentwide buyout authority. Upon OPM approval, agencies may use this authority as an important workforce reshaping tool in support of their human capital needs. OPM also provided agencies with four additional flexibilities. These new authorities provide agencies with: (1) increased flexibility in assessing applicants using alternative (category-based) rating and selection procedures; (2) the ability to select qualified candidates for competitive service positions using direct-hire procedures; (3) authority to pay or reimburse academic degree training costs from appropriated or other available funds and increased flexibility in academic degree training to address agency-specific human capital objectives; and (4) revised voluntary early retirement authority criteria to address reshaping and restructuring issues. These authorities provide agencies with additional tools to recruit, retain, and reshape their workforce to meet critical mission goals and objectives. These interim regulations

allowed agencies immediate access to these new tools while simultaneously soliciting comments on potential program improvements. OPM is currently reviewing the comments received and will publish final regulations during the coming year.

Human Capital Management

The CHCO Act also established a new chapter 14, Agency Chief Human Capital Officers, within title 5, U.S. Code, as well as a requirement for OPM to establish by regulation systems for assessing the management of human capital in Federal agencies. Provisions of the NDAA established a related requirement for agencies to conduct annual employee surveys under regulations issued by OPM. In the coming year, OPM will be addressing these and related general human capital management requirements through implementing regulations.

BILLING CODE 6325–44–S

PENSION BENEFIT GUARANTY CORPORATION (PBGC)

Statement of Regulatory and Deregulatory Priorities

PBGC Insurance Programs

The Pension Benefit Guaranty Corporation (PBGC) administers two insurance programs for private defined benefit plans under title IV of the Employee Retirement Income Security Act of 1974 (ERISA): A single-employer plan termination insurance program and a multiemployer plan insolvency insurance program. The PBGC protects the pensions of over 44 million working men and women in about 31,000 private defined benefit plans, including about 1,600 multiemployer plans.

The PBGC receives no funds from general tax revenues. Operations are financed by insurance premiums, investment income, assets from pension plans trusteed by the PBGC, and recoveries from the companies formerly responsible for the trusteed plans.

To carry out these functions, the PBGC must issue regulations interpreting such matters as the termination process, establishment of procedures for the payment of premiums, and assessment and collection of employer liability.

Single-Employer Program

Under the single-employer program, the PBGC pays guaranteed and certain other pension benefits to participants and beneficiaries if their plan terminates with insufficient assets (distress and involuntary terminations). At the end of fiscal year 2003, the PBGC was trustee of about 3,300 plans and paid $2.5 billion in benefits to about 459,000 people during 2003. Another 475,000 people will receive benefits when they retire in the future.

Most terminating single-employer plans terminate with sufficient assets to pay all benefits. The PBGC has administrative responsibility for these terminations (standard terminations), but its role is limited to seeing that proper procedures are followed and participants and beneficiaries receive their plan benefits.

The private defined benefit pension system has been under pressure for some time and has become a matter of public concern. In July 2003, the Administration issued an initial set of legislative proposals that would: (1) Improve the accuracy of pension liability measurements by modifying the discount interest rate; (2) increase the transparency of pension plan information and make public pension underfunding information provided to PBGC for companies with over $50 million in underfunding; and (3) require immediate funding of accruals, benefit increases, and lump sum payments in certain situations involving a financially distressed company and fix PBGC's guarantee limit as of the date a plan sponsor files for bankruptcy. In addition, the Administration is developing comprehensive pension reform proposals to improve retirement security for workers and to strengthen the pension insurance system.

Multiemployer Program

The multiemployer program (which covers about 9.7 million workers and retirees in about 1,600 insured plans) is funded and administered separately from the single-employer program and differs in several significant ways. The multiemployer program covers only collectively bargained plans involving more than one unrelated employer. The PBGC provides financial assistance (in the form of a loan) to the plan if the plan is unable to pay benefits at the guaranteed level. Guaranteed benefits are less than single-employer guaranteed benefits. PBGC financial assistance occurs infrequently.

Objectives and Priorities

PBGC regulatory objectives and priorities are developed in the context of the statutory purposes of title IV: (1) To encourage continuation and maintenance of voluntary private pension plans, (2) to provide for the timely and uninterrupted payment of pension benefits to participants and beneficiaries, and (3) to maintain the premiums that support the insurance programs at the lowest possible levels consistent with carrying out the PBGC's statutory obligations (ERISA section 4002(a)). In addition, PBGC receives no taxpayer monies. It is a self-financing government corporation. Principal revenue sources are premiums paid by plan sponsors and income generated by assets held by PBGC.

The PBGC implements its statutory purposes by developing regulations designed: (1) To assure the security of the pension benefits of workers, retirees, and beneficiaries; (2) to improve services to participants; (3) to ensure that the statutory provisions designed to minimize losses for participants and PBGC in the event of plan termination are effectively implemented; (4) to encourage the continuation and maintenance of voluntary private pension plans; (5) to facilitate the collection of monies owed to plans and to the PBGC, while keeping the related costs and burdens as low as possible; (6) to simplify the termination process; and (7) to minimize reporting and other burdens.

Regulatory Priorities

The PBGC regulatory priorities are focused on changes to improve transparency and to simplify filing with PBGC by increasing use of electronic filing. PBGC policymaking gives consideration to the special needs and concerns of small business.

Improve Transparency of Information

PBGC is developing a regulatory package to improve transparency of information to enable plan participants, investors, and PBGC to make more informed decisions and to encourage more responsible funding of pension plans. The transparency proposals relate to three areas—plan actuarial information and employer financial information that is required of certain employers with large amounts of pension underfunding, notice to PBGC that is required for certain events that threaten plan funding, and funding information that is required to be provided in an annual Participant Notice by certain underfunded plans. In addition, in order to improve compliance with the Participant Notice requirements, PBGC, in May 2004, published a Notice in the Federal Register providing a voluntary correction program designed to encourage correction of recent compliance failures and to facilitate future compliance. At the same time, PBGC proposed a new Participant Notice penalty policy that will be used for future violations of the Participant Notice requirements.

Simplify Filing by Increasing Use of Electronic Filing

The PBGC introduced optional electronic filing of premiums in 2004 with an online filing system that employs PBGC software. PBGC will be specifying a common data standard so that private vendors can develop software that filers can use in lieu of PBGC software. PBGC will be moving toward requiring electronic premium filing for all plans, which will simplify their paperwork, improve accuracy of PBGC's premium records and database, and enable more prompt payment of premium refunds. In addition, electronic filing will be required for plan actuarial and employer financial information reported to PBGC by employers with large amounts of pension underfunding. Electronic filing will reduce the filing burden, improve

accuracy, and better enable PBGC to monitor and manage risks posed by these plans.

Relief for Small Businesses

A large percentage of the plans insured by the PBGC are small or maintained by small employers. The PBGC takes the special needs and concerns of small entities into account in developing its regulatory policies. For example, the May 2004 proposed revisions to the penalty structure for failure to comply with the Participant Notice requirements scale down the penalty rate based on the number of plan participants.

The PBGC will continue to review its regulations to look for further simplification opportunities. The PBGC's regulatory plan for October 1, 2004, to September 30, 2005, consists of two significant regulatory actions.

PBGC

PROPOSED RULE STAGE

144. ALLOCATION OF ASSETS IN SINGLE–EMPLOYER PLANS; VALUATION OF BENEFITS AND ASSETS

Priority:

Other Significant

Legal Authority:

29 USC 1302(b)(3); 29 USC 1341; 29 USC 1301(a); 29 USC 1344; 29 USC 1362

CFR Citation:

29 CFR 4044, subpart B

Legal Deadline:

None

Abstract:

The PBGC is considering amending its benefit valuation and asset allocation regulations by adopting more current mortality tables and otherwise simplifying and improving its valuation assumptions and methods.

Statement of Need:

The PBGC's regulations prescribe rules for valuing a terminating plan's benefits for several purposes, including (1) determining employer liability and (2) allocating assets to determine benefit entitlements. The PBGC's interest assumption for valuing benefits, when combined with the PBGC's mortality assumption, is intended to reflect the market price of single-premium, nonparticipating group annuity contracts for terminating plans. In developing its interest assumptions, the PBGC uses data from surveys conducted by the American Council of Life Insurers. The PBGC currently uses a mortality assumption based on the 1983 Group Annuity Mortality Table in its benefit valuation and asset allocation regulations (29 CFR parts 4044 and 4281).

In May 1995, the Society of Actuaries Group Annuity Valuation Table Task Force issued a report that recommends new mortality tables for a new Group Annuity Reserve Valuation Standard and a new Group Annuity Mortality Valuation Standard. In December 1996, the National Association of Insurance Commissioners adopted the new tables as models for determining reserve liabilities for group annuities. The PBGC is considering incorporating these tables into its regulations and making other modifications.

Summary of Legal Basis:

The PBGC has the authority to issue rules and regulations necessary to carry out the purposes of title IV of ERISA.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Cost estimates are not yet available. However, the PBGC expects that this regulation will not have a material effect on costs.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/97	62 FR 12982
ANPRM Comment Period End	05/19/97	
NPRM	12/00/04	
NPRM Comment Period End	02/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

URL For More Information:

www.pbgc.gov/regs

URL For Public Comments:

www.pbgc.gov/regs

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RIN: 1212–AA55

PBGC

145. • TRANSPARENCY OF INFORMATION RELATED TO PLAN LIABILITIES

Priority:

Other Significant

Legal Authority:

29 USC 1302(b)(3); 29 USC 1310; 29 USC 1311; 29 USC 1343

CFR Citation:

29 CFR 4010; 29 CFR 4011; 29 CFR 4043

Legal Deadline:

None

Abstract:

The PBGC is considering amending its regulations on required reporting or disclosure of certain plan actuarial and employer financial information (29 CFR 4010), participant notices (29 CFR 4011), and reportable events (29 CFR 4043) to improve disclosure and provide for electronic filing of certain information.

Statement of Need:

The PBGC's regulations require disclosure of various information to PBGC relating to employer financial condition and plan liabilities (29 CFR 4010) and events that may threaten future funding of a plan (''reportable events'') (29 CFR 4043). PBGC is considering proposing a standard format and electronic filing of section 4010 information and inclusion of additional detail to assist PBGC in evaluating currently reported data. PBGC also is considering proposing to add several new reportable events and eliminate some existing waivers from reporting, in order to provide PBGC better information about events that may threaten plan funding. PBGC regulations also require disclosure of plan funding status to participants (''Participant Notice'') by certain underfunded plans (29 CFR 4011). PBGC is considering proposing that a

more accurate measure of plan liabilities be used for purposes of the Participant Notice.

Summary of Legal Basis:

The PBGC has the authority to issue rules and regulations necessary to carry out the purposes of title IV of ERISA.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Cost estimates are not yet available. However, the PBGC expects that this regulation will not have a material effect on costs.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	
NPRM Comment Period End	12/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

URL For More Information:

www.pbgc.gov/regs

URL For Public Comments:

www.pbgc.gov/regs

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RIN: 1212–AB01

BILLING CODE 7708–01–S

SMALL BUSINESS ADMINISTRATION (SBA)

Statement of Regulatory Priorities

Overview

The Small Business Administration's (SBA) mission is to maintain and strengthen the Nation's economy by enabling the establishment and viability of small businesses and by assisting in economic recovery of communities after disasters. In order to accomplish this mission, SBA focuses on improving the economic environment for small businesses; bridging the competitive opportunity gap facing small business entrepreneurs; and providing financial assistance for the restoration of homes and businesses affected by disasters.

SBA is committed to:

- Working with its financial partners to improve small businesses'access to capital through SBA's loan and venture capital programs;
- Providing technical assistance to small businesses throughits resource partners;
- Increasing contracting and business opportunities forsmall businesses;
- Providing affordable, timely, and easily accessible financialassistance to businesses, homeowners, and renters after a disaster;
- Measuring outcomes, such as revenue growth, job creation,business longevity, and recovery rate after a disaster to ensure that SBA's programs and services are delivered efficiently and effectively.

SBA's regulatory actions reflect the goals and objectives of the Agency and are designed to provide the small business and residential communities with the information and guidance they need to succeed as entrepreneurs and restore their homes or other property after a disaster. All of SBA's rules concern small businesses and programs that promote small businesses. During the coming year, SBA's regulatory priorities will focus on strengthening SBA's management of its programs and services, increasing subcontracting opportunities for small businesses, facilitating their involvement in innovative manufacturing, modernizing the Small Business Technology Transfer Program, and strengthening the management of the Small Business Lending Company Program.

SBA

PROPOSED RULE STAGE

146. SMALL BUSINESS LENDING COMPANIES REGULATIONS

Priority:

Other Significant

Legal Authority:

15 USC 634(b)(6); 15 USC 636(a); 15 USC 636(b)

CFR Citation:

13 CFR 120.470

Legal Deadline:

None

Abstract:

This rulemaking would amend 13 CFR 120.470 to clarify and strengthen the rules regarding Small Business Lending Companies (SBLCs) monitoring and oversight for safety and soundness, compliance, and related areas.

Statement of Need:

Section 7(a) of the Small Business Act states that the Small Business Administration (SBA) may provide financing to small businesses ''directly or in cooperation with banks or other financial institutions.'' Presently, SBA guarantees loans through approximately 7,000 lenders. Of these lenders, about 14 are Small Business Lending Companies (SBLCs) that are not otherwise regulated by Federal or State chartering, licensing, or similar regulatory control. SBA examines or audits these SBLCs periodically. Congressional and Administration policy to privatize SBA lending and levels in loan volume require that SBA increase its SBLC oversight. To that end, SBA will draft regulations that strengthen the Agency's management of the SBLC Program.

Summary of Legal Basis:

Not required by statute or court order.

Alternatives:

This rulemaking amends and expands SBA's existing regulations on the SBLC Program.

Anticipated Cost and Benefits:

This rulemaking is designed to strengthen SBA's regulations regarding the SBLC Program. Some additional costs associated with additional reporting by the SBLCs to the SBA is anticipated.

Risks:

This regulation poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

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SBA

147. ● PROPOSED SMALL BUSINESS INNOVATION RESEARCH (SBIR) POLICY DIRECTIVE

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 638(j)(1)

CFR Citation:

None

Legal Deadline:

None

Abstract:

This proposed policy directive incorporates Executive Order 13329 ''Encouraging Innovation in Manufacturing,'' issued February 24, 2004, and its requirements into SBA's current SBIR Policy Directive.

Statement of Need:

On February 24, 2004, the President signed Executive Order 13329 ''Encouraging Innovation in Manufacturing.'' The purpose of the Executive order is to ensure that Federal Government agencies and

departments properly and effectively assist the private sector in its manufacturing innovation efforts including through the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs. Specifically, the Small Business Administration (SBA) is required to: 1) Establish, after consultation with the Director of the Office and Science and Technology Policy, formats and schedules for submission of reports by the heads of departments and agencies; 2) issue to departments and agencies guidelines and directives (in addition to the formats and schedules) as the Administrator determines from time to time are necessary to implement the Executive order, after such guidelines and directives are submitted to the President, through the Director of the Office of Science and Technology Policy, for approval and are approved by the President. In addition, the heads of the agencies and departments with one or more SBIR or STTR programs are required: 1) To the extent permitted by law and in a manner consistent with the mission of that department or agency, to give high priority within such programs to manufacturing-related research and development to advance innovation including innovation in manufacturing and 2) to submit reports annually to the Administrator of the SBA and the Director of the Office of Science and Technology Policy concerning the efforts of such departments or agencies in implementing this order.

Summary of Legal Basis:

In 1982, Congress enacted the Small Business Innovation Development Act of 1982 (SBIDA), Public Law 97-219 (codified at 15 U.S.C. 638), which established the Small Business Innovation Research Program (SBIR Program). SBIDA requires the SBA to ''issue Policy Directives for the general conduct of the SBIR programs within the Federal Government.'' (15 U.S.C. 638(j)(1)) In December of 2000, Congress enacted the Small Business Innovation Research Program Reauthorization Act of 2000 (Reauthorization Act), Public Law 106-554. The Reauthorization Act extends the SBIR Program through September 30, 2008. SBA published its first Policy Directive, Policy Directive No. 65-01, 22 years ago (47 FR 52966, November 24, 1982). The last SBIR Policy Directive amendments were published 2 years ago (67 FR 60072-60098, September 24, 2002).

Alternatives:

There are no practical alternatives that accomplish the objectives established by Executive Order 13329. An alternative to amending the SBIR and STTR Policy Directives that was considered was to issue a Special Policy Information Notice (SPIN) to the participating SBIR and STTR agencies and departments. SPINs have been used in the past in order to provide clarifying guidance on existing definitions or policy matters to the participating SBIR and STTR agencies and departments. As Executive Order 13329 was a new Presidential initiative, a SPIN was not deemed the appropriate medium for providing guidance to the participants. Amending the Policy Directives was identified as the method for effective implementation of Executive Order 13329.

Anticipated Cost and Benefits:

This Policy Directive does not impose any new substantive costs to small businesses. Further, implementing the Executive Order does not impose any substantive cost to the Federal Government. Instead, implementing this Executive Order ensures that the Federal agencies and departments are assisting the private sector in its manufacturing innovation efforts.

Risks:

The amendments to the SBIR and STTR Policy Directives and the implementation of Executive Order 13329 pose no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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SBA

FINAL RULE STAGE

148. SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM POLICY DIRECTIVE

Priority:

Other Significant

Legal Authority:

15 USC 638; PL 107–50

CFR Citation:

None

Legal Deadline:

Final, Statutory, February 15, 2002, Small Business Technology Transfer Program Reauthorization Act of 2001, enacted 10/15/2001, requires publication of policy directive modifications.

Abstract:

This policy directive will incorporate recently enacted statutory requirements. The purpose of the directive is to provide guidance to participating Federal agencies for the general conduct of the Small Business Technology Transfer Program.

Statement of Need:

In 1992, Congress enacted the Small Business Technology Transfer Act of 1992 (STTR Act), Public Law No. 102-564 (codified at 15 U.S.C. 638). The STTR Act established the Small Business Technology Transfer Program (STTR Program) as a pilot program that required Federal agencies with extramural budgets for research or research and development (R/R&D) in excess of $1 billion per fiscal year to enter into funding agreements with small business concerns (SBCs) that engage in a collaborative relationship with a research institution. The purpose of the STTR Program is to stimulate a partnership of ideas and technologies between innovative SBCs and research institutions. The program assists the small business and research communities by developing commercially viable technologies. The STTR Program is a phased process, uniform throughout the Federal Government, of soliciting proposals and awarding funding agreements for R/R&D to meet stated agency needs or missions. The STTR Act requires the U.S. Small Business Administration (SBA) to ''issue a policy directive for the general conduct of the STTR

Programs within the Federal Government.'' (15 U.S.C. 638(p)(1)) SBA published its first STRR Policy Directive in 1993 (58 FR 42607-42620, August 10, 1993). This Policy Directive fulfills SBA's statutory obligation to provide guidance to the participating Federal agencies for the general operation of the STTR Program. Federal agencies participating in the STTR Program (STTR agencies) are obligated to follow the guidance provided by this Policy Directive. Each agency is required to review its rules, policies, and guidance on the STTR Program to ensure consistency with this Policy Directive and to make any necessary changes in accordance with each agency's normal procedures. This is consistent with the statutory authority provided to the SBA concerning the STTR Program.

Summary of Legal Basis:

In 1992, Congress enacted the Small Business Technology Transfer Act of 1992 (STTR Act), Public Law No. 102-564 (codified at 15 U.S.C. 638). Congress has since amended the STTR Act, most recently with the enactment of the Small Business Technology Transfer Program Reauthorization Act of 2001 (Reauthorization Act), Public Law No. 107-50. The Reauthorization Act extends the STTR Program through September 30, 2009, and changed its status from a pilot program to a permanent one.

Alternatives:

There are no alternatives since it is mandated by law to issue a policy directive for the general conduct of the program.

Anticipated Cost and Benefits:

This directive does not impose any new substantive costs to small businesses or to the Federal Government. Instead, the directive ensures that the Federal agencies and departments are assisting the private sector consistent with the directive. The Small Business Technology Transfer Program Reauthorization Act of 2001 benefits small businesses by requiring participating agencies to increase the amount of their extramural budget to be reserved for the STTR Program from 0.15 percent to 0.3 percent and permits agencies to increase the dollar value of STTR Phase II awards from $500,000 to $750,000.

Risks:

This policy directive poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
Notice of Proposed Policy Directive	06/16/03	68 FR 35748
Comment Period End	07/16/03	
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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SBA

149. SMALL BUSINESS GOVERNMENT CONTRACTING PROGRAMS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

15 USC 634(b)(6); 15 USC 637; 15 USC 644; 31 USC 9701; 31 USC 9702

CFR Citation:

13 CFR 125

Legal Deadline:

None

Abstract:

The U.S. Small Business Administration (SBA) proposes to amend its regulation governing small business subcontracting assistance. As proposed, the rule would implement additional subcontracting goals required by statute, clarify prime contractor responsibilities in providing subcontracting opportunities for small businesses, and provide additional guidance on evaluating the good faith efforts of large businesses to comply with subcontracting plans.

Statement of Need:

On January 31, 2003, SBA published a proposed rule in the Federal Register, 67 FR 47244, to solicit comments on its proposal to implement several recommendations included in the Office of Management and Budget's October 2002 report entitled ''Contract Bundling: A Strategy for Increasing Federal Contracting Opportunities for Small Business.'' Several of the commenters identified the need for additional guidance on evaluating large prime contractor performance and their efforts to achieve subcontracting plan goals for small business participation, including examples of what constitute ''good-faith'' efforts to comply with subcontracting plans. SBA accepted these comments and, in addition to the Final Bundling Rule published on October 20, 2003, published a proposed rule on that date addressing the major issues in subcontracting. In addition to providing guidance on evaluating large prime contractor performance and good-faith efforts, the proposed rule also authorized the use of goals in subcontracting plans, and/or past performance in meeting such goals, as a factor in source selection when placing orders against Federal Supply Schedules, Governmentwide acquisition contracts, and multi-agency contracts; implemented statutory provisions and other administrative procedures relating to subcontracting goals and assistance; listed the various categories of small businesses that must be afforded maximum practicable subcontracting opportunities; and clarified the responsibilities of prime contractors and SBA's Commercial Market Representatives (CMRs) under the subcontracting assistance program.

Summary of Legal Basis:

The subcontracting assistance program described in this rule is authorized by section 8(d) of the Small Business Act. The new regulatory provisions incorporated into SBA's regulations at 13 CFR 125.3 by means of this rule are intended to strengthen SBA's implementation of the statute and to respond to the President's agenda for small business.

Alternatives:

The alternatives to this rule considered are: (a) To work with the Federal Acquisition Regulation (FAR) Council to strengthen the coverage in 48 CFR, subpart 19.7, and the related FAR clauses or (b) leave the existing coverage in 13 and 48 CFR unchanged. The first of these alternatives has been attempted in the past and has proven to be a lengthy process, difficult to implement, and the second is unacceptable because SBA would have to publish Fact Sheets, Standard Operating Procedures, and Best Practice Guides, which do not carry the same weight or authority as a regulation and

would not, therefore, be as effective in strengthening the program.

Anticipated Cost and Benefits:

This rule does not impose any new substantive responsibilities, nor does it require any new reporting or recordkeeping requirements on small business. Instead, this proposed rule clarifies the existing statutory responsibilities under the subcontracting assistance program, including the responsibilities of prime contractors to maximize small business subcontracting opportunities. It also provides guidance to Government officials in monitoring and determining the achievements of subcontracting goals. In fiscal year 2002, the most recent year for which the Government has reliable subcontracting data, small business received approximately $34.4 billion in subcontract awards representing more than 35 percent of all subcontract dollars. As a result of this regulation, subcontracting opportunities in the year(s) following publication of the Final Rule.

Risks:

This regulation poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	10/20/03	68 FR 60015
NPRM Comment Period End	12/19/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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BILLING CODE 8025–01–S

SOCIAL SECURITY ADMINISTRATION (SSA)

Statement of Regulatory Priorities

The Social Security Administration (SSA) administers the retirement, survivors, and disability insurance programs under title II of the Social Security Act (the Act) and the Supplemental Security Income (SSI) program under title XVI of the Act. As directed by Congress, we also assist in administering portions of the Medicare program. Our regulations codify the requirements for eligibility and entitlement to benefits under the programs that we administer. Generally, SSA's regulations do not impose burdens on the private sector or on State or local governments.

Our 19 entries for the Regulatory Plan represent areas of major importance to the administration of the retirement, survivors, disability, SSI, and Medicare benefit programs. Each individual initiative is described more fully after this Statement of Regulatory Priorities. Several of these regulatory priorities reflect the provisions of two major laws that were recently enacted—the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173) and the Social Security Protection Act of 2004 (Pub. L. 108-203).

Serve the Public

Providing the best service possible to the public remains a principal objective of SSA. To that end, we have included in the Plan three initiatives to improve public service.

We plan to revise our regulations to permit an Administrative Law Judge to incorporate into the written decision, when wholly favorable, the findings and reasons stated orally at a hearing, if they remain applicable. We believe this revision may reduce the time needed to issue wholly favorable decisions after a hearing.

We are including a proposed rule that would describe additional safeguards against inappropriate disclosure of personal information and set out special procedures concerning access to medical records.

Furthermore, we are including another proposed rule that would, among other changes, revise our privacy and disclosure rules to further preserve the anonymity and protect the physical well being of employees who are threatened by others.

Improve the Disability Process

As the continued improvement of the disability program is an area of vital interest to SSA, we have included in the Plan seven initiatives that address disability.

Two initiatives would update the medical listings used to determine disability: a final rule on neoplastic diseases and a proposed rule on immune system disorders. The revisions will ensure that the listings reflect advances in medical knowledge, treatment, and methods of evaluating these impairments.

A final rule will provide for continued benefit payments to certain individuals who recover medically while participating in certain vocational rehabilitation programs.

A proposed rule would revise several areas of our regulations on the Ticket to Work program to improve the support of disabled individuals who want and need assistance to return to the workforce.

Another proposed rule would establish time limits and other criteria for individuals receiving disability benefits who wish to initiate plans to achieve self-support.

A proposed rule would explain the standards we use to evaluate the work activity of an individual receiving disability benefits, and when we will conduct a continuing disability review.

Another proposed rule would, among other changes, require us to issue a receipt when an individual receiving disability benefits reports a change in work activity or earnings. This rule would also include home schooling as a form of regular school attendance for purposes of the Student Earned Income Exclusion. This rule reflects provisions of the Social Security Protection Act of 2004.

Improve Stewardship

SSA bears a responsibility to ensure we are effective stewards of the public trust placed in us. We are including in the Plan several regulatory initiatives designed to strengthen our stewardship and program integrity activities; some also reflect the goal to improve financial performance contained in the President's Management Agenda.

For beneficiaries who are not able to manage their own benefits due to legal incompetence or medical infirmity, we must assure that benefits paid to representatives on their behalf are used properly. We are developing proposed rules that reflect provisions of the Social Security Protection Act of 2004 intended to strengthen our oversight of the representative payee program.

The Debt Collection Improvement Act of 1996, as amended by the Foster Care Independence Act of 1999, provided SSA with new tools for our efforts in collecting debts, including the use of administrative wage garnishment. We are developing a proposed rule on Federal salary offset that will enable us to collect qualifying, delinquent title II and XVI debts owed by former beneficiaries who are currently employed by the Federal government.

One final rule will expand our ability to recover overpayments made in one of our programs from benefits payable under other programs we administer. This final rule reflects a provision of the Social Security Protection Act of 2004.

A proposed rule would prohibit title II benefits to persons fleeing prosecution, custody, or confinement after conviction, and to persons violating probation or parole. This proposed rule reflects a provision of the Social Security Protection Act of 2004.

Another proposed rule would enhance our program integrity efforts by expanding our civil monetary penalties program. Included, among other activities, would be solicitations or mailings by outside individuals or entities that mislead the public into believing that SSA either approves, endorses, or authorizes the solicitations or mailings.

Simplify the SSI Program

SSA is including two rules that would simplify our SSI regulations.

One final rule will modify three areas concerning what we consider as income or resources available to an applicant or recipient. We will no longer consider gifts of clothing as income when we decide whether a person can receive SSI benefits or when we compute the amount of benefits. We will also exclude, from our determination of resources, one automobile if it is used for transportation, without consideration of its value. Finally, we will no longer count household goods and personal effects as resources when we decide whether a person can receive SSI benefits.

A proposed rule would change our rules for deeming of income and resources from a stepparent to an eligible child when the child resides with a stepparent but not the natural or adoptive parent. We believe this change will simplify the rules concerning deeming under these circumstances.

Implement Medicare Legislation

SSA does not have overall responsibility for the Medicare program under title XVIII of the Social Security Act. However, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 directs SSA to assist in administering portions of the Medicare program. We are including in the Plan two proposed rules that would implement the legislation.

First, we propose to include rules concerning Medicare Prescription Drug premium and cost-sharing subsidies (Medicare part D).

Second, we propose rules on reduction of premium subsidies for the Supplementary Medical Insurance Benefit program (Medicare part B).

SSA

PROPOSED RULE STAGE

150. PRIVACY AND DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION (711P)

Priority:

Other Significant

Legal Authority:

5 USC 552; 5 USC 552a; 42 USC 1306(a); 42 USC 902(a)(5)

CFR Citation:

20 CFR 401.30; 20 CFR 401.45; 20 CFR 401.55; 20 CFR 401.150; 20 CFR 401.180

Legal Deadline:

None

Abstract:

We propose to revise our privacy and disclosure rules to:

1. More fully describe the role and function of the Privacy Officer;

2. Describe safeguards against inappropriate disclosure of personal information when individuals request information about themselves by electronic means (e.g., through the Internet);

3. Conform to special procedures on an individual's access to medical records; and

4. Add a new section to grant direct access to a minor's medical records by the minor's parent or legal guardian acting on the minor's behalf.

Statement of Need:

These revised regulations are necessary to:

1. Provide the expanded regulatory support for the existing responsibilities and functions of the Privacy Officer as required by the Privacy Act and related Office of Management and Budget (OMB) guidelines;

2. Articulate the safeguards that ensure the appropriate procedures for access to and disclosure of personally identifiable information in the electronic environment;

3. Conform the regulations to our practice and systems of records, which set out special procedures under which individuals whose medical records may potentially present an adverse effect may have access to this information; and

4. Conform to the special procedures in our systems of records for access to medical records.

Summary of Legal Basis:

Revisions are needed to incorporate into the regulations special procedures for providing individuals access to their medical records to ensure the ultimate disclosure of the records to the requesting individual, as set out in our systems of records.

Alternatives:

None.

Anticipated Cost and Benefits:

1. Revised role of Privacy Officer:

Cost - To be determined.

Benefit - Increased public awareness of the privacy officer's role and responsibility in protecting the privacy and disclosure of the information SSA collects and maintains; general oversight to the Agency on privacy and disclosure activities.

2. Description of safeguards against inappropriate disclosure of personal information by electronic means:

Cost - To be determined.

Benefit - Increase public awareness of the safeguards employed by SSA to maintain the security, confidentiality, and integrity of the information we collect and maintain.

3. Conform to special procedures on an individual's access to medical records; and

4. Add a new section to grant direct access to a minor's medical records by the minor's parent or legal guardian acting on the minor's behalf:

Cost - To be determined.

Benefit - Regulatory guidelines will facilitate access for individuals whose medical records may have adverse effects.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

151. FEDERAL SALARY OFFSET (WITHHOLDING A PORTION OF A FEDERAL EMPLOYEE'S SALARY TO COLLECT A DELINQUENT DEBT OWED TO THE SOCIAL SECURITY ADMINISTRATION) (721P)

Priority:

Other Significant

Legal Authority:

42 USC 404; 42 USC 405; 42 USC 902; 42 USC 1383; 5 USC 5514

CFR Citation:

20 CFR 422

Legal Deadline:

None

Abstract:

This initiative would enable the Social Security Administration (SSA) to

collect from Federal salaries qualifying, delinquent title II and title XVI overpayment debts, and administrative debts owed by individuals who are currently Federal employees. The debt collection would be accomplished by the partial reduction of the employee's disposable salary.

Statement of Need:

This regulation is required by 5 U.S.C. 5514(b) and by regulations of the Department of the Treasury (Treasury) and the Office of Personnel Management (OPM) in order for SSA to participate in the Federal Salary Offset program. Treasury's regulation is 31 CFR 285.7; OPM's regulation is 5 CFR 550.1104.

Summary of Legal Basis:

SSA's use of the Federal Salary Offset program is authorized by 42 U.S.C. 404(f), 42 U.S.C. 1383(b) and 5 U.S.C. 5514.

Alternatives:

None. SSA must have regulations, approved by OPM, in order to use Federal salary offset to collect debts owed by Federal employees. See 5 U.S.C. 5514(b), 5 CFR 550.1104, and 31 CFR 285.7.

Anticipated Cost and Benefits:

Undetermined at this time.

Risks:

At this time we have not identified any risks associated with the proposal.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	
Final Action	09/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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SSA

152. EXEMPTION OF WORK ACTIVITY AS A BASIS FOR A CONTINUING DISABILITY REVIEW (TICKET TO WORK AND WORK INCENTIVES IMPROVEMENT ACT OF 1999) (725P)

Priority:

Other Significant

Legal Authority:

42 USC 421(m)

CFR Citation:

20 CFR 404.903; 20 CFR 404.1574; 20 CFR 404.1575; 20 CFR 404.1590; 20 CFR 404.1592a; 20 CFR 404.1594; 20 CFR 416.974; 20 CFR 416.990; 20 CFR 416.994; 20 CFR 416.1403

Legal Deadline:

None

Abstract:

We are proposing to amend our regulations to explain how we will implement section 221(m) of the Social Security Act (the Act). We are also proposing to amend our regulation to eliminate the use of the secondary substantial gainful activity amount for evaluating work done by an employee prior to January 2001. Section 221(m) affects our rules for when we will conduct a continuing disability review if a beneficiary works and receives benefits under title II of the Act based on disability. (We interpret this section to include beneficiaries who receive both title II disability benefits and Supplemental Security Income (SSI) payments based on disability.) It also affects the way we evaluate work activity when deciding if a beneficiary has engaged in substantial gainful activity, and affects the standards we use when we determine whether disability continues or ends.

Statement of Need:

This regulation is necessary to clarify how SSA will implement section 221(m) of the Social Security Act, which prohibits starting continuing disability reviews for certain beneficiaries based on work activity, and limits the use of the work activity of certain beneficiaries as evidence that the individual is no longer disabled.

Summary of Legal Basis:

This regulation implements section 221(m) of the Social Security Act, which was added by section 111 of Public Law 106-170.

Alternatives:

None.

Anticipated Cost and Benefits:

Over a five year period, this regulation will result in a net administrative cost of about $10 million and an SSA workyear savings of 420 workyears. The estimates for costs are $165 million in the first five years.

Risks:

At this time we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

153. REVISED MEDICAL CRITERIA FOR EVALUATING IMMUNE SYSTEM DISORDERS (804P)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

We propose to update and revise the rules that we use to evaluate immune system disorders of adults and children who apply for, or receive, disability benefits under title II and Supplemental Security Income (SSI) payments based on disability under title XVI of the Social Security Act (the Act). The rules we plan on revising are sections 14.00 and 114.00 in the Listing of Impairments in appendix 1 to subpart P of part 404 of our regulations (the listings). These listings include such disorders as HIV infection, other Immunoglobulin deficiency syndromes or deficiencies of cell-mediated immunity, System Lupus Erythematosus, Scleroderma, Polymyositis, Inflammatory Arthritis, and other connective tissue disorders.

Statement of Need:

These regulations are necessary to update the listings for evaluating immune system disorders to reflect advances in medical knowledge, treatment, and methods of evaluating these diseases. They ensure the determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that individuals who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

Summary of Legal Basis:

Administrative-not required by statute or court order

Alternatives:

We considered not revising the listings or making only minor technical changes. However, we believe that proposing these revisions is preferable because of the medical advances that have been made in treating and evaluating these types of diseases. The current listings are now over 11 years old. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings do not reflect state-of-art medical knowledge and technology.

Anticipated Cost and Benefits:

We anticipate that if finalized, these proposed rules would result in negligible program and administrative costs.

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	05/09/03	68 FR 24896
ANPRM Comment Period End	07/08/03	
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

154. AMENDMENTS TO THE TICKET TO WORK AND SELF–SUFFICIENCY PROGRAM (967P)

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

42 USC 902(a)(5); 42 USC 1320b–19; PL 106–170, sec 101

CFR Citation:

20 CFR 411.115; 20 CFR 411.125 to 411.140; 20 CFR 411.150 to 411.155; 20 CFR 411.171; 20 CFR 411.350 to 411.375; 20 CFR 411.385 to 411.395; 20 CFR 411.500 to 411.510; 20 CFR 411.525 to 411.565; 20 CFR 411.575 to 411.585

Legal Deadline:

None

Abstract:

These proposed rules are intended to amend the final rules implementing the Ticket to Work and Self-Sufficiency Program under section 1148 of the Social Security Act: to expand beneficiary eligibility to receive tickets under this program; to clarify the rules for assignment of a beneficiaries' ticket to a State vocational rehabilitation (VR) agency; to revise the rules for payment when a beneficiary receives services from both a State VR agency and an employment network (EN); and, consistent with the Commissioner's authority in section 1148(h) of the Act, to revise the rules for milestone and outcome payments to ENs, in order to increase the incentives for providers of employment and other support services to participate in this program.

Statement of Need:

This proposed regulatory action is necessary to respond to our experience and recommendations we have received since we began implementation of the Ticket to Work and Self-Sufficiency Program in February 2002, in order to increase the incentives for providers of employment services, vocational rehabilitation services, and other support services to participate in this program, and to expand the options available to beneficiaries with disabilities to obtain services to assist them to go to work and attain self-sufficiency.

Summary of Legal Basis:

None.

Alternatives:

We considered not revising the current regulations implementing the Ticket to Work program. However, we believe that these revisions to eligibility to receive a ticket, to clarify the rules for assignment of a ticket to a State VR agency, and to amend the rules for paying ENs are necessary to increase participation in the Ticket to Work program by providers of services and by beneficiaries with disabilities, in order to ensure that these beneficiaries can seek the services necessary to obtain and retain employment and reduce their dependency on cash benefit programs.

Anticipated Cost and Benefits:

We anticipated initial costs to increase due to up-front payments to ENs, and potential savings in later years as ENs are encouraged to serve additional beneficiaries and assist them to achieve self-sufficiency and reduce their dependency on cash benefit programs, including the Supplemental Security Income and Social Security Disability Insurance programs.

Risks:

At this time, we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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RIN: 0960–AF89

SSA

155. ELIMINATION OF PARENT–TO–CHILD DEEMING FOR INDIVIDUALS WHO NO LONGER MEET THE DEFINITION OF SPOUSE OF THE NATURAL OR ADOPTIVE PARENT (793P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

Sec 1614(f)(2) of the Social Security Act

CFR Citation:

20 CFR 416.1160; 20 CFR 416.1165; 20 CFR 416.1202; 20 CFR 416.1851

Legal Deadline:

None

Abstract:

We propose to change the Supplemental Security Income (SSI) parent-to-child deeming rules to no longer consider the income and resources of a stepparent when an eligible child resides in the household with a stepparent, but not his or her natural or adoptive parent. We will clarify that a stepparent no longer meets the definition of a ''parent'' when his or her spouse dies or leaves the household. Thus, an eligible child is not subject to deeming from a stepparent unless the child lives with both his or her natural or adoptive parent and the stepparent. We also propose changing the age at which an individual is no longer considered an ineligible child for purposes of deeming from 21 to 22. We believe this change will simplify our rules for both the public and our public contact employees.

Statement of Need:

The U.S. Court of Appeals, Second Circuit, ruled on a case involving a natural parent who abandoned the family home leaving her spouse with sole physical custody of an eligible child. Social Security Acquiescence Ruling 99-1(2) currently applies the Court's decision to the States of Connecticut, Vermont, and New York. The proposed rules will set uniform national policy with respect to this issue. Further, changing the definition of ''ineligible child'' for purposes of deeming will make uniform all regulatory definitions of ''child'' for SSI purposes. This will simplify our rules, making them less cumbersome to administer and easier for the public to understand and follow.

Summary of Legal Basis:

None.

Alternatives:

None.

Anticipated Cost and Benefits:

We estimate that the program costs and administrative costs for these regulatory changes would be negligible.

Risks:

These proposed rules will ensure our parent-to-child deeming rules are consistent with respect to our current regulatory definition of ''parent'' and ''child.'' Policy will uniformly be set nationwide and will make our rules less difficult for the public to understand.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	
Final Action	09/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Related to 0960–AF24

RIN: 0960–AF96

SSA

156. RULES FOR HELPING BLIND AND DISABLED INDIVIDUALS ACHIEVE SELF–SUPPORT (506P)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 1381a; 42 USC 1382; 42 USC 1382a; 42 USC 1382b; 42 USC 1382c(f); 42 USC 1382j; 42 USC 1383; 42 USC 1382 note

CFR Citation:

20 CFR 416.1180; 20 CFR 416.1181; 20 CFR 416.1226

Legal Deadline:

None

Abstract:

We are proposing to amend our regulations to explain how we implement section 203 of the Social Security Independence and Program Improvements Act of 1994 (Pub. L. 103-296). Section 203 of this law amended section 1633 of the Social Security Act

to require us to establish by regulations criteria for time limits and other criteria related to plans to achieve self-support (PASS). The law requires that the time limits take into account the length of time that a person needs to achieve his or her occupational goal, within a reasonable period, and other factors as determined by the Commissioner to be appropriate.

Statement of Need:

This regulation is necessary to implement the changes in section 1633 of the Social Security Act regarding time limits and other criteria deemed necessary by the Commissioner.

Summary of Legal Basis:

42 U.S.C. 1383b authorizes the Commissioner to promulgate regulations for the purpose of establishing criteria for time-limits and other criteria deemed necessary related to the PASS program.

Alternatives:

None.

Anticipated Cost and Benefits:

We estimate that the administrative impact would be negligible.

Risks:

At this time we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Previously reported as 0960–AE17

RIN: 0960–AG00

SSA

157. MEDICARE PRESCRIPTION DRUG PREMIUM AND COST–SHARING (1024P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

PL 108–173; 42 USC 405

CFR Citation:

None

Legal Deadline:

None

Abstract:

We propose to add to our regulations, a new part 418 that would contain our rules applicable to claims for premium and cost-sharing subsidies under Medicare and to include a new subpart D, Medicare part D Subsidies. These rules would describe: how we determine whether an individual is eligible for premium and cost-sharing subsidies; how we determine subsidy eligibility; how we redetermine subsidy eligibility; the subsidy application process; when eligibility for premium and cost-sharing subsidies terminates; reporting requirements; and how individuals may appeal a determination we make under the part D subsidy Program.

Statement of Need:

SSA is responsible for determining premium and cost-sharing subsidy eligibility for the new Medicare Prescription Drug Benefit. The provision will be implemented in January 2007.

Summary of Legal Basis:

Section 1860D-14 of the Social Security Act provides for premium and cost-sharing subsidies for certain low-income individuals, and directs the Social Security Administration to develop a simplified application process.

Alternatives:

None.

Anticipated Cost and Benefits:

The Centers for Medicare and Medicaid Services (CMS) has developed detailed cost estimates for implementation of the Prescription Drug Benefits program. These costs are explained in a CMS Notice of Proposed Rulemaking (CMS-4068P; 69 FR 46632; 08/03/2004). SSA administrative costs are not yet known. The benefit of developing agency regulations for a simplified subsidy application are that many beneficiaries with incomes below 150 percent of the poverty level, and limited resources, will be able to get help with paying premiums and cost-sharing for Medicare part D coverage.

Risks:

There are inherent risks in any form of public benefit which requires means-testing. The risks for the prescription drug benefit premium and cost-sharing subsidy program are increased by the requirement that SSA use a simplified application process.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	
Final Action	09/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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RIN: 0960–AG03

SSA

158. ● CIVIL MONETARY PENALTIES, ASSESSMENTS, AND RECOMMENDED EXCLUSIONS (2362P)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 1320a–8; 42 USC 1320b–10

CFR Citation:

20 CFR 498.100 TO 498.104; 20 CFR 498.106; 20 CFR 498.109; 20 CFR 498.114; 20 CFR 498.128

Legal Deadline:

None

Abstract:

The mission of the Social Security Administration, Office of the Inspector General (SSA/OIG), is to protect SSA programs and operations from fraud, waste, and abuse. Critical to this mission is ensuring that SSA provide Social Security benefits in the correct amount to those who meet the applicable requirements. Therefore, anyone who makes a false statement of material fact to obtain or retain benefits to which they are not entitled adversely impacts both SSA programs and the mission of the OIG to protect those programs. Also critical to SSA's operations is the relationship of trust that it has established with citizens of this country; particularly the elderly and/or disabled individuals for who Social Security is vital to their continued existence. Therefore, it is imperative that outside individuals/entities not abuse or damage that trust by using certain words associated with SSA in any solicitation/mailing in such a way to mislead the public into believing that SSA either approves, endorses, or authorizes such solicitation/mailing. The Social Security Act provides authority to impose civil monetary penalties and assessments against anyone who knowingly submits a false statement of material fact to SSA to obtain or retain benefits to which they are not entitled and civil monetary penalties against any individual or organization who misleads the public into believing that they are affiliated with or approved or endorsed by SSA by utilizing SSA's symbols and program words. Congress determined that expansion of the civil monetary penalty authority was needed to assure the integrity of SSA's programs and operations. These proposed regulations are required to enhance our program integrity efforts.

Statement of Need:

These proposed regulations, would reflect certain provisions of Public Law 106-169 and 108-203, modify the existing procedures for the imposition of a civil monetary penalty and assessment, as applicable, under sections 1129 of the Social Security Act (42 U.S.C. 1320a-8) by: (1) amending the regulations to reflect the expanded authority under section 1129 to impose a civil monetary penalty and assessment for fraud involved in the receipt of benefits under title VIII of the Social Security Act; and (2) adding as new categories for civil monetary penalty and assessment under section 1129 (i) representative payees with respect to wrongful conversions, and (ii) individuals who withhold the disclosure of material facts to the SSA.

These proposed regulations would also reflect certain provisions of Public Law 108-203 and modify the existing procedures for the imposition of a civil monetary penalty under section 1140 of the Social Security Act (42 U.S.C. 1320b-10) by: (1) requiring an advertiser or direct marketer who offers to assist an individual in obtaining products or services for a fee, that SSA otherwise provides free of charge, to include a written notice on the solicitation/mailing that the product or service is available from SSA free of charge; and (2) expanding the list of terms in section 1140 that encompass the scope of words or phrases that the statute prohibits from being used in a misleading manner.

Summary of Legal Basis:

These proposed regulations would implement section 251(b)(6) of Public Law 106-169 and sections 111, 201, 204 and 207 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

Cost—None.

Benefits—These regulations are required to enhance our program integrity efforts.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0960–AG08

SSA

159. ● REPRESENTATIVE PAYMENT; ADDITIONAL PROTECTIONS FOR PERSONS WITH REPRESENTATIVE PAYEES (2422P)

Priority:

Other Significant

Legal Authority:

42 USC 405(j); 42 USC 1007; 42 USC 1383(a)(2)

CFR Citation:

20 CFR 404.2022; 20 CFR 404.2035; 20 CFR 404.2040(a); 20 CFR 404.2045; 20 CFR 404.2065; 20 CFR 408.622; 20 CFR

408.635; 20 CFR 408.645; 20 CFR 408.665; 20 CFR 416.622; 20 CFR 416.635; 20 CFR 416.640(a); 20 CFR 416.645

Legal Deadline:

None

Abstract:

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries judged incapable of managing or directing someone else to manage their benefits. Congress determined that improvements to the representative payment procedures were needed to assure program integrity. These proposed regulations are required to further our program integrity efforts.

Statement of Need:

These proposed regulations, which reflect certain provisions of Public Law 108-203, would modify existing representative payee procedures by: (1) expanding the scope of disqualification to prohibit an individual from serving as representative payee if he or she is convicted of offenses resulting in imprisonment for more than one year or is fleeing to avoid prosecution, custody, or confinement after conviction; (2) requiring annual certifications from nongovernmental fee for service organizational payees that they are licensed and bonded; (3) requiring a fee for service representative payee to forfeit their fee for the months during which funds were misused; (4) requiring a representative payee to receive benefits in person at a local social security field office if they fail to provide an annual accounting of benefits; and (5) explaining financial requirements for representative payees.

Summary of Legal Basis:

These proposed regulations implement sections 102, 103, 104 and 106 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

Any costs associated with these regulations are reflected in the President's budget as part of legislative implementation. They are required to further our program integrity efforts.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	
Final Action	08/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Organizations

Government Levels Affected:

None

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RIN: 0960–AG09

SSA

160. • ISSUANCE OF WORK REPORT RECEIPTS, PAYMENT OF TRIAL WORK PERIOD MONTHS AFTER A FRAUD CONVICTION AND CHANGES TO THE STUDENT EARNED INCOME EXCLUSION (2502P)

Priority:

Other Significant

Legal Authority:

42 USC 402; 42 USC 403; 42 USC 404(a); 42 USC 404(e); 42 USC 405(a) to 405(d); 42 USC 405(h); 42 USC 405 note; 42 USC 416(1); 42 USC 421(a); 42 USC 421(i); 42 USC 421 note ; 42 USC 422(c); 42 USC 423(e); 42 USC 425; 42 USC 902(a); 42 USC 902(5); 42 USC 902 note; 42 USC 1320 a–8a; 42 USC 1320 b–17; 42 USC 1381; 42 USC 1382; 42 USC 1382 note; 42 USC 1383

CFR Citation:

20 CFR 404.401a; 20 CFR 404.471; 20 CFR 404.903; 20 CFR 404.1588; 20 CFR 404.1592; 20 CFR 416.708(c); 20 CFR 416.1112(c)(3); 20 CFR 416.1403; 20 CFR 416.1861

Legal Deadline:

None

Abstract:

We are proposing to amend our rules to carry out sections 202, 208, and 432 of the Social Security Protection Act (SSPA) of 2004. The SSPA provides safeguards to Social Security and Supplemental Security Income (SSI) beneficiaries who have representative payees and enhances program protections. Section 202 of the SSPA requires us to issue a receipt to you each time you report a change in your work activity or give us documentation of a change in your earnings if you receive benefits based on disability under titles II or XVI of the Act. In section 208, benefits for certain months during the trial work period becomes nonpayable if you are convicted by a Federal court of fraudulently concealing work activity. Section 432 changes the way we decide if you are eligible for the Student Earned Income Exclusion. We also propose to change the SSI student policy to include home schooling as a form of regular school attendance.

Statement of Need:

This regulation is necessary to implement the program improvements established in the SSPA. The regulation will improve our service to individual beneficiaries who attempt to work and improve our ability to protect the programs from certain types of fraud.

Summary of Legal Basis:

This regulation implements sections 202, 208, and 432 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

Improved service to beneficiaries and improved protections from fraud for the programs.

Risks:

At this time we have not identified any risks to this proposal.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG10

SSA

161. ● INCOME RELATED MEDICARE PART B PREMIUM SUBSIDY REDUCTION (2101P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

42 USC 405; PL 108–173

CFR Citation:

20 CFR 418 (New)

Legal Deadline:

None

Abstract:

We propose to add to our regulations a new part 418 that would include our rules applicable to reduction of premium subsidies for high income beneficiaries. Section 811 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 amends section 1839 of the Act. Starting in 2007, the new subsection 1839(i) requires that Medicare part B enrollees with high income receive a reduced part B premium subsidy. The statute establishes four income range ''notches'' above a threshold, and prescribes a percentage adjustment of premiums for each notch. As income increases, the premium subsidy decreases; in effect, the higher the income, the higher the part B premium. All beneficiaries will continue to receive some part B premium subsidy. The income threshold in 2007 is $80,000 ($160,000 for an individual who files a joint income tax return). The premium adjustments will be phased in over a five year period between 2007 and 2011. After 2007, the threshold amount and all of the notch amounts will be annually adjusted for inflation.

Statement of Need:

Regulations required by statute.

Summary of Legal Basis:

Section 1839(i) of the Social Security Act.

Alternatives:

None. The Social Security Act directs the Commissioner to establish regulations to implement this provision. The statute requires the Commissioner to establish regulations regarding temporary use of tax year data from a year other than the year ordinarily used to determine premium adjustments, establishment of premiums for Medicare part B enrollees who do not file income taxes, and specification of ''life-changing events'' that meet the standard for use of more recent tax year data.

Anticipated Cost and Benefits:

The Income Related Medicare part B premium adjustment was established to produce Federal savings in the Medicare program. The Congressional Budget Office estimates that this provision will produce $13.3 billion in savings between 2007 and 2013. SSA will have administrative costs in implementing the provision, which have been considered in the savings estimates.

Risks:

None identified.

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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RIN: 0960–AG11

SSA

162. ● DENIAL OF TITLE II BENEFITS TO PERSONS FLEEING PROSECUTION, CUSTODY, OR CONFINEMENT, AND TO PERSONS VIOLATING PROBATION OR PAROLE (2222P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

42 USC 402(x)

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

These regulations will propose rules for prohibiting title II benefits to persons fleeing prosecution or custody, or confinement after conviction and to persons violating probation or parole. We will also propose rules for establishing that good cause exists for continuing to pay such benefits.

Statement of Need:

Public Law 108-203, the Social Security Protection Act of 2004, extends the fugitive felon nonpayment provision to title II beneficiaries effective January 2005. It also provides a good cause provision for titles II and XVI. The good cause provision requires the Commissioner to apply good cause if a court finds the person not guilty, charges are dismissed, a warrant for arrest is vacated, there are similar exonerating circumstances identified by the court, or the individual establishes that he or she was the victim of identity fraud and the warrant was issued on such basis. Public Law 108-

203 also gives the Commissioner the discretionary authority to establish good cause based on mitigating factors if the criminal offense is non-violent and not drug-related, and in the case of probation or parole violators, both the violation and the underlying offense are non-violent and not drug-related.

Summary of Legal Basis:

Section 203 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

There are no anticipated costs and benefits resulting from this regulatory action. Any program savings from nonpayment to fugitive felons will be the result of implementing Public Law 108-203.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0960–AG12

SSA

163. ● PRIVACY AND DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION; AVAILABILITY OF INFORMATION AND RECORDS TO THE PUBLIC (2562P)

Priority:

Other Significant

Legal Authority:

5 USC 552; 5 USC 552a; 42 USC 1306(a); 42 USC 902(a)(5)

CFR Citation:

20 CFR 401 app A(c)(4); 20 CFR 402.45(e)

Legal Deadline:

None

Abstract:

We propose to revise our privacy and disclosure rules to:

1. Add a new section to set out detailed procedures to further preserve the anonymity and protect the physical well-being of employees in abusive relationships or who fear for their physical well-being because of threats from others.

2. Conform SSA's Freedom of Information Act regulations in this respect more closely to Office of Personnel Management (OPM) regulations; and

3. Develop procedures for the protection in the electronic environment of personally identifiable information for at-risk employees.

Statement of Need:

The revised regulations are needed to:

1. Set out detailed procedures to ensure uniform application of the policy and equal protection for all at-risk employees;

2. Conform the regulations to our practice and systems of records, which set out guidelines to guard against the inappropriate release of personally identifiable information for at-risk employees; and

3. Describe the safeguards that ensure the appropriate procedures for the protection of personally identifiable information in the electronic environment.

Summary of Legal Basis:

Revisions are needed to incorporate into the regulations detailed procedures for the protection of personally identifiable information for at-risk employees.

Alternatives:

None.

Anticipated Cost and Benefits:

1. Develop uniform procedures for providing protection for all at-risk employees.

Cost—None.

Benefit—Protects the anonymity and physical well-being, as appropriate, of those at-risk employees who fear for their physical safety.

2. Conform the regulations more closely to the OPM regulations.

Cost—None.

Benefit—Regulatory guidelines will allow decision makers to use their own discretion to determine whether release of personally identifiable information would constitute an unwarranted invasion of personal privacy under the Freedom of Information Act, thereby placing employees at risk.

3. Description of safeguards against inappropriate disclosure of personal information by electronic means.

Cost—None.

Benefit—Increase employee awareness of the safeguards employed by SSA to maintain the security, confidentiality, and integrity of the information maintained for the well-being of all employees.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

FINAL RULE STAGE

164. REVISED MEDICAL CRITERIA FOR EVALUATING MALIGNANT NEOPLASTIC DISEASES (399F)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

Sections 13.00 and 113.00 (malignant neoplastic diseases) of appendix 1 to subpart P of part 404 of our regulations (404.1501 through 404.1599) describe those impairments that are considered severe enough to prevent a person from doing any gainful activity, or for a child claiming SSI payments under title XVI, that causes marked and severe functional limitations. We are revising these sections to ensure that the medical evaluation criteria are up-to-date and consistent with the latest advances in medical knowledge and treatment. The Supplemental Security Income program incorporates and uses the same medical criteria as the Old-Age, Survivors, and Disability Insurance program.

Statement of Need:

These regulations are necessary to update the listings for evaluating malignant neoplastic diseases to reflect advances in medical knowledge, treatment and methods of evaluating these diseases. They ensure that determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that individuals who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

Summary of Legal Basis:

Administrative-not required by statute or court order.

Alternatives:

In the NPRM, We proposed changes to the childhood listings for malignant solid tumors and neuroblastoma. As we reviewed our proposed changes in response to public comments, we realized that we need to further consider how to include these disorders in our listings. In the interim, we have decided to retain our current criteria for malignant solid tumors in children and neuroblastoma.

We also considered continuing to use current rules for malignant neoplastic diseases. However, we believe that proposing these revisions is preferable because of the medical advances that have been made in treating and evaluating these types of diseases. The current listings are now over 15 years old. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings do not reflect state-of-the-art medical knowledge and technology.

Anticipated Cost and Benefits:

1. Title II

We estimate that, if finalized, these proposed rules would result in increased program outlays (in millions of dollars) to the title II program ($18 million total in a 10-year period beginning in fiscal year 2004).

2. Title XVI

We estimate that, if finalized, these proposed rules will result in reduced program outlays resulting in the following program savings (in the millions of dollars) to the SSI program ($4 million total in a 10-year period beginning in fiscal year 2004). (Note: Totals may not be equal to the sum of the annual totals due to rounding-out.)

(Note: Federal SSI payments due on October 1st in fiscal years 2006, 2007, and 2012 are included with payments for the prior fiscal year.)

Administrative Savings-

We do not expect any administrative savings to result from these proposed regulations.

Administrative Costs-

We expect, if finalized, there will be some administrative costs associated with these proposed rules. If finalized, the proposed rules are expected to result in administrative costs less than 25 work years and less than $2 million per year.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/27/01	66 FR 59305
NPRM Comment Period End	01/28/02	
NPRM Comment Period End Extended	04/18/02	67 FR 19138
Final Action	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

165. ELIMINATION OF CLOTHING FROM THE DEFINITIONS OF INCOME AND IN–KIND SUPPORT AND MAINTENANCE, EXCLUSIONS OF ONE AUTOMOBILE, AND HOUSEHOLD GOODS AND PERSONAL EFFECTS UNDER SSI FROM RESOURCES (950F)

Priority:

Other Significant

Legal Authority:

Sec 1612 of the Social Security Act; Sec 1613(a)(2)(A) of the Social Security Act

CFR Citation:

20 CFR 416.1102 to 416.1104; 20 CFR 416.1121; 20 CFR 416.1124; 20 CFR 416.1130; 20 CFR 416.1133; 20 CFR 416.1140; 20 CFR 416.1142; 20 CFR 416.1144 to 416.1145; 20 CFR 416.1147 to 416.1149; 20 CFR 416.1157; 20 CFR 416.1210; 20 CFR 416.1216; 20 CFR 416.1218

Legal Deadline:

None

Abstract:

We will make the following changes to our rules on determining income and resources under the Supplemental Security Income (SSI) program.

1. We will remove clothing from the definition of income and from the definition of in-kind support and maintenance. As a result, we generally will not count gifts of clothing as income when we decide whether a person can receive SSI benefits or when we compute the amount of benefits.

2. We will simplify our rules on how we exclude an automobile in determining the resources of a SSI applicant or recipient. Specifically, we will exclude one automobile from resources if it is used for transportation, without consideration of its value.

3. We will change our resources counting rules in the SSI program by eliminating the dollar value limit for the exclusion of household goods and personal effects. As a result, we would not count household goods and personal effects as resources when we decide whether a person can receive SSI benefits.

Statement of Need:

These changes will simplify our rules, making them less cumbersome to administer and easier for the public to understand and follow, thereby reducing the potential for payment errors. These changes also will make SSI financial eligibility rules more consistent with those of other means-tested Federal programs. The changes also will eliminate the need to ask claimants, beneficiaries, and other members of their households certain questions that have been viewed as intrusive. By no longer counting gifts of clothing as income, we will remove a disincentive for family members to help needy relatives.

Summary of Legal Basis:

None.

Alternatives:

Clothing –

None.

Automobile –

We considered revising the regulations to provide that SSA will assume that the recipient's automobile meets the use requirements for total exclusion of one automobile, absent evidence to the contrary. We did not select this option because it would not change the rule but only how we apply it. It does not go far enough in simplifying the SSI program. By revising the use requirements to exclude a car if it is used for transportation, thus replacing the four present specific transportation exclusion criteria, we will simplify the process.

We considered excluding the value of one automobile, regardless of use. We did not select this option because it would allow for the routine exclusion of an automobile even if it were not used for transportation. Such an approach would exclude an inoperable vehicle, a vehicle not being used at all, or a vehicle only used for recreation (such as a dune buggy). We maintain that it is unreasonable to exclude from resources the value of a vehicle that is not used for transportation.

We also considered increasing the excludable value of an automobile not meeting the use test to $11,000. We did not select this option because it would not simplify the SSI program.

Household Goods and Personal Effects –

Instead of excluding the entire value of household goods and personal effects, we considered raising the excludable limit to $10,000 from the current level of $2,000. We decided not to pursue this option because it would not provide any policy simplification. It would increase the amount excluded but it would not eliminate the need for the current time-consuming and complex procedures for determining the market value of an individual's household goods and personal effects.

Anticipated Cost and Benefits:

We estimate that the program costs and administrative costs for these regulatory changes would be negligible.

The proposed rules will simplify the administrative process of valuing noncash items. The change to the household goods and personal effects exclusion would simplify our rules and improve work efficiency by eliminating the need to inventory an individual's household goods and personal effects and determine their current market value. The changes will also serve to make our rules less intrusive and more protective of the dignity of individuals seeking SSI benefits.

Risks:

These changes will simplify complex SSI rules without disadvantaging SSI applicants or recipients or significantly increasing program or administrative costs.

Clothing –

There are no significant concerns.

Automobile –

Our experience shows that most SSI beneficiaries do not own expensive cars. Still, it is possible that a beneficiary may, under our proposal, own an automobile that is used for transportation (and therefore excluded) and that is worth a considerable amount of money.Household Goods and Personal Effects –

Under the proposed change to the household goods and personal effects exclusion, we would continue to recognize that individuals applying for SSI may own items that have investment value and which may be quite valuable. Such items as gems, jewelry, and collectibles would still be considered countable resources and subject to the SSI resource limit. Thus, the proposed exclusion for household goods and personal effects would not create an unintended exclusion for items that have investment value.

Timetable:

Action	Date	FR Cite
NPRM	01/06/04	69 FR 554
NPRM Comment Period End	03/08/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

166. CONTINUATION OF BENEFIT PAYMENTS TO CERTAIN INDIVIDUALS WHO ARE PARTICIPATING IN A PROGRAM OF VOCATIONAL REHABILITATION SERVICES, EMPLOYMENT SERVICES, OR OTHER SUPPORT SERVICES (925F)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 425(b); 42 USC 1383(a)(6)

CFR Citation:

20 CFR 404.316; 20 CFR 404.327 (New); 20 CFR 404.328 (New); 20 CFR 404.337;

20 CFR 404.352; 20 CFR 404.902; 20 CFR 404.1586; 20 CFR 404.1596; 20 CFR 404.1597; 20 CFR 416.1320; 20 CFR 416.1331; 20 CFR 416.1338; 20 CFR 416.1402

Legal Deadline:

None

Abstract:

These final rules revise the regulations that provide for the continuation of benefit payments to certain individuals who recover medically while participating in a vocational rehabilitation program with a State vocational rehabilitation agency. We are revising these regulations because of statutory amendments, which extend eligibility for these continued benefit payments to certain individuals who recover medically while participating in another appropriate program of vocational rehabilitation services. These include individuals participating in the Ticket to Work and Self-Sufficiency Program or another program of vocational rehabilitation services, employment services, or other support services approved by the Commissioner of Social Security.

Prior to November 1991, the Social Security Act provided for the continuation of payment of Social Security Disability Insurance and Supplemental Security Income disability and blindness benefits to individuals whose disability or blindness ended for medical reasons while they were participating in an approved State vocational rehabilitation program under title I of the Rehabilitation Act of 1973, if the Commissioner of Social Security determined that completion or continuation of the program would increase the likelihood of the individual's permanent removal from the disability benefit rolls. The Omnibus Budget Reconciliation Act of 1987 extended eligibility for continued benefits to individuals who receive Supplemental Security Income benefits based on blindness. (We implemented this change by issuing operating instructions effective April 1, 1988, the effective date of the amendment.) The Omnibus Budget Reconciliation Act of 1990 extended eligibility for continued benefits to individuals participating in an approved non-State vocational rehabilitation program at the time their disability ended. (We implemented this change by issuing operating instructions effective November 1991, the effective date of the amendments.) The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 requires the redetermination of eligibility based on disability of individuals who attain age 18, based on the rules for determining initial eligibility for adults. These redeterminations are not continuing disability reviews, however, we are revising our regulations to provide that an individual whose disability has ended as a result of an age-18 redetermination may qualify for continued benefits based on participation in an approved program and increased likelihood of permanent removal from the disability rolls, if the individual meets all other requirements for continued benefits. The Ticket to Work and Work Incentives Improvement Act of 1999 authorizes continued benefits for a person who medically recovers while participating in a program consisting of the Ticket to Work program or another program of vocational rehabilitation services, employment services, or other support services approved by the Commissioner of Social Security, provided that the other requirements for benefit continuation are met.

These final rules will also explain what we mean by ''an appropriate program of vocational rehabilitation services, employment services, or other support services.'' They will explain when an individual will be considered to be ''participating'' in the program. They will explain how we will determine whether an individual's completion of or continuation in an appropriate program of vocational rehabilitation services, employment services, or other support services will increase the likelihood that the individual will not have to return to the disability rolls. They will also explain that, for students age 18 through 21, ''an appropriate program of vocational rehabilitation services, employment services, or other support services'' includes an individualized education plan developed under policies and procedures approved by the Secretary of Education for assistance to States for the education of children under the Individuals with Disabilities Education Act, as amended.

Statement of Need:

These final regulations are necessary to conform our regulations to amendments enacted in the Ticket to Work and Work Incentives Improvement Act of 1999, as well as the amendments enacted in the Omnibus Budget Reconciliation Act of 1990 and the Omnibus Budget Reconciliation Act of 1987; and as the result of a provision enacted in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Summary of Legal Basis:

None.

Alternatives:

None.

Anticipated Cost and Benefits:

For the five-year period from fiscal year *2004 through 2008, the estimated effects on Federal Supplemental Security Income payments for increased payments for children range from $4 million in fiscal year 2004 to $46 million in fiscal year 2008. The estimated impact on the Federal share of Medicaid payments during this five-year period range from $3 million in fiscal year 2004 to $41 million in fiscal year 2008.

*Updated estimates for the five-year period from fiscal 2005 through 2009, are pending.

Risks:

At this time, we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	08/01/03	68 FR 45180
NPRM Comment Period End	09/30/03	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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SSA

167. ADMINISTRATIVE REVIEW PROCESS; INCORPORATION BY REFERENCE OF ORAL FINDINGS OF FACT AND RATIONALE IN WHOLLY FAVORABLE WRITTEN DECISIONS (964I)

Priority:

Other Significant

Legal Authority:

42 USC 405(a); 42 USC 405(b); 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.953; 20 CFR 416.1453

Legal Deadline:

None

Abstract:

These interim final rules revise our regulations to provide that if an Administrative Law Judge (ALJ) enters a wholly favorable, oral decision into the record of a hearing, the ALJ may subsequently issue a written decision that gives the findings and reasons for the decision by incorporating by reference the findings and reasons stated orally at the hearing, provided that the ALJ does not determine subsequent to the hearing that the oral findings and reasons should be changed.

Statement of Need:

In fiscal year 2002, we announced a number of short-term actions to reduce delays in processing requests for ALJ hearings. One of these actions was to allow ALJs to issue oral decisions from the bench at the close of the hearing. We have found that ALJs are not frequently issuing oral decisions from the bench because of the duplication of work involved in issuing the oral decision and then subsequently issuing a written decision that fulfills existing provisions of our regulations requiring ALJs to issue written decisions that give the findings of fact and the reasons for the decision. We believe we can make it easier to use the bench decision procedure to reduce the time required to issue wholly favorable decisions by amending our regulations to explicitly authorize ALJs to issue wholly favorable written decisions that incorporate by reference the findings and rational stated orally in a bench decision.

Summary of Legal Basis:

None.

Alternatives:

Interpret our existing regulations to allow ALJs to issue written, wholly favorable decisions that give the findings of fact and rationale for the decision by incorporating by reference the findings and rationale stated in an oral decision that the ALJ entered into the record at the hearing.

Anticipated Cost and Benefits:

Improved public service by facilitating use of the oral decision procedure to reduce the time required to issue wholly favorable decisions.

The administrative savings resulting from these interim final rules have been determined to be negligible (i.e., less than $2 million or 25 workyears).

Risks:

None.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/20/04	69 FR 61594
Interim Final Rule Comment Period End	12/20/04	
Final Action	04/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

168. • EXPANDED AUTHORITY FOR CROSS–PROGRAM RECOVERY OF BENEFIT OVERPAYMENTS (2221F)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 404; 42 USC 405(a); 42 USC 902(a); 42 USC 1008; 42 USC 1010(a); 42 USC 1320b–17; 42 USC 1383(b); 42 USC 1383(d)

CFR Citation:

20 CFR 404.530; 20 CFR 404.535; 20 CFR 404.540; 20 CFR 404.545; 20 CFR 408.930; 20 CFR 408.931; 20 CFR 408.932; 20 CFR 408.933; 20 CFR 416.570; 20 CFR 416.572; 20 CFR 416.573; 20 CFR 416.574; 20 CFR 416.575

Legal Deadline:

None

Abstract:

To implement section 210 of the Social Security Protection Act (SSPA) of 2004 (Pub. L. 108-203, enacted on March 2, 2004), we will revise our regulations on the recovery of overpayments incurred under one of our programs from benefits payable to the overpaid individual under other programs we administer. Provisions of the SSPA expand the authority for cross-program recovery of overpayments made in our various programs. These programs are Social Security benefits under title II of the Social Security Act (the Act), Special Veterans Benefits under title VIII of the Act and Supplemental Security Income (SSI) benefits under title XVI of the Act. Implementation of these regulatory revisions when they become effective will yield significant program savings.

Section 210 of the SSPA repealed 42 USC 1320b-18 and cross-program recovery provisions in 42 USC 1008 and amended 42 USC 1320b-17 of the Act. It allows recovery from monthly benefits generally at a rate not to exceed 10 percent of the monthly benefit and unlimited withholding of past-due benefits in one program to recover an overpayment paid under another program. It also allows for cross-program recovery even if the individual is entitled under the program in which the overpayment was made.

Statement of Need:

These revisions of our regulations are needed to implement section 210 of the Social Security Protection Act (SSPA) of 2004.

Summary of Legal Basis:

These regulations implement section 210 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

We anticipate significant program savings (approximately $150 million over 5 years) because these final rules, will allow the Agency to recover more overpaid funds, and to recover them more quickly, than it could under prior statutory authority. The net administrative impact estimate is pending. Decisions regarding implementation are not final. However, any administrative impact is attributable to Public Law 108-203 and not to this regulation.

Risks:

This regulation will protect the trust funds and general funds by recovering outstanding overpayments (paid under three titles of the Act) more quickly. It will also reduce the administrative cost of recontacting beneficiaries to attempt to obtain refunds of outstanding overpayments.

Timetable:

Action	Date	FR Cite
NPRM	08/24/04	69 FR 51962
NPRM Comment Period End	09/23/04	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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BILLING CODE 4191–02–S

CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Statement of Regulatory Priorities

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of death and injury associated with consumer products. To achieve this goal, the Commission:

- participates in the development or revision of voluntary product safety standards;
- develops mandatory product safety standards or banning rules when other, less restrictive, efforts are inadequate to address a safety hazard;
- obtains repair, replacement, or refund of the purchase price for defective products that present a substantial product hazard; and
- develops information and education campaigns about the safety of consumer products.

When deciding which of these approaches to take in any specific case, the Commission gathers the best available data about the nature and extent of the hazard presented by the product. The Commission then analyzes this information to determine the best way to reduce the hazard in each case. The Commission's rules require the Commission to consider, among other factors, the following criteria when deciding the level of priority for any particular project:

- frequency and severity of injury;
- causality of injury;
- chronic illness and future injuries;
- costs and benefits of Commission action;
- unforeseen nature of the risk;
- vulnerability of the population at risk;
- probability of exposure to the hazard.

Additionally, if the Commission proposes a mandatory safety standard for a particular product, the Commission is generally required to make statutory cost/benefit findings and adopt the least burdensome requirements that adequately protect the public.

The Commission's statutory authority requires it to rely on voluntary standards rather than mandatory standards whenever a voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury and it is likely that there will be substantial compliance with the voluntary standard. As a result, much of the Commission's work involves cooperative efforts with other participants in the voluntary standard-setting process rather than promulgating mandatory standards.

In fiscal year 2005, the Commission's significant rulemaking activities will involve addressing risks of fire associated with ignition of upholstered furniture and mattresses and bedding.

The emphasis on this rulemaking activity in the Commission's FY 2005 regulatory plan is consistent with the Commission's statutory mandate and its criteria for setting priorities.

CPSC

PROPOSED RULE STAGE

169. FLAMMABILITY STANDARD FOR UPHOLSTERED FURNITURE

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

15 USC 1193, Flammable Fabrics Act; 5 USC 801

CFR Citation:

16 CFR 1640

Legal Deadline:

None

Abstract:

On June 15, 1994, the Commission published an advance notice of proposed rulemaking (ANPRM) to begin a proceeding for development of a flammability standard to address risks of death, injury, and property damage from fires associated with ignition of upholstered furniture by small open-flame sources such as matches, lighters, or candles. CPSC staff conducted research and developed a draft flammability performance standard. The draft standard was first presented to stakeholders at a 1996 ASTM voluntary standards meeting. The staff also worked with industry and voluntary standards groups to develop possible alternatives to a federal rule.

In 1998, the Commission held a public hearing to gather additional information beyond that available to the agency on the potential toxicity, health risks, and environmental effects associated with flame-retardant chemicals that might be used to meet a standard. In CPSC's 1999 appropriations legislation, Congress directed the Commission to contract with the National Academy of Sciences (NAS) for an independent study of potential health hazards associated with the use of flame retardant chemicals that might be used in upholstered furniture fabrics to meet a CPSC standard. The final NAS report was published in July 2000. The report concluded that of 16 flame-retardant chemicals reviewed, 8 could be used in upholstered furniture fabrics without presenting health hazards to consumers.

In 2002, the staff held a public meeting to receive any new technical information and recommendations from interested parties on the project. In 2003, the staff forwarded a package to the Commission analyzing the information received at the meeting and a package recommending that the Commission expand its proceeding to cover both small open flame and cigarette ignition risks.

On October 23, 2003, the Commission issued a new ANPRM expanding the scope of the proceeding to include both cigarette and small open flame-ignited fire risks. The staff held a public meeting to discuss public comments on April 9, 2004. The staff is currently analyzing the comments and preparing alternatives for Commission consideration.

CPSC is also considering possible impacts of flame-retardant chemical use on worker safety and the environment. At the CPSC staff's request, the National Institute for Occupational Safety and Health studied potential worker exposure to and risks from certain flame-retardant chemicals that may be used by textile and furniture producers to comply with an upholstered furniture flammability standard. NIOSH preliminarily concluded that significant worker health effects were unlikely. CPSC staff is also working with the Environmental Protection Agency to develop a significant new use rule (SNUR) for flame-retardant compounds used in residential upholstered furniture fabrics under that agency's Toxic Substances Control Act Authority.

Statement of Need:

For 1995-1999, an annual average of approximately 6,600 residential fires in which upholstered furniture was the first item to ignite resulted in an estimated 460 deaths, 1,110 civilian injuries, and about $130 million in property damage that could be addressed by a flammability standard. The total annual societal cost

attributable to these upholstered furniture fire losses was approximately $2.75 billion. This total includes fires ignited by small open-flame sources and cigarettes.

Summary of Legal Basis:

Section 4 of the Flammable Fabrics Act (FFA) (15 U.S.C. 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is ''needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage.'' The Commission's regulatory proceeding could result in several actions, one of which could be the development of a mandatory standard requiring that upholstered furniture sold in the United States meet mandatory labeling requirements, resist ignition, or meet other performance criteria under test conditions specified in the standard.

Alternatives:

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of upholstered furniture; (2) The Commission could issue mandatory requirements for labeling of upholstered furniture, in addition to, or as an alternative to, the requirements of a mandatory flammability standard; and (3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result.

Anticipated Cost and Benefits:

The estimated annual cost of imposing a mandatory standard to address ignition of upholstered furniture will depend upon the test requirements imposed by the standard and the steps manufacturers take to meet those requirements. Again, depending upon the test requirements, a standard may reduce cigarette and small open flame-ignited fire losses, the total annual societal cost of which was over $3.3 billion for 1995-1999. Thus, the potential benefits of a mandatory standard to address the risk of ignition of upholstered furniture could be significant, even if the standard did not prevent all such fires.

Risks:

The estimated total annual cost to society from all residential fires associated with upholstered furniture was $3.3 billion for 1995-1999. Societal costs associated with upholstered furniture fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs.

Timetable:

Action	Date	FR Cite
ANPRM	06/15/94	59 FR 30735
ANPRM Comment Period End	08/15/94	
Staff Briefing of Commission on NPRM	12/18/97	
Commission Voted To Defer Action Pending Results of Toxicity Hearing	03/02/98	
Commission Hearing May 5 & 6, 1998 on Possible Toxicity of Flame Retardant Chemicals	03/17/98	63 FR 13017
NAS Study Completed (Required by Congress)	07/10/00	
Staff Sent Briefing Package to Commission	11/01/01	
Meeting Notice	03/20/02	67 FR 12916
Staff Held Public Meeting	06/18/02	
Second Day of Public Meeting	06/19/02	
Staff Sent Analysis of Information From Public Meeting to the Commission	02/06/03	
Staff Sent Regulatory Options to Commission	07/12/03	
Notice of September 24 Public Meeting	08/27/03	68 FR 51564
Commission Decision	10/17/03	
ANPRM	10/23/03	68 FR 60629
ANPRM Comment Period End	12/22/03	
Staff Sends Briefing Package to Commission	11/00/04	
Staff Briefs Commission on Draft NPRM	12/00/04	
Commission Decision	To Be	Determined
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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CPSC

170. PROPOSED STANDARD TO ADDRESS OPEN–FLAME IGNITION OF MATTRESSES/BEDDING

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

15 USC 1193, Flammable Fabrics Act; 5 USC 801

CFR Citation:

16 CFR 1633

Legal Deadline:

None

Abstract:

On October 11, 2001, the Commission published an advance notice of proposed rulemaking (ANPRM) to begin a proceeding for development of a flammability standard to address risks of death, injury, and property damage from fires associated with ignition of mattresses/bedding by small open-flame sources such as lighters, candles, or matches. This ANPRM was issued after the Commission staff conducted a field investigation study of these incidents and worked with industry members to improve consumer information programs and conducted research to define and measure the fire hazard presented by mattress/bedding ignitions in residential fires.

The Commission also received four petitions from the Children's Coalition for Fire-Safe Mattresses proposing (1) an open flame standard similar to the full-scale test set forth in California Technical Bulletin 129, (2) an open flame standard similar to the component test set forth in British Standard 5852, (3) a warning label for mattresses warning of polyurethane foam fire hazards, and (4) a permanent, fire-proof mattress identification tag. The Commission granted the first two petitions and denied the others.

The Commission staff reviewed public comments on the ANPRM and has continued working with the Sleep Products Safety Council (representing manufacturers and suppliers to the industry), the National Institute of Standards and Technology, the State of California Bureau of Home Furnishings, and others to complete the development of an appropriate test method and criteria for a standard to address open flame ignition of mattresses. The staff is preparing a decision package for Commission consideration, including a draft proposed standard with supporting materials, draft notice of proposed rulemaking (NPRM), and possible options to separately address the bedclothes contribution to mattress fires.

Statement of Need:

Based on national fire estimates for the years 1995-1999, ignition of mattresses and bedding resulted in an estimated 18,500 residential fires, 440 civilian deaths, 2,160 civilian injuries, and $259.5 million in property loss annually that could be addressed by a flammability standard. Since mattress fires often involve the ignition source of burning bedding, initially ignited by a smaller source, a standard incorporating an ignition source representing burning bedding could address deaths and injuries from fires caused by smoking materials, traditional small open flame sources, as well as other heat sources.

Summary of Legal Basis:

Section 4 of the Flammable Fabrics Act (FFA) (15 U.S.C. 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is ''needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage.'' The Commission's regulatory proceeding could result in the development of a mandatory standard requiring that mattresses sold in the United States meet mandatory labeling requirements and performance criteria limiting the size of the fire produced when a mattress is exposed to a large ignition source representing burning bedclothes.

Alternatives:

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of mattresses;

(2) The Commission could issue mandatory requirements for labeling of mattresses, in addition to, or as an alternative to, the requirements of a mandatory flammability standard; or

(3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result.

Anticipated Cost and Benefits:

The estimated annual cost of imposing a mandatory standard to address ignition of mattresses by open-flame sources will depend upon the performance requirements imposed by the standard and the steps manufacturers take to meet those requirements. A standard incorporating an ignition source representing burning bedclothes could address deaths and injuries from fires caused by smoking materials, traditional small open flame sources, as well as other heat sources.

Risks:

The estimated total cost to society from all residential fires associated with mattresses/bedding was about $3 billion in 1999. Societal costs associated with mattress/bedding fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs.

Timetable:

Action	Date	FR Cite
ANPRM	10/11/01	66 FR 51886
ANPRM Comment Period End	12/10/01	
Staff Sent Briefing Package to Commission	11/01/04	
Staff Briefs Commission on NPRM Draft	12/00/04	
Commission Decision	To Be	Determined
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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BILLING CODE 6355–01–S

FEDERAL HOUSING FINANCE BOARD (FHFB)

Statement of Regulatory and Deregulatory Priorities

The Federal Housing Finance Board (Finance Board) is an independent agency that is charged under the Federal Home Loan Bank Act (Bank Act) with supervising and regulating the Nation's Federal Home Loan Bank (Bank) System. The Bank System comprises 12 regional cooperative Banks that are owned by their respective member financial institutions. The Banks provide wholesale credit to members and certain nonmembers to be used for mortgage lending and related community lending activities. The Banks also acquire mortgage assets from members as a means of advancing their housing finance mission. The Bank System also includes the Office of Finance, which issues Bank System consolidated obligations. The Finance Board is required to prepare a regulatory plan pursuant to section 4 of Executive Order 12866. At this time, the Finance Board does not anticipate taking any significant regulatory or deregulatory actions during 2005 that would be required to be included in a regulatory plan.

The Finance Board's highest regulatory priorities during 2005 continue to be to ensure the safety and soundness of the Bank System and to ensure that the Banks fulfill their housing finance and community investment mission. In furtherance of these statutory mandates, the Finance Board expects to consider regulations that will:

- More clearly delineate the responsibilities and the accountability of the board of directors for governance of a Bank, thereby strengthening the role of the boards in the Banks' operations;
- Streamline the Finance Board's review of new business activities proposed by a Bank to more clearly focus the regulatory review process on ensuring that a new product, service, or activity will not endanger the continued safe and sound operation of the Bank;
- Streamline the community support requirements to eliminate unnecessary regulatory burden, while preserving the statutory intent of ensuring that members' access to long-term advances reflects such factors as their record of performance under the Community Reinvestment Act and their record of lending to first-time homebuyers;
- Improve the operations and efficiency of the Affordable Housing Program by more clearly delineating the Banks' responsibilities for program administration and for satisfying the statutory directive that the subsidy benefit very low-income, low-income, and moderate-income households.

BILLING CODE 6725–01–S

FEDERAL MARITIME COMMISSION (FMC)

Statement of Regulatory and Deregulatory Priorities

The Federal Maritime Commission's (Commission) regulatory objectives are guided by the Agency's basic vision. The Commission's vision is to administer the shipping statutes as effectively as possible to provide fairness and efficiency in the United States maritime commerce. The Commission's regulations are designed to implement each of the statutes the Agency administers in a manner consistent with this vision in a way that minimizes regulatory costs, fosters economic efficiencies, and promotes international harmony.

The Ocean Shipping Reform Act of 1998 (OSRA) continues to impact the Federal regulatory scheme regarding international ocean shipping. The legislation required new regulations, as well as the revision of many of the Commission's substantive regulations. One of the principal changes was the elimination of the requirement that carriers file tariffs with the Commission listing their rates and charges. Carriers are now required to publish their rates in private automated systems. The Commission continues to assess its regulations implementing this requirement, as well as other requirements of the new legislation.

Common carriers remain concerned as to the content requirements of agreements filed with the Commission. Carriers have expressed a desire for better delineation as to what matters do or do not have to be filed and have suggested that the Commission's rules should provide protections for confidential business information, provide maximum flexibility for carriers to modify cooperative arrangements, and include guidance tailored for different types of agreements. The Commission instituted a rulemaking proceeding in calendar year 2003 to address these and other issues concerning the regulations governing agreements filed with the Commission. This matter continues to be assessed and will be finalized before the end of calendar year 2004. The Commission also oversees the financial responsibility of passenger vessel operators to indemnify passengers and other persons in cases of death or injury and to indemnify passengers for nonperformance of voyages. The Commission has received a number of comments in response to its rulemaking proposal to update the nonperformance coverage requirements to correspond more closely with current industry conditions. Included among these submissions is a 2004 request that the Commission consider a report providing an update on developments in the industry. The Commission is continuing its review of this request as well as the other matters submitted in this proceeding.

The principal objective or priority of the Agency's current regulatory plan will be to continue to assess major existing regulations for continuing need, burden on the regulated industry, and clarity. The Commission has received requests from a segment of the common carrier community with regard to their tariff publishing obligations. The Commission has invited comments on these requests and is in the process of evaluating them. If the Commission determines to act favorably on these requests, it is possible there could be specific rulemaking proposals presented for the Commission's consideration.

The Commission's review of existing regulations exemplifies its objective to regulate fairly and effectively while imposing a minimum burden on the regulated entities, following the principles stated by the President in Executive Order 12866.

Description of the Most Significant Regulatory Actions

The Commission currently has no actions under consideration that constitute ''significant regulatory actions'' under the definition in Executive Order 12866.

BILLING CODE 6730–01–S

FEDERAL TRADE COMMISSION (FTC)

Statement of Regulatory Priorities

I. REGULATORY PRIORITIES

Background

The Federal Trade Commission (FTC or Commission) is an independent agency charged with protecting American consumers from ''unfair methods of competition'' and ''unfair or deceptive acts or practices'' in the marketplace. The Commission strives to ensure that consumers benefit from a vigorously competitive marketplace. The Commission's work is rooted in a belief that free markets work — that competition among producers and information in the hands of consumers bring the best products at the lowest prices for consumers, spur efficiency and innovation, and strengthen the economy.

The Commission pursues its goal of promoting competition in the marketplace through two different, but complementary, approaches. First, for competition to thrive, curbing deception and fraud is critical. Through its consumer protection activities, the Commission seeks to ensure that consumers receive accurate, truthful, and non-misleading information in the marketplace. At the same time, for consumers to have a choice of products and services at competitive prices and quality, the marketplace must be free from anticompetitive business practices. Thus, the second part of the Commission's basic mission—antitrust enforcement—is to prohibit anticompetitive mergers or other anticompetitive business practices without unduly interfering with the legitimate activities of businesses. These two complementary missions make the Commission unique insofar as it is the Nation's only Federal agency to be given this combination of statutory authority to protect consumers.

The Commission is, first and foremost, a law enforcement agency. It pursues its mandate primarily through case-by-case enforcement of the Federal Trade Commission Act and other statutes. The Commission, however, is also charged with the responsibility of issuing and enforcing regulations under a number of statutes. Pursuant to the FTC Act, for example, the Commission currently has in place thirteen trade regulation rules. The Commission also has adopted a number of voluntary industry guides. Most of the regulations and guides pertain to consumer protection matters and are generally intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions.

Industry Self-Regulation, Textile Leniency Policy, and Compliance Partnerships With Industry

The Commission continues to be committed to protecting consumers by means that burden businesses the least. To that end, it has encouraged industry self-regulation, developed a corporate leniency policy for certain rule violations, and established compliance partnerships where appropriate.

The Commission has issued reports that encourage industry self-regulation in several areas. In the entertainment industry, the Commission has encouraged industry groups to improve their self-regulatory programs to discourage the marketing of violent R-rated movies, Mature-rated electronic games and music labeling with a parental advisory to children. Recently, the Commission issued the latest of a series of reports on industry practices. The Commission recommended in its report that all three industries continue to improve compliance with existing ad placement guidelines and rating information practices and consider developing 'best practices' to avoid advertising in venues popular with teen audiences. *See* Federal Trade Commission, Marketing Violent Entertainment to Children: A Fourth Follow-Up Review of Industry Practices in the Motion Picture, Music Recording & Electronic Game Industries (July 2004), http://www.ftc.gov/os/2004/07/040708kidsviolencerpt.pdf. During the fall of 2003, the Commission sponsored a one-day workshop bringing together industry and parent and consumer groups to discuss the state of industry self regulation. *See* http://www.ftc.gov/bcp/workshops/violence/index/html. The Commission also continues to encourage companies in the alcohol industry to engage in self-regulation to ensure that advertising for products containing alcohol is not directed at underage youths. This year, the Commission will work with industry to facilitate compliance with the improved self-regulatory standards announced in the FTC's report, Alcohol Marketing and Advertising (Sept. 2003), http://ftc.gov/os/2003/09/alcohol08report.pdf.

In addition, in the weight-loss product advertising area, the Commission has proposed a strengthened self-regulatory response from the industry and more media responsibility to address the widespread problem of blatantly false efficacy claims. Specifically, the Commission authorized the release of a media reference guide to assist media in identifying facially false weight-loss claims. Federal Trade Commission Staff, *Red Flag: A Reference Guide for Media on Bogus Weight Loss Claim Detection* (2003), available at: http://www.ftc.gov/bcp/online/pubs/buspubs/redflag.pdf. In addition, the FTC has supported a joint effort by the Electronic Retailing Association and the National Advertising Review Council to develop a self-regulatory, rapid review process to identify unsubstantiated claims in direct response to advertisements, such as infomercials.

Also, with respect to the Children's Online Privacy Protection Act (COPPA), the Commission has approved the safe harbor programs of three organizations whose self-regulatory guidelines and programs protect children's privacy to the same or greater extent as COPPA.

Recently, the Commission announced the Textile Corporate Leniency Policy Statement for minor and inadvertent violations of the Textile or Wool Rules that are self-reported by the company. 67 FR 71566 (Dec. 2, 2002). Generally, the purpose of the Textile Corporate Leniency Policy is to help increase overall compliance with the rules while also minimizing the burden on business of correcting (through relabeling) inadvertent labeling errors that are not likely to cause injury to consumers. Under this policy, the Commission announced the factors that staff will consider in allowing the mislabeled goods to be sold without relabeling. The policy follows the Commission's Civil Penalty Leniency Program for small businesses, but is not limited to small businesses or situations involving civil penalties and excludes fraud cases. Since the Textile Corporate Leniency Program was announced, 25 companies have been granted ''leniency'' for self-reported minor violations of FTC textile regulations.

The Commission has also engaged industry in compliance partnerships in at least two areas involving the funeral and franchise industries. Specifically, the Commission's Funeral Rule Offender Program, conducted in partnership with the National Funeral Directors Association, is designed to educate funeral home operators found in violation of the requirements of the Funeral Rule, 16 CFR part 453, so that they can meet the rule's disclosure requirements. Approximately 215 funeral homes have participated in the program since its inception in 1996. In

addition, the Commission established the Franchise Rule Alternative Law Enforcement Program in partnership with the International Franchise Association (IFA), a nonprofit organization that represents both franchisors and franchisees. This program is designed to assist franchisors found to have a minor or technical violation of the Franchise Rule, 16 CFR part 436, in complying with the rule. Violations involving fraud or other section 5 violations are not candidates for referral to the program. The IFA teaches the franchisor how to comply with the rule and monitors its business for a period of years. Where appropriate, the program will offer franchisees the opportunity to mediate claims arising from the law violations. Since December 1998, fourteen companies have agreed to participate in the program.

New Rulemakings Required by Statute

Since the Commission's 2003 Regulatory Plan was published, the Congress enacted several laws requiring the Commission to undertake rulemakings and studies. These include at least 25 new rulemakings and eight studies required by the Fair and Accurate Credit Transactions Act of 2003, Pub. L. No. 108-159 (FACTA or the FACT Act); the rulemaking and study required by the Fairness to Contact Lens Consumers Act of 2003, Pub. L. No. 108-64; the rulemakings and reports required by the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, Pub. L. No. 108-187 (CAN-Spam Act); and the rulemaking pursuant to the Federal Deposit Insurance Corporation Improvements Act of 1991. Pub. L. 102-242. These rulemakings are proceeding according to schedule and are detailed more extensively in the *Unified Agenda.*

Ten-Year Review Program

In 1992, the Commission implemented a program to review its rules and guides regularly. The Commission's review program is patterned after provisions in the Regulatory Flexibility Act, 5 USC 601-612. Under the Commission's program, however, rules have been reviewed on a ten-year schedule as resources permit. For many rules this has resulted in more frequent reviews than is generally required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, in that it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a ''significant economic impact upon a substantial number of small entities.'' 5 USC 610. The program's goal is to ensure that all of the Commission's rules and guides remain beneficial and in the public interest. It complies with the Small Business Regulatory Enforcement Act of 1996, Pub. L. 104-121. This program is consistent with the Administration's ''smart'' regulation agenda to streamline regulations and reporting requirements and Section 5(a) of Executive Order 12866, 58 FR 51735 (Sept. 30, 1993).

As part of its continuing ten-year plan, the Commission examines the effect of rules and guides on small businesses and on the marketplace in general. These reviews often lead to the revision or rescission of rules and guides to ensure that the Commission's consumer protection and competition goals are achieved efficiently and at the least cost to business. In a number of instances, the Commission has determined that existing rules and guides were no longer necessary nor in the public interest. As a result of the review program, the Commission has repealed 48 percent of its trade regulation rules and 57 percent of its guides since 1992.

Calendar Year 2004-05 Reviews

All of the matters currently under review pertain to consumer protection and are intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions. During early 2004, the Commission published a revised timetable for its regulatory review program deferring all review for one year because of ongoing review proceedings as well as the addition of at least 27 rulemakings required by new legislation. 69 FR 3867 (Jan. 27, 2004). In January 2005, the Commission plans to publish a notice announcing the new rules and guides, if any, that will be reviewed during 2005.

Ongoing Reviews

As part of the Commission's ten-year review program, in 2003 the Commission continued reviews of eight rules, two guides, and one interpretation. It is expected that during the spring of 2005, the Commission will issue separate notices requesting comments both on the Statement of General Policy or Interpretations under the Fair Credit Reporting Act (also known as FCRA Commentary) and for the Guides Concerning the Use of Endorsements and Testimonials in Advertising. Other reviews are proceeding.

First, with respect to the Premerger Notification and Report Form, the Commission issued a Notice of Proposed Rulemaking (NPRM) to reconcile, as far as practical, the current disparate treatment of corporations, partnerships, limited liability companies, and other types of non-corporate entities under the rules. *See* 69 FR 18686 (Apr. 8, 2004). The staff expects to forward its recommendation about this issue to the Commission by the end of 2004 or early 2005. In the same time frame, the Commission anticipates amending the Hart-Scott-Rodino Rules to allow parties to file the premerger notification and report form electronically via the Internet.

Second, in the review of the Franchise Rule, 16 CFR part 436, the Commission announced on August 25, 2004, the issuance of a staff report, *''Disclosure Requirements and Prohibitions Concerning Franchising,''* which summarizes the rulemaking record to date, analyzes the various alternatives, and sets forth the staff's recommendations to the Commission on the various proposed amendments to the Franchise Rule, 69 FR 53661 (Sept. 2, 2004). Among other things, staff proposes that the Commission retain the Franchise Rule while updating it to account for new technologies and to provide prospective franchisees with more disclosure about the nature of the franchise relationship, while minimizing the discrepancies between Federal and State law. Public comments are being accepted until November 12, 2004. Staff will review the comments and anticipates sending its recommendation to the Commission in late 2005. The Commission did not review or approve the staff report.

Third, in the review of the R-Value Rule for home insulation, 16 CFR part 460, the Commission reviewed the comments received on the Advance Notice of Proposed Rulemaking (ANPRM) and issued an NPRM, which announced a number of proposed amendments to the rule. 68 FR 41872 (July 15, 2003). After assessing the public comments, staff expects to forward its recommendation to the Commission regarding substantive amendments to the rule by late 2004.

Fourth, for the rulemaking on Privacy of Consumer Financial Information, 16 CFR part 313, the Commission and banking agencies published an ANPRM and requested public comments on a variety of subjects including the goals, language, and mandatory or permissible

aspects of privacy notices. 68 FR 75164 (Dec. 30, 2003). Since the issuance of rules in 2000 in accordance with Gramm-Leach-Bliley Act, 15 USC 6801 *et seq.,* requirements that financial institutions provide notice of their privacy policies to their customers, the agencies have been trying to develop more useful privacy notices to consumers. The comment period for the ANPRM ended on March 26, 2004. Staff for the agencies are reviewing comments and continuing to work together to determine the next steps.

Fifth, the Commission's review of the Pay-Per-Call Rule, 16 CFR part 308, is ongoing. The Commission has held workshops to discuss proposed amendments to this rule, including provisions to combat telephone bill ''cramming''—inserting unauthorized charges on consumers' phone bills—and other abuses in the sale of products and services that are billed to the telephone including voicemail, 900-number services, and other telephone based information and entertainment services. The most recent workshop focused on discussions of the use of 800 and other toll-free numbers to offer pay-per-call services, the scope of the rule, the dispute resolution process, the requirements for a presubscription agreement, and the need for obtaining express authorization from consumers before placing charges on their telephone bills. Staff anticipates forwarding its recommendation to the Commission during the spring of 2005.

Sixth, the Commission's review of the Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Regulations), 16 CFR part 307, is ongoing. The Smokeless Regulations govern the format and display of statutorily mandated health warnings on all packages and advertisements for smokeless tobacco. In fiscal year 2000, the Commission undertook its periodic review of the Smokeless Regulations to determine whether the Regulations continue to effectively meet the goals of the Act and to seek information concerning the regulations' economic impact in order to decide whether they should be amended. Staff is currently assessing the public comments and anticipates forwarding its recommendations to the Commission by April 2005.

Finally, the Commission began its regulatory review of certain aspects of the Funeral Industry Practices Rule (Funeral Rule), 16 CFR part 453, in 1999. The Funeral Rule, which became effective in 1984, and was amended in 1994, requires providers of funeral goods and services to give consumers itemized lists of funeral goods and services that state prices and descriptions and also contain specific disclosures. The rule enables consumers to select and purchase only the goods and services they want, except for those that may be required by law and a basic services fee. Also, funeral providers must seek authorization before performing some services, such as embalming. In addition to an assessment of the rule's overall costs and benefits and continuing need for the rule, the review will examine whether changes in the funeral industry warrant broadening the scope of the rule to include non-traditional providers of funeral goods or services and revising or clarifying certain prohibitions in the rule. *See* 64 FR 24250 (May 5, 1999). In response to requests of industry members, the Commission determined to extend the comment period. A public workshop conference was subsequently held to explore issues raised in the comments submitted. Staff expects to forward its recommendation to the Commission by July 2005.

Final and Other Actions

Since publication of the 2003 Regulatory Plan, the Commission has taken final actions on several rulemakings. After amending the Telemarketing Sales Rule (TSR), 16 CFR part 310 (68 FR 4580, Jan. 29, 2003), to establish a national ''do not call'' registry, the Commission opened the registry on June 26, 2003. Consumers can register for free in two ways: online at DONOTCALL.GOV or by telephone at 1(888) 382-1222. As of October 1, 2003, it became illegal for most telemarketers to call a number listed on the registry. Also, the Commission issued additional amendments to the TSR on July 31, 2003, that imposed fees on entities accessing the ''do not call'' registry. *See* 68 FR 45134.

The Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, required that the Commission amend the TSR to require telemarketers subject to the TSR to access the ''do-not-call'' lists once a month rather than every three months. The Commission has implemented these provisions by promulgating regulations, effective January 1, 2005, requiring the telemarketers to scrub their lists at least every 31 days. 69 FR 16368 (Mar. 29, 2004).

Also pursuant to the Consolidated Appropriations Act of 2004, the Do-Not-Call Implementation Act, Pub. L. No. 108-10 (2003), and the Telemarketing Fraud and Abuse Prevention Act, 15 USC 6101-08, the Commission published an NPRM that would amend the TSR to revise fees charged for industry access to the national ''do-not-call'' registry. 69 FR 23701 (Apr. 30, 2004). In addition, the Commission has promulgated a new fee structure for accessing the ''do-not-call'' lists that became effective September 1, 2004. *See* 69 FR 45580 (July 30, 2004). Under the new fee structure, the annual fee for each area code of data accessed will be $40, and the maximum amount that any entity would be charged — for access to 280 area codes of data or more would be $11,000. The final rule continues to allow all entities accessing the Registry to obtain the first five area codes of data for free and allows those entities exempt from the Registry's requirements to obtain access at no charge.

Second, on February 4, 2004, the Commission published a Federal Register notice announcing that it would retain the Trade Regulation Rule on Ophthalmic Practice Rules (Eyeglass Rule) in its present form. 69 FR 5451. In that notice, the Commission also discussed the comments received in response to the Commission's request for comments on the rule and analyzed the effect of the Fairness to Contact Lens Consumers Act, 15 USC 7601-7610, on the Eyeglass Rule. A separate Federal Register Notice, also published on February 4, 2004, containing an NPRM under the Fairness to Contact Lens Consumers Act, makes two clerical amendments to the Eyeglass Rule, which clarify the distinction between that rule and the proposed Contact Lens Rule. 69 FR 5440, 5450. On July 2, 2004, the Commission issued its final Contact Lens Rule as required by the Fairness to Contact Lens Consumers Act. 69 FR 40482.

Third, as required by the CAN-SPAM Act of 2003, the Commission issued a rule prescribing that a mark be included in commercial e-mail that contains sexually oriented materials. 69 FR 21024 (Apr. 19, 2004). This rule went into effect on May 19, 2004. The Commission is also required to issue a rule defining the relevant criteria to facilitate the determination of the ''primary purpose'' of an electronic message by December 6, 2004. *See* 69 FR 11776 (Mar. 11, 2004) (ANPRM); 69 FR 50091 (Aug. 13, 2004) (NPRM). Besides other CAN-SPAM related discretionary rulemakings that are ongoing, the Commission is also required to issue four separate reports to the Congress within the next two years.

Fourth, the Commission has actively been issuing, sometimes in conjunction

with other federal agencies, rules according to the statutory mandate of the FACT Act. First, on December 24, 2003, the Commission and the Board of Governors of the Federal Reserve System (the Federal Reserve Board) jointly adopted Interim Final Rules that established December 31, 2003, as the effective date for provisions of the Act that determine the relationship between the Fair Credit Reporting Act (FCRA) and state laws and provisions that authorize rulemakings or other implementing actions by agencies. 68 FR 74467. On February 11, 2004, these Interim Final Rules were made final. Also, on that date, the Commission and the Federal Reserve Board published joint final rules that established a schedule of effective dates for many of the provisions of the FACT Act for which the Act itself did not specifically provide an effective date. 69 FR 6526. On February 24, 2004, the Commission published an Interim Final Rule effective on March 3, 2004, that prohibited consumer reporting agencies from avoiding treatment as nationwide consumer reporting agencies. 69 FR 8532. The Commission requested comments on that Interim Final Rule, and the comment period closed on April 23, 2004.

On May 20, 2004, the Commission issued a final rule effective on June 21, 2004, making technical changes to earlier rules, establishing a general organizational scheme for subchapter F of chapter I of title 16 of the Code of Federal Regulations, and setting forth general provisions applicable to all FTC rules under the FCRA. 69 FR 29061. On June 24, 2004, the FTC issued a final rule effective on December 1, 2004, for the provision of free consumer reports to consumers, including (1) a central source whereby consumers can make one request and receive their consumer report from each of the three major nationwide consumer reporting agencies and (2) rules with respect to the provision of free consumer reports by ''nationwide specialty consumer reporting agencies, '' as defined in the new FCRA section 603(w). 69 FR 35468 (June 24, 2004).

By December 2004, the FTC must promulgate, in coordination with the Federal Reserve Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, the National Credit Union Administration, and the Securities and Exchange Commission, rules (1) providing for the proper disposal of consumer report information, 69 FR 21388 (Apr. 20, 2004) (NPRM); (2) governing consumers' new right to opt out of marketing by affiliates, 69 FR 33324 (June 15, 2004) (NPRM); 69 FR 43546 (July 21, 2004) (Extension of Comment Period); and (3) improving the required notice to consumers regarding their right to opt out of prescreened solicitations. 69 FR 58861 (Oct. 1, 2004) (NRPM). Although there is no statutory deadline, the FTC must also issue a rule (1) setting the required duration of the new active duty fraud alert; and (2) defining certain terms that are relevant to new identity theft victims' rights. 69 FR 23370 (Apr. 28, 2004) (NPRM). The Commission issued the final rule on October 29, 2004, 69 FR 63922. The FTC is also required to promulgate a summary of consumers' identity theft rights, 69 FR 42616 (July 16, 2004) (Proposed Summaries and Notices), and to amend the existing general summary of consumer rights to include consumers' rights to a credit score and free annual credit report. The Commission expects to do so by December 2004.

Fifth, as part of the Commission's regulatory review program, on March 3, 2003, staff requested public comments on the economic impact and benefits of the Rules and Rules and Regulations under the Hobby Protection Act and whether changes in the relevant technologies — such as e-mail and the Internet — affect the rule since it was issued. 68 FR 9856. On March 3, 2004, the Commission retained the Hobby Protection Act Regulations without amendment. 69 FR 9943.

Sixth, in the review of the Labeling Requirements for Alternative Fuels and Alternative-Fueled Vehicles, 16 CFR part 309, the Commission requested comments about the need to retain the rule and specific options for modifying the alternative-fueled-not-including hybrids-vehicle label in light of new Environmental Protection Agency (EPA) tailpipe standards. *See* 69 FR 55332 (Sept. 14, 2004). After assessing the public comments, the Commission amended the rule to delete vehicle-specific information from the labels and added a reference to the EPA's green vehicle guide website, http://www.epa.gov/greenvehicle, which provides detailed comparative information about vehicle emissions generally and by vehicle model. 69 FR 55332 (Sept. 14, 2004). The amendment will become effective on March 31, 2005.

Lastly, for the review of the Tire Advertising and Labeling Guides (Tire Guides), the Commission issued a notice seeking public comment about, among other things, whether there is a continuing need for the Tire Guides and what changes, if any, should be made to them to increase the benefits of the Guides to purchasers. 68 FR 50984 (Aug. 25, 2003). On September 17, 2004, the Commission announced the repeal of the Tire Guides. 69 FR 56932 (Sept. 23, 2004).

Summary

In both content and process, the FTC's ongoing and proposed regulatory actions are consistent with the President's priorities. The actions under consideration inform and protect consumers and reduce the regulatory burdens on businesses. The Commission will continue working toward these goals. The Commission's ten-year review program is patterned after provisions in the Regulatory Flexibility Act and complies with the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission's ten-year program also is consistent with section 5(a) of Executive Order 12866, 58 FR 51735 (Sept. 30, 1993), which directs executive branch agencies to develop a plan to reevaluate periodically all of their significant existing regulations. In addition, the Telemarketing Sales Rule, 16 CFR part 310 (2003), is consistent with the President's Statement of Regulatory Philosophy and Principles, Executive Order 12866, section 1(a), which directs agencies to promulgate only such regulations as are, *inter alia,* required by law or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public.

As set forth in Executive Order 12866, the Commission continues to identify and weigh the costs and benefits of proposed actions and possible alternative actions, and to receive the broadest practicable array of comment from affected consumers, businesses, and the public at large. As stated above, since 1992 the Commission has repealed 48 percent of its trade regulation rules and 57 percent of its industry guides that existed in 1992 because they had ceased to serve a useful purpose. In sum, the Commission's regulatory actions are aimed at efficiently and fairly promoting the ability of ''private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.'' Executive Order 12866, section 1.

Rulemakings that Respond to Public Regulatory Reform Nominations

During March 2002, OMB requested public nominations for regulatory reforms. The Office of Information and Regulatory Affairs (OIRA) conducted a preliminary review of the public comments received and found five FTC activities that one or more commenters had nominated for reform. In a March 7, 2003 letter, the FTC responded that the agency systematically reviews all regulations and guides on a ten-year basis and explained how the agency had already reviewed or was about to review the activity at issue or why some of the other activities were not good candidates for reform as contemplated by the Smarter Regulations Report.

II. REGULATORY ACTIONS

The Commission does not plan to propose any rules that would be a ''significant regulatory action'' under the definition in Executive Order 12866.

BILLING CODE 6750–01–S

NATIONAL INDIAN GAMING COMMISSION (NIGC)

Statement of Regulatory Priorities

The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (NIGC or the Commission). The stated purpose of the Commission is to regulate the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments. It is the Commission's intention to provide regulation of Indian gaming to adequately shield it from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players.

The regulatory priorities for the next fiscal year reflect the Commission's commitment to upholding the principles of IGRA. The gaming industry changes rapidly with advancements in machine technology. It is crucial for the vitality of Indian gaming that regulators have the ability to respond quickly to these changes. To that end, the Commission has decided that the development of technical standards for game classifications, gaming machines, and related gaming systems is an important initiative for the promotion and protection of tribal gaming.

Additionally, the Commission will be making technical amendments to the minimal internal control standards. These amendments will correct isolated problems that have been brought to the Commission's attention by tribal gaming operators and regulators.

The Commission has been innovative in using active outreach efforts to inform its generic policy development and its rulemaking efforts. For example, the Commission has had great success in using regional meetings, both formal and informal, with tribal governments to gather views on current and proposed Commission initiatives. The Commission anticipates that these consultations with regulated tribes will play an important role in the development of technical standards.

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