
The Regulatory Plan

INTRODUCTION TO THE FALL 2006 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 applicable Executive orders, 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 which rules are formally under review at OMB and which rules 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. Many of the nominations involved rules and guidance documents that were recently issued or already under review by the agencies, or involved independent agency rules or guidance documents. OMB determined that the remaining 122 rules and 34 guidance documents were not under active review, and referred them to the agencies for their evaluation as possible reforms. 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. In response to the solicitation, OMB received 189 distinct reform nominations from 41 commenters. Of these, Federal agencies and OMB have determined that 76 of the 189 nominations have potential merit and justify further action. 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. With the implementation of these guidelines, agencies are now aware that ensuring the high quality of government information disseminations 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, on December 16, 2004, OMB issued a Final Information Quality Bulletin for Peer Review. This Bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. The Bulletin describes 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/memoranda/fy2005/m05-03.pdf>.

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 2006 Regulatory Plan continues OIRA's effort to ensure coordination across Federal agencies in pursuing analytically sound regulatory policies.

The Administration's 2006 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 2006 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.

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

- Regulations that respond to public nominations submitted to OMB in 2001 or 2002.
- Regulations that address 2004 nominations for promising regulatory reforms in the manufacturing sector.

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.

DEPARTMENT OF AGRICULTURE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
1	Procurement of Commodities for Foreign Donation	0560-AH40	Final Rule Stage
2	Animal Welfare; Regulations and Standards for Birds	0579-AC02	Proposed Rule Stage
3	Importation of Plants for Planting; Establishing a New Category of Plants for Planting Not Authorized for Importation Pending Risk Assessment	0579-AC03	Proposed Rule Stage
4	Revision of Fruits and Vegetables Import Regulations	0579-AB80	Final Rule Stage
5	Phytophthora Ramorum; Quarantine and Regulations	0579-AB82	Final Rule Stage
6	Special Nutrition Programs: Fluid Milk Substitutions	0584-AD58	Proposed Rule Stage
7	Child and Adult Care Food Program: Improving Management and Program Integrity	0584-AC24	Final Rule Stage
8	FSP: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002	0584-AD30	Final Rule Stage
9	Quality Control Provisions of Title IV of Public Law 107-171	0584-AD31	Final Rule Stage
10	Direct Certification of Children in Food Stamp Households and Certification of Homeless, Migrant and Runaway Children for Free Meals in the NSLP, SBP, and SMP	0584-AD60	Final Rule Stage
11	Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): WIC Vendor Cost Containment	0584-AD71	Final Rule Stage
12	Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages	0584-AD77	Final Rule Stage
13	Egg Products Inspection Regulations	0583-AC58	Proposed Rule Stage
14	Performance Standards for the Production of Processed Meat and Poultry Products; Control of Listeria Monocytogenes in Ready-to-Eat Meat and Poultry Products	0583-AC46	Final Rule Stage
15	Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products	0583-AC60	Final Rule Stage
16	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
17	Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems	0583-AD00	Final Rule Stage
18	Prohibition on the Use of Air-Injection Stunners for the Slaughter of Cattle	0583-AD03	Final Rule Stage
19	Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls	0583-AD10	Final Rule Stage
20	Forest Service National Environmental Policy Act Procedures	0596-AC49	Proposed Rule Stage
21	National Forest System Land Management Planning Categorical Exclusion (Final Directive, Forest Service Handbook 1909.15, Chapter 30)	0596-AB86	Final Rule Stage
22	National Forest System Land Management Planning Directive (Final Directive, Forest Service Handbook 1909.12, Chapter 70-Wilderness Evaluation)	0596-AC57	Final Rule Stage

DEPARTMENT OF COMMERCE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
23	Right Whale Ship Strike Reduction	0648-AS36	Final Rule Stage
24	Implement and Administer a Coupon Program for Digital-to-Analog Converter Boxes	0660-AA16	Final Rule Stage

DEPARTMENT OF DEFENSE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
25	TRICARE Outpatient Prospective Payment System (OPPS)	0720-AB03	Final Rule Stage
26	TRICARE; Certain Survivors of Deceased Active Duty Members; and Adoption Intermediaries	0720-AB04	Final Rule Stage
27	Expand Eligibility of Selected Reserve Members Under the TRICARE Program	0720-AB05	Final Rule Stage

DEPARTMENT OF ENERGY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
28	Energy Conservation Standards for Residential Electric and Gas Ranges and Ovens and Microwave Ovens, Dishwashers, Dehumidifiers, and Commercial Clothes Washers	1904-AB49	Prerule Stage
29		1904-AB59	Prerule Stage
30		1904-AA78	Proposed Rule Stage
31	Energy Efficiency Standards for Electric Distribution Transformers	1904-AB08	Final Rule Stage
32	Energy Efficiency Standards for Ceiling Fan Light Kits	1904-AB61	Final Rule Stage
33	Loan Guarantees for Projects That Employ Innovative Technologies	1901-AB21	Proposed Rule Stage
34	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
35	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920-AA12	Final Rule Stage
36		0910-AC52	Proposed Rule Stage
37	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910-AF11	Proposed Rule Stage
38	Expanded Access to Investigational Drugs for Treatment Use	0910-AF14	Proposed Rule Stage
39	Label Requirement for Food That Has Been Refused Admission Into the United States	0910-AF61	Proposed Rule Stage
40	Medical Device Reporting; Electronic Submission Requirements	0910-AF86	Proposed Rule Stage
41	Electronic Registration and Listing for Devices	0910-AF88	Proposed Rule Stage
42	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910-AB88	Final Rule Stage
43	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910-AC41	Final Rule Stage
44	Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates (CMS-1529-P)	0938-AO30	Proposed Rule Stage
45	Standards for E-Prescribing Under Medicare Part D (CMS-0016-P)	0938-AO66	Proposed Rule Stage
46	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-P)	0938-AO70	Proposed Rule Stage
47	Revisions to the Medicare Advantage and Part D Prescription Drug Contract Confidentiality and Disclosure, Determinations, Appeals, and Intermediate Sanctions Processes (CMS-4124-P)	0938-AO78	Proposed Rule Stage
48	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-F)	0938-AN14	Final Rule Stage

DEPARTMENT OF HOMELAND SECURITY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
49	Minimum Standards for Driver's Licenses and Identification Cards Acceptable to Federal Agencies for Official Purposes	1601-AA37	Proposed Rule Stage
50	United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT), Enrollment of Additional Aliens in US-VISIT	1601-AA35	Final Rule Stage
51	Chemical Security Anti-terrorism Standards	1601-AA41	Final Rule Stage

DEPARTMENT OF HOMELAND SECURITY (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
52	Special Immigrant and Nonimmigrant Religious Workers	1615-AA16	Proposed Rule Stage
53	Adjustment of Status to Lawful Permanent Resident for Aliens in T and U Nonimmigrant Status	1615-AA60	Final Rule Stage
54	New Classification for Victims of Certain Criminal Activity; Eligibility for the U Nonimmigrant Status	1615-AA67	Final Rule Stage
55	Removal of Standardized Request for Evidence Processing Timeframe	1615-AB13	Final Rule Stage
56	Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System (USCG-2005-21869)	1625-AA99	Proposed Rule Stage
57	Passenger Manifest for Commercial Aircraft Arriving In and Departing From the United States; Passengers and Crew Manifests for Commercial Vessels Departing From the United States	1651-AA62	Final Rule Stage

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
58	Permanent Foundations for Manufactured Housing (FR-5075)	2502-AI45	Proposed Rule Stage
59	Capital Fund Program (FR-4880)	2577-AC50	Proposed Rule Stage
60	Revisions to the Public Housing Assessment System (PHAS) (FR-5094)	2577-AC68	Proposed Rule Stage

DEPARTMENT OF THE INTERIOR

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
61	Valuation of Oil From Indian Leases	1010-AD00	Final Rule Stage
62	Placement of Excess Spoil	1029-AC04	Proposed Rule Stage
63	Oil Shale Leasing and Operations	1004-AD90	Proposed Rule Stage

DEPARTMENT OF JUSTICE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
64	Nondiscrimination on the Basis of Disability in Public Accommodations and Commercial Facilities	1190-AA44	Proposed Rule Stage
65	Nondiscrimination on the Basis of Disability in State and Local Government Services	1190-AA46	Proposed Rule Stage

DEPARTMENT OF LABOR

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
66	Family and Medical Leave Act of 1993; Conform to the Supreme Court's Ragsdale Decision	1215-AB35	Prerule Stage
67	Alternative Trade Adjustment Assistance Benefits; Amendment of Regulations	1205-AB40	Proposed Rule Stage

DEPARTMENT OF LABOR (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
68	Revision of the Department of Labor Regulations for Petitions and Determinations of Eligibility to Apply for Trade Adjustment Assistance for Workers	1205-AB44	Proposed Rule Stage
69	Revision to the Department of Labor Benefit Regulations for Trade Adjustment Assistance for Workers Under the Trade Act of 1974, as Amended	1205-AB32	Final Rule Stage
70	Labor Certification for the Permanent Employment of Aliens in the United States; Reducing the Incentives and Opportunities for Fraud and Abuse and Enhancing Program Integrity	1205-AB42	Final Rule Stage
71	Amendment of Regulation Relating to Definition of Plan Assets—Participant Contributions	1210-AB02	Proposed Rule Stage
72	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
73	Prohibiting Discrimination Against Participants and Beneficiaries Based on Health Status	1210-AA77	Final Rule Stage
74	Section 404 Regulation—Default Investment Alternatives Under Participant Directed Individual Account Plans	1210-AB10	Final Rule Stage
75	Personal Continuous Dust Monitors	1219-AB48	Prerule Stage
76	Sealing of Abandoned Areas	1219-AB52	Proposed Rule Stage
77	Mine Rescue Teams	1219-AB53	Proposed Rule Stage
78	Diesel Particulate Matter: Conversion Factor from Total Carbon to Elemental Carbon	1219-AB55	Proposed Rule Stage
79	Asbestos Exposure Limit	1219-AB24	Final Rule Stage
80	Emergency Mine Evacuation	1219-AB46	Final Rule Stage
81	Criteria and Procedures for Proposed Assessment of Civil Penalties	1219-AB51	Final Rule Stage
82	Occupational Exposure to Crystalline Silica	1218-AB70	Prerule Stage
83	Hazard Communication	1218-AC20	Prerule Stage
84	Cranes and Derricks	1218-AC01	Proposed Rule Stage

DEPARTMENT OF TRANSPORTATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
85	Commuter Operations in Very Light Jets (VLJS)	2120-AI84	Proposed Rule Stage
86	Aging Aircraft Program (Widespread Fatigue Damage)	2120-AI05	Final Rule Stage
87	Transport Airplane Fuel Tank Flammability Reduction	2120-AI23	Final Rule Stage
88	Medical Certification Requirements as Part of the Commercial Driver's License	2126-AA10	Proposed Rule Stage
89	Unified Registration System	2126-AA22	Proposed Rule Stage
90	National Registry of Certified Medical Examiners	2126-AA97	Proposed Rule Stage
91	Roof Crush Resistance	2127-AG51	Final Rule Stage
92	Side Impact Protection Upgrade—FMVSS No. 214	2127-AJ10	Final Rule Stage
93	Reduced Stopping Distance Requirements for Truck Tractors	2127-AJ37	Final Rule Stage
94	Electronic Stability Control (ESC)	2127-AJ77	Final Rule Stage

DEPARTMENT OF THE TREASURY

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

DEPARTMENT OF THE TREASURY (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
96	Risk-Based Capital Guidelines; Capital Adequacy Guidelines; Capital Maintenance: Domestic Capital Modifications (Basel IA)	1557-AC95	Proposed Rule Stage
97	Implementation of a Revised Basel Capital Accord (Basel II)	1550-AB56	Proposed Rule Stage

ENVIRONMENTAL PROTECTION AGENCY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
98	Endocrine Disrupter Screening Program (EDSP); Implementing the Screening and Testing Phase	2070-AD61	Prerule Stage
99	Standards for the Management of Coal Combustion Wastes Generated by Commercial Electric Power Producers	2050-AE81	Prerule Stage
100	Review of the National Ambient Air Quality Standards for Carbon Monoxide	2060-AI43	Proposed Rule Stage
101	Control of Emissions From New Locomotives and New Marine Diesel Engines Less Than 30 Liters per Cylinder	2060-AM06	Proposed Rule Stage
102	Control of Emissions From Nonroad Spark-Ignition Engines and Equipment	2060-AM34	Proposed Rule Stage
103	Implementing Periodic Monitoring in Federal and State Operating Permit Programs	2060-AN00	Proposed Rule Stage
104	Review of the National Ambient Air Quality Standards for Ozone	2060-AN24	Proposed Rule Stage
105	Prevention of Significant Deterioration, Nonattainment New Source Review, and New Source Performance Standards: Emissions Test for Electric Generating Units	2060-AN28	Proposed Rule Stage
106	Review of the National Ambient Air Quality Standards for Lead	2060-AN83	Proposed Rule Stage
107	Test Rule; Testing of Certain High Production Volume (HPV) Chemicals	2070-AD16	Proposed Rule Stage
108	Pesticides; Competency Standards for Occupational Users	2070-AJ20	Proposed Rule Stage
109	Pesticides; Agricultural Worker Protection Standard Revisions	2070-AJ22	Proposed Rule Stage
110	Pesticide Agricultural Container Recycling Program	2070-AJ29	Proposed Rule Stage
111	Revisions to the Spill Prevention, Control, and Countermeasure (SPCC) Rule, 40 CFR Part 112	2050-AG16	Proposed Rule Stage
112	Expanding the Comparable Fuels Exclusion under RCRA	2050-AG24	Proposed Rule Stage
113	Definition of Solid Wastes Revisions	2050-AG31	Proposed Rule Stage
114	NESHAP: Hazardous Organic NESHAP (HON) Residual Risk Standards	2060-AK14	Final Rule Stage
115	NESHAP: Halogenated Solvent Cleaning—Residual Risk Standards	2060-AK22	Final Rule Stage
116	Control of Hazardous Air Pollutants From Mobile Sources	2060-AK70	Final Rule Stage
117	Clean Air Fine Particle Implementation Rule	2060-AK74	Final Rule Stage
118	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Debottlenecking, Aggregation and Project Netting	2060-AL75	Final Rule Stage
119	Fuel Economy Labeling of Motor Vehicles: Revisions to Improve Calculation of Fuel Economy Estimates	2060-AN14	Final Rule Stage
120	Amendment of the Standards for Radioactive Waste Disposal in Yucca Mountain, Nevada	2060-AN15	Final Rule Stage
121	Renewable Fuels Standard Rule	2060-AN76	Final Rule Stage
122	Final Rule for Implementation of the New Source Review (NSR) Program for PM2.5	2060-AN86	Final Rule Stage
123	Pesticides; Data Requirements for Conventional Chemicals	2070-AC12	Final Rule Stage
124	Lead-Based Paint Activities; Amendments for Renovation, Repair, and Painting	2070-AC83	Final Rule Stage
125	Pesticides; Data Requirements for Biochemical and Microbial Products	2070-AD51	Final Rule Stage

ENVIRONMENTAL PROTECTION AGENCY (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
126	Notification of Chemical Exports under TSCA Section 12(b)	2070-AJ01	Final Rule Stage
127	Testing Agreement for Perfluorooctanoic Acid (PFOA)	2070-AJ06	Final Rule Stage
128	Hazardous Waste Manifest Revisions-Standards and Procedures for Electronic Manifests	2050-AG20	Final Rule Stage
129	Oil Pollution Prevention; Spill Prevention, Control, and Countermeasure (SPCC) Requirements—Amendments	2050-AG23	Final Rule Stage
130	National Pollutant Discharge Elimination System Permit Requirements for Peak Wet Weather Discharges from Publicly Owned Treatment Work Treatment Plants Serving Sanitary Sewer Collection Systems Policy	2040-AD87	Final Rule Stage
131	Concentrated Animal Feeding Operation Rule	2040-AE80	Final Rule Stage
132	Water Transfers Rule	2040-AE86	Final Rule Stage
133	Implementation Guidance for Mercury Water Quality Criteria	2040-AE87	Final Rule Stage
134	Toxics Release Inventory Reporting Burden Reduction Rule	2025-AA14	Final Rule Stage

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
134A	Coordination of Retired 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
135	Federal Records Management	3095-AB16	Proposed Rule Stage

SMALL BUSINESS ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
136	Small Business Lending Company and Lender Oversight Regulations	3245-AE14	Proposed Rule Stage
137	Size for Purposes of Long Term Contracts; Small Business Size Regulations; 8(a) Business Development/Small Disadvantaged Business Status Determinations	3245-AF06	Final Rule Stage

SOCIAL SECURITY ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
138	Revised Medical Criteria for Evaluating Mental Disorders (886P)	0960-AF69	Proposed Rule Stage
139	Additional Insured Status Requirements for Certain Alien Workers (2882P)	0960-AG22	Proposed Rule Stage
140	Consultative Examination - Annual Onsite Review by DDSs (3338P)	0960-AG41	Proposed Rule Stage
141	Revised Medical Criteria for Evaluating Impairments of the Digestive System (800F)	0960-AF28	Final Rule Stage
142	Revised Medical Criteria for Evaluating Immune System Disorders (804F)	0960-AF33	Final Rule Stage
143	Mandatory Exclusion of Health Care Providers and Representatives From Participating in Programs Administered by SSA, Including Representative Payment (954F)	0960-AF85	Final Rule Stage
144	Amendments to the Ticket to Work and Self-Sufficiency Program (967F)	0960-AF89	Final Rule Stage
145	Age as a Factor in Evaluating Disability (3183F)	0960-AG29	Final Rule Stage

CONSUMER PRODUCT SAFETY COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
146	Flammability Standard for Upholstered Furniture	3041-AB35	Proposed Rule Stage

NATIONAL INDIAN GAMING COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
147	Technical Amendments to the Minimum Internal Control Standards	3141-AA27	Final Rule Stage
148	Technical Standards for Gaming Machines and Gaming Systems	3141-AA29	Final Rule Stage
149	Game Classification Standards	3141-AA31	Final Rule Stage

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DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

USDA's regulations cover 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 continue regulatory work to protect the health and value of U.S. agricultural and natural resources while facilitating trade flows. This includes amending regulations related to the importation of fruits and vegetables, nursery products, and animals and animal products, and continuing work related to regulation of plant and animal biotechnologies. In addition, USDA will propose specific standards for the humane handling, care, treatment, and transportation of birds under the Animal Welfare Act.
- 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. In May 2006, an enhanced small business outreach program was established. The agency will collaborate in this initiative with other USDA agencies and cooperating State partners. 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 2007, FNS will continue to promote nutritional knowledge and education while minimizing participant and vendor fraud.
- USDA has a priority to improve access to natural resources of Forest

Service land by developing leases and expedited reviews of permits. If accomplished, the use of oil or natural gas could be used in accelerating the completion of projects while maintaining the safety of public health, environment and working to reduce dependence on foreign oil.

- USDA will continue to promote economic opportunities for agriculture and rural communities through its Federal Biobased Product Preferred Procurement Program (FB4P). The Department will continue to designate groups of biobased products to receive procurement preference from Federal agencies and contractors. In addition, USDA intends to publish rules establishing the Voluntary Labeling Program for biobased products.

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) and the E-Government Act, 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, USDA implemented an electronic authentication capability that allows customers to "sign-on" once and conduct business with all USDA agencies. Supporting 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 USDA 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 emergency producer assistance as a result of natural disasters, 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 2007:

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' 2006 regulatory plan supports USDA's Strategic Goal 5, "Improve the Nation's Nutrition and Health," and its three related objectives:

Improve Access to Nutritious Food. This objective represents FNS' efforts to improve nutrition by providing access to program benefits (Food Stamps, WIC, and school meals) and distributing State administrative funds to support program operations. To advance this objective, FNS plans to finalize rules implementing provisions of the Farm Security and Rural Investment Act of 2002 (P.L. 107-171) to simplify program administration, support work, and improve access to benefits in the Food Stamp Program. The Agency will also issue rules implementing provisions of the Child Nutrition and WIC Reauthorization Act of 2004 (P.L. 108-265) to ensure access to the Child Nutrition Programs for low-income children receiving Food Stamps through direct certification, and to establish automatic eligibility for homeless children.

Promote Healthier Eating Habits and Lifestyles. This objective represents FNS' efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion, and to ensure that program benefits meet the appropriate nutrition standards to effectively improve nutrition for program participants. In support of this objective, FNS plans to propose a rule revising requirements that allow schools to substitute nutritionally-equivalent non-dairy beverages for fluid milk at the request of a recipient's parent. FNS will also propose changes to improve food packages in the WIC program to reflect current dietary guidance, based on recommendations made by an Institute of Medicine expert panel.

Improve Nutrition Assistance Program Management and Customer Service. This objective 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. In support of this objective, FNS plans to finalize rules in the Food Stamp Program (FSP) to improve program operations and

monitoring at the State and institution levels. For example, the proposed Food Stamp Program Disqualified Recipient Reporting and Computer Matching rule would require State agencies at certification and periodically thereafter to match persons in households applying for benefits against several databases to ensure prisoners, deceased, and other disqualified individuals are not receiving food stamp benefits. FNS will also publish rules implementing several changes to the Food Stamp Quality Control system, and related performance incentives for States, required by P. L. 107-171, and propose rules to correct and clarify provisions of the July 6, 2000, final regulation on recipient claims.

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 streamline excessively prescriptive regulations, to revise or remove regulations that are inconsistent with the Agency's hazard analysis and critical control point regulations, and to ensure that it can address emerging food safety challenges. FSIS' 2006 regulatory plan supports USDA's Strategic Goal 5, "Enhance Protection and Safety of the Nation's Agriculture and Food Supply," and the related objective to reduce the incidence of food borne illnesses related to meat, poultry, and egg products in the U.S.

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

Expand the Use of Performance Standards: 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 also contained provisions addressing post-lethality contamination of RTE products with *Listeria monocytogenes*. In June 2003, FSIS published an interim final rule requiring establishments to prevent *L. monocytogenes* contamination of RTE products. The Agency is evaluating the effectiveness of this interim rule, which in 2004 was the subject of a regulatory

reform nomination to OMB. FSIS has carefully reviewed its economic analysis of the interim rule in response to this recommendation and is planning to adjust provisions of the rule to reduce the information collection burden on small businesses. FSIS also is planning further action with respect to other elements of the 2001 proposal, based on quantitative risk assessments of target pathogens in processed products.

FSIS plans to propose amending the poultry products inspection regulations by replacing, with a performance standard, the requirement for ready-to-cook poultry products to be chilled to 40(deg) F or below within certain time limits according to the weight of the dressed carcasses. Under the performance standard, poultry establishments would have to carry out slaughtering, dressing, and chilling operations in a manner that ensures no significant growth of pathogens, as demonstrated by control of the pathogens or indicator organisms. The existing time/temperature chilling regulations would remain available for use by establishments as a "safe harbor" for compliance with the new standard.

Bovine Spongiform Encephalopathy (BSE): In January 2004, FSIS published three interim final rules to prevent the agent of BSE from entering the human food supply. FSIS took this action in response to the confirmation of BSE in a cow in Washington State that had been imported from Canada. In addition, FSIS issued a Federal Register Notice in January 2004 that announced that the Agency would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample is determined to be negative. FSIS has been evaluating the comments received in response to the interim final rules to determine whether to implement additional measures to prevent human exposure to the BSE agent.

Expand the Use of Hazard Analysis and Critical Control Point (HACCP) Systems: FSIS also 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 FSIS approval of egg-product plant drawings, specifications, and equipment before their use, and to end the system for pre-marketing approval of labeling for egg products.

Improve Consumer Information: 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. Completing this rulemaking would respond to a regulatory reform recommendation made to OMB in 2002.

FSIS proposed March 7, 2006, to amend the Federal meat and poultry product regulations to provide that the Agency would make available to individual consumers lists of the retail consignees of meat and poultry products that a federally inspected meat or poultry products establishment has voluntarily recalled. FSIS believes that this information will be of value to consumers and the industry in clarifying which products should be removed from commerce and from consumers' possession because the products may be adulterated or misbranded.

Small business implications: The great majority of businesses regulated by FSIS are small businesses. With the possible exception of the poultry chilling proposal, the regulations listed above substantially affect small businesses. FSIS recognizes the difficulties faced by many small and very small establishments in complying with necessary, science-based food safety requirements and in assuming the associated technical and financial burdens. FSIS attempts to reduce the burdens of its regulations on small business by providing alternative dates of compliance, furnishing detailed compliance guidance material, and conducting outreach programs to small and very small establishments.

In May 2006, FSIS announced an enhanced small business outreach program that will ensure critical training, access to food safety experts, and information resources that are available in a form that is uniform, easily comprehended, and consistent. The Agency will collaborate in this initiative with other USDA Agencies and cooperating State partners. For example, FSIS will make plant owners and operators aware of loan programs, available through USDA's Rural Business and Cooperative programs, to help them in upgrading their facilities. FSIS employees will be meeting proactively with small and very small plant operators to learn more about their

specific needs and provide joint training sessions for small and very small plants and FSIS employees.

Animal and Plant Health Inspection Service

Mission: A major part of 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. APHIS also conducts programs to ensure the humane handling, care, treatment, and transportation of animals under the Animal Welfare Act.

Priorities: APHIS is continuing work that will result in a revision of its regulations concerning the introduction of organisms and products altered or produced through genetic engineering. This work consists of two parts. The first is to amend the existing plant-related regulations to reflect new consolidated authorities under the Plant Protection Act and to address new technological trends. The second is to develop a regulatory framework for transgenic animals. These regulatory changes are needed to address risks to plant and animal health. APHIS also plans to complete rulemaking to streamline the process for approving new fruits and vegetables for importation, and to propose changes to the regulations for importing nursery stock that will enhance our ability to protect plant health. 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.

With regard to animal welfare, APHIS plans to propose specific standards for the humane handling, care, treatment, and transportation of birds covered under the Animal Welfare Act.

APHIS' 2006 regulatory plan supports USDA's Strategic Goal 4, "Enhance Protection and Safety of the Nation's Agriculture and Food Supply," and the related objective to reduce the number and severity of agricultural pest and disease outbreaks.

Agricultural Marketing Service

Mission: The Agricultural Marketing Service (AMS) provides marketing services to producers, manufacturers, distributors, importers, exporters, and consumers of food products. The AMS also manages the Government's food purchases, supervises food quality grading, maintains food quality standards, and supervises the Federal research and promotion programs.

Priorities: AMS' priorities are to support Strategic Goal 2, "Enhance the Competitiveness and Sustainability of Rural and Farm Economies," by expanding domestic market opportunities for agricultural producers. In response to concerns raised by Fruit and Vegetable industry members that produce sellers may lose their status as trust creditors when using electronic invoicing systems, the Agricultural Marketing Service issued an advance notice of proposed rulemaking (ANPR) under the Perishable Agricultural Commodities Act (PACA) soliciting comments from the public, including buyers and sellers of fruits and vegetables. The ANPR was published on January 30, 2006, and the comment period ended March 16, 2006. The agency expects to proceed to rulemaking in the near future. The PACA established a code of fair trading practices in the marketing of fresh and frozen fruits and vegetables in interstate and foreign commerce. The law imposes a statutory trust on the assets, including inventory and receivables, of a licensee or firms operating subject to the PACA. The PACA provides that PACA licensees may preserve their trust rights by including specified language on billing or invoicing statements. In 1997, the PACA regulations were amended to state that electronic transmissions are considered "ordinary and usual billing and invoicing statements." A number of produce sellers have voiced concerns that their PACA trust rights may not be preserved when invoicing electronically. Additional concerns have been expressed that notice to sellers using the alternate method of trust notice (i.e., separate trust notice letter) is not being accepted by some buyers who require their suppliers to invoice electronically. Others in the industry have expressed concern about being charged a fee by the buyer to accept the notice to preserve their trust benefits if they send a paper invoice or separate trust notice.

The Agricultural Marketing Service (AMS) administers the National Organic Program (NOP) which is authorized by the Organic Food Production Act of

1990 (7 U.S.C. 6510 et seq.). Under the NOP, AMS establishes national standards for the production and handling of organically produced agricultural products. Since the implementation of the NOP, some members of the public have advocated for a more explicit regulatory standard on the relationship between livestock, particularly dairy animals, and grazing land. Appropriate access to pasture has been a topic of discussion in the organic community for many years, including by the National Organic Standards Board (NOSB). For these reasons, AMS published an Advance Notice of Proposed Rulemaking (ANPR) on April 13, 2006, to give the public the opportunity to comment on key issues that have been raised during previous rulemakings and National Organic Standards Board deliberations regarding access to pasture and temporary confinement based on an animal's stage of production. The comment period closed on June 12. AMS intends to publish a proposed rule this fall.

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: FSA's Regulatory Plan supports USDA Strategic Goal 2, "Enhance the Competitiveness and Sustainability of Rural and Farm Economies," and Strategic Goal 6, "Protect and Enhance the Nation's Natural Resource Base and Environment." FSA's immediate priority is to finish implementation of the disaster assistance programs required by the 2006 Emergency Appropriations Act (Pub. L. 109-148), and the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery of 2006. The disaster programs provide assistance to agricultural producers in areas that were affected by the unusual number and severity of hurricanes in 2005.

A primary mission of FSA is to administer the commodity and conservation programs provided by the Farm Security and Rural Investment Act of 2002 (2002 Act). Generally, these programs are authorized by the 2002 Act with respect to the 2002 through 2007 crop years. Accordingly, FSA envisions no major changes in the last year of the regulations used to administer these programs. However, the Agency does

expect major initiatives for a new Farm Bill to be proposed by this Administration for the 2008 and subsequent crop years. FSA will develop and issue the necessary regulations and make program funds available to eligible clientele in as timely a manner as possible. As these and future changes required by Administration initiatives and new legislation are made, the Agency's focus will be to implement the changes in such a way as to provide benefits while minimizing program complexity and regulatory burden for program participants. Opportunities will be taken to clarify, simplify, and reduce confusion whenever possible. In addition, the Agency will continue to streamline its farm loan programs operated under the Consolidated Farm and Rural Development Act, as amended (Pub. L. 87-128).

The Agency plans to publish a final rule to adopt new procedures to be used by the Commodity Credit Corporation (CCC) in the evaluation of bids in connection with the procurement of commodities for foreign donation under various food aid authorities. CCC is amending the existing regulations to provide for the simultaneous review of commodity and ocean freight offers when evaluating lowest-landed cost options in connection with the procurement of commodities for foreign donation. Under the revised bid process, CCC can better control shipping costs, take advantage of efficiencies in load consolidation and ensure a more competitive commodity procurement process. Program savings should result from the ability to better position procured commodities at domestic ports based on actual shipping cost comparisons. Program savings are also expected as a result of greater head-to-head competition for program freight among U.S.-flagged carriers. These savings should allow for additional food aid quantities to move to donation countries. This rule will enhance bidding opportunities for potential vendors while allowing CCC to more efficiently acquire commodities.

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: Forest Service's regulatory plan supports USDA Strategic Goal 6, "Protect and Enhance the Nation's Natural Resource Base and Environment." The agency's priorities for fall 2006 include publishing a proposed regulation to revise 36 CFR Part 220 regarding the agency's implementation of the National Environmental Policy Act (NEPA). The proposed regulation would move existing agency NEPA procedures required by 40 CFR 1507.3 from the internal Forest Service Handbook 1909.15 to the Code of Federal Regulations. Codifying agency NEPA procedures would make it easier for the Forest Service to revise internal agency guidance.

The agency plans to publish two final directives to Forest Service Environmental Policy and Procedures Handbook 1909.15, chapter 30. The existing agency NEPA procedures would be updated to allow the use of a categorical exclusion when a land management plan is not making decisions that will result in significant impacts on the human environment and where no extraordinary circumstances exist that would prohibit the use of the categorical exclusion. Notice of the proposed categorical exclusion and request for comment was published January 5, 2005 (70 FR 3).

The second final directive to Forest Service Environmental Policy and Procedures Handbook 1909.15, chapter 30 applies to issuance of Surface Use Plans of Operation for exploration or development of an oil and gas lease. The final directive will allow for expedited review of permits to accelerate the completion of projects while maintaining safety, public health and environmental protection. Notice of the proposed directive and request for comment was published December 13, 2005 (70 FR 238).

Forest Service also plans to publish a final directive to Forest Service National Forest System Land Management Planning Handbook 1909.12, chapter 70, regarding wilderness evaluation. The final planning rule was published on January 5, 2005 (70 FR 1023), and an interim directive to chapter 70 regarding wilderness evaluation was published on March 23, 2005 (70 FR 14637). The final directive updates guidance for the identification, inventory, evaluation, and recommendation of areas within National Forest System lands that satisfy the definition of wilderness

found in section 2(c) of the 1964 Wilderness Act.

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 2007 will be to make final adjustments to 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 and experience gained from the implementation of the programs. 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. NRCS' 2006 regulatory plan supports USDA's Strategic Goal 6, "Protect and Enhance the Nation's Natural Resource Base and Environment," and the related objectives to protect and conserve natural resources that form the foundation for healthy lands.

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 rules during FY 2007:

Interim Final Rule for the Environmental Quality Incentives Programs (EQIP): This revision to the final rule is to: 1) consider public comments about which resource concerns should be given national priority in the implementation of EQIP in future years; 2) clarify the cost-share rates (actual versus average cost); and 3) expansion of conservation practice definitions with varying payment incentives for a single conservation practice applied at different levels to achieve additional environmental benefits.

The rulemaking for EQIP consists of making minor changes to existing rules.

Final Rule for the Farmland and Ranchland Protection Program (FRPP):

This action will modify the FRPP final rule to clarify the amount of construction and forested acres permitted on FRPP easements and identify the procedure in which the United States would invoke its contingent rights.

Interim Final Rule for the Confidentiality of Conservation Program Information: If a producer believed that the proprietary information about their land and the agricultural operation provided to NRCS for participation in a conservation program would become "public" and thus subject to disclosure requirements under the Freedom of Information Act, the producer might not wish to participate in the voluntary conservation programs. Therefore, NRCS action to promulgate a rule is to ensure that NRCS or anyone acting on its behalf does not unlawfully release protected information.

Final Rule for the Healthy Forest Reserve Program (HFRP): This action implements HFRP — a voluntary program to restore and enhance forest ecosystems that promote the recovery of threatened and endangered species, improve biodiversity, and enhance carbon sequestration. Land can be enrolled through a 10-year cost-share agreement and an easement contract.

USDA—Farm Service Agency (FSA)

FINAL RULE STAGE

1. PROCUREMENT OF COMMODITIES FOR FOREIGN DONATION

Priority:

Other Significant

Legal Authority:

7 USC 1431; 7 USC 1721; 15 USC 714b

CFR Citation:

7 CFR 1496

Legal Deadline:

None

Abstract:

This rule proposes new procedures to be used by the Commodity Credit Corporation (CCC) in the evaluation of bids in connection with the procurement of commodities for donation overseas. This proposed rule would enhance bidding opportunities for potential vendors while allowing CCC to more efficiently acquire commodities. In general, CCC proposes to amend the existing regulations to

provide for the simultaneous review of commodity and ocean freight offers when evaluating lowest landed cost options in connection with the procurement of commodities.

Statement of Need:

Under the revised bid process, CCC can better control shipping costs, take advantage of efficiencies in load consolidation and ensure a more competitive commodity procurement process. The "two-step" process was designed at a time when donation commodities were shipped under ocean carrier tariffs that could be readily identified. Despite the irrelevance of published ocean tariffs and reliance on negotiated shipping service contracts today, the current "two-step" procurement process remains tied by regulation to the obsolete tariff system. 7 CFR Part 1496.5 (b)(4) states as follows: "Freight rates will be obtained from published ocean tariffs to make cost comparisons between various steamship companies and coastal ranges."

Without the changes that are being made to 7 CFR Part 1496 under this final rule, the Kansas City Commodity Office (KCCO) would be forced to continue to operate the identified donation programs without reliable rate information. The current collection process for non-binding rate indications is exceedingly cumbersome and time-consuming. In addition, the rate indications obtained are generally not representative of the rates under which the procured products will be shipped. The "two-step" process invites gaming and manipulation by participating ocean carriers. These problems render the lowest-landed-cost criteria under which the program operates nearly meaningless. Without the ability to determine accurate freight rates, KCCO cannot effectively manage these programs to maximize the quantity of food products donated under them.

Summary of Legal Basis:

15 U.S.C. 714b(h) provides that CCC may contract for the use, in accordance with the usual customs of trade and commerce, of plants and facilities for the physical handling, storage, processing, servicing, and transportation of the agricultural commodities subject to its control. The Commodity Credit Corporation may sell any commodity owned or controlled by the Corporation at any price that the Secretary determines will maximize returns to the Corporation, including minimizing the handling and

transportation costs in making delivery of the commodity.

Alternatives:

CCC has the alternative of maintaining the current "two-step" process used to procure and ship agricultural commodities.

Anticipated Cost and Benefits:

Program savings should result from the ability to better position procured commodities at domestic ports based on actual shipping cost comparisons. Program savings are also expected as a result of greater head-to-head competition for program freight among U.S.-flagged carriers. These savings should allow for additional food aid quantities to move to donation countries. This rule will enhance bidding opportunities for potential vendors while allowing CCC to more efficiently acquire commodities.

Risks:

The magnitude of the savings or losses from lower expected freight revenue will be driven by the behavior of carriers as they adjust to the new process. Such costs are difficult to quantify given the impossibility of predicting ocean carrier bidding behavior under the "one-step" system. Larger trends in program shipments and costs are expected to continue when the "one-step" freight bidding process is implemented. The existing trends reflect issues of port capacity and facilities, shipping trade and vessel availability, and the more general availability of container and inland freight equipment. The opportunity to better consolidate loads should support the continuation of these trends and, in doing so, lower freight costs for program shipments.

Timetable:

Action	Date	FR Cite
NPRM	12/16/05	70 FR 74717
NPRM Comment Period End	01/17/06	
NPRM Comment Period Extended	01/23/06	71 FR 3442
Public Meeting	02/21/06	
Second NPRM	04/07/06	71 FR 17767
Second NPRM Comment Period End	05/08/06	
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—Animal and Plant Health Inspection Service (APHIS)

PROPOSED RULE STAGE

2. ANIMAL WELFARE; REGULATIONS AND STANDARDS FOR BIRDS

Priority:

Other Significant

Legal Authority:

7 USC 2131 to 2159

CFR Citation:

9 CFR 1 to 3

Legal Deadline:

None

Abstract:

APHIS intends to establish standards for the humane handling, care, treatment, and transportation of birds other than birds bred for use in research.

Statement of Need:

The Farm Security and Rural Investment Act of 2002 amended the definition of animal in the Animal Welfare Act (AWA) by specifically excluding birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research. While the definition of animal in the regulations contained in 9 CFR part 1 has excluded rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, that definition has also excluded all birds (i.e., not just those birds bred for use in research). In line with this change to the definition of animal in the AWA, APHIS intends to establish standards in 9 CFR part 3 for the humane handling, care, treatment, and transportation of birds other than those birds bred for use in research.

Summary of Legal Basis:

The Animal Welfare Act (AWA) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, operators of auction sales, and carriers and immediate handlers. Animals covered by the AWA include birds that are not bred for use in research.

Alternatives:

To be identified.

Anticipated Cost and Benefits:

To be determined.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	
NPRM Comment Period End	11/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Additional Information:

Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

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USDA—APHIS

3. IMPORTATION OF PLANTS FOR PLANTING; ESTABLISHING A NEW CATEGORY OF PLANTS FOR PLANTING NOT AUTHORIZED FOR IMPORTATION PENDING RISK ASSESSMENT (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

7 USC 450; 7 USC 7701 to 7772; 7 USC 7781 to 7786; 21 USC 136 and 136a

CFR Citation:

7 CFR 319

Legal Deadline:

None

Abstract:

This action would establish a new category in the regulations governing the importation of nursery stock, also known as plants for planting. This category would list taxa of plants for planting whose importation is not authorized pending risk assessment. In order to determine whether to add a taxon of plants for planting to this category, we would review scientific information other than a pest risk assessment; the types of scientific information we would review would be listed in the regulations. If scientific information other than a pest risk assessment indicated that importation of the taxon of plants for planting posed a potential risk, we would then publish an interim rule adding the taxon to the proposed category and giving the public an opportunity to comment on the change. We would allow foreign governments to request that a pest risk assessment be conducted for a taxon whose importation is not authorized pending risk evaluation. After the pest risk assessment was completed, we would conduct rulemaking to remove the taxon from the proposed category. We are also proposing to expand the scope of the plants regulated in the plants for planting regulations to include non-vascular plants. These changes would allow us to react more quickly to evidence that a taxon of plants for planting may pose a pest risk while ensuring that our actions are based on scientific evidence.

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 quarantine 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, quarantine 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. The current regulations need to be amended to better address these risks.

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. 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:

In general, the costs associated with plant pests that are introduced into the United States via imported nursery stock are expected to increase in the absence of some action to revise the nursery stock regulations to better address pest risks. Specific costs and benefits will be determined.

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
NPRM	02/00/07	
NPRM Comment Period End	04/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Additional Information:

Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

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USDA—APHIS**FINAL RULE STAGE****4. REVISION OF FRUITS AND VEGETABLES IMPORT REGULATIONS****Priority:**

Other Significant

Legal Authority:

7 USC 450; 7 USC 7701 to 7772; 7 USC 7781 to 7786; 7 USC 8311; 21 USC 136 and 136a; 31 USC 9701

CFR Citation:

7 CFR 305; 7 CFR 319; 7 CFR 352

Legal Deadline:

None

Abstract:

This rule would revise and reorganize the regulations pertaining to the importation of fruits and vegetables to consolidate requirements of general applicability and eliminate redundant requirements, update terms and remove outdated requirements and references, update the regulations that apply to importations into territories under U.S.

administration, and make various editorial and nonsubstantive changes to regulations to make them easier to use. The rule would also make substantive changes to the regulations, including: (1) Establishing criteria within the regulations that, if met, would allow us to approve certain new fruits and vegetables for importation into the United States and to acknowledge pest-free areas in foreign countries without undertaking rulemaking; (2) doing away with the practice of listing specific commodities that may be imported subject to certain types of phytosanitary measures; and (3) providing for the issuance of special use permits for fruits and vegetables. These changes are intended to simplify and expedite our processes for approving certain new imports and pest-free areas while continuing to allow for public participation in the processes. If adopted, the rule would represent a significant structural revision of the fruits and vegetables import regulations and would establish a new process for approving certain new commodities for importation into the United States. It would not, however, allow the importation of any specific new fruits or vegetables, nor would it alter the conditions for importing currently approved fruits or vegetables except as specifically described in this document.

Statement of Need:

The volume of requests for new imports of fruits and vegetables has risen sharply in recent years with expanding global trade. APHIS is seeking an alternative process for certain new imports to expedite their evaluation and, where applicable, their approval.

Summary of Legal Basis:

Under the Plant Protection Act of 2000, it is the responsibility of the Secretary to facilitate . . . imports . . . in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests or noxious weeds. This proposed rule, if adopted, would expedite the process for approving certain new imports.

Alternatives:

One alternative to this proposed rule would be to simply continue under APHIS' current process of authorizing the importation of fruits and vegetables. In this case, we would continue to list all newly approved fruits and vegetables in the regulations through

notice-and-comment rulemaking, as we have been doing since 1987. This approach is unsatisfactory, because the number of requests we receive from foreign exporters and domestic importers to amend the regulations has been steadily increasing. Maintaining the current process will make it difficult to keep pace with the volume of import requests. Therefore, this alternative was rejected. We believe that the new approach would enable us to be more responsive to the import requests of our trading partners while maintaining the transparency of our decision-making afforded by notice-and-comment rulemaking.

Prior to 1987, APHIS authorized the importation of a fruit or vegetable by simply issuing a permit once the Agency was satisfied that the relevant criteria in the regulations had been met. Another alternative to this proposed rule would be to return to this method of authorizing fruit and vegetable importations. This approach is unsatisfactory, because it does not provide the opportunity for public analysis of and comment on the science associated with such imports. Therefore, this alternative was rejected. We believe that the new approach would enable us to be more responsive to the import requests of our trading partners while maintaining the transparency of our decisionmaking afforded by notice-and-comment rulemaking.

Anticipated Cost and Benefits:

There would be no new costs associated with this rule. Benefits could include more timely action on import requests, which could also lead to reciprocal action by trading partners as they evaluate our export requests.

Risks:

This action is administrative in nature and poses no direct specific risks. If new import requests are evaluated using the system proposed in this rule, each would be based on a unique risk analysis.

Timetable:

Action	Date	FR Cite
NPRM	04/27/06	71 FR 25010
NPRM Comment Period End	07/26/06	
NPRM Comment Period Reopened	08/01/06	71 FR 43385
NPRM Comment Period End	08/25/06	
Final Rule	03/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

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USDA-APHIS

5. PHYTOPHTHORA RAMORUM; QUARANTINE AND REGULATIONS

Priority:

Other Significant

Legal Authority:

7 USC 7701 to 7772; 7 USC 7781 to 7786; sec 301.75-15 also issued under sec 204, title II, PL 106-113, 113 Stat 1501A-293; secs 301.75-15 and 301.75-16 also issued under sec 203, title II, PL 106-224, 114 Stat 400 (7 USC 1421 note)

CFR Citation:

7 CFR 301

Legal Deadline:

None

Abstract:

This action will amend the Phytophthora ramorum regulations to make the regulations consistent with a Federal Order issued by APHIS in December 2004 that established restrictions on the interstate movement of nursery stock from nurseries in nonquarantined counties in California, Oregon, and Washington. This action will also update conditions for the movement of regulated articles of nursery stock from quarantined areas, as well as restrict the interstate movement of all other nursery stock from nurseries in quarantined areas. We are also updating the list of plants regulated because of P. ramorum and the list of areas that are quarantined for P. ramorum and making other

miscellaneous revisions to the regulations. These actions are necessary to prevent the spread of *P. ramorum* to noninfested areas of the United States. We will continue to update the regulations through additional rulemakings as new scientific information on this pathogen becomes available.

Statement of Need:

Since 1995, oaks and tanoaks have been dying in the coastal counties of California. Since then, other types of plants have been found to be infected or associated with this disease, referred to as Sudden Oak Death (SOD), ramorum leaf blight, ramorum dieback, or in Federal regulations, as *Phytophthora ramorum*. *P. ramorum* was first seen in 1995 in Mill Valley (Marin County) on tanoak. Since that time, the disease has been confirmed on various native hosts in 14 coastal California counties (Marin, Santa Cruz, Sonoma, Napa, San Mateo, Monterey, Santa Clara, Mendocino, Solano, Alameda, Contra Costa, Humboldt, Lake, and San Francisco) and in Curry County, Oregon. The pathogen has been confirmed to infect 39 host plant taxa, and there are over 30 additional taxa that are suspected to be hosts. In 2004, the pathogen was detected in plants shipped interstate from nonquarantined areas in California, Oregon, and Washington. Given the uncertainty associated with the spread of the pathogen and its potential effects on eastern oak forests, APHIS is taking action to define the extent of the pathogen's distribution in the United States and limit its artificial spread beyond infected areas through quarantine and a public education program. Completing this action is integral to having a scientifically sound quarantine as the foundation of our program.

Summary of Legal Basis:

The Plant Protection Act (7 U.S.C. 7701 to 7773) authorizes the Secretary to prohibit or restrict the movement in interstate commerce of any plant, plant product, or other article if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of a plant pest within the United States.

Alternatives:

The two most significant alternatives APHIS considered were to (1) eliminate the Federal quarantine for *P. ramorum* because of the likelihood that the pathogen has already spread to other parts of the United States via interstate

trade in articles that may be infested, and (2) quarantine the entire states of California, Oregon, and Washington and prohibit the interstate movement of *P. ramorum* host articles to protect against the interstate spread of the pathogen. We rejected the first alternative because of insufficient evidence about the presence of the pathogen in eastern U.S. nurseries or forests. The lack of evidence of spread despite the significant amount of trade in potentially infected material that has already occurred is the reason we did not select the second alternative. Our preferred action balances the need to protect eastern forests and nurseries with the goal of imposing only those restrictions on trade that are necessary to prevent the spread of the pathogen.

Anticipated Cost and Benefits:

The anticipated costs of this rulemaking mirror those of the Federal Order of 2004. Specifically, nurseries in regulated and quarantined areas will have to meet certain criteria prior to engaging in the interstate trade of nursery stock. Depending on the location of the nursery, the classification of nursery stock propagated within, and on the classification of articles to be shipped, the nursery will have to undergo annual inspection; and/or inspection, sampling, and testing of individual shipments in order to receive certification for interstate shipment. Currently, USDA covers the costs of annual inspection during normal business hours; however, as with all government subsidized programs, the budget allowable may differ from year to year. There are other intangible costs of rulemaking, such as the potential for lost revenue while holding plants during sampling and testing. Further, there have been some negative stigma associated with nursery stock from regulated areas of Oregon and Washington state as a result of the *P. ramorum* rulemaking and restrictions on interstate movement, although it is hard to quantify the effect of any perceived stigma.

Because knowledge of the *P. ramorum* pathogen and how it spreads is still in its infancy, the benefits of proactively addressing the situation in hopes of preventing widespread infestation far outweigh any costs associated with the rulemaking. The total value of sales of nursery stock reported in 2004 from operations with \$100,000 or more in sales in the United States was over \$4.8 billion. California, Oregon, and Washington alone account for about 25 percent of that total, with sales of over

\$1.2 billion. With new hosts being consistently added to the list, and our knowledge of the pathogen's pathways increasing, this rulemaking is necessary, not only for protecting the nursery industry in the Pacific northwest, but also for protecting the nursery industry nationwide.

Risks:

This rulemaking addresses risks associated with the interstate movement of articles that may spread *P. ramorum* to areas of the United States where the disease is not known to exist.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/00/07	
Interim Final Rule	03/00/07	
Comment Period		
End		

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Additional Information:

Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

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USDA—Food and Nutrition Service (FNS)

PROPOSED RULE STAGE

6. 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 provisions. (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, children who cannot consume milk will now have a

beverage nutritionally equivalent to milk.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	11/09/06	71 FR 65753
NPRM Comment Period End	01/08/07	
Final Action	01/00/08	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

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USDA—FNS

FINAL RULE STAGE

7. 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	

Action	Date	FR Cite
Interim Final Rule Comment Period End	09/01/05	
Final Action	09/00/07	

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**8. 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 will 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. (02-007)

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 final 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 were 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 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 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 implements the certification and eligibility provisions of Public Law 107-171, the Farm Security and Rural Investment Act of 2002. It simplifies State administration of the Food Stamp Program, increases eligibility for the program among certain groups, increases access to the program among low-income families and individuals, and increases benefit levels. The provisions of this rule 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

Action	Date	FR Cite
NPRM Comment Period End	06/15/04	
Final Action	12/00/06	
Final Action Effective	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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USDA—FNS

9. 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 rule finalizes the Interim rule “Non-Discretionary Quality Control Provisions of Title IV of Public Law 107-171” (published October 16, 2003 at 68 FR 59519) and the Proposed rule “Discretionary Quality Control Provisions of Title IV of Public Law 107-171” (published September 23, 2005 at 70 FR 55776).

The following quality control (QC) provisions required by Sections 4118 and 4119 of the Farm Security and Rural Investment Act of 2002 (Title IV of Public Law 107-171) and contained in the Interim rule are implemented by this final rule:

- 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.

The following provisions required by Sections 4118 and 4119 and additional policy and technical changes, and contained in the Proposed rule, are implemented by this final rule:

- Legislative changes based on or required by Sections 4118 and 4119
- 1) Eliminate enhanced funding;
 - 2) Establish timeframes for completing individual quality control reviews; and
 - 3) Establish procedures for adjusting liability determinations following appeal decisions.

Policy and technical changes

- 1) Require State agency QC reviewers to attempt to complete review when a household refuses to cooperate;
- 2) Mandate FNS validation of negative sample for purposes of high performance bonuses;
- 3) Revise procedures for conducting negative case reviews;
- 4) Revise time frames for household penalties for refusal to cooperate with State and Federal QC reviews;
- 5) Revise procedures for QC reviews of demonstration and SSA processed cases;
- 6) Eliminate requirement to report variances resulting from Federal information exchange systems (FIX) errors;
- 7) Eliminate references to integrated QC; and
- 8) Update definitions section to remove out-dated definitions. (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 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 the time frames for completing quality control reviews, the arbitration process, and determining the final error rates; the threshold for potential sanctions and the time period for the sanctions; the calculation for State error rates; the formula for determining liability amounts; the sanction notification; method of payment for liabilities; corrective action planning, and the elimination of enhanced funding. These provisions were effective for the fiscal year 2003 quality control review period and must have been implemented by FNS and State agencies during fiscal year 2003. This rule also deals in part with discretionary changes to the quality control system resulting from Public Law 107-171. 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 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	01/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State

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Related RIN: Merged with 0584-AD37

RIN: 0584-AD31

USDA—FNS

10. DIRECT CERTIFICATION OF CHILDREN IN FOOD STAMP HOUSEHOLDS AND CERTIFICATION OF HOMELESS, MIGRANT AND RUNAWAY CHILDREN FOR FREE MEALS IN THE NSLP, SBP, AND SMP

Priority:

Other Significant

Legal Authority:

PL 108-265, sec 104

CFR Citation:

7 CFR 245

Legal Deadline:

None

Abstract:

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 amended to establish categorical (automatic) eligibility for free meals and free milk upon documentation that a child is (1) homeless as defined by the McKinney-Vento Homeless Assistance Act; (2) a runaway served by grant programs under the Runaway and Homeless Youth Act; or (3) migratory as defined in sec. 1309(2) of the Elementary and Secondary Education Act. The rule also requires phase-in of mandatory direct certification for children who are members of households receiving food stamps and continues discretionary direct certification for other categorically eligible children. (04-018)

Statement of Need:

The changes made to the Richard B. Russell National School Lunch Act concerning direct certification 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	02/00/07	
Interim Final Rule Comment Period End	02/00/08	
Final Action	02/00/09	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

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Related RIN: Merged with 0584-AD62

RIN: 0584-AD60

USDA—FNS

11. SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC): WIC VENDOR COST CONTAINMENT

Priority:

Other Significant

Legal Authority:

42 USC 1786

CFR Citation:

7 CFR 246

Legal Deadline:

Final, Statutory, December 2005.

Abstract:

This final rule amends the WIC regulations to strengthen vendor cost containment. The rule incorporates into program regulations new legislative requirements that affect the selection, authorization, and reimbursement of retail vendors. These requirements are contained in the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108-265), which was enacted on June 30, 2004. The rule reflects the statutory provisions that require WIC State agencies to implement a vendor peer group system, competitive price selection criteria, and allowable reimbursement levels in a manner that ensures that the WIC Program pays authorized vendors competitive prices for supplemental foods. It also requires State agencies to ensure that vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments do not result in higher food costs to the program than do other vendors. The intent of these provisions is to maximize the number of women, infants, and children served with available Federal funding. (04-029)

Statement of Need:

This action is needed to implement the vendor cost containment provisions of the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108-265. The rule requires WIC State agencies to operate vendor management systems that effectively contain food costs by ensuring that prices paid for supplemental foods are competitive. The rule also responds to data which indicate that WIC food expenditures increasingly include payments to a type of vendor whose prices are not governed by the market forces that affect most retail grocers. As a result, the prices charged by these vendors tend to be higher than those of other retail grocery stores participating in the program. To ensure

that the program pays competitive prices, this rule codifies the new statutory requirements for State agencies to use in evaluating vendor applicants' prices during the vendor selection process and when paying vendors for supplemental foods following authorization.

Summary of Legal Basis:

Section 203 of Public Law 108-265, Child Nutrition and WIC Reauthorization Act of 2004.

Alternatives:

This rule implements the vendor peer group provisions of the Child Nutrition and WIC Reauthorization Act of 2004, which FNS believes is an effective means of controlling WIC food costs. While this Act mandates that States establish peer groups, competitive price criteria, and allowable reimbursement levels, and states that these requirements must result in the outcome of paying above-50-percent vendors no more than regular vendors, the rule does not specify particular criteria for peer groups or acceptable methods of setting competitive price criteria and allowable reimbursement levels. FNS considered mandating specific means of developing peer groups, competitive price criteria, and allowable reimbursement levels in order to ensure that the outcome of this legislation was achieved.

However, given States' responsibility to manage WIC as a discretionary grant program and the varying market conditions in each State, FNS believes that States need flexibility to develop their own peer groups, competitive price criteria, and allowable reimbursement levels. At the October 2004 meeting the FNS convened to gain input for this rule, States indicated that they needed the ability to design cost containment practices that would be effective in their own markets and would ensure participant access. In addition, there is little information about the effectiveness of particular cost containment practices in the variety of markets represented by the 89 WIC State agencies. Mandating more specific means of developing peer groups, competitive price criteria, and allowable reimbursement levels could have unintended negative consequences for participant access, food costs and administrative burden.

As States gain experience and the results of their vendor cost containment practices become apparent, FNS may develop further regulations and guidance to improve vendor cost

containment. In the interim, FNS believes that the current rule will substantially accomplish the goal of the Act of containing food costs and ensuring that above-50-percent vendors do not result in higher costs to the WIC Program than regular vendors.

Anticipated Cost and Benefits:

Costs: This rule places new requirements on State agencies; therefore, the cost implications of this rule relate primarily to administrative burden for WIC State agencies. These cost implications are partially dependent on the current practices of State agencies relative to the requirements of the rule. Detailed information regarding the cost implications of this rule is contained in the Regulatory Impact Analysis developed by FNS to accompany this rulemaking.

Benefits: The WIC Program will benefit from the provisions of this rule by reducing unnecessary food expenditures, thus increasing the potential to serve more eligible women, infants, and children for the same cost. This rule should have the effect of ensuring that payments to vendors, particularly vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments, reflect competitive prices for WIC foods. The Regulatory Impact Analysis prepared by FNS to accompany this rulemaking projects an estimated monthly cost savings of over \$6.25 million. (Details of this projection can be found in the complete Regulatory Impact Analysis.)

Risks:

Because the vendor peer group provisions in the Child Nutrition and WIC Reauthorization Act of 2004 and this rule provide for some flexibility in implementation, and because there is a wide degree of variation in food prices and current vendor cost containment practices across State agencies, the impact of many of the provisions of this rule is uncertain. Uncertainties include the administrative burden State agencies will incur and the savings that can be realized nationally or in any State agency. The major uncertainties for both administrative burden and program savings are discussed in greater detail in the Regulatory Impact Analysis.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/29/05	70 FR 71708

Action	Date	FR Cite
Interim Final Rule Comment Period End	11/29/06	
Interim Final Rule Effective	12/29/05	
Final Action	08/00/07	
Final Action Effective	09/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, Local, State, Tribal

URL For More Information:

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USDA—FNS

12. SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC): REVISIONS IN THE WIC FOOD PACKAGES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1786

CFR Citation:

7 CFR part 246

Legal Deadline:

Final, Statutory, November 2006, CN and WIC Reauthorization Act of 2004 requires issuance of final rule within 18 months of release of IOM Report.

Abstract:

This proposed rule would revise regulations governing the WIC food packages to change age specifications for assignment to infant feeding packages; establish infant formula feeding or breastfeeding categories for infants; revise the maximum monthly

allowances and minimum requirements for certain WIC foods; revise the substitution rates for certain WIC foods and allow additional foods as alternatives; add fruits and vegetables for WIC participants 6 months of age and older and eliminate juice from infants' food packages; add whole grains to food packages for children and women and baby food meat for fully breastfed infants 6 through 11 months of age; revise the purpose, content, and requirements for Food Package III; and address general provisions that apply to all food packages. The revisions reflect recommendations made by the Institute of Medicine in its report, WIC Food Packages: Time for a Change, and certain other administrative revisions deemed necessary by the Department. These revisions would bring the WIC food packages in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines, better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food, provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, and serve all participants with certain medical provisions under one food package to facilitate efficient management of medically fragile participants. (05-006)

Statement of Need:

The revisions proposed in this rulemaking reflect recommendations made by the Institute of Medicine (IOM) in its report, WIC Food Packages: Time for a Change, and certain administrative revisions deemed necessary by the Department. The Child Nutrition and WIC Reauthorization Act of 2004, enacted on June 30, 2004, requires the Department to issue a final rule within 18 months (November 2006) of receiving the IOM's report.

Summary of Legal Basis:

The Child Nutrition and WIC Reauthorization Act of 2004, enacted on June 30, 2004, requires the Department to issue a final rule within 18 months of receiving the Institute of Medicine's report on revisions to the WIC food packages. This report was published and released to the public on April 27, 2005.

Alternatives:

FNS is in the process of developing a regulatory impact analysis that will

address a variety of alternatives that are considered in the proposed rulemaking.

Anticipated Cost and Benefits:

The IOM was charged by FNS to develop recommendations that were cost-neutral. The regulatory impact analysis will provide a more detailed summary of specific costs/benefits associated with the proposed revisions to the WIC Food Packages.

Risks:

The proposed rule has 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 revised WIC food packages will be offered to State agencies and other entities as necessary.

Timetable:

Action	Date	FR Cite
NPRM	08/07/06	71 FR 44784
NPRM Comment Period End	11/06/06	
Interim Final Rule	09/00/07	
Interim Final Rule Effective	10/00/07	
Interim Final Rule Comment Period End	10/00/09	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Local, State, Tribal

URL For More Information:

www.fns.usda.gov/wic

URL For Public Comments:

www.fns.usda.gov/wic

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USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

13. EGG PRODUCTS INSPECTION REGULATIONS

Priority:

Economically Significant. Major under 5 USC 801.

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 establishments that pasteurize 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. 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 findings of Salmonella in pasteurized egg products.

Statement of Need:

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 on the 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 alternative.

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. FSIS has developed new risk assessments for SE in eggs and for Salmonella spp. in liquid egg products to evaluate the risk associated with the regulatory alternatives.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State

Federalism:

Undetermined

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USDA—FSIS

FINAL RULE STAGE

**14. PERFORMANCE STANDARDS FOR
 THE PRODUCTION OF PROCESSED
 MEAT AND POULTRY PRODUCTS;
 CONTROL OF LISTERIA
 MONOCYTOGENES IN
 READY-TO-EAT MEAT AND
 POULTRY PRODUCTS**
Priority:

Economically Significant. Major under
 5 USC 801.

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; 9 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, and measures, including testing, to control *Listeria monocytogenes* in RTE 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. With HACCP, food safety performance standards 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 fewer 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* O157: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. 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. Consequently, there will be fewer cases of foodborne illness.

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	

Action	Date	FR Cite
Interim Final Rule	01/31/05	
Comment Period End		
NPRM Comment Period Reopened	03/24/05	70 FR 15017
NPRM Comment Period End	05/09/05	
Affirmation of Interim Final Rule	02/00/07	
Final Action	06/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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USDA—FSIS

15. NUTRITION LABELING OF SINGLE-INGREDIENT PRODUCTS AND GROUND OR CHOPPED MEAT AND POULTRY PRODUCTS

Priority:

Economically Significant. Major under 5 USC 801.

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 nutrition information, FSIS has concluded that the major cuts of single-ingredient, raw meat and poultry 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	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0583-AC60

USDA—FSIS

**16. 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 under
 5 USC 801.

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	05/07/04	
Interim Final Rule Amendment	07/07/05	70 FR 53043
Interim Final Rule Amendment Comment Period End	10/07/05	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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USDA—FSIS

17. MEAT PRODUCED BY ADVANCED MEAT/BONE SEPARATION MACHINERY AND MEAT RECOVERY SYSTEMS

Priority:

Other Significant

Legal Authority:

21 USC 601 to 695

CFR Citation:

9 CFR 301.2; 9 CFR 318.24 (Revision); 9 CFR 320.1

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. The rule is designed, in part, to prevent human exposure to the Bovine Spongiform Encephalopathy (BSE) agent by ensuring that Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) systems are not a means of introducing central nervous system (CNS)-type tissue into product labeled as "meat." Meat may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older, using advances in mechanical meat/bone separation machinery; i.e., AMR systems. The recovered meat product may not incorporate any brain, trigeminal ganglia, spinal cord, or dorsal root ganglia tissues. In addition, there must be no more than a non-significant incorporation of bone solids or bone

marrow as measured by the presence of calcium and iron in excess of the requirements in the interim final rule. This rule also requires that federally inspected establishments that process cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials (SRMs), including non-complying products from beef AMR systems. These procedures are required to be incorporated into an establishment's HACCP plan, Sanitation Standard Operation Procedures, or other prerequisite program. FSIS took this action in response to the diagnosis on December 23, 2003, by the Department of Agriculture of a positive case of BSE in an adult Holstein cow in the State of Washington.

Statement of Need:

FSIS issued an interim final rule in part to prevent human exposure to the BSE agent by ensuring that AMR systems are not a means of introducing CNS-type tissue into product labeled as "meat." In addition to the measures related to BSE, FSIS is finalizing restrictions related to bone solids and bone marrow for livestock products. This rule sets out the criteria that FSIS will use to ensure that AMR products can be represented as "meat" and, therefore, are not adulterated or misbranded. Finally, the Agency is requiring that federally inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials (SRMs), including noncomplying product from AMR systems processing beef. A 2002 FSIS survey of establishments harvesting AMR product derived from beef vertebrae or beef vertebrae mixed with other types of beef bones indicated that 35 percent of the final AMRs product samples tested positive for spinal cord or dorsal root ganglia.

Summary of Legal Basis:

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

Alternatives:

No action.

Anticipated Cost and Benefits:

The interim final rule was determined to be not economically significant, but significant. The benefit of enforcing the misbranding provisions will ensure that the product does not contain materials

not consistent with boneless, comminuted meat.

Risks:

None

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/12/04	69 FR 1874
Interim Final Rule Comment Period End	05/07/04	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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Related RIN: Duplicate of 0583-AC51

RIN: 0583-AD00

USDA-FSIS

18. PROHIBITION ON THE USE OF AIR-INJECTION STUNNERS FOR THE SLAUGHTER OF CATTLE

Priority:

Other Significant

Legal Authority:

Federal Meat Inspection Act, 21 USC 601(m), 621

CFR Citation:

9 CFR 313

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to prohibit the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. This rulemaking responds to the findings of a risk assessment on bovine spongiform

encephalopathy (BSE) conducted by the Harvard Center for Risk Analysis (referred to as the Harvard study) and is part of a series of actions that the USDA is taking to strengthen its BSE prevention programs.

Statement of Need:

FSIS is taking this action to address the potential risk posed by stunning devices that may force visible pieces of central nervous system (CNS) tissue, known as macro-emboli, into the circulatory system of stunned cattle. In cattle in the end stages of bovine spongiform encephalopathy (BSE), CNS tissue contains the highest levels of the BSE agent. Thus, because CNS macro-emboli can potentially become lodged in edible tissues, this action is necessary to prevent potential human exposure to the BSE agent.

Summary of Legal Basis:

FSIS' authority to prohibit the use of captive bolt stunning devices that inject air into the cranium of cattle derives from the Federal Meat Inspection Act (21 U.S.C. 601(m), 621).

Alternatives:

FSIS considered the alternative of establishing a performance standard that stunning equipment would be required to meet to be used on cattle, and the alternative of no rulemaking. Under the performance standard option, the Agency would have developed a CNS tissue emboli performance standard that stunners would be required to meet to be permitted to be used on cattle. The benefits of this option are that it is more consistent with FSIS regulatory policy than banning a specific technology, and that it would prevent all methods of stunning that do not comply with the performance standard from being used on cattle, not just air-injection stunning. Thus, this option would prevent the need to regulate individual pieces of equipment.

A potential problem with this option is that there are relatively few studies on stunning methods and CNS tissue emboli. Thus, the Agency was concerned that if it were to establish a CNS tissue emboli performance standard for cattle stunning devices at this time, further studies could reveal that the performance standard selected does not achieve the result intended by the Agency. Therefore, FSIS decided to prohibit the use of the stunning method that all available studies do conclude result in CNS tissue macro-emboli, i.e., stunning that uses air-injection.

FSIS rejected the option of no rulemaking because the Agency determined that it does not address the potential risk of human exposure to the BSE agent presented by air-injection stunning.

Anticipated Cost and Benefits:

There are likely no anticipated costs associated with this rule because FSIS is not aware of any establishments that use air-injection stunning on cattle. However, although the U.S. beef slaughter industry no longer uses air-injection stunning devices, FSIS is taking this action to prohibit any future use of these devices, to help facilitate exports of U.S. products, and to ensure the safety of imported beef products into the United States.

Risks:

None

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/12/04	69 FR 1885
Interim Final Rule Comment Period End	05/07/04	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 0583-AD03

USDA-FSIS

19. AVAILABILITY OF LISTS OF RETAIL CONSIGNEES DURING MEAT OR POULTRY PRODUCT RECALLS

Priority:

Other Significant

Legal Authority:

5 USC 301, 552

CFR Citation:

9 CFR 390

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) has proposed to amend the federal meat and poultry products inspection regulations to provide that the Agency will make available to the public lists of the retail consignees of meat and poultry products that have been voluntarily recalled by a federally inspected meat or poultry products establishment. FSIS has proposed this action because it believes that making this information available will be of significant value to consumers and the industry. It will clarify what products should be removed from commerce and from consumers' possession because there is reason to believe they are adulterated or misbranded.

Statement of Need:

The objective to be accomplished by this regulatory action is to provide important information to consumers while ensuring the appropriate flexibility for FSIS to protect proprietary information.

While FSIS does not have mandatory recall authority under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), the Agency, to protect the public health, does ask establishments to voluntarily recall adulterated or misbranded meat and poultry products. FSIS verifies that such recalls are conducted expeditiously and effectively.

In 2002, FSIS promulgated regulations defining the circumstances and criteria under which it would share customer lists with States and other Federal agencies in connection with voluntary meat and poultry product recalls. In short, FSIS will disclose product distribution lists that have been obtained during voluntary recalls to States and other Federal government agencies to verify the removal of the recalled product, provided that the State or Federal agency has provided: (1) A written statement establishing its authority to protect confidential distribution lists from public disclosure; and (2) a written commitment not to disclose any information provided by FSIS without the written permission of the submitter of the information or written confirmation by FSIS that the

information no longer has confidential status. Currently, FSIS will not disclose distribution lists to the general public or to States or other Federal government agencies that have not provided to FSIS the written statement and commitment required by the Agency's Freedom of Information and public information regulations.

Consumer activists and States have increasingly demanded the public release of information on where recalled meat and poultry products have been shipped. The States have requested this information be provided without the limitations imposed by FSIS's regulations. Consumer groups have claimed that the public needs this information to fully protect itself. In response to these requests, FSIS is proposing to make available to the public the names of likely retail consignees of recalled meat and poultry products.

Summary of Legal Basis:

This proposed rule is authorized under 5 U.S.C. 301, Departmental regulations, and 5 U.S.C. 552, Public information; agency rules, opinions, orders, records, and proceedings. It is not the result of any specific mandate by the Congress or a Federal court.

Alternatives:

FSIS has prepared a regulatory impact analysis to evaluate the potential economic impacts of several alternatives on the public, the meat and poultry industry, and FSIS. These alternatives include: (1) Including local health departments as entities that could receive recall distribution lists; (2) making available to the general public recall distribution lists only in response to a Freedom of Information request; and (3) making lists available to State agencies with agreements with FSIS under 9 CFR 390.9.

Anticipated Cost and Benefits:

FSIS is analyzing the potential costs of this proposed rulemaking.

This proposed rule would provide information to consumers about meat and poultry products sold at retail establishments that are believed to be adulterated or misbranded and are therefore subject to being recalled. The consumption of such products may cause food borne illness and other adverse health consequences, including death. Providing information of this sort that is more accessible and likely to be used by the consumer will reduce the likelihood of food borne illnesses and related consequences.

Risks:

FSIS believes that this regulatory action may result in a further reduction in the risks associated with the consumption of meat and poultry products.

Timetable:

Action	Date	FR Cite
NPRM	03/07/06	71 FR 11326
NPRM Comment Period End	06/11/06	71 FR 27211
Final Action	05/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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USDA—Forest Service (FS)

PROPOSED RULE STAGE

20. • FOREST SERVICE NATIONAL ENVIRONMENTAL POLICY ACT PROCEDURES

Priority:

Other Significant

Legal Authority:

40 CFR 1507.3

CFR Citation:

36 CFR 220

Legal Deadline:

None

Abstract:

The Forest Service is proposing to move existing agency NEPA procedures required by 40 CFR 1507.3 from Forest Service Handbook 1909.15 to the CFR, add new procedures, and edit some existing procedures. Presently, Forest Service procedures are combined with

agency guidance in FSH 1909.15 along with quotations from the Council on Environmental Quality regulations. Having agency NEPA procedures in regulations, separate from guidance, will make it easier for the Forest Service to provide guidance through the agency directive system. Agency internal processes will continue to reside in FSH 1909.15 with references to both CEQ and Forest Service NEPA procedures.

Statement of Need:

The Forest Service is proposing to move existing agency NEPA procedures, required by the Council on Environmental Quality (CEQ) and codified at 40 CFR 1507.3, from the internal Forest Service Environmental Policy and Procedures Handbook (FSH) 1909.15 to the Code of Federal Regulations. New procedures would be added and existing procedures would be revised where clarity is needed to incorporate CEQ guidance and align agency NEPA procedures with agency decision processes.

Presently, the Forest Service NEPA procedures are combined with agency guidance in FSH 1909.15 along with quotations from the CEQ regulations. This handbook contains general guidance such as how to select an interdisciplinary team, thereby associating guidance with NEPA procedures. Guidance and quotes from the CEQ regulations are important to internal agency work, but bear little similarity to the agency procedures contemplated in the CEQ regulations (40 CFR 1507.3(b)). Changes to agency guidance in FSH 1909.15 currently involve consultation with CEQ because the handbook does not differentiate between NEPA guidance and "procedures." This makes it more difficult to update simple guidance.

Summary of Legal Basis:

The Council on Environmental Quality (CEQ) regulations (40 CFR 1507.3) direct Federal agencies to develop NEPA procedures to supplement the CEQ regulations. The CEQ regulations require agencies to provide for public notice and comment and CEQ consultation when developing and revising agency NEPA procedures.

Alternatives:

A possible alternative would be to have the CEQ revise its regulations or seek legislative changes.

Anticipated Cost and Benefits:

Codifying agency NEPA procedures in regulation, separate from guidance,

would make it easier for the Forest Service to provide guidance through the agency directive system. General guidance and internal processes would reside in the FSH 1909.15 handbook with references to both CEQ and Forest Service NEPA procedures set out in the CFR. This will make future revisions to internal agency guidance more responsive to new ideas and information. Having the agency NEPA procedures at the same level as the CEQ regulations would also give them equal status in court.

New procedures and revisions to existing procedures would further define how the agency must comply with NEPA where the CEQ regulations lack clarity, when additional CEQ guidance has been issued, or when there are more efficient or applicable procedures appropriate to agency decision making. With more flexibility in how NEPA documents are prepared, the NEPA process is expected to be more efficient and responsive to decision maker needs.

Risks:

More NEPA procedural requirements could be added which would add to the present processes. Also, given that some of the proposed procedures would allow more flexibility and options to comply with NEPA, the results could be a more complex set of regulations for the field to understand.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—FS

FINAL RULE STAGE

21. NATIONAL FOREST SYSTEM LAND MANAGEMENT PLANNING CATEGORICAL EXCLUSION (FINAL DIRECTIVE, FOREST SERVICE HANDBOOK 1909.15, CHAPTER 30)

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 requested comment on a proposed revision to its procedures for implementing the National Environmental Policy Act (NEPA) and Council on Environmental Quality (CEQ) regulations. This revision is being proposed at Forest Service Handbook 1909.15, chapter 30, which describes categorical exclusions, that is, categories of actions that will not result in significant impacts on the human environment and which are therefore exempt from requirements to prepare further NEPA documentation absent extraordinary circumstances. The proposal would add one such category of actions to the agency's NEPA procedures for final approvals on proposals to develop, amend, or revise land management plans that are comprised of five components, which are desired conditions, objectives, guidelines, suitability of areas, and special areas for a forest. This proposal was published in conjunction with the final Forest Service planning regulations published January 5, 2005.

Statement of Need:

On January 5, 2005, the Forest Service published a final rule in the Federal Register (70 FR 1023) revising Title 36, Code of Federal Regulations, Part 219, Subpart A, "National Forest System Land Management Planning." This final rule substantially changed the type of decisions made in land management plans. These plans developed under this regulation are aspirational, and do not result in significant impacts on the human environment. Accordingly, existing agency NEPA procedures need to be updated to allow the use of a

categorical exclusion when a land management plan is not making decisions that will result in significant impacts on the human environment and where no extraordinary circumstances exist that would prohibit the use of the categorical exclusion.

Summary of Legal Basis:

The National Forest Management Act (NFMA) is the legal basis for National Forest System Land Management Planning. It requires “specifying procedures to insure that land management plans are prepared in accordance with the National Environmental Policy Act [NEPA] of 1969, including, but not limited to, direction on when and for what plans an environmental impact statement required under section 102(2)(C) of that Act shall be prepared.” Notice of the proposed categorical exclusion and request for comment was published January 5, 2005 (70 FR 1062).

Alternatives:

The agency would continue using environmental impact statements or environmental assessments for the development, amendment, or revision of land management plans.

Anticipated Cost and Benefits:

A cost-benefit analysis was conducted to compare the costs and benefits of implementing the final National Forest System Land Management Planning regulation to the baseline, 1982 planning rule. This analysis is posted at the Forest Service web site address (www.fs.fed.us/emc/nfma/index2.html), along with other documents associated with the final rule. A basic assumption of the cost-benefit analysis is that the planning rule would be carried out using the planning categorical exclusion.

Based on costs that can be quantified, implementation of the final rule is expected to have an estimated annual average cost savings of \$4.6 million when compared to the 1982 planning rule, and an estimated annual average savings of \$36.9 million when compared to estimates of implementation of the 2000 planning rule. The final rule is expected to be less costly than the 2000 planning rule; some of those saved costs are expected to be shifted to monitoring and evaluation.

The appropriate use of a categorical exclusion to meet NEPA requirements will be a substantial savings over the cost of an environmental impact statement or environmental assessment.

Risks:

The directive will help strengthen the Forest Service’s ability to respond quickly and effectively to a variety of changing issues, such as new scientific information, new listing of species, the effects of wildfire, and unforeseen plan implementation activities. It will help reduce the risk of a land management plan being outdated.

Timetable:

Action	Date	FR Cite
NPRM	12/06/02	67 FR 72770
NPRM Comment Period End	03/24/03	
Final Rule	01/05/05	70 FR 1023
Proposed Directive	01/05/05	70 FR 1062
Comment Period End	03/07/05	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—FS

22. • NATIONAL FOREST SYSTEM LAND MANAGEMENT PLANNING DIRECTIVE (FINAL DIRECTIVE, FOREST SERVICE HANDBOOK 1909.12, CHAPTER 70-WILDERNESS EVALUATION)

Priority:

Other Significant

Legal Authority:

36 CFR 219

CFR Citation:

None

Legal Deadline:

None

Abstract:

On March 23, 2005, the Forest Service published 12 interim directives (70 FR

14637) to Forest Service Manual 1330 (New Management Strategies; 1900 (Planning; 1920 (Land and Resource Management Planning; and 1909.12 (Land and Resource Management Planning Handbook). These directives provide the detailed direction to agency employees necessary to implement the provisions of the final land and resource management planning rule, which was published on January 5, 2005 (70 FR 1023). On January 31, 2006 (71 FR 5124), all the chapters were finalized except for FSH 1909.12, chapter 70-Wilderness Evaluation. Once finalized, this chapter will provide guidance for the identification, inventory, evaluation, and recommendation of areas within National Forest System lands that satisfy the definition of wilderness found in section 2(c) of the 1964 Wilderness Act.

Statement of Need:

On January 5, 2005, the Forest Service published a final rule in the Federal Register (70 FR 1023) revising Title 36, Code of Federal Regulations, Part 219, Subpart A, “National Forest System Land Management Planning.” To meet the new requirements, this directive updates guidance for the identification, inventory, evaluation, and recommendation of areas within National Forest System lands that satisfy the definition of wilderness found in section 2(c) of the 1964 Wilderness Act.

Summary of Legal Basis:

The Wilderness Act of 1964 requires identification of potential wilderness areas. The National Forest Management Act of 1976 requires “specifying guidelines for land management plans developed to achieve the goals of the Program which — (A) insure consideration of the economic and environmental aspects of various systems of renewable resource management, including the related systems of silviculture and protection of forest resources, to provide for outdoor recreation (including wilderness), range, timber, watershed, wildlife, and fish;....”

The National Forest System Land Management Planning regulation requires the development of planning directives to set forth the legal authorities, objectives, policy, responsibilities, direction, and overall guidance needed by Forest Service line officers, agency employees, and others to use the rule. Notice of issuance of the interim directive for Chapter 70 — Wilderness Evaluation and a request for

comment was published March 23, 2005 (70 FR 14637) along with 11 other interim directives.

Alternatives:

As an alternative to publishing the final directive, the agency will use the interim directive until it expires on September 23, 2006. The interim directive could be extended for an additional 18 months beyond September 23, 2006. If the interim directive is not issued in final, before expiration, the agency would operate under the previous outdated directive.

Anticipated Cost and Benefits:

A cost-benefit analysis was conducted to compare the costs and benefits of implementing the final National Forest System Land Management Planning regulation to the baseline, 1982 planning rule. This analysis is posted on the Forest Service web site address (www.fs.fed.us/emc/nfma/index2.html), along with other documents associated with the final rule. A basic assumption of the cost-benefit analysis is that the planning rule would be carried out using updated directives.

Based on costs that can be quantified, implementation of the final rule is expected to have an estimated annual average cost savings of \$4.6 million when compared to the 1982 planning rule, and an estimated annual average savings of \$36.9 million when compared to estimates of implementation of the 2000 planning rule. The final rule is expected to be less costly than the 2000 planning rule; some of those saved costs are expected to be shifted to monitoring and evaluation.

Risks:

The interim directive expires on March 7, 2008. If it is not finalized, the directive will not be coordinated with conceptual and terminology changes made in the other 11 planning directives for implementation of the 2005 National Forest System Land Management Planning regulation. This lack of coordination would cause public and employee confusion, delaying the agency's ability to respond quickly and effectively to land management plan revision, changing issues, or unforeseen plan implementation activities.

Timetable:

Action	Date	FR Cite
Interim Final Directive	03/23/05	70 FR 14637
Comment Period End	06/21/05	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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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 competitiveness in 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' sure 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 the National Oceanic and Atmospheric Administration (NOAA) and the National Telecommunications and Information Administration (NTIA) plan actions that are considered the "most important" significant preregulatory or regulatory action for this Regulatory Plan year. During the next year, NOAA plans to complete one action entitled "Endangered Fish and Wildlife; Implement Speed Restrictions to Reduce the Threat of Ship Collisions with North Atlantic Right Whales," and NTIA plans to complete one action entitled "Implement and Administer a Coupon Program for Digital-to-Analog Converter Boxes." 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 Department has a long-standing policy to prohibit 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, one action is of particular significance and has been designated as one of the most important regulatory actions undertaken by the Department. This rule is entitled "Endangered Fish and Wildlife; Implement Speed Restrictions to Reduce the Threat of Ship Collisions with North Atlantic Right Whales." In this rulemaking, NOAA plans to implement a strategy to

reduce the known mortalities to North Atlantic right whales as a result of collisions with vessels, which account for more confirmed right whale deaths than any other human-related activity. The strategy addresses the lack of recovery of the endangered North Atlantic right whale by reducing the likelihood and threat of ship strike mortalities to the species. NOAA has developed a framework of proposed, new operational measures for the shipping industry as an element of this strategy, including consideration of routing and speed restrictions. These operational measures would be limited to areas and times when North Atlantic right whales and ships overlap to reduce the likelihood of ship strikes to the extent practicable.

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.

The Magnuson-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 provisions of 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 technology base, 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 other newly 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 Independent States 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.

National Telecommunications and Information Administration

The National Telecommunications and Information Administration (NTIA) is the President's principal adviser on telecommunications and information policy issues. The advent of the telecommunications and information revolution is bringing dramatic growth and change to the Nation's economic, social, and political life, and as a result, NTIA's fundamental mission is to promote market-based policies which lower prices to consumers and encourage innovation, while harnessing the resources of the Federal Government to support spectrum-based technologies which enhance efficiency and productivity.

Major Programs and Activities

NTIA's main role is to provide advice to the President on telecommunications and information policy issues. In this role, NTIA frequently works with other Executive Branch agencies to develop and present the Administration's position on these issues. In addition to representing the Executive Branch in both domestic and international telecommunications and information policy activities, NTIA also:

- Manages the Federal use of spectrum;
- Performs cutting-edge telecommunications research and engineering, including resolving technical telecommunications issues for the Federal Government and private sector; and
- Administers infrastructure and public telecommunications facilities grants.

During the next year, NTIA will be completing one action that rises to the level of "most important" significant preregulatory or regulatory action. This rule is entitled "Implement and Administer a Coupon Program for Digital-to-Analog Converter Boxes." In this action, NTIA would implement a digital-to-analog converter box coupon program pursuant to section 3005 of the Deficit Reduction Act of 2005 (the "Act"). The Act, among other things, requires the Federal Communications Commission (FCC) to require full-power television stations to cease analog broadcasting by February 18, 2009. Recognizing that consumers may wish to continue receiving broadcast programming over the air using analog-only televisions not connected to cable or satellite service, the Act authorizes NTIA to create an assistance program to provide \$40 coupons to consumers for use toward the purchase of digital-to-analog converter boxes. Through this coupon program, NTIA will facilitate public access to full-power broadcasting program over the air using analog-only television sets. Without converter boxes, consumers with analog-only television sets will be unable to view full-power television broadcasts unless they purchase digital television sets or subscribe to cable or satellite service.

DOC—National Oceanic and Atmospheric Administration (NOAA)

FINAL RULE STAGE

23. RIGHT WHALE SHIP STRIKE REDUCTION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

16 USC 1361

CFR Citation:

50 CFR 224

Legal Deadline:

None

Abstract:

These regulations would implement a strategy to reduce the known mortalities to North Atlantic right whales as a result of collisions with vessels, which account for more confirmed right whale deaths than any other human-related activity. The strategy addresses the lack of recovery of the endangered North Atlantic right whale by reducing the likelihood and threat of ship strike mortalities to the species. The National Marine Fisheries Service (NMFS) has developed a framework of proposed, new operational measures for the shipping industry as an element of this strategy, including consideration of routing and speed restrictions. These operational measures would be limited to areas and times when North Atlantic right whales and ships overlap to reduce the likelihood of ship strikes to the extent practicable.

Statement of Need:

The National Oceanic and Atmospheric Administration (NOAA) proposes regulations to implement speed restrictions on vessels 65 ft (19.8m) or greater in overall length in certain locations and at certain times of the year along the East Coast of the United States. These regulations are needed as current efforts to reduce occurrence of North Atlantic right whale deaths and serious injury from ship strikes have not been sufficient to alter the trajectory of this species toward extinction. The purpose of these proposed regulatory measures is to reduce the likelihood of deaths and serious injuries to endangered North Atlantic right whales that result from collisions with ships. These measures

are part of NMFS' Ship Strike Reduction Strategy to help recover the North Atlantic right whale.

Summary of Legal Basis:

NOAA is proposing these regulations pursuant to its rulemaking authority under Marine Mammal Protection Act (MMPA) section 112(a) (16 U.S.C. 1382(a)), and Endangered Species Act (ESA) section 11(f) (16 U.S.C. 1540(f)). These proposed regulations also are consistent with the purpose of the ESA "to provide a program for the conservation of [...] endangered species" and "the policy of Congress that all Federal departments and agencies shall seek to conserve endangered species [...] and shall utilize their authorities in furtherance of the purposes of [the ESA]." 16 U.S.C. 1531(b),(c).

Alternatives:

NMFS identified five alternatives to the action being proposed. Alternative 1 is No Action (Status Quo) in which NMFS would continue to implement existing measures and programs, largely non-regulatory, to reduce the likelihood of mortality from ship strikes. Alternative 2 includes all elements of Alternative 1 and involves use of Dynamically Managed Areas (DMA), which consists of certain vessel speed restrictions applying only when and where right whale sightings occur. Alternative 3 is vessel speed restrictions in designated areas. It includes all elements of Alternative 1 and implements large-scale speed restrictions throughout the range of North Atlantic right whales. Alternative 4 is the use of designated shipping routes. It includes all the elements of Alternative 1 and relies on altering some current vessel patterns to move vessels away from areas where whales are known to congregate. Alternative 5 is a combination that includes all elements of Alternatives 1 to 4. Alternative 6 (the preferred alternative and the approach that is the subject of the proposed rule) includes a combination of operational measures (routing measures and speed restrictions). The principal difference between Alternatives 5 and 6 is that Alternative 6 does not include large-scale speed restrictions (as identified in Alternative 3) but instead relies on speed restrictions in much smaller Seasonally Managed Areas.

Anticipated Cost and Benefits:

Benefits

The benefits of reducing the risk of right whale mortality caused by ship strikes are expected to be considerable.

Because ship strikes appear to be the leading anthropogenic cause of right whale mortalities, adopting measures to reduce the incidences of ship strikes will aid in the recovery of this highly endangered species. However, monetary estimates of these benefits are currently unavailable; therefore, the discussion of these benefits specific to right whales is descriptive. The full range of values of right whale recovery includes use values and nonuse values. Use values include those values associated with whale watching trips, or other viewing opportunities. Nonuse values include those values placed on knowing that right whales remain for future generations (bequest value) and values placed on knowing that right whales will continue to survive (existence value). The proposed action would be highly beneficial to the recovery of the right whale population as it also is designed to address the various ship strike scenarios that might occur.

Estimated Direct Economic Impact Shipping Industry:

Direct annual economic impact to commercial shipping is estimated at \$49.4 million at the 10 knot speed restriction. The following port areas may expect the greatest impact: New York/New Jersey (\$11.2 million), Hampton Roads, VA (\$7.5 million), Savannah, GA (\$5.3 million) and Charleston, SC (\$5.2 million).

Multi-port calls:

The speed restriction component of the proposed action leads to additional impacts to vessels coming into at least two restricted ports. The 2004 vessel arrival database indicates that the total number of multi-port string restricted arrivals to be 5,147. The additional direct economic impact of multi-port strings on the shipping industry due to the 10 knot speed restriction in 2004 is estimated at \$5.8 million.

Rerouting of Southbound Coastwise Shipping:

The proposed speed restrictions in the Mid-Atlantic region would be implemented for a 30 nautical mile buffer zone radiating out from each port area. Hence, the additional distance incurred by southbound vessels would be 80 nautical miles (20 nautical miles per arrival and departure at intermediate port calls). The 2003 vessel traffic database indicated that 3,688 containerships and ro-ro cargo ships would have traveled through speed restricted U.S. East Coast port areas ranging from Baltimore through Port Canaveral had the restrictions been

in place. Assuming half of these calls were in the southbound direction and that the typical vessel made calls at three U.S. East Coast ports per service, there would be about 615 southbound vessels that are likely to route outside of the seasonal speed restricted areas rather than proceed through the restricted areas at a lower speed. Based on an increase in routing of 80 nautical miles and an average operating speed of 20 knots, the containership would have increased sailing time of 4 hours. Using an average hourly operating cost at sea of \$1,000, the estimated economic impact for each southbound vessel would be \$4,000. For 2003 and 2004, the additional economic impact for containerships for coastwise shipping under Alternative 6 was estimated at \$2.5 million.

Commercial fishing vessels:

Using 2003 data, the estimated impact at 10 knots on commercial fishing vessels due to the proposed action is estimated to be \$686,000 for the Northeast Region and \$348,000 for the Southeast Region. The combined Northeast and Southeast regional economic impact of slightly more than \$1 million is approximately two-tenths of one percent of the U.S. East Coast commercial fishery landings of \$628.2 million in 2003.

Charter fishing vessels:

It is estimated that annual economic impact of a speed restriction of 10 knots for these vessels over 30 nautical miles for the proposed action would be approximately \$1.2 million. This calculation assumes 40 headboat vessels with 60 roundtrips per year and an hourly steaming operating cost of \$200.

Passenger ferries:

Under the proposed action, speed restrictions for Cape Cod Bay are implemented from January 1 through May 15. As such, the fast ferry service from Boston to Provincetown would remain in operation. Speed restrictions for Block Island Sound would be from November 1 through April 30. However, the speed restricted area for Block Island Sound under the proposed action would not extend to the shoreline and hence would not impact fast ferry operations. DMAs would also be implemented under the proposed action. The estimated economic impact for fast ferry service under the proposed action due to the presence of DMAs is \$2.6 million. For regular ferries, the economic impact due to the proposed action is estimated to be \$3.0 million for 10 knots speed restrictions.

The combined impacts to the high-speed and regular-speed passenger ferries bring the total estimated economic impacts to \$5.6 million.

Whale watching vessels:

Under the proposed action, speed restrictions for Cape Cod Bay are implemented from January 1 through May 15. Hence, the peak summer whale watching season would not be affected for high-speed or regular speed vessels. Similarly, the speed restrictions for the Off Race Point area are proposed for March through April would not impact the whale watching season.

Accordingly, the economic impact due to DMAs under the proposed action is an estimated \$0.9 million.

Indirect Economic Impacts of Port Diversions

Under the proposed action, speed restrictions for both Off Race Point area and the Great South Channel in the Northeast are in effect during the month of April causing many ships to route around this large area during that time. The diversion is assumed at 10 percent for containerships and ro-ro cargo ships during the restricted period. For port areas in Block Island Sound, two percent of containerships and ro-ro cargo ships are assumed to divert to other port areas to avoid speed restricted areas. For the affected Mid-Atlantic ports, 0.5 percent of restricted period containership and ro-ro cargo ship vessel calls are assumed to divert to other port areas.

Additional diversions away from the port area of Providence may also occur under the proposed action. This port area has speed restrictions in effect for 181 days as compared to 61 days for the port area of Boston. Therefore, 15 percent of the containership and ro-ro cargo ship restricted period calls at Providence are assumed to divert to the nearby port area of Boston.

NMFS anticipates that the use of recommended routes into the Southeastern Region ports of Brunswick and Fernandina are likely to result in a diversion of two percent of containerships and ro-ro cargo ships from these ports to Savannah. As a result of these diversions, NMFS anticipates additional delays relative to Savannah. Finally, 30 percent of the restricted period cruise vessel calls at Jacksonville are assumed to divert to Port Canaveral as that port is not affected by speed restrictions or the use of recommended routes.

The indirect economic impact of port diversions is estimated to be \$49.7

million for the 10 knot speed restriction. The largest negative indirect impacts are generated in the port areas of New York/New Jersey (\$21.2 million), Jacksonville, FL (\$15.5 million) and Hampton Roads, VA (\$12.4 million). The following port areas are expected to experience a positive indirect economic impact: Port Canaveral, FL (\$2.2 million) and Savannah, GA (\$1.7 million).

Risks:

The risk associated with not pursuing the proposed rulemaking is allowing the continued decline in the population of North Atlantic right whales. The North Atlantic right whale is in danger of extinction: some estimates have it on a trajectory of going extinct within 200 years if serious injury and death from certain human activities is not abated. NMFS conducts consultations under Section 7 of the Endangered Species Act (ESA) with other agencies with regard to activities undertaken or permitted by those agencies that may adversely affect North Atlantic right whales. NMFS routinely concludes that those activities, and the cumulative effect of other pressures on the population, will jeopardize the continued existence of the species in all or part of its range. The proposed regulations are expected to reduce or eliminate the threat of right whale deaths from collisions with ships, and, as a result, provide relief from a key threat to the species. NMFS is required under the ESA to take steps to recover the species. By failing to take adequate steps, including those identified in the rulemaking, NMFS would fail to meet its legal requirements under the ESA.

Timetable:

Action	Date	FR Cite
ANPRM	06/01/04	69 FR 30857
ANPRM Comment Period Extended	07/09/04	69 FR 41446
ANPRM Comment Period Extended	09/13/04	69 FR 55135
NPRM	06/26/06	71 FR 36299
NPRM Comment Period End	08/25/06	
Comment Period Extended	08/14/06	71 FR 46440
Comment Period End	10/05/06	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Public Compliance Cost:

Initial Cost: \$0
Yearly Recurring Cost: \$116,000,000
Base Year for Dollar Estimates: 2005

URL For More Information:

www.nmfs.noaa.gov/pr/pr2

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DOC—National Telecommunications and Information Administration (NTIA)

FINAL RULE STAGE

24. • IMPLEMENT AND ADMINISTER A COUPON PROGRAM FOR DIGITAL-TO-ANALOG CONVERTER BOXES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 109-171

CFR Citation:

47 CFR 301

Legal Deadline:

None

Abstract:

Pursuant to the Digital Television Transition and Public Safety Act of 2005 (the Act), the National Telecommunications and Information Administration (NTIA) proposes to implement a digital-to-analog converter box coupon program. The Act, among other things, requires the Federal Communications Commission (FCC) to require full-power television stations to cease analog broadcasting by February 18, 2009. Recognizing that consumers may wish to continue receiving broadcast programming over the air

using analog-only televisions not connected to cable or satellite service, the Act authorizes NTIA to create an assistance program to provide \$40 coupons to consumers for use toward the purchase of digital-to-analog converter boxes. Without converter boxes, consumers with analog-only television sets will be unable to view full-power television broadcasts unless they purchase digital television sets or subscribe to cable or satellite service.

Statement of Need:

This action is necessary to provide guidance for the digital-to-analog converter box coupon program. Converter boxes are necessary for consumers who wish to continue receiving full-power broadcast programming over the air using analog-only television sets after February 18, 2009—the date that the law requires full-power television stations to cease analog broadcasting. With respect to consumers, this action provides eligibility requirements, application procedures, and guidance on the use, value, and restrictions of the coupons. This action also provides specifications on eligible converter boxes that will assist manufacturers in developing converter boxes. Finally, this action provides guidance and sets for the rights and responsibilities of retailers.

Summary of Legal Basis:

Section 3005 of the Deficit Reduction Act of 2005 directs NTIA to implement and administer a program through which eligible U.S. households may obtain a maximum of two coupons of \$40 each to be applied toward the purchase of a digital-to-analog converter box. See title III of the Deficit Reduction Act of 2005, Pub. L. 109-171, 120 Stat. 4, 21 (Feb. 8, 2006).

Alternatives:

NTIA considered various ways to implement the program. NTIA proposed that eligible households will be only those that receive over-the-air broadcasts, and that coupons will be distributed on a first-come, first-served basis. An alternative for which the agency sought public comment through the proposed rule was whether other eligibility factors, such as a means test, should be used. NTIA also considered various formats for the actual coupon. In its proposed rule NTIA proposed a paper coupon but requested comment on an electronic coupon card. NTIA proposed options for addressing the expiration requirement. In its proposed rule, NTIA proposed that the expiration date will be three months after the

coupon's issuance date, which would be the date upon which the coupon is placed in the U.S. mail. NTIA also requested comment on an alternative to the definition of the issuance date, which would be the date upon which a consumer receives a coupon. Finally, NTIA proposed to require manufacturers to self-certify that the converter boxes meet the standards outlined in the proposed rule. However, it requested comment on whether there are existing industry or government organizations engaged in activities that can help speed the development of testing/certification processes within the allowed time frame of this program.

Anticipated Cost and Benefits:

The Act authorizes \$1.5 billion to operate the coupon program. The Act, however, is part of the Deficit Reduction Act of 2005 which the Congressional Budget Office predicts will reduce direct spending by about \$39 billion over the 2006 to 2010 period and by about \$99 billion over the 2006 to 2015 period. The direct costs to eligible households as a result of this rule is certainly less than if the coupon program was not instituted. Estimates of the cost of the converter box range between \$50 and \$70. Using the \$40 coupon, consumers can then expect to pay between \$10 and \$30 for each converter box purchased. Without the coupons, consumers would have to pay the full retail price of the converter box, or purchase a digital television.

This program, if implemented, imposes certain requirements if retailers and manufacturers decide to participate in the coupon program. Besides the time that it takes to submit a certification form to NTIA, there will be actual costs associated with meeting compliance requirements. These costs, however, are difficult to quantify because of many varying factors. However, NTIA anticipates that the costs would be minimal because retailers and manufacturers may already have the ability to meet the requirements associated with participation in this program. For example, retailers would have to ensure that employees are capable of educating customers about the necessity for and installation of converter boxes. The costs for this compliance would be calculated by the number of hours it would take to train employees. The estimate would depend on a number of factors such as the existing sales force's expertise, number of employees, salary levels, type of

converter box that is certified, and consumer knowledge.

This program, if implemented, would also require retailers to have systems in place that can be easily audited as well as systems that have the ability to prevent fraud and abuse in the coupon program. We assume that most businesses would have systems in place that can be easily audited, and therefore, we do not anticipate that businesses will have to assume a cost to purchase a new system for the coupon program. Retailers must also have systems in place that have the ability to prevent fraud and abuse in the coupon program. We assume that most retailers are familiar with and accept coupons for merchandise, and that they have in place systems to prevent fraud. The nature of this coupon program, however, may require participating retailers to assume additional costs associated with preventing fraud. These costs cannot be estimated at this point in the rulemaking process. There may be costs associated in complying with an audit. These costs would most likely be calculated in terms of employee hourly rates. The associated costs depend on the nature and extent of an audit.

There are also costs associated with handling coupons, that is, accepting the coupons, submitting the coupons for redemption, and retaining hard copies of the coupons. Again, these associated costs depend on a number of factors such as the particular systems that retailers currently have in place, as well as which of these costs can be absorbed within existing procedures that the retailer has in place.

Although there may be costs associated with accepting the coupons and selling the converter boxes, the coupon program does not restrict the retailer in pricing the converter box. Manufacturers and retailers may consider these associated costs and establish the wholesale and retail price of the converter boxes to recoup any associated costs. In fact, the coupon program anticipates that there will be a co-pay element to the purchase price. Thus, to the extent that a small retailer or manufacturer incurs costs as a result of this program, those costs can be recouped through the retail or wholesale price, which the retailer and manufacturer are at liberty to choose.

Risks:

One risk is that the final rule will not be promulgated in time for the

manufacturers to build the converter boxes. The Act states that consumers must be able to apply for coupons between January 1, 2008, and March 31, 2009. The agency has been informed that the specifications for the converter box, as directed in the final rule, must be available at least one year in advance. To the extent that the final rule is not issued by January 2007, converter boxes may not be available when the statutory application period begins.

Timetable:

Action	Date	FR Cite
NPRM	07/25/06	71 FR 42067
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

This action would establish the eligibility criteria, application process, coupon value and use restrictions, and manufacturer and retailer certification process. To implement this program, the Act authorizes NTIA to use up to \$990 million to fund the program, including \$100 million for program administration. NTIA is also authorized to expend up to \$1.5 billion for the program, including \$160 million for administration, upon a 60-day notice and certification to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate that the \$990 million is insufficient to fulfill coupon requests for eligible U.S. households.

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BILLING CODE 3510-BW-S

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, 17 Defense agencies, and 11 DoD field activities. It has over 1,380,000 military personnel and 676,000 civilians assigned as of June 30, 2006, 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 affect 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 affected 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 influence 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 implement 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.

Rulemakings That Support the Administration's Regulation Agenda to Streamline Regulations and Reporting Requirements

The Department will:

Consolidate all of the existing emergency procurement authorities into Part 18 of the FAR and Part 218 of the DFARS;

Direct use of electronic subcontracting and reporting system for both the summary and individual subcontract reporting, in conjunction with and as part of the integration with FPDS;

Rewrite the rules on Government property to organize and streamline management of Government property. Emphasize contractor accountability while reducing contract clauses and

reporting requirements. Allow contractors to provide item unique identification (IUID) data electronically in the IUID Registry for all DoD personal property in possession of the contractor, rather than annual reporting;

Simplify and clarify the coverage of multi-year acquisitions;

Provide simplified criteria for the release of supplies by the contractor based on complexity and criticality;

Finalize the rewrite of FAR Part 27, Patents, Data and Copyrights, to clarify, streamline, and update guidance and clauses on patents, data, and copyrights. Transform the DFARS regulations on patents, data and copyrights to clarify and simplify, dramatically reducing the amount of regulatory text and the number of required clauses;

Implement DFARS transformation proposals relating to the Material Inspection and Receiving Report, acquisition planning, transportation, contract pricing and cost accounting standards, and protests, disputes, and appeals; and

Delete obsolete restrictions on the acquisition of PAN Carbon Fiber.

Regulations of Particular Interest to Small Business

Of interest to small businesses are regulations to:

Permit subcontracts awarded to certain Alaska Native Corporations to be counted toward a contractor's goal for subcontracting with Small Business and Small Disadvantaged Business concerns and subcontracts to Indian tribes to be counted toward a contractor's goal for subcontracting with small business concerns, regardless of size, in accordance with section 702 of Pub. L. 107-117, as amended by section 3003 of Pub. L. 107-206;

Amend the FAR to address changes in the Small Business Administration regulations to implement changes in the HUBZone Program; and

Implement DFARS transformation proposals relating to small business programs.

Suggestions From the Public for Reform—Status of DoD Items

Rulemaking Actions in Response to Public Nominations

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, 2002, or 2004. 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, Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities, and Progress in Regulatory Reform: 2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities.

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 health affairs.

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 (Public Law 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 proposed rule was published for public comment on March 28, 2006 (71 FR 15520). The comment period expired on June 30, 2006 (71 FR 29604). The proposed regulation was developed by considering concepts in current Federal compensatory mitigation guidance documents, and updating and

modifying those concepts to improve compensatory mitigation decisionmaking and processes. The proposed rule takes a watershed approach to compensatory mitigation for permitted impacts to wetlands, streams, and other aquatic resources. Although the statute refers only to wetlands, the proposed rule is broader in scope, and addresses compensatory mitigation requirements for impacts to other aquatic resources, such as streams, in addition to wetlands. Comments received in response to the proposed rule are being evaluated, and a final rule will be prepared.

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

In 1990, the Army Corps of Engineers published as appendix C of 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 (ANPRM) to obtain the views of interested parties. After reviewing the comments received in response to the ANPRM, the Army Corps of Engineers held facilitated stakeholder meetings to determine the best course of action for revising its procedures to comply with the requirements of Section 106 of the National Historic Preservation Act. The Corps plans on holding additional focus group meetings facilitated by our eight division offices to gather input from federally recognized tribes on their recommendations concerning how government-to-government consultation could occur. Also, our division offices will solicit information on topics that any new alternative procedure should address.

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 the Defense Federal Acquisition Regulation Supplement (DFARS) and continues to lead Government efforts to:

- Improve the DFARS to enhance the efficiency and effectiveness of the acquisition process, while allowing the acquisition workforce flexibility to innovate. The DFARS contains only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant impact on contractors, offerors, and/or the public.
- Revise the uniform treatment of contractor personnel who are authorized to accompany the U.S. Armed Forces deployed outside the United States in contingency operations, humanitarian or peacekeeping operations, other military operations, or training exercises designated by the combatant commander, to implement the new DoD Instruction, and require training for contractor personnel who interact with detainees. Implement the DoD Law of War Program, requiring contractors to report violations.
- Coordinate with the Department of State to finalize a FAR rule to address uniform treatment of other contractor personnel who are performing outside the United States in a theater of operations during contingency operations; humanitarian or peacekeeping operations; other military operations; or military exercises designated by the combatant commander; or at a diplomatic or consular mission, when designated by the chief of mission.
- Finalize the FAR rule that authorizes set-asides for awards based on specific geographic areas under the

Robert T. Stafford Disaster Relief and Emergency Assistance Act, in order to implement the Local Community Recovery Act of 2006.

- Prohibit trafficking in persons by contractors, contractor employees, and subcontractors.
- Address contractor notification requirements associated with deficient processes or defective parts related to aviation critical safety items.
- Phase in DFARS requirements for contractors to affix radio frequency identification (RFID) tags to the exterior packaging of items delivered under DoD contracts, adding additional commodities and ship-to locations. 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.
- Improve debt collection by evaluating existing FAR controls and procedures for ensuring contract debts are identified and recovered in a timely manner, properly accounted for in each agency's books and records, and properly coordinated with the appropriate Government officials.

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 Board (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 Title 10 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 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 rule and agreed that it is not a "significant regulatory action" under EO 12866. The Department published the proposed rule in the **Federal Register** on January 28, 2005. The proposed rule addressed scope, characteristics, composition, funding, establishment, operation and adjournment. The public comment period ended on March 29, 2005. The Department received a total of 219 comments from 29 individuals and organizations.

The Department published final regulations governing the establishment and administration of Restoration Advisory Boards in the **Federal Register** on May 12, 2006 (71 FR 27610-27621). Corrections were published in the **Federal Register** on May 30, 2006 (71 FR 30719) and July 28, 2006 (71 FR 42756-42757).

Munitions Response Site Prioritization Protocol

Section 2710(b)(1) of Title 10, United States Code, directed the Secretary of Defense to develop a protocol for prioritizing response actions for each defense site known or suspected to contain unexploded ordnance, discarded military munitions, or munitions constituents. Following required consultations with State and tribal representatives, the Department published the proposed rule for public review and comment on August 22, 2003. The Department reviewed comments received during the public comment period, which ended on November 19, 2003, and revised the rule accordingly. The most significant change pertained to the module that evaluates health hazards associated with munitions constituents and other chemical constituents. The Department published the final rule in the **Federal Register** on October 5, 2005 (70 FR 58016-58054).

Health Affairs, Department of Defense

The Department of Defense is able to meet its dual mission of wartime readiness and peacetime health care by operating an extensive network of

medical treatment facilities. This network includes DoD's own military treatment facilities supplemented by civilian healthcare providers, facilities, and services under contract to DoD through the TRICARE program. TRICARE is a major health care program designed to improve the management and integration of DoD's health care delivery system. The program's goal is to increase access to health care services, improve health care quality, and control health care costs.

The TRICARE Management Activity plans to submit the following rules:

- **Interim Final Rule concerning Certain Survivors of Deceased Active Duty Members and Adoption Intermediaries:** The rule addresses two provisions of the National Defense Authorization Act for Fiscal Year 2006 (NDAA-06), Pub. L. 109-163. Section 715 of the NDAA-06 extends the time frame that certain dependents of Active Duty Service Members (ADSM) who die while on active duty for more than 30 days shall receive TRICARE medical benefits at active duty dependent payment rates. Second, Section 592 modifies the requirement for intermediaries who provide adoption placements. The economic impact of this rule is estimated to be less than \$100 million. It is anticipated that the final rule will be published by May 1, 2007.
- **Interim Final Rule on TRICARE Outpatient Prospective Payment System (OPPS):** The rule implements a prospective payment system for hospital outpatient services similar to that furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. The rule also recognizes applicable statutory requirements and changes arising from Medicare's continuing experience with its system, including certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While TRICARE intends to remain as true as possible to Medicare's basic OPPS methodology (i.e., adoption and updating of the Medicare data elements used in calculating the prospective payment amounts), there will be some significant deviations required to accommodate the uniqueness of the TRICARE program. These deviations have been designed to accommodate existing TRICARE benefit structure and claims processing procedures implemented under the TRICARE Next Generation Contracts (T-NEX)

while at the same time eliminating any undue financial burden to TRICARE Prime, Extra and Standard beneficiary populations. The economic impact of this rule is estimated to be less than \$100 million. It is anticipated that the final rule will be published by April 1, 2007. It is anticipated that an interim final rule will be required to be promulgated in order to implement a provision of the National Defense Authorization Act for FY07 to expand the TRICARE Reserve Select program to allow all members of the Selected Reserve to purchase their health care through the Military Health System at the same low cost, regardless of the member's duty status. The economic impact of this rule is estimated to be less than \$100 million. It is anticipated that the interim final rule will be published by June 1, 2007.

DOD—Office of Assistant Secretary for Health Affairs (DODOASHA)

FINAL RULE STAGE

25. • TRICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS)

Priority:

Other Significant

Legal Authority:

10 USC Ch 55; 5 USC 301; 10 USC 1079(j)(2)

CFR Citation:

32 CFR 199

Legal Deadline:

None

Abstract:

The interim final rule implements a prospective payment system for hospital outpatient services similar to that furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. The rule also recognizes applicable statutory requirements and changes arising from Medicare's continuing experience with its system, including certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While TRICARE intends to remain as true as possible to Medicare's basic OPPS methodology (i.e., adoption and updating of the Medicare data elements used in calculating the prospective payment

amounts), there will be some significant deviations required to accommodate the uniqueness of the TRICARE program. These deviations have been designed to accommodate existing TRICARE benefit structure and claims processing procedures implemented under the TRICARE Next Generation Contracts (T-NEX) while at the same time eliminating any undue financial burden to TRICARE Prime, Extra and Standard beneficiary populations.

Statement of Need:

The interim final rule is necessary to meet the standing Congressional mandate to adopt Medicare institutional payment methodologies whenever practicable.

Summary of Legal Basis:

Congress established enabling legislation under section 707 of the National Defense Authorization Act of Fiscal Year 2002 (NDAA-02), Pub. L. 107-107 (December 28, 2001) changing the statutory authorization in 10 U.S.C. 1079(j)(2) that TRICARE payment methods for institutional care be determined to the extent practicable, in accordance with the same reimbursement rules used by Medicare.

Alternatives:

The interim final rule implements statutorily required provisions for adoption and implementation of Medicare institutional reimbursement systems which are consistent with well established Congressional objectives. No other alternatives are applicable.

Anticipated Cost and Benefits:

It is projected that implementation of this rule will result in a health care dollar savings of \$50 to \$70 million per year with an estimated initial startup cost of \$4 to \$6 million and recurring administrative costs of approximately \$1 million per year.

Risks:

The interim final rule implements statutorily required provisions for adoption and implementation of Medicare institutional reimbursement systems which are consistent with well established Congressional objectives. No risk to the public is applicable.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/06	
Interim Final Rule Comment Period End	02/00/07	
Final Action	04/00/07	
Final Action Effective	06/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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RIN: 0720-AB03

DOD—DODOASHA

26. ● TRICARE; CERTAIN SURVIVORS OF DECEASED ACTIVE DUTY MEMBERS; AND ADOPTION INTERMEDIARIES

Priority:

Other Significant

Legal Authority:

10 USC Ch 55; 5 USC 301; PL 109-163

CFR Citation:

32 CFR 199

Legal Deadline:

Final, Statutory, October 7, 2001, Public Law 109-163.

Abstract:

The interim final addresses two provisions of the NDAA-FY06, Pub. L. 109-163. Section 715 of the NDAA-FY06 extends the time frame that certain dependents of Active Duty Service Members (ADSM) who die while on active duty for more than 30 days shall receive TRICARE medical benefits at active duty dependent payment rates. Second, Section 592 modifies the requirement for intermediaries who provide adoption placements.

Statement of Need:

This rule is necessary to comply with the statutory requirement.

Summary of Legal Basis:

This rule is required by the NDAA-FY06, Pub L 109-163.

Alternatives:

This rule is statutory. No other alternative is applicable.

Anticipated Cost and Benefits:

Estimated costs for FY07 (includes retroactive years to 2001). Health care costs \$533,000 and administrative costs of \$774,000 (which includes total startup costs of \$300,000). The benefit of this rule is that surviving children of ADSMs whose death occurs on or after October 7, 2001, will receive TRICARE benefits at the AD family member rate for the duration of their TRICARE eligibility.

Risks:

This rule implements a statutory provision to extend the time frame that surviving children of deceased ADSM whose death occurred on or after October 7, 2001, can receive TRICARE at active duty family member rates. Not implementing this statutory provision creates additional out-of-pocket costs for surviving children.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/06	
Interim Final Rule Comment Period End	02/00/07	
Interim Final Rule Effective	10/07/01	
Final Action	05/00/07	
Final Action Effective	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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RIN: 0720-AB04

DOD—DODOASHA

27. ● EXPAND ELIGIBILITY OF SELECTED RESERVE MEMBERS UNDER THE TRICARE PROGRAM

Priority:

Other Significant

Legal Authority:

10 USC Ch 55; 5 USC 301

CFR Citation:

32 CFR 199

Legal Deadline:

Final, Statutory, October 1, 2007, NDAA for FY07.

Abstract:

The proposal would expand the recently enacted Reserve health care benefit for Reservists (called TRICARE Reserve Select) to allow all members of the Selected Reserve to purchase their health care through the Military Health System at the same low cost, regardless of the member's duty status. Only members who are eligible for the Federal Health Benefits program would be excluded from this benefit. Participating Reserve Component members would be required to pay a monthly premium of 28 percent of the cost of care for the TRICARE Reserve Select plan and would be subject to the same deductibles, copayments and other non-premium payments applicable to dependents of active duty members who selected the same TRICARE option.

Statement of Need:

The Department of Defense (DoD) interim final rule identifies a process to comply with the Congressional mandate that all members of the Selected Reserve may be able to purchase their health care through the Military Health System, regardless of the member's duty status.

Summary of Legal Basis:

This regulation is proposed under the authorities the National Defense Authorization Act for Fiscal Year 2007.

Alternatives:

The interim final rule complies with the Congressional mandate. No other alternatives are applicable.

Anticipated Cost and Benefits:

It is estimated that implementing the rule equates to national incremental costs totaling less than \$100 million per year.

Benefits include: Access to health care for all Reservists, regardless of the member's duty status; however, at this time, the effect on readiness, recruitment, and retention are not known.

Risks:

The degree of risk to the public is low.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/07	

Action	Date	FR Cite
Interim Final Rule Comment Period End	08/00/07	
Final Action	09/00/07	
Final Action Effective	10/00/07	

Small Entities Affected:

No

Government Levels Affected:

Federal

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RIN: 0720-AB05

BILLING CODE 5001-06-S

**Regulatory Flexibility Analysis
Required:**

No

DEPARTMENT OF EDUCATION (ED)**Statement of Regulatory and Deregulatory Priorities***General*

We support States, local communities, institutions of higher education, and others in improving 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; such as ensuring that all students reach grade level standards in reading/language arts and mathematics; 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.

We administer programs that touch nearly every American at one point in their lives—nearly 54 million students attending 93,000 elementary and secondary schools in approximately 15,000 public school districts and almost 22 million postsecondary students.

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, and educators; State, local, and tribal governments; neighborhood groups, schools, colleges, 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 necessary, we seek customer participation at all stages in the rulemaking process. We invite the public to submit comments on all proposed regulations through the Internet or by regular mail.

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.

Initiatives

Among our initiatives is bringing No Child Left Behind to the high school

level. The President has called evidence of poor performance by America's high schools "a warning and a call to action." The Administration's response is a comprehensive proposal that builds on the stronger accountability of No Child Left Behind to improve the quality of secondary education and ensure that every student not only graduates from high school, but, also, graduates prepared to enter college or the workforce with the skills to succeed. This initiative includes creation of several new programs and significant funding increases for existing programs that can have a major impact on secondary education. The actual appropriations will depend on congressional action. The appropriations may, in turn, result in additional regulatory activities by the Department.

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 using scientifically based research to guide instruction, especially in reading for our youngest children.

Each State (including Puerto Rico and the District of Columbia) has submitted an accountability plan, which the Department approved. Each State has used its respective plan to hold schools and school districts accountable since 2002-03 for the academic achievement of all their students, including students in specific subgroups such as students with disabilities and limited English proficient (LEP) students. Beginning with the 2005-06 school year, each State assessed students in each of grades 3 through 8 and high school and used those results for school and district accountability.

With respect to students with disabilities and LEP students, in particular, the Department has initiated regulatory actions to address unique issues in the implementation of No Child Left Behind. Our current regulations 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 determinations of adequate

yearly progress (AYP), subject to a cap of one percent of the number of students in a school district or State.

We are also working on developing final regulations that would provide further flexibility by permitting a State to develop modified achievement standards and assessments for some students with disabilities who are not included in the regulations that apply to students with the most significant cognitive disabilities.

Finally, we have published final 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/language arts assessment, provided the student takes an English language proficiency assessment; and (2) include, for up to two years, former LEP students in the LEP subgroup when making determinations of AYP.

We are continuing 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 educational services; and helping districts create capacity in order to make public school choice available to all eligible students who wish to change schools.

We have recently peer-reviewed evidence of each State's standards and aligned assessment systems that implement No Child Left Behind's requirements for annual testing in reading/language arts and mathematics in grades 3 through 8 and once in high school. These new reading/language arts and mathematics standards and assessments had to be in place by the end of the 2005-06 school year.

Regulatory and Deregulatory Priorities for the Next Year

The Individuals with Disabilities Education Improvement Act of 2004 (Pub. L. 108-446) made substantial changes to the Individuals with Disabilities Education Act (IDEA). In addition to recently published final regulations designed to improve implementation of the education of children with disabilities program (including preschool services) under part B, we plan to issue in 2007 a notice of proposed rulemaking that would address issues in part B that were not covered by those final regulations. Also, in early 2007 we expect to issue proposed regulations to implement changes to the part C program—the

early intervention program for infants and toddlers with disabilities.

On July 3, 2006, we published interim final regulations, with a request for comments, and on November 1, 2006, we published final regulations implementing the Academic Competitiveness Grant (ACG) and National Science and Mathematics Access to Retain Talent Grant (National SMART Grant) programs. These regulations and amendments to regulations governing other higher education programs were needed to implement provisions of the HEA, as amended by the Higher Education Reconciliation Act of 2005 (HERA), enacted on February 8, 2006.

The regulations specify the eligibility requirements for a student to apply for and receive an award under these programs. The regulations also identify the roles of institutions of higher education, State educational agencies, and local educational agencies in administering the programs.

The interim final regulations are effective for the 2006-07 award year. The final regulations, which amend the interim final regulations, are effective for the 2007-08 award year.

In addition, we published on August 9, 2006, interim final regulations, with a request for comments, and on November 1, 2006, we published final regulations amending various regulations for Federal student aid programs authorized under title IV of the HEA. These regulations implement changes to the HEA resulting from the HERA and reflect provisions of the HERA that affect students, borrowers, and program participants.

On August 18, the Department announced in the **Federal Register** our intent to conduct negotiated rulemaking under title IV of the Higher Education Act. As we indicated when we announced the interim final regulations on July 3, we intend to develop proposed regulations for the new ACG and National SMART Grant programs for the third and subsequent years of implementation of these programs (that is, beginning July 1, 2008).

We also intend to consider the recommendations of the Secretary's Commission on the Future of Higher Education. The Commission released its report on September 19, 2006. To the extent possible within the existing

statutory framework of the HEA, the negotiated rulemaking process could be used to address the recommendations of the Commission for changes that could reduce regulatory burden; improve the administration of the Department's programs authorized by title IV of the HEA, including the Federal student aid programs; and improve the quality of information on cost, price, and student outcomes available to students and their families.

We expect that the negotiated rulemaking process will address other regulatory issues, including issues raised by the public during the regional hearings; issues resulting from changes made, other than those relating to the ACG and National SMART Grant programs, by the HERA; and items that have been identified by the Department as needed to improve program administration and accountability.

Other Potential Regulatory Activities

Recent reauthorization of the Carl D. Perkins Vocational and Technical Education Act of 1998 might result in regulatory activities by the Department. The reauthorization made changes designed to improve the State grant and other programs providing assistance under this statute and to help States and local communities strengthen career and technical education and improve educational opportunities for career and technical education students. In working with Congress on the reauthorization, the Administration has emphasized student achievement, particularly the academic achievement of career and technical education students, and increasing accountability and program quality.

Congress also is considering legislation to reauthorize the Adult Education and Family Literacy Act (AEFLA) (title II of the Workforce Investment Act of 1998)—including the National Institute for Literacy—and the Rehabilitation Act of 1973. The Administration is working with Congress to ensure that any changes to these laws improve and streamline the State grant and other programs providing assistance for adult basic education under the AEFLA and for vocational rehabilitation and independent living services for persons with disabilities under the Rehabilitation Act of 1973, and that they provide greater accountability in the

administration of programs under both statutes.

During the coming year other regulations may be necessitated by legislation or programmatic experience. In developing and promulgating any additional regulations we will be guided by the following Principles for Regulating:

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.

When regulating, we consider:

- Whether regulations are essential to promote quality and equality of opportunity in education.
- Whether a demonstrated problem cannot be resolved without regulation.
- Whether regulations are necessary to provide a legally binding interpretation to resolve ambiguity.
- Whether 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.

BILLING CODE 4000-01-S

DEPARTMENT OF ENERGY (DOE)

Statement of Regulatory and Derivational Priorities

The Department of Energy (Department or DOE) makes vital contributions to the Nation's welfare through its activities focused on improving national security, energy supply, energy efficiency, environmental remediation, and energy research. The Department's mission is to:

- Promote dependable, affordable and environmentally sound production and distribution of energy;
- Foster energy efficiency and conservation;
- Provide responsible stewardship of the Nation's nuclear weapons;
- Clean up the Department's sites and facilities, which include sites dating back to the Manhattan Project;
- Lead in the physical sciences and advance the biological, environmental and computational sciences; and
- Provide premier instruments of science for the Nation's research enterprise.

The Department's regulatory activities are essential to achieving its critical mission and to implementing major initiatives of the President's National Energy Policy. Among other things, the Regulatory Plan and the Unified Agenda contain the rulemakings the Department will be engaged in during the coming year to implement provisions of the Energy Policy Act of 2005 (EPACT 2005). The Regulatory Plan and Unified Agenda also reflect the Department's continuing commitment to cut costs, reduce regulatory burden, and increase responsiveness to the public.

Energy Efficiency Program for Consumer Products and Commercial Equipment

The Energy Policy Act of 2005, enacted on August 8, 2005, had a significant impact on the Department's priorities for its rulemaking activities related to energy efficiency standards, test procedures, and determinations. EPACT 2005 not only added new products to those already covered by the Energy Policy and Conservation Act (EPCA), but it also affects ongoing rulemakings. On October 18, 2005, DOE published a technical amendment to place in the Code of Federal Regulations the energy conservation standards, and related definitions, that Congress prescribed in EPACT 2005 for certain consumer products and commercial and

industrial equipment. In addition, on July 25, 2006, DOE published a Notice of Proposed Rulemaking (NOPR) to provide for new Federal energy efficiency and water conservation test procedures, and related definitions, for certain consumer products and certain commercial and industrial equipment under EPACT 2005. Consistent with EPACT 2005, the Department intends to continue its work on adoption of amended energy efficiency standards for residential furnaces and boilers and on new standards for electric distribution transformers.

On January 31, 2006, the Department released a schedule for setting new appliance efficiency standards that will save American consumers billions of dollars in energy costs. The five-year plan outlines how DOE will address the appliance standards rulemaking backlog and meet the statutory requirements established in the EPCA and EPACT 2005. The statutes require DOE to set appliance efficiency standards at levels that achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. Standards already in place for residential products are expected to save consumers nearly \$93 billion by 2020, and to save enough energy to operate all U.S. homes for approximately two years.

The five-year plan, which was developed considering the public comments received on the appliance standards program, provides for the issuance of one rulemaking for each of the 18 products in the backlog. The plan also provides for setting appliance standards for products required under EPACT 2005. The Department is aggressively implementing process improvements to speed up the development and issuance of appliance standards rules.

The overall plan for implementing the schedule is contained in the Report to Congress under section 141 of EPACT 2005, which was released January 31, 2006. The report and schedule is posted at:

http://www.eere.energy.gov/buildings/appliance_standards/2006_schedule_setting.html. The report identifies all products for which DOE has missed the deadlines established in EPCA (42 U.S.C. § 6291 et seq.). It also describes the reasons for such delays and the Secretary's plan for expeditiously prescribing new or amended standards. The first semi-annual update to the report was released August 10, 2006. Information and timetables concerning these actions can

also 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. In February 2006, the Department issued a final rule adding a new part, 10 CFR 851, Worker Safety and Health, that established basic requirements to ensure workers are protected from safety and health hazards at DOE facilities. The remaining action, 10 CFR part 834, Radiation Protection of the Public and the Environment, is scheduled for completion in 2008.

Loan Guarantees

Title XVII of the Energy Policy Act of 2005 (42 U.S.C. 16511-16514) authorizes the Secretary of Energy to issue loan guarantees for energy related projects that "avoid, reduce, or sequester air pollutants or anthropogenic emissions of greenhouse gases; and employ new or significantly improved technologies as compared to commercial technologies in service in the United States at the time the guarantee is issued." By reducing the financial risk of these innovative technologies, DOE hopes to facilitate their advancement to market. DOE believes that accelerated commercial use of new or improved technologies will help to sustain economic growth, yield environmental benefits, and produce a more stable and secure energy supply. DOE is committed to openness and public participation as it develops rules and criteria for loan guarantees and promptly will be taking action to

promulgate such rules. The Department intends to publish a notice of proposed rulemaking in December 2006.

DOE—Energy Efficiency and Renewable Energy (EE)

PRERULE STAGE

28. ENERGY CONSERVATION STANDARDS FOR RESIDENTIAL ELECTRIC AND GAS RANGES AND OVENS AND MICROWAVE OVENS, DISHWASHERS, DEHUMIDIFIERS, AND COMMERCIAL CLOTHES WASHERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6295(g) to (h)(cc); 42 USC 6313(e)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 1997.

Abstract:

The Department is committed to becoming current on all energy standards rulemakings, including the current standards for residential electric and gas ranges and ovens, microwave ovens, dishwashers, dehumidifiers, and commercial clothes washers. The EPACT 2005 amendments to EPCA, established initial energy efficiency standard level for commercial clothes washers.

Statement of Need:

The Department may determine that separate rulemakings may be warranted for some of these individual products or equipment.

Alternatives:

EPCA, as amended, requires DOE to conduct rulemaking to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technically feasible and economically justified. In making this determination, DOE conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified in the statute.

Timetable:

Action	Date	FR Cite
ANPRM	08/00/07	
NPRM	07/00/08	
Final Action	03/00/09	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

Merged dishwashers from RIN 1904-AA89 and added residential dehumidifiers and commercial clothes washers.

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Related RIN: Merged with 1904-AA89

RIN: 1904-AB49

DOE—EE

29. ENERGY EFFICIENCY STANDARDS FOR COMMERCIAL REFRIGERATION EQUIPMENT

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6313(c)

CFR Citation:

10 CFR 431

Legal Deadline:

Final, Statutory, January 1, 2009.

Abstract:

The EPACT 2005 amendments to EPCA require that standards be established for ice cream freezers; self-contained commercial refrigerators, freezers, and refrigerator-freezers without doors; and remote-condensing commercial refrigerators, freezers, and refrigerator-freezers.

Statement of Need:

EPCA, as amended, requires that DOE set energy efficiency standards that are

technologically feasible and economically justified.

Summary of Legal Basis:

The EPACT 2005 amendments to EPCA authorize DOE to establish energy conservation standards for commercial refrigeration equipment.

Alternatives:

EPCA, as amended, requires DOE to conduct rulemaking to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technically feasible and economically justified. In making this determination, DOE conducts a thorough analysis of alternative standard levels, based on criteria specified by statute.

Timetable:

Action	Date	FR Cite
ANPRM	07/00/07	
NPRM	05/00/08	
Final Action	01/01/09	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 1904-AB59

DOE—EE

PROPOSED RULE STAGE

30. ENERGY EFFICIENCY STANDARDS FOR RESIDENTIAL FURNACES AND BOILERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6295(f)

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. EPACT 2005 amended EPCA to authorize the Department to set standards for electricity used in furnaces to circulate air through duct work. Section 135(c).

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.

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 analysis from the Advance Notice of Proposed Rulemaking for energy conservation standards for furnace and boilers projects saving between 0.28 and 9.29 quadrillion BTUs of energy from 2012 to 2035,

with a national financial impact on the consumer in terms of national Net Present Value (NPV) ranging from \$0.1 to \$3.2 billion. (69 FR 45420)

Risks:

At higher efficiency levels, consumers risk unintended condensation of flue gases, whereas, without changes to the existing furnace and boiler standards, energy use and energy costs for consumers will continue to increase. Enhancing appliance energy efficiency also reduces atmospheric emissions such as CO₂ and NO_x. 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
ANPRM	07/29/04	69 FR 45419
ANPRM Comment Period End	11/10/04	
NPRM	10/06/06	71 FR 59204
NPRM Comment Period End	01/15/07	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local, State

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RIN: 1904-AA78

DOE—EE

FINAL RULE STAGE

31. ENERGY EFFICIENCY STANDARDS FOR ELECTRIC DISTRIBUTION TRANSFORMERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6317(a)(2)

CFR Citation:

10 CFR 431

Legal Deadline:

Final, Statutory, October 24, 1996.

Abstract:

Prior to enactment of EPACT 2005, the Energy Policy and Conservation Act, as amended, (EPCA) did not establish energy efficiency standards for electric distribution transformers. EPCA directed DOE to determine whether standards for electric distribution transformers were warranted. However, as a result of amendments adopted in EPACT 2005, Public Law No. 109-58, section 135(c)(4), EPCA now contains standards for low voltage dry-type electric distribution transformers, but not other types of distribution transformers. This rulemaking will determine whether it is appropriate to establish standards for these other types of electric distribution transformers.

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 authorizes the Department to establish energy conservation standards for various consumer products and commercial and industrial equipment, including distribution transformers, if DOE determines that energy conservation standards would be technologically feasible and economically justified, and would result in significant energy savings. Title III of EPCA sets forth a variety of provisions designed to improve energy efficiency. Part C of title III, 42 U.S.C. 6311 to 6317, establishes a program for "Certain Industrial Equipment," similar to the one for consumer products in part B, and includes distribution transformers. Since EPACT 2005, Public Law No. 109-58, section 135(c), establishes energy conservation standards for one group of transformers, low-voltage, dry-type distribution transformers, that category will no longer be covered by this rulemaking.

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.

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 analysis from the Notice of Proposed Rulemaking, 71 FR 44356, for energy conservation standards for distribution transformers projects savings of 2.4 quadrillion BTUs of energy from 2010 to 2038, with a national financial impact on the consumer in terms of national Net Present Value (NPV) up to 2.5 billion dollars.

Risks:

At higher efficiency levels, the limited availability of some core steels is an important issue. Other issues that pose some risks include significant capital investment requirements, core processing equipment, retooling, and R&D. Establishing standards that are too stringent could result in excessive increases in the cost of the product, with possible reductions in product utility (larger/bulkier/heavier transformers), with additional pressure on some manufacturers to move production out of the U.S. and a possible risk that some small manufacturers would exit.

Timetable:

Action	Date	FR Cite
Determination Notice	10/22/97	62 FR 54809
ANPRM	07/29/04	69 FR 45375
ANPRM Comment Period End	11/09/04	
NPRM	08/04/06	71 FR 44356
NPRM Comment Period End	10/13/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 1904-AB08

DOE-EE

32. ENERGY EFFICIENCY STANDARDS FOR CEILING FAN LIGHT KITS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6295(ff)(4)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 2007.

Abstract:

The EPACT 2005 amendments to EPCA require that DOE establish standards for ceiling fan light kits (other than those with prescribed standards in EPACT 2005) by January 1, 2007. If DOE does not meet this deadline, EPACT 2005 specifies that the energy consumption levels in 42 U.S.C. 6295 (ff)(4)(C) go into effect for products manufactured after January 1, 2009.

Statement of Need:

EPCA, as amended, require DOE to set appliance efficiency standards at technologically feasible and economically justified levels.

Summary of Legal Basis:

The EPACT 2005 amendments to EPCA authorize DOE to establish energy conservation standards for ceiling fan light kits.

Alternatives:

The statute requires DOE to conduct rulemaking 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, DOE conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. Pursuant to EPACT 2005, if

DOE does not complete the required rulemaking by January 1, 2007, energy efficiency levels specified in the statute go into effect for covered products manufactured after January 1, 2009.

Timetable:

Action	Date	FR Cite
Legislative Date for Final Rule	01/00/07	
Standards Effective Date (for products manufactured after 01/01/2009)	01/01/09	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

DOE will not complete the required rulemaking by January 1, 2007. Thus, the statutory standards specified in 42 U.S.C. 6295 (ff)(4)(C) will go into effect for products manufactured after January 1, 2009.

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RIN: 1904-AB61

DOE-Departmental and Others (ENDEP)

PROPOSED RULE STAGE

33. • LOAN GUARANTEES FOR PROJECTS THAT EMPLOY INNOVATIVE TECHNOLOGIES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 16511; 42 USC 16514

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

Title XVII of the Energy Policy Act of 2005 authorizes the Secretary of

Energy, after consultation with the Secretary of the Treasury, to make loan guarantees for projects that “avoid, reduce, or sequester air pollutants or anthropogenic emissions of greenhouse gases; and employ new or significantly improved technologies as compared to commercial technologies in service in the United States at the time the guarantee is issued.” Following publication of guidelines to govern an initial solicitation of projects seeking Federal loan guarantees in August 2006, this proposed rulemaking will establish policies and procedures applicable to all subsequent solicitations for project proposals. The default and audit provisions of the proposed rulemaking, however, will be applicable to all solicitations.

Statement of Need:

A principal purpose of the loan guarantee program is to encourage early commercial use in the United States of new or significantly improved technologies in energy projects. By facilitating the employment of such technologies, we can meet the principal energy challenges of enhancing energy security, repairing and modernizing our energy infrastructure, promoting energy conservation, and increasing our energy supplies in ways that protect and improve the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	
Final Action	10/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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DOE—ENDEP

FINAL RULE STAGE

34. 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 application optimization (As Low As is Reasonably Achievable, ALARA) process; 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
Second NPRM Comment Period End	10/02/95	
Integrate New EPA Guidance	12/00/06	
Final Action	10/00/08	

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 preference 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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BILLING CODE 6450-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**Statement of Regulatory Priorities**

The Department of Health and Human Services (HHS) conducts a broad range of programs mandated by Congress to protect and promote the health and well-being of all Americans, focused especially on those least able to help themselves. HHS responsibilities 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.

Since assuming the leadership of HHS, Secretary Michael O. Leavitt has consistently sought to make transparent his approach to overseeing the Department's programs, through his use of a 500-Day Plan and a recent statement of his nine major priorities. The 500-Day Plan and the statement of priorities are available for public review at <http://www.hhs.gov/secretaryspage.html>. The regulatory actions noted below reflect this policy framework.

Health Information Technology

The Secretary's strategy for promoting improvements in the Nation's health sector stresses maximum use of electronic information technology. The FY 2007 Regulatory Plan accordingly includes a notice of proposed rulemaking to require that clinical study data be provided to the Food and Drug Administration (FDA) in electronic format, using standard data structures, terminology, and code sets. The change would further increase the efficiency of the agency's review processes, speeding up the availability of new therapies. Additionally, the Plan includes: proposed actions to require medical-device firms to register electronically with the FDA, as well as to report post-marketing information to the agency electronically; and a proposal for the adoption of final standards for the electronic transmission of basic prescription-drug data.

Medicare Modernization

The Secretary's statement of priorities includes a focus on Medicare modernization. The Regulatory Plan, accordingly, highlights:

- a proposal to institute competitive bidding procedures to improve the effectiveness of Medicare's current

methodology for setting payment amounts for durable medical equipment; and

- final rules for hospital inpatient services for fiscal year 2008 and for long-term-care hospital services for rate year 2008.

Medicare Part D

The Secretary believes that every senior must have access to affordable prescription drugs, and that a reinforced regulatory framework for implementing the Medicare prescription drug benefit can further connect beneficiaries with the Part D program. The Plan accordingly includes a proposal to clarify current provisions affecting Part D Prescription Drug Plan sponsors and Medicare Advantage organizations, and the above-cited proposal for the adoption of final standards for the electronic transmission of basic prescription-drug data.

Disease Prevention

Also included among the Secretary's priorities is an emphasis on disease prevention and the need for individual responsibility for personal wellness. Three actions in the Plan reflect this concern:

- a final rule establishing good manufacturing practices for the dietary-supplement products favored by many Americans;
- a proposal to modify prescription drug labeling so that health care providers may better understand and communicate to their patients the risks and benefits associated with the use of prescribed medicines during pregnancy and lactation, and
- a proposal to amend existing regulations governing investigational new drugs — the rule would delineate new avenues of access for patients to obtain investigational drugs for treatment use.

Food Safety

The Secretary's 500-Day Plan also embraces the need to secure the homeland. The Regulatory Plan thus includes:

- a proposal to require owners or consignees to label imported food that has previously been refused entry into the United States. This action would prevent the introduction of unsafe food and facilitate the examination of imported food; and
- a final rule completing the rulemaking process requiring that the FDA be notified prior to the entry of imported food into the United States.

HHS—Centers for Disease Control and Prevention (CDC)**FINAL RULE STAGE****35. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE****Priority:**

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

Not Yet Determined

CFR Citation:

42 CFR 70; 42 CFR 71

Legal Deadline:

None

Abstract:

By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC maintains quarantine stations at eight major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and Severe Acute Respiratory Syndrome (SARS) and influenza caused by novel or reemerging influenza virus that are causing, or have the potential to cause, a pandemic.

Statement of Need:

The quarantine of persons believed to be infected with communicable diseases is a long-term prevention measure that has been used effectively to contain the spread of disease. As diseases evolve due to natural

occurrences or man-made events, it is important to ensure that prevention procedures reflect new threats and uniform ways to contain them. Recent experiences with emerging infectious diseases such as West Nile Virus, SARS, and monkeypox have illustrated the rapidity with which disease may spread throughout the world, and the impact communicable diseases, when left unchecked, may have on the global economy. Stopping an outbreak — whether it is naturally occurring or intentionally caused — requires the use of the most rapid and effective public health tools available. One of those tools is quarantine — restricting the movement of persons exposed to infection to prevent them from infecting others, including family members, friends, and neighbors. Quarantine of exposed persons may be the best initial way to prevent the uncontrolled spread of highly dangerous biologic agents — especially when combined with other health strategies such as vaccination, prophylactic drug treatment, patient isolation, and other appropriate infection control measures.

Summary of Legal Basis:

These regulations would be proposed under the authority of 25 U.S.C. 198, 231, 2001; 42 U.S.C. 243, 264 to 271. In addition, section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)) authorizes the “apprehension, detention, or conditional release” of persons to prevent the introduction, transmission, and spread of specified communicable diseases from foreign countries into the United States and from one State or possession into another. Among other public health powers, the lawful ability to inspect property, to medically examine and monitor persons, and to detain or quarantine exists in current regulations. Acknowledging the critical importance of protecting the public’s health, long-standing court decisions uphold the ability of Congress and State legislatures to enact quarantine and other public health laws, and to have them executed by public health officials.

Alternatives:

These regulations are necessary to ensure that HHS has the tools it needs to respond to public health emergencies and disease threats. Any less stringent alternatives would prevent the Department from the most effective possible pursuit of this objective.

Anticipated Cost and Benefits:

The primary cost impact of the proposed rule would be the collection and maintenance of crew and passenger manifest data by air and water carriers that are likely to modify computer systems and collect passenger information to come into compliance. The benefits of the rule would be measured in terms of the number of deaths and illnesses prevented by rapid intervention. When the costs and benefits of the rule are considered over a 20-year period benefits clearly outweigh costs.

Risks:

Failure to move forward with this rulemaking would hinder the Nation’s ability to use the most rapid and effective public health tools available when responding to public health emergencies and disease threats.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
Final Action	08/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

36. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Priority:

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

Legal Authority:

21 USC 355; 21 USC 371; 42 USC 262

CFR Citation:

21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments be provided in an electronic format that FDA can process, review, and archive. The proposal would also require the use of standardized data structure, terminology, and code sets contained in current FDA guidance (the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.

Statement of Need:

Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review.

FDA’s proposed rule would require the submission of study data in a standardized electronic format, and it provides that the specific format will be announced in FDA guidance. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study—in data collection, reporting, and analysis. The proposal would work in concert with ongoing agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Summary of Legal Basis:

Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the act (U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives:

FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This alternative was rejected because the agency would not fully benefit from standardization until it became the industry standard, which could take up to 20 years.

We also considered a number of different implementation scenarios, from shorter to longer time-periods. The two-year time-period was selected because the agency believes it would provide ample time for applicants to comply without too long a delay in the effective date. A longer time-period would delay the benefit from the increased efficiencies, such as standardization of review tools across applications, and the incremental cost saving to industry would be small.

Anticipated Cost and Benefits:

Approximately 70 percent of study data for NDAs and ANDAs are already submitted to FDA in electronic format consistent with our current guidance on electronic submission of data. The other 30 percent is either submitted on paper or in non-standardized electronic format. FDA estimates that the costs to industry resulting from the proposal would include some one-time costs and possibly some annual recurring costs. One-time costs would include, among other things, the cost of converting data to standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and validating the software and training personnel. Additional annual recurring costs may result from software purchases and licensing agreements for use of proprietary terminologies.

The proposal could result in many long-term benefits for industry, including improved patient safety through faster, more efficient, comprehensive, and accurate data review; enhanced communication among sponsors and clinicians.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910-AC52

HHS—FDA

37. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

CFR Citation:

21 CFR 201.56; 21 CFR 201.57; 21 CFR 201.80

Legal Deadline:

None

Abstract:

To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR 201.56, 201.57, and 201.80).

Statement of Need:

Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug during pregnancy. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. These stakeholders have expressed the view that the current categories are confusing and overly simplistic and thus are not adequate to communicate risks effectively. One of the deficiencies of the category system is that drugs may be assigned to the same category when the severity, incidence, and types of risk are quite different.

Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. It has also been strongly recommended that pregnancy labeling address the situation where a woman has taken drugs before she realizes she is pregnant. The labeling that would be required under the proposed rule would be responsive to the concerns discussed above, and others that have been expressed by critics of the current category system.

Summary of Legal Basis:

FDA 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 concerning the safe and effective use of drug products involves 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 and 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 or may withdraw 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 consequences which may result from use of the drug product under the conditions of use prescribed in the labeling or under customary 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 publish a proposed rule designed to help ensure that practitioners prescribing drugs (including biological products) to pregnant women and women of childbearing age would receive information essential to the safe and effective use of these drugs.

Alternatives:

The alternatives to the proposal include not amending our existing regulation governing the format and content of labeling for human prescription drugs and biological products. This alternative is inconsistent with widespread stakeholder dissatisfaction with the pregnancy labeling provided pursuant to the current regulation.

Anticipated Cost and Benefits:

The proposed rule would impose one-time costs for firms to modify drug product labeling. The extent of these modifications would depend on whether a product's labeling is affected by the physician labeling final rule (PLR) and on the scope of the implementation.

The revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation. A better understanding of risks and benefits would help women and their healthcare providers make informed decisions about whether or not to use drugs during pregnancy and lactation. Labeling under the rule would also provide information geared to women who took drugs before they

knew they were pregnant. Such information may often be reassuring to women and their health care providers.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

38. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Priority:

Other Significant

Legal Authority:

21 USC 355; 21 USC 360bbb; 21 USC 371; 42 USC 262

CFR Citation:

21 CFR 312.42; 21 CFR 312.300; 21 CFR 312.305; 21 CFR 312.310; 21 CFR 312.315; 21 CFR 312.320

Legal Deadline:

None

Abstract:

To amend the regulations governing investigational new drugs to describe the ways patients may obtain investigational drugs for treatment use under expanded access programs. Such use of investigational drugs would be available to: (1) Individual patients, including in emergencies; (2) intermediate size patient populations; and (3) larger populations under a treatment protocol or treatment IND.

Statement of Need:

The Food and Drug Administration Modernization Act of 1997 (Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the Act) to include specific provisions concerning expanded access to investigational drugs for treatment use. In particular, section 561(b) of the Act permits any person, acting through a licensed physician, to request access to an investigational drug to diagnose, monitor, or treat a serious disease or condition provided that a number of conditions are met. The proposed rule is needed to incorporate into FDA's regulations this and other provisions of the Modernization Act concerning access to investigational drugs.

In addition, by this proposed rule, the Agency seeks to increase awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use. The proposed rule would assist in achieving this goal by describing in detail the criteria, submission requirements, and safeguards applicable to different types of treatment uses.

Summary of Legal Basis:

FDA has the authority to impose requirements concerning the treatment use of investigational drugs under various sections of the Act, including sections 505(i), 561, and 701(a) (21 U.S.C. 355(i), 360bbb, and 371(a)).

Section 505(i) of the Act directs the Secretary to promulgate regulations exempting from the operation of the new drug approval requirements drugs intended solely for investigational use by experts qualified by scientific training and expertise to investigate the safety and effectiveness of drugs. The proposed rule explains procedures and criteria for obtaining FDA authorization for treatment uses of investigational drugs.

The Modernization Act provides significant additional authority for this proposed rule. Section 561(a) states that the Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations. Section 561(b) allows any person, acting through a physician licensed in accordance with State law, to request from a manufacturer or distributor an investigational drug for the diagnosis, monitoring, or treatment of a serious disease or condition if certain conditions are met. Section

561(c) closely tracks existing FDA's existing regulation at 21 CFR 312.34 providing for treatment use by large patient populations under a treatment protocol or treatment IND if a number of conditions are met.

Section 701(a) provides the Secretary with the general authority to promulgate regulations for the efficient enforcement of the Act. By clarifying the criteria and procedures relating to treatment use of investigational products, this proposed rule is expected to aid in the efficient enforcement of the Act.

Alternatives:

One alternative to the proposed rule that FDA considered was not to propose regulations implementing the expanded access provisions of the Modernization Act. However, the Agency believes that implementing regulations would further improve the availability of investigational drugs for treatment use by providing clear direction to sponsors, patients, and licensed physicians about the criteria for authorizing treatment use and what information must be submitted to FDA.

Another alternative FDA considered was to propose a regulation describing only individual patient and large scale expanded access criteria. However, the Agency concluded that it would be preferable to have a third category of expanded access for intermediate size patient populations.

Anticipated Cost and Benefits:

FDA expects that the total one-time costs of the proposed rule will be negligible. The Agency expects that the annual and annualized costs of the proposed rule will range from a low of about \$130,000 to \$260,000 in the first year following publication of any final rule based on this proposal, to a high of about \$350,000 to \$690,000 in the 4th and 5th years. These estimates suggest that total annual and annualized costs for the proposed rule would be between \$1.4 million and \$2.7 million for the 5-year period following implementation of any final rule based on this proposal. The Agency also expects that the estimated incremental cost burdens associated with this proposed rule are likely to be widely dispersed among affected entities.

The benefits of the proposed rule are expected to result from improved patient access to investigational drugs generally and from treatment use being made available for a broader variety of disease conditions and treatment

settings. In particular, the clarification of eligibility criteria and submission requirements would enhance patient access by easing the administrative burdens on individual physicians seeking investigational drugs for their patients and on sponsors who make investigational drugs available for treatment use.

Risks:

The agency foresees no risks associated with the proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Organizations

Government Levels Affected:

None

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HHS—FDA

39. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

Priority:

Other Significant

Legal Authority:

15 USC 1453 to 1455 ; 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

CFR Citation:

21 CFR 1.98

Legal Deadline:

None

Abstract:

The proposed rule would require owners or consignees to label imported

food that is refused entry into the United States. The label would read, "UNITED STATES: REFUSED ENTRY." The proposal would describe the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Statement of Need:

In 1998, the General Accounting Office issued a report titled, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable." The report stated that some food importers evade import controls and are able to introduce contaminated, adulterated, or unsafe food into the United States even after FDA refused to admit the food and the Customs Service ordered the food to be reexported or destroyed.

Additionally, in 1998, the Senate Permanent Subcommittee on Investigations conducted hearings on the safety of food imports. The subcommittee heard testimony about reimporting refused foods through another port (a practice known as "port shopping"). On July 3, 1999, then-President Clinton issued a memorandum to the Secretary of Health and Human Services and the Secretary of the Treasury directing them, in part, to take all actions available to "prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations" by requiring the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.

Consequently, on January 22, 2001, FDA and the Department of the Treasury jointly issued a proposed rule (66 FR 6502) that would require that imported food that has been refused admission for safety reasons be marked as "UNITED STATES: REFUSED ENTRY." The mark would make it easier to detect previously refused food and reduce, if not eliminate, "port shopping." However, on June 12, 2002, before FDA and Treasury could prescribe a final rule, the Bioterrorism Act became law. Section 308(a) of the Bioterrorism Act created a new section 801(n) of the Federal Food, Drug, and

Cosmetic Act (the act) to clarify FDA's authority to require the owner or consignee of a food that had been refused admission into the United States to "affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY.'" Although section 308(c) of the Bioterrorism Act stated that "nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law," the new statutory provision differed from the January 22, 2001, proposed rule and prompted FDA to withdraw the proposal on August 21, 2002 (67 FR 54138).

The new proposal would describe the label requirements for imported food that has been refused admission into the United States.

Summary of Legal Basis:

Section 801(a) of the act authorizes FDA to refuse to admit imported food if the food has been manufactured, processed, or packed under insanitary conditions, is forbidden or restricted in sale in the country in which it was produced, or is adulterated or misbranded. Additionally, as explained earlier, section 801(n) of the act gives FDA express authority to require the owner or consignee of a food that had been refused admission into the United States to "affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY.'" Sections 402 and 403 of the act describe when a food is adulterated or misbranded respectively. Section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the Act, while section 701(b) of the act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

The proposed rule is within FDA's authority at sections 402, 403, 701, and 801 of the act. In general, unsafe food is often adulterated under section 402 of the act, and may also be misbranded under section 403 of the act if the food purports to meet a particular definition, standard of identity, or standard of quality. Labeling refused foods will make it easier for FDA to refuse to admit previously-refused, adulterated or misbranded food imports into the United States.

Additionally, section 301 of the Public Health Service Act (PHS act) authorizes FDA to "render assistance" to appropriate health authorities in the conduct of or to promote coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of disease. Section 361 of the PHS act authorizes FDA to issue regulations to prevent the introduction, transmission, or spread of communicable diseases into the United States. Affixing a label to refused food products will help foreign health officials determine whether to take regulatory action against a particular product. It would also alert foreign officials to previously refused food and help prevent the introduction, transmission, or spread of communicable diseases into the United States by making it more difficult for unsafe food to reenter the United States.

Alternatives:

FDA considered exempting small businesses from the rule, but, because most importers and consignees would qualify as small businesses, this would negate the rule's purpose.

The agency also considered ordering the destruction of all refused food imports, but this would not be feasible because it would divert Federal resources to supervising or otherwise ensuring that the refused food imports are stored until they can be destroyed and that they are destroyed.

FDA also rejected affixing the label on some, but not all, imported food refused entry for safety reasons. While this alternative would be less costly, it would also be less efficient because some refused food imports would be able to reenter the United States and because a previously-refused, but unlabeled, food would be difficult to detect compared to a previously-refused and labeled food. This alternative would also result in arguments as to the criteria to be applied and whether a particular food should be labeled.

Anticipated Cost and Benefits:

Importers and consignees would bear the costs associated with affixing the label to refused food imports. The rule's costs would, therefore, consist of labor costs (to affix the mark) and equipment costs (the label equipment used). FDA will estimate these costs in the proposed rule.

The rule's principal benefit would be a reduction in the number of illnesses and injuries caused by unsafe imported

food. The Agency is unable to quantify the amount of illegal importation of previously refused foods, so it cannot accurately predict the value of reduced illnesses and injury.

Risks:

There is a possible risk previously refused, unpackaged food (such as loose grain in a railroad car) would be able to enter the United States because the food itself cannot be labeled, although the proposed rule would require the importer or consignee to affix a label on papers accompanying the product.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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HHS—FDA

40. • MEDICAL DEVICE REPORTING; ELECTRONIC SUBMISSION REQUIREMENTS

Priority:

Other Significant

Legal Authority:

21 USC 352; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation:

21 CFR 803

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to amend its

postmarket medical device reporting regulations to require that reports submitted to the agency by persons subject to mandatory reporting requirements be transmitted electronically in a form that FDA can process, review, and archive. FDA is taking this action to improve the agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the agency to more quickly review safety reports and identify emerging public health issues.

Statement of Need:

The proposed rule would require user facilities and medical device manufacturers and importers to send medical device adverse event reports electronically instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Summary of Legal Basis:

The agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The proposed rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA electronically instead of using a hard copy form.

Alternatives:

The alternatives to this rulemaking include not updating the medical device reporting requirements and not requiring electronic submission of this information. For over 20 years, medical device manufacturers, importers, and user facilities have sent adverse event reports to FDA on paper forms. Processing paper forms is a time consuming and expensive process. FDA believes this rulemaking is the preferable alternative.

Anticipated Cost and Benefits:

FDA estimates that over 80 percent of the adverse event reports it receives come directly from the reporter's computer databases. Computer applications are available that would take the information from the corporate database and produce an electronic file that can be sent to the FDA. Once reporters have developed the electronic reporting capability, they would save significant mailing and administrative processing costs. FDA is developing an electronic system for reporters who do not have the capability to produce the required electronic file.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

41. • ELECTRONIC REGISTRATION AND LISTING FOR DEVICES

Priority:

Other Significant

Legal Authority:

PL 107-188, sec 321; 21 USC 360(p)

CFR Citation:

21 CFR 807

Legal Deadline:

None

Abstract:

FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR 807 to reflect the new requirements in section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and 21 USC 360(p). This proposed rule would require domestic and foreign device establishments to submit registration and listing data electronically via the Internet using FDA's Unified Registration and Listing System. This proposed rule would convert the registration and listing process to a paperless process. For those companies

that do not have access to the web, FDA would offer an avenue by which they can register, list, and update information with a paper submission.

Statement of Need:

FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the new requirements in section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) and Section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This proposed rule would improve FDA's device establishment and registration and listing system and utilize the latest technology in the collection of this information.

Summary of Legal Basis:

The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 903 of the Federal Food, Drug, and Cosmetic 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. Because of the new statutory requirements, and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative to the paper system currently in place.

Anticipated Cost and Benefits:

The agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by Section 321 of the BT Act.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

FINAL RULE STAGE

42. 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 or 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	

Action	Date	FR Cite
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

43. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority:

Other Significant

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 (the act), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), 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.

Section 307 authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. FDA and the Bureau of Customs and Border Protection (CBP) issued an interim final rule (IFR) on October 10, 2003 (68 FR 58974). The IFR originally provided a 75-day comment period to ensure that those that comment on the IFR have the benefit of our outreach and educational efforts and have the experience with the systems, timeframes, and data elements. We reopened the comment period for an additional 90 days in April through July 2004 to allow for additional comment on the industry's experience with the prior notice system, and comment on the Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes. The final rule currently is under development, and it will confirm or amend the IFR, as appropriate. This final rule is not expected to have a significant impact on a substantial number of small entities.

Statement of Need:

This final rule is needed to complete the rulemaking process to implement section 307 of the Bioterrorism Act. The proposed rule was published on February 3, 2003 (68 FR 5428) and the interim final rule on October 10, 2003 (68 FR 58974).

Summary of Legal Basis:

Section 307 of the Bioterrorism Act amended the act 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 act 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:

An alternative is to leave the IFR in place and not to issue a final rule. However, we received numerous comments in response to the IFR that require a response. Finalizing this rule will assist industry and the public in better understanding and complying with the prior notice requirements.

Anticipated Cost and Benefits:

The final rule will amend the interim final rule already in place. We do not expect the changes from the interim final rule to be economically significant.

This final rule will require that FDA be notified prior to the arrival of the food.

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.

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

Action	Date	FR Cite
Interim Final Rule Comment Period Reopened End	07/13/04	
Final Rule	05/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—Centers for Medicare & Medicaid Services (CMS)**PROPOSED RULE STAGE****44. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS RY 2008: ANNUAL PAYMENT RATE UPDATES (CMS-1529-P)****Priority:**

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 106-113 sec 123 ; PL 106-554 sec 307(b)

CFR Citation:

42 CFR 412

Legal Deadline:

Final, Statutory, July 1, 2007.

Abstract:

This rule proposes the annual payment rate update for the 2008 prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions on LTCH PPS policy for public comment.

Statement of Need:

The statute requires that we annually update the annual payment rate

amounts for Medicare long-term care hospitals and also presents proposed changes in long-term care policy. The Rate Year (RY) 2008 proposed and final rules must be published by May 1, 2007 to be effective July 1, 2007. Under the Long-Term Care Hospitals Prospective Payment System (LTCH PPS), LTCHs are paid for each discharge based on the standard Federal rate, adjusted to reflect the resource utilization, as well as other facility-level and case-level adjustments. In addition to the update to the standard Federal rate, several of the other facility-level and case-level adjustments that affect LTCH PPS payments are updated or refined in the annual LTCH PPS proposed and final rules.

Summary of Legal Basis:

Medicare was granted the legal authority for payment to LTCHs under PL 106-113, section 123, and PL 106-554, section 307(b).

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

We project expenditures of approximately \$5.4 billion in RY 2007.

Risks:

If this regulation is not published timely, Medicare payments for inpatient hospital services provided at LTCHs may not be paid appropriately.

Timetable:

Action	Date	FR Cite
NPRM	01/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS**45. ● STANDARDS FOR E-PRESCRIBING UNDER MEDICARE PART D (CMS-0016-P)****Priority:**

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

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

42 USC 1395

CFR Citation:

42 CFR 423

Legal Deadline:

Final, Statutory, April 1, 2008.

Abstract:

This rule proposes standards for electronic prescribing (e-prescribing) under Medicare Part D. This rule would require Medicare Part D and Medicare Advantage plans to support electronic transmission of basic prescription data to and from doctors and pharmacies and to adopt final standards for e-prescribing as required by section 101 of the MMA.

Statement of Need:

This rule would implement section 101 of the MMA which includes the requirement that the Secretary promulgate final uniform standards for the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals.

Summary of Legal Basis:

Section 101 of the MMA requires that the Secretary promulgate final uniform standards for the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals by no later than 4/1/2008.

Alternatives:

This is a statutory requirement.

Anticipated Cost and Benefits:

All Medicare drug plans would be required to implement the standards. We expect that the standards would include transactions for communicating medication history and formulary information to prescribes, which would result in fewer adverse drug events and increased formulary compliance.

Risks:

If this regulation is not published timely, plans may not be aware of the uniform standards.

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

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

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HHS—CMS

46. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2008 RATES (CMS-1533-P)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

Sec 1888(d) of the Social Security Act

CFR Citation:

42 CFR 412

Legal Deadline:

NPRM, Statutory, April 1, 2007.

Final, Statutory, August 1, 2007.

Abstract:

This rule proposes to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems

Statement of Need:

The statute requires by law that we publish each year a proposed rule,

followed by a final rule, on the acute care hospital inpatient prospective payment systems (IPPS) annual updates to the payment rates and related hospital inpatient policy changes under the Medicare program. Medicare pays for acute care hospital inpatient services under a prospective payment system (IPPS) in which payment is made at a predetermined rate for the operating and capital-related costs associated with each hospital discharge. Payment rates for IPPS hospitals and the payment limits for hospitals excluded from IPPS are updated each year to take into account changes in the cost of goods and services used by hospitals, as well as other factors.

Summary of Legal Basis:

Section 1886(d) of the Social Security Act establishes payment for inpatient hospital services. The statute requires that a proposed rule be published by 4/1/07. It also requires that the final rule be published by 8/1/07.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

We project the payment rate updates to hospitals would increase by over \$3.4 billion from FY 2007 to FY 2008.

Risks:

If this regulation is not published timely, hospital inpatient services will not be paid appropriately.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—CMS

47. • REVISIONS TO THE MEDICARE ADVANTAGE AND PART D PRESCRIPTION DRUG CONTRACT CONFIDENTIALITY AND DISCLOSURE, DETERMINATIONS, APPEALS, AND INTERMEDIATE SANCTIONS PROCESSES (CMS-4124-P)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395(hh); 42 USC 1395(w-101) to 1395(w-152)

CFR Citation:

42 CFR 401.134, 42 CFR 422.506, 42 CFR 422.50; 42 CFR 423.509, 42 CFR 422.644 to 658, 42 CFR; 42 CFR 422.660 to 664; 42 CFR 423.650 to 652

Legal Deadline:

None

Abstract:

This proposed rule would clarify and modify the Medicare Advantage (MA) program provisions relating to disclosure of information, and contract determinations by MA Organizations and Part D Prescription Drug Plan sponsors. This proposed rule would also revise requirements concerning the reconsideration of determinations and clarifies the schedule for MA organizations and Part D plan sponsors to complete corrective action plans. In addition, it would clarify the intermediate sanction and civil money penalty (CMP) provisions relating to MA Organizations and Medicare Part D Prescription Drug Plan sponsors.

Statement of Need:

With the increase from 160 Managed Care Organizations (MCOs) to over 500 in 2006, CMS needs to strengthen both its methodology and available tools to oversee this extremely augmented program. In an effort to strengthen the Agency's compliance oversight, this rule would ensure effective management and enforcement of program objectives.

Summary of Legal Basis:

This proposed rule would clarify and modify provisions relating to disclosure of information, and contract determinations of Medicare Advantage (MA) Organizations and Part D Prescription Drug Plan sponsors. It also would revise requirements concerning the reconsideration of such determinations and to clarify the schedule for MA organizations and Part D plan sponsors to complete corrective

action plans. In addition, it would clarify the intermediate sanction and civil money penalty provisions relating to MA Organizations and Part D Prescription Drug Plan sponsors.

Alternatives:

None. Given the fact that CMS' compliance authorities are vested in Federal regulations, we do not see viable legal alternatives to revising existing Federal regulations to accomplish stated goals.

Anticipated Cost and Benefits:

We do not estimate any costs to the Government associated with promulgating and implementing this regulation. There is the potential for increased costs to Medicare managed care organizations as they change existing compliance infrastructures to accommodate these revised rules. This rule will benefit CMS in that it will strengthen the Agency's compliance authorities and in so doing, benefit Medicare beneficiaries who will have greater confidence that Medicare managed care organizations comply with Federal Medicare program requirements.

Risks:

If this regulation is not finalized, program objectives may not be effectively managed and enforced.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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HHS—CMS

FINAL RULE STAGE

48. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES (CMS-1270-F)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

PL 108-173, MMA; Deficit Reduction Act of 2005, PL 109-171, sec 5101

CFR Citation:

42 CFR 414.1; 42 CFR 424.1; 42 CFR 424.57

Legal Deadline:

Final, Statutory, December 31, 2007.

Abstract:

Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This rule also incorporates provisions from section 5105 of the DRA of 2005, which concerns beneficiary ownership of certain DMEs.

Statement of Need:

The statute requires that we establish and implement a new competitive bidding program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items in the Medicare program. This program changes the way that Medicare pays for these items under Part B of the Medicare program by utilizing bids submitted by DMEPOS suppliers to establish payment amounts. The final rule must be published timely to ensure that competition under the Medicare DMEPOS competitive bidding program begins in 10 of the largest metropolitan statistical areas (MSAs) in 2007.

Summary of Legal Basis:

Section 1847 of the Social Security Act (the Act) requires the Secretary to establish and implement competitive acquisition programs for certain items of DMEPOS. Section 1847(a)(1)(B) of the Act requires phased-in implementation so that competition under the programs occurs in 10 of the MSAs in 2007, 80 of the largest MSAs in 2009, and additional areas after 2009.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

The projected annual Medicare program savings from DMEPOS competitive bidding over the first 4 years of the program are estimated to be approximately \$110 million the first year and increasing to over \$1.2 billion by the fourth year.

Risks:

If this regulation is not published timely, we will be unable to meet the statutory implementation schedule and receive the anticipated savings.

Timetable:

Action	Date	FR Cite
NPRM	05/01/06	71 FR 25654
Final Action	03/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State

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DEPARTMENT OF HOMELAND SECURITY (DHS)

Statement of Regulatory Priorities

The Department of Homeland Security (DHS or the Department) was created in 2003 pursuant to the Homeland Security Act of 2002, Public Law 107-296. DHS is comprised of 22 Federal agencies brought together for the common mission of preventing terrorist attacks in the United States, reducing the vulnerability of the United States to terrorist attacks, and minimizing damage and assisting in recovery from acts of terrorism, natural disasters, or other emergencies that might occur in the United States. The Department's 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/xlibrary/assets/DHS_StratPlan_FINAL_spread.pdf.

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.

In 2005, the Secretary of Homeland Security announced a six-point agenda

to ensure that the Department's policies, operations, and structures are aligned in the best way to address the potential threats that face our nation. The Secretary's six-point agenda is intended to:

- Increase overall preparedness, particularly for catastrophic events;
- Create better transportation security systems to move people and cargo more securely and efficiently;
- Strengthen border security and interior enforcement and reform immigration processes;
- Enhance information sharing with our partners;
- Improve DHS financial management, human resource development, procurement and information technology; and
- Realign the DHS organization to maximize mission performance.

The regulations summarized in the Department's Fall Regulatory Program and in the Unified Agenda support the Department's Strategic Goals and the Secretary's six-point agenda and will improve the Department's ability to accomplish its primary missions.

DHS strives for organizational excellence and uses a centralized and unified approach in managing its regulatory resources. The Department's regulatory program, including the Unified Regulatory Agenda and Regulatory Plan, is managed by the Office of the General Counsel. In addition, DHS senior leadership reviews each significant regulatory project to ensure that the project fosters and supports the Department's Strategic Goals.

DHS also is committed to ensuring 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, and takes particular concern with the impact its rules have on small businesses. DHS and each of its components continue to emphasize the use of plain language in our notices and rulemaking documents to promote better understanding of regulations and increased public participation in the Department's rulemakings.

The Fall 2006 Regulatory Plan for DHS includes regulations issued by the

Office of the Secretary of Homeland Security that are sponsored by the Department's major divisions or directorates, including the Office of Information Analysis, DHS's Office of Policy and the US-VISIT program. Additionally, several DHS components are authorized to promulgate regulations. Those components include, but are not limited to: the United States Coast Guard, United States Citizenship and Immigration Services, the Bureau of Customs and Border Protection, the Transportation Security Administration, and the Bureau of Immigration and Customs Enforcement. The Fall 2006 Regulatory Plans for the Office of the Secretary and those DHS regulatory components with submissions for the 2006 Plan are discussed below.

Office of the Secretary

During fiscal year 2007, DHS will be initiating a rulemaking action to establish minimum standards for State-issued driver's licenses and identification cards that Federal agencies would accept for official purposes as required under the REAL ID Act of 2005.¹ The REAL ID Act, effective May 18, 2008, prohibits Federal agencies from accepting a driver's license or personal identification card (license) for an "official purpose" unless it has been issued by a State that has certified to, and been determined by DHS to meet, the requirements of the Act. The Act sets forth minimum document requirements, minimum issuance standards, and other requirements, including the following:

- Information and features that must appear on the face of the license, and inclusion of a common machine readable portion of a driver's license or identification card;
- Presentation and verification of information an applicant must provide before a license may be issued, including evidence that the applicant is a U.S. citizen or has lawful status in the United States;
- Physical security of locations where licenses are produced, the security of document materials and papers from which licenses are produced, and the background check of certain employees involved in the manufacture and production of licenses; and

¹ Division B—REAL ID Act of 2005, the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, Pub. L. 109-13, 119 Stat. 231, 302 (2005) (codified at 49 U.S.C. 30301 note).

- Physical security of the licenses to prevent tampering, counterfeiting, and duplication of the documents for a fraudulent purpose.

DHS is issuing this rule in consultation with the Department of Transportation, other representatives of the Federal Government, and representatives from many States, as required under the Act.

The Department also will be issuing regulations to establish security requirements for chemical facilities. Section 550 of the Homeland Security Appropriations Act of 2007 (October 4, 2006), directs the Department of Homeland Security to issue interim final regulations no later than six months after the date of enactment, establishing risk-based performance standards for the security of chemical facilities and requiring vulnerability assessments and the development and implementation of site security plans for chemical facilities. These regulations will apply to chemical facilities that present high levels of security risk, as determined by the Secretary of Homeland Security. DHS will be issuing an interim final rule in early 2007 to comply with the requirements of section 550 of the Homeland Security Appropriations Act of 2007.

DHS recently finalized the final rule on Procedures for Handling Critical Infrastructure Information (CII). This rule 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. This rule supports the Department's Strategic Goals of awareness, prevention, protection, and response by identifying and assessing the vulnerability of critical infrastructure and key assets.

During fiscal year 2007, the Office of the Secretary expects to expand the scope of 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 biometric identifiers. The goals of the US-VISIT program are to enhance the security of United States citizens and visitors to the United States, facilitate legitimate travel and trade, ensure the integrity of the United States immigration system, and protect the privacy of visitors to the United States. For fiscal year 2007, DHS plans to further expand the classes of

aliens that will be subject to US-VISIT requirements to eventually encompass all aliens, with certain limited exceptions. 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.

United States Coast Guard

The United States Coast Guard (Coast Guard) is a military, multi-mission, and maritime agency. Our 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 supports the Department's overarching goal of mobilizing and organizing our nation to secure the homeland from terrorist attacks, natural disasters, and other emergencies. In performing its duties, the Coast Guard has established five strategic goals — maritime safety, protection of natural resources, maritime security, maritime mobility and national defense. The rulemaking projects identified for the Coast Guard in the Unified Agenda, and the rule appearing in the Fall 2006 Regulatory Plan below, support these strategic goals and reflect our regulatory policies. Further, although the Coast Guard has placed an emphasis on maritime security and national defense since September 11, 2001, our emphasis on these vital issues has not prevented the Coast Guard from carrying out its other important regulatory responsibilities. The Coast Guard has issued many rules that are not security-related as indicated by the wide range of topics covered in its 54 rulemaking projects in this Unified Agenda.

“Vessel Requirements for Notices of Arrival and Departure (NOAD), and Automatic Identification System (AIS)” is a regulatory action of particular importance to the Coast Guard in the Department's Fall 2006 Regulatory Plan. Currently, the Coast Guard does not have a mechanism to capture vessel, crew, passenger, or specific cargo information on vessels less than or equal to 300 gross tons intending to arrive at or depart from U.S. ports unless they are arriving with certain dangerous cargo or are arriving at a port or place within the 7th Coast Guard District (primarily Florida and surrounding waters). To remedy this situation, the Coast Guard plans to issue “Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System,” a rule that

would expand the applicability of these requirements to better enable the Coast Guard to correlate vessel AIS data with NOAD data, enhance our ability to identify and track vessels, detect anomalies, improve navigation safety, and heighten our overall maritime domain awareness and security. This rulemaking would expand the applicability of NOADs to include all foreign commercial vessels, regardless of tonnage, and all U.S. commercial vessels arriving from a foreign port or place. This rulemaking supports the Commandant's strategic goals of maritime safety and maritime security.

The Coast Guard has supported the e-rulemaking initiative and, starting on the day of the first Federal Register publication in a 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 <http://dms.dot.gov>. 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.

U.S. Citizenship and Immigration Services

The mission of the U.S. Citizenship and Immigration Services (USCIS) is to protect national security while conveying our Nation's privileges of freedom and citizenship through the rule of law. The three strategic priorities of USCIS are national security, customer service and organizational excellence. USCIS' key regulatory initiatives for the 2007 President's Agenda are aligned with these strategic priorities and our mission. Key regulations focus on withholding adjudication in security sensitive cases, replacing non-secure identity cards, increasing flexibility in filing options to improve customer service and securing appropriate fees to ensure the soundness of our organization.

These key initiatives directly advance the President's policies and priorities, the mission and the core values of the Department of Homeland Security and DHS Objectives 2.6, 6.2, 7.2 and 7.7. USCIS seeks to welcome lawful immigrants while preventing exploitation of the immigration system and we seek to create and maintain a high-performing, integrated, public service organization. As a nation of immigrants, the United States has a strong commitment to welcoming those individuals who seek entry through our

legal immigration system, and also to assisting those in need of humanitarian protection against harm.

Based on a comprehensive review of the USCIS planned regulatory agenda, several rulemakings will be promulgated to directly support the aforementioned core priorities as delineated below.

National Security

USCIS has an essential role in supporting DHS's Strategic Goal to ensure the security and integrity of the immigration system by making certain that immigrants and nonimmigrants comply with the laws and security mandates to prevent those who seek to exploit our immigration benefits or engage in illegal activities from obtaining lawful status in this country. To further our national security objectives, USCIS is pursuing regulatory initiatives that will disallow the granting of immigration benefits while an applicant has an ongoing investigation. These regulatory initiatives include the following:

USCIS plans to issue a rule, "Special Immigrant and Nonimmigrant Religious Workers," proposing to amend its regulations regarding the special immigrant and nonimmigrant religious worker visa classifications. This rule addresses concerns about the integrity of the religious worker program by proposing a petition requirement for religious organizations seeking to classify an alien as an immigrant or nonimmigrant religious worker. This rule also proposes including an on-site inspection for religious organizations to ensure the legitimacy of petitioner organizations and employment offers made by such organizations. USCIS is proposing to establish a fee, in addition to the standard fee required for special immigrant or nonimmigrant visa petitions, to cover the cost of the on-site inspections.

This rule also would clarify several substantive and procedural issues that have arisen since the religious worker category was created. This rule proposes new definitions that describe more clearly the regulatory requirements, as well as add specific evidentiary requirements for petitioning employers and prospective religious workers.

USCIS also is issuing an interim rule "Withholding of Adjudication of Petitions and Applications for Immigration and Naturalization Benefits (Abeyance)," to amend USCIS regulations to allow the adjudication of a petition or application to be withheld until any pending investigations or

required background and security checks are completed and resolved to the satisfaction of the Secretary of Homeland Security or his delegate. The rule also modifies the regulations governing the adjudication of naturalization applications to ensure that background and security checks are completed before an alien may be naturalized.

Customer Service

USCIS strives to provide efficient, courteous, accurate and responsive services to those who seek and qualify for admission into our country as well as providing seamless, transparent and dedicated customer support services within the agency. To improve our customer service goals, USCIS is pursuing regulatory initiatives that will make immigration procedures consistent with new laws, improve interpretive services, standardize adjudication and filing procedures, and modernize application processing to facilitate effective data collection and reporting.

These regulatory initiatives include:

USCIS final rule "Removal of the Standardized Request for Evidence Processing Timeframe," which amends USCIS regulations to allow USCIS to set flexible times for requesting evidence based on the types and complexity of applications or petitions. This rule will remove the absolute requirement for, and the fixed regulatory time limitations on responses to, requests for evidence and notices of intent to deny. These changes will enable USCIS to set an appropriate deadline for responding to a request for evidence (RFE) or notice of intent to deny (NOID), specific to the type of case, benefit category, or classification, and thus improve the process of adjudication of applications and petitions by reducing the time a case is held awaiting evidence, and by reducing average case processing time. This rule will result in improved efficiency in the USCIS adjudication process.

USCIS also plans to issue a rule, "Implementation of Amendments Affecting Petitions for Employment Creation Aliens EB-5," to amend its regulations to implement changes made by the 21st Century Department of Justice Appropriations Authorization Act of 2001 (the Act). This legislation made various changes to the EB-5 Alien Entrepreneur immigrant classification.

The "New 'U' Nonimmigrant Classification for Victims of Certain Criminal Activity" rule will implement provisions of the Victims of Trafficking

and Violence Protection Act of 2000 and other related legislation. It will establish procedures for application and issuance of U nonimmigrant status for victims of certain statutorily enumerated crimes. Similarly, the "Adjustment of Status to Lawful Permanent Resident for Aliens in T and U Nonimmigrant Status" rule will implement provisions created by the Victims of Trafficking and Violence Protection Act of 2000 (VTVPA) that allow for the adjustment of status to lawful permanent resident for aliens who have completed three years in lawful T or U nonimmigrant status.

USCIS also plans to initiate a rulemaking action, "Petition to Classify Alien as Immediate Relative of a U.S. Citizen or as a Preference Immigrant; Self-Petitioning for Certain Battered or Abused Alien Spouses and Children," to implement provisions of the Battered Immigrant Women Protection Act of 2000 and the Violence Against Women and Department of Justice Reauthorization Act of 2005. Those provisions amend the Immigration and Naturalization Act provisions that allow battered spouses, children and parents of U.S. citizens and lawful permanent residents to petition for immigrant classification without the assistance or consent of the abuser.

USCIS also is restructuring its entire business processes to implement new procedures for the filing, processing, and adjudication of all benefit applications and petitions. USCIS is moving toward complete electronic filing and adjudication of benefits to streamline processing, modernize adjudications, and facilitate efficient and effective data collection and reporting.

USCIS will be issuing a rulemaking action "New Electronic Account, Adjudication, and Reporting System; New Procedures for Filing and Processing of Fiscal Year 2007 H-1B Petitions Subject to Annual Cap" as part of this business restructuring process.

Overall Excellence

USCIS seeks to optimize mission performance by consolidating and integrating roles and responsibilities, and creating better operating processes and procedures while using the latest technology. To achieve these goals, USCIS is pursuing regulatory initiatives that will adjust fees for certain applications in order to guarantee sufficient funding to process incoming applications/petitions and provide biometric services while ensuring national security, enhancing customer

service, and maintaining standard processing times.

The proposed rule "Adjustment of the Immigration Benefit Application / Petition and Biometric Fee Schedule" proposes to adjust the immigration benefit application and petition fees of the Immigration Examinations Fee Account (IEFA), and the biometric fee for applicants/petitioners who apply for certain immigration benefits for the fiscal year FY 2008 and FY 2009 biennial period. Fees collected from persons filing these benefits are deposited into the IEFA and used to fund the full cost of processing immigration benefit applications/petitions, biometric services, associated support services, and the cost of providing similar services to asylum and refugee applicants and other immigrants, at no charge.

"Adjustment of the Premium Processing Fee for Inflation" proposes to adjust the premium processing fee for employment-based petitions and applications according to the Consumer Price Index (CPI). USCIS uses this fee to provide certain premium-processing services to business customers, and to make infrastructure improvements in the adjudications and customer-service processes.

USCIS also plans to issue a rule, "Adding a Filing Fee for Re-registration and Extension of Temporary Protected Status," proposing to require each TPS initial registrant, re-registrant, or applicant for extension of temporary treatment benefits to submit a filing fee or a fee waiver request with their Form I-821, Application for Temporary Protected Status.

Customs and Border Protection

Under section 403(1) of the Homeland Security Act (HSA), the former U.S. Customs Service, including functions of the Secretary of the Treasury relating thereto, transferred to the Secretary of Homeland Security. As part of the initial organization of DHS, 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 also is 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 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 rule, "Passenger Manifests for Commercial Aircraft Arriving in and Departing from the United States," proposing to require transmission of manifest information for arriving and departing passengers and for departing vessel passengers and crewmembers at an earlier point in time than is now required. This proposed regulation is consistent with the legislative mandate of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA) to perform vetting of passenger or crew information prior to the departure of an aircraft or vessel. In addition, submission of this manifest information at an earlier point in time to CBP is a necessary component of the nation's continuing program of ensuring aviation and vessel safety and protecting national security. The new requirement also would assist in the efficient inspection and control of passengers

and crewmembers and would facilitate the effective enforcement of the customs, immigration and transportation security laws. CBP plans to issue the final rule in fiscal year 2007.

Also during fiscal year 2007, CBP plans to enhance homeland security further by issuing the following regulatory actions:

CBP is working with the State Department on a joint rulemaking initiative ("Documents Required for Travel in the Western Hemisphere") under section 7209 of the IRTPA, as amended by section 546 of the Department of Homeland Security Appropriations Act of 2007, which provides that travelers (including U.S. citizens) may enter the United States only with passports or such alternatives as the Secretary of Homeland Security may designate as satisfactorily establishing identity and citizenship. In the future, as a result of the implementation of the statute, as amended, travel to the United States by United States citizens and others from Western Hemisphere countries, including Canada and Mexico, will require a passport or acceptable alternative documents in circumstances where travel was previously permitted without such documents. DHS and the State Department jointly issued an advance notice of proposed rulemaking on September 1, 2005, to announce the travel initiative and to solicit public comments on the implementation of these requirements. On August 11, 2006, DHS and the State Department published a joint notice of proposed rulemaking announcing proposed travel document requirements for air and sea travel. CBP anticipates issuing a final rule for air travel in early fiscal year 2007 and a separate rulemaking action to implement the travel document requirements at sea and land border ports of entry throughout the fiscal year.

All the rules discussed above 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 2007, 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.

Immigration and Customs Enforcement

The mission of the Bureau of Immigration and Customs Enforcement (ICE) 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.

During fiscal year 2007, ICE will be pursuing rulemaking actions to implement major components of the President's and Department's strategic goals. ICE will continue to promulgate regulations as necessary to improve control of the reporting requirements 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 regulatory amendments to the Student Exchange Visitor Information System (SEVIS) and Student Exchange Visitor Program (SEVP). These actions will foster the Department's strategic goals of awareness and prevention.

In an effort to facilitate ICE's ability to carry out its legal obligation to remove aliens who have been issued a final order of removal, ICE is working to promulgate a joint final rule with the Department of Justice establishing that aliens who are not already in ICE custody at the time they become subject to a final order of removal, deportation or exclusion, have an affirmative obligation to surrender themselves to ICE after an order of removal becomes final. The rule limits the exercise of discretion in the consideration of applications for discretionary forms of relief within the authority of the Secretary of Homeland Security and the Attorney General with respect to aliens who have failed to surrender to ICE as required by the rule. This regulatory initiative promotes the Department's strategic goals of awareness and prevention.

In an effort to provide guidance to employers on employing legally authorized workers, ICE also will promulgate a final rule to reconcile millions of earnings reports (W-2 Forms) in which the name and social security number (SSN) of the employee do not match Social Security Administration (SSA) records. In some of these cases, SSA sends a letter that informs the employer of this fact. The letter is commonly referred to as a "no-match letter." There are many causes for such a no-match, but one common cause is

that the employee is an alien who is not authorized to work in the United States and is using a SSN that is false or was assigned to someone else. In addition to the SSA "no-match letters," ICE sends similar letters after it has inspected an employer's I-9 Forms and unsuccessfully attempted to confirm, in agency records, that an immigration status document or employment authorization document presented or referenced by an employee was assigned to that person. The amended rule will clarify whether an employer will be found to have constructive knowledge of the false SSN. This regulatory initiative promotes the Department's Secure Border Initiative.

Transportation Security Administration

The Transportation Security Administration's (TSA's) mission is to protect the nation's transportation systems by ensuring the freedom of movement for people and commerce. 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, which enable us to perform our daily activities while ultimately preparing us for the future.

In fiscal year 2007, TSA will promote DHS' Strategic Goals of awareness, prevention, protection, response, and service by emphasizing regulatory efforts that allow TSA to better identify, detect, and protect against threats to the domestic transportation system, while facilitating the efficient movement of transportation workers, cargo, and the traveling public.

In furtherance of this goal, TSA and the U.S. Coast Guard will issue a joint Final Rule to begin implementation of the Transportation Worker Identification Credential (TWIC) program, which will allow TSA to perform security threat assessments and issue biometric credentials to individuals requiring unescorted access to secure areas of maritime transportation facilities and vessels. The objective of the TWIC program is to reduce the threat of terrorism by preventing unauthorized persons from gaining access to secure areas.

In addition, TSA plans to issue a Notice of Proposed Rulemaking (NPRM) that would propose security requirements for rail transportation. This rulemaking would enhance security in the rail transportation mode by proposing requirements on freight and passenger railroads and on facilities with rail connections that ship certain hazardous materials. The rulemaking

would augment regulations issued by the Department of Transportation.

TSA will also continue testing and begin implementation of the Secure Flight program, in accordance with Sec. 4012(a)(1) of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA) (Pub. L. 108-458, 118 Stat. 3638, 3714, Dec. 17, 2004). Through rulemaking, TSA will begin to assume from aircraft operators the function of comparing passenger information to the consolidated and integrated watch list maintained by the Federal Government.

In addition, TSA will continue to facilitate the development of the Registered Traveler (RT) program through a new pilot program and rulemaking to establish the final program. The Registered Traveler program is expected to afford expedited security screening for passengers who have voluntarily submitted background information and biometric data, such as fingerprints or an iris scan, and have successfully undergone a security threat assessment. Major components of the RT program will be implemented by the private sector in accordance with TSA-issued standards. TSA will conduct the security threat assessments on individuals who wish to become RT members. In the next fiscal year, TSA plans to issue an NPRM proposing the program's process and eligibility requirements.

TSA will also propose to amend the current aviation security rules applicable to foreign air carriers to make them more consistent with the rules applicable to domestic air carriers and to add a new 49 CFR part 1554 regulation to improve the security of domestic and foreign aircraft repair stations, as required by Sec. 611(b)(1) of Vision 100 Century of Aviation Reauthorization Act (Pub. L. 108-176, 117 Stat. 2490, 2571, Dec. 12, 2003).

DHS Regulatory Plan for Fiscal Year 2007

A more detailed description of the priority regulations that comprise DHS' Fall 2006 Regulatory Plan follows.

DHS—Office of the Secretary (OS)

PROPOSED RULE STAGE

49. • MINIMUM STANDARDS FOR DRIVER'S LICENSES AND IDENTIFICATION CARDS ACCEPTABLE TO FEDERAL AGENCIES FOR OFFICIAL PURPOSES

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

Division B—REAL ID Act of 2005; The Emergency Supplemental Appropriations Act for Defense; The Global War on Terror and Tsunami Relief, 2005; PL 109–13, 119 Stat 231, 302 (May 11, 2005) (codified at 49 USC 30301 note)

CFR Citation:

6 CFR 37, et seq (New)

Legal Deadline:

Final, Statutory, May 11, 2008.

Abstract:

This regulation is designed to implement the REAL ID ACT. The Act prohibits Federal agencies from accepting a driver's license or personal identification card (license) for an "official purpose" unless it has been issued by a State that has certified to, and been determined by DHS to meet, the requirements of the Act. The Act sets forth minimum document requirements, minimum issuance standards, and other requirements, including: information and security features that must be incorporated into each card; the information that must be provided by an applicant to establish identity and immigration status before a card can be issued; physical security standards for locations where licenses are produced.

Statement of Need:

DHS will be initiating a rulemaking action to establish minimum standards for State-issued driver's licenses and identification cards that Federal agencies would accept for official purposes as required under the REAL ID Act of 2005. The REAL ID Act prohibits Federal agencies, effective May 18, 2008, from accepting a driver's license or personal identification card (license) for an "official purpose"

unless it has been issued by a State that has certified to, and been determined by DHS to meet, the requirements of the Act. The Act sets forth minimum document requirements, minimum issuance standards, and other requirements, including the following—

- Information and features that must appear on the face of the license, and inclusion of a common machine readable portion of a driver's license or identification card;
- Presentation and verification of information an applicant must provide before a license may be issued, including evidence that the applicant is a U.S. citizen or has lawful status in the United States;
- Physical security of locations where licenses are produced, the security of document materials and papers from which licenses are produced, and the background check of certain employees involved in the manufacture and production of licenses and;
- Physical security of the licenses to prevent tampering, counterfeiting, and duplication of the documents for a fraudulent purpose.

DHS is issuing this rule in consultation with the Department of Transportation, other representatives of the Federal government, and representatives from many States, as required under the Act.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Federal, Local, State

Federalism:

Undetermined

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DHS—OS

FINAL RULE STAGE

50. UNITED STATES VISITOR AND IMMIGRANT STATUS INDICATOR TECHNOLOGY PROGRAM (US-VISIT), ENROLLMENT OF ADDITIONAL ALIENS IN US-VISIT

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

PL 106–215, sec 2(a), 114 Stat 337 (June 15, 2000); PL 106–396, sec 205, 114 Stat 1637, 1641 (October 30, 2000); PL 107–56, sec 114, 115 Stat 271, 553 (October 26, 2001); PL 107–173, sec 302, 116 Stat 543, 552 (May 14, 2002)

CFR Citation:

8 CFR 215.8; 8 CFR 235.1

Legal Deadline:

None

Abstract:

In 2003, the Department of Homeland Security established the United States Visitor and Immigrant Status Technology Program (US-VISIT), whose objective is to create and maintain an integrated, automated entry-exit system that records the arrival and departure of aliens, verifies their identities, and authenticates their travel documents through comparison of biometric identifiers. The goals of the US-VISIT program are to enhance the security of United States citizens and visitors to the United States, facilitate legitimate travel and trade, ensure the integrity of the United States immigration system, and protect the privacy of visitors to the United States. In its early stages, US-VISIT applied only to nonimmigrants with visas and to those who did not require a visa as they were entering under the Visa Waiver Program. This rule would amend DHS regulations to provide that all aliens, including lawful Permanent Residents, may be enrolled into US-VISIT, with very few exceptions, such as diplomats and Canadian visitors.

Statement of Need:

On July 27, 2006, DHS published a proposed rule in the Federal Register that outlined DHS' plan to begin enrolling additional groups of aliens into the US-VISIT biometric screening protocol. (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 the comparison of biometric identifiers.) The expansion of US-VISIT biometric screening to these additional groups is needed in order to verify the identity and authenticity of aliens presenting United States issued travel documents upon an application for admission. The expansion is consistent with the implementation of the US-VISIT program to date, which has taken an incremental, phased-in approach to the biometric screening of aliens applying for admission to and exiting from the United States. This expansion will encompass the majority of aliens to-date not undergoing biometric screening by the US-VISIT program, with the exception of Canadian citizens entering the United States as either B-1 visitors for business or B-2 visitors for pleasure.

Summary of Legal Basis:

While the establishment of the US-VISIT program is found in the provisions of several public laws, the abstracts of which have been discussed in several rulemakings (See 69 FR 53318, for example) the authority for the expansion of the program to additional alien groups may be found in section 302(b)(2) of the Enhanced Border Security and Visa Entry Reform Act of 2002, Public Law 107-173, 116 Stat. 543, 552 (May 14, 2002). This section of law requires the United States to install at all ports of entry equipment and software that allows for the biometric comparison and authentication of all United States visas and all machine-readable, tamper-resistant travel and entry documents that are issued to aliens. The installation of the needed equipment and software is complete.

Timetable:

Action	Date	FR Cite
Proposed Rule	07/27/06	71 FR 42605
Comment Period End	08/28/06	
Final Rule	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Transferred from RIN 1650-AA06.

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RIN: 1601-AA35

DHS—OS

51. • CHEMICAL SECURITY ANTI-TERRORISM STANDARDS

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

Section 550 of the Homeland Security Appropriations Act of 2007, Pub. L. No. 109-295, § 550 (Oct. 4, 2006)

CFR Citation:

6 CFR 27

Legal Deadline:

Other, Statutory, April 4, 2007, Section 550 of the Homeland Security Appropriations Act of 2005.

Section 550 of the Homeland Security Appropriations Act of 2005 directs DHS to issue interim rules no later than 6 months after the effective date of the Act. The Act became effective on October 4, 2006 and so the statutory deadline for issuance of the interim rules under this provision is April 4, 2007.

Abstract:

Section 550 of the Homeland Security Appropriations Act of 2007 provided the Department of Homeland Security with authority to promulgate "interim final regulations" for the security of certain chemical facilities in the United States. See Pub. L. No. 109-295, § 550 (Oct. 4, 2006). In accordance with section 550, these regulations will establish risk-based performance standards and require vulnerability assessments and the development and implementation of site security plans. DHS currently plans to issue an advanced notice of rulemaking seeking comment both on practical and policy issues integral to the development of a chemical facility security program. The interim rule will follow.

Statement of Need:

Voluntary security programs have resulted in significant capital investments and implementation of responsible security measures by many companies in the chemical industry. The Secretary of Homeland Security, however, has concluded that voluntary efforts alone cannot provide sufficient security for the chemical sector.

Summary of Legal Basis:

This interim rule implements the requirements of section 550 of the Homeland Security Appropriation Act of 2007.

Anticipated Cost and Benefits:

The Department is developing a cost benefit analysis that will be published with the interim rules.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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DHS—U.S. Citizenship and Immigration Services (USCIS)

PROPOSED RULE STAGE

52. SPECIAL IMMIGRANT AND NONIMMIGRANT RELIGIOUS WORKERS

Priority:

Other Significant

Legal Authority:

8 USC 1101; 8 USC 1103; 8 USC 1151; 8 USC 1153; 8 USC 1154; 8 USC 1182; 8 USC 1186a; 8 USC 1255; 8 CFR 2

CFR Citation:

8 CFR 204

Legal Deadline:

None

Abstract:

This rule proposes to amend U.S. Citizenship and Immigration Services (USCIS) regulations regarding the special immigrant and nonimmigrant religious worker visa classifications. This rule addresses concerns about the integrity of the religious worker program by proposing a petition requirement for religious organizations seeking to classify an alien as an immigrant or nonimmigrant religious worker. This rule also proposes including an on-site inspection for religious organizations to ensure the legitimacy of petitioner organizations and employment offers made by such organizations. USCIS is proposing to establish a fee, in addition to the standard fee required for special immigrant or nonimmigrant visa petitions, to cover the cost of the on-site inspections.

This rule would also clarify several substantive and procedural issues that have arisen since the religious worker category was created. This rule proposes new definitions that describe more clearly the regulatory requirements, as well as add specific evidentiary requirements for petitioning employers and prospective religious workers.

Finally, this rule also proposes to amend how USCIS regulations reference the sunset date, the statutory deadline by which special immigrant religious workers, other than ministers, must immigrate or adjust status to permanent residence, so that regular updates to the regulations are not required each time Congress extends the sunset date.

Statement of Need:

This rule is needed to implement the recommendations contained in the GAO report Issues Concerning the Religious Worker Visa Program, Report GAO/NSIAD-99-67 (March 26, 1999). Finally, USCIS wishes to make the nonimmigrant religious worker regulations consistent with the rules governing the immigrant religious worker category to the extent possible, and this rule is necessary to achieve that objective.

The changes proposed in this rule, if implemented, would decrease the opportunity for fraud in the religious worker program. Moreover, this rulemaking will further enhance the Department's efforts in deterring fraud and domestic security.

Summary of Legal Basis:

While this action revises the regulations to reflect Congressional extension of this program, this action is not required in order to give effect to that extension.

Alternatives:

None because the Department has agreed to implement the recommendations contained in the aforementioned GAO report. Also the risk section below provides further reasons why there are no alternatives.

Anticipated Cost and Benefits:

A detailed cost benefit analysis will be included in the regulatory analysis in the proposed rule.

Risks:

Failure to promulgate this rule change leaves the religious worker program vulnerable to fraud and compromises DHS and USCIS national security goals.

Timetable:

Action	Date	FR Cite
NPRM (CIS No. 1436-94)	01/00/07	
NPRM Comment Period End	03/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

CIS No. 1436-94

Transferred from RIN 1115-AF12

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RIN: 1615-AA16

DHS—USCIS**FINAL RULE STAGE****53. ADJUSTMENT OF STATUS TO LAWFUL PERMANENT RESIDENT FOR ALIENS IN T AND U NONIMMIGRANT STATUS****Priority:**

Other Significant

Legal Authority:

5 USC 552; 5 USC 552a; 8 USC 1101 to 1104; 8 USC 1182; 8 USC 1184; 8 USC 1187; 8 USC 1201; 8 USC 1224; 8 USC 1225; 8 USC 1226; 8 USC 1227; 8 USC 1252; 8 USC 1252a; 8 USC 1255; 22 USC 7101; 22 USC 7105; ...

CFR Citation:

8 CFR 204; 8 CFR 214; 8 CFR 245

Legal Deadline:

Other, Statutory, January 5, 2006, Regulations need to be promulgated by July 5, 2006.

Abstract:

This rule sets forth measures by which certain victims of severe forms of trafficking who have been granted T nonimmigrant status and victims of certain criminal activity who have been granted U nonimmigrant status may apply for adjustment to permanent resident status in accordance with Public Law 106-386, Victims of Trafficking and Violence Protection Act of 2000, and Public Law 109-162, Violence Against Women and Department of Justice Reauthorization Act of 2005.

Statement of Need:

This rule is necessary to establish how an eligible alien with T nonimmigrant status can adjust his or her status to that of lawful permanent resident. Those with T nonimmigrant status are eligible to be granted lawful permanent residency if they can demonstrate they have complied with any reasonable request for assistance in the investigation or prosecution of acts of trafficking or that they will face extreme hardship involving unusual and severe harm if they were removed from the United States.

Summary of Legal Basis:

Public Law 106-386, Victims of Trafficking and Violence Protection Act of 2000.

Alternatives:

None.

Anticipated Cost and Benefits:

While there is no precise formula for determining anticipated costs, there will be additional costs for adjudicating applications and investigating cases deemed fraudulent. There may be applications that will not be approved for a variety of reasons, including failure to meet basic adjustment of status requirements. All applications will be reviewed and some will require extensive investigation both here and abroad to determine whether the applicant has complied with any reasonable request for assistance in the investigation and prosecution of the acts of trafficking.

The anticipated benefits of these expenditures include: Continued assistance to trafficked victims and their families, increased investigation and prosecution of traffickers in persons, and the elimination of abuses caused by trafficking activities.

Benefits that may be attributed to the implementation of this rule are expected to be:

- an increase in the number of cases brought forward for investigation and/or prosecution;

- heightened awareness of trafficking-in-persons issues by the law enforcement community; and

- enhanced ability to develop and work cases in trafficking in persons cross-organizationally and multi-jurisdictionally which may begin to influence changes in trafficking patterns.

Risks:

Risks associated with the implementation of the congressionally mandated new nonimmigrant classification include:

- increased workload for adjudicators which may impact overall efficiency and productivity; and

- increases in fraudulent applications/claims of such victimization in order to obtain lawful permanent residence.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/00/07	
Interim Final Rule	06/00/07	
Comment Period		
End		

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

CIS No. 2134-01

Transferred from RIN 1115-AG21

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RIN: 1615-AA60

DHS—USCIS

54. NEW CLASSIFICATION FOR VICTIMS OF CERTAIN CRIMINAL ACTIVITY; ELIGIBILITY FOR THE U NONIMMIGRANT STATUS

Priority:

Other Significant

Legal Authority:

5 USC 552; 5 USC 552a; 8 USC 1101; 8 USC 1101 note; 8 USC 1102; ...

CFR Citation:

8 CFR 103; 8 CFR 204; 8 CFR 212; 8 CFR 214; 8 CFR 299

Legal Deadline:

Other, Statutory, January 5, 2006, Regulations need to be promulgated by July 5, 2006.

Public Law 109-162, Violence Against Women and Department of Justice Reauthorization Act of 2005.

Abstract:

This rule sets forth application requirements for a new nonimmigrant status. The U classification is for non-U.S. Citizen/Lawful Permanent Resident victims of certain crimes who cooperate with an investigation or prosecution of those crimes. There is a limit of 10,000 principals per year.

This rule establishes the procedures to be followed in order to petition for the U nonimmigrant classifications. Specifically, the rule addresses: The essential elements that must be demonstrated to receive the nonimmigrant classification; procedures that must be followed to make an application; and evidentiary guidance

to assist in the petitioning process. Eligible victims will be allowed to remain in the United States.

Statement of Need:

This rule is necessary to establish the procedure for an eligible alien to obtain temporary immigration benefits as a victim of certain qualifying criminal activity while providing assistance to law enforcement officials at the Federal, State, and local levels investigating and prosecuting these crimes.

Summary of Legal Basis:

Public Law 106-386, Victims of Trafficking and Violence Protection Act of 2000; Public Law 109-162, Violence Against Women and Department of Justice Reauthorization Act.

Alternatives:

None.

Anticipated Cost and Benefits:

While there is no precise formula for determining anticipated costs, there have been and will be additional costs for adjudicating benefits and investigating claims, particularly those deemed fraudulent. Also, there are training costs for DHS staff. The U nonimmigrant classification allows victims of certain qualifying criminal activity to remain in the United States past the time of their assistance to law enforcement if their presence in the United States is justified on humanitarian grounds, to ensure family unity, or is otherwise in the public interest.

There may be applications that will not be approved for a variety of reasons, including failure to meet the basic U nonimmigrant status eligibility requirements. All applications will be reviewed and some will require investigation to determine whether they are fraudulent.

The anticipated benefits of these expenditures include: Assistance to victims of criminal activity and their families, and an increase in the number of cases brought forward for investigation and prosecution (and possible deportation) of the perpetrators of the criminal activity.

Risks:

Risks associated with the implementation of the congressionally mandated new nonimmigrant classification include:

- increased workload for adjudicators and investigators, which may impact overall efficiency and productivity; and

—increases in fraudulent applications/claims of such victimization in order to obtain U nonimmigrant status.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/00/07	
Interim Final Rule Comment Period End	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

Additional Information:

Transferred from RIN 1115-AG39

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RIN: 1615-AA67

DHS—USCIS

55. REMOVAL OF STANDARDIZED REQUEST FOR EVIDENCE PROCESSING TIMEFRAME

Priority:

Other Significant

Legal Authority:

8 USC 1103

CFR Citation:

8 CFR 103

Legal Deadline:

NPRM, Statutory, September 1, 2003, NPRM Comment Period Ends January 31, 2005.

Abstract:

This rule proposes to amend Department of Homeland Security regulations by removing the absolute requirement for, and the fixed regulatory time limitations on responses to a U.S. Citizenship and Immigration Services issued Request for

Evidence (RFE) or Notice of Intent to Deny (NOID). These changes will enable USCIS to set an appropriate deadline for responding to an RFE or NOID, specific to the type of case, benefit category, or classification, and thus improve the process of adjudication of applications and petitions by reducing the time a case is held awaiting evidence, and by reducing average case processing time. This rule will result in improved efficiency in the USCIS adjudication process.

In addition, this rule includes certain organizational changes necessitated by the implementation of the Homeland Security Act of 2002, Public Law 107-296. This rule also removes obsolete regulatory language related to the Replenishment Agricultural Worker (RAW) program under section 210A of the Immigration and Nationality Act (Act), which was repealed by section 219(ee)(1) of the Immigration and Technical Corrections Act of 1994, Public Law 103-416. The rule further removes references to the use of qualified designated entities for filing of applications for adjustment of status in the Seasonal Agricultural Workers (SAW) and legalization programs under section 210 and 245A of the Act. By including the organizational changes, the rule will also assist the public in understanding the delegation of authority for adjudicating cases.

Statement of Need:

In adjudicating an application or petition for benefits, USCIS often issues a Request for Evidence (RFE). This request may address documentary or evidentiary deficiencies in the case. Under current regulations, there are certain situations in which USCIS must issue an RFE, and in all cases in which an RFE is issued, USCIS must provide a standard 12-week response time. USCIS will replace the current 12-week response period reflected in 8 CFR 103.2(b)(8) with a more flexible approach, setting response periods based on various factors such as the type of benefit sought; the type of application or petition filed; the type of evidence needed for adjudication; the source and availability of documentation (both foreign and domestic); etc. USCIS will remove most provisions that require issuance of an RFE or Notice of Intent to Deny (NOID) in order to allow USCIS greater flexibility in deciding cases based on the information received, including initial evidence and other relevant materials. This rule amends 8 CFR 103.2(b)(8) by removing the mandatory

requirement that USCIS issue an RFE for initial evidence. Instead, USCIS, in its discretion, may deny a petition or application when required initial evidence is missing. If an applicant or petitioner fails to submit the required initial evidence, and USCIS decides to deny the application or petition rather than issue an RFE, the applicant or petitioner may file a motion to reopen, with fee, as provided under 8 CFR 103.5 or file a new application or petition. The applicant or petitioner may also file an appeal of the denial if other regulatory or statutory authority exists for such appeal.

Summary of Legal Basis:

This action is not required by court order or statute.

Alternatives:

The alternative is not promulgating a final rule and maintaining the mandatory 12-week response period. This would further exacerbate the current backlogged adjudication process by impeding timely approval of applications and petitions.

Anticipated Cost and Benefits:

The Department of Homeland Security has assessed both the costs and benefits of this rule as required by Executive Order 12866, section 1(b)(6) and has concluded that there are minimal costs to the Department associated with instructing adjudicators about the options for dealing with inadequate information. There are benefits to both USCIS and the public. USCIS will reduce the number of RFEs and NOIDs and the cycle time for responses to such notices, potentially reducing the pending backlog of cases. The public will receive fewer and more specific RFE or NOID notices and benefit from faster approval of applications and petitions.

Risks:

While there are no major risks associated with not promulgating this rule, the current process of RFE issuance sometimes slows the adjudication process. Some RFEs are simple enough to require resubmission within a few weeks; others may require more time. A fixed, standard response time does not make the most efficient use of adjudicative resources. In addition, there are circumstances in which USCIS is required by regulation to issue an RFE, even though it is apparent from the record that the application or petition must be denied. This forces the USCIS to focus time and

resources on RFEs in cases that are clearly not of merit.

Timetable:

Action	Date	FR Cite
NPRM	11/30/04	69 FR 69549
NPRM Comment Period End	01/31/05	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

CIS No. 2287-03

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RIN: 1615-AB13

DHS—U.S. Coast Guard (USCG)

PROPOSED RULE STAGE

56. VESSEL REQUIREMENTS FOR NOTICES OF ARRIVAL AND DEPARTURE, AND AUTOMATIC IDENTIFICATION SYSTEM (USCG-2005-21869)

Priority:

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

Legal Authority:

33 USC 1223, 1225, 1231; 46 USC 3716, 8502 and Chapter 701; sec 102 of PL 107-295

CFR Citation:

33 CFR 160; 33 CFR 161; 33 CFR 164

Legal Deadline:

None

Abstract:

This rulemaking would expand the applicability for Notice of Arrival and

Departure (NOAD) and Automatic Identification System (AIS) requirements. These expanded requirements would better enable the Coast Guard to correlate vessel AIS data with NOAD data, enhance our ability to identify and track vessels, detect anomalies, improve navigation safety, and heighten our overall maritime domain awareness.

The NOAD portion of this rulemaking would expand the applicability of the NOAD regulations by changing the minimum size of vessels covered below the current 300 gross tons, require that a notice of departure be submitted for all vessels required to submit a notice of arrival, and mandate electronic submission of NOAD notices to the National Vessel Movement Center.

Statement of Need:

We do not have a current mechanism in place to capture vessel, crew, passenger, or specific cargo information on vessels less than or equal to 300 gross tons (GT) intending to arrive at or depart from U.S. ports unless they are arriving with certain dangerous cargo (CDC) or are arriving at a port in the 7th Coast Guard District. The lack of NOA information on this large and diverse population of vessels represents a substantial gap in our maritime domain awareness (MDA). We can minimize this gap and enhance MDA by expanding the applicability of the NOAD regulation beyond vessels greater than 300 GT, cover all foreign commercial vessels and all U.S. commercial vessels coming from a foreign port; and enhance maritime domain awareness by tracking them (and others) with AIS. There is no current Coast Guard requirement for vessels to submit notification of departure information. This information is necessary in order to expand our MDA.

Summary of Legal Basis:

This rulemaking is based on Congressional authority provided in the Ports and Waterways Safety Act and the Maritime Transportation Security Act of 2002.

Alternatives:

Our goal is to increase MDA and to identify anomalies by correlating vessel AIS data with NOAD data. NOAD and AIS information from a greater number of vessels would provide even greater MDA than the proposed rule. We considered expanding NOAD and AIS to even more vessels, but we determined we needed additional legislative authority to expand AIS

beyond what we propose in this rulemaking; and that it was best to combine additional NOAD expansion with future AIS expansion.

Although not in conjunction with a proposed rule, the Coast Guard sought comment regarding expansion of AIS carriage to other waters and other vessels not subject to the current requirements (68 FR 39355-56, and 39370, July 1, 2003; USCG 2003-14878). Those comments were reviewed and considered in drafting this rule and will become part of this docket.

To fulfill our agency obligations, the Coast Guard needs to receive AIS reports and NOADs from vessels identified in this rulemaking that currently are not required to provide this information. Policy or other non-binding statements by the Coast Guard addressed to the owners of these vessels would not produce the information required to sufficiently enhance our MDA to produce the information required to fulfill our Agency obligations.

Anticipated Cost and Benefits:

We expect vessel owners to incur costs from the additional NOA requirements in order to comply with the mandatory requirement of submitting notices by utilizing the Coast Guard's electronic Notice of Arrival and Departure (eNOAD) system.

Currently, vessels greater than 300 gross tons, foreign commercial and recreational vessels less than 300 gross tons entering the 7th Coast Guard District, and all vessels carrying certain dangerous cargoes (CDCs) are required to submit NOAs.

This rulemaking will expand the applicability of NOADs to include all foreign commercial vessels, regardless of tonnage, and all U.S. commercial vessels arriving from a foreign port.

From the Coast Guard's database, we believe that we have an accurate estimate of the number of vessels greater than 300 gross tons submitting NOAs and the approximate number of voyages they make. These vessels are currently required to submit NOAs and will be required to submit NOAs/NODs through a mandatory submission method. Approximately 20,000 vessels greater than 300 gross tons, with foreign vessels comprising nearly 17,000 of this amount, and U.S. vessels comprising the balance, are currently affected. We, however cannot at this time provide an estimate of the number of vessels less than 300 gross tons that will be affected by this rulemaking or

the number of U.S. vessels coming from a foreign port since these vessels are not required to report nor do we have an effective means to capture this information. We will determine the affected population and include that information in the detailed regulatory analysis.

We anticipate unquantified benefits will be associated with both portions of this rulemaking. We anticipate that quantified benefits derived from marine casualty cases will be associated with the AIS portion of this rulemaking. A detailed benefit analysis will be included in the regulatory analysis.

Risks:

Considering the economic utility of U.S. ports, waterways, and coastal approaches, it is clear that a terrorist incident against our U.S. Maritime Transportation System (MTS) would have a disastrous impact on global shipping, international trade, and the world economy. By improving the ability of the Coast Guard both to identify potential terrorists coming to the United States while their vessel is far at sea and to coordinate appropriate responses and intercepts before the vessel reaches a U.S. port, this rulemaking would contribute significantly to the expansion of MDA, and consequently is instrumental in addressing the threat posed by terrorist actions against the MTS.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

With regard to the legal deadline, we have indicated in past notices and rulemaking documents, and it remains the case, that we have worked to coordinate implementation of AIS MTSA requirements with the development of our ability to take advantage of AIS data (68 FR 39355-56 and 39370, July 1, 2003).

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RIN: 1625-AA99

DHS—Bureau of Customs and Border Protection (BCBP)

FINAL RULE STAGE

57. PASSENGER MANIFEST FOR COMMERCIAL AIRCRAFT ARRIVING IN AND DEPARTING FROM THE UNITED STATES; PASSENGERS AND CREW MANIFESTS FOR COMMERCIAL VESSELS DEPARTING FROM THE UNITED STATES

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

5 USC 301; 19 USC 58b; 19 USC 66; 19 USC 1431; 19 USC 1433; 19 USC 1434; 19 USC 1436; 19 USC 1448; 19 USC 1459; 19 USC 1590; 19 USC 1594; 19 USC 1623; 19 USC 1624; 19 USC 1644; 19 USC 1644a; 19 USC 2071 note; 46 USC app 3; 46 USC 91; ...

CFR Citation:

19 CFR 4; 19 CFR 122

Legal Deadline:

None

Abstract:

Amendment of parts 4 and 122 of the Customs and Border Protection regulations to require the electronic transmission of manifest information relating to passengers on arriving and departing aircraft and for passengers

and crew on departing vessels prior to the departure of the vessels or aircraft.

Statement of Need:

Current Advance Passenger Information System (APIS) regulations require air carriers to electronically transmit passenger arrival manifests to Customs and Border Protection (CBP) no later than 15 minutes after the departure of the aircraft from any place outside the United States and passenger departure manifests no later than 15 minutes prior to departure of the aircraft from the United States. Manifests for crew members on passenger and all-cargo flights and non-crew members on all-cargo flights must be electronically transmitted to CBP no later than 60 minutes prior to the departure of any covered flight to, continuing within, or overflying the United States (19 CFR 122.49b(b)(2)) and no later than 60 minutes prior to the departure of any covered flight from the United States. The current regulations require vessel carriers to electronically transmit arrival passenger and crew member manifests at least 24 hours and up to 96 hours prior to the vessel's entry at a U.S. port or place of destination, depending on the length of the voyage. Also, a vessel carrier must electronically transmit passenger and crew member departure manifests to CBP no later than 15 minutes prior to the vessel's departure from the United States. These regulations serve to provide the nation, the carrier industries, and the international traveling public, additional security from the threat of terrorism and enhance CBP's ability to carry out its border enforcement mission.

The Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA) requires DHS to issue regulations and procedures to allow for pre-departure vetting of passengers onboard aircraft arriving in and departing from the United States and of passengers and crew onboard vessels arriving in and departing from the United States. This rulemaking is designed to implement these important IRTPA requirements and to further enhance national security and the security of the air and vessel travel industries in accordance with the Aviation and Transportation Security Act (ATSA) and Enhanced Border Security and Visa Entry Reform Act of 2002 (EBSA), both of which formed the statutory basis for the APIS regulations.

This proposed rule would require transmission of, as appropriate, passenger and/or crew member

information early enough in the process to prevent a high-risk passenger from boarding an aircraft and to prevent the departure of a vessel with such a passenger or crew member onboard. CBP's purpose in proposing this change is to place itself in a better position to: (1) Fully vet passenger and crew member information with sufficient time to effectively secure the aircraft or vessel, including time to coordinate with carrier personnel and domestic or foreign government authorities in order to take appropriate action warranted by the threat; (2) identify high-risk passengers and prevent them from boarding aircraft bound for or departing from the United States; and (3) identify high-risk passengers and crew members to prevent the departure of vessels from the United States with a high-risk passenger or crew member onboard. Achieving these goals would permit CBP to more effectively prevent an identified high-risk traveler from becoming a threat to passengers, crew, aircraft, vessels, or the public and would ensure that the electronic data transmission and screening process required under CBP regulations comports with the purposes of ATSA, EBSA, and IRTPA.

Summary of Legal Basis:

The APIS program is based on Congressional authority provided in the Aviation and Transportation Security Act (ATSA) and Enhanced Border Security and Visa Entry Reform Act of 2002 (EBSA). The amendments made by this rulemaking are based on Congressional authority provided in the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA).

Alternatives:

CBP considered a number of regulatory alternatives to the proposed rule.

(1) Do not promulgate any further manifest transmission requirements (No Action)—the baseline case where carriers would continue to submit APIS manifests for arriving aircraft passengers 15 minutes after departure and, for departing aircraft passengers, 15 minutes prior to departure. This alternative is inconsistent with the protective security objectives of ATSA, EBSA, and IRTPA.

(2) A pre-departure transmission requirement—this would require carriers to submit manifests earlier than is required under the status quo requirements for flights to and from the United States. Transmission of manifest information would be made at least 30 minutes prior to departure. For large

carriers, this alternative would not provide enough of a window for CBP to respond to a hit on the watch lists.

(3) A 60-minute transmission requirement only during periods of heightened threat conditions—this rule would require carriers to submit manifest data 60 minutes prior to departure only during periods of heightened threat conditions. This alternative would probably cause a great deal of disruption due to the unanticipated need to provide information earlier at irregular intervals. Additionally, the threat of terrorism is continuous, and specific threat information on flights may not emerge. Thus, the risks would not likely be diminished sufficiently to justify the costs. Finally, an alternating system of manifest transmission timing would likely affect carrier performance, with performance ratings suffering during the infrequent, non-routine elevations in threat level, the more critical period.

(4) A 120-minute transmission requirement—this rule would require carriers to submit manifests 120 minutes prior to departure. The costs would be higher than under the proposed rule because originating passengers, not just connecting passengers, would now be affected. High-risk passengers would be prevented from boarding aircraft. CBP would be able to more easily coordinate and plan a response to a hit on the watch lists well before the boarding process began. This alternative would be quite disruptive because even though passengers and carriers would have the predictability of a pre-determined transmission time, passenger check-in at the original departure airport would be greatly affected.

Anticipated Cost and Benefits:

We expect that air carriers and air passengers will be the parties primarily affected by the proposed rule. For APIS 60, costs will be driven by the number of air travelers that will need to arrive at their originating airports earlier and the number of air travelers who miss connecting flights and require rerouting as a result. For APIS Quick Query (AQQ), costs will be driven by implementation expenses, data transmission costs, and a small number of air travelers who miss connecting flights. For the high end of the range (i.e., under the APIS 60 procedure), CBP anticipates that passengers will provide APIS data upon check-in for their flights and that all carriers will

transmit that data, as an entire passenger and crew manifest, to CBP at least 60 minutes prior to departure of the aircraft. CBP estimates that this will result in 2 percent of passengers on large carriers and 0.25 percent of passengers on small carriers missing connecting flights and needing to be rerouted, with an average delay of 4 hours. Additionally, we estimate that 15 percent of passengers will need to arrive at the airport an average of 15 minutes earlier in order to make their flights. For the low end of the range (under the AQQ procedure), we assume that all large air carriers will implement AQQ to transmit information on individual passengers as each checks in. CBP estimates that this will significantly drive down even further the percentage of passengers requiring rerouting on large carriers to 0.5 percent. Travelers will not need to modify their behavior to arrive at the airport earlier. The percentage on small carriers remains 0.25 percent because we assume that small carriers will not implement AQQ; rather, they will continue to submit manifests at least 60 minutes prior to departure through eAPIS, CBP's web-based application for small carriers. Thus, costs for small air carriers are the same regardless of the regulatory option considered. The present value (PV) costs of the rulemaking are estimated to range from \$612 million to \$1.9 billion over the next 10 years (2006-2015, 2005 dollars, 7 percent discount rate).

We estimate four categories of benefits, or costs that could be avoided, under the APIS 60 procedure: (1) Costs for conducting interviews with identified high-risk individuals upon arrival in the United States; (2) costs for deporting a percentage of these individuals; (3) costs of delaying a high-risk aircraft at an airport; and (4) costs of rerouting aircraft if high-risk individuals are identified after takeoff. Monetizing the benefits of avoiding an actual terrorist incident has proven difficult because the damages caused by terrorism are a function of where the attack takes place, the nature of the attack, the number of people affected, the casualty rates, the psychological impacts of the attack, and, perhaps most importantly, the "ripple effects" as damages permeate throughout our society and economy far beyond the initial target. The average recurring benefits of the proposed rule are an estimated \$15 million per year. This is in addition to the non-quantified security benefits, which are the primary impetus for this rule. Over the 10-year period of analysis, PV benefits are an

estimated \$105 million at a 7 percent discount rate (\$128 million at a 3 percent discount rate). Given the quantified costs and benefits of the proposed rule, we can determine how much non-quantified security benefits would have to be for this rule to be cost-beneficial. The 10-year costs range from \$612 million to \$1.9 billion, and the benefits are an estimated \$103 million (all at the 7 percent discount rate). Thus, the non-quantified security benefits would have to be \$509 million to \$1.8 billion over the 10-year period in order for this proposed rule to be cost-beneficial. In one hypothetical security scenario involving only one aircraft and the people aboard, estimated costs of an incident could exceed \$790 million. This rule may not prevent such an incident, but if it did, the value of preventing such a limited incident would outweigh the costs at the low end of the range.

Risks:

Promulgation of this rule would increase CBP’s ability to effectively prevent an identified high-risk traveler from becoming a threat to passengers, crew, aircraft, vessels, or the public. Failure to do so would compromise DHS and CBP’s national security goals by not providing CBP with a valuable tool in securing the international transportation system.

Timetable:

Action	Date	FR Cite
NPRM	07/14/06	71 FR 40035
NPRM Comment Period End	08/14/06	
Other/NPRM Comment Period Extended	08/02/06	71 FR 43681
NPRM Comment Period End	10/12/06	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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Related RIN: Related to 1651-AA37

RIN: 1651-AA62
BILLING CODE 4410-10-S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The Department of Housing and Urban Development (HUD), as the nation's housing agency, is committed to increasing homeownership, particularly among minorities; creating affordable housing opportunities for low-income Americans; and supporting the homeless, elderly, people with disabilities, and people living with AIDS. HUD is also committed to promoting economic and community development, and enforcing the nation's fair housing laws.

Each year, through its programs and initiatives, HUD enables millions of individuals and families, including increasing numbers of minorities, to become homeowners or to obtain safe, decent, and affordable rental housing. HUD helps communities improve economic conditions and infrastructure in distressed areas, thereby making these communities more livable. HUD increases public awareness of fair housing laws, and it is through this awareness, coupled with enforcement of fair housing laws, that HUD reduces incidents of housing discrimination. Each year, HUD also continues to strengthen its partnerships with other federal agencies, state and local governments, and private sector organizations, including for-profit, nonprofit, faith-based, and community-based organizations. These partnerships help HUD advance its mission to increase homeownership, support community development, and increase access to affordable housing free from discrimination.

HUD's three programmatic strategic goals, embodied in HUD's mission statement — increasing homeownership, promoting access to decent affordable housing, and strengthening communities, form the foundation each fiscal year for the majority of HUD's proposals for new or revised regulatory programs and initiatives, and that is true for Fiscal Year (FY) 2007.

The regulatory plan for HUD for FY 2007 highlights certain significant regulatory policy proposals that are designed to advance HUD's mission.

Priority: Increasing Homeownership

Opening doors to homeownership has been a core aspect of HUD's mission stemming from the 1930s, when Congress created the Federal Housing Administration (FHA). HUD's primary programs for offering homeownership

opportunities are administered by FHA. By insuring mortgage loans, FHA allows lenders to offer lower down payments than would otherwise be available, low closing costs, and easy credit qualifying.

One way that HUD will expand homeownership opportunities in FY2007 is to make it easier for FHA to serve purchasers of affordable housing, such as manufactured homes. FHA would eliminate a feature of its Manufactured Housing program that contain prescriptive requirements pertaining to permanent foundations that do not provide for flexibility of design. The proposed amendment would promote affordable housing and the uniform quality and safety of manufactured homes.

Regulatory Action: Permanent Foundations For Manufactured Housing

This proposed rule would amend HUD's regulations governing manufactured homes erected on a permanent foundation that are to be the security for a Title II FHA-insured mortgage. In addition, this proposed rule would amend HUD's regulations governing manufactured homes erected on a permanent foundation that are to be security for a Title I FHA-insured mortgage. Current regulations contain prescriptive requirements pertaining to permanent foundations that do not provide for flexibility of design. HUD proposes to remove these requirements for both existing and newly constructed manufactured homes by instead deferring to the requirements established by the Model Manufactured Home Installation Standards (Model Installation Standards). A separate rule would establish the minimum acceptable standards nationwide for the installation and set-up of manufactured homes.

Priority: Improving the Quality of Public and Assisted Housing

Promoting decent affordable housing is a central part of HUD's mission. To this end, HUD seeks to improve the quality of the housing opportunities provided to families in public and assisted housing. Public housing is an important asset in which the federal government has invested for more than 7 decades. Throughout America, public housing provides homes for millions of Americans who have serious housing needs due to age, income, or disability. For many very low-income families and individuals, public housing represents the line between decent shelter and homelessness. To ensure that those of lesser means are well-housed in decent, safe, and viable communities, HUD

provides capital funds to maintain this asset. Capital funds are intended to cover modernization of public housing, as well as the costs of normal wear and tear. Through the use of capital funds, public housing agencies (PHAs) are able to undertake activities to modernize units, renovate properties, improve the safety and security of public housing, and make public housing accessible to persons with disabilities. HUD's goal is to ensure that PHAs can address their most serious capital issues when the need arises in order to avoid more costly and extensive renovations after need accrues for several years.

To accomplish these goals, HUD will focus on improving the management accountability and physical conditions of public and assisted housing through the following regulations.

Regulatory Action: Capital Fund Program

Section 519 of the Quality Housing and Work Responsibility Act amended section 9 of the United States Housing Act of 1937 (1937 Act) by providing for a Capital Fund that would make assistance available to PHAs to carry out capital and management improvement activities. The regulations implementing the new Capital Fund formula were promulgated in 2000. This proposed rule would establish the full regulatory framework for the Capital Fund Program. The Capital Fund Program addresses the capital and management improvement needs of PHAs and replaces the Comprehensive Grant Program and the Comprehensive Improvement Assistance Program. The proposed rule would complement the final rule that ensures the effective and timely obligation and expenditure of funds under the Public Housing Capital Fund Program.

While HUD provides assistance that helps to ensure that PHAs can address their most serious capital issues, HUD holds PHAs accountable for providing safe and decent housing, and protecting the federal investment in their properties. HUD does this by measuring the performance of PHAs and using this information to assist those PHAs that need improvement and holding those that do not improve accountable. HUD is committed to ensuring that PHAs perform effectively, particularly as they move to project-based funding.

Regulatory Action: Public Housing Assessment System (PHAS) Revision

This proposed rule would revise the PHAS regulation at 24 CFR part 902 to provide additional information, revise certain procedures, and establish other

procedures for the assessment of the physical condition, financial condition, management operations, resident services, and resident satisfaction. The rule would provide assessments of PHAs on a project level rather than on an entity-wide basis for all four of the PHAS indicators and would assess the management of PHA properties according to an asset management model, consistent with the management norms in multifamily, including project-based budgeting, and project-based accounting. The purpose of the PHAS is to function as a management tool that effectively and fairly measures a PHA's performance based on standards that are uniform and verifiable.

The Priority Regulations That Comprise HUD's FY 2007 Regulatory Plan

A more detailed description of the priority regulations that comprise HUD's FY 2007 Regulatory Plan follows.

HUD—Office of Housing (OH)

PROPOSED RULE STAGE

58. ● PERMANENT FOUNDATIONS FOR MANUFACTURED HOUSING (FR-5075)

Priority:

Other Significant

Legal Authority:

12 USC 1703; 42 USC 3535(d); 42 USC 5301 to 5320

CFR Citation:

24 CFR 201; 24 CFR 203

Legal Deadline:

None

Abstract:

This rule would amend HUD's regulations governing manufactured homes erected on a permanent foundation that are to be the security for a title II Federal Housing Administration (FHA) insured mortgage. The current regulations contain prescriptive requirements pertaining to permanent foundations that do not provide for flexibility of design. HUD proposes to remove these requirements for both existing and new construction manufactured homes and instead defer to the requirements established by the Model Manufactured Home Installation Standards (Model Installation Standards). (A separate rule would establish the minimum

acceptable standards nationwide for the installation and set-up of manufactured homes.) This rule will not supplant the current installation requirements entirely, but will permit them to be used in cases of FHA refinance transactions for any existing manufactured home that is currently security for an FHA-insured loan and which met FHA requirements at the time of the original endorsement. The rule would also amend HUD's regulations governing manufactured homes erected on a permanent foundation that are to be security for a title I FHA-insured mortgage. The proposed rule would promote affordable housing and the uniform quality and safety of manufactured homes.

Statement of Need:

The current regulations governing permanent foundations for manufactured housing may be too prescriptive in that they do not allow for flexibility of design. This rule is also necessary to avoid HUD having two inconsistent foundation standards for the installation of manufactured homes. The Manufactured Housing Improvements Act of 2000 amended the National Manufactured Housing Construction and Safety Act of 1974 (the Act) by establishing new requirements pertaining to the installation of manufactured homes. Among the requirements was a provision that HUD must promulgate Model Manufactured Installation Standards. FHA regulations need to be modified to reflect the new installation compliance standards under the Act for manufactured homes that are to be security for title I and title II FHA-insured mortgages.

Summary of Legal Basis:

The National Housing Act at 12 U.S.C. 1703 authorizes the Secretary to insure approved lenders against losses sustained as a result of borrower default on, among other things, manufactured home loans.

Alternatives:

The changes made by this proposed rule would modify an existing regulatory requirement and, therefore, must also be promulgated through regulation.

Anticipated Cost and Benefits:

This rule would require that the Minimum Property Standards applicable to the installation of manufactured homes meet or exceed the Model Installation Standards, as

will be codified at 24 CFR part 3285. This rule would increase flexibility of design, resulting in reduced cost to builders and consumers. Such a change would also serve to protect the health and safety of occupants of manufactured homes and FHA's interest in the property. Overall, this change would promote affordable housing and conform FHA's installation requirements to nationwide minimum standards. Further, manufactured homes that already securitize FHA-insured loans would not be affected by the regulatory change, and, therefore, would bear no compliance costs.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Joyce Richardson
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Department of Housing and Urban Development
Office of Housing
Washington, DC
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RIN: 2502-AI45

HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

59. 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 new Capital Fund Program for the capital and management improvement needs of public housing agencies (PHAs). This rule will implement the regulatory framework for the Capital Fund Program 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 at 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, which amended sections 9 and 5 of, and added section 35(g) to, the U.S. Housing Act of 1937.

Alternatives:

The amendments to the U.S. Housing Act of 1937 made by the Quality Housing and Work Responsibility Act regarding the Capital Fund Program required a formula system to be established to govern funding of PHAs' public housing capital needs. This formula was established by final rule issued on March 16, 2000. 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 would 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, would provide increased benefits to the PHAs. Likewise, uniform program administration of these funds would 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	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Acting Director, Office of Capital Improvements
Department of Housing and Urban Development
Office of Public and Indian Housing
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RIN: 2577-AC50

HUD—PIH

60. • REVISIONS TO THE PUBLIC HOUSING ASSESSMENT SYSTEM (PHAS) (FR-5094)

Priority:

Other Significant

Legal Authority:

42 USC 1437d(j); 42 USC 3535(d)

CFR Citation:

24 CFR 902

Legal Deadline:

None

Abstract:

This rule will revise the regulations for the Public Housing Assessment System (PHAS) to reflect the asset-based management requirements for public housing. The purpose of the PHAS is to provide a management tool for effectively and fairly measuring the performance of a public housing agency (PHA) in essential housing operations, based on standards that are uniform and verifiable. On September 19, 2005, HUD published a final rule amending the regulations for the Public Housing Operating Fund Program to provide a

new formula for distributing operating subsidies to PHAs and to establish requirements for PHAs to convert to asset management. The rule would revise the PHAS regulations to reflect the new asset-based management requirements of the September 19, 2005, Operating Fund final rule. In particular, the rule would provide for the assessment of PHAs on a project-level, rather than on an entity-wide level. Further, the rule would revise the PHAS regulations to assess PHAs according to an asset management model, consistent with the norms of multifamily housing rental management, including the use of project-based budgeting and project-based accounting.

Statement of Need:

The September 19, 2005, Operating Fund Program final rule redirected the focus of the public housing program to a property-based management model. This change adopted the recommendations of the congressionally mandated study of the costs of operating well-run public housing. However, the PHAS regulations are currently not reflective of this significant change in the direction and management of public housing, but rather reflect the former agency-centric public housing management model. The PHAS regulations must be updated to incorporate the asset-based management requirements. Updating of the regulations will help to ensure that the PHAS continues to provide appropriate standards for the fair and effective evaluation of PHA performance in the management of public housing.

Summary of Legal Basis:

Section 6(j) of the United States Housing Act of 1937 (42 U.S.C. 1437d(j)) requires the Secretary of Housing and Urban Development to develop and publish, in the Federal Register, indicators to assess the management performance of PHAs and resident management corporations. Section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)) establishes the Department's general rulemaking authority, authorizing the Secretary to make such rules and regulations as may be necessary to carry out the functions of the Department.

Alternatives:

As noted above, HUD is statutorily required to publish the indicators for assessing public housing management

performance. The policies and procedures governing the measurement of public housing performance under the PHAS are codified in HUD's regulations at 24 CFR part 902. Accordingly, any revisions to these policies and requirement must also be implemented through notice and comment rulemaking. Promulgation of these changes through other, non-rulemaking means (such as through notice of handbook) would not be enforceable.

Anticipated Cost and Benefits:

The rule would not impose any new significant costs on PHAs. As noted above, the proposed regulatory changes costs update the indicators for assessing PHA performance to reflect the existing asset-based management requirements

established by the September 19, 2005, Operating Fund Program final rule. The benefit of the regulatory changes will be to update and conform the PHAS requirements with the asset-based management requirement, thereby helping to ensure the continued validity, fairness, and effectiveness of the performance indicators.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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BILLING CODE 4210-67-S

DEPARTMENT OF THE INTERIOR (DOI) Major Regulatory Areas**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 390 park units, 545 wildlife refuges, 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, regulates surface coal mining operations, 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 over 400 million visitors annually in our national parks, Bureau of Land Management public lands, national wildlife refuges, and Bureau of Reclamation recreation areas. To fulfill these responsibilities, the Department generates scientific and other 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 approaches focused on achieving cost-effective, timely results;
- Incorporate the best available science, and utilize peer review where appropriate;
- Promote partnerships with States, tribes, local governments, 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.

All of the Department's bureaus and offices have significant regulatory responsibilities.

The Office of Surface Mining Reclamation and Enforcement (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 and has been extended through September 2007.

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 development oversight 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 Indians;
- 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, 13132, 13175, 13211, and 12988, 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 work 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 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 departmental 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 National Environmental Policy Act policies that streamline decisionmaking and enhance citizen participation are institutionalized;
- Issuance of revised procedures in the Departmental Manual to clarify the responsibility to offer cooperating agency status to qualified agencies and governments, and to make clear the role of cooperating agencies in the implementation of the Department's NEPA compliance process;
- Increased outreach to involved parties in the Natural Resources Damage Assessment Program, stressing cooperation and restoration of affected sites;
- Streamlined decisionmaking pertaining to fuels-reduction projects under the Healthy Forests Initiative

and Healthy Forests Restoration Act; and

- Promulgated hydropower license rules jointly with the Departments of Agriculture and Commerce, in consultation with FERC, that streamline the licensing and appeals process as called for in the Energy Policy Act of 2005.

Implementing the President's National Energy Policy and the Energy Policy Act

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, waters, and facilities managed by the Department account for nearly 30 percent of all the energy produced in the United States.

Through over 100 actions, the Department is implementing the President's energy policy and the Energy Policy Act of 2005, including numerous regulatory actions. The Bureau of Land Management and the Minerals Management Service are developing proposed rules to implement the Energy Policy Act. The Office of Surface Mining is developing regulations that will promote better mining and reclamation practices while maintaining a stable regulatory framework conducive to coal production. OSM anticipates that Congress will reauthorize the Abandoned Mine Land Fee. However, OSM has published contingency rulemaking plans should Congress decide otherwise. These and other regulatory actions within the Department will streamline permitting processes and encourage energy production while maintaining environmental protections.

The Energy Policy Act of 2005 directed Interior to promulgate regulations regarding tar sands leasing, geothermal leasing and oil and gas lease acreage. These were all issued this fiscal year. Further, other energy-related regulations were issued. The Minerals Management Service, for example, issued final regulations regarding geological and geophysical exploration on the Outer Continental Shelf (OCS), incident reporting, data release definitions, and cost recovery.

The Bureau of Land Management has seen a sharp and sustained increase in the submission of oil and natural gas drilling permit applications. BLM met the challenge by initiating numerous innovative streamlining strategies to

reduce the backlog of pending drilling permits. As BLM continues to make steady progress in reducing the backlog, it must work even more aggressively in the face of rising energy prices and increased demand for drilling permits. To aid in this effort, new process improvement tools have become available with the passage of the Energy Policy Act. With these tools, BLM will further reduce and ultimately eliminate the backlog of pending permits while allowing the development of energy resources in an environmentally responsible manner.

BLM is continuing its program of environmental Best Management Practices (BMPs) to help ensure the continued development of energy resources in an environmentally responsible manner. BMPs are innovative, dynamic, and improved environmental protection practices aimed at reducing impacts to the many natural resources BLM manages on behalf of the public. The BLM requires that appropriate environmental BMPs be considered for use in all new oil and gas drilling and production operations on the public lands administered by the BLM. A full discussion and many examples of BMPs can be found at BLM's BMP website: www.blm.gov/bmp

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, protecting threatened and endangered species, 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 with State and local governments, tribes, 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 in April 2004 was a rule change intended to provide greater clarity as to what is allowable under incidental take permits and to provide greater private landowner protections under safe harbor agreements.

The U.S. Geological Survey (USGS) is developing a policy and procedures for reporting, investigating, and adjudicating allegations of scientific misconduct by USGS employees and volunteers in accordance with the Federal policy on research misconduct. All covered employees and volunteers will be informed of their obligation to follow this policy and required to sign a statement indicating they have received, read, and understand the policy. These efforts will help to protect the public from the effects of inaccurate or misleading information produced through scientific activities and help to ensure scientific integrity in the conduct of scientific activities.

In 2006, the Secretaries of Interior and Agriculture, Western Governors, county commissioners, and other affected parties will complete a revision of the 10-Year Comprehensive Strategy Implementation Plan, a collaborative national effort to reduce the risk wildland fire poses to people, communities, and the environment. The revision incorporates new understanding and lessons learned over the last five years. It draws upon new tools like LANDFIRE (an advanced natural resource geographic information system), NFPORS (a comprehensive interagency fuels treatment, community assistance, and post-fire rehabilitation tracking system), and the emergence of Community Wildfire Protection Plans (CWPP) called for in the Healthy Forests Restoration Act signed by the President in December 2003. The revision contains new performance measures and implementation tasks covering collaboration, fire prevention and suppression, hazardous fuels reduction, pre- and post-fire landscape restoration, and community assistance.

Since the President announced the Healthy Forests Initiative in 2002, the Department has made extensive progress in reducing hazardous fuels. From 2003 to 2005, the bureaus treated an average of over 1,260,000 acres annually compared to 728,000 acres in 2001. The Department shifted emphasis toward the wildland urban interface (WUI), each year treating three times as many WUI acres as were reached in 2001. The Department has rapidly inculcated the new tools provided by the Healthy Forests Initiative and the Healthy Forests Restoration Act into its work. The Department now uses the streamlined NEPA-compliance on some 80 percent of new hazardous fuels NEPA work while, in 2006, over 45 percent of all fuels treatments accomplished were associated with either a streamlined NEPA tool or a CWPP.

The National Park Service is developing a new winter use plan and EIS for Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr. Memorial Parkway. NPS received nearly 33,000 comments as a result of preliminary public outreach in summer 2005 and has been briefing cooperating agencies and stakeholders since July 2005 as part of a public engagement plan that calls for informing interested parties of the status of the plan and soliciting stakeholder input. Our public engagement plan has also included the following:

- Pre-alternative concepts were presented to cooperating agencies and stakeholder groups beginning in November 2005.
- Open houses were held in Bozeman, Montana and Jackson, Wyoming in March 2006 to announce emerging alternatives for the Draft EIS, and a cooperating agency workshop on the preliminary alternatives occurred in April in Idaho Falls, Idaho.
- The parks shared draft winter monitoring reports with the cooperating agencies for technical review, and the parks provided draft air quality, soundscapes, and economic modeling analysis of the preliminary alternatives for review by cooperating agencies. The cooperating agencies will also have the opportunity to review the preliminary draft EIS, and the preliminary document will be posted on the parks' web sites for technical review.
- By late winter 2007, the Draft EIS will be available for public review, and the proposed rule will be published.

NPS has also completed final personal watercraft rules for 12 park areas. Rules for the last two park areas are in the final rule stages and will be completed by the end of 2006.

On August 31, Park Service management approved the 2006 edition of the National Park Service Management Policies. This edition has received extensive review and comment from the Service's career employees, as well as from tens of thousands of citizens who care deeply about the national park system.

The Bureau of Land Management has published a grazing administration rule ensuring that grazing decisions comply with the Administrative Procedure Act, removing provisions on conservation use permits found unlawful in Federal Court decisions, requiring BLM to consider social and economic factors when considering changes to grazing use, and promulgating other improvements in the regulations on grazing on public lands that will allow more effective and efficient management of the grazing program.

In December 2004, President Bush issued the U.S. Ocean Action Plan, in response to the U.S. Commission on Ocean Policy Report. The Action Plan includes a series of proposals from across the Government that included policy proposals, legislative recommendations, and regulatory initiatives. DOI has a number of responsibilities under the Action plan including: implementation of interim regulations and joint permits to support the President's Proclamation establishing the Northwestern Hawaiian Islands National Marine Monument; development of a seamless network to protect and conserve the Nation's ocean and coastal refuges, reserves, parks and sanctuaries; and creation of a National Water Quality Network.

The Department has submitted over a dozen proposed categorical exclusions provided for under NEPA to expedite a range of activities that the agencies routinely conduct. These range from periodic road closures over dams to activities related to improving forest health and energy related activities.

Minimizing Regulatory Burdens

We are using the regulatory process to improve results while easing regulatory burdens. 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 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. As a result of the recently enacted energy legislation, the Administration developed a joint rule involving the Departments of Agriculture, Commerce, and the Interior that establishes a trial-type hearing for a review of disputes over "material facts" included in hydropower licenses.

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, BLM uses Resource Advisory Councils (RACs) made up of affected parties to help prepare land management plans and regulations that it issues under the Federal Land Policy and Management Act and other statutes.

The Department reviewed and reformed its NEPA compliance program and in 2004 implemented new procedures to improve public participation and reduce paperwork and redundancy of effort in the field. The reforms include: consensus-based management, public participation, community-based training, use of integrated analysis, adaptive management, and tiered and transferred analysis. To promote greater transparency and public accountability, the Department is now publishing these procedures for codification in the Code of Federal Regulations. The proposed regulations supplement the CEQ regulations and must be used in

conjunction with them. The regulations will ensure that field staff have the tools to tailor their implementation of the NEPA process to local needs and interests.

The Federal Lands Recreation Enhancement Act (REA; PL 108-447), enacted in December 2004, requires that the Forest Service and BLM establish Recreation Resource Advisory Committees (RRACs), or use existing BLM RACs to perform the duties of RRACs. These committees will make recreation fee program recommendations to the two agencies on agency proposals to implement or eliminate certain recreation fees; to expand or limit their fee programs; and to implement fee level changes. After holding numerous "listening sessions" across the country in order to hear recommendations from the public on the appropriate configuration of the RRACs, the agencies established an organizational structure that was approved by both the Department of the Interior and the Department of Agriculture. The Departments signed an Interagency Agreement establishing the framework, processes, and collaborative RRAC approach the two agencies will use to comply with the REA's public participation requirements. The RRACs are expected to begin reviewing agency fee proposals in 2007.

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;
- Through a negotiated rulemaking process, the Bureau of Indian Affairs has finalized its roads program rule, which reflects 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 help draft a proposed rule.

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. On April 17, 2006, Reclamation finalized its rules implementing this authority.

Rules of Particular Interest to Small Businesses

The NPS 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 NPS rules to allow personal watercraft (PWC) use are also of great interest to small businesses that rent or sell PWC in the vicinity of the 15 park units involved in the rulemakings. The rulemaking process has been underway for a number of years and there are currently rules allowing PWC use in 12 park units and rulemaking actions for 2 additional units are in final stages of completion.

The FWS 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. As a result of the 9th Circuit's ruling on "Gifford Pinchot," invalidating the FWS's regulatory definition of destruction or adverse modification of critical habitat, the Department is considering a rulemaking.

The BLM has developed Stewardship Contracting Guidance that provides a framework for the preparation, implementation, and tracking of BLM stewardship projects, in accordance with section 323 of Public Law 108-7, the Consolidated Appropriations Resolution, 2003, which authorizes BLM to enter into stewardship projects with private persons or public or private entities, by contract or by agreement, to perform services to achieve land management goals for the national forests or public lands that meet local and rural community needs. The legislation also authorizes the value of timber or other forest products removed to be applied as an offset against the cost of services received.

The Future of DOI

Interior is in the process of updating its 2003-2008 strategic plan in accordance with the Government

Performance and Results Act requirement to update such plans every three years. Employee teams from bureaus and offices across Interior were engaged in the revision process since last Fall. Senior Departmental leadership were involved in reviews and approval of recommended changes before releasing the draft plan for public comment. The draft *GPRA Strategic Plan: 2007-12* was the subject of a number of public meetings, tribal government-to-government consultations, and employee focus groups during August and September 2006. Modifications based on analysis of the comments received are expected to be completed and the final plan published by the end of the calendar year.

The revised *GPRA Strategic Plan* will:

- Incorporate key Administration and Secretarial priorities into Interior's goals and performance measures
- Provide for more "results-oriented" goals for Interior programs
- Provide the basis for the Departmental Annual Performance Plan

Interior bureaus will continue to prepare internal plans to support their budget initiatives and to meet management excellence and accountability needs.

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 BIA's rulemaking and policy development processes 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.

Title V, Section 503 of the Energy Policy Act of 2005, requires the Secretary of the Interior to promulgate

regulations that implement new provisions concerning energy resource development on tribal lands. Specifically, the Indian Energy Development and Self-Determination Act, Title XXVI, Section 2604 of the Energy Policy Act, as amended, authorizes the Secretary to enter into Tribal Energy Resource Agreements (TERA) with Indian tribes. The intent of these agreements is to promote tribal oversight and management of energy and mineral resource development on tribal lands and further the goal of Indian self-determination. A TERA offers a tribe an entirely new alternative for entering into energy-related business agreements and leases and for granting rights-of-way for pipelines, electric transmission and distribution lines without the Secretary's review and approval.

The Department held a series of public meetings and tribal consultations in January 2006 to solicit stakeholder and tribal comment on the implementation of the Act. In addition, the Department, in two letters to tribal leaders, solicited direct involvement of tribes in drafting a framework for development of the proposed regulations.

The implementation of these regulations will further the Federal Government's policy of providing enhanced self-determination and economic development opportunities for American Indian tribes and support the Administration's National Energy Policy by increasing utilization of domestic energy resources. The proposed rule was published in the Federal Register on August 21, 2006.

The Bureau of Land Management

The Bureau of Land Management 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, 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 operates include: the Federal Land Policy and Management Act of 1976; the General Mining Law 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 Horse and Burro Act.

BLM's Regulatory Program mirrors statutory responsibilities and Agency objectives, including the following:

- Supporting the objectives of the Energy Policy Act of 2005 by developing regulations that will facilitate the domestic production of energy, including renewable energies such as biomass, wind, solar, and other alternative sources of energy;
- Providing for a wide variety of public uses while maintaining the long-term health and diversity of the land and preserving significant natural, cultural, and historic resource values;
- Understanding the arid, semi-arid, arctic, and other ecosystems we manage and committing ourselves to using the best scientific and technical information to make resource management decisions;
- Understanding the needs of the people who use the BLM-managed public lands and providing them with quality service;
- Securing the recovery of 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 objectives of the Regulatory Program include preparing regulations that:

- Are the product of communication, coordination, and consultation with all affected interests and 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 require updating to reflect statutory or policy changes, and whether they are achieving desired results.

The BLM's regulatory priorities include:

- Completing rules to facilitate implementation of the Energy Policy Act of 2005 in order to encourage domestic production of energy;
- Completing amendments of the recreation permit regulations in order to bring them into conformance with new governing law, including the Federal Lands Recreation Enhancement Act; and

- Completing the reorganization and updating of the regulations on locating, recording, and maintaining mining claims and mill and tunnel sites to eliminate obsolete provisions and make the regulations easier to follow.

Most BLM regulations affect small business. Many business entities that operate on public lands qualify as small businesses as the term is defined by the Small Business Administration (SBA). The BLM's regulations do not specifically target small businesses. The BLM strives to ensure that regulations do not unduly burden business entities whether or not they are considered small businesses.

The BLM's mining and grazing rules have traditionally generated the greatest concern for small businesses, because most livestock operators and mining companies are small entities, as classified by the SBA.

Minerals Management Service

Minerals Management Service (MMS) has two major responsibilities. The first, administered by the Minerals Revenue Management program (MRM), is timely and accurate collection, distribution, accounting for, and substantiating of revenues associated with mineral production from leased Federal and Indian lands. The second, administered by the Offshore Minerals Management program (OMM), 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. Both of these responsibilities are carried out under the provisions of the Federal Oil and Gas Royalty Management Act, the Federal minerals leasing acts, the Outer Continental Shelf Lands Act, the Indian mineral leasing acts, and other related statutes.

The MMS regulatory philosophy is to develop clear, enforceable rules that support the missions of each program.

This year, through MRM, the MMS published proposed rules for Indian Oil Valuation (February 13, 2006) and Geothermal Valuation (July 21, 2006). The Indian Oil rule proposed to establish value for oil produced from wells on Indian leases. The Geothermal Valuation proposed rule complied with a Congressional mandate under the Energy Policy Act of 2005. The Federal Gas Valuation rule established what transportation deductions are allowed in determining royalties. The Indian Oil Valuation rule will establish value for oil produced from wells on Indian lands. These two rules will benefit the

Government and citizens by establishing clear rules to determine royalties oil produced from Indian leases and geothermal resources from Federal lease lands. Clear rules will reduce the number of disputes and lower the costs to the Government of collecting royalties. Furthermore, they support the mission of MMS by promoting timely and accurate collection of royalties from Federal and Indian mineral leases.

Through OMM, the MMS published a final rule to recover costs for certain services MMS provides the oil and gas industry (July 19, 2006). This rulemaking implemented the President's policy, as outlined in OMB Circular No. 25, that when a service provides special benefits to an identifiable recipient, beyond those that accrue to the general public, the Federal government should impose a charge for the service to recover the cost of providing the service. The Department of the Interior mirrors this policy (330 DM 1.3A). MMS is also preparing a proposed rule on non-discriminatory access to pipelines. These rules support the mission of MMS to manage the resources in the Outer Continental Shelf in a manner that provides for safety, protection of the environment, and conservation of natural resources.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement 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 changes its role from regulating mining activities directly to overseeing and evaluating State programs. Today, 24 of the 26 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.

OSM has sought to develop and maintain a stable regulatory program for surface coal mining that is safe, cost-effective, and environmentally sound. A stable regulatory program provides regulatory certainty so that coal companies know what is expected of them and citizens know what is intended and how they can participate. During the development and maintenance of its program, OSM has recognized the need to (a) respond to local conditions, (b) provide flexibility to react to technological change, (c) be sensitive to geographic diversity, and (d) eliminate burdensome recordkeeping and reporting requirements that over time have proved unnecessary to ensure an effective regulatory program.

OSM's major regulatory objectives for 2006 include:

- Maintaining 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;
- Continued consultation, cooperation, and communication with interested 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; and
- Completion of ongoing rulemaking initiatives resulting from litigation by the coal industry and environmental groups, efforts by OSM to address areas of concern that have arisen during the course of implementing its regulatory program, and legislative requirements.

U.S. Fish and Wildlife Service

The mission of the U.S. Fish and Wildlife Service is to work 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. FWS carries 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 FWS-managed 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 its 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 545 national wildlife refuges and in national fish hatcheries. The Service authorizes only uses 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 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.

Within the next year the Service will develop and begin implementation of a number of policy initiatives aimed at facilitating meaningful conservation of listed species and guide our efforts towards conservation goals. These policies approach conservation challenges informed by the experiences and lessons learned from over 30 years of implementation and infuse a strong dose of common sense to our approach. The ultimate goal is to facilitate meaningful participation of the public and the pursuit of cooperative conservation approaches, as well as removing obstacles by exploiting inherent and unexplored flexibilities in the statute and existing regulations.

FWS is working in partnership with NOAA and the State of Hawaii to develop joint measures for implementing the Northwestern Hawaiian Islands National Marine Monument. Initial regulations incorporating the President's directions to the Interior and Commerce Secretaries for management of the Monument were published in the Federal Register on August 29, 2006. Additionally, the Service is working with its partners to develop unified permits for administrative and general uses, such as transporting materials and supplies to Midway Atoll.

National Park Service

The National Park Service conserves 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 resources conservation and outdoor recreation throughout this country and the world.

There are 390 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 National Park Service 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 National Park Service also administers the following programs: the State portion of the Land and Water Conservation Fund, Nationwide Outdoor Recreation coordination and information and State comprehensive outdoor recreation planning, planning and technical assistance for the National Wild and Scenic Rivers System and the National Trails System; natural area programs; Preserve America grant program; the National Register of Historic Places; national historic landmarks; historic preservation; technical preservation services; Historic American Buildings survey; Historic American Engineering Record; and interagency archeological services.

The National Park Service maintains regulations that help manage public use, access, and recreation in units of the National Park System. The Service provides visitor and resource protection to ensure public safety and prevent derogation of resources. The regulatory program develops and reviews regulations, maintaining consistency with State and local laws, to allow these uses only if they are compatible with the purpose for which each area was established.

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 has implemented 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 problem solving.

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 by natural resource trustees to assess appropriate restoration for injury to natural resources caused by hazardous substances. The Restoration Program has established of the Natural Resources Damage Assessment and Restoration Program Advisory Committee that will provide advice and recommendation on DOI's authorities and responsibilities, including its responsibility to promulgate regulations in the implementation of the National Resource Damage provisions of CERCLA.

DOI—Minerals Management Service (MMS)

FINAL RULE STAGE

61. 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	02/13/06	71 FR 7453
Supplemental NPRM Comment Period End	04/14/06	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

Agency Contact:

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Related RIN: Previously reported as 1010-AC24

RIN: 1010-AD00

**DOI—Office of Surface Mining
Reclamation and Enforcement
(OSMRE)**

PROPOSED RULE STAGE

62. PLACEMENT OF EXCESS SPOIL

Priority:

Other Significant

Legal Authority:

30 USC 1201 et seq

CFR Citation:

30 CFR 701; 30 CFR 773; 30 CFR 780;
30 CFR 781; 30 CFR 785; 30 CFR 816;
30 CFR 817

Legal Deadline:

None

Abstract:

This rule will establish permit application requirements and review procedures for applications that propose to place excess spoil from surface coal mining operations into waters of the United States. In addition, it will modify the backfilling and grading regulations to minimize the creation of excess spoil and it will revise the regulations governing surface coal mining operations within 100 feet of a perennial or intermittent stream to more closely track the underlying statutory provisions.

Statement of Need:

This rule will modify the backfilling and grading regulations to minimize the creation of excess spoil and it will revise the regulations governing surface coal mining operations within 100 feet of a perennial or intermittent stream to more closely track the underlying statutory provisions.

Summary of Legal Basis:

General rulemaking authority: Section 201(c)(2) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1211(c)(2), directs the Secretary of the Interior (the Secretary), acting through OSM, to publish and promulgate such rules and regulations as may be necessary to carry out the purposes and provisions of SMCRA.

Excess Spoil rulemaking authority: Section 515(b)(3) of SMCRA, 30 U.S.C. 1265(b)(3) requires that all surface coal mining and reclamation operations backfill, compact (if necessary to ensure stability and to prevent leaching of toxic materials), and grade to restore the approximate original contour of the

land unless an alternative post-mining land use requires a level or gently rolling contour. The provision also provides for exceptions to this requirement stating that there are situations when it may not be possible to return all the spoil to the mined area, particularly if the volume of overburden is large relative to the thickness of coal. In those situations, the operator is required to demonstrate that due to volumetric expansion the amount of overburden and other spoil and waste material is more than sufficient to restore the approximate original contour. The operator is also required to backfill, grade, and compact (where advisable) any excess overburden and other spoil and waste material to obtain the lowest possible grade but not more than the angle of repose in order to achieve an ecologically sound land use compatible with the surrounding region and to prevent slides, erosion and water pollution.

Section 515(b)(22) of SMCRA, 30 U.S.C. 1265(b)(22) imposes specific controls for the disposal of excess spoil to assure mass stability and to prevent mass movement and erosion. Among the various controls, section 515(b)(22)(D) requires that the excess spoil disposal area should not contain springs, natural water courses, or wet weather seeps unless lateral drains are constructed from the wet areas to the main underdrain. Section 515(b)(22)(I) requires that all other related provisions of SMCRA be met.

Section 515(b)(21), 30 U.S.C. 1265(b)(21), requires the protection of offsite areas from slides and damage by among other requirements not depositing spoil material outside the permit area.

Special requirements for spoil handling are also provided for those surface coal operations located in steep slope areas. Section 515(d)(1), 30 U.S.C. 1265(d)(1), requires that no spoil material . . . be placed on the downslope below the mine bench or mining cut: Provided, That spoil material in excess of that required for the reconstruction of the approximate original contour under the provisions of paragraph 515(b)(3) or 515(d)(2) shall be permanently stored pursuant to section 515(b)(22).

Stream Buffer Zone rulemaking authority: Section 515(b)(10) of SMCRA, 30 U.S.C 1265(b)(10), requires coal operations to minimize the disturbances to the prevailing hydrologic balance at the mine-site and in associated offsite areas and to the quality and quantity of water in surface

and ground water systems both during and after surface coal mining operations and during reclamation. Section 515(b)(10)(B)(i) specifies that coal operations must prevent, to the extent possible using the best technology currently available, additional contributions of suspended solids to streamflow, or runoff outside of the permit area but in no event shall the contributions be in excess of requirements set by applicable State or Federal law.

Section 515(b)(24) of SMCRA, 30 U.S.C. 1265(b)(24), requires that coal operations use best technology currently available to minimize disturbances and adverse impacts on fish, wildlife, and related environmental values; and enhance such resources where practicable.

Alternatives:

Alternatives being considered include:

A. No Action Alternative

This alternative would result in no changes to the excess spoil and stream buffer zone regulations as they currently exist in the Federal program.

B. Strengthening the Excess Spoil Requirements

We are considering changes to the excess spoil regulations that would add the following: Require the applicant to demonstrate that the volume of excess spoil generated has been minimized, that fills would be no larger than necessary, and to submit alternative spoil disposal plans in order to identify the plan that minimizes adverse environmental effects.

C. Clarifying the Stream Buffer Zone Requirements

We are considering revising the stream buffer zone regulation at 30 CFR 816.57 and 817.57 to clarify under which circumstances the regulatory authority can allow surface coal mining activities within 100 feet of an intermittent or perennial stream. We will consider a clarification that would closely follow our historic interpretation and implementation of the current stream buffer zone rule.

Anticipated Cost and Benefits:

It is anticipated that some of the regulatory changes will result in an increase in the costs and burdens placed on coal operators and on some primacy States. Preliminary estimates indicate that the total annual increase for operators would be approximately \$240,000, and for the primacy States the total annual increase is estimated

at approximately \$25,000. These increases are due to the requirement to document the analyses and findings required by the regulatory changes. This estimated increase in costs would likely only affect those coal operators and States (Kentucky, Virginia, and West Virginia) located in the steep slope terrain of the central Appalachian coalfields, where the bulk of excess spoil is generated. Because all of the regulatory agencies in the Appalachian coalfields have implemented policies to minimize the volume of excess spoil, no significant additional costs of implementing these regulatory changes are anticipated other than those required to document the strengthened requirements to consider all alternative excess spoil construction and disposal sites.

One of the primary benefits of the rule is an expected reduction in the placement of excess spoil with resulting positive environmental consequences. The rule is also expected to clarify mining requirements for steep slope and mountaintop mining operations in Appalachia and thereby establish regulatory certainty for the coal industry which has been hesitant to expend large sums of money on this type of mining operations because of legal uncertainty.

Timetable:

Action	Date	FR Cite
NPRM	01/07/04	69 FR 1036
Second NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

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DOI—Bureau of Land Management (BLM)

PROPOSED RULE STAGE

63. • OIL SHALE LEASING AND OPERATIONS

Priority:

Other Significant

Legal Authority:

Sec. 369(d) of the Energy Policy Act of 2005

CFR Citation:

43 CFR 3900

Legal Deadline:

None

Abstract:

The Energy Policy Act of 2005 envisions a three-step approach to the development of oil shale resources. The first step is the creation of a limited Research, Development, and Demonstration (RDD) Leasing Program designed to evaluate and test promising oil shale technology. Step 2 in the process is the completion of a Programmatic Environmental Impact Statement for leasing of Oil Shale and Tar Sands on public lands, with an emphasis on the most geologically prospective lands within the States of Colorado, Utah, and Wyoming. The third step in the process is the creation of rules regulating the leasing and development of the oil shale. This rule would create the regulations necessary to develop converted RDD leases and make commercial exploration, leasing, and development possible.

Statement of Need:

Currently there are no regulations in place that allow leasing and development of oil shale resources. The rule would establish the regulatory framework allowing commercial leasing and development of oil shale.

Summary of Legal Basis:

Sec. 369(d) of the Energy Policy Act of 2005 requires that the Secretary of the Interior publish final regulations establishing a commercial leasing program for Oil Shale and Tar Sands.

Alternatives:

There is no alternative to creation of the regulations. Creation of the

regulations is mandated by sec. 369(d) of the Energy Policy Act of 2005.

Anticipated Cost and Benefits:

BLM anticipates the following benefit: Increased Federal revenue and domestic fuel production, decreased dependency on energy imports, and the expansion of local economies through employment and taxes.

The major categories of costs include: BLM administrative costs, including enforcement and monitoring, and compliance costs for lessees.

Risks:

Development of the oil shale resources will place additional demands on the lands localities containing the oil shale resources. These demands will result in increased resource conflicts (i.e., oil and gas, nahcolite, and wildlife) and pressure on local governments/infrastructure (i.e., law enforcement, schools, hospitals and roads).

Timetable:

Action	Date	FR Cite
ANPRM	08/25/06	71 FR 50378
ANPRM Comment Period End	09/25/06	
Comment Period Extended	09/26/06	71 FR 56085
ANPRM Comment Period End	10/25/06	
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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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 was 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 raised two sets of questions for public comment, and proposed 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 was 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.

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.

On August 9, 2006, the Attorney General announced a series of initiatives to improve the quality of adjudications before immigration judges, in response to the review of the Immigration Courts and the Board of Immigration Appeals which he ordered.

2. 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. 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 2007, 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 Combat Methamphetamine Epidemic Act of 2005, which further regulates the importation, manufacture, and sale of drug products containing the scheduled listed chemical products ephedrine, pseudoephedrine, and phenylpropanolamine.

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: improve drug abuse treatment services and early release consideration; improve disciplinary procedures; and reduce the introduction of contraband through various means (such as clarifying drug and alcohol surveillance testing programs). In addition, the Bureau will finalize regulations relating to limiting the communications of inmates identified as having an identifiable link to terrorist-related activities.

DOJ—Civil Rights Division (CRT)

PROPOSED RULE STAGE

64. 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 was 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 raised questions for public comment and proposed 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 that are subject to title III of the ADA.

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	
ANPRM Comment Period Extended	01/19/05	70 FR 2992
ANPRM Comment Period End	05/31/05	
NPRM	08/00/07	
NPRM Comment Period End	12/00/07	

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

65. 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 (ADAAG), 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 was 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 raised questions for public comment and proposed 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 that are subject to title III of the ADA.

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 effects 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	
ANPRM Comment Period Extended	01/19/05	70 FR 2992
ANPRM Comment Period End	05/31/05	
NPRM	08/00/07	
NPRM Comment Period End	12/00/07	

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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BILLING CODE 4410-BP-S

DEPARTMENT OF LABOR (DOL)

2006 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 workplaces, as well as protection of their wages and pensions. The Secretary of Labor has made protecting America's workers a top priority, and has combined tough enforcement with compliance assistance to ensure the health, safety and economic security of the American workforce. While the vast majority of employers work hard to keep their employees and workplaces safe and secure, strong enforcement is needed to protect employees whose employers otherwise would not comply with safety and health, wage, and pension laws and regulations.

The Secretary's compliance assistance initiative provides employers with the knowledge and tools they need to carry out their legal obligations, and is based on the proven success that comes when government, employers, unions and employees work together. 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 19 high priority items for regulatory action. Ten 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.

The Mine Safety and Health Administration (MSHA) administers the Federal Mine Safety and Health Act of 1977 (Mine Act). MSHA is undertaking a number of significant regulatory actions to provide increased protection to miners from accidents and assist in their evacuation from the mine should a mine emergency occur. In addition, the Agency is strengthening its procedures for assessing and collecting civil penalties, and in some cases, increasing the penalty amount proposed. MSHA is implementing major portions of the Mine Improvement and New Emergency Response Act of 2006 (MINER Act) through portions of these rulemakings.

On March 9, 2006, MSHA published an Emergency Temporary Standard on Emergency Mine Evacuations (ETS) (1219-AB46), to protect miners from the grave danger that they face when they must evacuate a mine after an emergency occurs. The ETS contains provisions for immediate accident notification applicable to all underground and surface mines. In addition, the ETS addresses self-contained self-rescuer storage and use; evacuation and self-rescuer training; and the installation and maintenance of lifelines in underground coal mines. By December 8, 2006, MSHA will promulgate a Final Rule on Emergency Mine Evacuations.

MSHA is proposing to amend 30 CFR part 100 Criteria and Procedures for Proposed Assessment of Civil Penalties (1219-AB51) to strengthen criteria for assessing proposed civil monetary penalties and increase the amounts MSHA may propose for some penalties. These changes are intended to improve the safety and health of miners by assuring greater compliance with the Mine Act and MSHA's safety and health standards.

In mid 2007, MSHA will propose separate rulemakings to address Mine Rescue Teams (1219-AB53) in

underground mines and Sealing of Abandoned Areas (1219-AB52) in underground coal mines, both to be completed in 2007. The Mine Rescue Team rule will include provisions for the number, training, composition and certification of mine rescue teams. The rule for Sealing of Abandoned Areas will address the pressure value requirement for seals.

In addition to these and other important safety initiatives, MSHA also remains committed to ensuring healthier workplaces for the nation's miners. MSHA plans to publish a Request for Information on the use of the personal continuous dust monitor upon completion of a research report from the National Institute for Occupational Safety and Health. This new technology is designed to continuously measure a coal miner's exposure to respirable coal mine dust. Such information, available immediately at the miner's work location has the potential to reduce the occurrence of respirable lung disease among coal miners.

On May, 18, 2006, MSHA promulgated its final rule on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (1219-AB55), phasing in the final diesel particulate matter (DPM) exposure limit over a two-year period, with the final limit of 160TC $\mu\text{g}/\text{m}^3$ to become effective on May 20, 2008. The 160TC $\mu\text{g}/\text{m}^3$ exposure limit is expressed in terms of a "TC" or "total carbon" limit. MSHA is initiating a new rulemaking to convert the total carbon or "TC" limit to a comparable elemental carbon or "EC" limit.

Finally, MSHA is continuing work on its final rule on Asbestos Exposure (1219-AB24), a rule that will provide increased protection to miners potentially exposed to health hazards associated with asbestos.

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 first 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 silica exposure 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 plans to complete an external peer review of the health effects and risk assessment by April 2007.

OSHA has initiated rulemaking to revise its Hazard Communication Standard (HCS) to adopt provisions to make it consistent with a globally harmonized approach to hazard communication. First promulgated in 1983, the HCS requires chemical manufacturers and importers of chemicals to evaluate the hazards of the chemicals they produce or import, and prepare labels and safety data sheets to communicate the hazards and protective measures to users of their products. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including labels on containers, safety data sheets, and employee training. OSHA estimates that the HCS covers over 945,000 hazardous chemical products in 7 million American workplaces. OSHA and other Federal agencies have participated in long-term international negotiations to develop the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Adopted by the United Nations in 2003, the GHS includes harmonized criteria for health, physical and environmental hazards, as well as specifications for container labels and safety data sheets. There is an international goal to have as many countries as possible implement the GHS by 2008. Revising the HCS to be consistent with the GHS is expected to improve the communication of hazards in American workplaces, as well as facilitate international trade in chemicals.

OSHA is continuing work on its rulemaking to update the 1971 Cranes and Derricks standards using the recommendations of a negotiated rulemaking committee. The committee submitted its recommendations in July 2004. OSHA has convened a Small Business Regulatory Enforcement Fairness Act panel to obtain input from small businesses and expects to receive the panel's report in October 2006.

Protection of pension and health benefits continues to be a priority of the Secretary of Labor. Consistent with the Secretary's priorities for FY 2007, 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 of the Employee Retirement Income Security Act (ERISA) (RIN 1210-AA54). With respect to pension plans, the Department will be developing guidance to encourage the automatic enrollment of participants in 401(k) plans and the use of default investment options that will enhance retirement savings (RIN 1210-AB10). The Department also will be establishing standards to improve the disclosure of information concerning plan service provider fees and potential conflicts of interest to assist fiduciaries and participants in making informed decisions about their plans (RIN 1210-AB07 and 1210-AB08). In addition, the Department is initiating a review of the "independence" standards applicable to qualified public accountants engaged on behalf of participants and beneficiaries in ERISA-covered employee benefit plans (RIN 1210-AB09).

ERISA's requirements affect an estimated 733,000 private sector employee pension benefit plans (covering approximately 107 million participants); an estimated 2.5 million group health benefit plans (covering 135 million participants and dependents); and 3.5 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 changes to the Trade Adjustment Assistance (TAA) program, as enacted in the Trade Act of 2002. The regulations will be issued in three parts: (1) a regulation covering the TAA program benefits (RIN 1205-AB32); (2) a regulation covering the new Alternative TAA program for Older Workers (RIN 1205-AB40); and (3) a regulation covering petition filings and investigations (RIN 1205-AB44). 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.

ETA's second priority is the Labor Certification for the Permanent Employment of Aliens in the United States; Reducing the Incentives and Opportunities for Fraud and Abuse and Enhancing Program Integrity (RIN 1205-AB42). This regulation implements changes to reduce the incentives and opportunities for employer fraud and abuse related to the permanent employment of aliens in the United States.

The Employment Standards Administration (ESA) has one priority regulatory initiative. ESA's initiative pertains to regulations issued under the Family and Medical Leave Act (FMLA) that were also discussed in OMB's 2001, 2002 and 2004 Reports to Congress on the Costs and Benefits of Regulations. ESA continues to review the 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, for possible revisions to the FMLA regulations.

DOL—Employment Standards Administration (ESA)

PRERULE STAGE

66. 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 request information on the FMLA regulations.

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 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 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. The Department is requesting information 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. 2654.

Alternatives:

After completing a review and analysis of the Supreme Court's decision in *Ragsdale* and other judicial decisions, regulatory alternatives may be developed for notice-and-comment rulemaking.

Timetable:

Action	Date	FR Cite
RFI	12/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1215-AB35

DOL—Employment and Training Administration (ETA)

PROPOSED RULE STAGE

67. ALTERNATIVE TRADE ADJUSTMENT ASSISTANCE BENEFITS; AMENDMENT OF REGULATIONS

Priority:

Other Significant

Legal Authority:

19 USC 2320; Secretary's Order No. 3-81, 46 FR 31117

CFR Citation:

29 CFR 90; 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, generally 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. They also create the Alternative Trade Adjustment Assistance (ATAA) program for older workers, which was effective no later than one year after the enactment of the amendments on August 6, 2002.

It is the Department'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 655 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of 9 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 was originally divided into two parts: the first covering TAA benefits (subpart A and subparts C through H); and the second covering petitions and certifications (subpart B and certain definitions in subpart A) and ATAA (subpart I). To expedite the publication of guidance on ATAA, this second NPRM is divided, and ATAA will proceed under this original RIN 1205-AB40.

This proposed rulemaking covers the issuance of ATAA benefits for older workers (subpart I). Separate notices of proposed rulemaking cover benefits (subpart A and subparts C through H) and petitions and determinations (subpart B and certain definitions in subpart A).

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 was required 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 ATAA 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	10/18/06	71 FR 61618
NPRM Comment Period End	12/18/06	

Regulatory Flexibility Analysis Required:

None

Government Levels Affected:

Federal, State

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Related RIN: Related to 1205-AB32

RIN: 1205-AB40

DOL—ETA

68. • REVISION OF THE DEPARTMENT OF LABOR REGULATIONS FOR PETITIONS AND DETERMINATIONS OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE FOR WORKERS

Priority:

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

Legal Authority:

19 USC 2320; Secretary's Order 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. They also create the Alternative Trade Adjustment Assistance (ATAA) program for older workers, which was effective no later than one year after the enactment of the amendments on August 6, 2002.

It is the Department'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 655 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of 9 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 Allowance (TRA); subpart H-Administration by Applicable State Agencies; subpart I-Alternative Trade Adjustment Assistance (ATAA) for Older Workers.

Because of the complexity of the subject matter of the States' needs for definitive instructions on providing TAA benefits, the rulemaking for part 618 was originally divided into two parts: the first covering TAA benefits (subpart A and subparts C through H); and the second covering petitions and certifications (subpart B and certain definitions in subpart A) and ATAA (subpart I). To expedite the publication of guidance on ATAA, this second NPRM is divided, and ATAA proceeded under its original RIN 1205-AB40.

This proposed rulemaking covers petitions and determinations (subpart B and certain definitions in subpart A) of the regulations. Separate notices of proposed rulemaking cover remaining (subpart A and subparts C through H) and the issuance of ATAA benefits for older workers (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, provided for 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 benefits 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 relocation allowances, and income support.

The Department was required 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. In light of changes in the petition process made by the Reform Act, as well as the need to clearly spell out that process for the public and the courts, it is imperative that the regulations be in an easy to read and understandable format.

Summary of Legal Basis:

The regulation is authorized by 19 USC 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	04/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Federalism:

Undetermined

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Related RIN: Related to 1205-AB32,
Related to 1205-AB40

RIN: 1205-AB44

DOL—ETA

FINAL RULE STAGE

69. 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 9 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 three parts. This notice of proposed rulemaking covers the general provisions (most of subpart A) and TAA benefits portions (subpart C through subpart H) of the regulations. Separate notices of proposed rulemaking will cover the two remaining subparts and reserved definitions in subpart A. One NPRM, subpart I will cover benefits under the alternative Trade Adjustment Assistance program. The other NPRM, subpart B will cover the petitions and certification process.

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 was afforded an opportunity to provide comments on the TAA program changes when the Department published 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	08/25/06	71 FR 50760
NPRM Comment Period End	10/24/06	
Final Action	04/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

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Related RIN: Related to 1205-AB40

RIN: 1205-AB32

DOL-ETA

70. LABOR CERTIFICATION FOR THE PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES; REDUCING THE INCENTIVES AND OPPORTUNITIES FOR FRAUD AND ABUSE AND ENHANCING PROGRAM INTEGRITY

Priority:

Other Significant

Legal Authority:

8 USC 1182(a)(5)(A)

CFR Citation:

20 CFR 656

Legal Deadline:

None

Abstract:

The Department of Labor proposed changes to reduce the incentives and opportunities for fraud and abuse related to the permanent employment of aliens in the United States. Among other key changes, the Department is eliminating the current practice of allowing the substitution of alien beneficiaries on applications and approved labor certifications. DOL proposed to further reduce the likelihood of the submission of fraudulent applications for the permanent employment of aliens in the United States by proposing a 45-day deadline for employers to file approved permanent labor certifications in support of a petition with the Department of Homeland Security. The Final Rule expressly prohibits the sale,

barter, or purchase of permanent labor certifications or applications, as well as related payments. The proposed rule also addresses enforcement mechanisms to protect program integrity, including debarment with appeal rights. These amendments would apply to employers using both the Application for Alien Employment Certification (Form ETA 750) or the Application for Permanent Employment Certification (Form ETA 9089).

Statement of Need:

The Immigration and Nationality Act of 1952, as amended, established the permanent labor certification (PERM) program. Through this program, an employer submits a petition to the Department of Homeland Security (DHS) requesting a visa to admit a certain immigrant alien to work permanently in the United States. This petition process requires the Secretary of the Department of Labor (DOL) to certify specific information to the Secretary of Homeland Security and the Secretary of State before DHS may approve the employer's petition request and the Department of State (DOS) may issue a visa to admit such alien.

Specifically, DOL must certify that there is not a U.S. worker able, available, willing and qualified at the time of an application for a visa, and that the employment of the alien will not adversely affect the wages and working conditions of similarly employed U.S. workers. If DOL determines that there is no able, available, willing and qualified U.S. worker and employment of the immigrant alien will not adversely affect the wages and working conditions of similarly employed U.S. workers, then a permanent labor certification is granted. If DOL cannot make both of the above findings, then the application is denied.

This proposed regulation is intended to enhance program integrity and reduce the incentives and opportunities for fraud and abuse. First, the regulation would eliminate the current practice of allowing substitution of alien beneficiaries on the certification applications. Second, the regulation would implement a 45-day period for employers to file approved certifications with DHS. Third, the regulation would expressly prohibit the sale, barter, or purchase of PERM applications and certifications and other related payments. Finally, the regulation would highlight existing law regarding fraudulent activity or falsifying information and

corresponding sanctions for such findings.

Summary of Legal Basis:

This regulation is authorized by 8 USC 1182(a)(5)(A); INA §212(a)(5)(A).

Alternatives:

The public was afforded an opportunity to provide comments on the Fraud and Abuse rule implementation when the Department published the proposed rule in the Federal Register (71 FR 7656).

Anticipated Cost and Benefits:

The Department believes any potential increase in applications filed as a result of either employers withdrawing and then filing a corrected application or employers allowing a certification to expire and then filing a new application or recruitment costs associated with this rule would be more than offset by an anticipated reduction in average processing time because the Department will not expend resources to process as many fraudulent applications. Aliens will save money if they are not forced to pay employer expenses nor provide kickbacks to certain agents and employers. Any cost savings realized, however, will not be greater than \$100 million.

Risks:

This action does not affect public health, safety or the environment.

Timetable:

Action	Date	FR Cite
NPRM	02/13/06	71 FR 7656
NPRM Comment Period End	04/14/06	
Final Action	04/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1205-AB42

DOL—Employee Benefits Security Administration (EBSA)

PROPOSED RULE STAGE

71. 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 not 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 include 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	12/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

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RIN: 1210-AB02

DOL—EBSA

FINAL RULE STAGE

**72. 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 to 1172; 29 USC
 1191c

CFR Citation:

29 CFR 2590

Legal Deadline:

None

Abstract:

The Health Insurance Portability and
 Accountability Act of 1996 (HIPAA)
 amended title I of ERISA, the Internal
 Revenue Code, and the Public Health
 Service Act with parallel provisions
 designed to improve health care access,
 portability and renewability. The
 Departments of Labor, the Treasury,
 and the Health and Human Services are
 mutually dependent due to shared
 interpretive jurisdiction and are
 proceeding concurrently to provide
 additional regulatory guidance
 regarding 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	
NPRM	12/30/04	69 FR 78800
Request for Information	12/30/04	69 FR 78825
Final Rule	12/30/04	69 FR 78720
Final Action Effective	02/28/05	
Request for Information/ Comment Period End	03/30/05	
NPRM Comment Period End	03/30/05	
Final Action	09/00/07	

**Regulatory Flexibility Analysis
 Required:**

No

Government Levels Affected:

None

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DOL—EBSA

**73. PROHIBITING DISCRIMINATION
 AGAINST PARTICIPANTS AND
 BENEFICIARIES BASED ON HEALTH
 STATUS**

Priority:

Other Significant

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:

The Health Insurance Portability and
 Accountability Act of 1996 (HIPAA)
 amended title I of ERISA, the Internal
 Revenue Code, and the Public Health
 Service Act with parallel provisions to
 prohibit discrimination by a group
 health plan or a health insurance issuer
 based on any health status-related
 factor. The Departments of Labor, the
 Treasury, and Health and Human
 Services are mutually dependent due to
 shared interpretive jurisdiction and are
 proceeding concurrently to provide
 final regulatory guidance regarding
 these provisions.

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	12/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

This item has been split off from RIN 1210-AA54.

Agency Contact:

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RIN: 1210-AA77

DOL—EBSA

**74. SECTION 404 REGULATION—
DEFAULT INVESTMENT
ALTERNATIVES UNDER PARTICIPANT
DIRECTED INDIVIDUAL ACCOUNT
PLANS**

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

29 USC 1104(c)(5); 29 USC 1135

CFR Citation:

29 CFR 2550

Legal Deadline:

Final, Statutory, February 19, 2007.

Abstract:

This rulemaking would establish a relief under which a fiduciary of a

participant directed individual account pension plan will be deemed to have satisfied his or her fiduciary responsibilities with respect to investment and asset allocation decisions made on behalf of individual participants and beneficiaries who fail to give investment direction. This rulemaking will describe the types of investments that qualify as default investments in order to obtain fiduciary relief. As with other investment alternatives available under the plan, fiduciaries will continue to be responsible for the prudent selection and monitoring of qualifying default investment alternatives.

Statement of Need:

Section 404(c)(1) of ERISA provides that, where a participant or beneficiary of an employee pension benefit plan exercises control over assets in an individual account maintained for him or her under the plan, the participant or beneficiary is not considered a fiduciary by reason of his or her exercise of control and other plan fiduciaries are relieved of liability under part 4 of title I of ERISA for the results of such exercise of control. As part of the Pension Protection Act of 2006, section 404(c) was amended to provide relief accorded by section 404(c)(1) to fiduciaries that invest participant assets in certain types of investment alternatives in the absence of participant investment direction. The Pension Protection Act directed the Department to issue final default investment regulations under section 404(c)(5)(A) of ERISA no later than 6 months of the date of enactment of the Pension Protection Act. This rulemaking responds to a need on the part of plan sponsors and fiduciaries for guidance on the selection of default investments for plan participants who fail to make an investment election. Such guidance would also improve retirement savings for millions of American workers.

Summary of Legal Basis:

Promulgation of this regulation is authorized by sections 505 and 404(c) of ERISA.

Alternatives:

Regulatory alternatives were considered in developing the proposed rule and published in the Federal Register.

Anticipated Cost and Benefits:

Costs and benefits of regulatory alternatives were estimated and taken into account in developing the

proposed rule and published in the Federal Register.

Risks:

Failure to provide guidance on default investment options for individual account plans may result in diminished retirement savings for the many participants who fail to make an investment election with regard to their accounts. In addition, failure to issue final default investment regulations under section 404(c)(5)(A) of ERISA no later than 6 months of the date of enactment of the Pension Protection Act would contravene section 624 of the Pension Protection Act.

Timetable:

Action	Date	FR Cite
NPRM	09/27/06	71 FR 56806
NPRM Comment Period End	11/13/06	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1210-AB10

**DOL—Mine Safety and Health
Administration (MSHA)**

PRERULE STAGE

**75. • PERSONAL CONTINUOUS DUST
MONITORS**

Priority:

Other Significant

Legal Authority:

30 USC 811

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

On June 24, 2003, MSHA announced that all work on its Plan Verification and Single-Sample Respirable Coal Mine Dust final rules would cease and the rulemaking record would remain open in order to obtain information concerning Personal Continuous Dust Monitors (PCDMs) currently being tested by NIOSH. A Federal Register notice was published on July 3, 2003, extending the comment periods indefinitely. All detailed field and laboratory testing on the PDM by NIOSH and MSHA has now been successfully completed, and NIOSH has completed the final report documenting the results of the collaborative research to date. NIOSH and MSHA conducted joint PCDM workshops to explore options and related implementation issues for maximizing the PCDM technology in prevention of "black lung" disease among coal miners. Once the public has had an opportunity to review the NIOSH report, MSHA will solicit public input on potential applications of this new monitoring technology in coal mines.

Statement of Need:

Respirable coal mine dust levels in this country are significantly lower than they were over two decades ago. Despite this progress, there continues to be concern about our current sampling programs' ability to accurately measure and maintain respirable coal mine dust at or below the applicable standard. The new PCDM, unlike the technology that has been employed since 1970 to measure concentrations of respirable coal mine dust, offers the capability to provide accurate and timely continuous readings of the dust level during the shift. Responses to this Request for Information (RFI) will assist the Agency in determining: (1) How to deploy the PCDM in coal mines and utilize its coal dust monitoring capability to further improve miner health protection from disabling occupational lung disease; and (2) the regulatory and non-regulatory actions that are needed to promote its use for exposure monitoring and control.

Summary of Legal Basis:

This RFI is authorized by sections 101 and 103 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

This RFI would explore options for amending and improving health protection from that afforded by the existing standards.

Anticipated Cost and Benefits:

MSHA will develop a preliminary economic analysis to accompany any proposed rule that may be developed.

Risks:

Respirable coal dust is one of the most serious occupational hazards in the mining industry. Occupational exposure to excessive levels of respirable coal mine dust can cause black lung, which is potentially disabling and can cause death. MSHA is pursuing both regulatory and nonregulatory actions to eliminate this disease through the control of coal mine respirable dust levels in mines and reduction of miners' exposure.

Timetable:

Action	Date	FR Cite
Request for Information	01/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219-AB48

DOL—MSHA

PROPOSED RULE STAGE

76. • SEALING OF ABANDONED AREAS

Priority:

Other Significant

Legal Authority:

30 USC 811; Section 10 of MINER Act

CFR Citation:

30 CFR 75.335

Legal Deadline:

Final, Statutory, December 15, 2007.

Abstract:

On June 15, 2006, Public Law 109-236, the Mine Improvement and New Emergency Response Act (MINER Act) of 2006 became effective. Section 10 of the MINER Act requires that the Secretary of Labor finalize mandatory health and safety standards relating to the sealing of abandoned areas in underground coal mines no later than 18 months after enactment. Such health and safety standards shall provide for an increase in the 20 pounds per square inch standard currently set forth in section 75.335(a) (2) of title 30, Code of Federal Regulations.

Statement of Need:

Section 10 of the MINER Act requires the Secretary of Labor to finalize mandatory standards relating to the sealing of abandoned areas in underground coal mines no later than December 15, 2007, and that provide for an increase in the 20 psi standard currently in effect. Adequate seals are crucial to containing explosions and preventing the migration of potentially explosive methane-air mixtures from worked out areas to the working areas of an underground coal mine. The MINER Act as well as data from MSHA's evaluation of alternative seals in underground coal mines has led the Agency to determine that revisions to existing standards for alternative seals are necessary.

Summary of Legal Basis:

Promulgation of this regulation is authorized by the Federal Mine Safety and Health Act of 1977 and the MINER Act of 2006.

Alternatives:

The Mine Safety and Health Administration is reviewing the information from the Darby No. 1 Mine and Sago Mine accidents to determine if the use of alternative seal techniques contributed to those accidents. The Agency is also conducting test explosions in experimental mines to determine the relationships between seal design and construction and the ability to withstand explosive forces. This information will assist the Agency in developing new standards consistent with the requirements of the MINER Act.

Anticipated Cost and Benefits:

MSHA will develop a preliminary regulatory economic analysis to accompany any rule that may be developed.

Risks:

Recent accidents and MSHA data show that there are problems with the construction and use of alternative methods and materials to create seals. Properly constructed seals are crucial to containing explosions and preventing the migration of potentially explosive methane-air mixtures from worked out areas to the working areas of an underground coal mine. The exact scope of the problem is unknown at this time. However, the reliability of at least 30,000 seals in underground coal mines is in question because of their potential to endanger miners who work in mines with sealed areas.

Timetable:

Action	Date	FR Cite
NPRM	05/00/07	
Final Action	12/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219-AB52

DOL—MSHA**77. • MINE RESCUE TEAMS****Priority:**

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

30 USC 957; 30 USC 811; 30 USC 825;
Section 4 of the MINER Act

CFR Citation:

30 CFR 49; 30 CFR 57; 30 CFR 75

Legal Deadline:

Final, Statutory, December 15, 2007.

Abstract:

On June 15, 2006 Public Law 109-236 or the Mine Improvement and New Emergency Response Act (MINER Act) of 2006 became effective. This rulemaking will implement section 4 of the MINER Act by amending existing standards and developing new standards to provide for increased availability of mine rescue teams and to specify additional training and qualification requirements for teams and team members. Currently, requirements for mine rescue teams are set forth in 30 CFR part 49.

Statement of Need:

Section 4 of the MINER Act requires that the Secretary of Labor finalize mandatory health and safety standards relating to mine rescue teams in underground coal mines no later than December 15, 2007. Current standards require properly trained mine rescue teams to be immediately available to assist in rescue of miners during mine emergencies. In almost all cases, because of the inherent dangers of roof or rib falls, fires, explosions, and gas or water inundations in underground coal mining, local fire and rescue personnel are not qualified for rescue operations in underground coal mines. Unqualified rescuers can pose an even graver danger to themselves and other rescuers. The increased mechanization of underground coal mining, the reduction in hiring, and the rising cost of training mine rescue teams have resulted in a wide variety of alternative arrangements, especially for small mine operators. The MINER Act requires team members to have underground coal mining experience and instruction in specific topics, and requires teams to participate in mine rescue contests and to periodically renew their qualifications. The MINER Act also provides mine operators options for using multi-employer teams, State-sponsored teams, and commercial teams to ensure the availability of qualified mine rescue teams.

Summary of Legal Basis:

Promulgation of this regulation is authorized by the Federal Mine Safety and Health Act of 1977 and the MINER Act of 2006.

Alternatives:

MSHA is considering amendments, revisions, and additions to existing standards to implement the provisions of the MINER Act.

Anticipated Cost and Benefits:

MSHA will develop a preliminary regulatory economic analysis to accompany any proposed rule that may be developed.

Risks:

The two mine explosions at the Sago Mine in January, 2006 and the Darby No. 1 Mine in May, 2006 resulted in the deaths of 17 underground coal miners. Explosions, fires, and the migration of potentially explosive methane-air mixtures from worked out areas to the working areas of an underground coal mine endanger all miners who work in the mine, including potential rescuers.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	
Final Action	12/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 1219-AB53

DOL—MSHA**78. • DIESEL PARTICULATE MATTER: CONVERSION FACTOR FROM TOTAL CARBON TO ELEMENTAL CARBON****Priority:**

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 57

Legal Deadline:

None

Abstract:

On May, 18, 2006, MSHA promulgated its final rule on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (71 FR 28924), phasing in the final diesel particulate matter (DPM) exposure limit over a two-year period, with the final limit of 160TC µg/m³ to become effective on May 20, 2008. The DPM exposure limit is expressed in terms of a "TC" or "total carbon" limit. MSHA is initiating a new rulemaking to establish the most appropriate measure for determining compliance with the final DPM exposure limit. Using the latest available evidence, MSHA will be examining the most appropriate conversion factor for a comparable elemental carbon (EC) limit.

Statement of Need:

The May 18, 2006 final rule at 30 CFR 57.5060(b)(3) requires mine operators to ensure that the miners' personal exposures to diesel particulate matter (DPM) in an underground mine do not exceed an airborne concentration of 160 micrograms of total carbon per cubic meter of air during an average eight-hour equivalent full shift, effective May 20, 2008. This rulemaking proposes the EC conversion factor for the 160 TC µg/m³ limit, which would allow mine operators to implement the requirements of the May 18, 2006 final rule.

Summary of Legal Basis:

Promulgation of this regulation is authorized by section 101 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 will prepare estimates of the anticipated costs and benefits associated with the selected conversion factor.

Risks:

A number of 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. MSHA believes that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate matter. Proceeding with a separate rulemaking to determine the correct TC to EC conversion factor for the phased-in final limits will more effectively reduce miners' exposures to DPM.

Timetable:

Action	Date	FR Cite
NPRM	05/00/07	
Final Action	05/00/08	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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DOL—MSHA

FINAL RULE STAGE

79. 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). A report by the Office of the

Inspector General (OIG) recommended that MSHA lower its PEL 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. MSHA proposed a rule to lower its permissible exposure limit for asbestos to reduce the occurrence of asbestos-induced occupational disease.

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 12fibers/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 in 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 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 30 minutes. These lowered limits reflected newer information and studies on the 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. While sampling, the MSHA staff also discussed with miners and mine operators the potential hazards of asbestos and the types of preventive measures that could be implemented to reduce exposures.

MSHA's proposed rule did not include standards to address take-home contamination from asbestos nor did MSHA propose to change its analytical method for asbestos. The final rule will be based, in part, on comments and testimony to the proposed rule, as well as MSHA sampling and inspection experience.

Anticipated Cost and Benefits:

MSHA is developing a regulatory economic analysis to accompany the final rule.

Risks:

Miners could be exposed to the hazards of asbestos during mine operations where 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, lung cancer, mesothelioma, and other forms of cancers.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/02	67 FR 15134
Notice of Change to Public Meetings	04/18/02	67 FR 19140
ANPRM Comment Period End	06/27/02	
NPRM	07/29/05	70 FR 42950
NPRM Comment Period End	11/21/05	70 FR 43950
Public Hearing	10/18/05	70 FR 43950
Final Action	03/00/07	

Regulatory Flexibility Analysis Required:

No

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.

URL For More Information:

www.msha.gov

URL For Public Comments:

www.msha.gov

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RIN: 1219-AB24

DOL-MSHA

80. EMERGENCY MINE EVACUATION

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813; 30 USC 825; 30 USC 876

CFR Citation:

30 CFR 48; 30 CFR 50; 30 CFR 75

Legal Deadline:

Final, Statutory, December 9, 2006.

Abstract:

The Mine Safety and Health Administration (MSHA) published an emergency temporary standard on March 9, 2006. Under section 101(b) of the Federal Mine Safety and Health Act of 1977 (Mine Act) the emergency temporary standard was effective immediately. MSHA, however, must publish a final rule no later than nine months after publication of an emergency temporary standard in accordance with section 101(b) of the Mine Act. Therefore, MSHA is issuing a final rule. In addition, the final rule will incorporate relevant requirements of the Mine Improvement and Emergency Response Act (MINER Act). This final rule will include requirements for immediate accident notification applicable to all underground and surface mines. In addition, this final rule also will address requirements for self-contained self-rescuer storage and use; emergency evacuation and self-rescuer training and drills; and the installation and maintenance of lifelines that are applicable to all underground coal mines.

Statement of Need:

MSHA issued the emergency temporary standard, which focused on the evacuation of underground coal mines and immediate accident notification,

applicable to all underground and surface mines, to fill a critical need when a mine emergency occurs. Because the emergency temporary standard was immediately effective, MSHA has gained experienced with the rule. MSHA affirms that the requirements implemented under the emergency temporary standard provide all miners additional critical protection through prompt accident reporting, and in addition provide all underground coal miners additional critical tools and training to complete a successful mine evacuation.

Summary of Legal Basis:

Promulgation of this regulation is authorized by section 101 of the Federal Mine Safety and Health Act of 1977 and the Mine Improvement and New Emergency Response Act of 2006 (Public Law 109-236).

Alternatives:

This final rule would provide: (1) the safety protections afforded to miners by the existing temporary standard; and (2) additional protections through implementation of parts of the MINER Act.

Anticipated Cost and Benefits:

The anticipated costs and benefits of the final rule focus on miners having the tools to successfully escape a serious mine accident that requires emergency evacuation of the mine. MSHA will prepare a regulatory economic analysis for the final rule.

Risks:

Mining continues to be one of the most hazardous occupations in the United States. In calendar year 2004, there were 634 underground coal mine operators employing 33,490 miners and 3,697 contractor workers who work underground in coal mines. In total, there were 214,450 miners and 72,739 contract workers who work in the 14,480 U.S. mines. In 2004, 56 miners died in mining accidents, over 8,000 miners suffered nonfatal injuries resulting in lost work days; and over 3,400 miners suffered injuries that resulted in no lost work days. The final rule requirements, once implemented, will give underground coal miners necessary tools to successfully escape a serious mine accident.

Timetable:

Action	Date	FR Cite
Emergency Temporary Standard	03/09/06	71 FR 12252

Action	Date	FR Cite
Emergency Temporary Standard Effective	04/10/06	
Change of Public Hearing Dates	03/27/06	71 FR 15028
Emergency Mine Evacuation Public Hearing	04/24/06	
Emergency Mine Evacuation Public Hearing	04/26/06	
Emergency Mine Evacuation Public Hearing	04/28/06	
Emergency Mine Evacuation Public Hearing	05/09/06	
Civil Penalties NPRM	09/08/06	71 FR 53054
Civil Penalties—NPRM Comment Period End	10/23/06	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219-AB46

DOL—MSHA

81. CRITERIA AND PROCEDURES FOR PROPOSED ASSESSMENT OF CIVIL PENALTIES

Priority:

Other Significant

Legal Authority:

30 USC 815; 30 USC 820; 30 USC 957; Section 8 of the MINER Act

CFR Citation:

30 CFR 100

Legal Deadline:

None

Abstract:

MSHA is proposing to amend its civil penalty regulations to increase penalty amounts, to revise the process for proposing civil penalties and to implement requirements of the Mine Improvement and New Emergency Response Act (MINER Act) of 2006. The key civil penalty provisions of the MINER Act are: minimum penalties of \$2,000 and \$4,000, respectively, for unwarrantable failure citations and orders; penalties of not less than \$5,000 and not more than \$60,000 for failure to timely notify MSHA of a death or an injury or entrapment with a reasonable potential to cause death; and penalties of up to \$220,000 for “flagrant” violations — those involving “a reckless or repeated failure to make reasonable efforts to eliminate a known violation of a mandatory health or safety standard that substantially and proximately caused, or reasonably could have been expected to cause, death or serious bodily injury.” Updating these regulations will strengthen incentives for compliance.

Statement of Need:

A recent upward trend in citations for violations of MSHA’s safety and health regulations, coupled with a high number of fatalities at mines this year, have called into question the effectiveness of the current civil penalty regulations. Congress responded by passing the MINER Act to provide MSHA with statutory authority for some of the needed changes to the civil penalty regulations. MSHA is proposing additional changes to strengthen existing regulations, which will be an important tool in the reduction of fatalities and improvement in miner safety and health.

Summary of Legal Basis:

Promulgation of this regulation is authorized by the Federal Mine Safety and Health Act of 1977 and the MINER Act of 2006.

Alternatives:

The Agency considered a variety of approaches to calculating civil penalties and is proposing the approach that it believes best achieves the objectives of the Agency.

Anticipated Cost and Benefits:

Using 2005 violation and assessment data as a baseline, MSHA estimates that all violations in 2005, if assessed under the proposed rule, would result in approximately \$68 million in penalties annually, which is an increase of \$43 million. However, MSHA projects that

the higher penalties will induce operators to increase compliance efforts, thereby decreasing the number of violations by about 19% and resulting in increased penalties of \$21 million.

MSHA believes the projected increased compliance with health and safety regulations would result in fewer injuries and fatalities, but such benefits have not been scientifically established. Accordingly, MSHA has not prepared a quantitative estimate of the expected reduction in injuries and fatalities.

Risks:

The Mine Act imposes civil penalties as a means of ensuring compliance with the requirements of the Act. The Congress intended that the imposition of civil penalties would induce mine operators to be proactive in their approach to mine safety and health, and take necessary action to prevent safety and health hazards before they occur. MSHA’s regulations apply to 14,480 mine operators and 6,693 independent contractors, as well as the 214,450 miners and 72,739 contract workers they employ.

Timetable:

Action	Date	FR Cite
NPRM	09/08/06	71 FR 53054
NPRM Comment Period End	11/09/06	71 FR 62572
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219-AB51

DOL—Occupational Safety and Health Administration (OSHA)**PRERULE STAGE****82. 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. 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 Health Effects and Risk Assessment	04/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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DOL—OSHA**83. HAZARD COMMUNICATION****Priority:**

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910.1200; 29 CFR 1915.1200; 29 CFR 1917.28; 29 CFR 1918.90; 29 CFR 1926.59; 29 CFR 1928.21

Legal Deadline:

None

Abstract:

OSHA's Hazard Communication Standard (HCS) requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import, and prepare labels and material safety data sheets to convey the hazards and associated protective measures to users of the chemicals. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including labels on containers, material safety data sheets, and training for employees. Within the United States (US), there are other Federal agencies that also have requirements for classification and labeling of chemicals at different stages of the life cycle. Internationally, there are a number of countries that have developed similar laws that require information about chemicals to be prepared and transmitted to affected parties. These laws vary with regard to the scope of substances covered, definitions of hazards, the specificity of requirements (e.g., specification of a format for MSDSs), and the use of symbols and pictograms. The inconsistencies between the various laws are substantial enough that different labels and safety data sheets must often be used for the same product when it is marketed in different nations.

The diverse and sometimes conflicting national and international requirements can create confusion among those who seek to use hazard information. Labels and safety data sheets may include symbols and hazard statements that are unfamiliar to readers or not well understood. Containers may be labeled with such a large volume of information that important statements are not easily recognized. Development of multiple sets of labels and safety data sheets is a major compliance burden for chemical manufacturers, distributors, and transporters involved in international trade. Small businesses may have particular difficulty in coping with the complexities and costs involved.

As a result of this situation, and in recognition of the extensive international trade in chemicals, there has been a longstanding effort to

harmonize these requirements and develop a system that can be used around the world. In 2003, the United Nations adopted the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Countries are now considering adoption of the GHS into their national regulatory systems. There is an international goal to have as many countries as possible implement the GHS by 2008. OSHA is considering modifying its HCS to make it consistent with the GHS. This would involve changing the criteria for classifying health and physical hazards, adopting standardized labeling requirements, and requiring a standardized order of information for safety data sheets.

Statement of Need:

Multiple sets of requirements for labels and safety data sheets present a compliance burden for U.S. manufacturers, distributors and transports involved in international trade. Adoption of the GHS would facilitate international trade in chemicals, reduce the burdens caused by having to comply with differing requirements for the same product, and allow companies that have not had the resources to deal with those burdens to be involved in international trade. This is particularly important for small producers who may be precluded currently from international trade because of the compliance resources required to address the extensive regulatory requirements for classification and labeling of chemicals. Thus every producer is likely to experience some benefits from domestic harmonization, in addition to the benefits that will accrue to producers involved in international trade.

Additionally, comprehensibility of hazard information will be enhanced as the GHS will: (1) Provide consistent information and definitions for hazardous chemicals; (2) address stakeholder concerns regarding the need for a standardized format for material safety data sheets; and (3) increase understanding by using standardized pictograms and harmonized hazard statements.

Several nations, as well as the European Union, are preparing proposals for adoption of the GHS. US manufacturers, employers, and employees will be a disadvantage in the event that our system of hazard communication is not compliant with the GHS.

Summary of Legal Basis:

The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women. (29 USC 651)

Alternatives:

The alternative to the proposed rulemaking would be to take no regulatory action.

Anticipated Cost and Benefits:

The estimates of the costs and benefits are still under development.

Risks:

OSHA's risk analysis is under development.

Timetable:

Action	Date	FR Cite
ANPRM	09/12/06	71 FR 53617
ANPRM Comment Period End	11/13/06	
Review Comments	02/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 1218-AC20

DOL—OSHA

PROPOSED RULE STAGE

84. CRANES AND DERRICKS

Priority:

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

Legal Authority:

29 USC 651(b); 29 USC 655(b); 40 USC 333

CFR Citation:

29 CFR 1926

Legal Deadline:

None

Abstract:

A number of industry stakeholders asked OSHA to update the cranes and derricks portion of subpart N (29 CFR 1926.550), specifically requesting that negotiated rulemaking be used.

In 2002 OSHA published a notice of intent to establish a negotiated rulemaking committee. A year later, in 2003, committee members were announced and the Cranes and Derricks Negotiated Rulemaking Committee was established and held its first meeting. In July 2004, the committee reached consensus on all issues resulting in a final consensus document.

Statement of Need:

There have been considerable technological changes since the consensus standards upon which the 1971 OSHA standard is based were developed. In addition, industry consensus standards for derricks and crawler, truck and locomotive cranes were updated as recently as 2004.

The industry indicated that over the past 30 years, considerable changes in both work processes and crane technology have occurred. There are estimated to be 64 to 82 fatalities associated with cranes each year in

construction, and a more up to date standard would help prevent them.

Summary of Legal Basis:

The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women. (29 USC 651)

Alternatives:

The alternative to the proposed rulemaking would be to take no regulatory action and not update the standards in 29 CFR 1926.550 pertaining to cranes and derricks.

Anticipated Cost and Benefits:

The estimates of the costs and benefits are still under development.

Risks:

OSHA's risk analysis is under development.

Timetable:

Action	Date	FR Cite
Notice of Intent To Establish Negotiated Rulemaking	07/16/02	67 FR 46612
Comment Period End	09/16/02	
Request for Comments on Proposed Committee Members	02/27/03	68 FR 9036

Action	Date	FR Cite
Request for Comment Period End	03/31/03	68 FR 9036
Established Negotiated Rulemaking Committee	06/12/03	68 FR 35172
Rulemaking Negotiations Completed	07/30/04	
SBREFA Report	10/17/06	
NPRM	10/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

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DEPARTMENT OF TRANSPORTATION (DOT)

Statement of Regulatory Priorities

The Department of Transportation (DOT) consists of ten operating administrations, 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 the Department has been to increase the timeliness of DOT rulemaking actions and address the large number of old rulemakings. To implement this, the following actions have been 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.

The Department will also 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 role in the Department's efforts to improve our economic analyses; risk assessments; regulatory flexibility analyses; other related analyses; and data quality, including peer reviews.

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 2007, OST will continue its efforts 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.

OST also is helping to coordinate the activities of several operating administrations that advance the Department's congestion initiative. Specific rulemakings concerning congestion relief can be found under the headings of the operating administrations.

Federal Aviation Administration (FAA)

The Federal Aviation Administration is charged with safely and efficiently operating and maintaining the most complex aviation system in the world. It is guided by its Flight Plan goals — Increased Safety, Greater Capacity, International Leadership, and Organizational Excellence. It issues regulations to provide a safe and efficient global aviation system for civil aircraft. Activities that may lead to rulemaking include:

- Promotion and expansion of safety information sharing efforts such as FAA-industry partnerships and data-driven safety programs that prioritize and address risks before they lead to accidents. Specifically, FAA will continue implementing Commercial Aviation Safety Team projects related to controlled flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decision making, and cabin safety. Some of these projects may result in rulemaking and guidance materials.
- Continuing to work cooperatively to harmonize the U.S. aviation regulations with those of other countries. 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. Standardization should help the U.S. aerospace industry remain internationally competitive. The FAA continues to publish regulations based on recommendations of Aviation Rulemaking Committees that are the result of cooperative rulemaking between the U.S. and other countries.

Top regulatory priorities for 2006-2007 include a proposal concerning

commuter operations in very light jets, a rulemaking to address Fuel Tank Flammability Reduction in Transport Category Airplanes, 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:

- (1) Airplanes being operated beyond their original design service goals;
- (2) The 1988 Aloha Boeing 737 accident; and
- (3) The Aging Airplane Safety Act of 1991.

Other significant rulemakings included in the Aging Airplane Program are:

- (1) Enhanced Airworthiness Program for Aging Systems/Fuel Tank Safety; and
- (2) Widespread Fatigue Damage Program.

FAA also is taking actions to advance the Department's congestion initiative. FAA is currently working on a congestion management rule for La Guardia Airport in New York (2120-AI87) and previously issued a similar rule for O'Hare Airport in Chicago.

Federal Highway Administration (FHWA)

The Federal Highway Administration (FHWA) carries out the Federal highway program in partnership with State and local agencies to meet the Nation's transportation needs. The FHWA's mission is to improve continually the safety, quality and performance of our Nation's highway system.

On August 10, 2005, President George W. Bush signed the Safe, Accountable, Flexible, and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU). SAFETEA-LU authorizes the Federal surface transportation programs for highways, highway safety, and transit for the five-year period from 2005-2009. FHWA intends to implement this legislation:

- in the least burdensome and restrictive way possible;
- 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; and
- to encourage significantly greater participation by the private sector in

financing and operating highway infrastructure, and increase State and local emphasis on operational and system pricing improvements than can reduce congestion.

Consistent with this mission, the FHWA will continue to advance the Department's congestion initiative that was announced in May, 2006. There are several regulations that impact this initiative, including:

- Surface Transportation Project Delivery Pilot Program (2125-AF13);
- Design Build (2125-AF12);
- Express Lane Demonstration Project (2125-AF07);
- Projects of National and Regional Significance (2125-AF08);
- Metropolitan Transportation Planning (2125-AF09)
- Environmental Review of Activities that Support the Deployment of ITS Projects (2125-AF15).

In addition to these congressionally directed rulemakings the FHWA has also been directed to complete the following rules:

- (1) Parks, Recreation Areas, Wildlife and Waterfowl Refuges, and Historic Sites (2125-AF14);
- (2) Worker Visibility (2125-AF11); and
- (3) Temporary Traffic Control Devices (2125-AF10).

These rulemakings are the FHWA's top regulatory priorities for 2006-2007. Additionally, the FHWA is in the process of reviewing all FHWA regulations to ensure that they are consistent with SAFETEA-LU and will update those regulations that are not consistent with the recently enacted legislation.

Finally, the FHWA continues to work to complete the rulemaking that proposes to amend the Manual on Uniform Traffic Control Devices (MUTCD) to include a standard for minimum maintained levels of traffic sign retroreflectivity and methods to maintain traffic sign retroreflectivity at or above these levels. This rulemaking (2125-AE98) addresses comments received in response to the Office of Management and Budget's (OMB's) request for regulatory reform nominations from the public. The OMB is required to submit an annual report to Congress on the costs and benefits of Federal regulations. The 2002 report included recommendations for regulatory reform that OMB requested from the public. One recommendation was that the FHWA should establish

standards for minimum levels of brightness of traffic signs. The FHWA has identified this rulemaking as responsive to that recommendation.

Federal Motor Carrier Safety Administration (FMCSA)

The mission of the Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries, and fatalities involving commercial trucks and buses. A strong regulatory program is a cornerstone of FMCSA's compliance and enforcement efforts to advance this safety mission. Developing new, amended, and more effective safety regulations is key to achieving increased safety on our Nation's highways. FMCSA regulations establish standards for drivers, carriers, States, and others that create improved safety conditions and operating practices. In its first 6 years of operation, FMCSA has responded to Congress' concerns over delays in timely rulemaking, as expressed in the Motor Carrier Safety Improvement Act of 1999 (MCSIA). FMCSA is making steady progress in systematically addressing this backlog.

First, FMCSA developed a directive establishing standard rulemaking procedures with ongoing oversight and involvement by senior agency leaders to lend structure and accountability to the rulemaking process. It continues to monitor the process and update the directive when additional issues are identified.

Second, FMCSA has made significant progress in reducing the backlog of rules including those not mandated by Congress but initiated by FMCSA itself to increase safety. FMCSA has completed all required MCSIA rulemakings, except "Medical Certification as Part of the Commercial Driver's License" (RIN 2126-AA10), which is among its highest priorities and is included in the Regulatory Plan. It will serve as a significant step in a comprehensive update of how FMCSA addresses the medical condition of drivers who operate commercial motor vehicles (CMVs). Also, the "Unified Registration System" rulemaking (RIN 2126-AA22) remains in the Agency's Regulatory Plan. This rule would create a new, unified and updated registration system that benefits both the users with simplified processes and FMCSA with better data. This new rule will include new provisions added by our reauthorization legislation, the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU).

SAFETEA-LU added a significant number of new regulatory projects to FMCSA's docket. The Agency is committed to using its resources and personnel in the most effective manner to promulgate these additional rules while still completing an already challenging rulemaking agenda. FMCSA has already completed one SAFETEA-LU rule this year, "Commercial Driver's License Standards; School Bus Endorsement" (RIN 2126-AA94). Additionally, FMCSA has added to its Regulatory Plan the "National Registry of Certified Medical Examiners" rulemaking (RIN 2126-AA97). This latter rulemaking would provide for a database or "National Registry" of medical examiners and would establish training, testing, and certification standards for the medical examiners who certify that interstate commercial motor vehicle drivers meet the FMCSA's physical qualifications standards.

FMCSA also continues work on its "Electronic On-Board Recorders for Hours-of-Service Compliance" (RIN 2126-AA89) rulemaking. This rule would implement performance standards for the use of electronic on-board recording devices and ensure that these standards reflect state-of-the-art information and management technologies.

In addition, under the Manufacturing Regulatory Reform Agenda, FMCSA continues work on its "Parts and Accessories Necessary for Safe Operations; Surge Brake Requirements" rulemaking. This rulemaking would allow the use of automatic hydraulic inertia brake systems (surge brakes) on trailers operated in interstate commerce.

In the past year, FMCSA issued a final rule on hours of service (HOS). This rule responded to both the concerns of the U.S. Court of Appeals for the D.C. Circuit and the action of Congress, which extended the effective date of the April 2003 HOS final rule until September 30, 2005. The new HOS final rule became effective on October 1, 2005. In addition, the Agency continues work on its Comprehensive Safety Analysis 2010 (CSA 2010) initiative, which will improve the way FMCSA conducts compliance and enforcement operations over the coming years. CSA 2010's goal is to improve large truck and bus safety by assessing a wider range of safety performance data of a larger segment of the motor carrier industry through an array of progressive compliance interventions. FMCSA is targeting 2010 for full deployment of this new operational model. The Agency anticipates that the results of CSA 2010

and its associated rulemakings will contribute further to the Agency's overall goal of decreasing CMV-related fatalities and injuries.

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 non-regulatory 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 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.

NHTSA continues to pursue the high priority vehicle safety area of vehicle compatibility. In FY 2007, a final rule is planned for a significant upgrade to the side impact standard, FMVSS No. 214. A notice of proposed rulemaking was published for the side impact upgrade in 2004. Publication of this final rule also will meet a regulatory requirement in the Safe, Accountable, Flexible, and Efficient Transportation Equity Act of 2005 (SAFETEA-LU). Significant actions in crash avoidance will include a final rule aimed at shortening heavy truck stopping distances. A notice of proposed rulemaking was published in 2005 for heavy truck stopping distances. A rulemaking notice is planned for FY 2007 that would propose requiring Electronic Stability Control (ESC) systems on all newly-manufactured passenger cars and light trucks. Publication of this notice also will meet a regulatory requirement in SAFETEA-LU. In addition, the Agency will publish an update to the NHTSA Vehicle Safety Rulemaking Priorities and Supporting Research plan, originally published in FY 2003 and updated in FY 2005. The plan highlights the agency's priority rulemaking actions to help address the most significant vehicle safety needs.

Relative to the Manufacturing Regulatory Reform Agenda, NHTSA is

engaged in two rulemaking activities that will be addressed in 2007. First, in response to requests from industry to organize FMVSS No. 108 in a more understandable way, a final rule is planned for an administrative rewrite of the standard. This action presents the newly organized text of FMVSS No. 108, including importing referenced requirements from applicable SAE standards directly into the text of FMVSS No. 108. Secondly, as part of the agency's comprehensive approach to occupant ejection mitigation, NHTSA plans to publish final rules for the FMVSS No. 214 side impact upgrade as well as the FMVSS No. 206 door retention performance upgrade. The latter rulemaking will be the first standard to harmonize with the first global technical regulation, and will respond to the requirements mandated in Title X, Subtitle C, Sec. 10301, section 30128 (c) (2) of SAFETEA-LU.

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 regulatory authority over all areas of railroad safety, fashioning regulations that have favorable benefit-to-cost ratios and that, where feasible, incorporate flexible performance standards and require cooperative action by all affected

parties. In order to foster an environment for 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 meets regularly, and its working groups are actively addressing the following tasks: (1) the development of safety standards for handling railroad equipment to reduce the number of human factor caused accidents; (2) revisions to the locomotive safety standards; and (3) the development of passenger train emergency systems. Recently, FRA published a final rule on locomotive crashworthiness that establishes comprehensive, minimum crashworthiness protection standards to reduce crew injuries and fatalities as a result of locomotive collisions.

Federal Transit Administration (FTA)

The Federal Transit Administration (FTA) provides financial assistance to State and local governments for public 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 public transportation needs have changed over the years, so have the requirements for Federal financial assistance under the Federal transit laws and related statutes. As a result of the

reauthorization legislation, the FTA's regulatory activity will include a number of substantive rulemakings. A few of those rulemakings are explicitly mandated by the statute. Others will become necessary simply to make amendments to current regulations to make them consistent with the statute. FTA's regulatory priorities for the coming year will be reflective of the directives and the programmatic priorities established by the statute.

FTA participates in the Department's congestion initiative. Current projects that will advance the initiative include Metropolitan Transportation Planning (2132-AA82) and New/Small Starts (2132-AA81).

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.

Pipeline and Hazardous Materials Safety Administration (PHMSA)

The Pipeline and Hazardous Materials Administration (PHMSA) has responsibility for rulemaking under two programs. Through the Associate Administrator for Hazardous Materials Safety, PHMSA 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, PHMSA 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.

A significant priority in the coming year will be an initiative to enhance the safety and security of hazardous materials transported by rail. Working

with the Department of Homeland Security's Transportation Security Administration and FRA, PHMSA is considering revising the Hazardous Materials Regulations to require rail carriers to (1) compile annual data on certain shipments of hazardous materials and use the data to analyze safety and security risks along rail transportation routes where those materials are transported; and (2) assess alternative routing options and make routing decisions based on those assessments. We may also address measures to enhance the safety and security of hazardous materials rail shipments stored during transportation.

Research and Innovative Technology Administration (RITA)

The Research and Innovative Technology Administration (RITA) seeks to identify and facilitate solutions to the challenges and opportunities facing America's transportation system through:

- coordination, facilitation, and review of the Department's research and development programs and activities;
- advancement, and research and development, of innovative technologies, including intelligent transportation systems;
- comprehensive transportation statistics research, analysis, and reporting;
- education and training in transportation and transportation-related fields; and
- managing the activities of the Volpe National Transportation Center.

Through its Bureau of Transportation Statistics, RITA collects, compiles, analyzes, and makes accessible information on the Nation's transportation system. RITA 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 airline operations and is used in supporting policy initiatives, negotiating international bilateral aviation agreements, awarding international route authorities, and meeting international treaty obligations.

RITA's regulatory priorities are to assist OST and all DOT modal administrations in updating existing regulations by applying research and technology results, and to provide information to transportation system decision makers.

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

85. • +COMMUTER OPERATIONS IN VERY LIGHT JETS (VLJS)

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 1155; 49 USC 40103; 49 USC 40113; 49 USC 40119; 49 USC 40120; 49 USC 44101; 49 USC 44111; 49 USC 44701 to 44702 ; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44711; 49 USC 44712; 49 USC 44713; 49 USC 44715; 49 USC 44716 to 44717; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912; 49 USC 46105; 49 USC 46306; 49 USC 46316; 49 USC 46504; 49 USC 46506 to 46507; 49 USC 47122; 49 USC 47508; 49 USC 47528 to 47531

CFR Citation:

14 CFR 1; 14 CFR 119; 14 CFR 121; 14 CFR 125; 14 CFR 135; 14 CFR 21; 14 CFR 23; 14 CFR 27; 14 CFR 29; 14 CFR 61; 14 CFR 91

Legal Deadline:

None

Abstract:

This rulemaking proposes changes to the certification and operation regulations to accommodate the entry into the airspace system of very light jets. These proposed regulations are necessary because of the introduction of a new type of airplane as a result of significant changes in the aviation industry. The proposals originated, in part, from recommendations from the Aviation Rulemaking Committee for Parts 135/125. The rulemaking will include aircraft certification, pilot crew, equipment, training, and dispatch requirements for the safe operation of this new type of airplane.

Statement of Need:

Several models of very light jets are currently under certification and are expected to start production late 2006. Current rules for on-demand and commuter operations do not adequately address these airplanes nor address the safety implications of the introduction of a new generation of aircraft fleet.

There also exists a regulatory barrier to using these airplanes in scheduled service. Some air carriers have proposed business models for use of these airplanes in scheduled service. Part 119 requires all turbojets used in scheduled service to operate under part 121. It also requires newly certificated (after March 1995) airplanes to be type certificated under part 25 if they are used in part 121 operations. These new generation turbojets are type certificated under part 23 and therefore cannot be used in scheduled service under either part 135 or 121.

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 could ignore the opportunity to codify the special conditions under which these airplanes were certificated, but that would be an undesirable alternative as various versions of special conditions could be developed.

Maintaining the current rules regarding scheduled operations is not in the public interest and deprives the public of a viable transportation option. In addition, the current rules do not adequately address the introduction of these new generation airplanes. The status quo on the additional safety

criteria could have a negative impact on safety.

Anticipated Cost and Benefits:

If the FAA requires two pilots for the initial operation of the VLJ, there obviously will be added costs. However, if these airplanes were operated in scheduled service under part 121, two pilots would be required. In addition, the requirement for dispatch for scheduled operations could be potentially very costly. Again, if these airplanes were operated under part 121 in scheduled operations, dispatch would be required. This rule provides a business opportunity to operate in scheduled service under part 135 which has lower operating and certification costs than part 121. There are costs for additional equipment and other safety enhancements; however, these are mitigated by the fact that the airplanes currently under certification will meet many of these items as part of their certification. The additional safety requirements will reduce the anticipated spike in number of accidents historically shown with the introduction of a new generation aircraft.

Risks:

The risk of not doing the rulemaking is that the airplanes would be operated under the unscheduled rules of part 145, which allow a single pilot. It would also create numerous petitions for exemption.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120-AI84

DOT—FAA

FINAL RULE STAGE

86. +AGING AIRCRAFT PROGRAM (WIDESPREAD FATIGUE DAMAGE)

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 41706; 49 USC 44101; 49 USC 44701 to 44702; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44713; 49 USC 44716 to 44717; 49 USC 44722; 49 USC 46105; 49 USC 1372; Pub L 107-71 sec 104; ...

CFR Citation:

14 CFR 121; 14 CFR 129

Legal Deadline:

None

Abstract:

This action is intended to prevent widespread fatigue damage by proposing to require that design approval holders establish operational limits on transport category airplanes. Design approval holders would also be required to determine if maintenance actions are needed to prevent widespread fatigue damage before an airplane reaches its operational limit. Operators of any affected airplane would be required to incorporate the operational limit and any necessary service information into their maintenance programs. Operation of an affected airplane beyond the operational limit would be prohibited, unless an operator has incorporated an extended operational limit and any necessary service information into its maintenance program.

Statement of Need:

History has shown that widespread fatigue damage (WFD) 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	04/18/06	71 FR 19927

Action	Date	FR Cite
NPRM Comment Period End	07/17/06	
NPRM Comment Period Extended	07/17/06	71 FR 38540
NPRM Extended Comment Period End	09/18/06	
Final Rule	09/00/07	

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

87. +TRANSPORT AIRPLANE FUEL TANK FLAMMABILITY REDUCTION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 44701 to 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 establishes 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 efforts and places an 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
NPRM	11/23/05	70 FR 70922
NPRM Comment Period Extended	03/21/06	71 FR 14122
Comment Period End	05/08/06	
Final Rule	09/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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

88. +MEDICAL CERTIFICATION REQUIREMENTS AS PART OF THE COMMERCIAL DRIVER'S LICENSE

Priority:

Other Significant

Legal Authority:

sec 215, PL 106-159; 113 Stat 1748, 1767 (1999); 49 USC 31305 note and 31502

CFR Citation:

49 CFR 383, 384, and 391

Legal Deadline:

None

Abstract:

This rulemaking would require those commercial drivers license (CDL) drivers who are required to obtain a Federal medical certification, to make

the current status of that certification part of the commercial drivers licensing and renewal process, as required by section 215 of the Motor Carrier Safety Improvement Act. Incorporating the current medical certification status information into the State-administered Commercial Drivers License Information System (CDLIS) driver record would improve highway safety by requiring those drivers who are federally required to obtain a medical certificate to provide proof of that medical certification in order to obtain or retain a CDL. It would enable electronic verification of the current medical certification status as part of existing employer and enforcement programs. It is proposed to eliminate the requirement for this portion of CDL operators to carry their medical examiners certificate in addition to their CDL since an electronic record would verify that there is a valid medical certificate.

Statement of Need:

This rule is required by Public Law 106-159. Section 215 of the Act requires that medical certification information be made part of the CDL. When applying for (or renewing) a CDL, 49 CFR part 383 requires drivers to self-certify whether they are subject to part 391 (Qualifications of Drivers). If they operate in interstate commerce and are not excepted, then part 383 requires these drivers to self-certify whether they meet the physical qualification requirements of part 391. Part 383 does not currently require drivers to provide any proof regarding their physical qualification to operate a CMV in order to obtain or retain a CDL. This rulemaking would require interstate CDL drivers who are not excepted to begin providing to their State driver-licensing agency (SDLA) an original or copy (at the States discretion) of each medical examiners certificate they obtain. The SDLA would modify their implementation of CDLIS and record information on that drivers Commercial Driver License Information System (CDLIS) individual driver record maintained by the State. The new required information would include both the self-certification regarding applicability of part 391, and for interstate drivers who are not excepted, the current medical certification status information. This combination of information about the applicability of part 391 and medical certification status would determine whether a CDL could be issued, transferred, upgraded, renewed, or retained.

Summary of Legal Basis:

Section 215 of the Motor Carrier Safety Improvement Act of 1999 (MCSIA) directed the Secretary of Transportation (Secretary) to initiate a rulemaking to provide for a Federal medical qualification certificate to be made a part of commercial drivers licenses. The physical qualifications requirements in 49 CFR part 391 are based on 49 U.S.C. 31136 and 31502. The physical qualifications standards are at 49 CFR 391.11. Part 391 regulations are applicable only to drivers who operate CMVs, as defined in 49 U.S.C. 31132. Thus, FMCSA interprets section 215 of MCSIA applicable only to interstate CDL holders.

The Commercial Motor Vehicle Safety Act of 1986 directed the Secretary to establish licensing standards for drivers that operate CMVs, as defined in 49 U.S.C. 31301. Those operators of CMVs as defined in 49 U.S.C. 31301, who are engaged solely in intrastate commerce, must obtain a CDL but are not required by current Federal regulations to obtain a medical certificate as proof of their physical qualifications to operate commercial vehicles. [49 CFR 383.71(a)(1)]. The Secretary delegated these authorities to FMCSA. [49 CFR § 1.73].

Alternatives:

All alternatives require SDLAs to modify CDLIS and record self-certification whether part 391 is applicable, i.e., whether or not driver operates in interstate commerce and is not excepted. If part 391 applicable, SDLA would record medical certification status. Under alternatives 1 and 2, SDLAs receive paper and perform data input. Under alternative 3, SDLAs would receive an electronic CDLIS transaction.

Under all three alternatives, the CDLIS driver record maintained by SDLA would serve as official record of whether driver is authorized to operate in interstate commerce and thus is required to be currently medically certified.

For drivers subject to part 391 and not excepted, employers would obtain medical certification status on the CDLIS motor vehicle record (MVR) from SDLA, as well as license status. Enforcement personnel would obtain current license status, whether driver operates in interstate commerce, and medical certification status via electronic checks.

1. CDL Renewal Cycle Same as Medical Certificate.

Driver provides each medical examiner's certificate to SDLA, which issues new CDL expiring same day as certificate. CDLs issued more often, and drivers pay fees States assess.

2. No Change in CDL Renewal Cycle-Distributed.

As in alternative 1, CDL drivers provide each medical examiner's certificate to SDLA. SDLAs develop capability to downgrade CDL if new certification not received by expiration.

3. No Change in CDL Renewal Cycle-Centralized.

Certificates go to central location. Status information electronically transmitted to SDLA, which develops capability to electronically receive and record on CDLIS driver record. As in alternative 2, SDLA downgrades CDL if new certificate not received by expiration.

Anticipated Cost and Benefits:

A preliminary regulatory evaluation for this rule was prepared and will be placed in the docket when the NPRM is published.

Risks:

In addition to assessing costs, the agency is assessing the safety benefits.

Timetable:

Action	Date	FR Cite
ANPRM	07/15/94	59 FR 36338
ANPRM Comment Period End	11/14/94	
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State

Additional Information:

Docket No. FMCSA-97-2210.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2126-AA10

DOT—FMCSA

89. +UNIFIED REGISTRATION SYSTEM

Priority:

Other Significant

Legal Authority:

49 USC 13908, as amended by sec 4304 of PL 109-159, 119 Stat 1144, 1763

CFR Citation:

49 CFR 360, 365, 366, 368, 387, and 390

Legal Deadline:

Final, Statutory, August 10, 2006.

Abstract:

This rulemaking would replace three current identification and registration systems: the US DOT number identification system, the commercial registration system, and the financial responsibility system, with an online Federal unified registration system. This program would serve as a clearinghouse and depository of information on, and identification of, brokers, freight forwarders, and others required to register with the Department of Transportation. The Agency is revising this rulemaking to address amendments directed by SAFETEA-LU. The replacement system for the Single State Registration System, which the ICC Termination Act originally directed be merged under URS, will be addressed separately.

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 DOT. Congress mandated that the Agency consider unifying the four current systems with a single, on-line Federal system. SAFETEA-LU [Pub. L. 109-159, 119 Stat. 2955, August 10, 2005] imposed new requirements for the Federal on-line replacement 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 which comprise 80% of motor carriers. For instance, we considered exempting existing carriers from certain new filing requirements (via a grandfather clause), with the view that it would minimize the compliance costs of this proposal. However, while reducing compliance costs (and thereby improving filing efficiency), it would also reduce, not enhance, 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 act 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 reduce the fairness of the registration process. Additionally, either option would reduce safety relative to the proposal discussed here.

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 is in the docket.

Risks:

The proposed rule is intended to streamline the registration process and ensure that FMCSA can more efficiently track CMVs and ensure their safe operation. The Unified Registration System imposes no operational responsibilities on drivers. Therefore, the proposed regulation would not impair a driver’s ability to operate vehicles safely; would not impact the physical condition of drivers; and would not have a deleterious effect on the physical condition of drivers, in accordance with the statutory mandate of 49 U.S.C. 31136 (a).

Timetable:

Action	Date	FR Cite
ANPRM	08/26/96	61 FR 43816
ANPRM Comment Period End	10/25/96	
NPRM	05/19/05	70 FR 28990
NPRM Comment Period End	08/17/05	
Supplemental NPRM	06/00/07	

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

90. +NATIONAL REGISTRY OF CERTIFIED MEDICAL EXAMINERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

Sec. 4116 of PL 109-59 (2005)

CFR Citation:

49 CFR 390; 49 CFR 391

Legal Deadline:

None

Abstract:

This rulemaking would establish training, testing and certification standards for medical examiners responsible for certifying that interstate commercial motor vehicle drivers meet established physical qualifications standards; provide a database (or National Registry) of medical examiners that meet the prescribed standards for use by motor carriers, drivers, and Federal and State enforcement personnel in determining whether a medical examiner is qualified to conduct examinations of interstate truck and bus drivers; and require medical examiners to transmit electronically to FMCSA the name of drivers and a numerical identifier for each driver that is examined. The rulemaking would also establish the process by which medical examiners that fail to meet or maintain the minimum standards would be removed from the National Registry. This action is in response to section 4116 of SAFETEA-LU.

Statement of Need:

In enacting the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) [PL 109-59, August 10, 2005], Congress recognized the need to improve the quality of the medical certification of drivers. SAFETEA-LU addresses the requirement for medical examiners to receive training in physical examination standards and be listed on the National Registry of Certified Medical Examiners (NRCME) (once established) as one step toward improving the quality of the commercial motor vehicle (CMV) driver physical examination process and the medical fitness of CMV drivers to operate CMVs. The impact will result from removing drivers who are not medically qualified to drive from interstate driving, and also from requiring drivers to seek medical treatment for conditions (such as hypertension) that are likely to impact safety and driver health. FMCSA has determined that focusing on driver

factors, including their medical fitness, is one strategy for improving safety and reducing fatalities on our highways.

Summary of Legal Basis:

The fundamental legal basis for the NRCME program comes from 49 U.S.C. 31149(d), which authorizes FMCSA to establish and maintain a current national registry of medical examiners. FMCSA is also directed to determine which medical examiners are qualified to perform examinations of CMV drivers and to issue medical certificates. FMCSA is authorized to remove from the registry any medical examiner who fails to meet or maintain qualifications established by FMCSA. In addition, in developing its regulations, FMCSA must consider both the effect of driver health on the safety of CMV operations and the effect of such operations on driver health, 49 U.S.C. 3113(a).

Alternatives:

FMCSA is considering how best to address the concerns expressed by Congress. In doing so, we are exploring several options. We will discuss the various alternatives in a planned notice of proposed rulemaking.

Anticipated Cost and Benefits:

Because FMCSA has not yet published a notice of proposed rulemaking, the anticipated costs and benefits have not yet been fully explored.

Risks:

FMCSA has not yet fully assessed the risks that might be associated with this activity.

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2126-AA97

DOT—National Highway Traffic Safety Administration (NHTSA)

FINAL RULE STAGE

91. +ROOF CRUSH RESISTANCE

Priority:

Other Significant

Legal Authority:

49 USC 322; 49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166

CFR Citation:

49 CFR 571.216

Legal Deadline:

Final, Statutory, July 1, 2008.

Abstract:

Mitigation of rollover fatal and serious injuries is one of the Agency's highest priorities. Rollover crashes constitute about 3 percent of passenger vehicle crashes, but about 1/3 of the fatalities. Since light trucks are more prone to rollover, and as their percentage of the U.S. fleet continues to increase, this crash mode continues to constitute a disproportionate segment of the Nation's highway safety problem. As part of the Agency's comprehensive approach to rollover, the Agency is considering whether an upgrade to the roof crush requirements is warranted. This rulemaking is significant because of public interest in vehicle safety.

Statement of Need:

Rollovers are especially lethal crashes. While rollovers comprise just 3% of all light passenger vehicle crashes, they account for almost one-third of all occupant fatalities in light vehicles, and more than 60 percent of occupant deaths in the SUV segment of the light vehicle population.

Agency data show that nearly 24,000 occupants are seriously injured and 10,000 occupants are fatally injured in approximately 273,000 non-convertible

light vehicle rollover crashes that occur each year. In order to identify how many of these occupants might benefit from the proposed upgrade, the agency analyzed real-world injury data in order to determine the number of occupant injuries that could be attributed to roof intrusion. The agency examined front outboard occupants who were belted, not fully ejected from their vehicles, whose most severe injury was associated with roof contact, and whose seating position was located below a roof component that experienced vertical intrusion as a result of a rollover crash. NHTSA estimates that there are about 807 seriously and approximately 596 fatally injured occupants per year that fit these criteria. The agency believes that some of these occupants would benefit from this upgrade.

Summary of Legal Basis:

Section 30111, title 49 of the USC, states that Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The agency will consider alternative performance criteria and test procedures suggested by various organizations in response to the NPRM. Alternative performance criteria include a platen displacement criteria on one (or both) sides of the vehicle, as well as combinations of headroom and platen displacement criterion. Alternative test procedures included: the Jordan Rollover System, the Controlled Rollover Impact System, the FMVSS No. 208 dolly rollover test, the inverted drop test, and the weight drop onto the roof test. The agency will also keep abreast of the latest developments in structural roof strength materials, and tooling technologies.

Anticipated Cost and Benefits:

In the NPRM, the agency estimated benefits of this proposal to range from 498 to 793 non-fatal injuries and 13 to 44 fatalities. The annual equivalent lives saved were estimated at 39 to 55.

The estimated average cost in 2003 dollars, per vehicle, of meeting the proposed requirements would be \$10.67 per affected vehicle. Added weight from design changes is estimated to increase lifetime fuel costs by \$5.33 to \$6.69 per vehicle. The cost per year for the vehicle fleet is estimated to be \$88-\$95 million. The cost per equivalent life saved is estimated to range from \$2.1 to \$3.4 million.

Risks:

Current motor vehicles provide numerous occupant protection systems, such as side curtain air bags, upper interior padding, and advanced safety belt systems, that mitigate occupant head-to-roof contact injuries. Nevertheless, an estimated 498-793 non-fatal injuries and 13-44 fatalities will continue to occur annually, absent the proposed change in regulation. Potential adverse risks the agency is also evaluating include a causal increase in rollover propensity that could overwhelm the anticipated benefits from this upgrade.

Timetable:

Action	Date	FR Cite
Request for Comments	10/22/01	66 FR 53376
RFC Comment Period End	12/06/01	
NPRM	08/23/05	70 FR 49223
NPRM Comment Period End	11/21/05	
Final Rule	08/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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Related RIN: Related to 2127-AH74

RIN: 2127-AG51

DOT-NHTSA

92. +SIDE IMPACT PROTECTION UPGRADE—FMVSS NO. 214

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; 49 USC 30166

CFR Citation:

49 CFR 571.214

Legal Deadline:

Final, Statutory, July 1, 2008.

Abstract:

Two Federal motor vehicle safety standards (FMVSS) — No. 201, “Occupant Protection in Interior Impact” and No. 214, “Side Impact Protection” — specify requirements for side impact protection. At present, FMVSS No. 214 specifies a moving deformable barrier (MDB) test addressing mainly the chest injury problem. The head injury reduction is partially addressed in FMVSS No. 201. This rulemaking would require in FMVSS No. 214 a vehicle-to-pole oblique impact test to reduce the number of fatal and serious head injuries, which are not addressed in FMVSS No. 201.

Statement of Need:

While the side impact protection standard currently specifies a MDB test for the purpose of reducing chest injuries, the head injury problem in side crashes is not addressed by the standard. In 1990, when the standard was published, no safety countermeasures were available to address this problem effectively. In 1995, the agency amended the occupant protection in the interior impact standard (FMVSS No. 201) to add an in-vehicle component test for enhanced upper interior head impact protection. However, head impacts with exterior objects, such as trees, poles, and narrow rigid structures, are not addressed in the requirements of FMVSS No. 201. These head impacts constitute a serious safety problem today. On the other hand, there are readily available countermeasures now, such as advanced inflatable head protection systems, which would provide occupant protection in these crashes. The agency has proposed to address this safety problem by amending the side impact protection standard (FMVSS No. 214) to add a vehicle-to-pole test.

Summary of Legal Basis:

Section 30111, title 49 of the USC, states that Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The agency will examine existing test procedures developed by various organizations, conduct research on the development of a new MDB and advanced dummy test devices, and keep abreast of the development of new head protection systems.

Anticipated Cost and Benefits:

The agency is evaluating the benefits and costs associated with requiring a vehicle-to-pole test in FMVSS No. 214.

Risks:

Current motor vehicles provide numerous occupant protection systems, such as air bags, safety seat belts, and strategically placed energy absorption padding. Nevertheless, approximately 2,311 fatalities and 5,891 non-fatal serious to critical injuries involving nearside occupants occur annually in non-rollover side crashes without full occupant ejections in our target population. "Nearside occupants" are those sitting on the struck side of the vehicle in which they are riding.

Timetable:

Action	Date	FR Cite
NPRM	05/14/04	69 FR 27990
Comment Period End	10/14/04	
Comment Period Extended	01/12/05	70 FR 2105
End of Extended Comment Period	04/12/05	
Final Rule	05/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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Related RIN: Related to 2127-AJ16,
Related to 2127-AI89

RIN: 2127-AJ10

DOT—NHTSA**93. +REDUCED STOPPING DISTANCE REQUIREMENTS FOR TRUCK TRACTORS****Priority:**

Other Significant

Legal Authority:

49 CFR 1.50; 49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166; 49 USC 322

CFR Citation:

49 CFR 571.121

Legal Deadline:

None

Abstract:

This rulemaking would reduce stopping distance requirements for truck tractors equipped with air brake systems. Advances in heavy vehicle braking systems show that improved stopping performance is attainable for these vehicles. Such improvements would reduce the stopping distance disparity with light vehicles, and would result in fewer deaths and injuries and reduce property damage due to fewer crashes between truck tractors and light vehicles.

Statement of Need:

Large trucks have longer stopping distances than light vehicles, increasing the chance of crashes in panic stopping situations. Crash data show that combination unit trucks (e.g., tractor-trailers) are highly involved in large truck fatal crashes with light vehicles. Agency test results indicate that significantly reduced tractor stopping distances may be achieved by using current-technology brake systems. The agency believes that sufficient test data exists to move forward with a proposal.

Summary of Legal Basis:

Section 30111, Title 49 of the USC, states that the Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The agency is not pursuing any alternatives to reduce stopping distances for this type of vehicle other than changes in the requirements in FMVSS No. 121.

Anticipated Cost and Benefits:

Reducing the stopping distance requirements (service brakes and/or emergency brakes) for tractors in FMVSS No. 121, Air Brake Systems, by 20 to 30 percent is expected to reduce unable-to-stop-in-time collisions between combination-unit trucks and light vehicles. Test data has indicated that stopping distance reductions of up to 30 percent may be achievable for all tractors in FMVSS No. 121. Evaluation is underway to determine the reductions in deaths, injuries, and property damage that could result from reductions in tractor stopping distances.

Risks:

The agency believes there are no substantial risks to this rulemaking, and that only beneficial outcomes will occur as the industry moves to improved tractor braking systems.

Timetable:

Action	Date	FR Cite
NPRM	12/15/05	70 FR 74270
NPRM Comment Period End	04/14/06	
Final Rule	05/00/07	

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: 2127-AJ37

DOT—NHTSA

94. +ELECTRONIC STABILITY CONTROL (ESC)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166; 49 USC 322

CFR Citation:

49 CFR 571.126

Legal Deadline:

NPRM, Statutory, October 1, 2006.
 Final, Statutory, April 1, 2009.

In the Safe, Accountable, Flexible and Efficient Transportation Equity Act of 2005: Legacy for Users (SAFETEA-LU), Congress directed NHTSA to establish performance criteria to reduce the occurrence of rollovers consistent with stability enhancing technologies.

Abstract:

This rulemaking would establish a new Federal motor vehicle safety standard to require electronic stability control (ESC) systems on all newly-manufactured passenger cars and light trucks. The vast majority of rollovers occur in single-vehicle crashes involving loss of control. Crash data studies by NHTSA and other organizations worldwide show that ESC causes a dramatic reduction in single-vehicle crashes by assisting drivers in maintaining control in critical driving situations. NHTSA studies show a reduction in single-vehicle crashes of 34 percent to 59 percent and a reduction in single-vehicle crashes with rollover of 71 percent to 84 percent. The requirement of ESC on cars and

trucks could save thousands of lives annually.

Statement of Need:

This rulemaking is part of a comprehensive plan to reduce the serious risk of rollover crashes and the risk of death and serious injury in those crashes. Electronic Stability Control (ESC) systems use automatic computer-controlled braking of individual wheels to assist the driver in maintaining control in critical driving situations in which the vehicle is beginning to lose directional stability at the rear wheels (spin out) or directional control at the front wheels (plow out). Based on our own crash data studies, NHTSA estimates that the installation of ESC will reduce single-vehicle crashes of passenger cars by 34 percent and single vehicle crashes of sport utility vehicles (SUVs) by 59 percent, with a much greater reduction of rollover crashes.

Summary of Legal Basis:

Section 30111, title 49 of the USC, states that Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The agency is not pursuing any alternatives to requiring ESC, which would be a new FMVSS No. 126.

Anticipated Cost and Benefits:

Vehicle costs are estimated to be \$368 (in 2005 dollars) for anti-lock brakes and an additional \$111 for electronic stability control for a total system cost of \$479 per vehicle. The total incremental cost of the proposal (over the MY 2011 installation rates and assuming 17 million passenger vehicles sold per year) are estimated to be \$985 million to install antilock brakes, electronic stability control, and malfunction lights. The average incremental cost per passenger vehicle is estimated to be \$58 (\$90 for the average passenger car and \$29 for the average light truck), a figure which reflects the fact that many baseline MY 2011 vehicles are projected to already come equipped with ESC components (particularly ABS).

We estimate that the proposal would save 1,536 to 2,211 lives and prevent 50,594 to 69,630 MAIS 1-5 injuries annually once all passenger vehicles have ESC. Fatalities and injuries associated with rollovers are a

significant portion of this total; we estimate that the proposal would reduce 1,161 to 1,445 fatalities and 43,901 to 49,010 MAIS 1-5 injuries associated with single-vehicle rollovers.

Risks:

The agency believes there are no substantial risks to this rulemaking, and that only beneficial outcomes will occur as the industry moves to installing Electronic Stability Control systems.

Timetable:

Action	Date	FR Cite
NPRM	09/18/06	71 FR 54711
NPRM Comment Period End	11/17/06	
Final Action	09/00/07	

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: 2127-AJ77

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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 system 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 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).

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

On November 26, 2002, the President signed into law the Terrorism Risk Insurance Act of 2002 (TRIA). The new law, which was enacted as a consequence of the events of September 11, 2001, established a temporary Federal reinsurance program under which the Federal Government shares the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers. The Act, originally scheduled to expire on December 31, 2005, was extended to December 31, 2007 by the Terrorism Risk Insurance Extension Act of 2005 (TRIEA).

The Office of the Assistant Secretary for Financial Institutions is responsible for developing and promulgating regulations implementing TRIA, as extended and amended TRIEA. 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 TRIA. The purposes of this legislation 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.

Over the past year, the Office of the Assistant Secretary has continued the ongoing work of implementing TRIA. The Office has issued interim guidance and regulations implementing Program changes authorized by TRIEA, and is developing regulations for recouping the Federal share of compensation to insurers through risk-spreading premiums. The issuance of final regulations for recoupment is expected in 2007.

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 the past fiscal year, among the Treasury-approved CBP customs-revenue function regulations issued were: an interim rule regarding procedures on the refund of excess customs duties paid on entries of textile or apparel goods entitled to retroactive application of preferential tariff treatment under the Dominican Republic-Central America-United States Free Trade Agreement; an interim rule on the Country of Origin of Textile and Apparel Products that implemented the changes brought about, in part, by the expiration of the Agreement on Textile and Clothing and the resulting elimination of quotas on the entry of textile and apparel products from World Trade Organizations (WTO) members; and a final rule, "Single Entry for Unassembled or Disassembled Entities Imported on Multiple Conveyances," which provides importers with more flexibility and implements the statutory changes made to the merchandise entry laws by the Tariff Suspension and Trade Act of 2000. CBP also finalized the interim regulations on the Andean Trade Promotion and Drug Eradication Act which implemented the trade benefit provisions contained in Title XXXI of the Trade Act of 2002.

During fiscal year 2007, Treasury and CBP plan to finalize several other 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 Caribbean Basin Economic Recovery Act
- The African Growth and Opportunity Act

CBP plans to finalize interim regulations to implement the preferential trade benefit provisions of the United States-Chile Free Trade Agreement Implementation Act. CBP also expects to issue interim regulations implementing the United States-Singapore Free Trade Agreement Implementation Act and the United States-Australia Free Trade Agreement Implementation Act.

In addition, Treasury and CBP plan to propose uniform rules governing the determination of the country of origin of imported merchandise. The uniform rules would extend the application of the North American Free Trade Agreement country of origin rules to all trade.

Another project Treasury and CBP will work to finalize is a proposal that would allow CBP to be more responsive to claims of piracy of copyrighted works. This rule would allow sound recordings and motion pictures or similar audio-visual works to be recorded with CBP while pending registration with the U.S. Copyright Office, and would allow recodation of all non-U.S. works without requiring registration with the U.S. Copyright Office.

Treasury and CBP also plan to continue developing amendments to improve regulatory procedures begun under the authority granted by the Customs Modernization provisions of the North American Free Trade Agreement 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. Consistent with this practice, we expect to publish a proposal to permanently establish the remote location filing program, which has been a test program under the Customs Mod Act. These regulations will allow remote location filing of electronic entries of merchandise from locations other than at the port of arrival of the merchandise or the location of examination of the merchandise.

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 the following programs: the Community Development Financial Institutions (CDFI) Program, the Bank Enterprise Award (BEA) Program, the Native American CDFI Assistance (NACA) Program, and the New Markets Tax Credit (NMTC) Program.

In fiscal year 2007, the Fund will provide financial assistance awards and technical assistance grants through the CDFI Program. Through the NACA Program, the Fund will provide 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 will provide financial incentives to encourage insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs.

Through the NMTC Program, the CDFI Fund will provide allocations of tax credits to qualified community development entities (CDEs). The CDEs in turn provide tax credits to private sector investors in exchange for their investment dollars; investment proceeds received by the CDEs are used to make loans and equity investments in low-income communities. The Fund, the Office of Tax Policy and the Internal Revenue Service jointly administer the NMTC Program.

Financial Crimes Enforcement Network

The Financial Crimes Enforcement Network (FinCEN) is the administrator of the Bank Secrecy Act (BSA) and FinCEN's regulations constitute the core of the Department's anti-money laundering initiatives and are an essential component of the Department's anti-terrorist financing and anti-narcotics efforts. FinCEN's responsibilities and objectives are keyed to, and flow from, that role.

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 require the establishment of anti-money laundering programs and compliance procedures. FinCEN has established regulatory objectives and priorities that implement its mission to safeguard the financial system from the abuses of financial crime, including terrorist financing, money laundering, and other illicit activity. These objectives include: issuing, interpreting, and enforcing compliance with regulations implementing the BSA; supporting, working with, and, as appropriate, overseeing compliance examination functions delegated to other federal regulators; managing the collection, processing, storage, and dissemination of data related to the BSA; maintaining a governmentwide access service to that same data, and for network users with overlapping interests; conducting analysis in support of policymakers, law enforcement, regulatory and intelligence agencies, and the financial sector; and coordinating with and collaborating on anti-terrorism and anti-money laundering initiatives with domestic law enforcement and intelligence agencies, and with foreign financial intelligence units.

During fiscal year 2006, FinCEN issued the following final rules: a final rule implementing section 312 of the USA PATRIOT Act, which requires certain financial institutions to implement appropriate, specific, and, where necessary, enhanced due diligence policies, procedures, and controls in connection with correspondent accounts established or maintained for certain foreign financial institutions, and appropriate due diligence and, where necessary, enhanced scrutiny in connection with private banking accounts established or maintained for non-U.S. persons; a final rule requiring mutual funds to report suspicious activity; final rules requiring certain insurance companies to establish anti-money laundering programs and report suspicious activity; and two final rules imposing special measures against foreign financial institutions deemed to be of primary money laundering concern pursuant to Section 311 of the USA PATRIOT Act.

FinCEN's regulatory priorities for fiscal year 2007 include the following projects:

- *Anti-Money Laundering Programs.* Pursuant to section 352 of the USA PATRIOT Act, certain financial institutions are required to establish

anti-money laundering programs. To the extent that final rules have not been adopted by the end of fiscal year 2006, FinCEN expects to finalize the anti-money laundering program rule for dealers in precious metals, precious stones, or jewels and the anti-money laundering program rules proposed in May 2003 for investment advisers, commodity trading advisers, commodity pool operators, and unregistered investment companies. FinCEN will continue to research and analyze issues regarding potential regulation of the loan and finance industry (including pawnbrokers). FinCEN also will continue to consider regulatory options regarding certain corporate and trust service providers. Finally, FinCEN will determine whether to issue proposed rules for other financial institutions—vehicle 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.

- **Money Services Businesses.** FinCEN will continue to implement and refine its strategy with regard to money services businesses, including: using analytical tools and establishing partnerships with law enforcement to identify unregistered money services businesses; continuing to revise, simplify, and clarify the regulatory framework for money services businesses; and developing and delivering internal and external education, outreach, and training on relevant regulatory topics regarding the money services business industry for both the money services business and banking industries, law enforcement, and other regulatory agencies.
- **Wire Transfers.** FinCEN will proceed with the rulemaking process to consider lowering the current \$3,000 recordkeeping and “travel rule” thresholds; collaborate with the Office of Foreign Assets Control (OFAC) and NACHA (the Electronic Payments Association) regarding the availability of originator information on automated clearing house wire transfers; collaborate with OFAC, law enforcement, the federal banking agencies (the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Office of the Comptroller of the Currency, and the Office of Thrift Supervision) and industry to address potential abuse of

cover payments; and work with law enforcement to assess the relative value of postal address vs. e-mail address information or telephone numbers as required fields under the recordkeeping and travel rules.

- **Other Requirements.** FinCEN will also continue to explore issuing a proposed rule that would require all financial institutions that file BSA reports to do so electronically. FinCEN will also consider the need for regulatory action in conjunction with the feasibility study being prepared pursuant to the Intelligence Reform and Terrorism Prevention Act of 2004 concerning the issue of obtaining information about certain cross-border funds transfers and transmittals of funds. Additionally, FinCEN will continue to issue proposed and final rules pursuant to section 311 of the USA PATRIOT Act, as appropriate. Finally, FinCEN expects to propose various technical and other regulatory amendments in conjunction with its ongoing, comprehensive review of existing regulations.

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 2007 the Internal Revenue Service will accord priority to the following regulatory projects:

- **Unified Rule for Loss on Subsidiary Stock.** Prior to the opinion in *Rite Aid Corp. v. United States*, 255 F.3d 1357 (2001), Treas. Reg. § 1.1502-20 (the loss disallowance rule or LDR) addressed both noneconomic and duplicated loss on subsidiary stock by

members of consolidated groups. In *Rite Aid*, the Federal Circuit rejected the validity of the duplicated loss component of the LDR. Following *Rite Aid*, the IRS and Treasury issued temporary regulations, Treas. Reg. §§ 1.337(d)-2T (to address noneconomic loss on subsidiary stock) and 1.1502-35T (to address loss duplication within consolidated groups). The regulations were promulgated as interim measures to address both concerns while a broader study of the issues was conducted. Both regulations were finalized, but the preamble to each regulation alerted taxpayers of the ongoing nature of the study and the intent to propose a new approach to both issues. During fiscal year 2007, the IRS and Treasury intend to propose a unified approach to addressing both concerns.

- **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 and, if their securities are not inventory, 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 issued proposed regulations on May 24, 2005, that allow dealers in securities (and electing dealers in commodities or traders in securities or commodities) to use the safe harbor method to satisfy the statutory requirement to determine the fair market value of items marked to market. The safe harbor method set forth in the proposed regulations permits taxpayers to use as fair market value for section 475 purposes the value used on certain financial statements, if certain conditions are met. In addition, there are some limitations on the use of the safe harbor method in situations where fair market value and financial accounting fair value principles are not sufficiently consistent. The IRS and Treasury intend to finalize these regulations during fiscal year 2007.

- *Charitable Contributions of Vehicles.* Section 170(a) of the Internal Revenue Code allows as an income tax deduction any charitable contribution paid within the taxable year, subject to the terms and limitations of section 170. Section 170(f)(12), which was added to the Code by the American Jobs Creation Act of 2004 (AJCA), provides new rules for the deduction of a charitable contribution of a vehicle, and requires charities that accept vehicle contributions to report those contributions to the IRS. Section 6720, which was also added to the Code by the AJCA, imposes a penalty on charities that do not (1) properly report vehicle contributions to the IRS, or (2) provide adequate substantiation of vehicle contributions to donors. The new rules under both sections have generated many questions from stakeholders. Charities have questions concerning their fundraising practices; compliance with the new rules; and how to avoid the imposition of the penalty. Donors have questions concerning what is needed to claim a deduction for a donated vehicle, and how to calculate the deduction. During fiscal year 2007, the IRS and Treasury intend to issue temporary and proposed regulations to provide understandable rules and clarify this area of the law.
- *Deduction and Capitalization of Costs for Tangible Assets.* Section 162 of the Internal Revenue Code generally allows a current deduction for ordinary and necessary expenses paid or incurred in carrying on any trade or business. Under section 263(a) of the Code, no immediate deduction is allowed for amounts paid out for new property having a useful life substantially beyond the taxable year, or for permanent improvements or betterments made to increase the value of any property or estate. Those 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 amount paid to acquire, produce, or improve property is a deductible expense or a capital expenditure. Although existing regulations provide that a deductible repair expense 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 August 2006, the IRS and Treasury issued proposed regulations in this area. During fiscal year 2007, the IRS and Treasury intend to finalize those regulations.
- *Transfer Pricing Initiatives.* On August 22, 2005, the IRS and Treasury issued proposed regulations providing guidance on "cost sharing arrangements," where related parties agree to share the costs and risks of intangible development in proportion to their reasonable expectations of their share of anticipated benefits from their separate exploitation of the developed intangibles. The proposed regulations are designed to prevent abuses possible under the existing rules, and to ensure that Congressional intent underlying section 482 of the Internal Revenue Code is fulfilled by requiring that cost sharing arrangements between controlled taxpayers produce results consistent with the arm's length standard. On August 1, 2006, the IRS and Treasury issued proposed and temporary regulations that provide guidance regarding the treatment of controlled services transactions under section 482 and the allocation of income from intangibles, in particular with respect to contributions by a controlled party to the value of an intangible owned by another controlled party. The regulations provide much-needed guidance on the transfer pricing methods to determine the arm's length price in a services transaction, including a new method that allows routine back-office services to be charged at cost with no markup. As part of a continuing effort to modernize the transfer pricing rules to keep them current with changing business practices, the IRS and Treasury intend to finalize both the cost-sharing and services regulations during fiscal year 2007. Additionally, proposed regulations will be issued under section 367(d) of the Code, which provides that a transfer by a U.S. person of an intangible to a foreign corporation in certain nonrecognition transactions will be treated as a sale of that property for a series of payments contingent on the property's productivity, use, or disposition. The IRS and Treasury will coordinate the provisions to prevent intangible value going to offshore affiliates without arm's length consideration, whether intangibles are transferred directly, embedded in the performance of services, contributed via incorporation or reorganization, or conveyed in the course of a cost sharing arrangement.
- *Foreign Tax Credit Guidance Initiatives.* The IRS and Treasury anticipate issuing guidance under section 901 and other provisions of the Internal Revenue Code to address inappropriate use of the foreign tax credit. On August 3, 2006, the IRS and Treasury issued proposed regulations to address the operation of the foreign tax credit rules in the context of foreign consolidated regimes and with respect to so-called hybrid entities, entities that are treated as separate taxable entities under either U.S. or foreign law but as transparent entities under the other country's tax law. The IRS and Treasury expect to issue final regulations in this area and also expect to issue guidance addressing the inappropriate creation or transfer of foreign tax liability in order to obtain foreign tax credits. Additional guidance will provide rules relating to the reduction in the number of foreign tax credit categories and other provisions added by the AJCA. The guidance will provide for tax treatment that is consistent with the policies of the foreign tax credit provisions and applicable law.
- *Transactions Involving Foreign Corporations.* The IRS and Treasury anticipate issuing guidance during fiscal year 2007 to address various issues in connection with acquisitions, dispositions and other transactions involving foreign corporations. The guidance will include a third set of regulations that address the application of the inversion rules of section 7874 of the Internal Revenue Code to acquisitions by a foreign corporation of a domestic corporation (or a trade or business of a domestic partnership). The first two sets of regulations under section 7874 were issued in fiscal year 2006. The guidance will also address the treatment of nonrecognition transactions on gain recognition agreements entered into by U.S. persons as a result of stock transfers made to foreign corporations. Additional guidance will be issued to address certain reorganizations involving foreign corporations to ensure that international tax policies are taken into account. Finally, guidance will be issued to address payments and distributions involving controlled foreign corporations, including the treatment of distributions involving previously taxed earnings, and an exception to the "subpart F" anti-deferral rules,

added by the Tax Increase Prevention and Reconciliation Act of 2005 (TIPRA), for certain dividends, interest, rents and royalties.

- **Deduction for Qualified Production Activities Income.** Section 199, which was added to the Internal Revenue Code by the AJCA, allows taxpayers to deduct a percentage of income derived from qualified production activities performed in the United States. The IRS and Treasury issued temporary and proposed regulations on June 1, 2006, that provide guidance on the application of section 199 to transactions involving computer software provided over the Internet. The IRS and Treasury intend to finalize those regulations and issue temporary and proposed regulations on the application of section 199, as amended by TIPRA.
- **Accuracy-Related Penalties on Understatements.** Section 6662A, which was added to the Internal Revenue Code by the AJCA, provides a new penalty for understatements with respect to reportable transactions. Section 6664(d), which was also added to the Code by the AJCA, provides a defense to the penalty under section 6662A if the taxpayer acted with reasonable cause and in good faith. Additionally, section 6662(d) of the Code was amended by the AJCA to modify the accuracy-related penalty for substantial understatements of income tax. In January 2005, the IRS and Treasury issued Notice 2005-12 to provide interim guidance relating to these provisions. The IRS and Treasury intend to issue regulations providing further guidance relating to these provisions. The IRS and Treasury also intend to provide further guidance regarding the administration of these penalties.
- **Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans.** Section 409A was added to the Internal Revenue Code by the AJCA. It provides that unless certain requirements are met, all amounts deferred under a nonqualified deferred compensation plan for all taxable years are currently includible in gross income to the extent not subject to a substantial risk of forfeiture and not previously included in gross income, and are subject to certain additional taxes. The IRS and Treasury issued proposed regulations on October 4, 2005, that provided guidance on a broad range of issues under section 409A. During fiscal year

2007, the IRS and Treasury intend to finalize those regulations.

Additionally, the recently enacted Pension Protection Act of 2006 will certainly merit significant regulatory attention during the coming fiscal year but the specific regulations under that Act that will be top priorities are currently being determined.

Office of the Comptroller of the Currency

The Office of the Comptroller of the Currency was created by Congress to charter national banks, to oversee a nationwide system of banking institutions, and to assure that national banks are safe and sound, competitive and profitable, and capable of serving in the best possible manner the banking needs of their customers.

The OCC seeks to assure a banking system in which national banks soundly manage their risks, maintain the ability to compete effectively with other providers of financial services, meet the needs of their communities for credit and financial services, comply with laws and regulations, and provide fair access to financial services and fair treatment of their customers.

The OCC's regulatory program furthers these goals. For example, pursuant to 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 (Federal banking agencies), is conducting a review of its regulations to identify opportunities to streamline our regulations and reduce unnecessary regulatory burden. To date, the banking agencies' review has included: (1) issuing six 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 suggestions, which we, along with the other agencies, are evaluating. The agencies have fulfilled the statutory requirement to publish all categories of their regulations for public comment and are preparing a summary of the comments and recommendations received together with a report to Congress on our conclusions.

Much of the OCC's regulatory activity in fiscal year 2006 focused on the

implementation of new statutes. For example, significant final rules issued during fiscal year 2006 include:

- **One-Year Post-Employment Restrictions for Senior Examiners** (12 CFR Parts 4 and 19). The Federal banking agencies issued a final rule on November 17, 2005 (70 FR 69633) to implement section 6303(b) of the Intelligence Reform and Terrorism Prevention Act of 2004, which imposes a one-year post-employment restriction on "senior examiners" of depository institutions and depository institution holding companies. A senior examiner employed or commissioned by an agency may not knowingly accept compensation as an employee, officer, director, or consultant from certain depository institutions or depository institution holding companies they examined, or from certain related entities, for one year after the examiner leaves the employment or service of the agency. Violation results in the examiner being subject to an order of removal and prohibition from the relevant bank and all insured depository institutions for up to 5 years, a civil money penalty of up to \$250,000, or both.
 - **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) issued a final rule on November 22, 2005 (70 FR 70664) to implement section 411 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act). 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 OCC's regulatory priorities for fiscal year 2007 principally include the completion of rulemakings required by the FACT Act, the implementation of new regulatory capital standards and, consistent with the interagency EGRPRA project, revising our rules to reduce regulatory burden. The OCC plans to issue the following:
- **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, National Credit Union Administration, and Federal Trade Commission (the agencies) are planning to issue a rule to establish guidelines and regulations to implement sections 114 and 315 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 indicate 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. Section 315 requires the agencies to jointly issue regulations providing guidance regarding reasonable policies and procedures that a user of consumer reports should employ when such user receives a notice of address discrepancy from a consumer reporting agency informing the user of a substantial discrepancy between the address for the consumer that the user provided to request the consumer report and the address(es) in the file for the consumer. The proposed rules implementing this section require users of consumer reports to validate the identity of the consumer upon receipt of a notice of address discrepancy and provide consumer reporting agencies with updated information about a consumer's address. The agencies issued a notice of proposed rulemaking on July 18, 2006. 71 FR 40786.

- *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 (the 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. 69 FR 42502.

- *Fair Credit Reporting, Accuracy and Integrity of Information Furnished to Consumer Reporting Agencies* (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, National Credit Union Administration, Federal Trade Commission, and Securities and Exchange Commission (the agencies) are planning to issue a joint rule to implement section 312 of the Fair and Accurate Credit Transactions Act of 2003. Section 312 requires the agencies to consult and coordinate with each other in order to issue consistent and comparable regulations requiring persons that furnish information to a consumer reporting agency to establish reasonable policies and procedures for the implementation of the agencies' guidelines regarding the accuracy and integrity of information relating to consumers. In addition, the agencies are to prescribe regulations jointly that identify the circumstances under which a furnisher of information to a consumer reporting agency shall be required to reinvestigate a dispute concerning the accuracy of information contained in a consumer report based on the consumer's direct request to the furnisher. The agencies issued an advance notice of proposed rulemaking on March 22, 2006. 71 FR 14419.
- *Risk-Based Capital Guidelines: Implementation of New Basel Capital Accord* (12 CFR Part 3). The banking agencies issued a notice of proposed rulemaking based on the International Convergence of Capital Measurement and Capital Standards: A Revised Framework, the new capital adequacy standards, commonly known as Basel II. The banking agencies published the notice of proposed rulemaking (NPRM) on September 25, 2006 at 71 FR 55830 soliciting industry comments on a proposal for implementing Basel II in the United States. In particular, the NPRM 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 NPRM 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 has included this rulemaking project in Part II of the Regulatory Plan.
- *Risk-Based Capital Guidelines; Capital Adequacy Guidelines; Capital Maintenance: Domestic Capital Modifications* (Basel IA) (12 CFR Part 3). The banking agencies plan to issue a notice of proposed rulemaking to amend various provisions of the capital rules for those banks that will not be subject to the new Basel Capital Accord (Basel II) capital framework as an alternative. The banking agencies issued an advance notice of proposed rulemaking on October 20, 2005. 70 FR 61068. The OCC has included this rulemaking project in Part II of the Regulatory Plan.
- *Risk-Based Capital Standards: Market Risk* (12 CFR Part 3). The OCC issued a notice of proposed rulemaking (NPRM) to amend the current market risk capital requirements for national banks. The NPRM is part of a rulemaking with the other banking agencies and was published on September 25, 2006 at 71 FR 55958. The NPRM would make the current market risk capital requirements generally more risk sensitive with respect to the capital treatment of trading activities in banks and bank holding companies. Specifically, the Federal banking agencies propose to require banks to hold additional capital for the risk of default of trading positions beyond the 10-day horizon required by the current market risk capital requirement.
- *Regulatory Burden Reduction and Technical Amendments*. The OCC plans to issue a notice of proposed rulemaking to further the goal of reducing regulatory burden for national banks. These proposed changes would relieve burden by eliminating or streamlining existing requirements or procedures, enhancing national banks' flexibility in conducting authorized activities, eliminating uncertainty by harmonizing a rule with other OCC regulations or with the rules of another agency, or by making technical revisions to update OCC

rules to reflect changes in the law or in other regulations. In a few cases, proposed revisions also would be made to add or enhance requirements for safety and soundness reasons.

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, the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (FRB), and the Federal Deposit Insurance Corporation (FDIC) (collectively, the banking agencies) continue to work together on regulations where they share the responsibility to implement statutory requirements. For example, the banking agencies are working jointly on several rules to update capital standards to maintain and improve consistency in agency rules. Significant capital rules issued during FY 2006 include two notices of proposed rulemaking (NPRMs) that implement revisions to the *International Convergence of Capital Management and Capital Standards: A Revised Framework (Basel II)*. These rules are:

- *Risk-Based Capital Guidelines: Implementation of New Basel Capital Accord*. This joint NPRM prescribes a new risk-based capital adequacy framework that would require some, and permit other, qualifying banks, savings associations, and bank holding companies to use an internal ratings-based approach (IRB) to calculate regulatory credit risk capital requirements, and to use advanced measurement approaches to calculate regulatory operational risk capital requirements. The NPRM specifies the criteria that a banking organization must meet to use these advanced approaches. 71 FR 55830 (Sept. 25, 2006). As a related matter, the banking agencies shortly will publish proposed guidance on credit risk, operation risk and internal economic capital maintenance. The OTS has included this rulemaking project in Part II of the Regulatory Plan.

- *Risk-Based Capital Standards; Market Risk*. In this joint NPRM, which was issued simultaneously with the Basel II NPR, OTS proposed to require savings associations to measure and hold capital to cover their exposure to market risk. The other banking agencies are proposing to revise their existing market risk capital rules to implement changes to the market risk framework in *Basel II*. These changes would enhance risk sensitivity of the existing market risk capital rules and introduce requirements for public disclosure of certain qualitative and quantitative information about market risk. The proposed texts of the agencies' rules are substantively identical. 71 FR 55958 (Sept. 25, 2006). As a related matter, the banking agencies plan to issue a NPRM to increase the risk sensitivity of the existing risk-based capital rules currently applicable to all U.S. banks, savings associations, and bank holding companies. The banking agencies published an ANPRM on this issue on October 20, 2005 (70 FR 61068), and will issue the NPRM in early FY 2007.

Significant final rules issued during fiscal year 2006 include:

- *One-Year Post-Employment Restrictions for Senior Examiners*. The banking agencies issued a joint final rule implementing section 6303(b) of the Intelligence Reform and Terrorism Prevention Act of 2004. The final rule imposes a one-year post-employment restriction on "senior examiners" of depository institutions and depository institution holding companies. A senior examiner employed or commissioned by a banking agency may not knowingly accept compensation as an employee, officer, director, or consultant from certain depository institutions or depository institution holding companies that he or she examined, or from certain related entities, for one year after the examiner leaves the employment or service of the banking agency. 70 FR 69633 (Nov. 17, 2005).
- *Fair Credit Reporting - Medical Information*. The banking agencies and the National Credit Union Administration (NCUA) issued an interim final rule implementing section 411 of the FACT Act, which amended the Fair Credit Reporting Act (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. The final rule was published on November 22, 2005 at 70 FR 70664.

- *Community Reinvestment Act - Community Development*. OTS issued a final rule revising the definition of "community development" for CRA purposes. The revised definition adds activities that revitalize or stabilize designated disaster areas or distressed or underserved, nonmetropolitan middle-income geographies OTS designates under criteria the rule establishes. The final rule was published on April 12, 2006, at 71 FR 18614.

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 finalize its current interim final rule to reduce regulatory burden on savings associations by updating and revising various application and reporting requirements.

Other significant proposed rules issued in fiscal year 2006 include:

- *Subordinated Debt Securities and Mandatorily Redeemable Preferred Stock*. OTS issued a NPRM updating rules governing the inclusion of subordinated debt and mandatorily redeemable stock in supplementary capital. The proposed rule deleted unnecessary and outdated requirements and conformed OTS rules more closely to the other banking agencies. 71 FR 27862 (July 3, 2006).

OTS anticipates implementing sections of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act) as follows:

- *Fair Credit Reporting Affiliate Marketing Regulations*. The banking agencies and the NCUA plan to issue a final rule implementing section 214 of the FACT Act, which amended the FCRA. 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 published a proposed rule on July 15, 2004, at 69 FR 42502.
- *Fair Credit Reporting - Accuracy and Integrity of Information Furnished to Consumer Reporting Agencies*. The banking agencies and the NCUA,

Securities and Exchange Commission (SEC), and Federal Trade Commission (FTC) are planning to issue a joint rule to implement section 312 of the FACT Act. Section 312 requires the agencies to consult and coordinate with each other in order to issue consistent and comparable regulations requiring persons that furnish information to a consumer reporting agency to establish reasonable policies and procedures for the implementation of the agencies' guidelines regarding the accuracy and integrity of information relating to consumers. In addition, the agencies are to jointly prescribe regulations that identify the circumstances under which a furnisher of information to a consumer reporting agency shall be required to reinvestigate a dispute concerning the accuracy of information contained in a consumer report based on the consumer's direct request to the furnisher. The agencies published an ANPRM on March 22, 2006, at 71 FR 14419.

- *Fair Credit Reporting - Identity Theft Red Flags and Address Discrepancies.* The banking agencies, NCUA, and FTC also plan to issue a proposed rule implementing section 114 and 315 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. Section 315 requires the agencies to jointly issue regulations providing guidance regarding reasonable policies and procedures that a user of consumer reports should employ when such user receives a notice of address discrepancy from a consumer reporting agency, informing the user of a substantial discrepancy between the address for the consumer that the user provided to request the consumer report and the address(es) in the file for the consumer. The agencies published a proposed rule on July 18, 2006.

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 alcohol 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 2007, 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. In FY 2005, TTB evaluated all of the 36 CFR parts in title 27 and prioritized them as "high," "medium," or "low" in terms of the need for complete revision or regulation modernization. TTB determined importance based on industry member numbers, revenue collected, and enforcement and compliance issues identified through field audits and permit qualifications, statutory changes, significant industry innovations, and other factors. The 10 CFR parts that TTB ranked as "high" include the five parts directing operation of the major taxpayers under the Internal Revenue Code of 1986: Part 19 - Distilled Spirits Plants; Part 24 - Wine; Part 25 - Beer; Part 40 - Manufacture of Tobacco Products and Cigarette Papers and Tubes; and Part 53 - Manufacturers Excise Taxes - Firearms and Ammunition. These five CFR parts represent nearly all the tax revenue that TTB collects, or \$14.6 billion in FY 2004. Work has begun on parts 19 and 25. The remaining five parts rated

"high" consist of regulations covering imports and exports (Part 27 - Importation of Distilled Spirits, Wine and Beer; Part 28 - Exportation of Alcohol; and Part 41 - Exportation of Tobacco Products and Cigarette Papers and Tubes), the American Viticultural Area program (Part 9), and TTB procedures (Part 70).

In addition to TTB's modernization updates, in FY 2007 the Bureau will conclude its alcohol beverage allergen rulemaking initiative and will publish proposed regulatory changes regarding serving facts for alcohol beverage labels and advertisements. In 2007, TTB will also publish regulations changes to clarify the distinction between cigars and cigarettes for excise tax purposes.

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.

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 2007, BPD plans to issue rules to implement a paperless process for Treasury auctions. A streamlined electronic form will replace the paper agreement for electronic access now in use; certain provisions from the paper agreement would be incorporated into the Uniform Offering Circular.

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 government-wide accounting programs. For fiscal year 2007, FMS's regulatory plan includes the following projects:

- *Management of Federal Agency Disbursements* (31 CFR Part 208). Near the end of fiscal year 2006, FMS issued an interim final rule amending 31 CFR Part 208 to facilitate the delivery of Federal payments to victims of disasters and emergencies. This amendment provides Treasury the authority to establish accounts at financial institutions to allow for the electronic delivery of Federal payments for victims of disasters and emergencies. FMS requested comments on this interim final rule and will review whether any clarifications should be added to the rule in light of any comments received.
- *Administrative Offset Under Reciprocal Agreements With States* (31 CFR Part 285). FMS plans to issue an interim rule amending 31 CFR Part 285 to implement a provision of the Debt Collection Improvement Act of 1996 (DCIA) that authorizes Treasury to offset certain Federal payments to States, provided that the States enter into a reciprocal agreement with Treasury. After consulting with the States, FMS has developed an operational program to accomplish such offsets. This rule sets forth the requirements for States to submit debts to Treasury for collection by offset, and it sets parameters for the reciprocal agreements.
- *Collection and Cash Management Modernization*. FMS, as part of its Enterprise Architecture, plans to implement a Collection and Cash Management Modernization program, which will restructure the Treasury's collections, settlement, cash concentration/reporting, forecasting, investment, and collateral management programs. This effort will likely require revisions to 31 CFR Parts 202 and 203.

TREAS—Comptroller of the Currency (OCC)

PROPOSED RULE STAGE

95. IMPLEMENTATION OF A REVISED BASEL CAPITAL ACCORD (BASEL II)

Priority:

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

Unfunded Mandates:

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

Legal Authority:

12 USC 93a; 12 USC 3907; 12 USC 3909

CFR Citation:

12 CFR 3

Legal Deadline:

None

Abstract:

As part of 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, OCC is amending various provisions of the capital rules for national banks. This change involves the implementation of the new framework for the Basel Capital Accord (Basel II). 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" into the standards and requirements that will govern the largest banks in the United States.

Summary of Legal Basis:

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 and 3909. 12 U.S.C. 3907(a)(2) specifically authorizes OCC to establish

minimum capital levels for financial institutions that 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	09/25/06	71 FR 55830
NPRM Comment Period End	01/23/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Split from 1557-AB14

RIN: 1557-AC91

TREAS—OCC

96. RISK-BASED CAPITAL GUIDELINES; CAPITAL ADEQUACY GUIDELINES; CAPITAL MAINTENANCE; DOMESTIC CAPITAL MODIFICATIONS (BASEL IA)

Priority:

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

Legal Authority:

12 USC 93a; 12 USC 3907; 12 USC 3909

CFR Citation:

12 CFR 3

Legal Deadline:

None

Abstract:

As part of OCC's ongoing efforts to develop and refine the capital standards to enhance their risk sensitivity and ensure the safety and soundness of the national banking system, OCC is proposing to amend various provisions of the capital rules. This change involves amending the current risk-based capital rules for those banks that will not be subject to the new Basel Capital Accord (Basel II) capital framework. OCC is conducting this rulemaking jointly with the other Federal banking agencies.

Statement of Need:

This rulemaking is necessary to enhance the risk-sensitivity of the risk-based capital rules for those banks that will not be subject to the New Basel Capital Accord (Basel II) capital framework.

Summary of Legal Basis:

The OCC is implementing the Basel IA capital framework for domestic financial institutions that chose to adopt it. 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 and 3909.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Not yet determined.

Risks:

Not yet determined.

Timetable:

Action	Date	FR Cite
ANPRM	10/20/05	70 FR 61068
ANPRM Comment Period End	01/18/06	
NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 1557-AC95

TREAS—Office of Thrift Supervision (OTS)

PROPOSED RULE STAGE

97. IMPLEMENTATION OF A REVISED BASEL CAPITAL ACCORD (BASEL II)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

12 USC 1462; 12 USC 1462a; 12 USC 1463; 12 USC 1464; 12 USC 1467a; 12 USC 1828 (note)

CFR Citation:

12 CFR 567

Legal Deadline:

None

Abstract:

In 2003, the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (collectively, the "Federal Banking Agencies") sought industry comment on a proposed framework for implementing the New Basel Capital Accord in the United States. The advance notice of proposed rulemaking (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 would be used to determine banking organizations that would be required to use the advanced approaches, subject to meeting certain qualifying criteria, supervisory standards, and disclosure requirements. Other banking organizations that would meet the criteria, standards, and requirements also would be eligible to use the

advanced approaches. Under the advanced approaches, banking organizations would use internal estimates of certain risk components as key inputs in the determination of their regulatory capital requirements.

In the fourth quarter of 2004, the Federal Banking Agencies began a quantitative impact study to help determine the potential impact of implementing the capital framework set forth in the "International Convergence of Capital Measurement and Capital Standards: A Revised Framework," which updates and makes some significant revisions to the preliminary New Basel Capital Accord document from 2003, upon which the above ANPRM was based.

After review of the results of the quantitative impact study and after further review and full consideration of public comments received on the ANPRM, the Federal Banking Agencies plan to publish a notice of proposed rulemaking for implementation of this capital framework.

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 revised the 1988 "International Convergence of Capital Measurement and Capital Standards" into the standards and requirements that will govern the largest savings associations in the United States.

Summary of Legal Basis:

OTS is implementing the Basel II capital framework for certain domestic financial institutions. This initiative is based on the OTS's general rulemaking authority under the Home Owners' Loan Act, and its authority under 12 USC 1464(t). 12 USC 1464(t)(1) specifically authorizes OTS to establish minimum capital levels for savings associations, including risk-based capital standards.

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
ANPRM Comment Period End	11/03/03	
NPRM	09/25/06	71 FR 55830
NPRM Comment Period End	01/23/07	

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**Regulatory Flexibility Analysis
Required:**

No

Government Levels Affected:

None

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Related RIN: Related to 1550-AB11

RIN: 1550-AB56

BILLING CODE 4811-42-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 38 CFR Part 3. 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.

BILLING CODE 8320-01-S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Priorities

OVERVIEW

The United States Environmental Protection Agency (EPA) is the primary Federal agency charged with safeguarding the quality of the natural environment and protecting human health from deleterious pollutants. For over 35 years, the Agency has been working to provide improvements in cleaner air, purer water, and better-protected land. The actions taken by EPA have led to measurable improvement in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful chemicals and pesticides.

Between 1970 and 2004, total emissions of the six major air pollutants dropped by 54 percent. This is particularly impressive when noted that the gross domestic product increased 187 percent, energy consumption increased 47 percent, and U.S. population grew by 40 percent during the same time. Through land restoration efforts, 600,000 acres of contaminated land now provide ecological, economic, and recreational benefits. In 2004, EPA and its partners took action to restore, enhance, and protect nearly 830,000 acres of wetlands. EPA continues to build on its past success by using regulatory and innovative approaches to achieve effective results. In doing so, the Agency uses three guiding principles to govern its work to maintain the strongest level of environmental protection.

Results and Accountability

In order to be an effective steward in protecting the environment and responsive to national priorities, EPA uses tools aimed at achieving results and demonstrating accountability. To this end, the Agency uses transparent management tools and measures to provide the public with results as efficiently and effectively as possible. EPA continues to vigorously enforce environmental laws using both compliance assistance and strong enforcement programs. This is a key focus of the President's Management Agenda, which is designed to make Government citizen-centered, results-oriented, and market-based.

Innovation and Collaboration

In facing complex environmental challenges, the Agency values new strategic approaches. By collaborating

with other Federal, State, tribal, and local governments and engaging private-sector entities, stakeholders, and the public, the Agency aims to solve problems using innovative methods that go beyond conventional regulatory controls. The expertise, perspectives, and resources of EPA's partners allow it to foster new approaches and develop new initiatives to expand environmental protection.

Best Available Science

EPA maintains its commitment to sound science and uses the best information available in decisionmaking while anticipating potential environmental threats, evaluating risks, identifying solutions, and developing protective standards. It is crucial to the success of the Agency to respond to emerging information in order to gain new understanding, reduce uncertainties, and, if necessary, change approaches concerning how they should be addressed.

Accelerating Environmental Protection

Using these principles as its framework, EPA is focused on accelerating environmental protection while maintaining the nation's economic competitiveness. Part of this focus centers on maintaining and supporting successful measures already taken.

Cleaner air and affordable energy: Since 1970, EPA has been working to provide cleaner, healthier air to all Americans by collaborating with partners and stakeholders to implement the Clean Air Act and subsequent amendments. The Agency's strategy for protecting human health relies on national regulatory, voluntary, and market-based programs carried out in combination with State, tribal, and local efforts. For example, the Agency is currently seeking to expand the use of biofuels and promote diesel emission reductions. Meanwhile, EPA promotes clean air and energy security through voluntary conservation programs like Energy Star and SmartWay transport. Additionally, the Agency will continue to make timely permitting decisions and foster technological innovations to support the clean development of domestic energy resources.

Clean and safe water: The EPA and its state, tribal, and local partners have made significant improvements in protecting and restoring the nation's waters. The Agency's goals, stemming from the Clean Water Act and the Safe Drinking Water Act, include the improvement of the quality of drinking

water, and the protection and restoration of waters and beaches for fishing, swimming, and recreation. The importance of safe drinking water supplies was never more evident than in the aftermath of Hurricane Katrina. The strength of the Agency's initiative was evident as EPA, State, and local officials, systems operators, and volunteers dedicated their efforts around the clock to assist affected communities in repairing the infrastructure of drinking water systems and restoring sources of safe drinking water. EPA will continue to develop innovative, market-based, and sustainable solutions for water infrastructure financing and management while advancing regional collaborations for the Chesapeake Bay, Great Lakes, and Gulf of Mexico and working on restoring and protecting America's wetlands and watersheds.

Healthy communities and ecosystems: In keeping with its role of stewardship in an ever-changing global environment and working in service to both human health and the quality of the environment, EPA will continue efforts to improve communities by restoring contaminated properties, including brownfields, to environmental and economic vitality and encouraging voluntary community clean-up of potentially dangerous abandoned mine sites. These efforts will be paired with the promotion of community-level activities through increased resource conservation, including waste minimization through source reduction and recycling.

Global environment: As the EPA works to improve its role as steward to local communities, it serves as a participant in global activity to protect and restore the shared resources and the environment. To that end, the Agency is dedicated to finding solutions to issues that have far-reaching, global implications. EPA strives to promote energy security, and simultaneously advances international collaboration on environmental issues, such as reduction of air pollution and greenhouse gas emissions. The means to achieving these results include agreements like the Asia-Pacific Partnership on Clean Development and the Methane-to-Market Partnership.

Stronger EPA: As the Agency continues to uphold the President's Management Agenda, it could not ensure its success without a diverse, talented, and highly-skilled workforce. Equipped with the energy, intensity, and vitality of its professional staff, EPA is better able to devote prevention,

preparedness, and research efforts toward national security and respond to natural disasters.

Rules Expected to Impact Small Entities

EPA continues to focus on implementing its 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 www.epa.gov/regagenda). The priority items that are expected to have a significant impact on a substantial number of small entities include:

Control of Hazardous Air Pollutants from Mobile Sources (2060-AK70)

Control of Emissions from Spark-Ignition Engines and Fuel Systems from Marine Vessels and Small Equipment (2060-AM34)

Lead-Based Paint Activities; Amendments for Renovation, Repair and Painting (2070-AC83)

EPA's Regulatory Plan is an important element of the Agency's strategy for achieving environmental results within the framework described above. The Agency's regulatory program includes several efforts that will reduce the burden placed on small businesses while ensuring the integrity of the environment. Many of these have been nominated for Agency Action through the public nomination process initiated by the Office of Management and Budget (OMB) in 2001, 2002, and 2004. Taken as a whole, the Agency's Regulatory Plan will ensure that the nation continues to achieve improvements in environmental quality while minimizing burden to states and the regulated community.

HIGHLIGHTS OF EPA'S REGULATORY PLAN

Office of Air and Radiation

A principal regulatory priority of EPA's Office of Air and Radiation (OAR) in 2006 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, an effect of particular concern in national parks and other scenic areas. In addition to ozone and particulate pollution, OAR is continuing to address toxic air pollution by controlling toxic emissions from both stationary sources and mobile sources such as cars and trucks. OAR is also working to increase the effectiveness and efficiency of its permitting and monitoring programs, which are among the main mechanisms through which clean-air protections are implemented. Finally, OAR is revising previously-issued safety standards for nuclear-waste storage in response to a court decision. These efforts are described briefly below.

To help control ozone and particulate pollution, OAR continues to develop rules as part of its program to reduce emissions from mobile sources. These rules will require additional emission reductions from certain marine vessels, locomotives, and small equipment, and will add requirements for fuel economy labeling and renewable-fuel content in gasoline. These rules 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 has been 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. The ozone implementation rule was finalized last year; the particulate implementation rule will be finalized this fall.

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 October, EPA promulgated a rule revising the existing NAAQS for particulates. A rule to either revise or reaffirm the current ozone NAAQS will be proposed and promulgated in 2007. Rules addressing

lead and carbon monoxide will follow in 2008 and 2009, respectively.

EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990. The largest part of this effort is the "Maximum Achievable Control Technology" (MACT) program, which is now entering its second phase consisting of evaluation of the effectiveness of work done so far, and assessment of the need for additional controls. Rulemakings are currently underway covering industries dealing with hazardous organic chemical production and halogenated solvent cleaning. We are also developing a rulemaking requiring additional reductions in toxic emissions from mobile sources such as cars and trucks.

Since many air quality programs are administered through permitting and monitoring programs, OAR continues to work toward improving these programs to increase efficiency and reduce regulatory burden. Currently, OAR is continuing to develop 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. OAR is also developing a rulemaking to clarify and better define the kinds of monitoring required in Federal and State operating permit programs.

In 2006, EPA also expects to complete a rulemaking amending the radiation standards governing the development of the Yucca Mountain site in Nevada, the nation's designated geologic repository for spent nuclear fuel and high-level radioactive waste. These standards were initially issued in 2001 and were partially remanded by a Federal court in 2004. To address the remand, EPA must reassess the time frame for compliance in light of the National Academy's recommendation that compliance must be addressed at the time of peak dose, which may be as long as several hundred thousand years into the future.

Office of Environmental Information

EPA's Office of Environmental Information (OEI) ensures 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 Toxics Release Inventory (TRI) Burden Reduction Rule.

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, EPA initiated two rulemakings to address both short-term and longer-term reporting requirement modifications while maintaining the practical utility of the TRI data. The TRI Reporting Forms Modification Rule, which addressed relatively minor modifications to the TRI reporting forms, was published in the Federal Register on July 12, 2005 (70 FR 39931). TRI continued its efforts to reduce the TRI reporting burden and published the TRI Burden Reduction Proposed Rule in October 2005 (70 FR 57822). The second regulatory proposal examines more significant reporting modifications with greater potential impact on reporting burden. The TRI Burden Reduction Rule offers burden reduction options that are technically, practically and legally feasible in order to meet the goals and statutory obligations set forth for TRI reporting. The rule will reduce burden associated with TRI reporting while maintaining EPA's commitment to providing valuable information to the public.

Through the Central Data Exchange (CDX) system, EPA is also committed to providing electronic access to its stakeholders to meet EPA's reporting requirements. 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. CDX is on track to provide electronic reporting services for all significant environmental data collections over the next two years. CDX enables EPA and participating program offices to work with stakeholders - including State, tribal and local governments and regulated industries - to enable streamlined, electronic submission of data via the Internet.

By enabling the regulated community to utilize CDX as a reporting tool, the TRI Program received about 60% of its submissions on line for Reporting Year (RY) 2005. To take advantage of CDX's paperless reporting feature, TRI

reporters must use the EPA-provided TRI Made-Easy (TRI-ME) Software. For RY 2005, over 95 percent of all facilities used TRI-ME to prepare their reports. This reflects an upward trend toward greater Internet reporting via CDX and 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 provide greater electronic means of accessing TRI data.

Over the past several years, CDX also added 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

The primary goal of EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) is to prevent and reduce pesticide and industrial chemical risks to humans, communities and ecosystems. OPPTS employs a mix of regulatory and non-regulatory methods to achieve this goal. During the past fiscal year, OPPTS proposed and finalized a number of significant regulatory actions that are briefly highlighted below. For more information about these regulatory actions, as well as information about our other programs and activities, please visit our Web site at www.epa.gov/oppts. Looking forward to the coming fiscal year, OPPTS expects to issue several significant regulatory actions that are also highlighted below.

In late 2006 EPA will complete a 10-year review of food-use pesticides, as mandated by the Food Quality Protection Act of 1996 (FQPA). The changes in pesticide use patterns resulting from this review have included outright phase-out of hundreds of pesticides, elimination of certain uses, stricter use provisions, and establishment of food tolerances. Americans today can be confident that pesticides used in the United States meet the highest health and safety standards.

Associated with this review of food-use chemicals, early in 2006, EPA issued a final rule that significantly strengthened and expanded the protections for participants in environmental research in three ways. The rule categorically banned intentional dosing human testing for pesticides when the subjects are pregnant women, nursing women or children. The rule also formalized and further strengthened existing protections for subjects in human research conducted or supported by EPA, as well as to intentional dosing human studies for pesticides conducted by others who intend to submit the research to EPA. This action assures that the best available, ethically sound science is used in our decisionmaking processes.

To ensure that pesticides are continuously reviewed against the latest health and safety standards, in August of 2006, OPPTS began implementing a new 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 in 2006 and reregistration program in 2008.

Also in 2006, EPA published a final rule to revise the regulations governing emergency exemptions that allow unregistered uses of pesticides to address emergency pest conditions for a limited time. These revisions reduced the burden to both applicants and EPA, provided for consistent determinations of "significant economic loss" as the basis for an emergency, and updated and clarified the regulations to be consistent with the requirements of FQPA. As a result, the final rule is expected to allow EPA to respond to these emergencies more quickly without compromising existing protections for human health and the environment.

In 2007, EPA will continue its work towards the Administration goal of eliminating childhood lead poisoning as

a national health concern by 2010 by developing a comprehensive program for the management of renovation, repair and painting activities involving lead-based paint hazards. The program will be comprised of a combination of approaches including an extensive education and outreach campaign for lead-safe work practices and training for industry, an outreach campaign designed to expand consumer awareness and create demand for the use of lead-safe work practices, and the establishment of final regulatory requirements. As a part of this effort, EPA issued a proposed rule on January 10, 2006, that would minimize the introduction of lead hazards resulting from the disturbance of lead-based paint during renovation, repair, and painting activities in most housing built before 1978 by requiring that all persons and firms who conduct such work for compensation follow lead-safe work practice standards and be trained and certified in the use of lead-safe work practices, and that providers of renovation training be accredited.

In 2006 and 2007, EPA will continue working collaboratively with stakeholders to better understand the sources and exposure pathways leading to the presence of PFOA in humans and the environment. EPA works with multiple parties to produce missing information on PFOA through enforceable consent agreements, memoranda of understanding, and voluntary commitments, continues to provide data to help answer many important questions about these chemicals. PFOA or perfluorooctanoic acid, a synthetic (man-made) chemical that does not occur naturally in the environment, is used to make fluoropolymers, substances with special properties that have thousands of important manufacturing and industrial applications. Consumer products made with fluoropolymers include non-stick cookware, and breathable, all-weather clothing. EPA began its investigation because PFOA is persistent in the environment and was being found at very low levels both in the environment and in the blood of the general U.S. population. EPA summarized its concerns and identified data gaps and uncertainties about PFOA in a notice published in the Federal Register on April 16, 2003.

EPA continues to implement the voluntary HPV Challenge Program, a collaborative partnership between EPA and industry stakeholders, to develop health and safety screening information on sponsored high production volume

chemicals. To complement this voluntary effort, OPPTS expects to issue a second proposed test rule under the Toxic Substances Control Act (TSCA) in early 2007 that will require testing for a number of the HPV chemicals that were not sponsored as part of the voluntary HPV Challenge Program in order to develop critical information about the environmental fate and potential hazards of those chemicals. When combined with information about exposure and uses, the information developed will allow the Agency and others to evaluate potential health and environmental risks, and take appropriate actions.

EPA thoroughly evaluates pesticides to ensure that they will meet Federal safety standards to protect human health and the environment before they can be marketed and used in the United States. EPA uses data submitted by pesticide producers to form the basis for the pesticide risk assessments and decisions as to whether pesticides meet the safety standards. Although the Agency has kept pace with evolving scientific understanding of pesticide risks by requiring the submission of the data needed on a case-by-case basis, OPPTS expects to issue final rules in 2007 that update the data requirements for biochemical, microbial, and conventional chemical pesticides to formally reflect evolving data needs. EPA also intends to propose in 2007 additional data requirements for antimicrobial pesticides and plant-incorporated protectants.

To update and strengthen the protections for pesticide applicators and agricultural workers, in late 2007, OPPTS expects to propose changes to the Federal regulations for the certified pesticide applicator program (CPAP). Many changes in State programs have occurred since the CPAP regulations were promulgated in the 1970s, such that State programs go beyond the current Federal regulations in training and certifying pesticide applicators. The Agency anticipates revisions that will broaden the scope of the certification program to include additional occupational users, and strengthen the demonstration of competency as a requirement of certification. In conjunction with the applicator certification improvements, OPPTS will also propose improvements to the agricultural worker protection program in a separate but related proposed rule. The Agency expects these changes will strengthen the regulations to better protect pesticide applicators,

agricultural workers, the public, and the environment.

To further waste minimization and recycling goals, OPPTS intends to propose that manufacturers of agricultural and professional specialty pesticides support pesticide container recycling by either managing and operating their own programs, or contracting with a recycling organization. This proposal is intended to bolster current voluntary programs that have demonstrated that pesticide containers can be safely and efficiently recycled.

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 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 2007, EPA anticipates publishing the preliminary procedures for use in implementing the screening and testing phase of the EDSP.

In response to comments submitted to OMB as part of OMB's Regulatory Reform of the U.S. Manufacturing Sector (2005) report, EPA issued a proposed rule on February 9, 2006, to streamline the TSCA section 12(b) export notification requirement in terms of the exporter's activities, as well as streamlining the Agency's procedures to notify foreign governments. OPPTS also proposed to eliminate reporting for de minimis concentration levels and proposed other improvement to the export notification regulations. EPA expects to issue a final rule early in FY2007.

In addition, in response to another comment submitted to OMB as part of OMB's Regulatory Reform of the U.S. Manufacturing Sector (2005) Report, about the use of mercury-containing

switches in convenience lights and braking systems installed in new cars, EPA proposed a TSCA Section 5 Significant New Use Rule (SNUR) on July 11, 2006, to ensure that the Agency is notified and provided the opportunity to evaluate and, if necessary, to prohibit or limit the use of mercury in automobiles switches before U.S. manufacture, import or processing occurs for that purpose in order to prevent unreasonable risk of injury to human health or the environment. EPA expects to finalize this SNUR in 2007.

Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) contributes to the Agency's overall mission of protecting public health and the environment by focusing on the safe management of wastes; preparing for, preventing and responding to chemical and oil spills, accidents, and emergencies; enhancing homeland security; and cleaning up contaminated property and making it available for reuse. EPA carries out these missions in partnership with other Federal agencies, States, tribes, local governments, communities, nongovernmental organizations, and the private sector. To further these missions, OSWER has identified several regulatory priorities for the upcoming fiscal year that will promote stewardship and resource conservation and focus regulatory efforts on risk reduction and statutory compliance.

EPA is considering expanding the comparable fuels program. This program currently allows specific industrial wastes to be excluded from the Resource Conservation and Recovery Act (RCRA) hazardous waste requirements when they are used as a fuel and do not contain hazardous constituent levels exceeding those in a typical benchmark fuel that facilities could otherwise use. If EPA is successful in finding additional industrial wastes that could be used safely for their energy value without the expense of a RCRA permit, it would promote the use of these industrial wastes as a renewable domestic source of energy and reduce our use of fossil fuels. It also could significantly reduce the cost of recovering the energy from some hazardous wastes already used as fuels.

The "definition of solid waste" determines the recyclable secondary materials that are regulated under the RCRA hazardous waste regulations and those that are not. The RCRA regulatory definition of solid waste classifies

recyclable hazardous secondary materials as either regulated hazardous wastes or unregulated materials. Many materials that are reclaimed as part of the recycling process are regulated as hazardous wastes. This can discourage recycling of the wastes, due to requirements for permits (which trigger corrective action), manifests, and the other requirements imposed by the Subtitle C hazardous waste regulations. EPA is considering innovative approaches that will increase the safe recycling of hazardous waste, while still ensuring that these materials are properly handled.

EPA is continuing its pursuit to improve and modernize the hazardous waste tracking system by developing an "e-manifest." This system will allow electronic processing of hazardous waste transactions that will greatly enhance tracking capabilities, while significantly reducing administrative burden and costs for governments and the regulated community. The e-manifest will build on the new standardized manifest form that took effect in September 2006, and will ensure the continued safe management of hazardous waste.

EPA is seeking to amend the Spill Prevention, Control, and Countermeasure (SPCC) Plan requirements to reduce the burden imposed on the regulated community for complying with the SPCC requirements, while maintaining protection of human health and the environment.

The Office of Management and Budget's Reports to Congress on the Costs and Benefits of Regulations for 2001, 2002 and 2004 included reform nominations for the Agency to consider. All the rulemakings mentioned above support reform nominations. In addition, two additional rulemakings under development also pertain to the reform nominations: (1) a rule to streamline laboratory waste management in academic and research laboratories and (2) a rule to manage the cement kiln dust, a by-product of the cement manufacturing process. The Agency is developing final rules for both these efforts. For the former rule, the Agency proposed a set of alternative standards that are more tailored to the way laboratories operate. The goal is to further protect human health and the environment through application of RCRA standards that are harmonious with the way laboratories operate. For the latter rule, the Agency proposed a comprehensive set of standards for the management of cement kiln dust. The

goal is to encourage the additional reuse and safer management of chemicals in laboratories, while continuing to protect human health and the environment.

Office of Water

EPA's Office of Water's (OW) primary goals are to ensure that drinking water is safe; to restore and maintain oceans, watersheds, and their aquatic ecosystems to protect human health; to support economic and recreational activities; and to 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 National Pollutant Discharge Elimination System permit requirements.

OW is planning to finalize three actions affecting National Pollutant Discharge Elimination System (NPDES) permitting requirements in FY 2007. The first is a rule addressing the NPDES permitting requirements and Effluent Limitations Guidelines and Standards (ELGs) for concentrated animal feeding operations (CAFOs) in response to the order issued by the Second Circuit Court of Appeals in *Waterkeeper Alliance et al. v. EPA*, 399 F.3d 486 (2nd Cir. 2005). This final rule will respond to the court order while furthering the statutory goal of restoring and maintaining the nation's water quality and effectively ensuring that CAFOs properly manage manure generated by their operations. A second action is the Water Transfers rulemaking. EPA will finalize the proposed rule which amends the Clean Water Act regulations to clarify that NPDES permits are not required for water transfers. Lastly, EPA also plans to issue a policy regarding NPDES permit requirements for peak wet weather diversions at publicly owned treatment works (POTW) treatment plants serving separate sanitary sewer collection systems.

EPA

PRERULE STAGE

98. ENDOCRINE DISRUPTER SCREENING PROGRAM (EDSP); IMPLEMENTING THE SCREENING AND TESTING PHASE

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:

Section 408(p) of the Federal Food, Drug, and Cosmetic Act, as amended by the 1996 Food Quality Protection Act, directs EPA to establish and implement a program whereby industry will be required to screen and test all pesticide chemicals to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate. The requirements of Section 408(p) were implemented through the creation of the Endocrine Disruptor Screening Program (EDSP) in 1998. The EDSP has the following three components that are proceeding simultaneously: 1) developing and validating assays; 2) setting chemical testing priorities; and 3) establishing 408(p) testing orders and related data procedures. A Federal Advisory Committee Act committee is providing advice to the EDSP on assay development and validation. For chemical testing priorities, the approach to selecting the first 50-100 chemicals was finalized in a September 2005 Federal Register Notice (70 FR 56449) and EPA is implementing that approach. For establishing the testing orders and related data procedures, EPA intends to focus on the initial 50-100 chemicals. The agency intends to conduct a review of the data received from the screening of the initial group of chemicals to evaluate whether the program could be improved or optimized, and if so, how.

Statement of Need:

The Endocrine Disruptor Screening Program Implementation of the Screening and Testing Phase fulfills the statutory direction and authority to screen pesticide chemicals and drinking water contaminants for their potential to disrupt the endocrine system and adversely affect human health and wildlife.

Summary of Legal Basis:

The screening and testing phase of the Endocrine Disruptor Screening Program (EDSP) potentially will encompass a

broad range of types of chemicals, including pesticide chemicals, TSCA chemicals, chemicals that may be found in sources of drinking water, chemicals that may have an effect that is cumulative to the effect of a pesticide chemical, chemicals that are both pesticide chemicals and TSCA chemicals, and other chemicals that are combinations of these types of chemicals. As discussed in the Proposed Statement of Policy, EPA has a number of authorities at its disposal to require testing of these types of chemicals. The Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(p) provides EPA authority to require testing of all pesticide chemicals and any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if EPA determines that a substantial population may be exposed to the substance. 21 U.S.C. 346a(p). Likewise, the Safe Drinking Water Act (SDWA) provides EPA with authority to require testing of any substance that may be found in sources of drinking water if EPA determines that a substantial population may be exposed to the substance. 42 U.S.C. 300j-17. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides EPA with authority to require testing of pesticides if EPA determines that additional data are required to maintain in effect an existing registration. 7 USC sec 136a(c)(2)(B). The Toxic Substances Control Act (TSCA) provides authority for EPA to require testing of TSCA chemicals, provided that it makes certain hazard and/or exposure findings. 15 USC sec 2603. In addition, EPA has authority to issue consent orders to require testing when interested parties agree on an acceptable testing program. 51 Fed. Reg. 23706 (June 30, 1986).

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:

It is too early to project the costs and benefits of this program accurately.

However, a preliminary rough estimate by industry indicated a cost of \$200,000 per chemical. It is also too early to quantify the benefits of this program quantitatively. The goal of the program is to reduce the risks identified below.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk from exposure to chemicals operating through an endocrine mediated pathway. Epidemiological studies on the associations between chemical exposures and adverse endocrine changes continue to evaluate this problem in humans. 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	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4728; EPA publication information: Split from RIN 2070-AD26. In August 2000, the Agency submitted the required Status Report to Congress. In March 2002, the Agency submitted the requested status report to Congress on the Endocrine Disruptor Methods Validation subcommittee under the National Advisory Council on Environmental Policy and Technology.

URL For More Information:

www.epa.gov/scipoly/oscpendo/index.htm*COM001*

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RIN: 2070-AD61

EPA

**99. STANDARDS FOR THE
 MANAGEMENT OF COAL
 COMBUSTION WASTES GENERATED
 BY COMMERCIAL ELECTRIC POWER
 PRODUCERS**

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6907(a)(3); 42 USC 6944(a)

CFR Citation:

40 CFR 257

Legal Deadline:

None

Abstract:

This action is for the development of non-hazardous waste regulations under subtitle D of the RCRA statute. The regulations will apply to landfill and surface impoundment facilities that manage coal combustion wastes generated by steam electric power generators, i.e., electric utilities and independent power producers. This action results from EPA's regulatory determination for fossil fuel combustion wastes (see 65 FR 32214, May 22, 2000), which concluded that waste management regulations under RCRA are appropriate for certain coal combustion wastes. The intended benefits of this action will be to prevent contamination or damage to ground waters and surface waters, thereby avoiding risk to human health and the

environment, including ecological risks. The Agency is currently analyzing the human health and eco risks, costs, and economic impact of this action as it develops the proposed regulation. The Agency has considered alternatives to this action, including regulating these wastes as hazardous wastes under subtitle C of RCRA, but has rejected this approach as discussed in the regulatory determination (see 65 FR 32214, May 22, 2000). EPA has also considered issuing guidance instead of regulations to industry and State and local governments to focus on these remaining waste management issues, particularly since the industry has improved its waste management practices and most State regulatory programs are similarly improving. To this end, the Agency will be issuing a Notice of Data Availability (NODA) announcing the availability for public inspection and comment on new information and data on the management of coal combustion wastes that the Agency will consider in deciding next steps in this effort.

Statement of Need:

The Agency is in the process of developing non-hazardous waste regulations under RCRA Subtitle D for the management of coal combustion wastes in landfills and surface impoundments. The Agency found that in 1995, liners were installed in only 57% of landfills and 26% of surface impoundments. Additionally, while 85% of landfills practiced groundwater monitoring, only 38% of surface impoundments did so. EPA is concerned that the lack of liners and groundwater monitoring could pose risks to human health and the environment.

Summary of Legal Basis:

RCRA Section 8002

Alternatives:

The Agency has considered alternatives to this action, including regulating these wastes as hazardous wastes under subtitle C of RCRA, but has rejected this approach as discussed in the regulatory determination (see 65 FR 32214, May 22, 2000). EPA has also considered issuing guidance instead of regulations to industry and State and local governments to focus on these remaining waste management issues.

Anticipated Cost and Benefits:

In the May 2000 regulatory determination the Agency stated that the decision to develop non-hazardous waste regulations for coal combustion

wastes is a "significant regulatory action." The benefits of the action will be reduced risks to human health and the environment.

Risks:

Risks posed by the mismanagement of coal combustion wastes include contamination of groundwater and surface water from metals, such as arsenic, boron, cadmium, and selenium.

Timetable:

Action	Date	FR Cite
NODA	12/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 4470; This effort may also impact Federal, State, local or tribal governments that own coal-burning commercial electric power generating facilities.

Sectors Affected:

221112 Fossil Fuel Electric Power Generation

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RIN: 2050-AE81

EPA

PROPOSED RULE STAGE

100. REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR CARBON MONOXIDE

Priority:

Other Significant

Legal Authority:

42 USC 7409

CFR Citation:

40 CFR 50

Legal Deadline:

Final, Statutory, May 31, 2001, Clean Air Act requires reviews every 5 years.

Abstract:

Review of the National Ambient Air Quality Standards (NAAQS) for carbon monoxide (CO) every 5 years is mandated by the Clean Air Act. This review assesses the available scientific data about the health and environmental effects of CO and translates the science into terms that can be used in making recommendations about whether or how the standards should be changed. The last review of the CO NAAQS was completed in 1994 with a final decision that revisions were not appropriate at that time.

Statement of Need:

As new health research becomes available on the effects of carbon monoxide, the Clean Air Act requires EPA to review the adequacy of the existing NAAQS at 5-year intervals.

Summary of Legal Basis:

The Clean Air Act requires review and revision of the NAAQS every five years.

Alternatives:

Alternatives for revising or maintaining the NAAQS will be assessed at a later point in the review cycle, after the scientific assessment of risk is completed.

Anticipated Cost and Benefits:

Costs and benefits will be evaluated later in the review cycle.

Risks:

Risk information will be available later in the review cycle.

Timetable:

Action	Date	FR Cite
NPRM	01/00/09	
Final Action	11/00/09	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Additional Information:

SAN No. 4266

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RIN: 2060-AI43

EPA

101. CONTROL OF EMISSIONS FROM NEW LOCOMOTIVES AND NEW MARINE DIESEL ENGINES LESS THAN 30 LITERS PER CYLINDER

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7522-7621

CFR Citation:

40 CFR 92; 40 CFR 94

Legal Deadline:

None

Abstract:

Emissions from locomotive and marine diesel engines contribute significantly to unhealthful levels of ambient particulate matter and ozone in many parts of the United States. These engines are highly mobile and are not easily controlled at a State or local level. EPA currently regulates the manufacturers of these engines when

they are produced or remanufactured at a level similar to early 1990s on-highway diesel trucks. This rulemaking will propose to set an additional tier of more stringent particulate matter and nitrogen oxides emission standards for new marine diesel engines below 30 liters per cylinder (Category 1 and Category 2 marine diesel engines) and new locomotive engines. The standards under consideration are expected to be based on the use of high-efficiency aftertreatment technologies like those that will be used to meet EPA's recent heavy-duty and nonroad diesel standards. These technologies, which could reduce emissions by 90 percent, would be enabled by the availability and use of low sulfur diesel fuel.

Statement of Need:

Further reductions in nitrogen oxide (NOx) and particulate emissions are needed to help States attain national air-quality standards for particulates and for ozone, for which NOx is a precursor.

Summary of Legal Basis:

42 USC 7547

Alternatives:

Alternatives will be developed as the rulemaking proceeds. We recently issued an Advanced Notice of Proposed Rulemaking to gather ideas and comments from the interested public.

Anticipated Cost and Benefits:

Cost and benefit information will be developed as the rulemaking proceeds.

Risks:

The risks addressed by this rule are primarily those resulting from exposure to particulate matter and ozone. Risk information will be quantified as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
ANPRM	06/29/04	69 FR 39276
NPRM	05/00/07	
Final Action	05/00/08	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 4871

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EPA**102. CONTROL OF EMISSIONS FROM NONROAD SPARK-IGNITION ENGINES AND EQUIPMENT****Priority:**

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7521-7601(a)

CFR Citation:

40 CFR 90

Legal Deadline:

NPRM, Statutory, December 1, 2004.
 Final, Statutory, December 31, 2005.

Abstract:

In this action, we are proposing exhaust emission standards for spark-ignition marine engines and small land-based engines (<19 kW). We are also proposing evaporative emission standards for vessels and equipment using these engines. Nationwide, these emission sources contribute to ozone, carbon monoxide (CO), and particulate matter (PM) nonattainment. These pollutants cause a range of adverse health effects, especially in terms of respiratory impairment and related illnesses. The proposed standards would help States achieve and maintain air quality standards. In addition, these standards would help reduce acute exposure to CO, air toxics, and PM.

Statement of Need:

EPA has been directed by Congress to set new emission requirements for small spark-ignition (gasoline) engines. The Agency has previously acted to set standards for these nonroad engine source categories as there are significant health and welfare benefits associated with such controls. Even with existing standards, these sources continue to be contributors to air pollution inventories and further reductions will be helpful to State and local governments and tribes in their development of National Ambient Air Quality Standards plans.

Summary of Legal Basis:

Section 213 of the Clean Air Act gives EPA authority to set emissions requirements for nonroad engines. The engines covered under this proposed rulemaking are all considered nonroad engines. California may set its own emissions standards - unlike other mobile source categories, states are prohibited from adopting California emission standards for small spark ignition engines below 50 horsepower.

Alternatives:

A range of alternatives for the various exhaust and evaporative emissions standards is being discussed as part of the rulemaking development process. Alternatives include more stringent standards and different time frames for adopting the new requirements.

Anticipated Cost and Benefits:

There are potential significant health and welfare benefits associated with additional emissions control requirements for small spark-ignition engines. New standards can potentially achieve reductions in VOC emissions as well as other pollutants. Costs and benefits will be quantified and reported as part of the rulemaking process.

Risks:

Impacts of the proposed standards on health indicators will be discussed as part of the rulemaking development.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	
Final Action	11/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4882;

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EPA**103. IMPLEMENTING PERIODIC MONITORING IN FEDERAL AND STATE OPERATING PERMIT PROGRAMS****Priority:**

Other Significant

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 70.6(c)(1); 40 CFR 71.6(c)(1); 40 CFR 64

Legal Deadline:

None

Abstract:

This rule would revise the Compliance Assurance Monitoring rule (40 CFR part 64) to be implemented through the operating permits rule (40 CFR Parts 70 and 71) to define when periodic monitoring for monitoring stationary source compliance must be created, and to include specific criteria that periodic monitoring must meet. This rule satisfies our 4-step strategy announced in the final Umbrella Monitoring Rule (published January 22, 2004) to address monitoring inadequacies. The four steps were: 1) to clarify the role of title V permits in monitoring [Umbrella Monitoring Rule]; 2) to provide guidance for improved monitoring in PM-Fine SIP's; 3) to take comment on correction of inadequate monitoring provisions in underlying rules; and 4) to provide guidance on periodic monitoring. We have completed the RIA data collection and most of the analyses, and are beginning review with OPEI and an economic sub-work group.

Statement of Need:

The "periodic monitoring" rules, 40 CFR 70.6(a)(3)(i)(B) and 71.6(a)(3)(i)(B), require that "[w]here the applicable requirement does not require periodic testing or instrumental or noninstrumental monitoring (which may consist of recordkeeping designed to serve as monitoring), [each title V permit must contain] periodic monitoring sufficient to yield reliable data from the relevant time period that are representative of the source's compliance with the permit, as reported pursuant to [§ 70.6(a)(3)(iii) or § 71.6(a)(3)(iii)]. Such monitoring requirements shall assure use of terms, test methods, units, averaging periods, and other statistical conventions consistent with the applicable requirement. Recordkeeping provisions may be sufficient to meet the

requirements of [§70.6(a)(3)(i)(B) and §71.6(a)(3)(i)(B)].” Sections 70.6(c)(1) and 71.6(c)(1), called the umbrella monitoring rule, require that each title V permit contain, “[c]onsistent with paragraph (a)(3) of this section, compliance certification, testing, monitoring, reporting, and recordkeeping requirements sufficient to assure compliance with the terms and conditions of the permit.” On January 22, 2004 (69 Federal Register 3202), EPA announced that the Agency has determined that the correct interpretation of §§ 70.6(c)(1) and 71.6(c)(1) is that these sections do not provide a basis for requiring or authorizing review and enhancement of existing monitoring in title V permits independent of any review and enhancement as may be required under the periodic monitoring rules, the CAM rule (40 CFR part 64)(62 FR 54900, October 22, 1997) where it applies, and other applicable requirements under the Act. This action is to publish a separate proposed rule to address what monitoring constitutes periodic monitoring under §§ 70.6(a)(3)(i)(B) and 71.6(a)(3)(i)(B) and what types of monitoring should be created under these provisions. The intended effect of the rule revisions in this proposal is to focus case-by-case reviews on those applicable requirements for which we can identify potential gaps in the existing monitoring provisions.

Summary of Legal Basis:

Section 502(b)(2) of the Act requires EPA to promulgate regulations establishing minimum requirements for operating permit programs, including “[m]onitoring and reporting requirements.” 42 U.S.C. § 7661a(b)(2). Second, section 504(b) authorizes EPA to prescribe “procedures and methods” for monitoring “by rule.” 42 U.S.C. “7661c(b). Section 504(b) provides: “The Administrator may by rule prescribe procedures and methods for determining compliance and for monitoring and analysis of pollutants regulated under this Act, but continuous emissions monitoring need not be required if alternative methods are available that provide sufficiently reliable and timely information for determining compliance. . . .” Other provisions of title V refer to the monitoring required in individual operating permits. Section 504(c) of the Act, which contains the most detailed statutory language concerning monitoring, requires that “[e]ach [title V permit] shall set forth inspection, entry, monitoring, compliance certification, and reporting

requirements to assure compliance with the permit terms and conditions.” 42 U.S.C. section 7661c(c). Section 504(c) further specifies that “[s]uch monitoring and reporting requirements shall conform to any applicable regulation under [section 504(b)]. . . .” Section 504(a) more generally requires that “[e]ach [title V permit] shall include enforceable emission limitations and standards, . . . and such other conditions as are necessary to assure compliance with applicable requirements of this Act, including the requirements of the applicable implementation plan.” 42 U.S.C. section 7661c(a).

Alternatives:

Some existing monitoring required under applicable requirements could be improved and will be addressed in connection with both the upcoming PM2.5 implementation rulemaking and by improving monitoring in certain Federal rules or monitoring in SIP rules not addressed in connection with the PM2.5 implementation guidance or rulemaking over a longer time frame.

Anticipated Cost and Benefits:

We are assessing the benefits associated with improved monitoring including the reduction in source owner response time to potential excess emissions problems. Such reduced response time to take corrective action that will be required by the rule will result in measurable emissions reductions that will be balanced against the cost of increased equipment, data collection, and recordkeeping costs. We estimate the total costs of the rule to be more than \$100 million.

Risks:

There are no environmental and health risks associated with implementing this monitoring rule; the underlying rules with emissions limits address those risks for each subject source category. The effect of the monitoring resulting from this rule will be to reduce the occurrence of excess emissions episodes that raise such risks.

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4699.2; Split from RIN 2060-AK29.

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RIN: 2060-AN00

EPA

104. REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7408; 42 USC7409

CFR Citation:

40 CFR 50

Legal Deadline:

Final, Statutory, July 18, 2002, CAA Amendments of 1977.

NPRM, Judicial, March 28, 2007, Consent Decree.

Final, Judicial, December 19, 2007, Consent Decree.

Abstract:

The Clean Air Act Amendments of 1977 require EPA to review and, if necessary, revise national ambient air quality standards (NAAQS) periodically. On July 18, 1997, the EPA published a final rule revising the NAAQS for ozone. The primary and secondary NAAQS were strengthened to provide increased protection against both health and environmental effects of ozone. The EPA’s work plan/schedule for the next review of the ozone Criteria Document was published on November 2002. The first external review draft Criteria Document, a rigorous assessment of relevant scientific information, was released on January 31, 2005. The EPA’s Office of Air Quality Planning

and Standards will prepare a Staff Paper for the Administrator, which will evaluate the policy implications of the key studies and scientific information contained in the Criteria Document and additional technical analyses, and identify critical elements that EPA staff believe should be considered in reviewing the standards. The Criteria Document and Staff Paper will be reviewed by the Clean Air Scientific Advisory Committee and the public, and both final documents will reflect the input received through these reviews. As the ozone NAAQS review is completed, the Administrator's proposal to reaffirm or revise the ozone NAAQS will be published with a request for public comment. Input received during the public comment period will be considered in the Administrator's final decision.

Statement of Need:

As established in the Clean Air Act, the national ambient air quality standards for ozone are to be reviewed every five years.

Summary of Legal Basis:

Section 109 of the Clean Air Act (42 USC 7409) directs the Administrator to propose and promulgate "primary" and "secondary" national ambient air quality standards for pollutants identified under section 108 (the "criteria" pollutants). The "primary" standards are established for the protection of public health, while "secondary" standards are to protect against public welfare or ecosystem effects.

Alternatives:

The main alternatives for the Administrator's decision on the review of the national ambient air quality standards for ozone are whether to reaffirm or revise the existing standards.

Anticipated Cost and Benefits:

Costs and benefits of revising or reaffirming the national ambient air quality standards for ozone cannot be determined at present; a regulatory impact analysis will be conducted along with the review of the standards.

Risks:

The current national ambient air quality standards for ozone are intended to protect against public health risks associated with morbidity and/or premature mortality and public welfare risks associated with adverse vegetation and ecosystem effects. During the course of this review, risk

assessments will be conducted to evaluate health and welfare risks associated with retention or revision of the ozone standards.

Timetable:

Action	Date	FR Cite
Notice	12/29/05	70 FR 77155
NPRM	03/00/07	
Final Action	12/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 5008

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RIN: 2060-AN24

EPA

105. PREVENTION OF SIGNIFICANT DETERIORATION, NONATTAINMENT NEW SOURCE REVIEW, AND NEW SOURCE PERFORMANCE STANDARDS: EMISSIONS TEST FOR ELECTRIC GENERATING UNITS

Priority:

Other Significant

Legal Authority:

Clean Air Act, Title I Parts C and D and Section 111(a)(4)

CFR Citation:

40 CFR Part 51; 40 CFR Part 52

Legal Deadline:

None

Abstract:

This rulemaking would create a revised emissions test for existing electric

generating units (EGUs) that are subject to the regulations governing the Prevention of Significant Deterioration (PSD) and nonattainment major New Source Review (NSR) programs mandated by parts C and D of title I of the Clean Air Act (CAA). This revised emissions test would be available for EGUs that are also subject to the EPA-administered Clean Air Interstate Rule (CAIR) NO_x Annual Trading Program or the CAIR SO₂ Trading Program. This emissions test could be extended to other CAIR and non-CAIR EGUs. For existing major stationary sources, the NSR base program emissions test is applied when the source proposes to modify an emissions unit such that the change is a physical change or change in the method of operation, and the test compares actual emissions to either potential emissions or projected actual emissions. Under this rulemaking's revised NSR emissions test (a maximum hourly test like that used in the NSPS program), we would compare the EGU's maximum hourly emissions (considering controls) before the change for the past 5 years to the maximum hourly emissions after the change. The maximum hourly emissions will be either a maximum achieved and maximum achievable hourly emissions, measured on an input or an output basis. The supplemental notice will include proposed regulatory language for the maximum achieved and achievable options (input and output basis for each). The supplemental notice will also include data, information, and analyses concerning the impacts of the proposed options. The supplemental notice will also include an option in which the current regulations (annual emissions test) are retained, but the baseline period is extended from 5 to 10 years.

Statement of Need:

Utilization of this rulemaking's alternative NSR applicability test for existing EGUs would encourage increased utilization at the more efficient units by displacing energy production at less efficient ones.

Summary of Legal Basis:

Parts C and D of title I of the Clean Air Act; CAA section 111(a)(4)

Alternatives:

The proposed basis for the applicability test is a comparison of maximum hourly emissions, which will enhance the implementation and environmental benefits for existing EGUs. We request

comment on alternative bases for an alternative applicability test.

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	10/20/05	70 FR 61081
Supplemental NPRM	12/00/06	
Final Action	04/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4794.2; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/AIR/2005/October/Day-20/a20983.htm>; Split from RIN 2060-AM95.

URL For More Information:

www.epa.gov/nsr

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RIN: 2060-AN28

EPA

106. REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR LEAD

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 7408; 42 USC 7409

CFR Citation:

40 CFR 50

Legal Deadline:

Final, Judicial, September 1, 2008, Court-ordered schedule.

Abstract:

On October 5, 1978 the EPA promulgated primary and secondary NAAQS for lead under section 109 of the Act (43 FR 46258). Both primary and secondary standards were set at a level of 1.5 µg/m3 as a quarterly average (maximum arithmetic mean averaged over a calendar quarter). Subsequent to this initial standard-setting, the Clean Air Act requires that the standard be reviewed periodically. The last such review occurred during the period 1986-1990. For that review, an Air Quality Criteria Document (AQCD) was completed in 1986 with a supplement in 1990. Based on information contained in the AQCD, an EPA Staff Paper and Exposure Assessment were prepared. Following the completion of these documents, the agency did not propose any revisions to the 1978 Pb NAAQS. The current review of the Pb air-quality criteria was initiated in November 2004 by EPA's National Center for Environmental Assessment (NCEA) with a general call for information published in the Federal Register. In January 2005, NCEA released a work plan for the review and revision of the Pb AQCD. Workshops were held to provide author feedback on a developing draft of the AQCD in August 2005. The draft AQCD was released December 1, 2005. The EPA Office of Air Quality Planning and Standards will prepare a Staff Paper for the Administrator, which will evaluate the policy implications of the key studies and scientific information contained in the AQCD and additional technical analyses, and identify critical elements that EPA staff believe should be considered in reviewing the standards. The AQCD and Staff Paper will be reviewed by the Clean Air Scientific Advisory Committee (CASAC) and the public, and both final documents will reflect the input received through these reviews. As the lead NAAQS review is completed, the Administrator's proposal to reaffirm or revise the lead NAAQS will be published with a request for public comment. Input received during the public comment period will be considered in the Administrator's final decision.

Statement of Need:

As established in the Clean Air Act, the national ambient air quality standards for lead are to be reviewed every five years.

Summary of Legal Basis:

Section 109 of the Clean Air Act (42 USC 7409) directs the Administrator to propose and promulgate "primary" and "secondary" national ambient air quality standards for pollutants identified under Section 108 (the "criteria" pollutants). The "primary" standards are established for the protection of public health, while the "secondary" standards are to protect against public welfare or ecosystem effects.

Alternatives:

The main alternatives for the Administrator's decision on the review of the national ambient air quality standards for lead are whether to reaffirm or revise the existing standards.

Anticipated Cost and Benefits:

Costs and benefits of revising or reaffirming the national ambient air quality standards for lead cannot be determined at present; a regulatory analysis will be conducted along with the review of the standards.

Risks:

The current national ambient air quality standards for lead are intended to protect against public health risks associated with neurological effects in children and cardiovascular effects in adult males. During the course of this review, a risk assessment will be conducted to evaluate health risks associated with the retention or revision of the lead standards. Welfare effects will also be reviewed in relation to retention or revision of the current standard.

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	
Final Action	09/00/08	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN No. 5059

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RIN: 2060-AN83

EPA**107. TEST RULE; TESTING OF CERTAIN HIGH PRODUCTION VOLUME (HPV) CHEMICALS****Priority:**

Other Significant

Legal Authority:

15 USC 2603

CFR Citation:

40 CFR 790 - 799

Legal Deadline:

None

Abstract:

EPA is issuing 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. When finalized on March 16, 2006, the number of chemicals included in the first final rule was reduced to 17 based on new information on annual production

volumes, worker exposure, and commitments to the voluntary HPV Challenge Program. Subsequent test rules, including a proposed rule scheduled to be published in spring of 2007 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% 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% 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 necessary 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	03/16/06	71 FR 13709
Second NPRM	09/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 3990; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-TOX/2000/December/Day-26/t32497.htm>; EPA Docket information: EPA-HQ-OPPT-2005-0033

Sectors Affected:

325 Chemical Manufacturing; 32411 Petroleum Refineries

URL For More Information:

www.epa.gov/opptintr/chemtest

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RIN: 2070-AD16

EPA

108. PESTICIDES; COMPETENCY STANDARDS FOR OCCUPATIONAL USERS

Priority:

Other Significant

Legal Authority:

7 USC 136; 7 USC 136i; 7 USC 136w

CFR Citation:

40 CFR 171; 40 CFR 156; 40 CFR 152

Legal Deadline:

None

Abstract:

The EPA is proposing change to Federal regulations guiding the certified pesticide applicator program (40 CFR 171). Change is sought to strengthen the regulations so that they may better protect pesticide applicators and the public from harm due to pesticide exposure. Changes would include having occupational users of pesticides demonstrate competency by meeting minimum competency requirements, and requiring additional competency determinations of those who use the most toxic pesticides in a manner that could result in significant exposure to the public. The need for change arose from EPA discussions with key stakeholders. EPA has been in extensive discussions with stakeholders since 1997 when the Certification and Training Assessment Group (CTAG) was established. CTAG is a forum used by regulatory and academic stakeholders to discuss the current state of, and the need for improvements in, the national certified pesticide

applicator program. Throughout these extensive interactions with stakeholders, EPA has learned of the need for changes to the regulation.

Statement of Need:

The regulations governing the Federal and State certification of pesticide applicators, 40 CFR part 171, were originally promulgated in 1974. Since that time State certification programs have gone beyond the Federal regulations in a number of areas. In 1997 a group of stakeholders, the Certification and Training Assessment Group (CTAG) was established to evaluate the current situation and future direction of the program. CTAG, comprised of representatives of state pesticide regulatory agencies, cooperative extension services, and EPA Regions and Headquarters, and tribes, offered suggestions for change to the certification program to improve protections for public health and the environment.

Summary of Legal Basis:

7 U.S.C. 136w

Alternatives:

EPA is considering various alternatives to regulation change based upon stakeholder input. The Agency is in the formative stages of this regulatory effort, and alternatives have not yet been fully identified and evaluated.

Anticipated Cost and Benefits:

EPA will develop an economic analysis to support this rule.

Risks:

The proposed regulation would require that occupational users of pesticides meet minimum competency standards and require additional competency determinations of those who use the most toxic pesticides in a manner that could result in significant exposure to the public. These changes would strengthen the regulations that protect pesticide applicators and the public from potential harm due to pesticide exposure.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Tribal

Additional Information:

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RIN: 2070-AJ20

EPA

109. PESTICIDES; AGRICULTURAL WORKER PROTECTION STANDARD REVISIONS

Priority:

Other Significant

Legal Authority:

7 USC 136; 7 USC 136w

CFR Citation:

40 CFR 156; 40 CFR 170

Legal Deadline:

None

Abstract:

The EPA is developing a proposal to revise the Federal regulations guiding agricultural worker protection (40 CFR 170). The changes under consideration are intended to help agricultural workers protect themselves from potential exposure to pesticides and pesticide residues. In addition, EPA is proposing to make adjustments to improve and clarify current requirements and facilitate enforcement. Other changes sought are to establish a right-to-know Hazard Communication program and make improvements to pesticide safety training, with improved worker safety the intended outcome. The need for change arose from EPA discussions with key stakeholders beginning in 1996 and continuing through 2004. EPA held nine public meetings throughout the country during which the public submitted written and verbal

comments on issues of their concern. In 2000 through 2004, EPA held meetings where invited stakeholders identified their issues and concerns with the regulations.

Statement of Need:

The regulations governing the protection of agricultural workers, 40 CFR part 170, were promulgated in 1992. Since that time, stakeholders provided input on areas to improve the regulation, particularly to better protect agricultural field workers and handlers from pesticide risks.

Summary of Legal Basis:

7 U.S.C. 136w

Alternatives:

EPA is considering various alternatives to regulation change based upon stakeholder input. The Agency is in the formative stages of this regulatory effort, and alternatives have not been fully identified and evaluated.

Anticipated Cost and Benefits:

EPA will develop an economic analysis to support this rule.

Risks:

This proposal would reduce the risks to agricultural workers from potential exposure to pesticides and pesticide exposure.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Additional Information:

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RIN: 2070-AJ22

EPA

110. PESTICIDE AGRICULTURAL CONTAINER RECYCLING PROGRAM

Priority:

Other Significant

Legal Authority:

7 USC 136 to 136y

CFR Citation:

40 CFR 165

Legal Deadline:

None

Abstract:

EPA will propose to require that manufacturers of agricultural and professional specialty pesticides support (either by managing and operating, or contracting with another organization) a container recycling program that meets the standards of the American National Standards Institute (ANSI). The proposed regulation will ensure the continued operation of an existing but endangered nationwide infrastructure for voluntary recycling of plastic pesticide containers.

Statement of Need:

State regulatory agencies and large pesticide manufacturers have requested that EPA issue a regulation. The current voluntary pesticide container recycling program is not self-sustainable and the program is in danger of collapsing in spite of a nationwide infrastructure that has developed to support the collection and recycling of pesticide containers. Over the past 12 years, the Agricultural Container Recycling Council (ACRC) has operated a voluntary recycling

program and has recycled over 80 million pounds of plastic pesticide containers with an annual budget of less than \$4 million. The voluntary program is at risk of collapse because not all registrants participate financially and some companies have resigned, or plan to resign. If the existing system fails, the infrastructure would be lost and would have to be replaced. In addition, without a recycling program, less desirable or improper disposal of at least 8 to 10 million additional pounds of plastic containers would be inevitable. The containers would be burned, added to landfills or buried, in many cases jeopardizing ground water.

Summary of Legal Basis:

FIFRA sections 19(e) and (f) mandate container design requirements and procedures and standards for the safe removal of pesticides from containers before disposal. This rule would facilitate safe recycling as a part of safe disposal or reuse. FIFRA sections 3, 6, 19(a) and 25 provide authority for EPA to promulgate a rule making participation in a recycling program a condition of registration.

Alternatives:

The following non-regulatory approaches have been considered: 1) Continue to pursue a voluntary program. This is not likely to be successful because it would rely heavily on a few registrants to cover program costs for all other registrants. The lack of support by non-participating registrants would not change. 2) Support the development of state laws. States want a national program to eliminate the inefficiencies that would be inherent in 50 separate infrastructures. 3) Encourage non-monetary incentives such as awards. This would not resolve the inequities inherent in the current voluntary system. 4) Encourage a phase-out of disposable containers. This would not be effective since most member companies are using refillable containers. The following regulatory approach was considered: Propose a detailed rule prescribing how recycling would be accomplished and by whom. This would significantly increase the cost of the rule and would reduce flexibility without much added benefit.

Anticipated Cost and Benefits:

The existing voluntary program has an annual budget of less than \$4 million. Current estimates are that ACRC member companies account for 80 to 85% of the pesticides sold annually in the agricultural pesticide market. We

would need to estimate the sales and container usage of registrants in the professional specialty pesticides market and identify the remaining sales in the agricultural market. The proposed rule is in line with EPA's mission to protect human health and safeguard the environment. By providing an opportunity for end users nationwide to recycle plastic pesticide containers, we will reduce the use of less desirable disposal methods, leading to less litter, reduced soil and ground water contamination from burial and/or land filling, and less air pollution from the open burning of containers. Also, containers would have to be properly rinsed before being recycled, leading to less possibilities for illness and injury from pesticides and their residues.

Risks:

This proposal would reduce risks to human health and the environment by lessening the amount of litter, reducing soil and ground water contamination caused by burial and/or land filling, and less air pollution from the open burning of containers. Also, proper rinsing prior to recycling would reduce risks of illness and injury from pesticides and their residues.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 5050

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RIN: 2070-AJ29

EPA

111. REVISIONS TO THE SPILL PREVENTION, CONTROL, AND COUNTERMEASURE (SPCC) RULE, 40 CFR PART 112

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

33 USC 1321

CFR Citation:

40 CFR 112

Legal Deadline:

None

Abstract:

EPA will propose to amend 40 CFR part 112, which includes the Spill Prevention, Control, and Countermeasure (SPCC) rule promulgated under the authority of the Clean Water Act. The proposed rule may include a variety of issues associated with the July 2002 SPCC final rule. Specific decisions on the scope of the rulemaking will be determined after the final rule associated with the Notices of Data Availability has been completed and in relation to EPA guidance.

Statement of Need:

The proposed rule is necessary to clarify the regulatory obligations of SPCC facility owners and operators and to reduce the regulatory burden where appropriate.

Summary of Legal Basis:

The legal basis is 33 USC 1321 et seq.

Alternatives:

Undetermined.

Anticipated Cost and Benefits:

Undetermined.

Risks:

Undetermined.

Timetable:

Action	Date	FR Cite
Notice Clarifying Certain Issues	05/25/04	69 FR 29728
NPRM 1 Year Compliance Extension	06/17/04	69 FR 34014
Final 18 Months Compliance Extension	08/11/04	69 FR 48794
NODA re: Certain Facilities	09/20/04	69 FR 56184
NODA re: Oil-filled and Process Equipment	09/20/04	69 FR 56182
NPRM	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 2634.2; Split from RIN 2050-AC62.

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RIN: 2050-AG16

EPA

112. EXPANDING THE COMPARABLE FUELS EXCLUSION UNDER RCRA

Priority:

Other Significant

Legal Authority:

RCRA 4004

CFR Citation:

40 CFR 261.38

Legal Deadline:

None

Abstract:

EPA currently excludes specific industrial wastes, also known as comparable fuels, from most Resource Conservation and Recovery Act (RCRA) hazardous waste management requirements when the wastes are used for energy production and do not contain hazardous constituent levels that exceed those found in a typical benchmark fuel that facilities would otherwise use. Using such wastes as fuel saves energy by reducing the amount of hazardous waste that would otherwise be treated and disposed, promotes energy production from a domestic, renewable source, and reduces use of fossil fuels. With an interest in supplementing the nation's energy supplies and to ensure that energy sources are managed only to the degree necessary to protect human health and the environment, EPA, as part of the Resource Conservation Challenge, is examining the effectiveness of the current comparable fuel program and considering whether other industrial wastes could be safely used as fuel as well.

Statement of Need:

EPA is considering expanding the comparable fuels program. This program allows specific industrial wastes to be excluded from the Resource Conservation and Recovery Act (RCRA) when they are used for energy production and do not contain hazardous constituent levels exceeding those in a typical benchmark fuel that facilities would otherwise use. If EPA is successful in finding other industrial wastes that could be used for energy, this would not only save energy by reducing the amount of hazardous waste that would be otherwise treated and disposed, but also promote energy production from a domestic, renewable source and reduce our use of fossil fuels. EPA is also examining the effectiveness of the current comparable fuel program to determine whether changes could be made to the existing program to make it more effective.

Summary of Legal Basis:

This action is discretionary on the Agency's part.

Alternatives:

To make significant changes to the existing comparable fuels standard, EPA must modify the existing regulations. EPA intends to first

propose and seek comment on potential regulatory modifications.

Anticipated Cost and Benefits:

When the existing comparable fuel exemption was established, EPA estimated that the rule would result in annual savings of 11 to 36 million dollars for generators and would result in annual costs of 3 to 13 million dollars for hazardous waste combustors. The savings to generators were made up of avoided hazardous waste combustion costs and revenues from sale of comparable fuels, less the analytical costs. Costs to hazardous waste combustion facilities stem from lost revenue from wastes are diverted to the comparable fuels market. EPA has not conducted a preliminary estimate of costs and benefits from modifications to the existing comparable fuels rule, as options to be proposed have not been selected. Prior to proposing options, EPA intends to reach out to a broad group of stakeholders to receive input on potential regulatory approaches that could be proposed. When EPA selects the approaches to be proposed, we will be in a position to estimate costs and benefits of any regulatory actions.

Risks:

The rationale for the Agency's approach to establishing the existing comparable fuels standards is that if a hazardous waste-derived fuel is comparable to a fossil fuel in terms of hazardous and other key constituents and has a heating value indicative of a fuel, EPA has discretion to classify such material as a fuel product, not as a waste. Given that a comparable fuel would have legitimate energy value and the same hazardous constituents in comparable concentrations to those in fossil fuel (and satisfies other parameters related to comparability as well), classifying such material as a fuel product and not as a waste promotes RCRA's resource recovery goals without creating any risk greater than those posed by the commonly used commercial fuels. If EPA maintains this "benchmark" approach in its revisions, the risks associated with any changes will remain unchanged. Until EPA establishes what approaches to propose for modifications to the comparable fuel standards, it is not possible to provide a description of the risks associated with such a proposal.

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4977

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RIN: 2050-AG24

EPA

113. • DEFINITION OF SOLID WASTES REVISIONS

Priority:

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

Legal Authority:

42 USC 6903 "RCRA Section 1004"

CFR Citation:

40 CFR 261.2

Legal Deadline:

None

Abstract:

On October 28, 2003 (68 FR 61558), EPA proposed revisions to the definition of solid waste for hazardous secondary materials being reclaimed in a continuous process in the generating industry in an effort to increase the recycling of such materials. The Agency also took comment on a broader proposal to exclude hazardous secondary materials from being a solid waste under RCRA Subtitle C. This proposal was in part prompted by various court decisions about the extent of RCRA jurisdiction over hazardous secondary materials being recycled. In

the same notice, the Agency also proposed criteria for determining whether or not hazardous secondary materials are recycled legitimately; the legitimacy criteria would apply to both those hazardous secondary materials that were excluded, as well as those that would remain subject to regulation under Subtitle C of RCRA. EPA received numerous comments on the proposal. In addition, EPA has conducted studies of recycling practices and the circumstances under which recycling of hazardous secondary materials are reclaimed in an environmentally sound manner, as well as when such reclamation has caused environmental problems. Based on the comments received and the new information being made available for public comment, the Agency will be issuing a supplemental proposal that would exclude from being a solid waste certain hazardous secondary materials that are reclaimed. We are also taking comment on revisions being considered to the legitimacy criteria, as well as taking comment on a variance process regarding hazardous secondary materials that are recycled.

Statement of Need:

EPA is revising the definition of solid waste to increase recycling.

Summary of Legal Basis:

Association of Battery Recyclers v. EPA, 203 F. 2d 1047 (D.C. Cir. 2000); American Mining Congress v. EPA, 824 F. 2d 1177 (D.C. Cir. 1987) and other cases

Alternatives:

We have solicited comment in the proposal on several alternative regulatory options, including a broad exclusion for legitimately recycled materials, and are evaluating public comments on all available options.

Anticipated Cost and Benefits:

We expect that this rule will increase the recycling of wastes covered by the rule. We have prepared an economic analysis for the proposed rule, and we are presently developing preliminary costs and benefits for all our regulatory options. When an option is chosen and a final rule is drafted, we will prepare a detailed economic analysis quantifying the costs and benefits.

Risks:

We are developing conditions for the rule so that there will be no negative impacts on human health and the environment.

Timetable:

Action	Date	FR Cite
NPRM	10/28/03	68 FR 61558
Supplemental NPRM	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4670.1; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-WASTE/2003/October/Day-28/f26754.htm>; Split from RIN 2050-AE98.

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RIN: 2050-AG31

EPA

FINAL RULE STAGE

114. NESHAP: HAZARDOUS ORGANIC NESHAP (HON) RESIDUAL RISK STANDARDS

Priority:

Other Significant

Legal Authority:

42 USC 7412

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, April 22, 2003.

Final, Judicial, December 15, 2006, Court ordered deadline for final rule.

Abstract:

EPA developed technology-based standards for this source category under section 112(d) of the CAA. The current action, required by section 112(f) of the CAA, is to assess residual risks and develop additional emission standards, as necessary, to provide an ample margin of safety. This rule will cover the major sources of air emissions within the synthetic organic chemical industry.

Statement of Need:

Section 112(f) of the Clean Air Act requires EPA to assess residual risks that remain after implementation of technology-based standards for each category of major sources of air-toxic emissions. Section 112(f) also mandates EPA to develop additional emission standards for these sources, as necessary, to provide an ample margin of safety. This rule will cover the major sources of air emissions within the synthetic organic chemical industry.

Summary of Legal Basis:

Clean Air Act Section 112

Alternatives:

Option 1 is no revision to NESHAP. Option 2 requires additional controls on equipment leaks and controls on some storage tanks and process vents that are controlled under the current rule.

Anticipated Cost and Benefits:

Under Option 2 exposures for 450,000 people would be reduced from above 1 in a million to below 1 in a million at an annualized cost of \$13 million.

Risks:

Baseline cancer incidence is 0.1 cases per year and risk to most exposed individual is 100 in a million.

Timetable:

Action	Date	FR Cite
NPRM Final Action	06/14/06 01/00/07	71 FR 34421

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN No. 4659; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2006/June/Day-14/a5219.htm>

Sectors Affected:

325 Chemical Manufacturing

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RIN: 2060-AK14

EPA**115. NESHAP: HALOGENATED SOLVENT CLEANING—RESIDUAL RISK STANDARDS****Priority:**

Other Significant

Legal Authority:

42 USC 7412

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, December 2, 2002.

Final, Judicial, December 15, 2006,
Consent Decree.

Abstract:

The Halogenated Solvent Cleaning NESHAP limits emissions of HAP from solvent cleaning machines that use any of the following halogenated solvents: methylene chloride, perchloroethylene, trichloroethylene, 1,1,1, -trichloroethane, carbon tetrachloride, chloroform, or any combination of these solvents in a total concentration greater than 5 percent by weight. Each individual solvent cleaning machine is an affected source. The Halogenated Solvent Cleaning NESHAP was projected to reduce nationwide emissions of hazardous air pollutants (HAP) from halogenated solvent cleaning machines by 85,300 tons per year, or 63 percent of the 1991 baseline emissions of 140,525 tons/year. On December 3, 1999, the rule was amended by adding compliance options for continuous web cleaning machines. Continuous web cleaning machines are

considered a subset of in-line cleaning machines and are defined as: "a solvent cleaning machine in which parts such as film, coils, wire, and metal strips are cleaned at speeds typically in excess of 11 feet per minute. Parts are generally uncoiled, cleaned such that the same part is simultaneously entering and exiting the solvent application area of the solvent cleaning machine, and then recoiled or cut." This action is required by the CAA to assess residual risk and develop standards as necessary to provide an ample margin of safety.

Statement of Need:

Section 112(f) of the Clean Air Act requires EPA to assess residual risks that remain after implementation of technology-based standards for each category of major sources of air-toxic emissions. Section 112(f) also mandates EPA to develop additional emission standards for these sources, as necessary, to provide an ample margin of safety. This rule will cover the major sources of air emissions within the halogenated solvent cleaning industry.

Summary of Legal Basis:

Section 112(f) of the Clean Air Act.

Alternatives:

Based on its findings, EPA is co-proposed and sought comment on two options to amend to the existing standards. Both options would impose an annual cap on emissions of the solvents methylene chloride, perchloroethylene and trichloroethylene and provide cost savings to the industry. The proposed emission caps provide affected facilities with the flexibility to reduce their emissions using any traditional methods available to reduce emissions from their degreasing operations.

Anticipated Cost and Benefits:

Costs and benefits were summarized in the NPRM. The differences between the two options is that the annual costs for Option 1 are completely offset by the solvent savings of up to \$1 million when compared to the annual costs of Option 2. Option 2 establishes a more stringent emission cap, reduces more individual risks compared to Option 1 and moves more people into the range that EPA considers acceptable with a margin of safety. Option 2 will require an increased number of facilities with risks already less than 1-in-a-million to comply with the standard. No significant small business impacts are expected under either Options 1 or 2.

Risks:

Risk information was summarized in the NPRM. EPA completed a risk assessment to evaluate the risks remaining now that hazardous air emissions have been controlled at these facilities through MACT. Residual risks were found to exist from a number of facilities. Also in preparation for the proposed action, EPA completed a technology review to determine if it was necessary to revise the existing standards to account for developments in work practices, processes, and control technologies.

Timetable:

Action	Date	FR Cite
NPRM	08/17/06	71 FR 47669
NPRM Comment Period End	10/02/06	
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Federalism:

Undetermined

Additional Information:

SAN No. 4668; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2006/August/Day-17/a6927.htm>

Sectors Affected:

335999 All Other Miscellaneous Electrical Equipment and Component Manufacturing; 332999 All Other Miscellaneous Fabricated Metal Product Manufacturing; 336999 All Other Transportation Equipment Manufacturing; 337124 Metal Household Furniture Manufacturing; 332116 Metal Stamping; 339 Miscellaneous Manufacturing; 336 Transportation Equipment Manufacturing

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RIN: 2060-AK22

EPA

116. CONTROL OF HAZARDOUS AIR POLLUTANTS FROM MOBILE SOURCES

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 7521

CFR Citation:

40 CFR Part 80; 40 CFR Part 86

Legal Deadline:

NPRM, Judicial, February 28, 2006, Consent Decree.

Final, Judicial, February 9, 2007, Consent Decree.

Abstract:

Motor vehicles are significant contributors to national emissions of several hazardous air pollutants. These pollutants are known or suspected to have serious health or environmental impacts. Reducing emissions of these pollutants will reduce risk to public health and welfare. The Clean Air Act requires EPA to periodically revise requirements to control emissions of these pollutants from mobile sources. EPA committed to this rulemaking in the preamble of the last rulemaking on this topic, promulgated on March 29, 2001. This rule will address the need for additional requirements, beyond those associated with existing programs and other forthcoming rules, to control hazardous air pollutants ("air toxics") from motor vehicles, nonroad engines and vehicles, and their fuels. Previous

mobile source programs for highway and nonroad sources and fuels have already reduced air toxics significantly and will provide substantial further reductions in coming years as new standards and programs are phased in. This mobile-source air toxics rule will provide an overview of these mobile source programs and associated toxics emissions reductions. The rule will then address potential changes to gasoline fuel parameters to reduce toxics such as benzene and the potential for additional vehicle controls. We are also considering portable fuel container controls due to their significant contribution to VOC emissions overall and the potential for exposure to evaporative benzene emissions.

Statement of Need:

Motor vehicles are significant contributors to national emissions of several hazardous air pollutants. These pollutants are known or suspected to have serious health or environmental impacts. Reducing emissions of these pollutants will reduce risk to public health and welfare. The Clean Air Act requires EPA to periodically revise requirements to control emissions of these pollutants from mobile sources. EPA committed to this rulemaking in the preamble of the last rulemaking on this topic, promulgated on March 29, 2001.

Summary of Legal Basis:

Clean Air Act Section 202

Alternatives:

The current proposal considers potential changes to gasoline fuel parameters to reduce toxics such as benzene and the potential for additional vehicle controls. We are also considering portable fuel container controls due to their significant contribution to VOC emissions overall and the potential for exposure to evaporative benzene emissions.

Anticipated Cost and Benefits:

These controls would significantly reduce emissions of benzene and other mobile source air toxics such as 1,3-butadiene, formaldehyde, acetaldehyde, acrolein, and naphthalene. This proposal would result in additional substantial benefits to public health and welfare by significantly reducing emissions of particulate matter from passenger vehicles. We project annual nationwide benzene reductions of 35,000 tons in 2015, increasing to 65,000 tons by 2030. Total reductions in mobile source air toxics would be

147,000 tons in 2015 and over 350,000 tons in 2030. Passenger vehicles in 2030 would emit 45% less benzene. Gas cans meeting the new standards would emit almost 80% less benzene. Gasoline would have 37% less benzene overall. We estimate that these reductions would have an average cost of less than 1 cent per gallon of gasoline and less than \$1 per vehicle. The average cost for gas cans would be less than \$2 per can. The reduced evaporation from gas cans would result in significant fuel savings, which would more than offset the increased cost for the gas can.

Risks:

Benzene is a known human carcinogen, and mobile sources are responsible for the majority of benzene emissions. The other mobile source air toxics are known or suspected to cause cancer or other serious health effects.

Timetable:

Action	Date	FR Cite
NPRM	03/29/06	71 FR 15804
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4748; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2006/March/Day-29/a2315a.htm>

Sectors Affected:

3361 Motor Vehicle Manufacturing; 3363 Motor Vehicle Parts Manufacturing; 32411 Petroleum Refineries; 4227 Petroleum and Petroleum Products Wholesalers

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RIN: 2060-AK70

EPA**117. CLEAN AIR FINE PARTICLE IMPLEMENTATION RULE****Priority:**

Other Significant

Legal Authority:

42 USC 7410; 42 USC 7501 et seq

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

In 1997, EPA promulgated National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM-2.5). EPA designations of 39 nonattainment areas for the PM2.5 standards became effective on April 5, 2005. The Clean Air Fine Particle Implementation Rule, which was proposed in the Federal Register on November 1, 2005, includes requirements and guidance for State and local air pollution agencies to follow in developing State implementation plans (SIPs) designed to bring areas into attainment with the 1997 standards. These SIP development activities include technical analyses to identify effective strategies for reducing emissions contributing to PM-2.5 levels, and the adoption of regulations as needed in order to attain the standards. 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	11/01/05	70 FR 65984
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4752; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2005/November/Day-01/a20455.htm>

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RIN: 2060-AK74

EPA**118. PREVENTION OF SIGNIFICANT DETERIORATION (PSD) AND NONATTAINMENT NEW SOURCE REVIEW (NSR): DEBOTTLENECKING, AGGREGATION AND PROJECT NETTING****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:

This project will revise rules governing the major new source review (NSR) programs mandated by parts C and D of title I of the Clean Air Act (CAA). The new regulations will clarify and codify our policy of when multiple activities at a single major stationary source must be considered together for the purposes of determining major NSR applicability ("aggregation"). Also, we are changing 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"). Finally, we are clarifying how emissions decreases from a project may be included in the calculation to determine if a significant emissions increase will result from a project ("project netting"). When final, these rules will improve implementation of the program by articulating and codifying principles for determining major NSR applicability that we currently address through guidance only. These rule changes reflect the EPA's consideration of the EPA's 2002 Report to the President and its associated recommendations as well as discussions with various stakeholders including representatives of environmental groups, State and local governments, and industry.

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.

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	09/14/06	71 FR 54235
Final Action	05/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

Additional Information:

SAN No. 4793

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RIN: 2060-AL75

EPA

119. FUEL ECONOMY LABELING OF MOTOR VEHICLES: REVISIONS TO IMPROVE CALCULATION OF FUEL ECONOMY ESTIMATES

Priority:

Other Significant

Legal Authority:

15 USC 2001 to 2003; 15 USC 2005 to 2006; 15 USC 2013

CFR Citation:

40 CFR 600

Legal Deadline:

None

Abstract:

The Energy Policy and Conservation Act of 1974 requires EPA to establish regulations that require auto manufacturers to display fuel economy estimates on a label for each new vehicle. EPA also has authority to prescribe the test procedures used to calculate these fuel economy estimates. These estimates allow consumers to compare the fuel economy of different vehicles. Current window stickers have two fuel economy estimates, "City" and "Highway." While actual driving conditions will cause variations from the EPA estimates, consumers should expect to achieve fuel economy that is reasonably close to those estimates. Since EPA last revised the methods for measuring fuel economy (1985), many conditions have changed - speed limits are higher, congestion has increased, and more vehicles are equipped with power-hungry accessories, like air conditioning. All of these factors will impact a vehicle's actual fuel economy. Some of these factors - aggressive and high-speed driving and air conditioner use in particular - have been addressed in EPA emission test procedures. In the past few years, there has been a growing awareness by consumers indicating that they are experiencing lower actual fuel economy than the EPA estimates. EPA has examined many factors that are not currently accounted for in our fuel economy estimates. EPA's initial analyses indicate that the fuel economy label estimates are overestimated, perhaps significantly for some vehicles. This action will provide consumers with more accurate and credible information regarding the comparative fuel economy of vehicles. This action will amend the way in which fuel economy estimates are calculated, primarily by incorporating the fuel economy results from additional vehicle tests performed today for emissions compliance purposes. It will also propose changes to how the fuel economy estimates and other related information are presented to consumers on the vehicle window sticker label. The changes in this action will not impact the Corporate Average Fuel Economy requirements.

Statement of Need:

Section 774 of the Energy Policy Act of 2005 requires EPA to update the fuel economy label calculation methodology to reflect a variety of factors not currently accounted for in the existing test procedures. Possible factors EPA will consider include how well the methodology reflects real-world driving conditions and advances in automotive technology.

Summary of Legal Basis:

Section 774 of the Energy Policy Act of 2005.

Alternatives:

EPA is considering several options, including adding new fuel economy tests and revising adjustment factors.

Anticipated Cost and Benefits:

Costs and benefits were summarized in the NPRM.

Risks:

Risk information was summarized in the NPRM.

Timetable:

Action	Date	FR Cite
NPRM	02/01/06	71 FR 5425
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4962; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2006/February/Day-01/a451.htm>; EPA Docket information: EPA-HQ-OAR-2005-0169

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RIN: 2060-AN14

EPA

120. AMENDMENT OF THE STANDARDS FOR RADIOACTIVE WASTE DISPOSAL IN YUCCA MOUNTAIN, NEVADA

Priority:

Other Significant

Legal Authority:

PL 102-486

CFR Citation:

40 CFR 197

Legal Deadline:

None

Abstract:

This action will amend the standards for Yucca Mountain, Nevada (40 CFR Part 197). These standards were issued in 2001 and were partially remanded by a Federal court in 2004. These amendments will address the remanded portion of the standards, viz., the compliance period. Yucca Mountain is the site of a potential geologic repository for spent nuclear fuel and high-level radioactive waste. It is about 100 miles northwest of Las Vegas, Nevada, and straddles the boundaries of the Nevada Test Site, Bureau of Land Management land, and an Air Force bombing range. The site is being developed by the Department of Energy (DOE). The DOE will submit a license application to the Nuclear Regulatory Commission (NRC). We (EPA) were given the authority to set Yucca Mountain-specific standards in the Energy Policy Act of 1992 (EnPA). The EnPA also requires NRC to adopt our standards in its licensing regulations and use them as a basis to judge compliance of the repository's performance. The Agency issued final Yucca Mountain standards in 2001. In July 2004, the DC Circuit Court returned the standards to EPA for reconsideration of the regulatory time frame. The Court found that the 10,000-year compliance period violates our authorizing statute for Yucca Mountain regulation because it is not "based upon and consistent with" scientific recommendations required from the National Academy of Sciences under the legislation. To address the Court's opinion, we must reassess the time frame in light of the National Academy's recommendation that compliance must be addressed at the time of peak dose, which may be as long as several hundred thousand years into the future.

Statement of Need:

Congress selected Yucca Mountain as the Nation's only candidate site for a repository for nuclear spent fuel and high-level radioactive waste. The Energy Policy Act of 1992 requires EPA to set Yucca-Mountain-specific standards. Standards were promulgated in 2001. In July 2004, the DC Circuit Court returned the standards to EPA for reconsideration of the regulatory time frame.

Summary of Legal Basis:

The Energy Policy Act of 1992 requires EPA to set Yucca-Mountain-specific standards. Standards were promulgated in 2001. In July 2004, the DC Circuit Court returned the standards to EPA for reconsideration of the regulatory time frame.

Alternatives:

To address the Court's opinion, we must reassess the time frame in light of the National Academy's recommendation that compliance must be addressed at the time of peak dose, which may be as long as several hundred thousand years into the future. Alternatives addressing that recommendation will be developed as the rulemaking proceeds.

Anticipated Cost and Benefits:

Cost and benefit information will be developed as the rulemaking proceeds.

Risks:

Risk information will be developed as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
NPRM	08/22/05	70 FR 49014
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4964; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-AIR/2005/August/Day-22/a16193.htm>

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RIN: 2060-AN15

EPA

121. RENEWABLE FUELS STANDARD RULE

Priority:

Other Significant

Legal Authority:

Pub. L. 109-58

CFR Citation:

40 CFR 80.1101

Legal Deadline:

Final, Statutory, August 6, 2006, The Energy Policy Act of 2005 requires that EPA promulgate RFS regulations by 08/06/2006.

Abstract:

The Energy Policy Act of 2005 (the "Act"), signed into law on August 8, 2005, requires EPA to promulgate regulations implementing the Renewable Fuels Standard (RFS) within one year of enactment. The RFS requires specific volumes of renewable fuel to be in gasoline sold in the U.S. starting with 4.0 billion gal/yr in 2006 up to 7.5 billion gal/yr in 2012. The Act provides that if EPA fails to promulgate regulations within one year, then a default value of 2.78% renewable fuel in gasoline will be in effect for 2006. We recently promulgated a rule ("Renewable Fuel Standards Requirements for 2006," 70 FR 77325, 12/30/05) to implement the default standard. The Agency must complete its obligation under the Act by promulgating a rule that implements the RFS for years 2007 and beyond. Such rule must establish how the renewable fuel standard is defined and calculated, what parties are liable, and how compliance with the standard is

to be determined. In addition, the rule must establish a system by which renewable fuel credits can be generated, and traded/sold between parties. This statutory provision is subject to multiple interpretations of key terms. The "Renewable Fuel Standard Requirements for 2006" that we promulgated on 12/30/05 interprets the default provision so that it can be implemented with certainty in the event EPA fails to promulgate the RFS within one year of enactment. It provides for refiners, importers and blenders to meet the 2.78% requirement collectively, rather than on an individual basis. Since our projections show that this value is highly likely to be met in 2006 under planned practices of the refining industry, we do not anticipate any impacts on the industry in general, nor any on small businesses. It will have no effect on State, local or tribal governments.

Statement of Need:

In The Energy Policy Act of 2005 (PL 109-58), Congress directed EPA to undertake this rulemaking to support the goal of increasing the production and use of renewable fuels.

Summary of Legal Basis:

The Energy Policy Act of 2005 (PL 109-58) requires EPA to promulgate regulations that implement the renewable fuels standard (RFS), which applies to refineries, importers and blenders as appropriate. The Act specifies required amounts of renewable fuel that must be in gasoline sold in the United States. EPA's regulations must define how the standard is to be computed, who is liable, and it must also include a credit trading system which is stipulated in the Act.

Alternatives:

The Energy Policy Act of 2005 set forth requirements for the use of Renewable Fuels. EPAct set forth specific requirements for the minimum volume of renewable fuels, a schedule to increase use, and requirements for establishing a credit and trading program. This rule intends to comply directly with EPAct requirements.

Anticipated Cost and Benefits:

On average, EPA estimates the cost of this increase in renewable fuels to range from 0.3 to 1 cent per gallon of gasoline. As part of the final rulemaking, EPA plans to include an updated analysis. However, currently, renewable fuel demand is projected to

exceed the levels required by the Energy Policy Act. The RFS does, however, establish a baseline that provides market certainty that at least a minimum amount of renewable fuel will be used should market conditions change. Depending on the volume of renewable fuel anticipated to be used in 2012, EPA estimates that this transition to renewable fuels will reduce petroleum consumption by 2.3 to 3.9 billion gallons or roughly 1.0 to 1.6 percent of the petroleum that would otherwise be used by the transportation sector. The preliminary analysis of the emissions and air quality impacts of the expanded use of renewable fuels indicates that carbon monoxide emissions from gasoline-powered vehicles and equipment will be reduced by 1.3 to 3.6 percent, benzene (a mobile source air toxic) emissions will be reduced by 1.7 to 6.2 percent and carbon dioxide equivalent greenhouse gas emissions will be reduced by 9 to 14 million tons or about 0.4 to 0.6 percent of the anticipated greenhouse gas emissions from the transportation sector in the United States in 2012. At the same time, other vehicle emissions may increase as a result of greater renewable fuel use. Nationwide, EPA estimates between a 28,000 and 97,000 ton increase in volatile organic compounds plus nitrogen oxides (VOC + NOx) emissions. However, the effects will vary significantly by region. EPA estimates that areas such as New York City, Chicago, and Los Angeles will experience no increase, while other areas may see an increase VOC emissions from 3 to 5 percent and an increase in NOx emissions from 4 to 6 percent from gasoline powered vehicles and equipment.

Risks:

Failure to comply with EPAct statutory mandate would void intention of providing stability and certainty for renewable market growth and support for expanding domestic energy production and reduced reliance on foreign sources of petroleum.

Timetable:

Action	Date	FR Cite
NPRM	09/22/06	71 FR 55552
NPRM Comment Period End	11/12/06	
Final Action	03/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN No. 5048

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RIN: 2060-AN76

EPA

122. • FINAL RULE FOR IMPLEMENTATION OF THE NEW SOURCE REVIEW (NSR) PROGRAM FOR PM2.5

Priority:

Other Significant

Legal Authority:

42 USC 7410; 42 USC 7501 et seq

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

In 1997, EPA promulgated National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM2.5). EPA designations of 39 nonattainment areas for the PM2.5 standards became effective on April 5, 2005. The Clean Air Fine Particle Implementation Rule, which was proposed in the Federal Register on November 1, 2005, includes requirements and guidance for State and local air pollution agencies to follow in developing State implementation plans (SIPs) designed to bring areas into attainment with the 1997 standards. The proposed rule also included the New Source Review (NSR) provisions for implementing the PM2.5 program. In this final action, we have

split the NSR provisions of the proposed rule as a separate package. This rule will address the applicability of NSR to precursors, Major Source Threshold and Significant Emissions Rate for PM2.5, preconstruction monitoring requirements, offset provisions and interpollutant trading of offsets and finally the transition provisions.

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 final rule is developed.

Anticipated Cost and Benefits:

This information will be provided as the final rule 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
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4752.2; Split from RIN 2060-AK74.

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RIN: 2060-AN86

EPA

123. PESTICIDES; DATA REQUIREMENTS FOR CONVENTIONAL CHEMICALS

Priority:

Other Significant

Legal Authority:

7 USC 136 to 136g

CFR Citation:

40 CFR 158

Legal Deadline:

None

Abstract:

EPA is revising its data requirements for the registration of conventional pesticide products. In this action, the Agency is revising 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. When promulgated, the data requirements will reflect current scientific knowledge and understanding. These revisions will 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 is reformatting the requirements and revising 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.

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. The codified data requirements have not been revised to keep pace with the updated data requirements. The proposed changes update and revise the data requirements, reformat the structure of part 158 and update procedures and policies for data submission. The changes 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 final rule will describe data and information needed to support multiple pesticide mandates under two statutes: the registration, reregistration, registration review, and experimental use permit programs under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the tolerance-setting and reassessment program under the Federal Food, Drug and Cosmetic Act (FFDCA). These programs are authorized under FIFRA sections 3, 4, and 5 and FFDCA sec 408.

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. 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:

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 \$51 million. Of this estimated total annual impact, about \$28.9 million per year represents new data requirements that have been imposed over the years but are not codified in the CFR. In addition, about \$21.6 million represents the cost of the proposed modified or expanded existing data requirements for certain tests and use patterns, and about \$1.9 million represents the cost of proposed new data requirements for data that have not yet been routinely required. The qualified benefits include improved usability and transparency for registrants, improved scientific basis for pesticide regulatory decisions, enhanced international harmonization with less duplication of data.

Risks:

The proposed revisions to the data requirements, 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. This information is used to assess the human health and environmental risks associated with the product. The data that will be required by this regulation 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 Federal Food Drug and Cosmetic Act (FFDCA).

Timetable:

Action	Date	FR Cite
NPRM	03/11/05	70 FR 12277
Notice of Public Meeting	04/01/05	70 FR 16785
NPRM: Extension of Comment Period	06/08/05	70 FR 33414
Final Action	04/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 2687; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-PEST/2005/March/Day-11/p4466.htm>;

Individual Document id in the EPA docket: <http://www.regulations.gov>

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

URL For More Information:

www.epa.gov/pesticides/regulating/data.htm

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RIN: 2070-AC12

EPA

124. LEAD-BASED PAINT ACTIVITIES; AMENDMENTS FOR RENOVATION, REPAIR, AND PAINTING

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

15 USC 2682 and 2684 (TSCA sections 402 and 404)

CFR Citation:

40 CFR 745

Legal Deadline:

Final, Statutory, October 28, 1996.

Abstract:

The Environmental Protection Agency is developing a comprehensive program for the management of renovation, repair and painting activities involving lead based paint hazards. The program will be comprised of a combination of approaches including an extensive education and outreach campaign for lead-safe work practices and training for industry, an outreach campaign

designed to expand consumer awareness and create demand for the use of lead-safe work practices and the proposal of regulatory requirements. On January 10, 2006, the EPA proposed regulatory requirements for renovation, repair and painting contractors involved in activities where, as a result of their work, lead hazards are created. [Modifications to the abatement requirements will also be considered to ensure compatibility between the existing requirements and any future renovation requirements.]

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:

This regulation is mandated by TSCA section 402(c). 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.

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 utilize several qualitative approaches to frame the benefits associated with an effective renovation rule.

Risks:

These rules are 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 to R&R workers appears to be less of a problem than to 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
NPRM	01/10/06	71 FR 1588
Notice of Availability; Supplemental Economic Analysis	03/02/06	71 FR 10628
Notice of Availability; Draft Pamphlet	03/08/06	71 FR 11570
Request for Comment; Lead Paint Test Kit Development	03/16/06	71 FR 13561
NPRM: Extension of Comment Period	04/06/06	71 FR 17409
Final Action	06/00/08	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 3557; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-TOX/2006/January/Day-10/t071.htm>; EPA Docket information: EPA-HQ-OPPT-2005-0049; Individual Document id in the EPA docket: www.regulations.gov

Sectors Affected:

23599 All Other Special Trade Contractors; 23551 Carpentry Contractors; 53111 Lessors of Residential Buildings and Dwellings; 23322 Multifamily Housing Construction; 23521 Painting and Wall Covering Contractors; 531311 Residential Property Managers; 23321 Single Family Housing Construction; 54138 Testing Laboratories

URL For More Information:

www.epa.gov/oppt/lead/pubs/renovation.htm

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RIN: 2070-AC83

EPA

125. PESTICIDES; DATA REQUIREMENTS FOR BIOCHEMICAL AND MICROBIAL PRODUCTS

Priority:

Other Significant

Legal Authority:

7 USC 136 to 136y

CFR Citation:

40 CFR 158

Legal Deadline:

None

Abstract:

EPA will update the data requirements necessary to register a biochemical or microbial pesticide product. The revisions will codify data requirements to reflect current regulatory and scientific standards. The data requirements will cover all scientific disciplines for biochemical and microbial pesticides, including product chemistry and residue chemistry, toxicology, and environmental fate and effects. The revision will not include plant incorporated protectants.

Statement of Need:

The Agency is in the process of updating its data requirements for pesticides. Current data requirements for biochemical and microbial pesticides were originally promulgated in 1984. Since the data requirements were first published in 1984, the information needed to support the registration of a biochemical or microbial 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. The codified data requirements have not been revised to keep pace with the updated data requirements. EPA has proposed to update and revise the data requirements. These revisions build upon those previously proposed for conventional chemicals, tailored to the lesser data needs for biochemical and microbial pesticides. The changes 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:

7 U.S.C. 136 to 136y

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. On a case by case basis, 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:

EPA has analyzed several economic alternatives for the proposed revisions to the biochemical and microbial pesticide data requirements, based upon consultations with stakeholders in industry, academia and individual registrants. EPA has considered both a low-cost and a high-cost alternative to the proposal. The rule is expected to reduce burdens and costs to registrants of biochemical and microbial pesticides. Current estimated savings are in the range of \$3 million annually, or \$63,000 per company. The qualified benefits include improved usability and transparency for registrants, improved scientific basis for pesticide regulatory decisions, and enhanced international harmonization with less duplication of data.

Risks:

The proposed revisions to the data requirements, 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. This information is used to assess the human health and environmental risks associated with the product. The data that will be required by this regulation 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 Federal Food Drug and Cosmetic Act (FFDCA).

Timetable:

Action	Date	FR Cite
NPRM	03/08/06	71 FR 12071
Final Action	06/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4596; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-PEST/2006/March/Day-08/p2185.htm>

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

URL For More Information:

www.epa.gov/pesticides/regulating/data.htm

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RIN: 2070-AD51

EPA**126. 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) 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. As part of OMB's Regulatory Reform of the U.S. Manufacturing Sector Report (2005), industry commented that the existing TSCA section 12(b) regulations do not provide a low-level cut-off for the export notification requirements. To address that concern, EPA committed to OMB that it would consider potential changes to the TSCA section 12(b) regulation within the scope of existing statutory authority and issue a proposed amendment to address the concern expressed by January 2006. EPA issued proposed amendments to the 12(b) export notification regulations on February 9, 2006 that included a de minimis concentration level below which notification would not be required along with several other changes. The public comment period on the proposed rule has ended and EPA is proceeding with development of a rule to finalize the proposed changes. Legislation is currently pending to address the implementation in the US of the Rotterdam Convention on Prior Informed Consent (PIC), which itself includes export notification requirements.

Statement of Need:

Industry nominated the implementing regulations for reform consideration twice. First 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.) And then again in 2004, see no. 39 in OMB's Regulatory Reform of the U.S. Manufacturing Sector Report (2005). The industry nominations stated that: many notifications are for minor substance/product ingredients or impurities that are not an imminent concern; compliance with export notification requirements is a significant cost to industry and a paper work burden to EPA; and that the scope and number of notifications has created confusion among importing countries. After careful consideration of these nominations, EPA published proposed

amendments to the 12(b) export notification regulations that, if finalized, will reduce the reporting burden on industry and EPA and also focus importing governments' attention on those chemicals for which EPA has proposed to make or has made a definitive finding that a chemical "presents or will present" an unreasonable risk to human health or the environment.

Summary of Legal Basis:

Section 12(b)(2) of the Toxic Substances Control Act (TSCA).

Alternatives:

In the proposed rule, EPA requested public comments on alternative approaches that could be considered, including whether there are more appropriate de minimis thresholds that should be used.

Anticipated Cost and Benefits:

The Economic Analysis for the proposed rule estimated that the proposed amendments would save the regulated community \$440,000 in costs over 20 years and would save the Federal government \$450,000 over 20 years.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	02/09/06	71 FR 6733
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4858; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-TOX/2006/February/Day-09/t1797.htm>; EPA Docket information: EPA-HQ-OPPT-2005-0058

URL For More Information:

www.epa.gov/opptintr/chemtest/12b.htm

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RIN: 2070-AJ01

EPA

127. TESTING AGREEMENT FOR PERFLUOROCTANOIC ACID (PFOA)

Priority:

Other Significant

Legal Authority:

15 USC 2603 "TSCA 4"

CFR Citation:

40 CFR 790 to 799

Legal Deadline:

None

Abstract:

PFOA is a synthetic (man-made) chemical that does not occur naturally in the environment. EPA identified data gaps regarding the sources and exposure pathways of PFOA and is seeking additional data concerning the potential relationship between fluoropolymer and fluorotelomer based polymer chemicals and PFOA. EPA has invited interested parties to monitor and participate in negotiations for developing several industry sponsored testing programs concerning fluoropolymers and fluorotelomer based polymers which may metabolize or degrade to PFOA. These testing programs would be set in place preferably as publicly negotiated enforceable consent agreements (ECAs) under section 4 of the Toxic Substances Control Act (TSCA) among EPA, industry, and interested parties under section 4 of TSCA, but may also be established as negotiated memoranda of understanding (MOUs) where circumstances preclude moving forward under ECAs. The goal of the PFOA ECA

process is to better understand the sources and exposure pathways leading to the presence of PFOA in humans and the environment.

Statement of Need:

In the late 1990's, EPA received information indicating that perfluorooctyl sulfonates (PFOS) were widespread in the blood of the general population, and presented concerns for persistence, bioaccumulation, and toxicity. Following discussions between EPA and 3M, the manufacturer of PFOS, the company terminated production of these chemicals. Findings on PFOS led EPA to review similar chemicals, including PFOA, starting in 2000, to determine whether they might present concerns similar to those associated with PFOS. PFOA is very persistent in the environment and was being found at very low levels both in the environment and in the blood of the general U.S. population. Studies indicated that PFOA can cause developmental and other adverse effects in laboratory animals. PFOA also appears to remain in the human body for a long time. All of these factors, taken together, prompted the Agency to investigate whether PFOA might pose a risk to human health and the environment at the levels currently being found, or at levels that might be reached in the future as more PFOA continues to be released into the environment. EPA does not have a full understanding of how people are exposed to PFOA, which is used as an essential processing aid in the manufacture of fluoropolymers, and may also be a breakdown product of other related chemicals, called fluorinated telomers. In April 2003, EPA released a preliminary risk assessment for PFOA and started a public process to identify and generate additional information to better understand the sources of PFOA and the pathways of human exposure. EPA is negotiating with multiple parties to produce missing information on PFOA through Enforceable Consent Agreements (ECAs), memoranda of understanding, and voluntary commitments. The ECA activities related to PFOA are addressed by the Regulatory Agenda entry.

Summary of Legal Basis:

These Consent Orders which incorporate Enforceable Consent Agreements (ECAs) will be issued under section 4(a) 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) of TSCA authorizes EPA to require manufacturers and processors of chemical substances and mixtures to test these chemicals to determine whether they have adverse health or environmental effects. Section 4(a) empowers the Agency to promulgate rules which require such testing. In addition, EPA has authority to enter into ECAs requiring testing where they provide procedural safeguards equivalent to those that apply where testing is conducted by rule (see 40 CFR 790).

Alternatives:

EPA identified the need to improve its understanding of the sources and pathways of exposure to PFOA in 2003 and initiated a process to develop needed new data on the issue. This new information will assist the Agency in determining if there are potential risks and what risk management steps may be appropriate. Specifically, EPA is working with industry and other stakeholders to obtain additional monitoring information on PFOA, exposures resulting from incineration or loss from products as they are used over time, and telomer biodegradation as a potential source of PFOA. The Agency is developing formal TSCA Section 4 Enforceable Consent Agreements (ECAs) and Memoranda of Understanding (MOUs) with industry in a public process involving a large number of interested parties, and is cooperating on voluntary research activities. Data needs which remain unmet through the MOUs and voluntary commitments may be addressed through additional ECAs and/or rulemaking.

Anticipated Cost and Benefits:

The potential benefits of these ECAs are substantial, as no one — whether in industry, government, or the public — can make reasoned risk management decisions in the absence of reliable health/environmental effects and exposure information. These ECAs are expected to reduce scientific uncertainties and to enable EPA and the public to more fully understand the pathways of human exposure and potential risks from PFOA. The costs

of the testing that would be imposed is estimated to be on the order of several hundred thousand dollars for each.

Risks:

PFOA is very persistent in the environment and was being found at very low levels both in the environment and in the blood of the general U.S. population. Studies indicated that PFOA can cause developmental and other adverse effects in laboratory animals. PFOA also appears to remain in the human body for a long time. Data collected and/or developed under these Consent Orders/ECAs, when combined with information about hazard, 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
Final: ECA and CO for Fluoropolymer Chemicals Incineration	07/08/05	70 FR 39630
Final: ECA and CO for Fluorotelomer-based Polymer Chemicals Incineration	07/08/05	70 FR 39624
Notice: Measurement of PFOA Generated from Thermal Degradation of Fluoropolymer Chemicals	12/00/06	
Stewardship Program	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 3493.1; EPA publication information: Final: ECA and CO for Fluorotelomer-based Polymer Chemicals Incineration - <http://www.epa.gov/fedrgstr/EPA-TOX/2005/July/Day-08/t13492.htm>; EPA Docket information: OPPT-2003-0012

URL For More Information:

www.epa.gov/oppt/pfoa/index.htm

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RIN: 2070-AJ06

EPA

128. HAZARDOUS WASTE MANIFEST REVISIONS—STANDARDS AND PROCEDURES FOR ELECTRONIC MANIFESTS

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6926; PL 105-277

CFR Citation:

40 CFR 260; 40 CFR 262; 40 CFR 263; 40 CFR 264; 40 CFR 265; 40 CFR 271

Legal Deadline:

None

Abstract:

This action is aimed at continuing the development of regulatory standards and procedures that will govern the initiation, signing, transmittal, and retention of hazardous waste manifests using electronic documents and systems. EPA proposed electronic manifest standards in May 2001, as part of a more general manifest revision action that also addressed standardizing the paper manifest form's data elements and procedures for its use across all states. The Manifest Form Revisions was decoupled from action on the electronic manifest, and the Final Form Revisions Rule was published on June 16, 2005. The May 2001 proposed rule included: (1) Electronic file formats for the manifest data elements; (2) electronic signature options; and (3) computer security controls aimed at ensuring data integrity and reliable

systems. Subsequently in May 2004, a stakeholder meeting collected additional stakeholder views on the future direction of the electronic manifest. Based on the record developed for the proposed standards and the additional views from stakeholders at the May 2004 meeting, EPA is considering final action on the proposed standards. However, since the publication of the proposed rule in 2001, EPA has found that there is a fairly broad consensus in favor of the development of a national e-manifest system by EPA. EPA is now considering the option of developing a national system, but EPA's ability to pursue this option will depend on new funding being authorized or on new authority for EPA to collect user fees.

Statement of Need:

The regulation is necessary to establish the standards and procedures under which hazardous waste handlers will be authorized to use electronic manifests in lieu of the existing paper manifest forms. The current regulations only allow the use of prescribed paper forms which must be carried physically with the waste shipment, signed by hand with each change of custody, and filed among each waste handler's operating records. This regulation will remove impediments in the current regulations to using electronic manifests, and it will specify the conditions under which electronic manifests may be obtained, completed, electronically signed, and transmitted, so that the electronic manifests may be used and accepted as the legal equivalent of the current paper forms.

Summary of Legal Basis:

There is currently not in place a statute or court order which requires EPA to adopt the electronic manifest regulation. However, members of Congress are currently considering a Bill that would mandate the development of an electronic manifest system by EPA, and such a Bill, if enacted during the 109th Congress, could include a regulatory deadline for promulgating a regulation authorizing the use of electronic manifests. Whether or not there is such a statutory mandate, EPA could develop a regulation addressing the e-Manifest under the authority of RCRA Section 3002(a)(5), which authorizes EPA to promulgate regulations establishing standards for generators of hazardous waste, including standards on "the use of a manifest system and any other reasonable means necessary to assure that all such hazardous waste generated

is designated for treatment, storage, or disposal in and arrives at" permitted facilities.

Alternatives:

Based on comments submitted on the proposed rule, and additional stakeholder input received at public meetings, EPA's preferred alternative is now the development of a consistent, national e-Manifest system that would be developed and operated under a Federal contract funded by user fees, and hosted on EPA's Central Data Exchange reporting system. Other alternatives include a national system that would be developed entirely privately; a decentralized option like the one suggested in the proposed rule, under which various private entities would develop numerous e-Manifest systems adhering to standards announced by EPA; and a no action alternative, under which all manifesting would continue only with paper manifests.

Anticipated Cost and Benefits:

The estimated 1st year or start-up costs for a national e-Manifest system are projected to be in the range of \$3.98 million to \$5.32 million. Annual operation and maintenance (O&M) costs for such a system are projected in the range \$2.03 million to \$2.48 million. Economic benefits from such a system include net savings to manifest users and to State RCRA agencies of about \$100 million per year, assuming that 75 percent of manifests can be completed electronically. These projected savings can also be expressed as a net unit savings of \$23 to \$40 per manifest. Non-economic benefits expected from the e-Manifest include: Better quality and more timely waste shipment data; nearly real time shipment tracking capabilities for users; enhanced inspection and compliance monitoring capabilities for regulators; more rapid notification and response to problems or discrepancies with waste shipments; more efficient or "one-stop" submission of manifest data to EPA and States; and new possibilities to manage manifest data and to simplify or consolidate existing systems for reporting and tracking manifest and biennial report data.

Risks:

This action addresses administrative requirements for tracking hazardous waste shipments and does not involve the control of "risks" in the sense that RCRA regulations typically address the risks posed by the management of hazardous wastes. There is not a formal

risk assessment developed for this action. Since the e-manifest regulation could authorize the use of an information technology (IT) system that would be developed to create and transmit electronic manifests, there would be information system management risks and information security risks associated with developing and operating such an IT system. EPA will assess and manage these information technology and security risks as part of the Capital Planning and Investment Control (CPIC) process that governs the management of EPA's IT investments.

Timetable:

Action	Date	FR Cite
NPRM	05/22/01	66 FR 28240
Notice of Public Meeting	04/01/04	69 FR 17145
NODA Final Action	04/18/06 04/00/08	71 FR 19842

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 31471; EPA publication information: NPRM - http://www.gpo.gov/su_docs/aces/fr-cont.html; Split from RIN 2050-AE21; EPA Docket information: EPA-HQ-RCRA-2001-0032

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; 56221 Waste Treatment and Disposal; 483 Water Transportation

URL For More Information:

www.epa.gov/epaoswer/hazwaste/gener/manifest/

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RIN: 2050-AG20

EPA

129. OIL POLLUTION PREVENTION; SPILL PREVENTION, CONTROL, AND COUNTERMEASURE (SPCC) REQUIREMENTS—AMENDMENTS

Priority:

Economically Significant

Legal Authority:

33 USC 1321

CFR Citation:

40 CFR 112

Legal Deadline:

None

Abstract:

On September 20, 2004, the Environmental Protection Agency (EPA or the Agency) issued two Notices of Data Availability (NODAs) concerning certain facilities and oil-filled and process equipment. Based on its review of the information received from the NODAs, EPA proposed to amend the Spill Prevention, Control, and Countermeasure (SPCC) Plan requirements to reduce the regulatory burden for certain facilities by: providing an option that would allow owners/operators of facilities that store less than 10,000 gallons of oil and meet other qualifying criteria to self-certify their SPCC Plans, in lieu of review and certification by a Professional Engineer; providing an alternative to the secondary containment requirement, without requiring a determination of impracticability, for facilities that have certain types of oil-filled equipment; defining and providing an exemption for motive power containers; and exempting airport mobile refuelers from the specifically sized secondary

containment requirements for bulk storage containers. In addition, the Agency also proposed to remove and reserve certain SPCC requirements for animal fats and vegetable oils and proposed a separate extension of the compliance dates for farms (see 70 FR 73524, December 12, 2005). In proposing these changes, EPA is significantly reducing the burden imposed on the regulated community in complying with the SPCC requirements, while maintaining protection of human health and the environment. EPA has also requested comments on the potential scope of future rulemaking.

Statement of Need:

The Office of Management and Budget (OMB) targeted certain rulemakings across the U.S. Environmental Protection Agency (EPA), including the SPCC rule, for regulatory reform on an expedited schedule. (Progress in Regulatory Reform: 2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities ("Thompson Report")). This rulemaking will provide streamlined, alternative approaches for compliance with oil spill prevention requirements for certain entities, and to improve net welfare by reducing the costs of regulation and improving compliance, resulting in greater environmental protection.

Summary of Legal Basis:

Section 311(j)(1)(C) of the Clean Water Act (CWA or the Act), 33 U.S.C. 1321(j)(1)(C), requires the President to issue regulations establishing procedures, methods, equipment, and other requirements to prevent discharges of oil from vessels and facilities and to contain such discharges. The President delegated the authority to regulate non-transportation-related onshore facilities to EPA in Executive Order 11548 (35 FR 11677, July 22, 1970), which has been replaced by Executive Order 12777 (56 FR 54757, October 22, 1991). No aspects of this action are required by statute or court orders.

Alternatives:

EPA considered alternative options for various aspects of this rulemaking in the December 2005 proposed rule, following receipt of public comments, and through logical outgrowth of the proposed rule. To address streamlined requirements for a defined set of "qualified facilities," alternative options included: (1) providing an

indefinite extension of deadlines or a suspension of all SPCC requirements; and (2) a multi-tiered structure of requirements based on a facility's total regulated storage based on the SBA proposal described in the Certain Facilities NODA published last year. To address streamlined requirements for small oil-filled operational equipment, alternative approaches considered included: (1) an option similar to the qualified facilities proposal, in which eligibility of a facility with oil-filled operational equipment would be determined by considering capacity thresholds and reportable discharge history from any oil-filled operational equipment; (2) a tiered set of requirements for electrical and other oil-filled operational equipment; (3) providing an indefinite extension of the Plan revision and implementation dates for certain types of oil-filled operational equipment; and (4) suspending all SPCC requirements for certain types of oil-filled operational equipment. For motive power containers greater than 55 gallons in size, alternative options included: (1) exemption of all motive power containers, except motive power containers on aircraft and mining equipment; (2) exemption of all motive power containers below a certain gallon threshold; and (3) exclusion of motive power containers only from the facility storage capacity calculation and bulk storage container requirements.

Anticipated Cost and Benefits:

Considered separately and applying a 7 percent discount rate, today's proposed regulatory changes could yield annualized compliance cost savings, in 2005 dollars, of about \$38 million for the "Qualified Facility" option, \$39 to \$67 million for "Oil-Filled Equipment" option (assuming 25 to 75 percent of facilities with oil-filled equipment affected); \$1 million to \$5 million for the "Motive Power" exemption (assuming 10 to 50 percent of facilities with motive power containers affected); and \$17 million to \$51 million for the "Mobile Refuelers" exemption (assuming 25 to 75 percent of facilities with mobile refuelers affected). The main benefit of the rule is the reductions in compliance costs due to streamlined requirements. EPA does not believe that these cost reductions would be offset by any significant losses in environmental protection.

Risks:

EPA has designed the final rule to minimize increases in environmental risk. Although the final rule may

increase the risk of discharge by an unknown magnitude by streamlining the rule for certain owners and operators of facilities, EPA believes that any environmental impact will be minimal, and will be offset by the benefits of increased compliance with the SPCC rule.

Timetable:

Action	Date	FR Cite
NODA re: Certain Facilities	09/20/04	69 FR 56184
NODA re: Oil-filled and Process Equipment	09/20/04	69 FR 56182
NPRM	12/12/05	70 FR 73524
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 2634.3; EPA publication information: NODA re certain facilities - <http://www.epa.gov/fedrgstr/EPA-WATER/2004/September/Day-20/w21065.htm>; Split from RIN 2050-AG16.

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RIN: 2050-AG23

EPA

130. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM PERMIT REQUIREMENTS FOR PEAK WET WEATHER DISCHARGES FROM PUBLICLY OWNED TREATMENT WORK TREATMENT PLANTS SERVING SANITARY SEWER COLLECTION SYSTEMS POLICY

Priority:

Other Significant

Legal Authority:

33 USC 1311, 1318, 1342, 1361

CFR Citation:

40 CFR 122.41(m)

Legal Deadline:

None

Abstract:

During periods of wet weather, wastewater flows received by municipal sewage treatment plants can significantly increase, which can create operational challenges for sewage treatment facilities. Where peak flows approach or exceed the design capacity of a treatment plant they can seriously reduce treatment efficiency or damage treatment units. In addition to hydraulic concerns, wastewater associated with peak flows may have low organic strength, which can also decrease treatment efficiencies. One engineering practice that some facilities use to protect biological treatment units from damage and to prevent overflows and backups elsewhere in the system is referred to as wet weather blending. Wet weather blending occurs during peak wet weather flow events when flows that exceed the capacity of the biological units are routed around the biological units and blended with effluent from the biological units prior to discharge. Regulatory agencies, sewage treatment plant operators, and representatives of environmental advocacy groups have expressed uncertainty about National Pollutant Discharge Elimination System (NPDES) requirements addressing such situations. EPA requested public comment on a proposed policy published on November 7, 2003. Based on a review of all the information received, EPA has decided not to finalize the policy as proposed in November 2003. On December 22, 2005, EPA requested public comment on an alternative Peak Flows Policy that is significantly different than the 2003 draft policy.

Statement of Need:

Regulatory agencies, municipal operators of wastewater facilities, and representatives of environmental advocacy groups have expressed uncertainty about the appropriate regulatory interpretation for peak wet weather diversions at publicly owned treatment works (POTW) treatment plants serving separate sanitary sewer collection systems. This policy is needed to clarify NPDES permit requirements for such wet weather diversions and to ensure a comprehensive regulatory approach reduces peak wet diversions.

Summary of Legal Basis:

33 USC 1251 et seq.

Alternatives:

On November 7, 2003, EPA requested public comment on a proposed policy which would have provided an alternative regulatory interpretation. Under the proposed interpretation in the November 7, 2003 proposed policy, a wet weather diversion around biological treatment units that was blended with the wastewaters from the biological units prior to discharge would not have been considered to constitute a prohibited bypass if the six criteria specified in the November 7, 2003 proposed policy were met. EPA received significant public comment on the proposed policy, including over 98,000 comments opposing the policy due to concerns about human health risks. On May 19, 2005, EPA indicated that after consideration of the comments, the Agency had no intention of finalizing the 2003 proposal. On July 26, 2005, Congress enacted the FY 2006 Department of the Interior, Environment, and Related Agencies Appropriations Act (P.L. 109-54). Section 203 of the Appropriations Act provides that none of the funds made available in the Act could be used to finalize, issue, implement or enforce the November 7, 2003 proposed blending policy. On December 22, 2005, EPA requested public comment on an alternative Peak Flows Policy that is significantly different than the 2003 draft policy.

Anticipated Cost and Benefits:

The costs and benefits associated with this policy have not been evaluated.

Risks:

The collection and treatment of municipal sewage and wastewater is vital to public health. During significant rain events, high volumes of water entering a sewage collection system can overwhelm the collection system or treatment plant. Operators of wastewater treatment plants must manage these high flows to both ensure the continued operation of the treatment process and to prevent backups and overflows of raw wastewater in basements or city streets. The proposed policy seeks to reduce public health risks by encouraging municipalities to make investments in ongoing maintenance and capital improvements to improve their system's long-term performance.

Timetable:

Action	Date	FR Cite
1st Draft Policy	11/07/03	68 FR 63042
2nd Draft Policy	12/22/05	70 FR 76013
Final Policy	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 4690; EPA publication information: 2nd Draft Policy - <http://www.epa.gov/fedrgstr/EPA-WATER/2005/December/Day-22/w7696.htm>; EPA Docket information: EPA-HQ-OW-2005-0523

Sectors Affected:

22132 Sewage Treatment Facilities

URL For More Information:

www.epa.gov/npdes

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RIN: 2040-AD87

EPA

131. CONCENTRATED ANIMAL FEEDING OPERATION RULE

Priority:

Other Significant

Legal Authority:

CWA 301, 304, 306, 307, 308, 402, 501

CFR Citation:

40 CFR Part 122; 40 CFR Part 412

Legal Deadline:

None

Abstract:

This rulemaking is in response to the Second Circuit's February 28, 2005,

decision in *Waterkeeper Alliance vs. EPA*, which vacated provisions in the Concentrated Animal Feeding Operations (CAFO) rule found at 40 CFR 412. Two vacancies from the case affect the 1) duty that all CAFOs need to apply for an NPDES permit, and 2) provisions that nutrient management plans (NMPs) need only be kept on-site. This proposed rule would remove the duty to apply for all CAFOs and replace it with a requirement for CAFOs to apply for a permit if they discharge or propose to discharge. The proposed rule also would establish a process to address the court's concerns that the information within NMPs be available for public comment, reviewed by the permit authority, and incorporated into the permit. It is EPA's intention to make only those changes necessary to address the issues raised by the court.

Statement of Need:

EPA is revising the National Pollutant Discharge Elimination System (NPDES) permitting requirements and Effluent Limitations Guidelines and Standards (ELGs) for concentrated animal feeding operations (CAFOs) in response to the decision issued by the Second Circuit Court of Appeals in *Waterkeeper Alliance v. EPA*, 399 F.3d 486 (2nd Cir. 2005), which vacated certain aspects of the 2003 CAFO rule and remanded other aspects for clarification. This rule responds to the court's decision while furthering the statutory goal of restoring and maintaining the nation's water quality and effectively ensuring that CAFOs properly manage manure generated by their operations.

Summary of Legal Basis:

Congress passed the Federal Water Pollution Control Act (1972), also known as the Clean Water Act (CWA), to "restore and maintain the chemical, physical, and biological integrity of the nation's waters" (33 U.S.C. 1251(a)). Among the core provisions, the CWA establishes the NPDES permit program to authorize and regulate the discharge of pollutants from point sources to waters of the U.S. 33 U.S.C. 1342. Section 502(14) of the CWA specifically includes CAFOs in the definition of the term "point source." Section 502(12) defines the term "discharge of a pollutant" to mean "any addition of any pollutant to navigable waters from any point source" (emphasis added). EPA has issued comprehensive regulations that implement the NPDES program at 40 CFR part 122. The Act also provides for the development of technology-based and water quality-

based effluent limitations that are imposed through NPDES permits to control the discharge of pollutants from point sources. CWA sections 301(a) and (b).

Alternatives:

Because this rulemaking is in response to the decision issued by the Second Circuit Court of Appeals in *Waterkeeper Alliance v. EPA* vacating or remanding certain aspects of the 2003 CAFO rule, there are no non-regulatory options that would satisfy the requirements of the court.

Anticipated Cost and Benefits:

Since there is no change in technical requirements, changes in impacts on respondents are estimated to result exclusively from changes in the information collection burden. EPA estimates that CAFOs will experience a net reduction in administrative burden of approximately \$15.4 million due to the court decision. At the same time, however, permitting authorities would have to bear a net \$0.5 million annual increase in administrative burden. In total, the administrative burden under the proposed rule is projected to decline to a total of approximately \$64 million annually for both regulated facilities and permit authorities, which constitutes a reduction of more than \$14.9 million compared to the 2003 CAFO rule.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	06/30/06	71 FR 37744
Final Action	06/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4996; NPRM - <http://www.epa.gov/fedrgstr/EPA-WATER/2006/June/Day-30/w5773.htm>

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RIN: 2040-AE80

EPA

132. WATER TRANSFERS RULE

Priority:

Other Significant

Legal Authority:

33 USC 1251 et seq

CFR Citation:

40 CFR 122.3

Legal Deadline:

None

Abstract:

This rulemaking addresses the question of whether the National Pollutant Discharge Elimination System (NPDES) permitting program under Section 402 of the Clean Water Act (CWA) is applicable to water control facilities that merely convey or connect navigable waters. For purposes of this action, the term "water transfer" refers to any activity that conveys or connects navigable waters (as that term is defined in the CWA) without subjecting the water to intervening industrial, municipal, or commercial use. This rulemaking focuses exclusively on water transfers and is not relevant to whether any other activity is subject to the CWA permitting requirement.

Statement of Need:

This rulemaking is needed to clarify that NPDES permits are not required for water transfers. In 2004, this question was presented before the Supreme Court in *South Florida Water Management District v. Miccosukee Tribe of Indians*. The Court declined to rule directly on the issue and remanded it back to the District Court for further deliberation, generating uncertainty among the potentially regulated community and other stakeholders.

Summary of Legal Basis:

The legal basis is 33 USC 1251 et seq.

Alternatives:

On August 5, 2005, EPA issued a legal memorandum entitled "Agency Interpretation on Applicability of Section 402 of the Clean Water Act to Water Transfers." Based on the statute as a whole, this memo concluded that Congress intended for water transfers to be subject to oversight by water resource management agencies and State non-NPDES authorities, rather than the NPDES permitting program. The interpretive memo stated that the Agency would initiate a rulemaking to this effect. The issuance of a rulemaking will provide the greatest certainty for stakeholders.

Anticipated Cost and Benefits:

There are no costs and benefits associated with this rulemaking.

Risks:

There are no risks associated with this rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	06/07/06	71 FR 32887
Final Action	03/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

Additional Information:

SAN No. 5040; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-WATER/2006/June/Day-07/w8814.htm>

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RIN: 2040-AE86

EPA

133. • IMPLEMENTATION GUIDANCE FOR MERCURY WATER QUALITY CRITERIA

Priority:

Other Significant

Legal Authority:

33 USC 1251 et seq

CFR Citation:

None

Legal Deadline:

None

Abstract:

In the 2001 Federal Register notice of the availability of EPA's recommended water quality criterion for methylmercury, EPA stated that it would develop associated procedures and guidance for implementing the criterion. For States and authorized tribes exercising responsibility under CWA section 303(c), this document provides technical guidance on how they might want to use the recommended 2001 fish tissue-based criterion to develop and implement their own water quality standards for methylmercury. The guidance addresses topics related to adoption and revision of standards, monitoring, waterbody assessment, TMDL development, and NPDES permitting. Also, EPA published a national advisory for fish consumption due to mercury in March 2003; the implementation guidance will clarify the relationship between this advisory and the recommended criterion. Since atmospheric deposition is considered to be a major source of mercury for many waterbodies, implementing this

criterion involves coordination across many media and program areas.

Statement of Need:

The methylmercury criterion is expressed as a fish and shellfish tissue value, and this raises both technical and programmatic implementation questions. EPA expects that, as a result of the revised methylmercury water quality criterion, together with a more sensitive method for detecting mercury in effluent and the water column, and increased monitoring of previously unmonitored waterbodies, the number of waterbodies that states report on CWA section 303(d) lists as impaired due to methylmercury contamination might continue to increase. Development of water quality standards, NPDES permits, and TMDLs present challenges because these activities typically have been based on a water concentration (e.g., as a measure of mercury levels in effluent). This guidance addresses issues associated with states and authorized tribes adopting the new water quality criterion into their water quality standards programs and implementation of the revised water quality criterion in TMDLs and NPDES permits. Further, because atmospheric deposition serves as a large source of mercury for many waterbodies, implementation of the criterion involves coordination across various media and program areas.

Summary of Legal Basis:

N/A

Alternatives:

N/A

Anticipated Cost and Benefits:

The costs and benefits associated with this guidance have not been evaluated.

Risks:

N/A

Timetable:

Action	Date	FR Cite
Final Document	01/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Tribal

Additional Information:

SAN No. 5098; FDMS Docket number: Docket ID No. EPA-HQ-OW-2006-0656

URL For More Information:

www.epa.gov/waterscience/criteria/methylmercury

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RIN: 2040-AE87

EPA

134. 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	10/04/05	70 FR 57822
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4896; EPA publication information: NPRM - <http://www.epa.gov/fedrgstr/EPA-WASTE/2005/October/Day-04/f19710.htm>

URL For More Information:

www.epa.gov/tri

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RIN: 2025-AA14

BILLING CODE 6560-50-S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

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 item in this Regulatory Plan involves a new exemption from the prohibitions of the ADEA for 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 is intended to 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. On February 4, 2005, AARP sued the EEOC seeking to prevent issuance of the final rule.

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.

FINAL RULE STAGE

134A. 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 considered 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	
Next Action		
Undetermined		

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

Additional Information:

On February 4, 2005, AARP sued the EEOC seeking to prevent issuance of the final rule.

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BILLING CODE 6570-01-S

**GENERAL SERVICES
ADMINISTRATION (GSA)****Statement of Regulatory and
Deregulatory Priorities**

The General Services Administration (GSA) establishes agency acquisition rules and guidance through the General Services Acquisition Regulation (GSAR), which contains agency acquisition policies and practices, contract clauses, solicitation provisions, and forms that control the relationship between GSA and contractors and prospective contractors.

GSA's fiscal year 2007 regulatory priority is to continue with the complete

rewrite of the GSAR. GSA is rewriting the GSAR to maintain consistency with the Federal Acquisition Regulation (FAR), and to implement streamlined and innovative acquisition procedures that contractors, offerors, and GSA contracting personnel can utilize when entering into and administering contractual relationships.

GSA will clarify the GSAR to —

- Provide consistency with the FAR;
- Eliminate coverage which duplicates the FAR or creates inconsistencies within the GSAR;
- Correct inappropriate references listed to indicate the basis for the regulation;

- Rewrite sections which have become irrelevant because of changes in technology or business processes, or which place unnecessary administrative burdens on contractors and the Government;
- Streamline or simplify the regulation;
- Roll up coverage from the services and regions/zones which should be in the GSAR;
- Provide new and/or augmented coverage; and
- Delete unnecessary burdens on small businesses.

BILLING CODE 6820-34-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 Earth and space. To carry out this Mission, NASA is authorized to: conduct research for the solution of problems of flight within and outside Earth's atmosphere; develop, construct, test, and operate aeronautical and space vehicles for research purposes; operate space transportation systems, including the Space Shuttle and the International Space Station; and perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with crewed, robotic, and expendable vehicles and arranges for the most effective use 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 2006 Strategic Plan, is to pioneer the future in space exploration, scientific discovery, and aeronautics research. This Mission is driven by *A Renewed Spirit of Discovery: The President's Vision for U.S. Space Exploration*, President George W. Bush's 2004 directive for the Nation's space program.

The fundamental goal of this directive is "to advance U.S. scientific, security, and economic interests through a robust space exploration program." In issuing it, the President committed the Nation to a journey of exploring the solar system, returning to the Moon in the next decade, then venturing further into the solar system, ultimately sending humans to Mars and beyond.

NASA enthusiastically embraced the challenge of extending a human presence throughout the solar system as the Agency's Vision, and in the NASA Authorization Act of 2005, Congress endorsed the Vision for Space Exploration and provided additional guidance for implementation. NASA is committed to achieving this Vision through activities centered around six Strategic Goals articulated in its 2006 Strategic Plan:

1. Fly the Shuttle as safely as possible until its retirement, not later than 2010.
2. Complete the International Space Station in a manner consistent with NASA's International Partner commitments and the needs of human exploration.
3. Develop a balanced program of science, exploration, and aeronautics consistent with the Agency's new exploration focus.
4. Bring a new Crew Exploration Vehicle into service as soon as possible after Shuttle retirement.
5. Encourage the pursuit of appropriate partnerships with the emerging commercial space sector.
6. Establish a lunar return program having the maximum possible utility for later missions to Mars and other destinations.

In pursuit of these activities, we are increasing internal collaboration, leveraging personnel and facilities, developing strong, healthy Centers, and fostering a safe environment of respect and open communication. We also will ensure clear accountability and solid program management and reporting practices.

Federal regulations can affect strongly the way NASA conducts activities related to its Goals, Mission, and Vision. The following are narrative descriptions of the most important regulations being planned for publication in the **Federal Register** during fiscal year (FY) 2006.

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 2006, except to conform to the FAR implementation of Earned Value Management and expected FAR changes to Part 27, Patents, Data, and Copyrights, and Part 45, Government Property. In a continuing effort to keep the NFS current with NASA initiatives and Federal procurement policy, minor revisions to the NFS will be published.

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 three regulatory priorities for fiscal year 2007. The first, included in The Regulatory Plan, is to revise and update our records management regulations in 36 CFR ch. XII, subchapter B. This regulatory activity is part of a major NARA initiative to review and redesign our records management program that started in 2000. 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. In fiscal year 2005, we issued a regulation relating to transitory e-mail in advance of the overall subchapter B revision. We will issue the proposed rule to revise subchapter B in 2007.

The second priority is to revise our fee schedule regulations in 36 CFR part 1258 to reflect changes in costs for providing copies of records. Our regulations in part 1258 establish the fees NARA may charge for copies of archival records, donated historical materials, Presidential records, some Nixon Presidential historical materials, records of Federal agencies stored in NARA records centers, and records filed with the Office of the Federal Register. NARA serves the public by specifying the fees in regulations.

Our third priority regulatory action is updating our regulations relating to the use of NARA facilities in 36 CFR part 1280. Specifically, the provisions for use of meeting space in the National Archives Building have changed as a

result of renovation of the building. We also intend to add information about use of meeting space at the National Archives at College Park. These regulations serve the public and Federal agencies.

NARA does not have any planned regulatory actions that relate to the events of September 11, 2001.

Regulations of Particular Concern to Small Businesses

None in fiscal year 2007.

NARA

PROPOSED RULE STAGE

135. 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. The proposed revision will be issued in fiscal year 2007 for Federal agency and public comment.

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 USC 2904); 2) approving the disposition of Federal records (44 USC 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 USC 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 USC 3101). Agency heads must also have an active, continuing records management program (44 USC 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	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

URL For More Information:

www.archives.gov/records-mgmt/initiatives/rm-redesign-project.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's mission is to ensure the Federal Government has an effective civilian workforce. OPM fulfills that mission by, among other things, providing human capital advice and leadership for the President and Federal agencies; delivering human resources policies, products, and services; and holding agencies accountable for their human capital practices. OPM's 2007 regulatory priorities are designed to support these activities.

Pay Regulations for Employees Affected by a Pandemic Health Crisis

On August 17, 2006, OPM issued interim regulations concerning pay actions for employees affected by a pandemic health crisis. These regulations were issued as part of OPM's effort to provide agencies with guidance to ensure they are able to fulfill their critical missions while at the same time protect employees if a pandemic health crisis occurs. The interim regulations clarify the rules for determining an employee's official worksite when he or she teleworks from an alternative worksite during an emergency situation, such as a pandemic health crisis. In addition, the interim regulations permit an agency to provide evacuation payments to an employee who is ordered to evacuate from his or her regular worksite and directed to work from home (or an alternative location mutually agreeable to the agency and the employee) during a pandemic health crisis. OPM expects to finalize these regulations in FY 2007.

Pay and Leave Flexibilities and Entitlements

In FY 2007, OPM will continue to enhance pay and leave flexibilities and entitlements to help Federal agencies better meet their strategic human capital needs. OPM anticipates finalizing a number of interim regulations issued in FY 2005 as a result of changes made to Federal pay and leave programs by the Federal Workforce Flexibility Act of 2004 (Public Law 108-411). This includes final regulations providing Federal agencies with the authority to pay recruitment and relocation incentives to help recruit and relocate employees to difficult-to-fill positions and the authority to pay retention incentives to help retain essential employees likely to leave their positions. This also includes final regulations governing pay setting for

employees covered by the General Schedule. In particular, these final regulations will:

- correct a number of pay anomalies regarding the administration of locality rates, special rates, and retained rates;
- enhance the superior qualifications and special need pay-setting authority, which provides agencies flexibility in setting pay for new and reappointed employees under the General Schedule; and
- improve the operation of the special rates program under which OPM may establish higher rates of pay for categories of General Schedule employees to address recruitment and retention needs.

OPM also plans to issue final regulations as a result of new authorities established by the Federal Workforce Flexibility Act of 2004. OPM will issue final regulations to provide agencies with the flexibility to grant new or reappointed employees credit for prior work experience in determining the employees' annual leave accrual rate. OPM will also issue final regulations governing the payment of compensatory time off for time spent by an employee in a travel status away from the employee's official duty station when such time is not otherwise compensable. Finally, OPM anticipates finalizing interim regulations issued in FY 2006 to increase the maximum uniform allowance rate for civilian Federal employees required to wear a uniform.

Human Capital Management

The provisions of Public Law 107-296 include the Chief Human Capital Officers Act of 2002 (Act), which, among other things, amended OPM's authorizing legislation in chapter 11 of title 5, United States Code, requiring OPM to design a set of systems, including appropriate metrics, for assessing the management of human capital by Federal agencies. On May 23, 2006, OPM published a proposed rule in the Federal Register, Human Capital Management in Agencies, that would implement the provisions of the Act, as well as Executive Order 13197, Governmentwide Accountability for Merit System Principles; Workforce Information (January 18, 2001). The proposed rule establishes a basic framework for planning and assessing human capital management progress and results, including compliance with relevant laws, rules and regulations, as assessed through agency human capital accountability systems and reported in

annual agency human capital accountability reports. OPM expects to issue the final rule in December 2006.

Awards

As part of the initiative to strengthen pay-for-performance concepts in the Federal Government, OPM issued proposed regulations on June 21, 2006, that clarified the use of performance-based cash awards. Because compensation reform is a necessary element of improving the management of human capital—a central goal of the *President's Management Agenda*—OPM is addressing lump-sum awards that are granted on the basis of a rating of record. The regulations require that agency programs for granting such awards, as designed and applied, make meaningful distinctions based on levels of performance so that better performers receive greater recognition. OPM expects to finalize these regulations by the time most agencies make their awards decisions in order to give practical effect to these regulations.

Human Resource Flexibilities

OPM continues to modernize the civil service and the hiring process. OPM issued the following proposed and interim regulations in support of this endeavor which we anticipate will be finalized in FY 2007. The salary offset (dual compensation) waivers regulation amends the criteria under which OPM may delegate dual compensation (salary offset) waiver authority to agencies. The Direct Hire for Acquisition Positions regulation allows non-DoD agencies to recruit and directly hire individuals into certain Federal acquisition positions.

No Fear Regulations

In July 2003, the President delegated to OPM responsibility for promulgating regulations pursuant to title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002. The provisions of title II relate to reimbursement of the Department of the Treasury's judgment fund, notice and training for applicants and employees, and reporting requirements by agencies. Final regulations concerning reimbursement of the judgment fund were promulgated on May 10, 2006. Final regulations concerning notice and training for applicants and employees were promulgated on July 20, 2006. Regulations concerning the reporting and best practices provisions of the law were promulgated as proposed regulations on January 25, 2006. At the request of Congress and stakeholder groups, the comment period for these

regulations was extended from late March 2006 to May 1, 2006. After working with the EEOC, the Office of Special Counsel, the Department of Justice, and the Department of the Treasury, OPM expects to have completed promulgation of all regulations concerning title II of the Act before the end of this calendar year.

Combined Federal Campaign

An aspect of maintaining an effective workforce has been to provide an outlet for Federal employees' charitable impulses. That program, the Combined Federal Campaign, is the nation's largest and most successful workplace fund-raising drive. In June 2007, OPM proposed significant changes to regulations governing the CFC. The proposed regulations, which marked the

first major revisions to CFC regulations in many years, are intended to streamline and modernize the Campaign, while continuing to ensure accountability of the participating charities and assure federal employee donors continue to have confidence in the charities that participate. OPM anticipates publishing these regulations in final form in time for use in the 2007 campaign.

BILLING CODE 6325-44-S

PENSION BENEFIT GUARANTY CORPORATION (PBGC)

Statement of Regulatory and Deregulatory Priorities

The Pension Benefit Guaranty Corporation (PBGC) protects the pensions of over 44 million working men and women in about 30,000 private defined benefit plans. The PBGC receives no funds from general tax revenues. Operations are financed by insurance premiums, investment income, assets from pension plans trusted by the PBGC, and recoveries from the companies formerly responsible for the trustee 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. The PBGC regulatory priorities are focused on improving transparency and increasing the use of electronic filing to simplify filing.

PBGC Insurance Programs

The 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.

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). Early in 2005, the Administration proposed reforms to improve funding of plans and restore the financial health of the insurance program, which had a \$23 billion deficit at the end of fiscal year 2005.

Multiemployer Program. The smaller multiemployer program covers 1,600 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. The multiemployer program, which is separately funded from the single-employer program, had a \$300 million deficit at the end of FY 2005.

2006 Legislation

Legislation signed into law in 2006 - the Deficit Reduction Act of 2005 and the Pension Protection Act of 2006 - contain various provisions that are intended to improve plan funding, enhance pension-related reporting and disclosure, and strengthen the insurance programs.

Among the provisions that apply to single-employer plans are:

- *Plan funding:* Accelerated funding requirements for underfunded plans, with a higher funding target for plans considered to be "at risk" of termination based on the financial status of the plan sponsor; and funding relief for commercial airlines, with certain protections for the insurance program.
- *Reporting and disclosure:* Improved disclosure of plan funding to participants in all single-employer plans; reporting of additional information to the PBGC; and disclosure of additional information to participants regarding termination of their plans.
- *Benefits and guarantees restriction:* Restrictions on accruals and lump sums for plans below certain funding levels; guarantee limitations on plant shutdown benefits; and a guarantee freeze when a sponsor enters bankruptcy.
- *Premiums:* An increased flat-rate premium (including indexing for future wage inflation), a more accurate measure of plan underfunding for the variable-rate premium (capped for small employers), and a new termination premium.
- *Missing Participants:* Expansion of the missing participants program to certain plans that previously were not eligible to participate.

Among the provisions that apply to multiemployer plans are:

- *Plan funding:* Accelerated funding requirements for most multiemployer plans, and additional funding rules for plans that are in endangered or critical status.
- *Disclosure:* Improved disclosure of plan funding to participants in all multiemployer plans.
- *Premiums:* An increased flat-rate premium (including indexing for future wage inflation).
- *Missing Participants:* As noted above, terminating multiemployer plans will be covered for the first time under the

expanded missing participants program.

Regulatory Objectives and Priorities

The PBGC's regulatory objectives and priorities are developed in the context of its statutory purposes: (1) encouraging voluntary private pension plans, (2) providing for the timely and uninterrupted payment of pension benefits and (3) keeping premiums at the lowest possible levels. The PBGC also attempts to minimize administrative burdens on plans and participants.

Over the last several years, the PBGC's regulatory priorities have focused on changes to improve transparency and to simplify filing with the PBGC by increasing use of electronic filing. In making policy, the PBGC gives consideration to the special needs and concerns of small business. With the passage of the Deficit Reduction Act and the Pension Protection Act, the PBGC is now applying this focus to implementation of the new laws.

Improve Transparency of Information

The PBGC has been moving forward to improve transparency of information to plan participants, investors, and the PBGC, to better inform them and to encourage more responsible funding of pension plans. In March 2005, the PBGC issued a final rule requiring the filing of certain additional items of supporting information for plan actuarial information and employer financial information that is required of certain employers with large amounts of pension underfunding. The PBGC is continuing to develop proposed amendments to the regulation that requires notice to the PBGC of certain events that threaten plan funding. The Pension Protection Act expands disclosure of plan funding information to plan participants and consolidates annual disclosure of plan funding under the Department of Labor, repealing Section 4011 of ERISA, under which some of that reporting has been within the jurisdiction of the PBGC. (Accordingly the PBGC is withdrawing from its Regulatory Agenda proposed amendments to improve the disclosure of plan funding information that certain underfunded plans are required to provide in an annual Participant Notice under Section 4011.) The new law also contains provisions for disclosure of certain information to participants regarding the termination of their underfunded plan.

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. In June 2006, the PBGC issued a final rule, effective July 1, 2006, that requires electronic filing of premium information for plans with 500 or more participants for plan years beginning on or after January 1, 2006 and for all plans for plan years beginning on or after January 1, 2007. The PBGC will grant case-by-case exemptions for filers that demonstrate good cause. Online filers will have a choice of using private-sector software that meets the PBGC's published standards or using the PBGC's software. Electronic premium filing will simplify filers' paperwork, improve accuracy of the PBGC's premium records and database, and enable more prompt payment of premium refunds. The PBGC is incorporating the new changes

to the flat-rate and variable-rate premiums into software so that it will be easy to comply with the premium changes under the new law. The PBGC also is developing regulations to address implementation of the new termination premium.

Plan actuarial and employer financial information required to be reported to the PBGC by employers with large amounts of pension underfunding is required to be filed electronically under a final regulation issued in March 2005. Electronic filing reduces the filing burden, improves accuracy, and better enables the PBGC to monitor and manage risks posed by these plans. The PBGC is developing a regulation to incorporate changes to the reporting requirements under the Pension Protection Act.

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, mandatory electronic filing of premiums will apply six months later to plans with fewer than 500 participants than to larger plans. Also, 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. In addition, a regulation implementing the cap on the variable-rate premium for plans of small employers will be among the first regulations that the PBGC issues under the Pension Protection Act.

The PBGC will continue to review its regulations to look for further simplification opportunities.

BILLING CODE 7709-01-S

SMALL BUSINESS ADMINISTRATION (SBA)

SBA

Statement of Regulatory Priorities

PROPOSED RULE STAGE

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 through its resource partners;
- Increasing contracting and business opportunities for small businesses;
- Providing affordable, timely and easily accessible financial assistance to businesses, homeowners and renters after a disaster; and
- 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. In the coming year, SBA's regulatory priorities will focus on strengthening SBA's management of its programs and services, including the Small Business Lending Company and Lender Oversight programs, Disaster programs and Size Standards programs.

136. SMALL BUSINESS LENDING COMPANY AND LENDER OVERSIGHT REGULATIONS

Priority:

Other Significant

Legal Authority:

15 USC 650

CFR Citation:

13 CFR 120

Legal Deadline:

None

Abstract:

This rule would implement the Small Business Administration's (SBA) statutory authority under the Small Business Reauthorization and Manufacturing Assistance Act of 2004 (Reauthorization Act) to regulate Small Business Lending Companies (SBLCs) and non-federally regulated lenders (NFRLs). It also would conform SBA rules to various changes in the Section 7(a) Business Loan Program and the Certified Development Company (CDC) Program enacted by the Reauthorization Act.

In particular, this rule would: (1) Define SBLCs and NFRLs; (2) clarify SBA's authority to regulate SBLCs and NFRLs; (3) authorize SBA to set minimum capital standards for SBLCs, to issue cease and desist orders, and revoke or suspend lending authority of SBLCs and NFRLs; (4) establish the Bureau of Premier Certified Lender Program Oversight in the Office of Lender Oversight; (5) transfer existing SBA enforcement authority over CDCs from the Office of Financial Assistance to the Office of Lender Oversight; and (6) define SBA's enforcement authorities relative to all SBA lenders participating in the 7(a) and CDC programs and intermediaries in the Microloan program.

Statement of Need:

Section 7(a) of the Small Business Act states that SBA may provide financing to small businesses "directly or in cooperation with banks or other financial institutions." Presently, SBA guarantees loans through approximately 5,000 lenders. Of these lenders, about 14 are SBLCs that are not otherwise regulated by Federal or State chartering/licensing agencies. SBA

examines these SBLCs periodically. Congressional and Administration policy to delegate lending responsibilities to SBLCs and other SBA lenders requires that SBA increase its lender oversight. To that end, SBA will draft regulations that strengthen the Agency's management of its business loan and lender oversight programs.

Summary of Legal Basis:

Small Business Act, section 23(b)(3).

Alternatives:

This rulemaking amends and expands SBA's existing regulations on the SBLC and lender oversight programs.

Anticipated Cost and Benefits:

This rulemaking is designed to strengthen SBA's regulations regarding the SBLC Program and business loan and lender oversight programs. Some additional costs associated with additional reporting by the SBLCs, NFRLs, and other SBA lenders to the SBA are anticipated.

Risks:

This regulation poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Federalism:

Undetermined

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SBA**FINAL RULE STAGE****137. SIZE FOR PURPOSES OF LONG TERM CONTRACTS; SMALL BUSINESS SIZE REGULATIONS; 8(A) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS****Priority:**

Other Significant

Legal Authority:

15 USC 632(a); 15 USC 634(b)(6)

CFR Citation:

13 CFR 121

Legal Deadline:

None

Abstract:

This rule would amend SBA's small business size regulations relating to the time at which size is determined for purposes of long term contracts. Currently, SBA determines the size of a concern as of the date the concern submits a written self-certification that it is small to the procuring agency as part of its initial offer. However, this practice is problematic because multiple award contracts may have terms of 5, 10, or 20 years. Thus, over the contract's duration, the firm may grow and no longer qualify as a small business, yet still receive the same benefits under the contract reserved exclusively for small businesses. SBA proposes to address this situation with this rule.

Statement of Need:

The SBA's small business size regulations (13 CFR 121) are used to determine eligibility for all SBA and Federal programs that require a concern to be a small business. Currently, SBA's regulations provide that SBA determines the size of a concern as of the date the concern submits a written self-certification that it is small to the procuring agency as part of its initial offer, including price. 13 CFR 121.404. Therefore, for a long-term (longer than 5 years) multiple award schedule (MAS), Federal Supply Schedule (FSS), multiple agency (MAC), or Government-wide Acquisition (GWAC) contract, size is determined as of the date of a concern's initial offer, including price. If a concern is small as of that date, agencies may place orders pursuant to the original contract

and consider these orders as awards to a "small business" for the length of that contract.

For long-term contracts, this has led to skewed and misleading results. Such contracts may have terms of five, ten, or twenty years, some even longer and can be amended to incorporate goods and services with varying size standards, and unlimited quantities. Therefore, orders to concerns receiving such contracts would be considered to be awards to small business even though a firm had grown to be large (either through natural growth or by merger or acquisition) during the term of the contract, and even though the firm is not small with respect to the size standard corresponding to the work to be performed under a particular order.

Summary of Legal Basis:

The Small Business Act provides that "the Administrator may specify detailed definitions or standards by which a business concern may be determined to be a small business concern for the purposes of this Act or any other Act." 15 U.S.C. § 632(a)(2)(A).

The U.S. Small Business Administration (SBA) has promulgated small business size regulations (13 CFR 121) which are used to determine eligibility for all SBA and Federal programs that require a concern to be a small business.

In addition, SBA's Office of Hearings and Appeals (OHA) decided a size appeal relating to an order issued pursuant to the FSS. In *Size Appeals of SETA Corporation and Federal Emergency Management Agency*, SBA No. SIZ-4477 (2002), OHA ruled that a request for quotations (RFQ) issued pursuant to a FSS contract was a new small business set-aside procurement. As such, OHA held that size should be determined as of the date of the firm's submission of its certification as an eligible small business with its price quotation in response to the RFQ, and not at the date of the firm's offer in response to the initial FSS solicitation.

Further, the U.S. General Accounting Office (GAO) weighed in on the issue in a bid protest. In *CMS Information Services, Inc., B-290541* (Aug. 7, 2002), the procuring agency limited competition to small businesses and required businesses to certify their size at the time they submitted their quotations. The protester argued that this certification requirement was improper because the offerors had each certified their size at the time they

submitted their initial offer to GSA for award of its FSS contract. GAO ruled that when an agency limits competition to small business vendors under a competitive RFQ issued pursuant to the FSS, the agency may properly require firms to certify as to their small business size status as of the time they submit their quotations.

In addition, GSA implemented a Federal Acquisition Regulation (FAR) deviation requiring contractors operating under the MAS Program or any other multiple award contract (such as the FAST program in GSA's Federal Technology Service), to recertify that the concern qualifies as a small business each time their contract is up for renewal. See GSA News Release # 9991 (November 15, 2002) (available at <http://www.gsa.gov/news>).

This evidence indicates that agencies may be counting orders issued pursuant to long-term contracts as awards to small businesses when, in reality, the order is actually made to an entity other than a small business. As a result, agencies, including GSA, are attempting to remedy the situation, as are administrative tribunals such as OHA and GAO. Consequently, SBA is proposing to revise its regulations at 13 CFR 121 to specifically address size as it relates to awards issued pursuant to long-term contracts.

Alternatives:

SBA considered two alternatives to the proposed rule. The first alternative would require that for an agency to count an award issued pursuant to a multiple award or schedule contract as an award to a small business, the concern must be small as of the date of each order (in addition to being small at the time of its self-certification for the multiple award or schedule contract). The second alternative would require a firm to re-certify its status as a small business at the time an option for a long-term contract is exercised. SBA felt that the first alternative might require size certifications too often (and could delay the procurement process), and that the second alternative would require them too infrequently (letting a firm that has been purchased by a large business immediately after receiving its long-term contract, for example, be considered a small business for almost five years after becoming large).

Anticipated Cost and Benefits:

As a result of re-certification, SBA estimates that initially, 2300 concerns will no longer be considered small

business concerns. As a result, buying activities will have to change their contract reporting data systems to reflect this change. If contracting agencies utilize an existing data base, the Government's On-line Representation and Certification Application (ORCA), as the collection medium for small business size re-certifications, no additional cost to the Government is anticipated.

But even if contracting agencies need to expand an existing application database to accommodate a new data field entry for this material to be collected and posted on the agency's website, this should be a one-time set-up cost with an approximate 10-year life. SBA estimates that it will cost \$250 annually. Alternatively, agencies can publish the list of re-certifications in the Federal Register. Depending on the number of long-term contracts issued by an agency, this could cost an agency approximately \$250 per year, as well.

SBA estimates that each procuring activity will have a GS-12 employee spend approximately one hour each

week reviewing and analyzing the re-certifications. According to the Federal Procurement Data Center, there are approximately 59 procuring activities buying goods and services. However, only about half of those activities issue long-term contracts.

Thus, approximately 30 agencies will have a GS-12 employee reviewing, analyzing and posting re-certifications, if this is the method employed by the agency to implement this rule.

30 Agencies x 1 hour = 30 hours/week

30 hours/week x 52 weeks/year = 1,560 hours/year

1,560 hours/year x \$30 (GS-12 hourly rate) = \$46,800/year

\$250 (set-up site) + \$46,800 (cost to review for all agencies) = \$47,050 total cost to the Government to implement per year.

Risks:

This final rule poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/25/03	68 FR 20350
NPRM Comment Period End	06/24/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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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), the Supplemental Security Income (SSI) program under title XVI of the Act and the Special Veterans Benefits under title XVIII 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 14 entries for the Regulatory Plan represent areas of major importance to the administration of the retirement, survivors, disability, SSI, and Medicare programs. Each individual initiative is described more fully after this Statement of Regulatory Priorities. Several of these regulatory priorities reflect the provisions of major laws that were recently enacted, e.g., 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). Six of our 14 entries were recently published in the **Federal Register** and appear in the Completed Actions section of the Unified Agenda.

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 7 initiatives that address disability.

We are including several initiatives that address issues involving attempts by disabled individuals to return to the workforce. A final 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 final rule will, 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 will also include home schooling as a form of regular school attendance for purposes of the Student Earned Income Exclusion and reflects provisions of the Social Security Protection Act of 2004. This final rule was published on November 17, 2006. We are including two final rules concerning the

continuing disability review (CDR) process. One will explain the standards we use to evaluate the work activity of an individual receiving disability benefits, and when we will conduct a CDR. This final rule was published on November 17, 2006. The other amends our regulations to suspend disability benefits when a beneficiary fails to cooperate with our request for information during a CDR. This final rule was published on October 17, 2006.

A final rule would revise the definitions of the age categories we use as a criterion in determining disability.

Four initiatives would update the medical listings used to determine disability: final rules on digestive system disorders, immune system disorders and evaluating visual disorders, and one proposed rule for evaluating mental disorders. The final rule on evaluating visual disorder published on November 20, 2006. The revisions will ensure that the listings reflect advances in medical knowledge, treatment, and methods of evaluating these impairments.

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; one also reflects 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 included a final rule that reflects provisions of the Social Security Protection Act of 2004 intended to strengthen our oversight of the representative payee program. This final rule was published on October 18, 2006.

Another final rule will exclude representatives and health care providers who are convicted of violating certain criminal statutes involving fraud and other matters in the title II or title XVI programs from participation in those programs.

A proposed rule would address annual onsite reviews of the facilities of consultative examination (CE) providers by State Disability Determination Services (DDS). This proposed rule will update the annual threshold amount of billing used to select CE providers for review. Raising the threshold amount

will enable DDS staff to perform this review function more efficiently.

Another proposed rule would reflect a provision of the Social Security Protection Act of 2004 concerning a requirement that certain non-citizen workers must meet to establish entitlement to benefits of title II of the Act.

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 included in the Plan one final rule that implements the legislation. This final rule addresses the reduction of premium subsidies for the Supplementary Medical Insurance Benefit program (Medicare part B), and was published on October 27, 2006.

SSA

PROPOSED RULE STAGE

138. REVISED MEDICAL CRITERIA FOR EVALUATING MENTAL DISORDERS (886P)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1; 20 CFR 404.1520; 20 CFR 404.1520a; 20 CFR 404.1528; 20 CFR 416.920a; 20 CFR 416.928

Legal Deadline:

None

Abstract:

We propose to update and revise the rules that we use to evaluate mental 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 12.00 and 112.00 in appendix 1 to subpart P of part 404 of our regulations (the listings). These listings include such disorders as affective disorders, schizophrenic disorder, intellectual disabilities, and autistic disorders.

Statement of Need:

These regulations are necessary to update the listings for evaluating mental disorders 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:

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. We have not comprehensively revised the current listings in over 15 years. 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:

The administrative cost of this regulation is to be determined.

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	03/17/03	68 FR 12639
ANPRM Comment Period End	06/16/03	
NPRM	01/00/07	
Final Action	11/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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SSA

139. ADDITIONAL INSURED STATUS REQUIREMENTS FOR CERTAIN ALIEN WORKERS (2882P)

Priority:

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

Legal Authority:

42 USC 414(c); 42 USC 423(a)(1)(C); PL 108-203, sec 211

CFR Citation:

20 CFR 404.110; 20 CFR 404.120; 20 CFR 404.130; 20 CFR 404.315; 20 CFR 404.1912; 20 CFR 404.1931

Legal Deadline:

None

Abstract:

The proposed rule will revise our regulations on insured status to include an additional insured status requirement under section 211 of Public Law 108-203—the Social Security Protection Act of 2004 (SSPA)—for alien workers who were originally assigned a Social Security number (SSN) on or after January 1, 2004. Under this law, an alien worker must meet either of the following additional requirements to be fully or currently insured and to establish entitlement to any title II benefit based on his/her earnings:

- The alien worker must have been issued an SSN for work purposes at any time on or after January 1, 2004; or
- The alien worker must have been admitted to the United States at any time as a nonimmigrant visitor for business (immigration category “B-1”) or as an “alien crewman” (immigration category “D-1” or “D-2”).

If an alien worker whose SSN was originally assigned on or after January

1, 2004, does not meet either of these requirements, then he/she is not fully or currently insured; thus entitlement is precluded. This is true even if the alien worker appears to have the required number of quarters of coverage (QCs) in accordance with the regular insured status provisions. While the additional insured status requirement applies directly to certain alien workers, it also affects the entitlement of any person seeking a benefit on the record of an alien who is subject to this law.

An alien worker who was properly assigned a SSN before January 1, 2004, is not subject to section 211 of the SSPA.

Statement of Need:

We are codifying the statutory changes in our rules even though we have already implemented section 211 of the SSPA by issuing instructions to claims adjudicators in our Program Operations Manual System (POMS). By incorporating the changes mandated by the law in our regulations, our program rules and operating instructions will be consistent with the statute.

Summary of Legal Basis:

The proposed revisions to our regulations are needed to implement section 211 of the SSPA.

Alternatives:

None

Anticipated Cost and Benefits:

Administrative start-up costs were nominal since we already implemented the law via POMS instructions and adjudicator training. No systems changes were needed. Benefits include savings to the title II Trust Funds and in administrative enumeration costs since some claimants who are denied under this law will not be able to get an SSN card for non-work purposes.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	
Final Action	02/00/08	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

140. • CONSULTATIVE EXAMINATION – ANNUAL ONSITE REVIEW BY DDSS (3338P)

Priority:

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

Legal Authority:

42 USC 421(a)(1)

CFR Citation:

20 CFR 404.1519s; 20 CFR 416.919s

Legal Deadline:

None

Abstract:

We are amending our regulations to reflect the impact of inflation since 1991 when they were implemented. We propose to change the threshold amount to require the State disability determination services (DDSs) to perform an onsite review of consultative examination (CE) providers from \$100,000 to \$150,000.

Statement of Need:

The change to these regulations is necessary to update the threshold amount of annual billing by CE providers that will trigger mandatory onsite review by DDS staff. The workload associated with the regulatory requirement to perform onsite reviews at the largest CE providers has increased substantially due to inflation since 1991. Therefore, mid-tier and even smaller CE providers are now receiving mandatory onsite reviews. The change will restore the onsite review program to its intended purpose; to perform onsite review at the very large CE providers to ensure that those providers have facilities which meet SSA standards.

Summary of Legal Basis:

Administrative—Not required by statute or court order.

Alternatives:

We considered not raising the amount, but determined that requiring onsite review for all CE providers with billings of \$100,000 or more is an unnecessary burden for State DDSs and does not provide better service to the public.

Anticipated Cost and Benefits:

There are no additional costs. The change would lower the number of required onsite reviews. The expectation is the DDS personnel would have the flexibility to perform optional reviews and complete other higher priority work.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	
Final Action	01/00/08	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

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SSA

FINAL RULE STAGE

141. REVISED MEDICAL CRITERIA FOR EVALUATING IMPAIRMENTS OF THE DIGESTIVE SYSTEM (800F)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

Sections 5.00 and 105.00, Digestive Disorders, of appendix 1 subpart P of part 404 of our regulations (404.1501 through 404.1599) describe those digestive 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 SSI program incorporates by reference 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 digestive listings to reflect advances in medical knowledge, treatment, and methods of evaluating digestive impairments. They ensure that determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that people 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 and thus, continuing to use our current criteria. 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 impairments. Portions of the current listings are now over 20 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:

To be determined.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/14/01	66 FR 57009
NPRM Comment Period End	01/14/02	
NPRM Comment Period Reopened	11/08/04	69 FR 64702
Comment Period End	01/07/05	
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960-AF28

SSA

142. REVISED MEDICAL CRITERIA FOR EVALUATING IMMUNE SYSTEM DISORDERS (804F)

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 will 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 will revise 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/AIDS, systemic lupus erythematosus, and inflammatory arthritis.

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 13 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:

We anticipate that if finalized, these proposed rules will 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	08/04/06	71 FR 44431
NPRM Comment Period End	10/03/06	
Final Action	08/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960-AF33

SSA

143. MANDATORY EXCLUSION OF HEALTH CARE PROVIDERS AND REPRESENTATIVES FROM PARTICIPATING IN PROGRAMS ADMINISTERED BY SSA, INCLUDING REPRESENTATIVE PAYMENT (954F)

Priority:

Other Significant

Legal Authority:

PL 106-169, sec 208; 42 USC 1320b-6

CFR Citation:

20 CFR 404.1503b; 20 CFR 416.903b

Legal Deadline:

None

Abstract:

This final rule will exclude representatives and health care providers who are convicted of violating certain criminal statutes involving fraud and other matters in the title II or title XVI programs administered by SSA, or who are assessed a civil monetary penalty for making false or misleading statements related to such programs, from participation in those programs. The minimum exclusion period is five years, but exclusions can be permanent.

Statement of Need:

These regulations are necessary to clarify how SSA will implement Section 1136 of the Social Security Act, which requires exclusion of representative and health care providers who have committed fraud in SSA programs.

Summary of Legal Basis:

These regulations implement Section 1136 of the Social Security Act which was added by Section 208 of Public Law 106-169.

Alternatives:

None—Required by legislation.

Anticipated Cost and Benefits:

Any administrative costs are attributable to the legislation and not to the regulation itself.

Risks:

At this time we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	07/02/04	69 FR 40338
NPRM Comment	08/31/04	
Period End		
Final Action	03/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

144. AMENDMENTS TO THE TICKET TO WORK AND SELF-SUFFICIENCY PROGRAM (967F)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 1320b-19; PL 106-170, sec 101

CFR Citation:

20 CFR 411.110; 20 CFR 411.120 to 411.155; 20 CFR 411.165; 20 CFR

411.166; 20 CFR 411.170; 20 CFR 411.171; 20 CFR 411.175; 20 CFR 411.180; 20 CFR 411.190; 20 CFR 411.191; 20 CFR 411.210; 20 CFR 411.325; 20 CFR 411.350 to 411.370; 20 CFR 411.385 to 411.390; 20 CFR 411.500 to 411.515; 20 CFR 411.525 to 411.565; 20 CFR 411.566; 20 CFR 411.575 to 411.590

Legal Deadline:

None

Abstract:

These final rules will revise our current rules that implement the Ticket to Work and Self-Sufficiency Program under section 1148 of the Social Security Act. The rules will expand beneficiary eligibility to receive tickets under this program; clarify the rules for assignment of a beneficiary's ticket to a State vocational rehabilitation (VR) agency; 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, revise the rules for milestone and outcome payments, in order to increase the incentives for providers of employment services, vocational rehabilitation services, and other support services to participate in this program.

Statement of Need:

These final rules are necessary to respond to our experience and the recommendations we have received since we began implementation of the Ticket to Work and Self-Sufficiency Program in February 2002. These changes are intended to increase the incentives for providers of employment, 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:

Not required by statute or court order.

Alternatives:

We considered not revising the current regulations implementing the Ticket to Work program. However, we believe that these revisions to the eligibility to receive a ticket, the clarification of the rules for assignment of a ticket to a State VR agency, and the amendment of the rules for paying ENs are necessary to increase participation in the Ticket to Work program by both

service providers and the beneficiaries with disabilities. This will increase the opportunities for the beneficiaries to seek the services necessary to obtain and retain employment and reduce their dependency on cash benefit programs.

Anticipated Cost and Benefits:

We anticipate initial costs to increase due to up-front payments to ENs, and then increased program savings in later years as ENs assist more beneficiaries to achieve self-sufficiency and reduce 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	09/30/05	70 FR 57222
NPRM Comment	12/29/05	
Period End		
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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SSA

145. AGE AS A FACTOR IN EVALUATING DISABILITY (3183F)

Priority:

Other Significant

Legal Authority:

42 USC 221(a); 42 USC 221(i); 42 USC 222(c); 42 USC 402; 42 USC 405(a); 42

USC 405(b); 42 USC 405(d) to 405(h); 42 USC 416i; 42 USC 423; 42 USC 902(a)(5); 42 USC 1382; 42 USC 1382(h); 42 USC 1382b(a); 42 USC 1382b(c); 42 USC 1382c; 42 USC 1383(a); 42 USC 1383(c)

CFR Citation:

20 CFR 404.1562 to 404.1563; 20 CFR 404.1568; 20 CFR 404, subpart P, app 2; 20 CFR 416.962; 20 CFR 416.963; 20 CFR 416.968

Legal Deadline:

None

Abstract:

These final rules will revise the definitions of the age categories we use as one of the criteria in determining disability under titles II and XVI of the Social Security Act (the Act). The changes reflect our adjudicative experience, advances in medical treatment and healthcare, changes in the workforce since we originally published our rules for considering age in 1978, and current and future increases in the full retirement age under Social Security law. The changes will not affect the rules under part 404 of our regulations for individuals age 55 or older who have statutory

blindness. They also will not affect our other rules that are dependent on age, such as the age at which you can qualify for early retirement benefits or for Medicare as a retired individual.

Statement of Need:

These changes are needed to ensure that our regulations are as up-to-date as possible. We have not substantively revised the age categories we use for determining disability since we first published them more than 25 years ago.

Summary of Legal Basis:

Administrative. Not required by statute or court order.

Alternatives:

None.

Anticipated Cost and Benefits:

To be determined.

Risks:

At this time, we have not identified any risks to this proposal.

Timetable:

Action	Date	FR Cite
NPRM	11/04/05	70 FR 67101
NPRM Comment Period End	01/03/06	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

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 2007, the Commission's significant rulemaking activity will involve addressing risks of fire associated with ignition of upholstered furniture. The emphasis on this rulemaking activity in the Commission's FY 2007 regulatory plan is consistent with the Commission's statutory mandate and its criteria for setting priorities.

CPSC

PROPOSED RULE STAGE

146. 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 developed revised drafts of the standard addressing both cigarette and small open flame ignition, and held public meetings on October 28, 2004 and May 18, 2005 to present and discuss the revised drafts. On January 31, 2006, the staff sent a status report to the Commission. The next step is for staff to prepare a briefing package for the Commission.

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 (a) 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, and (b) identify and encourage the use of environmentally-preferable flame retardants under a Design for the Environment industry/government partnership. The Design for the

Environment report was published in September 2005.

Statement of Need:

For 1999-2002, an annual average of approximately 4,800 residential fires in which upholstered furniture was the first item to ignite resulted in an estimated 360 deaths, 740 civilian injuries, and about \$133 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 \$2.1 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 annual societal cost of which was \$2.1 billion for 1999-2002. 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 average annual cost to society from all residential fires associated with upholstered furniture was \$2.1 billion for 1999-2002. 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 Meeting Notice	11/01/01	
Staff Held Public Meeting	03/20/02	67 FR 12916
Second Day of Public Meeting	06/18/02	
	06/19/02	

Action	Date	FR Cite
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 ANPRM	10/17/03	
ANPRM Comment Period End	10/23/03	68 FR 60629
Staff Held Public Meeting	12/22/03	
Staff Held Public Meeting	10/28/04	
Staff Held Public Meeting	05/18/05	
Staff Sends Status Report to Commission	01/31/06	
Staff Sends Briefing Package to Commission	11/03/06	
Technical Reports Provided to Commission	12/00/06	

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 2007 that would be required to be included in a regulatory plan.

The Finance Board's highest regulatory priorities during 2007 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:

- 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.

- Streamline the regulations governing the Banks' acquired member asset programs, to make the provisions less prescriptive while preserving the key provisions relating to safety and soundness and advancement of the Banks' housing finance mission.
- Update the regulations relating to the capital structure of the Banks to enhance their safety and soundness by ensuring that the amount and composition of their capital is appropriate in light of the risks undertaken in the course of their lines of business.
- Improve the regulations relating to the investments made by the Banks to coordinate with the repeal of the provisions of the Financial Management Policy that currently govern Bank investment portfolios.

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 vision statement. The Commission's vision is to administer the shipping statutes as effectively as possible to provide fairness and efficiency in the United States foreign 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 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. The Commission continues to assess its regulations implementing this legislation.

The Commission is presently in the process of a comprehensive review of Commission regulations to ensure alignment with emerging industry trends and business practices, particularly as they relate to ocean transportation intermediaries and vessel-operating common carriers. It is likely that proposals for change to certain Commission regulations will come from that examination. In addition, the Commission anticipates an automated Form FMC-18 system to be implemented in phases throughout FY 2006 and 2007.

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, and the Commission is continuing its review of these comments 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 also receives requests from the public seeking new regulations or modifications of existing regulations. If circumstances so warrant, the Commission on its own initiative, or upon request, will institute an appropriate rulemaking proceeding.

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. Fraud and deception injure both consumers and honest competitors alike and undermine competitive markets. 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. In addition, the Commission 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 and Compliance Partnerships With Industry

The Commission vigorously protects consumers through a variety of tools including both regulatory and non-regulatory approaches. 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 held workshops and issued reports that encourage industry self-regulation in several areas. As detailed below, privacy, information security, and information sharing continue to be at the forefront of the Commission’s consumer protection program:

(a) On November 6-9, 2006, the Federal Trade Commission hosted hearings on “Protecting Consumers in the Next Tech-ade.” The FTC plans to bring together experts from the business, government, and technology sectors, consumer advocates, academicians, and law enforcement officials to explore the ways in which convergence and the globalization of commerce impact consumer protection. These hearings will provide an opportunity to examine changes that have occurred in marketing and technology over the past decade, and to garner experts’ views on coming challenges and opportunities for consumers, businesses, and governmental bodies.

(b) To encourage better cybersecurity practices, the Commission has partnered with other agencies and organizations to launch a website called OnGuardOnline.gov which provides practical tips from the Federal Government and the technology industry to help consumers be on guard against Internet fraud, secure their computer, and protect their personal information.

(c) The Commission has also undertaken efforts to educate consumers about the risks associated with downloading and using peer-to-peer file-sharing (P2P) software programs. A March 2005 “Cyber Security Tip” warns consumers that use of P2P technology presents a number of risks, including the installation of malicious code, exposure of sensitive or personal information, susceptibility of the consumer’s computer to attack, and exposure to legal liability. In a June 2005 report, the FTC staff encouraged implementation of

industry proposals regarding risk disclosures and will continue to monitor this area. See *Peer-to-Peer File-Sharing Technology: Consumer Protection and Competition Issues Staff Report Federal Trade Commission* (June 2005), available at <http://www.ftc.gov/reports/p2p05/050623p2prpt.pdf>.

(d) During November 2004, the Commission convened an E-mail Authentication Summit, co-sponsored by the National Institute of Standards at the Commerce Department. Since then, the Commission has been encouraging the development of a compatible authentication standard that would provide accountability for e-mail communication.

(e) The Commission also explored the consumer protection and privacy implications of Radio Frequency Identification (RFID) at a public forum and subsequently published a staff report recommending that industry initiatives that are transparent could play an important role in addressing privacy concerns raised by certain RFID applications. See *RFID: Radio Frequency Identification: Applications and Implications for Consumers: A Workshop Report From the Staff of the Federal Trade Commission* (March 2005), available at <http://www.ftc.gov/os/2005/03/050308rfidrpt.pdf>. The report also recommended that industry self-regulatory programs should include meaningful accountability provisions to help ensure compliance.

(f) The Commission held a 2004 public workshop on spyware which when surreptitiously installed on a personal computer, can wreak havoc by highlighting the browser, launching a barrage of pop-up ads, extracting sensitive personal information, or rendering the computer unusable. Following the workshop, the Commission released a staff workshop report concluding in part that industry should develop standards for defining spyware and disclosing information about it to consumers, expand efforts to educate consumers about spyware risks and help law enforcement efforts. See *Spyware Workshop: Monitoring Software On Your Personal Computer: Spyware, Adware, and Other Software Staff Report Federal Trade Commission* (March 2005), available at <http://www.ftc.gov/os/2005/03/050307spywarerpt.pdf>.

(g) With respect to the Children’s Online Privacy Protection Act (COPPA), the Commission has approved the safe harbor programs of four organizations

whose self-regulatory guidelines and programs protect children's privacy to the same or greater extent as COPPA. The organizations with these programs include the Children's Advertising Review Unit of the Council of Better Business Bureaus (CARU), an arm of the advertising industry's self-regulatory program; the Entertainment Software Rating Board (ESRB); TRUSTe, an Internet privacy seal program; and Privo, Inc.

In other areas, like the entertainment industry, the Commission has encouraged industry groups to improve their self-regulatory programs to discourage the marketing to children of violent R-rated movies, Mature-rated electronic games, and music labeled with a parental advisory. The motion picture, electronic game and music industries have each set in place self-regulatory systems that rate or label products in an effort to help parents seeking to limit their children's exposure to violent materials. Since 1999, the Commission has issued five reports on these three industries, examining compliance with their own voluntary marketing guidelines. In 2004, the Commission issued the latest of a series of reports on industry practices. Although the Commission found that violent R-rated movies and M-rated games were still being advertised in media with large teen audiences, the Commission's review reveals that the movie and game industries continue to comply, for the most part, with their self-regulatory limits on ad placement. The recording industry, however, is an example of a less successful self-regulatory attempt. The Commission recommended in its latest 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. The reports also examined the extent to which underage consumers can buy rated or labeled products. Even though the movie theater industry has made real progress in this area, and to a lesser extent so have game retailers, the Commission also noted that there remains room for improvement in retailers' practices because the Commission found that teens could still purchase rated or labeled entertainment products at a significant number of stores and theaters. 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 A Report*

to Congress (July 2004), <http://www.ftc.gov/os/2004/07/040708kidsviolencecrpt.pdf>. Most recently, the Commission has issued consumer education materials to assist parents in understanding video game ratings. The Commission plans to issue another report in this area by the end of 2006.

The Commission has encouraged the actions of three alcohol industry trade associations, the Distilled Spirits Council of the United States, the Beer Institute, and the Wine Institute, to develop and implement voluntary advertising codes governing the placement and content of alcohol advertising. In particular, the Commission 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. The Commission has worked and will continue to work with industry to facilitate compliance with the self-regulatory standards announced in the FTC's report, Federal Trade Commission, *Alcohol Marketing and Advertising A Report to Congress* (Sept. 2003), available at <http://www.ftc.gov/os/2003/09/alcohol08report.pdf>. However, to ensure that self-regulation is working and whether changes need to be made with those guidelines to ensure their continued viability, the Commission announced in March 2006 that it will be conducting a new study of these alcohol industry self-regulatory programs. The Commission has requested approval from The Office of Management and Budget (OMB) to issue compulsory process orders to leading alcohol companies and request information from advertisers. The OMB clearance process requires that the Commission publish two notices in the Federal Register requesting comments on the proposal. The agency anticipates issuing the orders in Fall 2006 and completing its report in Spring 2007.

The Commission will also launch an alcohol consumer education program, www.dontserveteens.gov, in late Summer 2006. The program communicates the message that responsible adults do not serve alcohol to teens because it is unsafe, irresponsible, and illegal, and it includes a website, television and radio public service announcements and print material to be posted in alcohol retail outlets. Throughout the remainder of 2006 and 2007, the Commission will engage in outreach to promote effective dissemination of this message.

In the weight loss product advertising area, the Commission has consistently proposed a strengthened self-regulatory response from the industry and more media oversight to address the problem of facially false efficacy claims. Specifically, the Commission authorized the release of a media reference guide to assist media in identifying facially false weight-loss advertising. 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>. The Commission asked the media to refuse to run advertisements that make "Red Flag" claims. The media appears to be responding to this challenge, as shown by a follow-up report that analyzed data gathered during 2004. See *2004 Weight Loss Advertising Survey Staff Report Federal Trade Commission* (April 2005), available at <http://www.ftc.gov/os/2005/04/050411weightlosssurvey04.pdf>. The FTC's survey of weight loss advertisements found that the number of ads with red flag claims had fallen from almost 50% to 15%. In addition, the FTC has encouraged a joint effort by the Electronic Retailing Association and the Better Business Bureau's National Advertising Review Council to develop a self-regulatory program that could promptly address deceptive infomercial claims.

To address concerns about the nation's growing childhood obesity problem, the Commission and the Department of Health and Human Services (HHS) released a report during 2006 recommending concrete steps that industry can take to change their marketing and other practices to make progress against childhood obesity. See *Perspectives On Marketing, Self-Regulation, & Childhood Obesity: A Report on a Joint Workshop of the Federal Trade Commission and the Department of Health and Human Services* (April 2006) (materials available at <http://www.ftc.gov/os/2006/05/PerspectivesOnMarketingSelf-Regulation%26ChildhoodObesityFTCandHHSReportonJointWorkshop.pdf>). This report was the product of a joint FTC-HHS workshop in June 2005 that brought together a wide range of speakers to examine ways, including self-regulation, to promote competition among food manufacturers to produce and promote healthier food choices for children (materials are available at <http://www.ftc.gov/bcp/workshops/foodmarketingtokids/>). The 2006 Report

noted that the current Children's Advertising Review Unit (CARU) Guides are a good foundation for industry self-regulation, but the agencies recommended that the Guides be expanded and their enforcement enhanced. The Report noted that both agencies plan to monitor closely progress on these recommendations.

Finally, the Commission continues to apply 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. Since the Textile Corporate Leniency Program was announced, 89 companies have been granted "leniency" for self-reported minor violations of FTC textile regulations.

The Commission also has 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 234 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, 18 companies have agreed to participate in the program.

Rulemakings and Studies Required by Statute

In 2003, the Congress enacted several laws requiring the Commission to undertake rulemakings and studies. These include at least 14 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 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 and are described more extensively in the Unified Agenda. The Final Actions section below describes any final actions taken on these rulemakings.

On August 8, 2005, the President signed the Energy Policy Act of 2005 which required the Commission to complete two rulemakings while authorizing other discretionary rulemaking actions. Pursuant to this statute, the Commission was required to initiate a rulemaking within 90 days of enactment examining the effectiveness of the energy efficiency related consumer product labeling program. Further, the Commission was required to complete this rulemaking within two years of enactment. The statute also required the Commission to issue labeling requirements for ceiling fans concerning the electricity used by the fans to circulate air in a room. The rulemakings for appliance labeling effectiveness and for ceiling fan labeling are proceeding according to schedule. The statute also amended the statutory definitions of some covered lighting products that may require the Commission to make conforming amendments to the current rule. The statute also authorizes the Commission or the Secretary of the Department of Energy (DOE), as appropriate, to require labels for a number of products. The Commission and DOE are consulting about how to proceed in this area. Another section of the Act gives the Commission discretionary authority to issue retail electricity rules related to slamming (unauthorized account switches), cramming (unauthorized charges), and privacy.

The Energy Policy Act of 2005 also required the Commission to conduct an investigation to determine if the price of gasoline was being artificially raised by reducing refinery capacity or by any other form of market manipulation or price gouging practices. In addition, in

Section 632 of the Commission's appropriations legislation for fiscal year 2006, Congress directed the Commission to investigate nationwide gasoline prices and possible price gouging in the aftermath of Hurricane Katrina. Because the issues raised by these two statutory commands were closely related, the Commission conducted a single investigation in response to these directives. On May 11, 2006, the Commission issued a report entitled "Investigation of Gasoline Price Manipulation and Post-Katrina Gasoline Price Increases", which can be found at <http://www.ftc.gov/reports/060518PublicGasolinePricesInvestigationReportFinal.pdf>. In its investigation, the FTC found no instances of illegal market manipulation that led to higher prices during the relevant time periods but found 15 examples of pricing at the refining, wholesale, or retail level that fit the relevant legislation's definition of evidence of "price gouging." Other factors such as regional or local market trends, however, appeared to explain these firms' prices in nearly all cases. Further, the report reiterated the FTC's position that federal gasoline price gouging legislation, in addition to being difficult to enforce, could cause more problems for consumers than it solves, and that competitive market forces should be allowed to determine the price of gasoline drivers pay at the pump.

Other New Regulatory Activities

After issuing a staff advisory opinion indicating that the Commission's current Guides for Jewelry, Precious Metals and Pewter Industries, 16 CFR part 23, did not address descriptions of new platinum alloy products, the Commission issued a Request for Public Comments on whether the platinum section of the Guides for Jewelry, Precious Metals and Pewter Industries, should be amended to provide guidance on how to non-deceptively mark or describe products containing between 500 and 850 parts per thousand pure platinum and no other platinum group metals. 70 FR 38834 (July 6, 2005). After an extension, the comment period closed on October 12, 2005. Staff is reviewing the comments and expects to make recommendations to the Commission by the end of 2006.

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, 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 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 review 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 2005-06 Reviews

Most 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 2006, the Commission announced its ten-year schedule of review and that it would initiate the review of two rules and one guide during 2006: (1) the Test Procedures and Labeling Standards for Recycled Oil Rule (the Recycled Oil Rule), 16 CFR part 311, (2) the Used Motor Vehicle Trade Regulation Rule (the Used Motor Vehicle Rule), 16 CFR part 455, and (3) Guides for the Nursery Industry (the Nursery Guides), 16 CFR part 18. 70 FR 77077 (Dec. 29, 2005).

For the Recycled Oil Rule, the Commission requested comments on July 6, 2006, on whether to retain or amend the Rule. 71 FR 38322. The notice asked nine specific questions about the rule that the public may wish to address. The comment period ended on September 5, 2006, and staff plans to forward its recommendation to the Commission in early 2007. For the Used Motor Vehicle Rule, staff anticipates that the Commission will issue a request for comments on whether to retain or amend the Rule by early 2007. Finally, the Commission plans to issue a similar request for comments relating to the Nursery Guides by the end of 2006.

Ongoing Reviews

The Commission staff is continuing its review of several rules and guides. First, for the Telemarketing Sales Rule (TSR), 16 FR part 310, the Commission published an NPRM on November 17, 2004, proposing to allow prerecorded messages in certain defined situations, seeking comments regarding a possible change in the method used to calculate the percentage of abandoned calls, and announcing the agency's forbearance from enforcing the Commission's current call abandonment provisions against callers who engage in prerecorded message telemarketing as long as they complied with the proposed change. 69 FR 67287. The comment period ended on January 10, 2005. On October 4, 2006, the Commission issued a revised NPRM concerning these issues. 71 FR 58716. The revised and extended comment period ends on December 18, 2006. 71 FR 65762. The Commission proposes making explicit that the TSR prevents sellers and telemarketers from delivering a prerecorded message when a person answers a telemarketing call, except in the very limited circumstances permitted in the call abandonment safe harbor, and when a consumer has consented, in writing, to receive such calls. The NPRM also proposes to change the method for measuring the maximum allowable call abandonment rate in the call abandonment safe harbor provision from "3% per day per calling campaign" to "3% per 30-day period per calling campaign." The Commission also announced that the Commission will no longer forbear after January 2, 2007, from initiating enforcement actions for violations of the TSR's call abandonment provision against companies that use prerecorded messages.

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). The Commission did not review or approve the staff report. 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 were accepted until November 12, 2004. Staff is reviewing the comments and anticipates sending its recommendation to the Commission by Fall 2006.

Third, the proposed Business Opportunities Rule stems from the ongoing review of the Franchise Rule, where staff recommended that the Franchise Rule be split into two parts; one part addressing franchise issues and one part addressing business opportunity issues. Thereafter, the Commission published an NPRM seeking comments on the proposed Business Opportunities Rule. 71 FR 19054 (Apr. 12, 2006). This proposed rule would address fraud in the offer and sale of business opportunity ventures by requiring business opportunity sellers to furnish specific pre-sale disclosures to prospective purchasers, as well as prohibiting specific conduct that the rulemaking record and the Commission's law enforcement experience show are prevalent problems. The NPRM comment period ended on July 17, 2006, and the rebuttal comment period was extended to September 29, 2006. Staff anticipates publishing a report by the end of 2007.

Fourth, for the rulemakings on the Fair and Accurate Credit Transactions Act of 2003 (FACTA), the Commission has three active proposals, including:

(A) Furnisher Rules—The Commission, in coordination with the banking agencies and the National Credit Union Administration, issued an ANPRM for proposed guidelines and rules concerning the accuracy of information furnished to consumer reporting agencies, and rules relating to the ability of consumers to dispute information directly with furnishers of information. 71 FR 14419 (Mar. 22, 2006). The comment period closed on

May 22, 2006, and the agencies are now assessing the comments.

(B) Identity Theft Red Flags Rules—The Commission and the banking agencies jointly published proposed rules that would, among other things, require card issuers to investigate requests for card changes and would require credit report users to investigate when the address on a credit report differs from the address on a credit application. 71 FR 40786 (Jul. 18, 2006). The comment period closed on September 18, 2006, and the agencies are reviewing the comments.

(C) Risk Based Pricing Rule—The Commission jointly with the Federal Reserve expects to publish a risk-based pricing proposal for comment by the end of 2006. This statutorily-required rulemaking would address the form, content, time, manner, definitions, exceptions, and model of a risk-based pricing notice.

Fifth, for the Hart-Scott-Rodino Premerger Notification Rules (HSR Rules), Bureau of Competition staff is continuing to review various HSR Rule provisions. Staff anticipates sending its recommendation to the Commission by Fall 2007.

Sixth, for the Rules on the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (the CAN-SPAM Act Rules), the Commission issued an NPRM on May 12, 2005, that proposed rule provisions on five discretionary topics: (1) defining the term “person,” a term used repeatedly throughout the Act but not defined there; (2) modifying the definition of “sender” to make it easier to determine which of multiple parties advertising in a single e-mail message will be responsible for complying with the Act’s “opt-out” requirements; (3) clarifying that Post Office boxes and private mailboxes established pursuant to United States Postal Service regulations constitute “valid physical postal addresses” within the meaning of the Act; (4) shortening from ten days to three the time a sender may take before honoring a recipient’s opt-out request; and (5) clarifying that to submit a valid opt-out request, a recipient cannot be required to pay a fee, provide information other than his or her e-mail address and opt-out preferences, or take any steps other than sending a reply e-mail message or visiting a single Internet Web page. 70 FR 25426. The comment period closed on June 27, 2005, and staff anticipates sending a final recommendation to the Commission by late 2006.

Seventh, 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 the Gramm-Leach-Bliley Act, 15 USC 6801 et seq., which requires 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 seven agencies are jointly funding consumer research and testing to inform the development of alternative privacy notices that are easier for consumers to understand and use.

Eighth, 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 in 2007.

Ninth, 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). 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 April 2007.

Finally, the Commission’s review of the Pay-Per-Call Rule, 16 CFR part 308, is continuing. 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 pre-subscription agreement, and the need for obtaining express authorization from consumers before placing charges on their telephone bills. The review record has remained open to encourage additional comments on questions related to expansion of the rule’s coverage. Staff anticipates forwarding its recommendation to the Commission by April 2007.

In addition, during 2007, the Commission anticipates issuing 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.

Final Actions

Since publication of the 2005 Regulatory Plan, the Commission has taken final actions on several rulemakings. First, on March 8, 2005, the Commission concluded its regulatory review of the Children’s Online Privacy Protection Rule (COPPA Rule), 16 CFR part 312, by retaining COPPA without any changes. 71 FR 13247 (Mar. 15, 2006). Congress required this review be completed within five years of the effective date of the implementation of the rule, and that it include assessment of: (1) the effect on practices relating to the collection

and disclosure of information relating to children; (2) children's ability to obtain access to information of their choice online; and (3) the availability of web sites directed to children. The public comments received during the review uniformly stated that COPPA has provided greater protection to children's personal information online, that there is a continuing need for the Rule, and that the Rule should be retained. Specifically, many commenters emphasized that the Rule provides web site operators with a clear set of standards to follow and that operators have received few, if any, complaints from parents about the standards and how they are implemented. The FTC plans to submit to the Congress in late 2006 an assessment of COPPA's implementation, including a discussion of the three issues noted above.

Second, for the HSR Rules, the Commission most recently issued a Final Rule to allow filing parties the option for the electronic submission via the Internet of Premerger Notification and Report Forms. 71 FR 35995 (Jun. 23, 2006). This rule was effective upon publication. The Commission also issued three other HSR-related Final Rules: (1) allowing filing parties to provide Internet links to certain documents instead of paper copies, effective on January 11, 2006, 70 FR 73369; (2) clarifying that "stale filings" expire eighteen months after they are received by the Agencies, 70 FR 73369; & (3) requiring all filers to use 2002 NAICS data and codes (replacing 1997 codes and revenue information) beginning January 30, 2006. 70 FR 77312.

Finally, with respect to the TSR Rules, the Commission also published an NPRM concerning a revised fee structure for the National Do-Not-Call Registry on May 1, 2006. 71 FR 25512. The comment period ended on June 1, 2006. The Commission published final fee changes for the National Do-Not-Call Registry on July 31, 2006, with an effective date of September 1, 2006. 71

FR 43048. Under the new structure, the annual fee for each area code of data accessed will be \$62, and the maximum amount charged to entities accessing 280 area codes or more will be \$17,050. The rulemaking still allows telemarketers 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. The revised fees were effective on September 1, 2006.

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 final rules issued by the Commission continue to be 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. 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. In 2004, OIRA requested recommendations for reform in the manufacturing sector. OIRA received two nominations for FTC action but determined not to include them in the Report to Congress on agency responses to reform nominations in the manufacturing sector.¹

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.

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¹ The two nominations were 1) a comment concerning the DOE and FTC requirements for reporting water usage (the FTC's response indicated that the agencies have accepted the requested data based on third party reports since 1993); and 2) a comment that the DOE, FTC and EPA should work with industry to streamline duplicative energy labels (the FTC's response noted that since 2000, where appropriate, manufacturers have been allowed to place the Energy Star logo on EnergyGuide Labels and noted that the two labels provide different information to the consumer).

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). The stated purpose of the NIGC 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 NIGC's intention to provide regulation of Indian gaming to adequately shield it from organized crime and other corrupting influences, to ensure that each Indian tribe is the primary beneficiary of its gaming operation(s), 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 NIGC'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 NIGC has decided that the development of technical standards and game classifications for gaming machines and related gaming systems is an important initiative for the promotion and protection of tribal gaming.

Additionally, the NIGC will be continuing to make technical amendments to the minimal internal control standards (MICS). These amendments will correct isolated problems that have been brought to the NIGC's attention by tribal gaming operators and regulators.

The NIGC has been innovative in using active outreach efforts to inform its policy development and its rulemaking efforts. For example, the NIGC has had great success in using regional meetings, both formal and informal, with tribal governments to gather views on current and proposed NIGC initiatives. The NIGC anticipates that these consultations with regulated tribes will continue to play an important role in the development of the NIGC's rulemaking efforts.

NIGC

FINAL RULE STAGE

147. TECHNICAL AMENDMENTS TO THE MINIMUM INTERNAL CONTROL STANDARDS

Priority:

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

Legal Authority:

25 USC 2702; 25 USC 2706(b)(10)

CFR Citation:

25 CFR 542

Legal Deadline:

None

Abstract:

The National Indian Gaming Commission is making technical changes to the Minimum Internal Control Standards (MICS) in response to changes in technology and the gaming industry. The Commission will routinely revise the MICS in response to these changes.

Statement of Need:

Periodic technical adjustments and revisions to the Minimum Internal Control Standards (MICS) are necessary in order to keep the MICS effective in protecting tribal gaming assets and the interests of tribal stakeholders and the gaming public.

Summary of Legal Basis:

It is the goal of NIGC to provide regulation of Indian gaming to shield it from organized crime and other corrupting influences as well as assuring that gaming is conducted fairly and honestly. (25 U.S.C. 2702). The Commission is charged with the responsibility of monitoring gaming conducted on Indian lands. (25 U.S.C. 2706(b)(1)). The Indian Gaming Regulatory Act expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the (Act)." (25 U.S.C. 2706(b)(10)). The Commission relies on these sections of the statute to authorize the promulgation of MICS to ensure uniformity and integrity in tribal gaming.

Alternatives:

If the Commission does not periodically update the MICS, the regulations that govern tribal gaming will not address

changing technology and gaming methods.

Anticipated Cost and Benefits:

Updated MICS will aid tribal governments in the regulation of their gaming activities.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
First NPRM	12/01/04	69 FR 69847
Second NPRM	03/10/05	70 FR 11893
Final Action on First Rule	05/04/05	70 FR 23011
Final Action on Second Rule	08/12/05	70 FR 47097
Third NPRM	11/15/05	70 FR 69293
Final Action on Third Rule (1)	05/11/06	71 FR 27385
Final Action on Third Rule (Surveillance)	12/00/06	
Fourth NPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

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NIGC

148. TECHNICAL STANDARDS FOR GAMING MACHINES AND GAMING SYSTEMS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

25 USC 2706

CFR Citation:

25 CFR 547

Legal Deadline:

None

Abstract:

It is necessary for the National Indian Gaming Commission (NIGC) to promulgate regulations establishing technical standards in order to assure the integrity of electronic equipment used with the play of class II games. Technical standards will address actual operation of gaming machines and systems and the equipment related to their operation.

Statement of Need:

Technical standards are needed to assure machine games are operated in a manner that ensures uniformity and integrity in tribal gaming.

Summary of Legal Basis:

It is the goal of NIGC to provide regulation of Indian gaming to shield it from organized crime and other corrupting influences as well as assuring that gaming is conducted fairly and honestly. (25 U.S.C. 2702). The Commission is charged with the responsibility of monitoring gaming conducted on Indian lands. (25 U.S.C. 2706(b)(1)). The Indian Gaming Regulatory Act expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the (Act)." (25 U.S.C. 2706(b)(10)). The Commission relies on these sections of the statute to authorize the promulgation of technical standards for gaming machines to ensure uniformity and integrity in tribal gaming.

Alternatives:

If the Commission does not issue a rule establishing technical standards for gaming machines, tribal gaming will not have the benefit of a standard that can help promote the integrity of the equipment in class II gaming.

Anticipated Cost and Benefits:

The development of technical standards will reduce the cost of regulation to the Federal Government. Additionally, technical standards will aid tribal governments in the regulations of their gaming activities as well as prevent loss associated with defective or substandard gaming devices. The only anticipated cost will be to gaming machine manufacturers.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	08/11/06	71 FR 46336
Final Action	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Federalism:

Undetermined

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NIGC

149. GAME CLASSIFICATION STANDARDS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

25 USC 2706

CFR Citation:

25 CFR 546

Legal Deadline:

None

Abstract:

It is necessary for the National Indian Gaming Commission (NIGC) to promulgate regulations establishing game classification standards because of the distinction between class II and class III gaming set forth in the Indian Gaming Regulatory Act (IGRA). Technical changes make it difficult for regulators to keep up with the gaming industry. By establishing classification standards, tribal gaming commissions, the primary regulators of tribal gaming, will more easily be able to distinguish between class II and class III machines.

Statement of Need:

Gaming Classification standards are needed to assure that regulators can

determine whether gaming machines are class II or class III devices under IGRA.

Summary of Legal Basis:

It is the goal of NIGC to provide regulation of Indian gaming to shield it from organized crime and other corrupting influences as well as assuring that gaming is conducted fairly and honestly. (25 U.S.C. 2702). The Commission is charged with the responsibility of monitoring gaming conducted on Indian lands. (25 U.S.C. 2706(b)(1)). IGRA expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the (Act)." (25 U.S.C. 2706(b)(10)). The Commission relies on these sections of the statute to authorize the promulgation of technical standards for game classifications and for gaming machines to ensure uniformity and integrity in tribal gaming.

Alternatives:

The Commission can either: (1) Issue a rule establishing game classifications and gaming machines, or (2) continue evaluating classifications on a case-by-case basis.

Anticipated Cost and Benefits:

The development of classification standards will reduce the cost of regulation to the Federal Government. Additionally, classification standards will aid tribal governments in the regulations of their gaming activities. There are anticipated costs to gaming machine manufacturers and tribal governments. The NIGC is conducting a cost/benefit analysis.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
NPRM (definition for electronic or electromechanical facsimile)	05/25/06	71 FR 30232
NPRM (main)	05/25/06	71 FR 30238
Final Action	04/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Federalism:

Undetermined

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