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Part II

Regulatory Information Service Center

Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions

REGULATORY INFORMATION SERVICE CENTER

Introduction to The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions

AGENCY: Regulatory Information Service Center.

ACTION: Introduction to The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions.

SUMMARY: The Regulatory Flexibility Act requires that agencies publish semiannual regulatory agendas describing regulatory actions they are developing (5 U.S.C. 602). Executive Order 12866 ''Regulatory Planning and Review,'' signed September 30, 1993 (58 FR 51735) and Office of Management and Budget memoranda implementing section 4 of that Order establish minimum standards for agencies' agendas, including specific types of information for each entry. Section 4 of Executive Order 12866 also directs that each agency prepare, as part of its submission to the fall edition of the Unified Agenda, a regulatory plan of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year.

The Regulatory Plan (Plan) and the **Unified Agenda of Federal Regulatory and Deregulatory Actions** (Unified Agenda) help agencies fulfill these requirements. This publication contains the plans of 28 Federal agencies and the regulatory agendas for these and 32 other Federal agencies.

ADDRESSES: Regulatory Information Service Center (MI), General Services Administration, 1800 F Street NW., Suite 3033, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: For further information about specific regulatory actions, please refer to the Agency Contact listed for each entry.

To provide comment on or to obtain further information about this publication, contact: Ronald C. Kelly, Executive Director, Regulatory Information Service Center (MI), General Services Administration, 1800 F Street NW., Suite 3033, Washington, DC 20405, (202) 482-7340. You may also send comments to us by e-mail at:

RISC@gsa.gov

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INTRODUCTION TO THE REGULATORY PLAN AND THE UNIFIED AGENDA OF FEDERAL REGULATORY AND DEREGULATORY ACTIONS

I. What Are The Regulatory Plan and the Unified Agenda?

The Regulatory Plan serves as a defining statement of the Administration's regulatory and deregulatory policies and priorities. The Plan is part of the fall edition of the Unified Agenda. Each participating agency's regulatory plan contains: (1) A narrative statement of the agency's regulatory priorities and, for most agencies, (2) a description of the most important significant regulatory and deregulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year. This edition includes the regulatory plans of 28 agencies.

The Unified Agenda provides information, in a uniform format, about regulations that the Government is considering or reviewing. The Unified Agenda has appeared in the **Federal Register** twice each year since 1983. This edition includes regulatory agendas from 60 Federal agencies. Agencies of the United States Congress are not included.

The Regulatory Information Service Center (the Center) compiles the Plan and the Unified Agenda for the Office of Information and Regulatory Affairs (OIRA), part of the Office of Management and Budget. OIRA is responsible for overseeing the Federal Government's regulatory, paperwork, and information resource management activities, including implementation of Executive Order 12866. The Center also provides information about Federal regulatory activity to the President and his Executive Office, the Congress, agency managers, and the public.

The activities included in the Agenda are, in general, those that will have a regulatory action within the next 12 months. Agencies may choose to include activities that will have a longer timeframe than 12 months. Agency agendas also show actions or reviews completed or withdrawn since the last Unified Agenda. Executive Order 12866 does not require agencies to include regulations concerning military or foreign affairs functions or regulations related to agency organization, management, or personnel matters.

Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change. Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed. **The Regulatory Plan** and the Unified Agenda do not create a legal obligation on agencies to adhere to schedules in this publication or to confine their regulatory activities to those regulations that appear within it.

II. Why Are The Regulatory Plan and the Unified Agenda Published?

The Regulatory Plan and the Unified Agenda help agencies comply with their obligations under the Regulatory Flexibility Act and various Executive orders and other statutes.

Regulatory Flexibility Act

The *Regulatory Flexibility Act* requires agencies to identify those rules that may have a significant economic impact on a substantial number of small entities (5 U.S.C. 602). Agencies meet that requirement by including the information in their submissions for the Unified Agenda. Agencies may also indicate those regulations that they are reviewing as part of their periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610). Executive Order 13272 entitled ''Proper Consideration of Small Entities in Agency Rulemaking,'' signed August 13, 2002 (67 FR 53461) provides additional guidance on compliance with the Act.

Executive Order 12866

Executive Order 12866 entitled ''Regulatory Planning and Review,'' signed September 30, 1993 (58 FR 51735) requires covered agencies to prepare an agenda of all regulations under development or review. The Order also requires that certain agencies prepare annually a regulatory plan of their ''most important significant regulatory actions,'' which appears as part of the fall Unified Agenda.

Executive Order 13132

Executive Order 13132 entitled ''Federalism,'' signed August 4, 1999 (64 FR 43255) directs agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have ''federalism implications'' as defined in the Order. Under the Order, an agency that is proposing regulations with federalism implications, which either preempt State law or impose nonstatutory unfunded substantial direct compliance costs on State and local governments, must consult with State and local officials early in the process of developing the regulation. In addition, the agency must provide to the Director of the Office of Management and Budget a federalism summary

impact statement for such regulations, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which those concerns have been met. As part of this effort, agencies include in their submissions for the Unified Agenda information on whether their regulatory actions may have an effect on the various levels of government and whether those actions have federalism implications.

Unfunded Mandates Reform Act of 1995

The *Unfunded Mandates Reform Act of 1995* (Pub. L. 104-4, title II) requires agencies to prepare written assessments of the costs and benefits of significant regulatory actions ''that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more . . . in any 1 year . . . .'' The requirement does not apply to independent regulatory agencies, nor does it apply to certain subject areas excluded by section 4 of the Act. Affected agencies identify in the Unified Agenda those regulatory actions they believe are subject to title II of the Act.

Executive Order 13211

Executive Order 13211 entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' signed May 18, 2001 (66 FR 28355) directs agencies to provide, to the extent possible, information regarding the adverse effects that agency actions may have on the supply, distribution, and use of energy. Under the Order, the agency must prepare and submit a Statement of Energy Effects to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for ''those matters identified as significant energy actions.'' As part of this effort, agencies may optionally include in their submissions for the Unified Agenda information on whether they have prepared or plan to prepare a Statement of Energy Effects for their regulatory actions.

Small Business Regulatory Enforcement Fairness Act

The *Small Business Regulatory Enforcement Fairness Act* (Pub. L. 104-121, title II) established a procedure for congressional review of rules (5 U.S.C. 801 et seq.), which defers, unless exempted, the effective date of a ''major'' rule for at least 60 days from the publication of the final rule in the **Federal Register**. The Act specifies that a rule is ''major'' if it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of OIRA will make the final determination as to whether a rule is major.

III. How Are The Regulatory Plan and the Unified Agenda Organized?

The Regulatory Plan appears in part II of this edition of the **Federal Register**. The Plan is a single document beginning with an introduction, followed by a table of contents, followed by each agency's section of the Plan. Following the Plan, each agency's agenda appears as a separate part. The sections of the Plan and the parts of the Unified Agenda are organized alphabetically in four groups: Cabinet departments; other executive agencies; the Federal Acquisition Regulation, a joint authority (Agenda only); and independent regulatory agencies. Agencies may in turn be divided into subagencies.

Each agency's section of the Plan contains a narrative statement of regulatory priorities and, for most agencies, a description of the agency's most important significant regulatory and deregulatory actions. Each agency's part of the Agenda begins with a preamble providing information specific to that part followed by a table of contents. Following the table of contents is a description of the agency's regulatory and deregulatory actions.

In the Agenda, each agency presents its entries under one of five headings according to the rulemaking stage of the entry. In the Plan, only the first three stages are applicable. The stages are:

1. *Prerule Stage* — actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations.
2. *Proposed Rule Stage* — actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step.
3. *Final Rule Stage* — actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step.
4. *Long-Term Actions* — items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda. Some of the entries in this section may contain abbreviated information.
5. *Completed Actions* — actions or reviews the agency has completed or withdrawn since publishing its last agenda. This section also includes items the agency began and completed between issues of the Agenda.

In the Agenda, an agency may use subheadings to identify regulations that it has grouped according to particular topics. When these subheadings are used, they appear above the title of the first regulation in each group.

A bullet (•) preceding the title of an entry indicates that the entry is appearing in the Unified Agenda for the first time.

All entries are numbered sequentially from the beginning to the end of the publication. The sequence number preceding the title of each entry identifies the location of the entry in this edition. This sequence number is used as the reference in the table of contents and in all indexes to enable readers to find entries. Entries in the Plan are also in the Unified Agenda with the same Regulation Identifier Number (RIN) but with different sequence numbers. For these entries, the Plan sequence number is used as the reference in all indexes.

This publication contains six indexes.

- Index A lists regulatory actions for which agencies have indicated that they are conducting a periodic review under section 610(c) of the Regulatory Flexibility Act.
- Index B lists the regulatory actions for which agencies believe that the Regulatory Flexibility Act may require a Regulatory Flexibility Analysis.
- Index C lists additional regulatory actions for which agencies have chosen to indicate that some impact on small entities is likely even though a Regulatory Flexibility Analysis may not be required.
- Index D lists regulatory actions that agencies believe may have effects on levels of government.
- Index E lists regulatory actions that agencies believe may have federalism implications as defined in Executive Order 13132.
- Index F is a subject index based on the **Federal Register Thesaurus of Indexing Terms**.

IV. What Information Appears for Each Entry?

All entries in the Unified Agenda contain uniform data elements including, at a minimum, the following information:

Title of the Regulation — a brief description of the subject of the regulation, possibly including section 610 review designation. The notation ''Section 610 Review'' following the title indicates that the agency has selected the rule for its periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610(c)). Some agencies have indicated completions of section 610 reviews or rulemaking actions resulting from completed section 610 reviews.

Priority — an indication of the significance of the regulation. Agencies assign each entry to one of the following five categories of significance.

(1) Economically Significant

As defined in Executive Order 12866, a rulemaking action that will have an annual effect on the economy of $100 million or more or will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The definition of an ''economically significant'' rule is similar but not identical to the definition of a ''major'' rule under 5 U.S.C. 801 (Pub. L. 104-121). (See below.)

(2) Other Significant

A rulemaking that is not Economically Significant but is considered Significant by the agency. This category includes rules that the agency anticipates will be reviewed under Executive Order 12866 or rules that are a priority of the agency head. These rules may or may not be included in the agency's regulatory plan.

(3) Substantive, Nonsignificant

A rulemaking that has substantive impacts but is neither Significant, nor Routine and Frequent, nor Informational/Administrative/Other.

(4) Routine and Frequent

A rulemaking that is a specific case of a multiple recurring application of a regulatory program in the Code of Federal Regulations and that does not alter the body of the regulation.

(5) Informational/Administrative/Other

A rulemaking that is primarily informational or pertains to agency matters not central to accomplishing the agency's regulatory mandate but that the agency places in the Unified Agenda to inform the public of the activity.

In addition, if a rule is ''major'' under 5 U.S.C. 801 (Pub. L. 104-121) because it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act, this is indicated under the ''Priority'' heading. The Act provides that the Administrator of the Office of Information and Regulatory Affairs will make the final determination as to whether a rule is major.

Unfunded Mandates — whether the rule is covered by section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). The Act requires that, before issuing an NPRM likely to result in a mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of more than $100 million in 1 year, agencies, other than independent regulatory agencies, shall prepare a written statement containing an assessment of the anticipated costs and benefits of the Federal mandate. If the agency believes the entry is not subject to the Act, this data element will not be printed.

Legal Authority — the section(s) of the United States Code (U.S.C.) or Public Law (Pub. L.) or the Executive order (E.O.) that authorize(s) the regulatory action. Agencies may provide popular name references to laws in addition to these citations.

CFR Citation — the section(s) of the Code of Federal Regulations that will be affected by the action.

Legal Deadline — whether the action is subject to a statutory or judicial deadline, the date of that deadline, and whether the deadline pertains to an NPRM, a Final Action, or some other action.

Abstract — a brief description of the problem the regulation will address; the need for a Federal solution; to the extent available, alternatives that the agency is considering to address the problem; and potential costs and benefits of the action.

Timetable — the dates and citations (if available) for all past steps and a projected date for at least the next step for the regulatory action. A date printed in the form 02/00/06 means the agency is predicting the month and year the action will take place but not the day it will occur. In some instances, agencies may indicate what the next action will be, but the date of that action is ''To Be Determined.'' ''Next Action Undetermined'' indicates the agency does not know what action it will take next.

Regulatory Flexibility Analysis Required — whether an analysis is required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because the rulemaking action is likely to have a significant economic impact on a substantial number of small entities as defined by the Act.

Small Entities Affected — the types of small entities (businesses, governmental jurisdictions, or organizations) on which the rulemaking action is likely to have an impact as defined by the Regulatory Flexibility Act. Some agencies have chosen to indicate likely effects on small entities even though they believe that a Regulatory Flexibility Analysis will not be required.

Government Levels Affected — whether the action is expected to affect levels of government and, if so, whether the governments are State, local, tribal, or Federal.

Federalism — whether the action has ''federalism implications'' as defined in Executive Order 13132. This term refers to actions ''that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' If the action does not have federalism implications, this data element will not be printed. Independent regulatory agencies are not required to supply this information.

Agency Contact — the name and phone number of at least one person in the agency who is knowledgeable about the rulemaking action. The agency may also provide the title, address, fax number, e-mail address, and TDD for each agency contact.

Some agencies have provided the following optional information:

URL for More Information — the Internet address of a site that provides more information about the entry.

URL for Public Comments — the Internet address of a site that will accept public comments on the entry. Alternatively, timely public comments may be submitted at the governmentwide e-rulemaking site, **http://www.regulations.gov**.

Additional Information — any information an agency wishes to include that does not have a specific data element.

Compliance Cost to the Public — the estimated gross compliance cost of the action.

Affected Sectors — the industrial sectors that the action may most affect, either directly or indirectly. Affected Sectors are identified by North American Industry Classification System (NAICS) codes.

Energy Effects — an indication of whether the agency has prepared or plans to prepare a Statement of Energy Effects for the action, as required by Executive Order 13211 ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' signed May 18, 2001 (66 FR 28355).

Related RINs— one or more past or current RINs associated with activity related to this action, such as merged RINs, split RINs, new activity for previously completed RINs, or duplicate RINs.

Entries appearing in **The Regulatory Plan** include one or more of the following additional data elements, but will, at a minimum, include information in Statement of Need:

Statement of Need — a description of the need for the regulatory action.

Summary of the Legal Basis — a description of the legal basis for the action, including whether any aspect of the action is required by statute or court order.

Alternatives — a description of the alternatives the agency has considered or will consider as required by section 4(c)(1)(B) of Executive Order 12866.

Anticipated Costs and Benefits — a description of preliminary estimates of the anticipated costs and benefits of the action.

Risks — a description of the magnitude of the risk the action addresses, the amount by which the agency expects the action to reduce this risk, and the relation of the risk and this risk reduction effort to other risks and risk reduction efforts within the agency's jurisdiction.

V. Abbreviations

The following abbreviations appear throughout this publication:

ANPRM — An Advance Notice of Proposed Rulemaking is a preliminary notice, published in the **Federal Register**, announcing that an agency is considering a regulatory action. An agency may issue an ANPRM before it develops a detailed proposed rule. An ANPRM describes the general area that may be subject to regulation and usually asks for public comment on the issues and options being discussed. An ANPRM is issued only when an agency believes it needs to gather more information before proceeding to a notice of proposed rulemaking.

CFR — The Code of Federal Regulations is an annual codification of the general and permanent regulations published in the **Federal Register** by the agencies of the Federal Government. The Code is divided into 50 titles, each title covering a broad area subject to Federal regulation. The CFR is keyed to and kept up to date by the daily issues of the **Federal Register**.

EO — An Executive order is a directive from the President to Executive agencies, issued under constitutional or statutory authority. Executive orders are published in the **Federal Register** and in title 3 of the Code of Federal Regulations.

FR — The **Federal Register** is a daily Federal Government publication that provides a uniform system for publishing Presidential documents, all proposed and final regulations, notices of meetings, and other official documents issued by Federal agencies.

FY — The Federal fiscal year runs from October 1 to September 30.

NPRM — A Notice of Proposed Rulemaking is the document an agency issues and publishes in the **Federal Register** that describes and solicits public comments on a proposed regulatory action. Under the Administrative Procedure Act (5 U.S.C. 553), an NPRM must include, at a minimum:

- a statement of the time, place, and nature of the public rulemaking proceeding;
- a reference to the legal authority under which the rule is proposed; and
- either the terms or substance of the proposed rule or a description of the subjects and issues involved.

PL (or Pub. L.) — A Public Law is a law passed by Congress and signed by the President or enacted over his veto. It has general applicability, unlike a private law that applies only to those persons or entities specifically designated. Public laws are numbered in sequence throughout the 2-year life of each Congress; for example, PL 109-4 is the fourth public law of the 109th Congress.

RFA — A Regulatory Flexibility Analysis is a description and analysis of the impact of a rule on small entities, including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires each agency to prepare an initial RFA for public comment when it is required to publish an NPRM and to make available a final RFA when the final rule is published, unless the agency head certifies that the rule would not have a significant economic impact on a substantial number of small entities.

RIN — The Regulation Identifier Number is assigned by the Regulatory Information Service Center to identify each regulatory action listed in **The Regulatory Plan** and the Unified Agenda, as directed by Executive Order 12866 (section 4(b)). Additionally, OMB has asked agencies to include RINs in the headings of their Rule and Proposed Rule documents when publishing them in the **Federal Register**, to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development.

Seq. No. — The Sequence Number identifies the location of an entry in this publication. Note that a specific regulatory action will have the same RIN throughout its development but will generally have different sequence numbers in different editions of **The Regulatory Plan** and the Unified Agenda.

USC — The United States Code is a consolidation and codification of all general and permanent laws of the United States. The USC is divided into 50 titles, each title covering a broad area of Federal law.

VI. How Can Users Get Copies of the Plan and the Agenda?

Printed copies of this edition of the **Federal Register** are available from the Superintendent of Documents, U.S.

Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954. Telephone: (202) 512-1800 or 1-866-512-1800 (toll-free).

Copies of individual agency materials may be available directly from the agency or may be found on the agency's website. Please contact the particular agency for further information.

All editions of **The Regulatory Plan** and the **Unified Agenda of Federal Regulatory and Deregulatory Actions** since Fall 1995 are also available in electronic form. You can search the Agenda and the Plan at:

http://reginfo.gov

You may also search the Agenda and the Plan on the Government Printing Office's GPO Access web site at:

http://www.gpoaccess.gov/ua/index.html

Dated: October 7, 2005.

Ronald C. Kelly,

Executive Director.

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The Regulatory Plan

INTRODUCTION TO THE FALL 2005 REGULATORY PLAN

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

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

Federal Regulatory Policy

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

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

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

For new rulemakings and programs, OIRA has enhanced the transparency of OMB's regulatory review process. OIRA's website now enables the public to find 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. Of the 156 reform nominations that OMB determined were ripe for consideration by Cabinet-level agencies and the Environmental Protection Agency, agencies decided to pursue 34 rules and 11 guidance documents for reform. 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. Although we are still in the early phases of implementation, agencies are 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 Governmentwide 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, the Administration is currently increasing the impact of OMB's analytical perspective. The OIRA Administrator is using the ''prompt letter'' to agencies as a new way to suggest promising regulatory priorities and highlight issues that may warrant regulatory attention. Though not meant to have legal authority, these prompt letters are designed to bring issues to the attention of agencies in a transparent manner that permits public scrutiny and debate. Prompt letters may highlight regulations that should be pursued, rescinded, revised, or further investigated. For example, OIRA's first set of prompts suggested lifesaving opportunities at FDA, NHTSA, OSHA and EPA. In a letter to FDA, OIRA suggested that priority be given to completing a promising rulemaking (started in the previous Administration), to require that food labels report the trans-fatty acid content of foods. (Trans-fats are now recognized as a significant contributor to coronary heart disease.) FDA has issued a final rule that will require the disclosure of trans-fat content in food labels. Similarly, OSHA has responded to an OIRA prompt letter by notifying each employer in the country of the lifesaving effects and cost-effectiveness of automatic defibrillators, a lifesaving technology designed to save lives during sudden cardiac arrest. A list of all of the prompt letters is available at OIRA's website at http://www.whitehouse.gov/omb/inforeg/prompt__letter.html.

In addition to increasing the level of public involvement and transparency in its review of regulations, the Bush Administration has sought to enhance the role of analysis in the development of effective regulations. On September 17, 2003, OMB issued revised guidance to agencies on regulatory analysis.[1] Key features of the revised guidance include more emphasis on cost-effectiveness, more careful evaluation of qualitative and intangible values, and a greater emphasis on considering the uncertainty inherent in estimates of impact. OIRA was very interested in updating the guidance in light of these and other innovations now commonplace in the research community. The 2005 Regulatory Plan continues OIRA's effort to ensure coordination across Federal agencies in pursuing analytically sound regulatory policies.

The Administration's 2005 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

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

regulatory agenda. Accordingly, the 2005 Regulatory Plan highlights the following themes:

- Regulations that are particularly good examples of the Administration's ''smart'' regulation agenda to streamline regulations and reporting requirements, which is a key part of the President's economic plan.
- Regulations that are of particular concern to small businesses.
- Regulations that respond to public nominations submitted to OMB in 2001 or 2002.
- 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	National Organic Program: Harvey v. Johanns	0581–AC54	Proposed Rule Stage
2	Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Fish, Perishable Agricultural Commodities, and Peanuts (LS-03-04)	0581–AC26	Final Rule Stage
3	California Clingstone Peach Diversion Program (Tree Pull), FV05-82-01	0581–AC45	Final Rule Stage
4	Tuberculosis in Cattle; Import Requirements	0579–AB44	Proposed Rule Stage
5	Animal Welfare; Regulations and Standards for Birds, Rats, and Mice	0579–AB69	Proposed Rule Stage
6	Revision of Fruits and Vegetables Import Regulations	0579–AB80	Proposed Rule Stage
7	Revision of the Nursery Stock Regulations	0579–AB85	Proposed Rule Stage
8	Importation of Boneless Beef from Japan	0579–AB93	Proposed Rule Stage
9	Importation of Small Lots of Seed Without Phytosanitary Certificates	0579–AB78	Final Rule Stage
10	Phytophthora Ramorum; Quarantine and Regulations	0579–AB82	Final Rule Stage
11	FSP: Discretionary Quality Control Provisions of Title IV of Public Law 107-171	0584–AD37	Proposed Rule Stage
12	Special Nutrition Programs: Fluid Milk Substitutions	0584–AD58	Proposed Rule Stage
13	Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages	0584–AD77	Proposed Rule Stage
14	FSP: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD30	Final Rule Stage
15	FSP: Non-Discretionary Quality Control Provisions of Title IV of Public Law 107-171	0584–AD31	Final Rule Stage
16	FSP: Employment and Training Program Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD32	Final Rule Stage
17	Categorical Eligibility and Direct Certification for Free and Reduced Price Meals and Free Milk in Schools	0584–AD60	Final Rule Stage
18	Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): WIC Vendor Cost Containment	0584–AD71	Final Rule Stage
19	Performance Standards for Pumped or Massaged Bacon	0583–AC49	Proposed Rule Stage
20	Egg Products Inspection Regulations	0583–AC58	Proposed Rule Stage
21	Performance Standard for Chilling of Ready-To-Cook Poultry	0583–AC87	Proposed Rule Stage
22	Sharing of Firms' Distribution Lists of Retail Consignees During Meat or Poultry Product Recalls	0583–AD10	Proposed Rule Stage
23	Performance Standards for the Production of Processed Meat and Poultry Products	0583–AC46	Final Rule Stage
24	Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products	0583–AC60	Final Rule Stage
25	Food Standards; General Principles and Food Standards Modernization	0583–AC72	Final Rule Stage
26	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
27	Travel Management (Proposed Directives, Forest Service Manual 2300 and 7700)	0596–AC39	Proposed Rule Stage

DEPARTMENT OF COMMERCE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
28	Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementation of Regulations	0648–AS83	Proposed Rule Stage
29	Fisheries of the United States; National Standard 1	0648–AQ63	Final Rule Stage

DEPARTMENT OF EDUCATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
30	Assistance to States for the Education of Children With Disabilities; Preschool Grants for Children With Disabilities; and Service Obligations Under Special Education—Personnel Development	1820–AB57	Final Rule Stage

DEPARTMENT OF ENERGY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
31	Rulemaking To Determine Whether the Energy Conservation Standards for Residential Central Air Conditioners and Air Conditioning Heat Pumps Should Be Amended	1904–AB47	Prerule Stage
32	Rulemaking To Determine Whether the Energy Conservation Standards for Residential Water Heaters Should Be Amended	1904–AB48	Prerule Stage
33	Rulemaking To Determine Whether the Energy Conservation Standards for Electric and Gas Ranges and Ovens, and for Microwave Ovens Should Be Amended	1904–AB49	Prerule Stage
34	Rulemaking To Determine Whether the Energy Conservation Standards for Fluorescent Lamp Ballasts Should Be Amended	1904–AB50	Prerule Stage
35	Rulemaking To Determine Whether the Energy Conservation Standards for Room Air Conditioners Should Be Amended	1904–AB51	Prerule Stage
36	Energy Efficiency Standards for Residential Furnaces and Boilers	1904–AA78	Proposed Rule Stage
37	Energy Efficiency Standards for Electric Distribution Transformers	1904–AB08	Proposed Rule Stage
38	Acquisition of Petroleum for Strategic Petroleum Reserve	1901–AB16	Proposed Rule Stage
39	Radiation Protection of the Public and the Environment	1901–AA38	Final Rule Stage
40	Worker Safety and Health	1901–AA99	Final Rule Stage
41	Standby Support for Advanced Nuclear Facility Delays	1901–AB17	Final Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
42	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920–AA12	Proposed Rule Stage
43	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs	0910–AA49	Proposed Rule Stage
44	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52	Proposed Rule Stage
45	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11	Proposed Rule Stage
46	Expanded Access to Investigational Drugs for Treatment Use	0910–AF14	Proposed Rule Stage
47	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products	0910–AA94	Final Rule Stage
48	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88	Final Rule Stage
49	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35	Final Rule Stage
50	Innovations in Fee-for-Service Payment Systems to Improve Quality and Outcomes (CMS-1298-ANPR)	0938–AN91	Prerule Stage
51	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies and Residual Issues (CMS-1270-P)	0938–AN14	Proposed Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
52	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates (CMS-1488-P)	0938–AO12	Proposed Rule Stage
53	Organ Procurement Organization Conditions for Coverage (CMS-3064-IFR)	0938–AK81	Final Rule Stage
54	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-FC)	0938–AN46	Final Rule Stage
55	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-FC)	0938–AN84	Final Rule Stage

DEPARTMENT OF HOMELAND SECURITY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
56	Procedures for Handling Critical Infrastructure Information	1601–AA14	Final Rule Stage
57	Regulations Implementing the Support Antiterrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act)	1601–AA15	Final Rule Stage
58	Protection of Human Subjects	1601–AA29	Final Rule Stage
59	Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents (USCG-2001-8773)	1625–AA27	Final Rule Stage
60	Validation of Merchant Mariners' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry (USCG-2004-17455)	1625–AA85	Final Rule Stage
61	Vessel Requirements for Notices of Arrival and Departure, and Carriage of Automatic Identification System (USCG-2005-21869)	1625–AA99	Final Rule Stage

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
62	Amendments to HUD's Environmental Regulations (FR-4954)	2501–AD11	Proposed Rule Stage
63	Disposition of HUD-Acquired Single Family Property Amendments (FR-4952)	2502–AI27	Proposed Rule Stage
64	Housing Opportunities for Persons With AIDS (HOPWA) (FR-4708)	2506–AC11	Proposed Rule Stage
65	GNMA: Excess Yield Securities (FR-4958)	2503–AA18	Proposed Rule Stage
66	Streamlining Public Housing Programs (FR-4990)	2577–AC59	Proposed Rule Stage
67	Housing Choice Voucher Program Homeownership Option; Eligibility of Units Not Yet Under Construction (FR-4991)	2577–AC60	Proposed Rule Stage

DEPARTMENT OF THE INTERIOR

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
68	Valuation of Oil From Indian Leases	1010–AD00	Proposed Rule Stage
69	Relief or Reduction in Royalty Rates - New Deep Gas and Offshore Alaska Provisions	1010–AD31	Proposed Rule Stage
70	Placement of Excess Spoil	1029–AC04	Proposed Rule Stage
71	Grazing Administration—Exclusive of Alaska	1004–AD42	Final Rule Stage

DEPARTMENT OF JUSTICE

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
72	Nondiscrimination on the Basis of Disability in Public Accommodations and Commercial Facilities	1190–AA44	Proposed Rule Stage
73	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
74	Family and Medical Leave Act of 1993; Conform to the Supreme Court's Ragsdale Decision	1215–AB35	Proposed Rule Stage
75	Revision to the Department of Labor Benefit Regulations for Trade Adjustment Assistance for Workers Under the Trade Act of 1974, as Amended	1205–AB32	Proposed Rule Stage
76	Revision to the Department of Labor Regulations for Petitions and Determinations of Eligibility To Apply for Trade Adjustment Assistance for Workers and Issuance of Regulations for the Alternative TAA	1205–AB40	Proposed Rule Stage
77	Amendment of Regulation Relating to Definition of Plan Assets—Participant Contributions	1210–AB02	Proposed Rule Stage
78	Amendment of Section 404(c) Regulation Default Investments	1210–AB10	Proposed Rule Stage
79	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
80	Prohibiting Discrimination Against Participants and Beneficiaries Based on Health Status	1210–AA77	Final Rule Stage
81	Rulemaking Relating to Termination of Abandoned Individual Account Plans	1210–AA97	Final Rule Stage
82	Asbestos Exposure Limit	1219–AB24	Final Rule Stage
83	Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners	1219–AB29	Final Rule Stage
84	Occupational Exposure to Crystalline Silica	1218–AB70	Prerule Stage
85	Assigned Protection Factors: Amendments to the Final Rule on Respiratory Protection	1218–AA05	Final Rule Stage
86	Occupational Exposure to Hexavalent Chromium (Preventing Occupational Illness: Chromium)	1218–AB45	Final Rule Stage
87	Uniformed Services Employment and Reemployment Rights Act Regulations	1293–AA09	Final Rule Stage

DEPARTMENT OF TRANSPORTATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
88	Aging Aircraft Program (Widespread Fatigue Damage)	2120–AI05	Proposed Rule Stage
89	Transport Airplane Fuel Tank Flammability Reduction	2120–AI23	Proposed Rule Stage
90	Enhanced Airworthiness Program for Airplane Systems (EAPAS) and SFAR 88	2120–AI31	Proposed Rule Stage
91	Aging Aircraft Safety—Development of TC and STC Holder Data	2120–AI32	Proposed Rule Stage
92	Medical Certification Requirements as Part of the CDL	2126–AA10	Proposed Rule Stage
93	Unified Registration System	2126–AA22	Final Rule Stage
94	Reduced Stopping Distance Requirements for Truck Tractors	2127–AJ37	Proposed Rule Stage
95	Light Truck Average Fuel Economy Standards, Model Year 2008 and Possibly Beyond	2127–AJ61	Proposed Rule Stage
96	5th Percentile Dummy Belted Barrier Crash Test Requirements — Standard 208	2127–AI98	Final Rule Stage
97	Side Impact Protection Upgrade - FMVSS No. 214	2127–AJ10	Final Rule Stage

DEPARTMENT OF THE TREASURY

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

DEPARTMENT OF VETERANS AFFAIRS

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

ENVIRONMENTAL PROTECTION AGENCY

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
100	Review of the National Ambient Air Quality Standards for Particulate Matter	2060–AI44	Proposed Rule Stage
101	Control of Hazardous Air Pollutants From Mobile Sources	2060–AK70	Proposed Rule Stage
102	Clean Air Fine Particle Implementation Rule	2060–AK74	Proposed Rule Stage
103	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Allowables Plantwide Applicability Limit (PAL), Aggregation, and Debottlenecking	2060–AL75	Proposed Rule Stage
104	Control of Emissions From New Locomotives and New Marine Diesel Engines Less Than 30 Liters Per Cylinder	2060–AM06	Proposed Rule Stage
105	Control of Emissions from Spark-Ignition Engines and Fuel Systems from Marine Vessels and Small Equipment	2060–AM34	Proposed Rule Stage
106	Implementing Periodic Monitoring in Federal and State Operating Permit Programs	2060–AN00	Proposed Rule Stage
107	Fuel Economy Labeling of Motor Vehicles: Revisions to Improve Calculation of Fuel Economy Estimates	2060–AN14	Proposed Rule Stage
108	Amendment of the Standards for Radioactive Waste Disposal in Yucca Mountain, Nevada	2060–AN15	Proposed Rule Stage
109	Review of the National Ambient Air Quality Standards for Ozone	2060–AN24	Proposed Rule Stage
110	Prevention of Significant Deterioration and Nonattainment New Source Review: Alternative Applicability Test for Electric Generating Units	2060–AN28	Proposed Rule Stage
111	Renewable Fuel Standards Requirements for 2006	2060–AN51	Proposed Rule Stage
112	Lead-Based Paint Activities; Amendments for Renovation, Repair and Painting	2070–AC83	Proposed Rule Stage
113	Notification of Chemical Exports Under TSCA Section 12(b)	2070–AJ01	Proposed Rule Stage
114	Administrative Reporting Exemption for Certain Air Releases of NOx	2050–AF02	Proposed Rule Stage
115	Revisions to the Spill Prevention, Control, and Countermeasure (SPCC) Rule, 40 CFR Part 112	2050–AG16	Proposed Rule Stage
116	Regulatory Actions Associated with the Notices of Data Availability on the Spill Prevention, Control, and Countermeasure (SPCC) Rule, 40 CFR Part 112	2050–AG23	Proposed Rule Stage
117	Expanding the Comparable Fuels Exclusion Under RCRA	2050–AG24	Proposed Rule Stage

ENVIRONMENTAL PROTECTION AGENCY (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
118	Toxics Release Inventory Reporting Burden Reduction Rule	2025–AA14	Proposed Rule Stage
119	Inclusion of Delaware and New Jersey in the Clean Air Interstate Rule	2060–AM95	Final Rule Stage
120	Rule on Section 126 Petition from NC to Reduce Interstate Transport of Fine PM and O3; FIPs to Reduce Interstate Transport of Fine PM & O3; Revisions to CAIR Rule; Revisions to Acid Rain Program	2060–AM99	Final Rule Stage
121	Regional Haze Regulations; Revisions to Provisions Governing Alternative to Source-Specific Best Available Retrofit Technology (BART) Determinations	2060–AN22	Final Rule Stage
122	Implementation Rule for 8-Hour Ozone NAAQS - Phase 2	2060–AN23	Final Rule Stage
123	Test Rule; Testing of Certain High Production Volume (HPV) Chemicals	2070–AD16	Final Rule Stage
124	Pesticides; Procedures for the Registration Review Program	2070–AD29	Final Rule Stage
125	Pesticides; Emergency Exemption Process Revisions	2070–AD36	Final Rule Stage
126	Protections for Test Subjects in Human Research	2070–AD57	Final Rule Stage
127	RCRA Burden Reduction Initiative	2050–AE50	Final Rule Stage
128	Revisions to the Definition of Solid Waste	2050–AE98	Final Rule Stage
129	National Primary Drinking Water Regulations: Ground Water Rule	2040–AA97	Final Rule Stage
130	National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule	2040–AD37	Final Rule Stage
131	National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule	2040–AD38	Final Rule Stage

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

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

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

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

PENSION BENEFIT GUARANTY CORPORATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
134	Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets	1212–AA55	Final Rule Stage

SMALL BUSINESS ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
135	Small Business Lending Company and Lender Oversight Regulations	3245–AE14	Proposed Rule Stage
136	Small Business Technology Transfer Program Policy Directive	3245–AE96	Final Rule Stage
137	Small Business Innovation Research (SBIR) Policy Directive	3245–AF21	Final Rule Stage

SOCIAL SECURITY ADMINISTRATION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
138	Federal Salary Offset (Withholding a Portion of a Federal Employee's Salary To Collect a Delinquent Debt Owed to the Social Security Administration) (721P)	0960–AE89	Proposed Rule Stage
139	Exemption of Work Activity as a Basis for a Continuing Disability Review (Ticket to Work and Work Incentives Improvement Act of 1999) (725P)	0960–AE93	Proposed Rule Stage
140	Revised Medical Criteria for Evaluating Immune System Disorders (804P)	0960–AF33	Proposed Rule Stage
141	Revised Medical Criteria for Evaluating Mental Disorders (886P)	0960–AF69	Proposed Rule Stage
142	Amendments to the Ticket to Work and Self-Sufficiency Program (967P)	0960–AF89	Proposed Rule Stage
143	Representative Payment; Policies and Administrative Procedure for Imposing Penalties for False or Misleading Statements or Withholding of Information (2422P)	0960–AG09	Proposed Rule Stage
144	Issuance of Work Report Receipts, Payment of TWP Months After a Fraud Conviction, Changes to the SEIE, & Expansion of the Reentitlement Period for Childhood DIB Benefits (2502P)	0960–AG10	Proposed Rule Stage
145	Medicare Part B Income-Related Monthly Adjustment Amount (2101P)	0960–AG11	Proposed Rule Stage
146	Nonpayment of Benefits to Fugitive Felons and Probation or Parole Violators (2222P)	0960–AG12	Proposed Rule Stage
147	Changes to the Income and Resources Provisions for SSI Based on Sections 430, 435, and 436 of the Social Security Protection Act (SSPA) of 2004 (2482P)	0960–AG13	Proposed Rule Stage
148	Continuing Disability Review Failure To Cooperate Process (2763P)	0960–AG19	Proposed Rule Stage
149	Prohibition of Entitlement on Earnings Records for Certain Alien Workers (2882P)	0960–AG22	Proposed Rule Stage
150	Limiting Replacement of Social Security Number Cards (965P)	0960–AG25	Proposed Rule Stage
151	Age as a Factor in Evaluating Disability (3183P)	0960–AG29	Proposed Rule Stage
152	Administrative Review Process for Adjudicating Initial Disability Claims (3203F)	0960–AG31	Proposed Rule Stage
153	Evidentiary Requirements for Making Findings About Medical Equivalence (787F)	0960–AF19	Final Rule Stage
154	Revised Medical Criteria for Evaluating Impairments of the Digestive System (800F)	0960–AF28	Final Rule Stage
155	Revised Medical Criteria for Evaluating Cardiovascular Disorders (826F)	0960–AF48	Final Rule Stage
156	Rules for Helping Blind and Disabled Individuals Achieve Self-Support (506F)	0960–AG00	Final Rule Stage
157	Medicare Part D Subsidies (1024F)	0960–AG03	Final Rule Stage
158	Civil Monetary Penalties, Assessments, and Recommended Exclusions (2362F)	0960–AG08	Final Rule Stage

CONSUMER PRODUCT SAFETY COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
159	Flammability Standard for Upholstered Furniture	3041–AB35	Proposed Rule Stage
160	Proposed Standard To Address Open-Flame Ignition of Mattresses/Foundation Sets	3041–AC02	Final Rule Stage

NATIONAL INDIAN GAMING COMMISSION

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
161	Technical Amendments to the Minimum Internal Control Standards	3141–AA27	Proposed Rule Stage

NATIONAL INDIAN GAMING COMMISSION (Continued)

Sequence Number	Title	Regulation Identifier Number	Rulemaking Stage
162	Technical Standards for Gaming Machines and Gaming Systems	3141–AA29	Proposed Rule Stage
163	Game Classification Standards	3141–AA31	Proposed Rule Stage

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DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

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

- USDA will develop new regulations and review existing regulations to prevent the introduction or spread of pests and diseases into the United States. In addition, it will continue to work to minimize impediments to trade while protecting U.S. animal and plant resources.
- In the area of food safety, USDA will continue to develop science-based regulations that improve the safety of meat, poultry, and egg products in the least burdensome and most cost-effective manner. Regulations will be revised to address emerging food safety challenges, streamlined to remove excessively prescriptive regulations, and updated to be made consistent with hazard analysis and critical control point principles.
- As changes are made for the nutrition assistance programs, USDA will work to foster actions that will help improve diets, and particularly to prevent and reduce overweight and obesity. In 2006, this will include implementing refinements to the nutrition assistance programs included in reauthorization statutes as well as additional changes that will promote healthful eating and physical activity, while also improving the efficiency and integrity of program operations.
- USDA will finalize rulemaking for the Conservation Security Program (CSP). The program was implemented under an interim final rule in 2004. An amendment to the interim final rule was published in March 2005 and the Department is now making clarifications and modifications in response to the comments received.

Reducing Paperwork Burden on Customers

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

The Role of Regulations

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

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

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

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

Major Regulatory Priorities

This document represents summary information on prospective significant regulations as called for in Executive Order 12866. The following agencies are represented in this regulatory plan, along with a summary of their mission and key regulatory priorities for 2006:

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's 2005 regulatory plan supports the broad goals and objectives in the Agency's strategic plan, including:

Improved nutrition of children and low-income people. This goal represents FNS's efforts to improve nutrition by providing access to program benefits (Food Stamps, WIC food vouchers and nutrition services, school meals, commodities and State administrative funds), nutrition education, and quality

meals and other benefits. It includes three major objectives: 1) improved food security, which reflects nutrition assistance benefits issued to program participants; 2) FNS program participants making healthy food choices, which represents our efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion; and 3) improved nutritional quality of meals, food packages, commodities, and other program benefits, which represents our efforts to ensure that program benefits meet the appropriate nutrition standards to effectively improve nutrition for program participants.

In support of this goal, FNS plans to finalize rules implementing provisions of the Farm Security and Rural Investment Act of 2002 (P.L. 107-171), as well as under other authorities, to simplify program administration, support work, and improve access to benefits in the Food Stamp Program. FNS will also publish rules implementing provisions of the Child Nutrition and WIC Reauthorization Act of 2004 (P.L. 108-265) to ensure access to the Child Nutrition Programs for low-income children receiving Temporary Assistance for Needy Families through direct certification for homeless children, and to revise requirements allowing schools to substitute nutritionally-equivalent non-dairy beverages for fluid milk at the request of a recipient's parent. Finally, FNS will propose rule 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.

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

In support of this goal, FNS plans to finalize rules implementing provisions of P.L. 107-171 to modify the system of sanctions and incentives used to minimize certification errors in the Food Stamp Program, and to finalize rules that will simplify funding for the Food Stamp Employment and Training Program. FNS will also publish rules to improve management of retail food vendors in the WIC Program and to improve accountability and performance measurement in the Commodity Supplemental Food Program.

Food Safety and Inspection Service

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

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

In addition to preparing regulatory amendments based on this ongoing review, FSIS has published and implemented emergency regulations that had been developed under the Agency's proactive, risk-based policy to head off emerging and exotic threats to the safety of the Nation's meat, poultry, and egg product supply.

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

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

In January 2004, FSIS published three interim final rules to prevent the agent of bovine spongiform encephalopathy (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. In August 2004, FSIS, along with the USDA's Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration (FDA) published a joint Advance Notice of Proposed Rulemaking (ANPRM) that describes additional Federal measures that the agencies are considering to further mitigate the risk of BSE. FSIS is evaluating the comments received in response to the interim final rules and the ANPRM to determine whether FSIS should implement additional measures to prevent human exposure to the BSE agent.

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°F or below within certain time periods 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 ensured 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.

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 approval by FSIS of egg-product plant drawings, specifications, and equipment prior to use, and to end the system for pre-marketing approval of labeling for egg products.

FSIS will also propose to remove provisions that prescribe the levels of substances that must be used to produce massaged or pumped bacon. FSIS will propose to replace these prescriptive

provisions with an upper limit for nitrite and a performance standard that establishments producing massaged or pumped bacon would be required to meet.

Besides the foregoing initiatives, 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.

Finally, FSIS is proposing to amend the Federal meat and poultry products inspection regulations to provide that the Agency would make available to individual consumers, in response to requests under the Freedom of Information Act, 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 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.

''Smart'' regulation agenda: The President's smart regulation agenda involves modernizing existing rules and adopting new rules only when justified by sound science, economics, and law. Examples of FSIS rulemakings that support this initiative include the planned regulations for pumped bacon and for chilling ready-to-cook poultry. These rulemakings are intended to streamline regulations, improve regulatory consistency, provide science-based performance standards, and offer flexible compliance options to regulated establishments.

Response to public nominations for regulatory reform: As mentioned, FSIS has been evaluating the effectiveness of the interim final rule on control of L. monocytogenes in RTE products. Responding to the May 2004 nomination of the interim final rule as a candidate for regulatory reform, FSIS will evaluate the impacts of the rule on small businesses and determine what relief or mitigations may be necessary.

Small business concerns: Nearly all FSIS regulations affect small businesses in some way because the majority of FSIS-inspected establishments and other FSIS-regulated entities are small businesses. FSIS makes available to small and very small establishments technical materials and guidance on how to comply with FSIS regulations. The Agency conducts an active outreach program assisted by a network of State coordinators to help small businesses comply with FSIS regulations. The Agency maintains a small business outreach page on its Web site with links to sources of technical assistance.

Animal and Plant Health Inspection Service

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

Priorities: APHIS continues to work on regulatory initiatives to ensure that a comprehensive framework is in place to address the threats posed to animal and plant resources. One important animal health initiative underway is an update to the State classification standards and associated interstate movement requirements contained in the domestic bovine tuberculosis regulations and a parallel effort to harmonize the regulations regarding the importation of cattle from regions where bovine tuberculosis exists with the updated domestic regulations. APHIS also continues to work with its State partners and in cooperation with industry to develop a national animal identification system. This national system is intended to identify specific animals in the United States and record their movements over their lifespans, with the goal of enabling 48-hour traceback of the movements of any diseased or exposed animal. This will help to ensure rapid disease containment and maximum protection of America's animals. On the plant side, the Agency is considering revisions to its nursery stock regulations to reduce the pest risk posed by imported plants, roots, seeds, bulbs, and other propagative materials, and will continue to update the regulations pertaining to Sudden Oak Death as more becomes known about this fungal disease. APHIS is also working to revise its regulations for the introduction of organisms and products altered or produced through genetic engineering to reflect new consolidated authorities under the Plant Protection Act.

In addition, recognizing the need to minimize impediments to trade while providing necessary protection to animal and plant resources, APHIS is developing a proposal to streamline the process for approving new fruits and vegetables for importation and, in response to a public nomination for regulatory reform, a rule to allow the importation of small lots of seed under an import permit with specific conditions, instead of requiring a phytosanitary certificate from the government of the exporting country. 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.

Further, in line with a recent amendment to the definition of ''animal'' in the Animal Welfare Act, APHIS is considering changes to its regulations to promote the humane handling, care, treatment, and transportation of birds, rats, and mice not specifically excluded from coverage under the Act.

APHIS documents published in the **Federal Register** and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

Agricultural Marketing Service

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

Priorities: (1) On August 3, 2005, AMS issued a proposed rule that created a voluntary clingstone peach diversion program that would consist wholly of tree removal. This action would help the California clingstone peach industry address its oversupply problems. The program would offer payments to growers who remove a portion of their clingstone peach trees from production for a period of 10 years. The program would result in the removal of a maximum of 4,000 bearing acres of clingstone peach trees. Producers would benefit from this action by bringing supply more in line with demand. Furthermore, this action would eliminate the need for the Agency to make emergency surplus removal

purchases. The U.S. Department of Agriculture would provide $5 million to the program while the industry would contribute $2 million. Comments on the proposed rule were due by September 2, 2005.

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

(3) On June 9, 2005, the U.S. District Court for the District of Maine, in the case of Harvey v. Johanns (Civil No. 02-216-P-H), issued an order finding that, in two instances, the U.S. Department of Agriculture exceeded its statutory authority in developing the National Organic Program (NOP) regulations. With respect to the use of synthetic substances in products labeled as organic (minimum 95% organic content) and the exemption of certain dairy animals from organic feed requirements, the court directed USDA to conduct notice and comment rulemaking not later than 360 days from the date of the Court's order. AMS intends to publish a proposed rule by December 31, 2005.

(4) On April 12, 2003, Congress amended the Organic Foods Production Act (OFPA) to authorize certification of wild seafood. In response to this, AMS plans to amend the National Organic Program (NOP) regulations to add practice standards for organic certification of wild-caught and aquatic farm-raised species. Under the OFPA, an organic certification program must be established for producers and handlers of agricultural products that have been produced using organic methods. The NOP has been reviewing organic certification of fish including wild-caught and aquaculture operations in response to a FY 2000 congressional mandate to develop regulations for the certification of seafood. The NOP has engaged in public meetings and workshops and conducted public comment proceedings on this subject. The NOP on May 25, 2005, convened an aquaculture working group to develop draft organic standards for the production, handling and labeling of food derived from aquaculture. Efforts to convene a similar group to develop draft organic standards for the production, handling and labeling of food derived from wild-harvest fisheries are ongoing. Draft standards developed as a result of these groups' work will be forwarded to the NOSB for review and consideration as recommendations to the Secretary.

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

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 forest and range conservation.

Priorities: The Forest Service's priorities for fall 2005 are to publish a final regulation revising 36 CFR parts 212, 251, 261, and 295, regarding travel management on National Forest System (NFS) lands to clarify policy related to motor vehicle use; to publish a direct final regulation revising 36 CFR parts 251 subpart B, 261 subpart A, and 291 that implements the Federal Lands Recreation Enhancement Act (REA) (16 U.S.C. 6801-6814); and to publish final directives revising Forest Service Manual, Chapters 1330, 1900, and Forest Service Handbook 1909.12, regarding National Forest System Land Management Planning.

The final regulation regarding travel management on National Forest System lands clarifies policy related to motor vehicle use, including the use of off-highway vehicles. This final rule requires Forest Service administrative units and ranger districts to designate those roads, trails, and areas that are open to motor vehicle use. The final rule will prohibit the use of motor vehicles off the designated system, as well as use of motor vehicles on routes and in areas that is not consistent with the designations. The clear identification of roads, trails, and areas for motor vehicle use on each National Forest will enhance management of National Forest System lands; sustain natural resource values through more effective management of motor vehicle use; enhance opportunities for motorized recreation experiences on National Forest System lands; address needs for access to National Forest System lands; and preserve areas of opportunity in each National Forest for nonmotorized travel and experiences. The final rule is consistent with provisions of Executive Order 11644 and Executive Order 11989 regarding off-road use of motor vehicles on Federal lands. A proposed rule was published in the **Federal Register** on July 15, 2004 (69 FR 42381).

The Federal Lands Recreation Enhancement Act repealed and supplanted section 4 of the Land and Water Conservation Fund Act (16 U.S.C. 4601-6a) as the authority for special recreation permits issued by federal land management agencies and for recreation fees charged by federal land management agencies, including the Forest Service. The direct final rule adds a definition for recreation fee and revises the prohibition for failure to pay recreation fees in 36 CFR part 261, subpart A, to conform to the Federal Lands Recreation Enhancement Act.

The final Land and Resource Management Planning directives to the Forest Service Manual 1330 — New Management Strategies; 1900 — Planning; 1920 — Land and Resource Management Planning; and Forest Service Handbook 1909.12 — Land and Resource Management Planning Handbook provide detailed direction to agency employees necessary to implement the provisions in the final planning rule adopted at 36 CFR part 219 governing land and resource management planning. The final rule was published on January 5, 2005 (70 FR 1023), and the interim directives were published on March 23, 2005 (70 FR 14637).

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's priority for FY 2006 will be to make final adjustments to a few of the rules related to the conservation provisions of the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), in response to public comments received and experience gained from the implementation of the programs. NRCS believes that these clarifications and modifications will ensure efficient and responsive delivery of conservation programs to landowners and land users and help further the agency mission to help people conserve, maintain, and improve our natural resources and the environment.

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 2006:

1. Final Rule for the Conservation Security Program (CSP)
2. Amendment to the Final Rule for the Environmental Quality Incentives Program (EQIP)

The rulemakings for CSP and EQIP are minor changes to existing rules.

USDA—Agricultural Marketing Service (AMS)

PROPOSED RULE STAGE

1. ● NATIONAL ORGANIC PROGRAM: HARVEY V. JOHANNS

Priority:

Other Significant

Legal Authority:

7 USC 6501

CFR Citation:

7 CFR 205

Legal Deadline:

NPRM, Judicial, June 9, 2006.

Abstract:

The Agricultural Marketing Service is revising certain sections of the National Organic Program regulations to comply with the final judgment in the case of Harvey v. Johanns issued on June 9, 2005, by the United States District Court, District of Maine. The proposed regulatory action would: prohibit the use of the term ''organic'' on products containing a minimum of 95 percent organic ingredients when such products also contain added synthetic ingredients unless such synthetics are otherwise authorized by statute or regulation, and prohibit anything less than 100 percent organic feed for organic dairy animals during conversion. The rulemaking must be completed by June 6, 2006.

Statement of Need:

This regulatory action is needed to comply with a Consent Final Judgment and Order issued June 9, 2005, in the U.S. District Court for the District of Maine, in the case of Harvey v. Johanns (Civil No. 02-216-P-H). This regulatory action must be completed within one year of the court order (June 9, 2006).

Summary of Legal Basis:

This regulatory action is required as part of the Consent Final Judgment and Order issued June 9, 2005, in the U.S. District Court for the District of Maine, in the case of Harvey v. Johanns (Civil No. 02-216-P-H).

Alternatives:

There are no alternatives to this regulatory action as alternatives are precluded by the language of the court order and by the language of the Organic Foods Production Act (OFPA). The court has held that the OFPA prohibits the use of the term ''organic'' on products containing a minimum of 95 percent organic ingredients when such products also contain added synthetic ingredients unless such synthetics are otherwise authorized by statute or regulation; use of the USDA seal on such ''organic'' products is precluded. The court order also prohibits anything less than 100 percent organic feed for organic dairy animals during conversion.

Anticipated Cost and Benefits:

The agency's analysis of anticipated costs and benefits of the regulatory action is in the very early stages. The agency currently assumes zero benefits to the regulatory action.

The agency's early analysis indicates the costs of this regulatory action with respect to the dairy sector could exceed $4.1 million annually. Preliminary analysis of the costs of this regulatory action with respect to the processed products in on-going due to the complexity of the sector and associated product lines. Our analysis of this sector is based on an assumption that up to 90 percent of the multi-ingredient organic products will have to be relabeled as ''made with organic'' products. Sales revenue for such relabeled products may be affected by the court's prohibition of the use of the USDA seal. Therefore, the agency will also analyze the costs of manufacturer's investment in and goodwill associated with the USDA seal on products sold, labeled or represented as ''organic''.

Risks:

AMS has not identified any risks at this time.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

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RIN: 0581–AC54

USDA—AMS

FINAL RULE STAGE

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

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

7 USC 1621 through 1627, Agricultural Marketing Act of 1946

CFR Citation:

7 CFR 60

Legal Deadline:

Final, Statutory, September 30, 2006.

Abstract:

The Farm Security and Rural Investment Act of 2002 (Farm Bill) (Pub. L. 107-171) and the 2002 Supplemental Appropriations Act (2002 Appropriations) (Pub. L. 107-206) amended the Agricultural Marketing Act of 1946 (Act) (7 U.S.C. 1621 et seq.) to require retailers to notify their customers of the country of origin of covered commodities beginning September 30, 2004. Covered commodities include muscle cuts of beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities; and peanuts. The FY 2004 Consolidated Appropriations bill (2004 Appropriations) (Pub. L. 108-199) delayed the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006.

Statement of Need:

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

Summary of Legal Basis:

Section 10816 of Public Law 107-171 amended the Agricultural Marketing Act of 1946 to require retailers to inform consumers of the country of origin for covered commodities beginning September 30, 2004. The 2004 Appropriations delayed the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006.

Alternatives:

The October 30, 2004, proposed rule specifically invited comment on several alternatives including alternative definitions for ''processed food item,'' alternative labeling of mixed origin, and alternatives to using ''slaughtered'' on the label. In addition, the October 5, 2004, interim final rule contained an impact analysis which included an analysis of alternative approaches. The interim final rule also invited comment on several key issues including the definition of a processed food item.

Anticipated Cost and Benefits:

USDA has examined the economic impact of the rule as required by Executive Order 12866. The estimated benefits associated with this rule are likely to be small. The estimated 1st-year incremental cost for directly affected firms are estimated at $89 million for fish and shellfish only. The estimated cost to the U.S. economy in terms of reduced purchasing power resulting from a loss in productivity after a 10-year period of adjustment are estimated at $6.2 million. A final cost benefit assessment for the other covered commodities will be completed in the final rule.

Risks:

AMS has not identified any risks at this time.

Timetable:

Action	Date	FR Cite
NPRM	10/30/03	68 FR 61944
NPRM Comment Period End	12/29/03	
Interim Final Rule	10/05/04	69 FR 59708
Interim Final Rule Comment Period End	01/03/05	
Interim Final Rule Effective	04/04/05	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

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

Additional Information:

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

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USDA—AMS

3. CALIFORNIA CLINGSTONE PEACH DIVERSION PROGRAM (TREE PULL), FV05–82–01

Priority:

Other Significant

Legal Authority:

7 USC 612c

CFR Citation:

7 CFR 82

Legal Deadline:

None

Abstract:

The Agricultural Marketing Service is proposing regulations to specify procedures for a voluntary program that offers a $100 per-acre payment to growers who remove a portion of their clingstone peach trees from production. Funds to remove the trees would come from both USDA and the industry, with the program implemented by the California Canning Peach Association. The Association is a grower-owned marketing and bargaining cooperative representing nearly 600 growers who produce 80 percent of the clingstone peaches grown in California. The program would ensure that removal is not part of a normal process of tree replacement. Also, the growers must guarantee that they have not made prior arrangements to sell the land or remove the trees for commercial purposes.

Statement of Need:

The program is designed to bring long-term clingstone peach supplies more in line with canned-market demands.

Summary of Legal Basis:

The program would be implemented under clause (3) of Section 32 of the Act of August 24, 1935, as amended, which allows the Secretary of Agriculture to use Section 32 funds to reestablish the purchasing power of U.S. farmers by making payments in connection with the normal production of any agricultural commodity for domestic consumption.

Alternatives:

The alternative of not establishing a tree removal program was also considered, however, under a tree removal program, supplies can be quickly aligned with demand.

Anticipated Cost and Benefits:

The major direct cost of the program would be the payment to growers for removing their clingstone peach trees. A total of $5 million, less the costs associated with local administration of the program, would be made available by USDA for the tree removal program. Administrative costs for reviewing applications and verifying tree removals are expected to be about $125,000. Total grower costs associated with the completion of diversion program applications, payment requests, and record maintenance for the period specified after tree removal are expected to be about $530. Payments made through this program could help California clingstone peach growers by addressing the over-supply problem that is adversely affecting their industry. The implementation of a tree removal program could reduce available supply more quickly than if the industry relied on market forces alone. While market forces could also result in supplies being reduced, such an adjustment may occur more slowly, with resultant economic hardships for growers and processors. In addition, a tree removal program could be beneficial in reducing the risk of loan default for lenders that financed clingstone peach growers. This program could also help small, under-capitalized growers stay in business.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	08/03/05	70 FR 44525
NPRM Comment Period End	09/02/05	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—Animal and Plant Health Inspection Service (APHIS)

PROPOSED RULE STAGE

4. TUBERCULOSIS IN CATTLE; IMPORT REQUIREMENTS (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8317

CFR Citation:

9 CFR 93

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulations regarding the importation of animals into the United States to establish several levels of risk classifications to be applied to foreign regions with regard to tuberculosis, and to establish requirements governing the importation of cattle based on each risk classification. These changes are necessary to help ensure that cattle infected with tuberculosis are not imported into the United States.

Statement of Need:

Bovine tuberculosis (tuberculosis) is a contagious, infectious, and communicable disease caused by Mycobacterium bovis. It affects cattle, bison, deer, elk, goats, and other warm-blooded species, including humans. Tuberculosis in infected animals and humans manifests itself in lesions of the lung, bone, and other body parts, causes weight loss and general debilitation, and can be fatal. At the beginning of the past century, tuberculosis caused more losses of livestock than all other livestock diseases combined. This prompted the establishment in the United States of the National Cooperative State/Federal Bovine Tuberculosis Eradication Program for tuberculosis in livestock. To protect against the spread of tuberculosis within the United States and aid in our domestic tuberculosis eradication effort, APHIS administers interstate movement regulations, which are contained in 9 CFR part 77. For the domestic eradication program to be successful, APHIS must also take measures to ensure that cattle imported into the United States are free of tuberculosis. The regulations governing the importation of cattle into the United States are contained in 9 CFR part 93.

Currently, the import regulations related to tuberculosis in cattle are the same for cattle from all foreign regions, with some exceptions for cattle imported from Mexico and Canada. Our domestic regulations, however, are based on the tuberculosis risk classification of States, or zones within States, and interstate movement requirements for cattle are based on the risk classification of the State or zone from which the cattle are moved. As our domestic eradication program has progressed, our criteria for State and zone classifications and corresponding interstate movement requirements have become more stringent. The import regulations need to be amended to be consistent with our domestic regulations and provide an equivalent level of protection.

Summary of Legal Basis:

The Animal Health Protection Act authorizes the Secretary of Agriculture to prohibit or restrict the importation, entry, and interstate movement of any article when necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

Alternatives:

One alternative would be to maintain consistent import restrictions regardless of the region of origin of cattle. This alternative was rejected because it

would not recognize levels of risk in foreign regions and because our import regulations would be inconsistent with our domestic regulations.

Anticipated Cost and Benefits:

This rulemaking could reduce the number of tuberculosis tests required for some cattle imported into the United States from Mexico. Specifically, feeder cattle from areas of Mexico that qualify for advanced tuberculosis status might require one or no test instead of two tests. A decrease in testing requirements would result in some cost savings to exporters. Those savings could be passed on to feeder cattle buyers in the United States. This could result in an increase in the number of feeder cattle imported from Mexico, resulting in some losses for U.S. sellers of feeder cattle (cow-calf operations). Feeder cattle buyers and sellers in the border States of Arizona, California, New Mexico, and Texas would be most likely to be affected. These losses and gains are not expected to be significant, however.

Risks:

This action would base tuberculosis-related import requirements for cattle on the tuberculosis-risk of the region of origin. It is also expected to encourage control and eradication efforts in Mexico, which would reduce the tuberculosis risk presented by cattle imported from that country.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	
NPRM Comment Period End	05/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—APHIS

5. ANIMAL WELFARE; REGULATIONS AND STANDARDS FOR BIRDS, RATS, AND MICE

Priority:

Other Significant

Legal Authority:

7 USC 2131 to 2159

CFR Citation:

9 CFR 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 and is considering establishing specific standards for rats and mice, other than rats of the genus Rattus and mice of the genus Mus 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. Currently, the general standards in 9 CFR part 3, subpart F, apply to covered rats and mice. APHIS is also considering adopting specific standards for those animals.

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, rats of the genus Rattus, and mice of the genus Mus 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
ANPRM	06/04/04	69 FR 31537
ANPRM Comment Period End	08/03/04	
ANPRM Comment Period Extended	07/21/04	69 FR 43538
ANPRM Comment Period End	11/01/04	
NPRM	09/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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Related RIN: Related to 0579–AB87

RIN: 0579–AB69

USDA—APHIS

6. REVISION OF FRUITS AND VEGETABLES IMPORT REGULATIONS

Priority:

Other Significant

Legal Authority:

7 USC 450; 7 USC 7701 to 7772; 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:

We considered making no changes to the existing fruit and vegetable import approval process, but the existing process can take upwards of 3 years to complete, and simply is not as responsive enough in this era of increased global trade. We also considered designing a new expedited approval process which would apply to all imports, regardless of the type or extent of risk mitigation measures required. We determined that it would be better to gauge domestic support for a limited system prior to expanding its use to fruits and vegetables that may require complicated risk mitigation strategies that are derived from complex risk analyses—often for fruit and vegetable imports that may be opposed by domestic stakeholders due to economic issues.

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	02/00/06	
NPRM Comment Period End	04/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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RIN: 0579–AB80

USDA—APHIS

7. REVISION OF THE NURSERY STOCK REGULATIONS (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

7 CFR 319

Legal Deadline:

None

Abstract:

APHIS intends to amend its regulations that govern the importation of nursery stock, also known as plants for planting. Under the current regulations, all plants for planting are allowed to enter the United States if they are accompanied by a phytosanitary certificate and if they are inspected and found to be free of plant pests, unless their importation is specifically prohibited or further restricted by the regulations. We are considering several possible changes to this approach, including establishing a category in the regulations for plants for planting that would be excluded from importation pending risk evaluation and approval; developing ongoing programs to reduce the risk of entry and establishment of quarantine pests via imported plants for planting; combining existing regulations governing the importation of plants for planting into one subpart; and reevaluating the risks posed by

importation of plants for planting whose importation is currently prohibited.

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 USC 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
ANPRM	12/10/04	69 FR 71736
ANPRM Comment Period End	03/10/05	
Comment Period Extended	03/10/05	70 FR 11886
Comment Period End	04/11/05	
Public Meeting and Reopening of Comment Period	05/02/05	70 FR 22612
Comment Period End	06/03/05	
NPRM	09/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—APHIS

8. ● IMPORTATION OF BONELESS BEEF FROM JAPAN

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8317

CFR Citation:

9 CFR 94

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulations governing the importation of meat and other edible animal products by allowing the importation of whole muscle-cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan under conditions that would prevent the introduction of bovine spongiform encephalopathy.

Statement of Need:

APHIS regulates the introduction of meat and edible products from ruminants due to bovine spongiform encephalopathy (BSE) under 9 CFR part 94. In response to a request from the Government of Japan and after analyzing the risk associated with the importation of whole muscle-cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan, APHIS has determined that it is unnecessary to continue to prohibit the importation this commodity from Japan, provided that certain conditions are met.

Summary of Legal Basis:

The Animal Health Protection Act authorizes the Secretary of Agriculture to prohibit or restrict the importation, entry, and interstate movement of any article if necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock, including BSE.

Alternatives:

APHIS could have continued to prohibit the importation of whole muscle-cuts of boneless beef from Japan or to impose a more restrictive set of import conditions. These alternatives were rejected because they are not necessary in order to prevent the introduction of BSE into the United States through boneless beef from Japan.

Anticipated Cost and Benefits:

Based on historic import levels and information from the Government of

Japan, APHIS expects this action to result in the importation from Japan of approximately 10 metric tons of boneless beef per year, which is a very small quantity when compared to U.S. boneless beef imports generally. Further, we expect that the type of beef imported would be Wagyu beef, which is a high-priced beef typically sold to a niche market of consumers. This action is expected to have little economic impact for most beef consumers and producers in the United States.

Risks:

This rulemaking sets import conditions that address the BSE-related risks of importing a commodity into the United States from a region where BSE is known to exist.

Timetable:

Action	Date	FR Cite
NPRM	08/18/05	70 FR 48494
NPRM Comment Period End	09/19/05	
Next Action Undetermined		

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

None

Additional Information:

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

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RIN: 0579–AB93

USDA—APHIS

FINAL RULE STAGE

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9. IMPORTATION OF SMALL LOTS OF SEED WITHOUT PHYTOSANITARY CERTIFICATES

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

7 CFR 319

Legal Deadline:

None

Abstract:

This rulemaking would amend the nursery stock regulations to allow the importation of small lots of seed under an import permit with specific conditions as an alternative to the current phytosanitary certificate requirement. This proposed change is necessary because several entities that import small lots of seed—individual importers, horticultural societies, arboreta, and small businesses—have had difficulty obtaining the necessary certificates and have been adversely affected by the phytosanitary certificate requirement. The proposed change would make it feasible for those entities to import small lots of seed and would ensure prompt and consistent service for such importers while continuing to protect against the introduction of plant pests into the United States and providing the Animal and Plant Inspection Service with necessary information about the quality, quantity, and diversity of the imported material.

Statement of Need:

APHIS prohibits or restricts the importation of living plants, plant parts, and seeds for propagation to prevent the introduction of plant pests and noxious weeds into the United States. Recently, APHIS began requiring a phytosanitary certificate of inspection for all imported nursery stock, including small lots of seed. In response to requests from several entities who have had difficulty obtaining a phytosanitary certificate for small lots of seed or found the costs to be too high, APHIS is amending the regulations to allow small lots of seed to be imported under an import permit, with specific conditions, instead of with a phytosanitary certificate. APHIS has determined that this alternative for small lots of seed will provide an equivalent level of phytosanitary protection.

Summary of Legal Basis:

The Plant Protection Act (7 USC 7701 to 7773) authorizes the Secretary to prohibit or restrict the importation of any plant, plant product, or other article if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction of a plant pest into the United States.

Alternatives:

APHIS could have continued requiring that imported seeds be inspected and be accompanied by a phytosanitary certificate. However, in the countries that do offer inspection and certification services for small lots of seed, the costs of these services has been prohibitive for the seed importers. As a result, seed importers have either been unable to obtain the necessary phytosanitary certificates for small lots of seed or have had to pay fees that greatly exceeded the value of the seeds themselves. We rejected this alternative because maintaining the status quo would not be an economically feasible option for importers of small lots of seed, and because our preferred action imposes only those restrictions on the importation of small lots of seed that are necessary to prevent the introduction of plant pests into the United States.

Anticipated Cost and Benefits:

The changes will result in a slight cost increase for the Federal Government since import permits and the port of entry inspection activities are currently provided without a fee. If the changes result in increased importation of small lots of seed, there could also be a slight increase in the workload for processing the permits, but, since imports of small lots of seed are a very small fraction of the total domestic supply of seeds, no significant change in supply or price is expected.

However, as a result of these changes, seed importers will be able to more widely acquire new kinds of seeds to expand plant diversity, private gardeners will benefit from an increased availability of special seeds, the entry of imported seeds through plant inspection stations will provide APHIS with a more accurate picture of seed import activity, and we expect that the risk of the introduction or dissemination of plant diseases due to illegal importation will be reduced.

Risks:

This rulemaking sets import conditions that address the risks associated with importing small lots of seed into the United States.

Timetable:

Action	Date	FR Cite
NPRM	04/29/04	69 FR 23451
NPRM Comment Period End	06/28/04	
Final Rule	12/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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USDA—APHIS

10. PHYTOPHTHORA RAMORUM; QUARANTINE AND REGULATIONS

Priority:

Other Significant

Legal Authority:

7 USC 7701 to 7772

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 and 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 USC 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 has 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	12/00/05	
Interim Final Rule Comment Period End	02/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Additional Information:

APHIS documents published in the Federal Register and related information are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

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RIN: 0579–AB82

USDA—Food and Nutrition Service (FNS)

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

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

Legal Deadline:

None

Abstract:

This proposed rule will implement several quality control changes to the Food Stamp Act required by sections 4118 and 4119 of title IV of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171). The provisions in this rule affect the following areas: 1) The elimination of enhanced funding; 2) revisions to the time frames for completing individual case reviews; 3) extending the time frames in the procedures for households that refuse to cooperate with QC reviews; 4) procedures for adjusting liability determinations following appeal decisions; 5) negative case reviews; and 6) conforming and technical changes. (02-015)

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/23/05	
NPRM Comment Period Ends	12/22/05	
Final Action	10/00/06	
Final Action Effective	11/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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Related RIN: Split from 0584–AD31

RIN: 0584–AD37

USDA—FNS

12. 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 nutritionally equivalent beverage to milk.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

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RIN: 0584–AD58

USDA—FNS

13. ● 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 package; 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	01/00/06	
NPRM Comment Period End	04/00/06	
Interim Final Rule	11/00/06	
Interim Final Rule Effective	11/00/06	
Interim Final Rule Comment Period End	05/00/08	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Local, State, Tribal

Federalism:

Undetermined

URL For More Information:

www.fns.usda.gov/wic

URL For Public Comments:

www.fns.usda.gov/wic

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RIN: 0584–AD77

USDA—FNS

FINAL RULE STAGE

14. 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
NPRM Comment Period End	06/15/04	
Final Action	12/00/05	
Final Action Effective	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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RIN: 0584–AD30

USDA—FNS

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

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

7 CFR 273; 7 CFR 275

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/16/03	68 FR 59519
Interim Final Rule Effective	12/15/03	
Interim Final Rule Comment Period End	01/14/04	
Final Action	10/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State

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RIN: 0584–AD31

USDA—FNS

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

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 107–171

CFR Citation:

7 CFR 273.7

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

None.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/19/04	69 FR 12981
NPRM Comment Period End	05/18/04	

Action	Date	FR Cite
Final Action	12/00/05	
Final Action Effective	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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RIN: 0584–AD32

USDA—FNS

17. CATEGORICAL ELIGIBILITY AND DIRECT CERTIFICATION FOR FREE AND REDUCED PRICE MEALS AND FREE MILK IN SCHOOLS

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 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	03/00/06	

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

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

Priority:

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

Legal Authority:

42 U.S.C. 1786

CFR Citation:

7 CFR 246

Legal Deadline:

Final, Statutory, December 2005.

Abstract:

This interim 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 (P.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	11/00/05	
Interim Final Rule Comment Period End	11/00/06	
Interim Final Rule Effective	12/00/05	
Final Action	02/00/07	
Final Action Effective	03/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, Local, State, Tribal

URL For More Information:

www.fns.usda.gov/wic

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RIN: 0584–AD71

USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

19. PERFORMANCE STANDARDS FOR PUMPED OR MASSAGED BACON

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq

CFR Citation:

9 CFR 424.22(b)

Legal Deadline:

None

Abstract:

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

Statement of Need:

FSIS is proposing to replace restrictive provisions concerning the processing of pumped or massaged bacon with an upper limit for nitrite and a performance standard. The proposed performance standard concerns limiting the presence of volatile nitrosamines in pumped or massaged bacon. These proposed changes are necessary to make the regulations concerning pumped or massaged bacon consistent with those governing Hazard Analysis and Critical Control Point (HACCP) systems.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0583–AC49

USDA—FSIS

20. 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. Plants would be expected to develop HACCP systems that ensure products meet the pathogen reduction performance standards. Finally, FSIS is proposing to amend the Federal egg products inspection regulations by removing current requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment prior to their use in official plants. The Agency also plans to eliminate the prior label approval system for egg products. This proposal will not encompass shell egg packers. In the near future, FSIS will initiate non-regulatory outreach efforts

for shell egg packers that will provide information intended to help them to safely process shell eggs intended for human consumption or further processing.

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

Statement of Need:

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

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

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

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

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

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

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

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

Risks:

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

To assess the potential risk-reduction impacts of this rulemaking on the public, an intra-Agency group of

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State

Federalism:

Undetermined

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USDA—FSIS

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

Priority:

Other Significant

Legal Authority:

21 USC 451 to 470

CFR Citation:

9 CFR 381.66

Legal Deadline:

None

Abstract:

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

Statement of Need:

This proposed rule addresses Federal regulations that are inconsistent with the PR/HACCP regulations because they restrict the ability of poultry processors to choose appropriate and effective measures to eliminate, reduce, or control biological hazards identified in their hazard analyses. The regulations also complicate efforts by establishments to comply with the terms of the January 9, 2001, final rule further restricting the amount of water that may be retained in raw meat or poultry products after post-evisceration processing; some establishments may have to use chilling procedures that result in higher levels of retained water in carcasses than may be necessary to achieve the same food safety objective. For example, establishments that operate automated chillers may have to subject poultry carcasses to higher agitation rates or longer dwell times in the chillers. Also, as discussed above, the time/temperature chilling regulations for poultry are inconsistent with the PR/HACCP regulations, the retained water regulations, and the meat inspection regulations.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

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

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

22. SHARING OF FIRMS' DISTRIBUTION 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) is proposing 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 is proposing 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. section 301, Departmental regulations, and 5 U.S.C. section 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 is preparing 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) Taking no regulatory action; (2) including local health departments as entities that could receive recall distribution lists; (3) making available to the general public, without any limitations, recall distribution lists, including all levels of distributors; (4) requiring recalling establishments to make their distribution lists available to any member of the public who requests it; and (5) allowing the Agency to make available to the general public the names of likely retail consignees of recalled meat and poultry products.

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	09/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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RIN: 0583–AD10

USDA—FSIS

FINAL RULE STAGE

23. PERFORMANCE STANDARDS FOR THE PRODUCTION OF PROCESSED 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. 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 less contaminated products entering commercial food distribution channels as a result of improved sanitation and process controls and in-plant verification. FSIS believes that the benefits of the rule would exceed the total costs of implementing its provisions.

The main provisions of the proposed rule are: Lethality performance standards for Salmonella and E. coli 0157:H7 and stabilization performance standards for C. perfringens that firms must meet when producing RTE meat and poultry products. Most of the costs of these requirements would be associated with one-time process performance validation in the first year of implementation of the rule and with revision of HACCP plans. Total direct industry-wide costs are estimated at $23.3 million on an annual basis. Annual net benefits are estimated at about $26.2 million annually. Benefits are expected to result from the entry into commercial food distribution channels of product with lower levels of contamination resulting from improved in-plant process verification and sanitation.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	02/27/01	66 FR 12590
NPRM Comment Period End	05/29/01	
NPRM Comment Period Extended	07/03/01	66 FR 35112
NPRM Comment Period End	09/10/01	
Interim Final Rule	06/06/03	68 FR 34208
Interim Final Rule Effective	10/06/03	
Interim Final Rule Comment Period End	01/31/05	
NPRM Comment Period Reopened	03/24/05	70 FR 15017
NPRM Comment Period End	05/09/05	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 0583–AC46

USDA—FSIS

24. 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 the nutrition information for the major cuts of single-ingredient, raw meat and poultry products that would be provided if significant participation in the voluntary nutrition labeling program existed, FSIS has concluded that these products would be misbranded.

Because consumers cannot easily estimate the level of fat in ground or chopped meat and poultry products and because producers are able to formulate precisely the fat content of ground or chopped products, FSIS has concluded that ground or chopped meat and poultry products that do not bear nutrition information on their labels would also be misbranded.

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

FSIS has concluded that the quantitative benefits will exceed the quantitative costs of the rule.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/18/01	66 FR 4970
NPRM Comment Period End	04/18/01	
Extension of Comment Period	04/20/01	66 FR 20213
NPRM Comment Period End	07/17/01	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

25. FOOD STANDARDS; GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

9 CFR 410; 21 CFR 130

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	05/20/05	70 FR 29214
Other/Final Rule	09/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

26. 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	09/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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USDA—Forest Service (FS)

PROPOSED RULE STAGE

27. ● TRAVEL MANAGEMENT (PROPOSED DIRECTIVES, FOREST SERVICE MANUAL 2300 AND 7700)

Priority:

Other Significant

Legal Authority:

E.O. 11644

CFR Citation:

None

Legal Deadline:

None

Abstract:

Once the final regulation entitled ''Travel Management; Designated Routes and Areas for Motor Vehicle Use (36 CFR part 212)'' is adopted, the Forest Service is planning to publish proposed directives to implement the regulation. The proposed directive changes are needed to provide guidance on implementation of the Travel Management regulation, conform terminology to the rule, and provide consistent direction on the process of designating roads, trails, and areas for motor vehicle use.

The proposed changes consolidate policy for travel planning for roads and trails in FSM 7710, while retaining separate chapters related to operations and maintenance for roads (FSM 7730) and trails (FSM 2350). The changes would expand the scope of the current roads analysis process to encompass motorized trails and areas, while streamlining travel analysis to ensure that it is completed in a timely manner.

Statement of Need:

Motor vehicles are a legitimate use of NFS lands — in the right places, and with proper management. Current regulations at 36 CFR part 295 were developed when Off-Highway Vehicles (OHVs) were less widely available and less powerful than today's models. The growing popularity and capabilities of OHVs demand new regulations so that the Forest Service can continue to provide these opportunities, while sustaining the health of NFS lands and resources. From 1972 to 2004, the number of Americans driving motor vehicles off road increased by a factor of ten. Whole new classes of vehicles have been introduced by manufacturers. These advances expand opportunities for Americans to enjoy Federal lands. However, the magnitude and intensity of motor vehicle use have increased to the point that without careful management, soil erosion, water quality, wildlife habitat, adjacent property owners, and the experiences of other visitors can be affected.

The clear identification of roads, trails, and areas for motor vehicle use on each National Forest will enhance management of National Forest System lands; sustain natural resource values through more effective management of motor vehicle use; enhance opportunities for motorized recreation experiences of National Forest System lands; address needs for access to National Forest System lands; and preserve areas of opportunity on each National Forest for nonmotorized travel and experiences.

On July 15, 2004, the Forest Service published a proposed rule in the Federal Register (69 FR 42381) seeking public comment in amending regulations at 36 CFR parts 212, 251, 261, and 295 to clarify policy related to motor vehicle use on NFS lands, including the use of OHVs. During the 60-day comment period that ended on September 13, 2004, the agency received 81,563 letters or electronic messages in response to the proposed rule. The final rule includes a response to comments submitted on the proposed rule.

Summary of Legal Basis:

There is no aspect of this action that is required by statute or court order. The final Travel Management rule is needed to provide consistent management of motor vehicle use on NFS lands so that the Forest Service can better meet the direction of E.O. 11644 and E.O. 11989.

Alternatives:

As an alternative to publishing the final Travel Management rule, the Forest Service could continue to operate under current regulations at 36 CFR part 295. These existing regulations provide that motor vehicle use off roads may be allowed, prohibited, or restricted, as determined through individual land management plans. Management of motor vehicle use under existing regulations has been inconsistent from one National Forest to another, and has sometimes failed to either keep pace with increasing demand or prevent damage to natural resources.

Anticipated Cost and Benefits:

The benefits and costs of the final rule and related proposed directives are described qualitatively because the rule is procedural. Actual travel management decisions will be made by field units with public input and appropriate environmental analysis and documentation. The benefits of the final rule include gains to users, the agency, and the environment. Sustainable, reliable, high-quality public access to National Forest System lands will lead to enhanced recreation opportunities for visitors. Both users and the agency will benefit from improved public communication, more effective law enforcement, and improved travel management planning. Other benefits include reduced environmental damage and a more consistent and defensible travel planning framework. The costs of the final rule include reductions in unconstrained cross-country motor vehicle use for those that value this activity, and short-term agency planning costs as many National Forests launch travel planning efforts following adoption of the rule.

Risks:

There are no risks addressed by the final rule and related proposed directives. Unmanaged cross-country motor vehicle travel can affect soil, water quality, wildlife habitat, cultural and historic resources, invasive species, private property owners, and the experiences of other recreational visitors. A managed system of routes and areas designated for motor vehicle use can provide sustainable recreation opportunities for visitors while addressing these effects. The final Travel Management rule will provide a consistent national framework for making travel management decisions at the local level, with public participation and appropriate environmental analysis.

Timetable:

Action	Date	FR Cite
Proposed Directive	01/00/06	

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

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

Responding to the Administration's Regulatory Philosophy and Principles

The vast majority of the Department's programs and activities do not involve regulation. Of the Department's 12 primary operating units, only the National Oceanic and Atmospheric Administration (NOAA) plans a ''most important'' significant preregulatory or regulatory action for this Regulatory Plan year. NOAA plans to complete two actions and has completed four actions that rise to the level of ''most important'' of the Department's ''significant regulatory actions''. The actions that will be completed in the next year are entitled: (1) Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementing Regulations; and (2) Fisheries of the United States; National Standard 1. The actions that have been completed are: (1) Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs - Crab Rationalization Program; (2) Designate Critical Habitat

for 7 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in California; (3) Designate Critical Habitat for 12 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington and Oregon; and (4) and Listing Determinations for 27 Evolutionarily Significant Units (ESUs) of West Coast Salmon and Oncorhynchus Mykiss. Further information on these actions are provided below.

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

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

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

National Oceanic and Atmospheric Administration

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

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

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

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

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

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

Magnuson-Stevens Act Rulemakings

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

While most of these rulemakings will be minor, involving only the opening or closing of a fishery under an existing FMP, five actions are of particular significance and have been designated as the most important regulatory actions undertaken by the Department. In the action entitled ''Northwest Hawaiian Islands National Marine Sanctuary; Designation and Implementation of Regulations,'' NOAA plans to designate the Northwest Hawaiian Islands as a national marine sanctuary and propose implementing regulations that best reflect the goals and objectives of the proposed sanctuary. In the action entitled ''Fisheries of the United States; National Standard 1,'' NMFS amends the national standard guidelines for national standard 1 to revise the criteria for determining overfishing and establishing rebuilding schedules. The four remaining actions that have been designated as the most important regulatory actions have been completed during the past year. In the action entitled ''Amendments 18 and 19 to the to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs in the Bering Sea and the Aleutian Islands - Crab Rationalization Program,'' NMFS rationalized the Bering Sea and Aleutian Islands crab fisheries in the United States Exclusive Economic Zone off Alaska by amending the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs. The goal of rationalization is to end the race for fish and solve the problems of overcapacity while providing for a balanced distribution of benefits and improving fisheries management and resource conservation. In the action entitled ''Listing Determinations for 27 ESUs of West Coast Salmon and Oncorhynchus Mykiss,'' NMFS listed ESUs as endangered or threatened, and also delisted ESUs as necessary. Finally, in the actions entitled ''Designate Critical Habitat for 7 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in alifornia''' and ''Designate Critical Habitat for 12 Evolutionarily Significant Units (ESUs) of Pacific Salmon and Steelhead in Washington and Oregon'' NMFS designated critical habitat for 20 Pacific salmon and O. mykiss Evolutionarily Significant Units (ECUS) listed under the Endangered Species Act of 1973. The geographic areas designated as critical habitat included lakes, riverine, and estuarian habitat in Washington, Oregon, Idaho, and California.

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.

DOC—National Oceanic and Atmospheric Administration (NOAA)

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

PL 106–513; 16 USC 1431 et seq

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The National Marine Sanctuaries Program, together with State and Federal partners and other stakeholders, designates the Northwest Hawaiian Islands as a national marine sanctuary and implements regulations that best reflects the goals and objectives of the proposed sanctuary.

Statement of Need:

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

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

Summary of Legal Basis:

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

Alternatives:

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

The fourth alternative establishes a sanctuary with fishing regulations that would protect the highest ecosystem values while allowing compatible fishing activities in areas where they are likely to have less impact on the ecosystem. It prohibits precious coral and crustacean harvest, and pelagic

longlining, but provides for commercial bottomfish/pelagic trolling, commercial pelagic trolling, various forms of recreational fishing, and Native Hawaiian cultural and subsistence uses through a permitting process. The fifth alternative is an iteration of the fourth alternative and prohibits the same fishing activities. It also provides for bottomfish/pelagic trolling, commercial pelagic trolling, various forms of recreational fishing and Native Hawaiian cultural subsistence uses. The sixth alternative was developed by the Reserve Advisory Council and is similar to alternative 2 but would close bottomfish/pelagic trolling within 1 year of sanctuary designation. It also calls for a zoning system to limit commercial and recreational pelagic fishing to minimize interactions with protected wildlife. The seventh alternative closes immediately the entire area to all extractive use, except for research or education.

Anticipated Cost and Benefits:

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

Risks:

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

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State

Federalism:

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

Agency Contact:

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DOC—NOAA

FINAL RULE STAGE

29. FISHERIES OF THE UNITED STATES; NATIONAL STANDARD 1

Priority:

Other Significant

Legal Authority:

16 USC 1801 et seq

CFR Citation:

50 CFR 600

Legal Deadline:

None

Abstract:

NMFS is considering revisions to the national standard guidelines for national standard 1 that specify criteria for determining overfishing and establishing rebuilding schedules. There have been concerns expressed by the scientific community, fisheries managers, the fishing industry, and environmental groups regarding the appropriateness of some aspects of these guidelines.

Statement of Need:

The overall intent of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) is to achieve optimum yield, prevent overfishing and rebuild overfished stocks in as short a time as possible. The National Marine Fisheries Service (NMFS) and the Regional Fishery Management Councils (Councils) are charged with the difficult, but important task of balancing the need to prevent overfishing and rebuild overfished stocks in as short a time as possible, taking into account the needs of fishing communities and fishing industry infrastructure, and evaluating actions in terms of overall benefits to the nation.

NMFS, the Councils, the public, and various stakeholders in fisheries in the

Exclusive Economic Zone (EEZ) have worked with the current version of the National Standards 1 (NS1) guidelines since June 1998, while developing overfishing definitions and rebuilding plans for various fisheries. Through this experience, NMFS has developed new perspectives about the utility of the current NS1 guidelines.

NMFS decided in November 2003, after receiving public comment on the current usefulness of the NS1 guidelines, and convening a NMFS Working Group (Working Group) to review the guidelines, that it would propose revisions to the guidelines. NMFS believes that the proposed revisions would improve the ability of the Councils to establish meaningful status determination criteria (SDC) and rebuilding plans that facilitate compliance with the Magnuson-Stevens Act.

Summary of Legal Basis:

The Magnuson-Stevens Act serves as the chief authority for fisheries management in the U.S. Exclusive Economic Zone. Section 301(a) of the Magnuson-Stevens Act contains 10 national standards with which all FMPs and their amendments must be consistent. Section 301(b) of the Magnuson-Stevens Act requires that ''the Secretary establish advisory guidelines (which shall not have the force and effect of law), based on the national standards, to assist in the development of fishery management plans.'' Guidelines for the national standards are codified in Subpart D of 50 CFR part 600. The guidelines for the national standards were last revised through a final rule published in the Federal Register on May 1, 1998 (63 FR 24212), by adding revisions to the guidelines for National Standards 1 (OY), 2 (scientific information), 4 (allocations), 5 (efficiency), and 7 (costs and benefits), and adding new guidelines for National Standards 8 (communities), 9 (bycatch), and 10 (safety of life at sea).

The guidelines for NS1 were revised extensively in the final rule published on May 1, 1998, to bring them into conformance to revisions to the Magnuson-Stevens Act, as amended in 1996 by the Sustainable Fisheries Act (SFA). In particular, the 1998 revisions to the NS1 guidelines addressed new requirements for FMPs brought about by SFA amendments to section 304(e) (rebuilding overfished fisheries).

Alternatives:

If the proposed revisions to terminology are adopted, NMFS would request that Regional Fishery Management Councils (Councils) begin using the new terms in place of the old terms, revise FMP language related to the revised terminology the next time a Council submits an FMP amendment for Secretarial review. NMFS would begin using the new terms in its next Annual Report to Congress of the Status of U.S. Fisheries. Any codified language existing under 50 CFR Part 600 for fisheries managed under the Magnuson-Stevens Act related to ''overfished'', ''minimum stock size threshold'', and ''maximum fishing mortality threshold,'' would be revised by NMFS.

For the proposed revisions to the NS1 guidelines other than terminology, the new guidelines would apply to some, but not all new actions submitted by a Council. Any new action, that includes new or revised SDC (''depleted'' or ''overfishing'' definitions), OY control rules or rebuilding plans, would need to be developed and evaluated according to the revised NS1 guidelines. However, if a Council action containing SDC, OY control rules or rebuilding plans is already under development and a draft environmental impact statement's (DEIS) notice of availability has already been published in the Federal Register, before the final rule implementing the revised NS1 guidelines is effective, then a Council could submit an FMP or FMP amendment under either the ''old'' or ''new'' NS1 guidelines. Likewise, if the public hearing draft of an FMP amendment or other regulatory action not containing an EIS has already been adopted by a Council for public hearing, before the final rule implementing the revised NS1 guidelines is effective, then a Council could submit an FMP or FMP amendment under either the ''old'' or ''new'' NS1 guidelines.

After any final rule implementing the revisions to the NS1 guidelines becomes effective, if a Council submits an action (e.g., annual specifications, an FMP amendment, interim rulemaking, or a regulatory amendment) that does not involve new or revised SDC, OY control rules, or rebuilding plans, then that action could be reviewed and approved without the FMP being amended to bring existing SDC, OY control rules, and rebuilding plans into conformance with the new guidelines. The proposed action would still need to be in conformance with all of the national standard guidelines to be approvable. Any FMP amendment or other regulatory action that involves: (1) Proposed SDC, an OY control rule, or a rebuilding plan for a stock not previously managed by SDC or by a rebuilding plan; or (2) proposed revisions to SDC, an OY control rule, or a rebuilding plan for a stock already managed under SDC or by a rebuilding plan, then the proposed SDC, OY control rule, and/or rebuilding plan would need to comply with the new NS1 guidelines.

Regarding the proposed recommendation that stocks in FMPs be managed according to core stocks and stock assemblages, if a Council determines that a given FMP only has core stocks (e.g., the Mid-Atlantic Council's Spiny Dogfish FMP, the New England Council's Atlantic Sea Scallops FMP, the Deep-Sea Red Crab FMP, and the FMP for the Gulf of Mexico Stone Crab Fishery), then the Council should make such a determination with accompanying rationale in its next FMP amendment.

In the case of an FMP that has a mixture of SDC-known stocks and stocks having an ''unknown status'' related to SDC (e.g., Snapper-Grouper FMP) when a Council begins to align its management under ''core stocks'' and ''stock assemblages,'' the Council could begin such alignment in a stepwise fashion (in a series of separate FMP actions) for given core stocks or stock assemblages, once new or revised SDC, OY control rules, or rebuilding plans are developed. If a Council determines that the stepwise method is problematic it could take action to realign all of the FMP's stocks into core stocks and stock assemblages in one action.

If some stocks are not being managed effectively under a given FMP because their status relative to SDC is unknown, and the proposed revisions to the NS1 guidelines are approved, then the Council should re-evaluate those stocks as soon as possible, to decide whether or not any grouping of some or all stocks having an unknown status could be managed by an SDC under one or more indicator stocks, or through stock assemblage-wide SDC. A Council should clearly designate which stocks in the FMP are in the FMPs and thus subject to SDC and to inclusion in the NMFS Annual Report to Congress on the Status of U.S. Fisheries. Stocks that are listed as threatened or endangered under the Endangered Species Act would be exempt from being evaluated according to SDC, but must be evaluated against SDC within 1 year of

being de-listed. Finally, stocks that are primarily dependent on artificial propagation from hatcheries would be exempt from being evaluated according to SDC. If any stocks are currently undergoing overfishing as part of an approved rebuilding plan (e.g., reductions in F are being phased in over a number of years until F is less than or equal to Film), then, the first time that the Council submits a revised rebuilding plan for those stocks, overfishing must be prevented, beginning in the first year of the revised rebuilding plan, except under circumstances listed under section 304(e)(4)(A) of the Magnuson-Stevens Act.

In general, the Councils would not be required to amend their SDC, OY control rules and rebuilding plans approved under the SFA by any ''date certain,'' with the following exceptions. In the event that NMFS, on behalf of the Secretary of Commerce, determines that a fishery is overfished or approaching an overfished condition under section 304(e)(1) or (e)(2) of the Magnuson-Stevens Act, or a rebuilding plan needs to be revised under section 304(e)(7) of the Magnuson-Stevens Act, then the Council needs to take action consistent with the revised NS1 guidelines. NMFS should notify the appropriate Council if overfishing is occurring in a fishery, even if the fish stock is not determined to be overfished, under the same procedures as described in Section 304(e) (1) and (2) of the Magnuson-Stevens Act.

If one or more stocks in an FMP do not currently have OY control rules, or the OY control rule equals its respective MY control rule, then the appropriate Council would need to develop and submit an FMP amendment or other appropriate regulatory action and analyses when the SDC or the rebuilding plan for such a fishery needs to be revised. Revisions are necessary when a stock's rebuilding plan is not making adequate progress under section 304(e)(7) of the Magnuson-Stevens Act, or new data or an assessment indicates that SDC or the rebuilding target needs revision. A Council can submit an OY control rule for Secretarial review before SDC or the rebuilding plan needs to be revised, if it chooses to do so.

Anticipated Cost and Benefits:

There will be no immediate economic or social impacts upon effectiveness of the final rule for the revised NS1 guidelines. Management actions that incorporate the new NS1 guidelines in their SDC, rebuilding plans would be evaluated individually and would not begin to have any economic or social impacts until about 1 1/2 to 2 years after the effective date of this action.

Risks:

The National Marine Fisheries Service intends to clarify, amplify and simplify the NS1 guidelines in several instances so that the regional fishery management councils and the public have a better understanding of how to: (1) Establish definitions for ''depleted'' and ''overfishing'' for fish stocks that vary in data quality, (2) construct and revise rebuilding plans, and (3) improve the ability of Councils and NMFS to comply with the requirements of section 304 of the Manson-Stevens Fishery Conservation and Management Act. The proposed revisions should improve the Councils' ability to protect stocks of unknown status (i.e., core stocks and stock assemblages provision), manage towards ending overfishing and rebuilding overfished stocks (i.e., biomass stock size limits, OY control rules, rebuilding targets, revision of rebuilding plans) and provide better clarity in the NS1 guidelines. Improved conservation of various stocks should enhance the likelihood that optimum yield will be attained for those stocks, a chief goal of the Manson-Stevens Act.

Timetable:

Action	Date	FR Cite
ANPRM	02/14/03	68 FR 7492
ANPRM Comment Period End	03/17/03	
Comment Period Extended	03/03/03	68 FR 9967
NPRM	06/22/05	70 FR 36240
Comment Period Extended	08/15/05	70 FR 47777
NPRM Comment Period End	08/22/05	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

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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, 16 Defense agencies, and 11 DoD field activities. It has over 1,390,000 military personnel and 675,000 civilians assigned as of June 30, 2005, and over 200 large and medium installations in the continental United States, U. S. territories, and foreign countries. The overall size, composition, and dispersion of the Department of Defense, coupled with an innovative regulatory program, presents a challenge to the management of the Defense regulatory efforts under Executive Order 12866 ''Regulatory Planning and Review'' of September 30, 1993.

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

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

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

Coordination

Interagency

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

Internal

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

Overall Priorities

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

Problem Identification

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

Conflicting Regulations

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

Alternatives

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

Risk Assessment

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

Cost-effectiveness

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

Cost-Benefit

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

Information-Based Decisions

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

Performance-Based Regulations

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

Outreach Initiatives

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

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

Coordination

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

Minimize Burden

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

Plain Language

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

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

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

Regulations Related to the Events of September 11, 2001

Defense Federal Acquisition Regulation Supplement (DFARS) Case 2003-D107, Firefighting Service Contracts, implements Section 331 of the National Defense Authorization Act for Fiscal Year 2004. Section 331 provides authority for contractor performance of firefighting functions at military installations or facilities for periods of one year or less, if the functions would otherwise have to be performed by members of the Armed Forces who are not readily available by reason of a deployment. The final rule was published in the **Federal Register** on December 15, 2004 (69 FR 75000).

Defense Federal Acquisition Regulation Supplement (DFARS) Case 2004-D032, Contractor Performance of Security Guard Functions, conditionally extends from December 1, 2005 to September 30, 2006, authority for contractor performance of security-guard functions at military installations

or facilities to meet the increased need for such functions since September 11, 2001. It implements Section 324 of the National Defense Authorization Act for Fiscal Year 2005, which requires DoD to submit a report to Congress on the use of this authority, no later than December 1, 2005, to permit extension of the authority. The final rule was published in the **Federal Register** on March 23, 2005 (70 FR 14576).

Federal Acquisition Regulation (FAR) Case 2003-022, Special Emergency Procurement Authority, implements Section 1443 of the Fiscal Year 2004 Consolidated Appropriations Act and also incorporates the higher thresholds authorized by Section 822 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005. This rule provides continuing authorities for acquisitions of property and services by or for an executive agency that are to be used in support of a contingency operation or to facilitate defense against or recovery from terrorism or nuclear, biological, chemical, or radiological attack. The final rule was published in the **Federal Register**on December 20, 2004 (69 FR 8312).

Regulations of Particular Interest to Small Business

The Department will work to clarify in the FAR that prime contractors must confirm HUBZone certification and permit small business credit for subcontracts awarded to certain Alaska Native Corporations and Indian tribes.

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 five 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, health affairs, and the Defense personnel system.

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

Compensatory Mitigation in the Army Regulatory Program

Section 314 of the National Defense Authorization Act for Fiscal Year 2004 (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 statutory deadline for publishing the final regulation is November 24, 2005.

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

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

In 1990, the Army Corps of Engineers published as appendix 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 will hold 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.

Defense Procurement and Acquisition

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

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

- Transform the Defense Federal Acquisition Regulation Supplement (DFARS) to improve the efficiency and effectiveness of the acquisition

process, while allowing the acquisition workforce flexibility to innovate. The transformed DFARS will contain only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal operating procedures of DoD or a significant cost or administrative impact on contractors or offerors.

- 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.
- Also coordinate with a representative of the Department of State to provide 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.
- Implement new Free Trade Agreements with Morocco and Dominican Republic-Central American FTA countries in the FAR and DFARS, as well as increased thresholds for all trade agreements.
- Phase in DFARS requirements for contractors to affix radio frequency identification (RFID) tags to the exterior packaging of items delivered under DoD contracts. This practice will improve visibility of DoD assets in the supply chain, increase the accuracy of shipment and receipt data, and reduce the amount of time it takes to deliver material to the warfighter.
- Require DoD contractors to provide Item Unique Identification (IUID) data electronically in the IUID Registry for all DoD personal property in possession of the contractor, in lieu of annual reporting of Government property.
- 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 agencies' books and records, and properly coordinated with the appropriate Government officials.
- Implement in the DFARS the statutory requirement that provides for up to 100 percent levy against contract payments for taxes owed by contractors, with consideration given to national security implications.
- Add the process of validating a central Contractor Registration registrant's taxpayer identification number (TIN) with the Internal Revenue Service to improve data accuracy in the Federal Procurement Data System.
- Permit use of a time-and-materials contract or a labor-hour contract for a procurement of certain commercial services.
- Ensure that IT security requirements are included in all relevant Government contracts. Require Federal agencies to acquire only approved products and services for a complete category of Authentication Services, which includes electronic authentication for browser-based access, Federal identity credentials for electronic and physical authentication, and Public Key Infrastructure services.
- Establish consistent procedures for protecting sensitive information from unauthorized use or disclosure, when the performance of support service contracts requires the prime contractor to have access to the sensitive information of other contractors.
- Adjust acquisition-related thresholds in the FAR and DFARS for inflation (except Davis-Bacon Act, Service Contract Act, and trade agreements).
- Finalize the rewrite of FAR Part 27, Patents, Data and Copyrights, to clarify, streamline, and update guidance and clauses on patents, data, and copyrights.
- Provide FAR guidance on acceptability of photocopies of powers of attorney for bid bonds and allow treatment of questions regarding the authenticity and enforceability of the power of attorney at the time of bid opening as a matter of responsibility.
- Review various FAR cost principles to determine whether certain FAR cost principles are still relevant in today's business environment, whether they place an unnecessary administrative burden on contractors and the Government, and whether they can be streamlined or simplified.
- Implement Earned Value Management in the FAR.
- Revise the FAR Part 45, Government Property, to organize and streamline the management of Government property.

Defense Installations and the Environment

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

Revitalizing Base Closure Communities and Addressing Impacts of Realignment

The Department of Defense, in order to promote an efficient and successful base closure and realignment implementation process, has submitted proposed changes to its existing regulations in 32 CFR parts 174, 175, and 176. These proposed changes would bring the regulations up-to-date with statutory requirements enacted after the 1995 round of base closures. The changes will also address changes in Departmental policy. The proposed rule making was published in the Federal Register for public comment August 9, 2005.

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 should 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 **Federal Register** 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. We are now preparing a draft final rule that will address the comments. No significant changes are being made to the draft final RAB Rule. The Department plans to publish the final rule in fiscal year 2006.

Munitions Response Site Prioritization Protocol

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

The Department met with State and tribal representatives and also representatives of other federal agencies during preparation of the proposed rule published on August 22, 2003. The Department reviewed and incorporated comments from the sixteen sets of comments received during the public comment period that ended on November 19, 2003. The draft final rule is under review within the Department, which plans to publish the final rule in fiscal year 2006.

Most of the changes pertain to clarification of terms and definitions based on comments received or new statutory definitions promulgated in the National Defense Authorization Act for 2004 and codified at 10 U.S.C. Section 101. The most significant change to the proposed rule pertains to the module that evaluates health hazards associated with munitions constituents and other chemical constituents. The Department also revised the rule to clarify that current landowners may participate in the application of the rule at Formerly Used Defense Sites and that the quality assurance panel that reviews each priority score will consist only of Department personnel.

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 healthcare initiative designed to improve the management and integration of DoD's healthcare delivery system. The program's goal is to increase access to healthcare services, improve healthcare quality, and control healthcare costs.

The TRICARE Management Activity plans to submit an interim final rule that prescribes double coverage payment procedures and makes revisions to TRICARE rules to accommodate beneficiaries who are eligible under both Medicare and TRICARE, and who participate in Medicare's outpatient prescription drug program under Medicare Part D. These revisions are mandated by the requirements contained in the CMS final rule for the Medicare Prescription Drug Benefit, Part D Plans with Other Prescription Drug Coverage, and the mandated effective date of January 1, 2006, for the Medicare Prescription Drug Benefit. This interim final rule outlines procedures whereby TRICARE becomes second payer for Medicare Part D enrollees. The rule also establishes requirements and procedures for implementation of improvements to the TRICARE Pharmacy Benefits Program regarding the Uniform Formulary process, as directed by Section 714 of the NDAA for FY05. The economic impact of this interim final rule is estimated to be less than $100 million. It is anticipated that the final rule will be published by February 1, 2006.

National Security Personnel System

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

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

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

Human Resources Management System

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

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

Labor Management Relations System

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

Employee Appeals

Section 9902(h) of Public Law 108-136 provides the Secretary of Defense with authority to establish an appeals process in conjunction with NSPS to provide employees fair treatment in decisions relating to their employment.

The new appeals will be designed to streamline appeals procedures while ensuring that employees are afforded the protections of due process, as required by law.

NSPS Design Process and Timeline

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

After DoD and OPM senior leadership decided upon the NSPS design options, proposed regulations establishing and governing NSPS were published via the **Federal Register** for public comment. The Department issued proposed NSPS regulations on February 14, 2005. A 30-day public comment period ended on March 16, 2005; over 58,000 comments were received. Statutory procedures for collaborating with employee representatives on the content of the regulations, known as ''meet and confer,'' are provided in sections 9902(f) and 9902(m)(3). The meet and confer process began on April 18, 2005. The meet and confer process was extended beyond the minimum 30 days provided for in the statute. Based upon the comments received and the input from employee representatives, changes were made to the proposed regulations. The final regulations are expected to be published in fiscal year 2006. After a 30-day notification period to Congress, the regulations will become effective and the phased implementation of NSPS will begin.

National Security Personnel System-Hiring Authorities

The NSPS regulations will provide the authority for the Secretary of Defense, together with the Director of OPM, to establish new hiring authorities for the Department. Concurrent with the initial implementation of the system, the Department, jointly with OPM, intends to establish several new hiring authorities during the first and second quarters of fiscal year 2006. This will be accomplished, in accordance with the NSPS regulations, via a notice in the **Federal Register**.

BILLING CODE 5001–06–S

DEPARTMENT OF EDUCATION (ED)

Statement of Regulatory and Deregulatory Priorities

General

We support States, local communities, institutions of higher education, and others 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; 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, grants, and loans that touch nearly every American at one point in their lives—approximately 14,000 public school districts, nearly 54 million students attending 93,000 elementary and secondary schools, and almost 22 million postsecondary students. We have forged effective partnerships with customers and others to develop policies, regulations, guidance, technical assistance, and approaches to compliance. We have a record of successful communication and shared policy development with affected persons and groups, including parents, students, educators, representatives of State, local, and tribal governments, neighborhood groups, schools, colleges, 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.

New Initiatives

Among our new undertakings is bringing No Child Left Behind to the high school level. The President has called recent 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.

Another new initiative is the Teacher Incentive Fund, a program to develop and implement innovative ways—including performance-based compensation systems—to provide financial incentives for teachers and principals who raise student achievement and close the achievement gap in some of the Nation's highest-need schools.

No Child Left Behind

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

Each State, Puerto Rico, and the District of Columbia has submitted an accountability plan, which the Department approved. Each submitting jurisdiction has used its respective plan to hold schools and school districts accountable in school years 2002-03, 2003-04, and 2004-05 for the academic achievement of all their students, including students in specific subgroups such as students with disabilities and limited English proficient (LEP) students.

With respect to students with disabilities and LEP students, in particular, the Department 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 adequate yearly progress (AYP) determinations, subject to a cap of one percent of the number of students in a school district or State.

We also published proposed regulations to permit a State to (1) exempt LEP students new to schools in the United States from one administration of the State's reading assessment and (2) include, for up to two years, former LEP students in the LEP subgroup when making AYP determinations.

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 are also peer-reviewing 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 must 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). These changes are designed to improve (1) implementation of the education of children with disabilities program (including preschool services) under part B and the early intervention program for infants and toddlers with disabilities under part C and (2) the effectiveness of national discretionary grants, contracts, and cooperative agreements for improving the education of children with disabilities under part D.

Consistent with those statutory changes, the Department published a notice of proposed rulemaking (NPRM) on June 21, 2005 proposing revisions to 34 CFR Parts 300, 301, and 304 concerning the education of children with disabilities program (including

preschool services) under part B of IDEA and the service obligation under the personnel development to improve services for children with disabilities program under part D of IDEA. The Department held a series of public hearings on this NPRM in June and July 2005 and received public comment until September 6, 2005. We anticipate issuing final regulations before spring 2006.

The Department also published, on June 29, 2005, an NPRM proposing to establish a National Instructional Materials Accessibility Standard, as directed by the reauthorized IDEA. We expect to issue final regulations on this standard in late fall 2005. Proposed regulations to implement changes to the part C program are expected to be issued in fall 2005, with final regulations issued some time in 2006.

Under No Child Left Behind, we are working on developing a notice of proposed rulemaking that would provide further flexibility by permitting a State to develop modified achievement standards and assessments for some students with disabilities in addition to students, referenced elsewhere in this plan, with the most significant cognitive disabilities.

Congress is developing legislation to amend and extend the Higher Education Act of 1965 (HEA). If enacted, changes to the regulations governing the grant, loan, and work assistance programs authorized under title IV of the HEA will be necessary in order to improve educational quality, expand access, and ensure affordability in postsecondary education. Any regulatory activity that becomes necessary as a result of amendments to the HEA would need to balance reduction in burden on program participants, especially on students, with the need to adequately safeguard taxpayers' funds. Unless the HEA is amended to remove the requirement, regulations governing HEA title IV programs will continue to be developed through negotiated rulemaking. The HEA also authorizes other important programs, and changes to regulations may be necessary to improve the implementation of the teacher-quality-enhancement programs under title II, the institutional-assistance programs under titles III and V, the international and foreign language studies programs under title VI, and the graduate education and postsecondary education improvement programs under title VII. Under current law, these programs are not subject to negotiated rulemaking.

Other Potential Regulatory Activities

Congress is developing legislation that would reauthorize a number of the Department's other major programs. Enactment of these legislative undertakings could result in various regulatory activities by the Department. These include reauthorization of the Carl D. Perkins Vocational and Technical Education Act of 1998, which would make changes designed to improve the State grant and other programs providing assistance under this statute and considered necessary to help States and local communities strengthen career and technical education and improve educational opportunities for career and technical education students. The Administration is working with Congress to ensure that this reauthorization emphasizes student achievement, particularly the academic achievement of career and technical education students, and increases 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 these changes 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.

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 a regulation is essential to promote quality and equality of opportunity in education.
- Whether a demonstrated problem cannot be resolved without regulation.
- Whether a regulation is 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.

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

FINAL RULE STAGE

30. ● ASSISTANCE TO STATES FOR THE EDUCATION OF CHILDREN WITH DISABILITIES; PRESCHOOL GRANTS FOR CHILDREN WITH DISABILITIES; AND SERVICE OBLIGATIONS UNDER SPECIAL EDUCATION—PERSONNEL DEVELOPMENT (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

20 U.S.C. 1221e–3, 1406, 1411–1419, 1462(h)

CFR Citation:

34 CFR 300, 301 and 304

Legal Deadline:

None

Abstract:

These regulations would amend the regulations governing the Assistance to States for Education of Children with Disabilities Program, the Preschool Grants for Children With Disabilities Program, and Service Obligations under the Special Education Personnel Development to Improve Services and

Results for Children with Disabilities Program. These amendments are needed to implement changes to the Individuals with Disabilities Education Act made by the recently enacted Individuals with Disabilities Education Improvement Act of 2004.

Statement of Need:

These regulations are necessary to implement the reauthorized statute.

Summary of Legal Basis:

New legislation.

Timetable:

Action	Date	FR Cite
Notice	01/10/02	67 FR 1411
NPRM	06/21/05	70 FR 35781
NPRM Comment Period End	09/06/05	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Related to 1820–AB54

RIN: 1820–AB57

BILLING CODE 4000–01–S

DEPARTMENT OF ENERGY (DOE)

Statement of Regulatory and Deregulatory 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, environmental remediation, and energy research. The Department's mission is to:

- Promote dependable, affordable and environmentally sound production and distribution of energy;
- Foster energy 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 premiere 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

EPACT 2005, enacted on August 8, 2005, will have 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 adds new products to those already covered by the Energy Policy and Conservation Act (EPCA), but it also affects ongoing rulemakings.

With respect to those ongoing rulemakings, DOE has made it a priority to take action to clear up the backlog of regulatory action on energy efficiency standards and test procedures that are overdue under EPCA. As part of the Department's annual priority-setting process for its consumer products and commercial equipment rulemakings to be carried out under the Process Rule, 61 FR 36974 (July 15, 1996), interested members of the public will have an opportunity to give input to help the Department prioritize the rulemakings it will conduct. The Department will continue actions necessary to clear up the backlog of standards and test procedures covered by the EPCA, such as the standards for certain commercial equipment covered by amendments to American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc./Illuminating Engineering Society of North America Standard 90.1. Information and timetables concerning these actions can be found in the Department's Regulatory Agenda, which appears elsewhere in this issue of the **Federal Register**.

EPACT 2005 adds both energy conservation standards and test procedure requirements to the program. The Department will incorporate the statutorily mandated and non-discretionary energy conservation standards of EPACT 2005 into the Department's regulations before the end of 2005. Included among these are standards for commercial central air conditioners and central air conditioning heat pumps. 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.

Nuclear Safety Regulations

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

Strategic Petroleum Reserve Acquisition Procedures

The Department is committed to maintaining the Strategic Petroleum Reserve as a cornerstone of U.S. energy security policy to protect against the damaging effects of a severe energy supply interruption. The Department's recent use of the Reserve to loan oil to companies adversely affected by Hurricane Katrina, and particularly the President's authorization to draw down and sell oil from the Reserve in response to that hurricane, demonstrated both the importance of the Reserve to national security and the excellent operating condition in which DOE has maintained the Reserve.

The Department will continue to work to ensure that sufficient Reserve inventory levels are maintained to provide the appropriate degree of security. Consistent with this goal and as required by EPACT 2005, the Department will be proposing in November 2005 procedures for the acquisition of petroleum to fill the Reserve to its authorized one billion barrel capacity. The procedures must take into account a number of factors including the need to maximize availability of domestic petroleum supply while minimizing costs and adverse impacts on current and future prices, supplies and inventories. In addition, the procedures must include criteria for reviewing requests for the deferral of scheduled deliveries. As directed by EPACT 2005, the Department intends to publish final procedures in February 2006.

Standby Support

EPACT 2005 authorizes the Secretary to enter into contracts for standby support for advanced nuclear power facilities for certain unexpected delays. These delays include those caused by failure of the Nuclear Regulatory Commission to comply with schedules for review and approval of inspection, tests, analyses, and acceptance criteria established under the combined Construction Permit and Operating License process, as well as delays caused by litigation of the commencement of full-power operations of an advanced nuclear facility. The

Department is committed to openness and public participation as it develops rules and criteria for standby support and promptly will be taking action to promulgate such rules.

DOE—Energy Efficiency and Renewable Energy (EE)

PRERULE STAGE

31. ● RULEMAKING TO DETERMINE WHETHER THE ENERGY CONSERVATION STANDARDS FOR RESIDENTIAL CENTRAL AIR CONDITIONERS AND AIR CONDITIONING HEAT PUMPS SHOULD BE AMENDED

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6295(d)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 2001, Overdue for review of whether amended standard is justified.

Abstract:

The Department is committed to becoming current on all energy standards rulemakings, including whether the current standards for residential central air conditioners and central air conditioning heat pumps should be amended.

Statement of Need:

Standards need to be periodically reviewed and updated, as required by EPCA, to reflect technological advances that make amended energy efficiency standards technologically feasible and economically justified.

Alternatives:

Congress has the ability to prescribe amended standards, as it did for some consumer products and industrial equipment through EPACT 2005, rather than DOE conducting rulemakings to determine whether amended standards are appropriate.

Timetable:

Action	Date	FR Cite
ANPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

The timetable for this action will be determined during the annual priority-setting of rulemakings.

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RIN: 1904–AB47

DOE—EE

32. ● RULEMAKING TO DETERMINE WHETHER THE ENERGY CONSERVATION STANDARDS FOR RESIDENTIAL WATER HEATERS SHOULD BE AMENDED

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6295(e)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 2000, Overdue for review of whether amended standard is justified.

Abstract:

The Department is committed to becoming current on all energy standards rulemakings, including whether the current standards for residential water heaters should be amended.

Statement of Need:

Standards need to be periodically reviewed and updated, as required by EPCA, to reflect technological advances that make amended energy efficiency standards technologically feasible and economically justified.

Alternatives:

Congress has the ability to prescribe amended standards, as it did for some consumer products and industrial equipment through EPACT 2005, rather than DOE conducting rulemakings to determine whether amended standards are appropriate

Timetable:

Action	Date	FR Cite
ANPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

The timetable for this action will be determined during the annual priority-setting of rulemakings.

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RIN: 1904–AB48

DOE—EE

33. ● RULEMAKING TO DETERMINE WHETHER THE ENERGY CONSERVATION STANDARDS FOR ELECTRIC AND GAS RANGES AND OVENS, AND FOR MICROWAVE OVENS SHOULD BE AMENDED

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6295(h)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 1997, Overdue for review of whether amended standard is justified.

Abstract:

The Department is committed to becoming current on all energy standards rulemakings, including whether the current standards for electric and gas ranges and ovens and microwave ovens should be amended.

Statement of Need:

The Department may determine that separate rulemakings may be warranted for some of these individual products or equipment. The timetable for this action will be determined during the annual priority-setting of rulemakings

Alternatives:

Congress has the ability to prescribe amended standards, as it did for some consumer products and industrial equipment through EPACT 2005, rather than DOE conducting rulemakings to determine whether amended standards are appropriate

Timetable:

Action	Date	FR Cite
ANPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

The timetable for this action will be determined during the annual priority-setting of rulemakings.

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RIN: 1904–AB49

DOE—EE

34. • RULEMAKING TO DETERMINE WHETHER THE ENERGY CONSERVATION STANDARDS FOR FLUORESCENT LAMP BALLASTS SHOULD BE AMENDED

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6295(g)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 2006.

Abstract:

This rulemaking is to determine whether the current standards for fluorescent lamp ballasts should be amended.

Statement of Need:

Standards need to be periodically reviewed and updated, as required by EPCA, to reflect technological advances that make amended energy efficiency standards technologically feasible and economically justified.

Alternatives:

Congress has the ability to prescribe amended standards, as it did for some consumer products and industrial equipment through EPACT 2005, rather than DOE conducting rulemakings to determine whether amended standards are appropriate.

Timetable:

Action	Date	FR Cite
ANPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

The timetable for this action will be determined during the annual priority-setting of rulemakings.

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RIN: 1904–AB50

DOE—EE

35. • RULEMAKING TO DETERMINE WHETHER THE ENERGY CONSERVATION STANDARDS FOR ROOM AIR CONDITIONERS SHOULD BE AMENDED

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 6295(c)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, September 24, 2002, Overdue for review of whether amended standard is justified.

Abstract:

The Department is committed to becoming current on all energy standards rulemakings, including whether the current standards for room air conditioners should be amended.

Statement of Need:

Standards need to be periodically reviewed and updated, as required by EPCA, to reflect technological advances that make amended energy efficiency standards technologically feasible and economically justified.

Alternatives:

Congress has the ability to prescribe amended standards, as it did for some consumer products and industrial equipment through EPACT 2005, rather than DOE conducting rulemakings to determine whether amended standards are appropriate.

Timetable:

Action	Date	FR Cite
ANPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Federalism:

Undetermined

Additional Information:

The timetable for this action will be determined during the annual priority-setting of rulemakings.

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RIN: 1904–AB51

DOE—EE

PROPOSED RULE STAGE

36. ENERGY EFFICIENCY STANDARDS FOR RESIDENTIAL FURNACES AND BOILERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 6295(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. The process improvements that were announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternatives in the appliance standards development process. For example, under this process, the Department will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The specific costs and benefits 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 NOx. Establishing standards that are too stringent could result in excessive increases in the cost of the product and possible reductions in product utility. It might also place an undue burden on manufacturers that could result in loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
ANPRM	09/08/93	58 FR 47326
Framework Workshop	07/17/01	
Venting Workshop	05/08/02	
ANPRM	07/29/04	69 FR 45419
DOE Review of Technical Support Documents	08/11/05	
Electricity Use Workshop	01/00/06	
NPRM	09/00/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local, State

Additional Information:

DOE is planning a workshop on electricity use because section 135(c) of EPACT 2005 expanded DOE's authority to consider electricity used by furnaces for moving air through the ductwork. DOE may revise the timetable if the outcome of the workshop indicates that such revision is appropriate.

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RIN: 1904–AA78

DOE—EE

37. ENERGY EFFICIENCY STANDARDS FOR ELECTRIC DISTRIBUTION TRANSFORMERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6317(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 recently adopted in EPACT 2005, Pub. L. No. 109-58, sec. 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. The Department will also incorporate into its regulations the standards recently incorporated into EPCA.

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 USC 6311-6317, establishes a program for ''Certain Industrial Equipment,'' similar to the one for consumer products in Part B, and includes distribution transformers. Since EPACT 2005, Pub. L. No 109-58, sec. 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. The process improvements that were announced July 15, 1996, 61 FR 36974, further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The specific costs and benefits for this rulemaking have not been established because the final standard levels have not been determined. Nevertheless, existing analysis from the Advance Notice of Proposed Rulemaking, 69 FR 45375, for energy conservation standards for distribution transformers projects savings of from 7 to 16 quadrillion Btus of energy from 2007 to 2035, with a national financial impact on the consumer in terms of national Net Present Value (NPV) ranging from 4 to 12.77 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
DOE Review of Technical Support Documents	08/11/05	
NPRM	09/00/06	
Final Action	09/00/07	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

The timetable for this action reflects program priorities, which were established with significant input from the public. The Department is also assessing how it should proceed to incorporate into its rules the standards prescribed in EPACT 2005 for low voltage dry-type electric distribution transformers.

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RIN: 1904–AB08

DOE—Departmental and Others (ENDEP)

PROPOSED RULE STAGE

38. ● ACQUISITION OF PETROLEUM FOR STRATEGIC PETROLEUM RESERVE

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6240

CFR Citation:

Not Yet Determined

Legal Deadline:

NPRM, Statutory, December 6, 2005.

Final, Statutory, February 6, 2006.

Abstract:

This action would establish procedures for the acquisition of petroleum to fill the Strategic Petroleum Reserve to the one billion barrel capacity authorized under Section 154(a) of the Energy Policy and Conservation Act. The procedures must include criteria for reviewing requests for deferral of scheduled deliveries.

Statement of Need:

The recently enacted Energy Policy Act of 2005 requires promulgation of these procedures. Procedures for filling strategic stocks must take into account the need to maximize availability of domestic petroleum supply while minimizing costs and adverse impacts on current and future prices, supplies and inventories

Summary of Legal Basis:

The Energy Policy and Conservation Act provides the Department with broad authority to acquire petroleum for the Reserve and sets broad objectives as to the manner in which such acquisition is made. The Energy Policy Act of 2005 amended the Energy Policy and Conservation Act to require the Department to develop, with public notice and opportunity to comment, and comply with procedures to acquire oil to fill the Strategic Petroleum Reserve. The proposed procedures shall address acquisition by various means, including purchase, transfer of royalty oil from the Department of the Interior and deferral of deliveries under contracted schedules. These governing objectives set forth in the Energy Policy and Conservation Act are the minimization of costs, vulnerability to a supply disruption, and impact on supply levels and market forces, while maximizing encouraging competition in the petroleum industry. While recent fill has utilized the receipt of royalties-in- kind from Federal offshore production and premium barrels generated through renegotiation of delivery schedules, proposed procedures will also address outright purchase of crude oil. DOE also may acquire oil, and may address in its procedures, country-to-country oil purchases, facility leases with payments in oil, contracts for oil not owned by the United States as provided for by section 171 of the Energy Policy and Conservation Act, and return of oil and associated in-kind premiums for withdrawals from the Reserve for oil exchanges

Alternatives:

The governing objectives for the procedures set forth in the Energy Policy and Conservation Act, are the minimization of costs, vulnerability to a supply disruption, and impact on supply levels and market forces, while encouraging competition in the petroleum industry. While recent fill has utilized the receipt of royalties-in-kind from Federal offshore production and premium barrels generated through renegotiation of delivery schedules, proposed procedures will also address outright purchase of crude oil. There are other circumstances during which the Department of Energy may acquire oil for the Strategic Petroleum Reserves.

Anticipated Cost and Benefits:

The specific costs and benefits for this rulemaking have not been established because of the uncertainty inherent in petroleum markets in general, the schedule of fill according to the development of strategic storage capacity and the timing of any drawdown in response to a supply disruption. However, several studies reinforce the value of a larger Reserve in mitigating the adverse economic impacts of a disruption, either through deterrence or supplemental supply. Additionally, global stockpiling is enhanced through example.

Risks:

This rulemaking may reduce the risk of adverse market price and supply impacts from filling the Reserve by providing transparency into acquisition procedures and assurances that the statutory objectives are met.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	
Final Action	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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DOE—ENDEP

FINAL RULE STAGE

39. 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
Integrate new EPA guidance	03/00/06	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Additional Information:

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

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DOE—ENDEP

40. WORKER SAFETY AND HEALTH

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

10 CFR 851

Legal Deadline:

Final, Statutory, December 2, 2003.

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

None

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	12/08/03	68 FR 68276
NPRM Comment Period End	02/06/04	
NPRM Suspension	02/27/04	69 FR 9277
Supplemental NPRM	01/26/05	70 FR 3811
Supplemental NPRM Comment Period End	04/26/05	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

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

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DOE—ENDEP

41. ● STANDBY SUPPORT FOR ADVANCED NUCLEAR FACILITY DELAYS

Priority:

Other Significant

Unfunded Mandates:

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

Legal Authority:

PL 109–58, sec 638

CFR Citation:

Not Yet Determined

Legal Deadline:

Final, Statutory, August 8, 2005.

Other, Statutory, May 6, 2006, Interim Final Rule.

Abstract:

The Energy Policy Act of 2005 (EPACT 2005) authorizes the Secretary to provide standby support for sponsors of advanced nuclear power facilities for certain unexpected delays such as those caused by litigation or Nuclear Regulatory Commission (NRC) licensing problems that delay a facility from obtaining full power operation.

Statement of Need:

A number of nuclear power facilities built in the U.S. during the 1970's and 1980's experienced long delays in obtaining authorization to operate at full power after completed and initial operating licenses were granted. As a result of these delays, the cost of many nuclear facilities built during this period increased dramatically. To reduce such delays, and as authorized the Congress in the Energy Policy Act of 1992, the NRC adopted a one-step combined ''Construction Permit and Operating Licensing'' process. However, the new Construction Permit and Operation Licensing process has not been tested, since no new nuclear power facility has been ordered and commissioned in over two decades. In response to concerns regarding the untested process, EPACT 2005 allows the Secretary of Energy to enter into contracts with sponsors of advanced nuclear power facilities for standby support payments to cover the costs related to certain ''covered delays'' (described below) in the licensing process.

Summary of Legal Basis:

EPACT 2005 provides for standby support contracts for a total of six advanced power reactors consisting of no more than three different designs. Under such contracts, the Department would pay for 100 percent of the covered costs associated with covered delays for the first two reactors, up to $500 million each, and 50 percent of the covered costs for the four remaining reactors, up to $250 million each. Covered delays include failure of the NRC to comply with schedules for review and approval of inspections, tests and analyses, and acceptance criteria established by the NRC, and litigation that delays the commencement of full-power operations of the advanced nuclear power facility. Covered costs include principal or interest on any debt obligation and the incremental difference between the fair market price of power purchases but for the delay and the contractual price or power from the advanced nuclear facility subject to the delay. The Department would not cover those costs that are caused by the failure of the project sponsor to take any action required by law or regulation, events within the control of the sponsor, or normal business risks.

Alternatives:

EPACT 2005, enacted on August 8, 2005, requires the Secretary of Energy to issue for public comment an interim final rulemaking governing contracts for standby support no later than 270 days after enactment, which is May 6, 2006. In addition, DOE is required to finalize the rule no later than August 8, 2006. The Department is currently working to formulate and implement the rule.

Anticipated Cost and Benefits:

The specific costs and benefits of this rulemaking have not been established because the specific aspects of the rule have not been determined.

Risks:

Regulatory uncertainty regarding the delay of full-power operations of the first advanced nuclear power facilities is viewed as a serious risk to sponsors of such nuclear facilities. A regulation providing sponsors standby support for advanced nuclear power facilities would provide financial incentives for sponsors to build such facilities. Absent such a regulation, it is less likely that sponsors will construct new nuclear facilities.

Timetable:

Action	Date	FR Cite
Notice of Inquiry	10/00/05	
Workshop	11/00/05	
Interim Final Rule	05/00/06	
Final Action	08/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Timetable reflects program priorities.

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RIN: 1901–AB17

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 the American public. HHS programs assist some of the nation's most vulnerable populations, including children, the elderly, and persons with disabilities. Specifically, these programs 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.

HHS Secretary Michael O. Leavitt uses a 500-Day Plan as a management tool to focus his energies in overseeing these programs. The Plan is an expression of many of Secretary Leavitt's priorities, and it provides direction to the daily leadership and management of the Department. (The public may electronically access the Secretary's 500-Day Plan at *http://www.hhs.gov/500DayPlan.)* The strategies articulated in the 500-Day Plan guide many actions the Department will take during the ensuing 500-day period to achieve significant progress for the American people over the long term.

''Modernizing Medicare and Medicaid'' is one of the goals cited in the 500-Day Plan. While HHS has largely completed the regulatory framework needed for implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, many other regulatory actions remain necessary to assure the continuing modernization of the Medicare and Medicaid programs. The Department wishes to emphasize the importance of the following Medicare and Medicaid-related actions by including them in its Fiscal Year (FY) 2006 Regulatory Plan:

- final rules establishing new requirements that organ procurement organizations and organ transplant centers must meet to have their services covered by Medicare. Promulgation of the outcome and performance measures in these rules will increase organ donation and transplantation in the United States. The rules will ensure that Medicare-covered transplants are performed in a safe and efficient manner, serving to keep Medicare requirements current with state-of-the-art medical practice in transplantation;
- a proposal to institute competitive bidding procedures to improve the effectiveness of Medicare's current methodology for setting payment amounts for durable medical equipment;
- proposed and final rules establishing annual adjustments in payment amounts under Medicare for physicians' services (for calendar year 2006), and for hospital inpatient and outpatient services (for FY 2007); and
- an advance notice of proposed rulemaking, seeking public input regarding ideas presented in the President's FY 2006 Budget and in a report to Congress by the Medicare Payment Advisory Commission recognizing needs for payment reforms to improve the quality and value of care delivered to Medicare beneficiaries. This initiative explores the concept of ''paying for performance'' as a means of promoting better quality of care in Medicare fee-for-service payment systems.

The Secretary's 500-Day Plan also includes a goal with emphasis on securing the homeland. The FY 2006 Regulatory Plan accordingly includes a notice of proposed rulemaking which would update existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The proposed regulations would offer for public comment procedures that adequately address quarantine in the 21st century. Some of the key provisions in the proposed regulations will include: requirements for expanded reporting of ill passengers on board foreign and interstate carriers; requirements that carriers maintain passenger and crew lists and submit such lists electronically upon request; and explicit due process protections. These procedures are expected to expedite and improve operations by allowing immediate medical follow-up of potentially infected passengers and their contacts.

Another of the Secretary's 500-Day Plan strategies involves the enabling of health care consumers to be better informed and to have more choices. The following regulatory actions included in the FY 2006 Regulatory Plan reflect this strategy:

- a proposal to move to electronic registration with the Food and Drug Administration (FDA) of drug companies and of listings of the drugs they produce, so that the agency may be better equipped to conduct its postmarketing surveillance programs, and to proactively communicate important information about drug products on the market to providers and patients;
- a proposal to amend FDA's regulations to require that clinical study data be provided in electronic format, using standard data structure, terminology, and code sets. The change would further increase the efficiency of the agency's review processes, thus speeding up the availability of new therapies;
- a final rule requiring the labeling of human drugs to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes, not for medical advice;
- a proposal to amend existing regulations governing investigational new drugs, to describe the way patients may obtain investigational drugs for treatment use. Treatment use of investigational drugs would be available to: individual patients, including in emergencies; intermediate size patient populations; and larger populations under a treatment protocol.
- a final rule establishing in regulation good manufacturing practices for the dietary-supplement products favored by many Americans; such a requirement will ensure both product safety and quality, and assure consumers that these products have the identity and quality declared in their labeling;
- a final rule to facilitate health care practitioners' access to prescription-drug labeling information through streamlined formatting requirements for such information, enabling them to better communicate important information to their patients; and
- a proposal to modify prescription drug labeling so that health care providers may better understand and communicate to their patients the risks and benefits of use of medicines during pregnancy and lactation.

HHS—Centers for Disease Control and Prevention (CDC)

PROPOSED RULE STAGE

42. 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 (HHS) 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. Interstate authority is split between CDC and the Food and Drug Administration (FDA), with CDC delegated interstate authority as it pertains to humans. CDC maintains quarantine stations at 8 major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President of the United States 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 remergent 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, 264-271. 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:

The proposed 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. From a due process perspective, the proposed regulation would clarify administrative procedures, and would detail the elements generally recognized as essential to comport with constitutional requirements. Those elements include: Reasonable and adequate notice; opportunity to be heard in a reasonable time and manner; access to legal counsel; review by an impartial decision-maker; and written articulation of the rationale underlying the decision.

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	11/00/05	

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

43. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

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

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

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

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AA49

HHS—FDA

44. SUBMISSION OF STANDARDIZED ELECTRONIC STUDY DATA FROM CLINICAL 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

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data (CSD) 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 CSD 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 to allow for more efficient and comprehensive review of CSD.

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 (CSD) that are submitted as part of the marketing application. At present, FDA accepts CSD in paper and electronic formats. When CSD are submitted to FDA only on paper, the information must be transcribed by hand into electronic form for review and analysis. This process is extremely time consuming and is prone to data entry error. CSD submitted to FDA in electronic format have generally been more efficient to process and review.

FDA's proposed rule would require the submission of CSD in a standardized electronic format. The standardized CSD format would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive CSD more efficiently. Standardization of CSD 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 CSD 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 CSD, but not requiring electronic submission of CSD 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:

FDA estimates that the costs to industry resulting from the proposal would include some one-time costs and some potential annual recurring costs. One-time costs would include, among other things, the cost of converting CSD to standard structures, terminology, and cost sets (i.e., purchase of software to convert CSD); the cost of submitting electronic CSD (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 and for the agency, including improved patient safety through more efficient, comprehensive, and accurate data review; enhanced communication among sponsors, clinicians, and FDA through improved access to and sharing of CSD; and reduced data management costs through the standardization of data formats.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

45. 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 201.57

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 and 201.57).

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). If the labeling is affected by the PLR, firms would be required to revise the pregnancy labeling section according to the new content and format requirements of the pregnancy rule and to submit the revised labeling to FDA for approval. For product labeling of older products not affected by the PLR, the current pregnancy category would be removed. In addition to the one-time costs, firms would incur ongoing incremental printing costs for product labeling affected by the PLR. Over 7 years, the present value of the total costs of the proposed rule is anticipated to range from about $25 million with a 7 percent discount rate to about $30 million with a 3 percent discount rate.

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	09/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

46. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 353; 21 USC 355; 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 (INDs) to describe the ways patients may obtain investigational drugs for treatment use. Treatment 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 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 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 those types of treatment use that are specifically described in the Modernization Act. However, the agency concluded that it would be preferable to establish, as authorized by the Modernization Act, a third category of treatment use that would be used for more than an individual patient, but fewer than the large numbers of patients in treatment INDs or treatment protocols.

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 fourth and fifth 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	04/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Organizations

Government Levels Affected:

None

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HHS—FDA

FINAL RULE STAGE

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

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

21 CFR 201

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

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

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

The proposed rule, published in 2000, described format and content requirements for prescription drug labeling that incorporate information and ideas gathered during this process. The comment period was extended until June 22, 2001, and the agency received close to 100 comments on the proposal.

Summary of Legal Basis:

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

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

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

Alternatives:

The alternatives to the final rule include not amending the content and

format requirements in sections 201.56 and 201.57 at all, or amending them to a lesser extent. The agency has determined that although drug product labeling, as currently designed, is useful to physicians, many find it difficult to locate specific information in labeling, and some of the most frequently consulted and most important information is obscured by other information. In addition, the agency's research showed that physicians strongly support the concept of including highlights of the most important prescribing information, a table of contents and numbering system that permits specific information to be easily located, and other requirements, such as the requirement for a minimum type size. Thus, the agency believes that the requirements in the final rule will greatly facilitate health care practitioners' access and use of prescription drug and biological product labeling information.

Anticipated Cost and Benefits:

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

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

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/22/00	65 FR 81082
NPRM Comment Period End	03/22/01	
NPRM Comment Period Reopened	03/30/01	66 FR 17375
NPRM Comment Period Reopening End	06/22/01	
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

48. 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	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

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

Priority:

Other Significant

Legal Authority:

21 USC 355b

CFR Citation:

21 CFR 201; 21 CFR 208; 21 CFR 209

Legal Deadline:

Final, Statutory, January 4, 2003.

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/22/04	69 FR 21778
NPRM Comment Period End	07/21/04	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—Centers for Medicare & Medicaid Services (CMS)

PRERULE STAGE

50. • INNOVATIONS IN FEE–FOR–SERVICE PAYMENT SYSTEMS TO IMPROVE QUALITY AND OUTCOMES (CMS–1298–ANPR)

Priority:

Other Significant

Legal Authority:

None

CFR Citation:

None

Legal Deadline:

None

Abstract:

This advance notice of proposed rulemaking explores the concept of ''paying for performance'' as a means of promoting better quality of care in Medicare fee-for-service payment systems. It explains the concept in general and reports on a number of activities of the Center for Medicare and Medicaid Services measuring and reporting and in possible ways these results could be used to create financial incentives for high quality care. The notice seeks public comments on these ideas.

Statement of Need:

The President's FY 2006 Budget and the Medicare Payment Advisory Commission (MedPAC) 2005 Report to Congress recognized the need for payment reforms to improve the quality and value of care delivered to Medicare beneficiaries. Currently, Medicare fee-for-service payment systems pay health care physicians and providers a pre-determined amount based on the number and complexity of covered services provided to patients regardless of quality, efficiency, or impact on beneficiary health outcomes. CMS is examining ways to introduce enhanced methods of payment into the Original Medicare program that will improve the quality and value of care delivered to Medicare beneficiaries, particularly the concept of ''paying for performance.'' This notice seeks public comment on paying for performance to create greater financial support and incentives for high quality care.

Summary of Legal Basis:

The purpose of this notice is to examine potential innovations to Medicare's fee-for-service payment systems and to seek public comment on those ideas. Because the notice only seeks comments, no specific legal authority is required.

Alternatives:

The notice examines and seeks public comment on paying for performance, one potential innovation to Medicare's fee-for-service payment systems. Interested parties are asked to comment on the issues set forth in the notice, but are free to comment on alternative innovations.

Anticipated Cost and Benefits:

This Medicare initiative explores the potential benefits of ''paying for performance'' as a means of promoting better quality of care and health outcomes for beneficiaries and for promoting efficiency in Medicare fee-for-service payment systems. No costs are anticipated at this time.

Risks:

Developing and implementing innovations in Medicare's fee-for-service payment systems requires careful planning and extensive interaction with interested parties. Seeking public comments will assist CMS in fully considering issues and developing policies.

Timetable:

Action	Date	FR Cite
ANPRM	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HHS—CMS

PROPOSED RULE STAGE

51. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES AND RESIDUAL ISSUES (CMS–1270–P)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 108–173, MMA

CFR Citation:

42 CFR 414.200; 42 CFR 405.502(g); 42 CFR 424.57; 42 CFR 410.38

Legal Deadline:

Final, Statutory, January 1, 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 also create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. (The statute requires competitive bidding be implemented by January 1, 2007.)

Statement of Need:

Section 302 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003

(MMA)(Pub.L. 108-173) authorizes the Secretary to use our competitive acquisition authority, as outlined in the U.S. Code Section 1847(a). Section302 (b)(1) of the Medicare Modernization Act, requires Medicare to replace the current DME payment methodology for certain items with a competitive bidding process to improve the effectiveness of its methodology for setting DME payment amounts.

The competitive bidding program is to be phased-in over a 4-year period beginning in 2007. The law requires that competitive bidding be conducted in ten of the largest metropolitan statistical areas in 2007, in 80 of the largest metropolitan statistical areas in 2009, and in additional areas after 2009.

Summary of Legal Basis:

MMA Section 302 (b)(1)

Alternatives:

None. Required by MMA.

Anticipated Cost and Benefits:

This initiative will result in substantial savings to the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	
Final Action	08/00/08	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State

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HHS—CMS

52. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2007 RATES (CMS–1488–P)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Sec 1886(d) of the Social Security Act

CFR Citation:

42 CFR 405; 42 CFR 412; 42 CFR 413; 42 CFR 415; 42 CFR 419; 42 CFR 422; 42 CFR 485

Legal Deadline:

NPRM, Statutory, April 1, 2006.

Final, Statutory, August 1, 2006.

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. The Addendum to this proposed rule proposes changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These proposed changes would apply to discharges occurring on or after 10/1/06. It also proposes rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

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 hospital, 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 this proposed rule be published by 4/1/06. It also requires that the subsequent final rule be published by 8/1/06.)

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

We project the payment rate updates to hospitals would increase by over $3 billion from FY 2006 to FY 2007. Total IPPS payments are approximately $110 billion.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—CMS

FINAL RULE STAGE

53. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–IFR) (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1302 et al

CFR Citation:

42 CFR 413; 42 CFR 441; 42 CFR 486; 42 CFR 498

Legal Deadline:

Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

Abstract:

This rule establishes conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from two years to four years and to promulgate new performance standards for OPOs.

Statement of Need:

As required by the Organ Procurement Organization Certification Act of 2000 and Section 219 of the Consolidated Appropriations Act, 2001, this rule sets forth multiple new outcome and process performance measures for OPOs, as well as a new appeals process for OPOs to appeal a decertification based on substantive and procedural grounds.

Summary of Legal Basis:

Section 1138(b) of the Social Security Act (the Act) provides the statutory qualifications and requirements that an OPO must meet to receive payment for organ procurement costs associated with procuring organs for hospitals under the Medicare and Medicaid programs. This section gives the Secretary broad authority to establish performance-related standards for OPOs. Under this authority, the Secretary established conditions for coverage for OPOs at 42 CFR 486.301, et seq. Section 1138(b) of the Act specifies that an OPO must be certified or re-certified by the Secretary as meeting the standards to be a qualified OPO as described in section 371(b) of the Public Health Service (PHS) Act. The PHS Act requirements were established by the National Organ Transplant Act of 1984 and include provisions for OPO board membership, staffing, agreements with hospitals, and membership in the OPTN. The Organ Procurement Organization Certification Act of 2000 (42 U.S.C. Section 273(b)(1)(D)) amended section 371(b) of the PHS Act to require CMS to promulgate multiple new outcome and process performance measures for OPOs and develop a new process for OPOs to appeal a de-certification based on substantive and procedural grounds.

In addition, section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. This section of the Act gives the Secretary broad authority to establish requirements for OPOs that are necessary for the efficient administration of the Medicare program.

Alternatives:

CMS has considered various alternatives in developing outcome and process performance measures. CMS will implement measures based on donor potential and other related factors in OPO service areas.

Anticipated Cost and Benefits:

CMS believes the provisions contained in this rule would have little or no economic impact on hospitals. CMS' best estimate of the impact of this proposed rule is a benefit of more than $1 billion each year, based on the number of lives we expect would be saved by an increase in organ donation and transplantation due to increased OPO performance, thereby decreasing deaths of patients waiting for organs. Increasing organ donation and transplantation is a priority for the Secretary as evidenced by the Secretary's Donation Initiative (Initiative); launch of the Initiative was one of the Secretary's first actions.

In addition, the rule includes requirements to guard against medical errors that can lead to transplantation of organs of the wrong blood type or transmission of infectious disease to transplant recipients.

Risks:

Failure to publish the rule may decrease organ donation and transplantation, thereby increasing deaths of patients waiting for organs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/01	66 FR 67109
NPRM	02/04/05	70 FR 6086
Interim Final Rule	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

54. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES (CMS–1501–FC)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

BBA; BBRA; BIPA; MMA

CFR Citation:

Not Yet Determined

Legal Deadline:

Final, Statutory, November 1, 2005.

Abstract:

The final rule would adjust payments under the Medicare hospital outpatient payment system beginning January 1, 2006.

Statement of Need:

Medicare pays over 4,200 hospitals for outpatient department services under the Outpatient Prospective Payment

System. The OPPS is based on groups of clinically similar services called Ambulatory Payment Classifications (APCs). CMS annually revises the APC payment amounts based on claims data, proposes new payment polices, and updates the payments for inflation using the market basket. The proposed and final rule solicit comments on the proposed OPPS payment rates and new policies. This final does not impact payments to Critical Access Hospitals as they are not paid under the OPPS.

Summary of Legal Basis:

Section 1833(t) of the Social Security Act establishes Medicare payment for hospital outpatient services. The proposed and final rules revise the Medicare hospital outpatient prospective payment system (OPPS) to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug Improvement, and Modernization Act (MMA) of 2003, Pub. L. 108-173. In addition, the proposed and final rule describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2006.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

The estimated outpatient hospital expenditures in 2006 will approximate more than $27 billion.

Timetable:

Action	Date	FR Cite
NPRM	07/25/05	70 FR 42674
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—CMS

55. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–FC)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Social Security Act, sec 1102; Social Security Act, sec 1871

CFR Citation:

42 CFR 410; 42 CFR 414

Legal Deadline:

Final, Statutory, November 1, 2005.

Abstract:

This rule would make several changes affecting the Medicare part B payment. This rule also finalizes portions of an interim final rule published on July 6, 2005 (70 FR 39022) establishing a competitive acquisition program for purchase of some Part B drugs.

Statement of Need:

The statute requires that we establish each year, by regulation, payment amounts for all physician's services furnished in all fee schedule areas. The statute also requires that annual adjustments to physician fee schedule RVUs not cause annual payments to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to preserve budget neutrality.

Under the physician fee schedule, we assign RVUs to each physician service according to the relative amount of resources involved in furnishing those services. There are three separate RVUs for each service corresponding with the relative physician work, practice expense, and malpractice costs associated with providing the service. The RVUs are converted to a dollar amount by multiplying them by a conversion factor.

The final rule has a statutory publication date of November 1, and implementation of January 1, 2006.

We explain the proposed changes to Medicare Part B physician payment policy. We also explain that we are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

Summary of Legal Basis:

Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848(b) (1) of the Act imposes a deadline of on later than November 1 for publication of the final physician fee schedule rule.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

We project expenditures of $56.5 billion in 2006. Including beneficiaries' deductible and coinsurance amounts, total payment for physician fee schedule services in 2006 are projected to be $74.3 billion.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	08/08/05	70 FR 45763
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

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Related RIN: Related to 0938–AN04

RIN: 0938–AN84

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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 attacks 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/interweb/assetlibrary/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.

Each regulatory project outlined in the Fall Regulatory Program and the Unified Agenda is linked to the Department's Strategic Plan and departmental goals and objectives.

On July 13, 2005, the Secretary of Homeland Security announced a new 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 Secretary's six-point agenda and will improve the Department's ability to accomplish its primary mission and strategic goals.

The Department 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 in the impact its rules have on small businesses. DHS and each of its components continue to emphasize the use plain language in our notices and rulemaking documents to promote better understanding of regulations and increased public participation in its rulemakings.

DHS joined the Environmental Protection Agency Federal Partner On-line Electronic Docket System (EDocket) in September 2004. In September 2005, EDOCKET will be replaced by the Federal Docket Management System (FDMS) located at www.regulations.gov. Because the Coast Guard and the Transportation Security Administration (TSA) originally were included in the Department of Transportation's (DOT) electronic Docketing Management System, those agencies currently remain on DOT's docket and their dockets continue to be accessible at dms.dot.gov. We anticipate that the Department, including the Coast Guard and TSA, will be fully migrated to FDMS during fiscal year 2006.

Office of the Secretary

The Fall 2005 Regulatory Plan for the Office of the Secretary of Homeland Security includes regulations sponsored by the Department's five major divisions or directorates: Border and Transportation Security; Emergency Preparedness and Response; Science and Technology; Information Analysis and Infrastructure Protection; and Management.[1] 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 Federal Emergency and Management Agency, the Bureau of Customs and Border Protection, the Transportation Security Administration, and the Bureau of Immigration and Customs Enforcement. The Regulatory Plans for these DHS components are discussed separately below.

During fiscal year 2006, DHS 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

[1] On July 13, 2005, the Secretary of Homeland Security announced a proposed reorganization of the Department. Pursuant to the reorganization, the directorates listed above may be subject to change during fiscal year 2006, and will be updated in the Spring Unified Agenda for 2006.

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. During 2004, the US-VISIT program was expanded to include persons entering the United States under the Visa Waiver Program. For fiscal year 2006, 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. DHS also is extending US-VISIT to all land border ports of entry and expects to make the program operational at these ports by December 31, 2005. 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.

DHS also expects to finalize the interim rule on Procedures for Handling Critical Infrastructure Information (CII). This rulemaking will establish 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 will support 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 2006, the Department intends to finalize its interim rule on the SAFETY ACT. The SAFETY ACT regulation implements the Support Anti-Terrorism by Fostering Effective Technology Act found at subtitle G of the Homeland Security Act of 2002 (Homeland Security Act). This rule would provide critical incentives for the development and deployment of antiterrorism technologies by providing liability protections for sellers of ''qualified antiterrorism technologies'' and others. This rule would amend the February 2004 interim rule which established uniform procedures to implement the Critical Infrastructure Information Act of 2002. These procedures govern the receipt, validation, handling, storage, marking and use of critical infrastructure information voluntarily submitted to the Department. The procedures are applicable to all Federal, State, local, and tribal government agencies and contractors that have access to, or handle, use or store critical infrastructure information that enjoys protection under the Critical Infrastructure Information Act of 2002.

United States Coast Guard

The United States 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. Each of the rulemaking projects identified for the Coast Guard in the Unified Agenda, and the three the rules appearing on the Fall 2005 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 55 rulemaking projects in the final-rule, long-term actions, or proposed-rule stages in this Unified Agenda.

There are three rules in the Department's Fall 2005 Regulatory Plan that are of particular interest to the Coast Guard: (1) Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents (Chemical Testing final rule); (2) Vessel Requirements for Notices of Arrival and Departure, Carriage of Automatic Identification System; and (3) Validation of Merchant Mariners' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry. The Chemical Testing final rule revises the requirements for alcohol testing after a serious marine incident to comply with the 1998 Coast Guard Authorization Act, Public Law 105-383. This final rule modifies the drug and alcohol testing rules following a serious marine incident to require that alcohol testing be conducted within 2 hours of a serious marine incident (SMI), requires most commercial vessels to have alcohol testing devices on board, and authorizes saliva as an acceptable specimen for alcohol testing. It also adds a 32-hour time limit for collecting drug test specimens following a serious marine incident. Commercial vessels able to conduct alcohol testing at a shore side testing facility with two hours of a serious marine incident will be exempt from the requirement to carry alcohol-testing devices on board. This final rule comports with the Coast Guard strategic goal of ensuring maritime safety.

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. To remedy this situation, the Coast Guard is issuing ''Vessel Requirements for Notices of Arrival and Departure (NOAD), and Carriage of Automatic Identification System (AIS),'' an interim final 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 interim rule would expand the applicability of NOADs to include all foreign commercial vessels, regardless of tonnage, and more U.S. commercial vessels including all of those arriving from a foreign port or place. This interim rule also would expand the Coast Guard's AIS carriage requirements to all commercial vessels identified in the Maritime Transportation Act of 2002, and include vessels carrying 50 passengers (vice the current 150 or more passengers for hire), carrying or towing certain dangerous cargo, certain dredges and certain high speed passenger craft. This rulemaking supports the Commandant's strategic goals of maritime safety and maritime security.

The Coast Guard interim rule ''Validation of Merchant Mariners' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry,'' would amend the maritime personnel licensing rules to include new security requirements when mariners apply for original, renewal, and raise of grade licenses and certificates of registry. This rule would require all applicants for licenses and certificates of registry to have their identity verified and their fingerprints taken for a criminal records check by

the Coast Guard. This interim final rule has the goal of furthering all five of the Commandant's strategic goals.

The Coast Guard, through the rulemaking projects identified in the Regulatory Plan and the Unified Agenda, plans to continue to meet its multi-mission, regulatory obligations as reflected in its strategic and policy goals, the Department's goal of securing the homeland from terrorist attacks, and the goals of the President's Six-Point Plan for Economic Growth.

The Coast Guard continues to use plain language in its notices and rulemaking documents to promote better understanding of regulations and increased public participation in its rulemakings. The Coast Guard encourages early public involvement in this process and takes particular concern in the impacts its rules have on small businesses. It 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 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 United States Citizenship and Immigration Services' (USCIS) mission is to restore public confidence in the integrity of America's immigration services by making certain that those immigrant applicants meeting our statutory and regulatory requirements, such as those provided by the Immigration and Nationalization Act (INA) and its implementing regulations, duly receive all rights and benefits granted by law. USCIS accomplishes this central mission through the granting of immigration and citizenship benefits to qualified beneficiaries, while working to ensure the integrity of our immigration system overall. In accordance with the USCIS mission statement, USCIS' key regulatory initiatives for DHS' 2005 Fall Regulatory Program and Unified Agenda focus on eliminating the USCIS benefit application backlog and providing immigration-related humanitarian relief to victims of human trafficking and abuse.

The USCIS key regulatory initiatives that govern nonimmigrant classes and admission requirements focus on eliminating the backlog of processing pending applications and petitions. USCIS has worked persistently to eliminate the backlog of pending applications and petitions since our establishment in March 2003. Promulgation of these rules will help in streamlining processing procedures and the paperwork burden thereby improving customer service. These regulations include: the Removal of the Standardized Request for Evidence Processing Timeframe; Fingerprinting Applicants and Petitioners for Immigration Benefits, Establishing a Fee for Fingerprinting by the Service; Administrative Appeals Office: Procedural Reforms to Improve Efficiency; Designating the Form I-140, Immigrant Petition for Alien Worker, Form I-539, Application to Extend/Change Nonimmigrant Status, and Form I-765, Application for Employment Authorization, for Premium Processing Services; and Affidavits of Support on Behalf of Immigrants. By clarifying the standards for adjudication of various benefit applications and petitions, extending the timeframes for filing of petitions, and eliminating the need for certain employers to reestablish that they have met certain requirements for filing a petition every time a new petition is filed, USCIS is able to streamline its adjudication process, thus reducing its backlog through faster adjudication, and ultimately decreasing benefit-processing times.

USCIS believes that these regulatory initiatives will improve the processing of applications and petitions by streamlining the processes and thereby helping to alleviate the backlog. USCIS further believes that theses initiatives have appropriate safeguards to prevent fraud and abuse. These regulatory activities foster many of the Department's Strategic Goals: awareness, prevention, protection and organizational excellence by placing USCIS in a better position to safeguard against any risk that may be posed by unlawful applicants to national security or public safety by ensuring that documents are issued after the completion of required background and security checks. This initiative also fosters the President's Six-point Plan for Economic Growth.

USCIS also plays a distinct role in supporting the United States humanitarian commitment to flexible and sound immigration and refugee programs. To further our humanitarian protection mandate, USCIS is pursuing regulatory initiatives that will assist victims of human trafficking, abuse, and certain crimes. USCIS is working to establish procedures to avail these individuals of humanitarian protection that will allow them to remain temporarily in the United States and, in appropriate circumstances, to adjust to lawful permanent resident (LPR) status. During fiscal year 2006, USCIS will be issuing the following regulations in furtherance of its humanitarian mandate: New Classification for Victims of Certain Criminal Activity, Eligibility for 'U' Nonimmigrant Status and Adjustment of Status for Victims of Trafficking.

USCIS' interim rule, ''New Classification for Victims of Certain Criminal Activity, Eligibility for 'U' Nonimmigrant Status,'' would implement section 1513(b) of the Victims of Trafficking and Violence Protection Act of 2000, Public Law 106-386. This rule establishes procedures for application and issuance of 'U' nonimmigrant status for victims of certain crimes, among them rape, torture, human trafficking, and domestic violence.

USCIS also will be finalizing its rule ''Adjustment of Status for Victims of Trafficking'' which rule enables victims of severe forms of trafficking in persons ('T' nonimmigrants) and victims of certain crimes ('U' nonimmigrants) to adjust to lawful permanent resident (LPR) status. Protection is made available to 'T' and 'U' nonimmigrants that can demonstrate they would suffer extreme hardship involving unusual and severe harm if removed from the United States. This rule establishes procedures, in appropriate circumstances, for them to adjust status to that of a lawful permanent resident.

Customs and Border Protection

Under section 403(1) of the 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 U.S.; maintaining export controls; and protecting American businesses from theft of their intellectual property.

In carrying out its priority mission, CBP's goal is to facilitate the processing of legitimate trade and people efficiently without compromising security. During the past fiscal year, consistent with its primary mission of homeland security, CBP issued a final rule that requires the electronic transmission of manifest information for passengers and crew members onboard commercial vessels and aircraft, in advance of arrival and departure from the United States, and for crewmembers and non-crew members onboard foreign commercial air carriers that continue within and overfly the United States, in advance of departure of those flights. Submission of this manifest information to CBP is a necessary component of the nation's continuing program of ensuring aviation and vessel safety and protecting national security. The required information also will assist in the efficient inspection and control of passengers and crewmembers and will facilitate the effective enforcement of the customs, immigration and transportation security laws,

During fiscal year 2006, CBP plans to enhance homeland security further by issuing several other regulatory documents. All the rules discussed above foster DHS' Strategic Goals of awareness and prevention.

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, CBP is working on a regulation 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.

CBP also is working with the State Department on a joint rulemaking initiative under section 7209 of the IRTPA, which provides that, by January 1, 2008, United States citizens and nonimmigrant aliens 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 new statute, 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 State 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. We anticipate issuing additional rulemaking actions during fiscal year 2006 to begin implementation of the requirements under the IRTPA.

During this fiscal year, CBP also plans to issue a proposal requiring that all containers are adequately secured with security seals. This rulemaking is consistent with a mandate in the Maritime Transportation Security Act of 2002, to develop performance standards to enhance the physical security of shipping containers, including standards for seals and locks.

In addition to its plans to continue issuing regulations to enhance border security, CBP, during fiscal year 2006, 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.

Emergency Preparedness and Response / Federal Emergency Management Agency

The mission of the Federal Emergency Management Agency (FEMA) is: ''[t]o lead the Nation to prepare for, mitigate the effects of, respond to, and recover from major disasters and emergencies, both natural and man-made, including acts of terrorism.'' FEMA is charged with developing and maintaining an integrated, nationwide operational capability to respond to and recover from disasters and emergencies, regardless of their cause, in partnership with other Federal agencies, State and local governments, volunteer organizations, and the private sector. FEMA coordinates and implements the Federal response to disasters declared by the President.

During 2005, FEMA issued an interim rule to establish a mechanism to distributed funds collected under The 9/11 Heroes Stamp Act of 2001. That Act directed the United States Postal Service to issue a postal stamp and distribute the proceeds through FEMA to the families of emergency relief personnel killed or permanently disabled while serving in the line of duty in connection with the terrorist attacks of September 11, 2001. FEMA anticipates finalizing this interim rule during fiscal year 2006. This regulation fosters the Department's strategic goal of recovery by assisting the families of emergency relief personnel who served in the line of duty on 9/11 in rebuilding their lives.

Immigration and Customs Enforcement

The Bureau of Immigration and Customs Enforcement (ICE), the largest investigative arm of DHS, is responsible for identifying and preventing security vulnerabilities to the nation's border, economic, transportation and infrastructure. Its mission is to prevent acts of terrorism by targeting the people, money, and materials that support terrorist and criminal activities. Established to combat the criminal and national security threats emergent in a post 9/11 environment, ICE combines a new investigative approach with new resources to provide unparalleled investigation, interdiction and security services to the public and our law enforcement partners in the federal and local sectors.

During fiscal year 2006, 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 streamline the removal process of persons who no longer have immigration status, ICE also will promulgate an interim final rule that requires aliens who become subject to a final order of removal to surrender themselves to the ICE within 30 days thereafter. This rule provides that aliens who are given notice of the mandatory duty to surrender and later fail to comply with the surrender obligation will be denied all discretionary immigration benefits for the remainder of their presence in the U.S. and for 10 years after their departure. This action enhances the integrity of the removal process by shifting the burden upon termination of removal proceedings—eliminating the requirement that the ICE seek out those subject of final removal orders—and instead requiring that such persons present themselves for removal. The surrender requirement will apply to aliens who receive notice of the obligation in the course of their immigration proceedings or concurrently with the final order of removal. This regulatory initiative promotes the Department's strategic goals of awareness and prevention.

Transportation Security Administration

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 that enable us to perform our daily activities while ultimately preparing us for the future.

In fiscal year 2006, TSA will promote DHS' Strategic Goals of awareness, prevention, protection, 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 cargo and the traveling public. TSA is partnering with other DHS components and with other Federal, State, and local agencies, to achieve common objectives and assure a uniform and appropriate standard of transportation security for the benefit of the American public.

In furtherance of this goal, TSA will 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 development of the Registered Traveler (RT) program, which will allow expedited 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.

TSA also will continue development of the Transportation Worker Identification Credential (TWIC) program, to be implemented by rulemaking, which will allow TSA to perform security threat assessments and issue biometric credentials to individuals requiring unescorted access to secure areas of transportation facilities, and thereby will prevent unauthorized persons from gaining access to secure areas.

Additionally, TSA continues to enhance air cargo security and the methods for screening of cargo through regulatory action and additional security programs. In appropriate instances, TSA will levy fees to offset all or a portion of the cost of certain security enhancements, such as certain background checks, and will revise the formula for computing the Aviation Security Infrastructure Fee (ASIF).

TSA also will 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 2006

A more detailed description of the priority regulations that comprise DHS' Fall 2005 Regulatory Plan follows.

DHS—Office of the Secretary (OS)

FINAL RULE STAGE

56. PROCEDURES FOR HANDLING CRITICAL INFRASTRUCTURE INFORMATION

Priority:

Other Significant

Legal Authority:

PL 107–296, 116 Stat 2135; 6 USC 131 to 134; Section 214 of The Homeland Security Act of 2002

CFR Citation:

6 CFR 29

Legal Deadline:

None

Abstract:

This notice of proposed rulemaking establishes the procedures necessary to fulfill the provisions of section 214(e) of the Critical Infrastructure Information (CII) Act of 2002. This regulation establishes uniform procedures for the receipt, care, and storage of CII voluntarily submitted to the Federal Government. These procedures apply to all Federal agencies that receive, care for, or store CII voluntarily submitted to the Federal Government pursuant to the CII Act of 2002 (6 USC 131 to 134). In addition, these procedures apply to United States Government contractors, to foreign, State, and local governments, and Government authorities, pursuant to their express agreements.

Statement of Need:

This final rule will establish procedures to implement section 214 of the CII Act of 2002 regarding the receipt, care, and storage of critical infrastructure information voluntarily submitted to the Department of Homeland Security. The protection of critical infrastructure reduces the vulnerability of the United States to acts of terrorism. The purpose of the regulation is to encourage potential submitters to share information pertaining to their particular and unique vulnerabilities, as well as those that may be systemic and sector-wide. As part of its

responsibilities under the CII Act of 2002, this information will be analyzed by the Department of Homeland Security to develop a more thorough understanding of the critical infrastructure vulnerabilities of the Nation. By offering the protections of the CII Act of 2002, the Department will ensure submitters that their information will be safeguarded from abuse.

Summary of Legal Basis:

This regulation is needed to finalize the interim final rule that implements section 214 of the Homeland Security Act by establishing uniform procedures for the receipt, care, and storage of critical infrastructure Information.

Alternatives:

The Department of Homeland Security believes that there is no alternative to protecting critical infrastructure information. Section 214 of the Homeland Security Act instructs DHS to establish uniform procedures for the receipt, care, and storage of critical infrastructure information that is voluntarily submitted to the Government.

Anticipated Cost and Benefits:

The Department of Homeland Security had considered the costs and benefits in the interim final rule. The interim rule affects non-Federal entities that have critical infrastructure information that they wish to share with DHS. The interim rule requires that when DHS receives, validates, and shares CII, DHS and the receiving parties, whether they are other Federal agencies or State or local governments with whom DHS has signed agreements detailing the procedures on how protected CII must be safeguarded, must take appropriate action to safeguard its contents. The interim rule does not require the use of safes or enhanced security equipment or the use of a crosscut shredder. Rather, the interim rule requires only that an affected entity or person restrict disclosure of, and access to, the protected information to those with a need to know, and destroy such information when it is no longer needed. Under the rule, a locked drawer or cabinet is an acceptable means of complying with the requirement to secure Protected Critical Infrastructure Information, and a normal paper shredder or manual destruction are acceptable means of destroying protected CII.

Risks:

This regulatory project will complement other DHS initiatives designed to detect, deter, and prevent terrorist attacks.

Timetable:

Action	Date	FR Cite
NPRM	04/15/03	68 FR 18524
NPRM Comment Period End	06/16/03	
Interim Final Rule	02/20/04	69 FR 8073
Interim Final Rule Effective	02/20/04	
Interim Final Rule Comment Period End	05/20/04	
Final Action	05/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State

Federalism:

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

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DHS—OS

57. REGULATIONS IMPLEMENTING THE SUPPORT ANTITERRORISM BY FOSTERING EFFECTIVE TECHNOLOGIES ACT OF 2002 (THE SAFETY ACT)

Priority:

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

Legal Authority:

Safety Act, 6 USC 441 to 444

CFR Citation:

6 CFR 25

Legal Deadline:

None

Abstract:

This second interim rule implements subtitle G of title VIII of the Homeland Security Act of 2002—the Support of Antiterrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act). As discussed in the SAFETY Act, through regulations promulgated by the Department of Homeland Security (the Department), it provides critical incentives for the development and deployment of antiterrorism technologies by providing liability protections for sellers of ''qualified antiterrorism technologies'' and others.

Statement of Need:

This regulation implements the SAFETY Act. The Department believes the current development of antiterrorism technologies has been slowed due to the potential liability risks associated with their development and eventual deployment. In a fully functioning insurance market, technology developers would be able to insure themselves against excessive liability risk; however, the terrorism risk insurance market appears to be in disequilibrium. The attacks of September 11 fundamentally changed the landscape of terrorism insurance. Congress, in the findings of the Terrorism Risk Insurance Act of 2003 (TRIA), concluded that temporary financial assistance in the insurance market is needed to ''allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses.'' TRIA section 101(b)(2). This second interim rulemaking addresses a similar concern, to the extent that potential technology developers are unable to efficiently insure against large losses due to an ongoing reassessment of terrorism issues in insurance markets.

Even after a temporary insurance market adjustment, purely private terrorism risk insurance markets may exhibit negative externalities. Because the risk pool of any single insurer may not be large enough to efficiently spread and therefore insure against the risk of damages from a terrorist attack, and because the potential for excessive liability may render any terrorism insurance prohibitively expensive, society may suffer from less than optimal technological protection against terrorist attacks. The measures set forth in the second interim rule are designed to meet this goal; they provide certain liability protection from lawsuits and consequently will increase the likelihood that businesses will pursue important technologies that may not be pursued without this protection.

Summary of Legal Basis:

On July 11, 2003, a notice of proposed rulemaking was published entitled ''Regulations Implementing the Support Antiterrorism by Fostering Effective

Technologies Act of 2002 (the SAFETY Act)'' in the Federal Register (68 FR 41420). No public hearing was requested and none was held. The first interim rule was published in October 2003. The Department finds that the need to foster antiterrorism technology by instituting liability protection measures, as soon as found practicable, furnishes good cause for this second interim rule to take effect immediately under both the Administrative Procedure Act, 5 U.S.C. 552(d)(3), and section 808 of the Congressional Review Act. The Department believes the current development of antiterrorism technologies has been slowed due to the potential liability risks associated with their development and eventual deployment. In a fully functioning insurance market, technology developers would be able to insure themselves against excessive liability risk; however, the terrorism risk insurance market appears to be in disequilibrium. The attacks of September 11 fundamentally changed the landscape of terrorism insurance. Congress, in its statement of findings and purpose in TRIA, concluded that temporary financial assistance in the insurance market is needed to ''allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses.'' TRIA section 101(b)(2).

Alternatives:

The Department considered public comments received on the interim rule and determined that another interim final rule with request for comments was needed.

Anticipated Cost and Benefits:

Costs and Benefits to Technology Development Firms

Since the second interim rulemaking puts in place an additional voluntary option for technology developers, the expected direct net benefits to firms of the second interim rulemaking will be positive; companies presumably will not choose to pursue the designation of ''antiterrorism technology'' unless they believe it to be a profitable endeavor. The Department cannot predict with certainty the number of applicants for this program. An additional source of uncertainty is the reaction of the insurance market to this designation. As mentioned above, insurance markets appear currently to be adjusting their strategy for terrorism risk, so little market information exists that would inform this estimate. The Department invited comments on these issues.

If a firm chooses to invest effort in pursuing the SAFETY Act liability protection, the direct costs to that firm will be the time and money required to submit the required paperwork and other information to the Department. Only companies that choose to request this protection will incur costs. Please see the accompanying PRA analysis for an estimate of these costs.

The direct benefits to firms include lower potential losses from liability for terrorist attacks, and as a consequence a lower burden from liability insurance for this type of technology. In this assessment, we were careful to only consider benefits and costs specifically due to the implementation of the second interim rule and not costs that would have been incurred by companies absent any interim rulemaking. The SAFETY Act requires the sellers of the technology to obtain liability insurance ''of such types and in such amounts'' certified by the Secretary. The entire cost of insurance is not a cost specifically imposed by the interim rulemaking, as companies in the course of good business practice routinely purchase insurance absent Federal requirements to do so. Any difference in the amount or price of insurance purchased as a result of the SAFETY Act would be a cost or benefit of this second interim rule for firms.

The wording of the SAFETY Act clearly states that sellers are not required to obtain liability insurance beyond the maximum amount of liability insurance reasonably available from private liability sources on the world market at prices and terms that will not unreasonably distort the sales price of the seller's antiterrorism technologies. We tentatively concluded, however, that this second interim rulemaking will impact both the prices and terms of liability insurance relative to the amount of insurance coverage absent the SAFETY Act. The probable effect of the second interim rule is to lower the quantity of liability coverage needed in order for a firm to protect itself from terrorism liability risks, which would be considered a benefit of this second interim rule to firms. The change will most likely be a shift back in demand that leads to a movement along the supply curve for technology firms already in this market; they probably will buy less liability coverage. This will have the effect of lowering the price per unit of coverage in this market.

The Department also expects, however, that the second interim rulemaking will lead to greater market entry, which will generate surplus for both technology firms and insurers. Again, this market is still in development, and the Department solicits comments on exactly how to predict the effect of this second interim rulemaking on technology development.

Costs and Benefits to Insurers

The Department has little information on the future structure of the terrorism risk insurance market, and how this second interim rulemaking affects that structure we continue to consider this matter. As stated above, this type of intervention could serve to lower the demand for insurance in the current market, thus the static effect on the profitability of insurers is negative. Thebenefits of the lower insurance burden to technology firms would be considered a cost to insurers; the static changes to insurance coverage would cause a transfer from insurers to technology firms. On the other hand, this type of intervention should serve to increase the surplus of insurers by making some types of insurance products possible that would have been prohibitive to customers or impossible for insurers to design in the absence of this second interim rulemaking.

Costs and Benefits to the Public

The benefits to the public of the second interim rulemaking were very difficult to put in dollar value terms since its ultimate objective is the development of new technologies that will help prevent or limit the damage from terrorist attacks. It is not possible to even determine whether these technologies could help prevent large or small scale attacks, as the SAFETY Act applies to a vast range of technologies, including products, services, software, and other forms of intellectual property that could have a widespread impact. In qualitative terms, the SAFETY Act removes a great deal of the risk and uncertainty associated with product liability and in the process creates a powerful incentive that will help fuel the development of critically needed antiterrorism technologies. Additionally, we expect the SAFETY Act to reduce the research and development costs of these technologies.

The tradeoff, however, may be that a greater number of technologies may be developed and qualify for this program that have a lower average effectiveness against terrorist attacks than technologies currently on the market,

or technologies that would be developed in the absence of the second interim rulemaking. In the absence of this rulemaking, strong liability discouragement implies that the fewer products that are deployed in support of antiterrorist efforts may be especially effective, since profit maximizing firms will always choose to develop the technologies with the highest demand first. It is the tentative conclusion of the Department that liability discouragement in this market is too strong or prohibitive, for the reasons mentioned above. The Department tentatively concludes that this second interim rule will have positive net benefits to the public, since it serves to strike a better balance between consumer protection and technological development. The Department welcomes comments informing this tradeoff argument, and public input on whether this second interim rulemaking does strike the correct balance.

Risks:

The United States remains at risk to terrorist attacks. It is in the public's interest to have this second interim rule effective immediately because its aim is to foster the development and deployment of antiterrorism technologies. Additionally, this second interim rule will clarify to the greatest extent possible the application of the liability protections created by the SAFETY Act, thus providing an instant incentive for prospective applicants to apply for its protections and for others to begin exploring new measures that will prevent or reduce acts of terrorism. The second interim rule will also provide the Department with sufficient program flexibility to address the specific circumstances of each particular request for the SAFETY Act coverage. The application process is interactive. Those persons availing themselves of the protections afforded in this second interim rule will also be interacting with the Department in the application process. Furthermore, the Department will continue to consider comments on this second interim rule. Since the use of the liability protections afforded in this second interim rulemaking is voluntary, there are no mandatory costs or burdens associated with the immediate implementation of this rule.

By having these provisions in place, the Department may begin processing applications for the liability protections and thus provide qualified sellers of antiterrorism technologies valuable incentives to develop and sell such technologies, as well as incentives for others to deploy such technologies. The purpose of those technologies is to detect, deter, mitigate, or assist in the recovery from a catastrophic act of terrorism. Thus, the Department finds that it is not only impracticable to delay an effective date of implementation, but it is also in the public's interest to make the second interim rule effective upon publication in the Federal Register.

Timetable:

Action	Date	FR Cite
NPRM	07/11/03	68 FR 41419
NPRM Comment Period End	08/11/03	
Interim Final Rule	08/16/03	68 FR 59683
Interim Final Rule Effective	10/16/03	
Interim Final Rule Comment Period End	12/15/03	
Interim Final Rule	05/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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DHS—OS

58. • PROTECTION OF HUMAN SUBJECTS

Priority:

Other Significant

Legal Authority:

Not Yet Determined

CFR Citation:

None

Legal Deadline:

None

Abstract:

In conducting human subjects research, the Department is obliged to comply with all applicable federal statutes, regulations, guidelines, and standards as implemented in the law. This final rule adopts the Department of Health and Human Services (HHS) policies and procedures set forth in 45 Code of Federal Regulations (CFR) Part 46, Subparts A-D by cross-referencing to the HHS regulations, rather than repeating these identical provisions.

Statement of Need:

In December 1981, a Presidential Commission was established to report on the protection of human research subjects involved in biomedical or behavioral research. The Commission conducted a review of the various rules and practices of federal agencies regarding the protection of human subjects of biomedical or behavioral research. Among other suggestions, the President's Commission recommended that ''all federal Departments and agencies adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR part 46).''

In May 1982, affected federal agencies formed a committee to consider the Commission's recommendations. On June 3, 1986, the committee published for public comment a model policy for the protection of human subjects. See 51 FR 20204. Five years later, on June 18, 1991, sixteen federal agencies jointly set forth a common ''Federal Policy for the Protection of Human Subjects,'' i.e., the ''Common Rule.'' See 56 FR 28003.

The Common Rule governs the conduct and oversight of research involving human subjects—it sets forth rules mandating the creation and maintenance of institutional review boards within agencies, establishes requirements for obtaining and documenting the informed consent of human subjects, etc. See 45 CFR part 46.

Summary of Legal Basis:

Section 8306 of the Intelligence Reform and Terrorism Prevention Act (IRTPA) of 2004 (Public Law 108-458) requires the Secretary of Homeland Security to ''ensure that the Department of Homeland Security complies with the protections for human research subjects, as described in part 46 of title 45, Code of Federal Regulations, or in equivalent regulations.''

Alternatives:

There are no real alternatives; the agency is required by statute to adopt regulations consistent with the Common Rule.

Risks:

There appear to be no significant risks.

Timetable:

Action	Date	FR Cite
Final Rule	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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DHS—U.S. Coast Guard (USCG)

FINAL RULE STAGE

59. MARINE CASUALTIES AND INVESTIGATIONS; CHEMICAL TESTING FOLLOWING SERIOUS MARINE INCIDENTS (USCG–2001–8773)

Priority:

Other Significant

Legal Authority:

PL 105–383, sec 304

CFR Citation:

46 CFR 4

Legal Deadline:

None

Abstract:

This project will revise the requirements for chemical testing following a serious marine incident. The revision will establish procedures to ensure that alcohol testing be conducted within two hours of a serious marine incident, as required by the Coast Guard Authorization Act of 1998. The rule will also make additional minor procedural changes to the part. This rule supports the Coast Guard strategic goal of maritime safety.

Statement of Need:

The Coast Guard proposes changing the alcohol testing requirements for commercial vessels following a serious marine incident. The 1998 Coast Guard Authorization Act requires the Coast Guard to establish procedures ensuring alcohol testing is conducted within two hours of a serious marine casualty. The Coast Guard proposes to establish requirements for testing within the statutory time limits, to expand the existing requirements for commercial vessels to have alcohol-testing devices on board, and to authorize use of a wider variety of testing devices. This rulemaking would also make additional minor procedural changes to part 4, including a time limit for conducting drug testing following a serious marine incident. This action is required to comply with the 1998 Coast Guard Authorization Act.

Summary of Legal Basis:

In 1998, Congress passed Public Law 105-383, which revised title 46, U.S. Code, by adding a new section 2303a, Post Serious Marine Casualty Alcohol Testing (hereafter section 2303a). Section 2303a requires the Coast Guard to establish procedures ensuring that after a serious marine casualty occurs, required alcohol testing is conducted no later than two hours after the casualty occurred. If the alcohol testing cannot be conducted within that timeframe because of safety concerns directly related to the casualty, section 2303a requires the alcohol testing to be conducted as soon thereafter as the safety concerns have been adequately addressed to permit such testing. However, section 2303a prohibits us from requiring alcohol testing to be conducted more than eight hours after the casualty occurs.

Alternatives:

We would use the standard rulemaking process to develop regulations for serious marine incident alcohol testing. Nonregulatory alternatives such as Navigation and Vessel Inspection Circulars and Marine Safety Manual have been considered and may be used for the development of policy and directives to provide the maritime industry and our field offices guidelines for implementation of the regulation. Nonregulatory alternatives cannot be substituted for the standards being proposed with this rule.

Anticipated Cost and Benefits:

A cost analysis was prepared and published with the notice of proposed rulemaking on February 28, 2003 (67 FR 9622). The benefits of this action will be to ensure that alcohol tests are conducted after serious marine incidents so that the public will be informed whether or not alcohol use contributed to the incident. This action will also deter improper alcohol use by commercial vessel personnel.

Risks:

Under current regulations, the risk of not obtaining a valid alcohol test after a serious marine incident is high because specific time frames are not given. This action will significantly reduce the risk of not obtaining a valid test.

Timetable:

Action	Date	FR Cite
NPRM	02/28/03	68 FR 9622
NPRM Comment Period End	06/30/03	
Notice of Public Meeting; Reopening of Comment Period	08/25/03	68 FR 50992
NPRM; Reopening of Comment Period	10/21/03	68 FR 60073
Comment Period End	11/20/03	
Final Rule	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

Additional Information:

Transferred from RIN 2115-AG07

Formerly listed in Unified Agenda as ''Post Casualty Drug and Alcohol Testing''

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 1625–AA27

DHS—USCG

60. VALIDATION OF MERCHANT MARINERS' VITAL INFORMATION AND ISSUANCE OF COAST GUARD MERCHANT MARINER'S LICENSES AND CERTIFICATES OF REGISTRY (USCG–2004–17455)

Priority:

Other Significant

Legal Authority:

46 USC 2103; DHS Delegation No. 0170.1, para (92)

CFR Citation:

46 CFR 10

Legal Deadline:

None

Abstract:

This rule would impose certain security-related requirements in order to obtain a license or certificate of registry. Applicants would be required to appear in person at least once during the application process, to provide two acceptable forms of identification, and be fingerprinted by Coast Guard personnel.

Statement of Need:

A Coast Guard-issued license authorizes its holder to serve in the capacity of vessel's officer allowing him or her to assume positions of responsibility in the command and control of merchant marine vessels. The harm that can be caused by persons who wrongfully obtain licenses with the intention of committing crimes or terrorist acts jeopardizes mariner safety and welfare, as well as national security. Our goal is to protect the licensing process from abuse. We recently identified several omissions and ambiguities in the former rule that could facilitate licensing abuse. This interim rule corrects those omissions and clarifies those ambiguities to promote maritime safety and security within the United States.

Summary of Legal Basis:

In the interests of marine safety and seamen's welfare, the Coast Guard was given general superintendence of merchant marine personnel by 46 U.S.C. 2103, 46 U.S.C. chapter 71, and Secretary of Homeland Security Delegation No. 0170.1. In 2002, Congress found that U.S. ports are susceptible to large-scale acts of terrorism that could cause a large loss of life or economic disruption, that ''ports are often a major locus of Federal crime,'' (Maritime Transportation Security Act of 2002, section 101, Public Law 107-295, 116 Stat. 2064) and that it is in the best interest of the United States to increase port security. This rulemaking aligns with a similar interim rule for Merchant Mariner's Documents (MMD) published on 6 January 2004.

Alternatives:

We considered non regulatory alternatives such as Navigation and Vessel Inspection Circulars and Marine Safety Manual Guidance, however, while these can be used for the development of policy and directives that provide guidance for the implementation of a regulation, they do not lay a sufficient legal basis for the Coast Guard to deny issuance of these credentials. We considered issuing an NPRM but believe we have sufficient good cause to go forward with an Interim Rule.

Anticipated Cost and Benefits:

This interim rule will affect mariners who apply for licenses and CORs. We estimate that the annual cost of this rulemaking will be $16 million. A detailed regulatory evaluation will be published in the preamble of the interim rule.

We anticipate several qualitative benefits from the new requirements established by this rule. All applicants for licenses and CORs will be required to have their fingerprints taken by Coast Guard personnel at an REC and will be required to have their ID checked by Coast Guard personnel at an REC. In the past, applicants could have had their fingerprints taken and their identity checked by outside entities and submitted them by mail without a guarantee of accuracy or validity. The cumulative effect of the changes in this rulemaking will be to increase the likelihood that the Coast Guard will process applications only from, and issue credentials only to, applicants who can prove they are who they claim to be, and whose backgrounds can be verified to make sure they meet security-related requirements.

Risks:

This rulemaking is intended to reduce the vulnerability of a transportation security incident occurring in US ports and waterways resulting from merchant mariners who fraudulently obtain licenses and CORs. These licenses and CORs could potentially be used to fraudulently portray ones self as a deck, engineer or staff officer.

Timetable:

Action	Date	FR Cite
Interim Rule	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 1625–AA85

DHS—USCG

61. ● VESSEL REQUIREMENTS FOR NOTICES OF ARRIVAL AND DEPARTURE, AND CARRIAGE OF 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 Pub. L. 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.

The AIS portion of the rulemaking would expand our AIS carriage requirements to all commercial vessels Congress specifically identified in the Maritime Transportation Security Act of 2002, and would include vessels carrying 50 or more passengers, vice the current 150 or more passengers for hire, carrying or towing certain dangerous cargo, certain dredges, and certain high speed passenger craft.

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, more U.S. 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. In order to expand our MDA this information is necessary.

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 interim 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, more U.S. commercial vessels, 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.

For the AIS portion of this rulemaking, we expect vessel owners to incur costs for the installation of AIS on board vessels that do not currently have AIS. The vessel groups affected are all commercial self-propelled vessels 65 feet or greater (including fishing and passenger vessels), towing vessels 26 feet or greater and over 600 horsepower, vessels carrying 50 or more passengers or certain dangerous cargoes; dredges and certain high speed passenger craft; operating on U.S. navigable waters. We estimate that the number of vessels affected by the AIS portion of this rulemaking is approximately 17,400 foreign and domestic vessels. The NOA and AIS populations will be reconciled in the 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:

In terms of threat, vulnerability, and consequence, there are few more valuable and vulnerable targets for terrorist attack than the U.S. Maritime Transportation System (MTS). Considering the economic utility of U.S. ports, waterways, and coastal approaches, it is clear that a terrorist incident against our MTS would have a disastrous impact on global shipping, international trade, and the world economy. This rulemaking is instrumental in expansion of MDA and consequently instrumental in reduction of those risks posed by terrorist actions against the MTS.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/00/06	

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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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The Regulatory Plan for the Department of Housing and Urban Development for Fiscal Year (FY) 2006 highlights the Department's most significant regulations and policy initiatives, as established by Secretary Jackson for the upcoming fiscal year. HUD plays a significant role in communities throughout America as the federal agency responsible for national policy and programs that address the housing needs of Americans, promote community development, and enforce fair housing laws.

To help HUD accomplish its critical role, HUD's regulatory priorities for FY2006 are primarily directed to regulatory changes that will reduce or eliminate administrative burdens, streamline procedures, or establish measures directed to facilitating homeownership and improving access to affordable housing. HUD's regulatory priorities for FY2006 build upon the objectives of America's Affordable Communities Initiative, a HUD-wide initiative devoted to removing and reducing regulatory barriers to affordable housing (rental or homeownership) at all levels of government. In June 2005, Secretary Jackson honored 14 communities from across the nation with the Robert L. Woodson Jr. Award for outstanding achievements in reducing regulatory barriers and promoting affordable housing in these communities. From the start of this initiative, however, HUD has emphasized that its role is not merely to encourage state and local governments to remove and reduce regulatory barriers to affordable housing, but to examine its own regulations to determine whether there are HUD program requirements that present barriers to homeownership or affordable housing and which can be removed through rulemaking. In a notice published in the Federal Register on May 20, 2005, HUD responded to several issues raised by public commenters about HUD's own regulations and committed itself to further examination of several regulatory areas that commenters believed presented barriers to affordable housing.

Consistent with HUD's commitment to examine its own regulations and remove barriers to affordable housing, where feasible and consistent with the Secretary's strategic goals for FY2006, the regulations highlighted in this regulatory plan and in the semiannual agenda of regulations, published elsewhere in today's Federal Register, are directed to implementing policies, procedures, and programs that support HUD's core mission.

Priority: Promoting Economic Opportunity and Ownership

In 2004, the homeownership rate in the United States reached its highest level in history. Today, nearly 70 percent of American families own their own homes. The number of homeowners in the United States reached 73.4 million, the most ever. Equally impressive is that for the first time in history the majority of minority Americans own their own homes. Homeownership creates community stakeholders who tend to be active in their communities. It inspires civic responsibility that supports stable communities and raises the quality of educational opportunities. Homeownership's potential to create wealth is also impressive. A home is the largest purchase most Americans will ever make. It represents a tangible asset that builds equity, borrowing power, and overall wealth.

While much has been accomplished, much more remains to be done. HUD is working to accomplish the administration's goal of increasing the number of minority homeowners by 5.5 million by the end of the decade. HUD is also working to increase the supply of affordable housing by seven million units over the next ten years.

Regulatory Action: Government National Mortgage Association: Excess Yield Securities

In furthering its statutory mission of expanding affordable housing in America by linking domestic and global capital markets to the nation's housing markets, the Government NationalMortgageAssociation (Ginnie Mae) is developing a new Excess Yield program under which Ginnie Mae will guarantee Excess Yield Securities. These securities are backed by the excess servicing income relating to one or more mortgage pools or loan packages underlying previously issued Ginnie Mae mortgage-backed securities. The Excess Yield Program will allow qualifying Ginnie Mae issuers to reduce the amount of mortgage servicing rights on their balance sheets, which will in turn reduce the amount of capital they are required to hold against that asset. It will also reduce their need to use costly hedging tools to hedge against fluctuations in the value of their mortgage servicing rights. By increasing the liquidity of mortgage servicing rights for Ginnie Mae issuers, the Excess Yield Program should lower the costs of, and encourage the origination of, government-insured and guaranteed single-family mortgages that back Ginnie Mae mortgage-backed securities. This will further Ginnie Mae's mission and directly benefit low- and moderate-income homebuyers.

Regulatory Action: Housing Choice Voucher Program Homeownership Option: Eligibility of Units Not Yet under Construction

Through the Housing Choice Voucher program, HUD pays rental subsidies so that eligible families can afford decent, safe, and sanitary housing. Under the homeownership option of the Housing Choice Voucher program, a public housing agency (PHA) may provide voucher assistance for an eligible family to purchase, rather than rent, a dwelling unit for residence by the family. The regulations for the homeownership option are codified in subpart M of the Housing Choice Voucher program regulations at 24 CFR part 982. Under the current homeownership option regulations, to be eligible for purchase with voucher assistance, a unit must be either an existing unit or under construction at the time the family enters into the contract for sale. Upon reconsideration, HUD believes that the housing eligibility requirements may be overly restrictive. Consistent with its effort to expand homeownership opportunities, HUD will revise this regulation to permit the use of voucher homeownership assistance for the purchase of units not yet under construction at the time the family contracts to purchase the home. HUD believes that this change will expand homeownership opportunities for eligible families moving to areas of job growth, where such growth will frequently trigger the construction of new housing developments. Further, many localities have established affordable housing requirements on developers of new housing subdivisions mandating that a specified percentage of the homes to be constructed be set-aside for purchase by low-income families. The revised regulation will also permit voucher families to benefit from these local affordable housing initiatives prior to the construction of new homes.

Priority: Serving Society's Most Vulnerable

HUD remains committed to the goal of ending chronic homelessness and has aggressively pursued policies to move more homeless families and individuals

into permanent housing. A chronically homeless person is a person who suffers from a disabling developmental, physical, or mental condition or a substance abuse addiction; has been homeless for a year or more; or has had repeated periods of extended homelessness. Research indicates that although just 10 percent of the homeless population experiences chronic homelessness, these individuals consume over half of all emergency homeless resources. Housing this population will free federal, state, and local emergency resources for families and individuals that need shorter-term assistance. HUD is working to meet this goal.

Regulatory Action: Housing Opportunities for Persons With AIDS (HOPWA)

In administering this federal program, the Department has identified a number of corrective and technical actions that would improve the clarity of the program regulations in how funds are used to address the pressing housing needs of low-income persons who are living with HIV/AIDS and their families. The Department will propose changes to improve on this partnership with the recipient States, local governments, and nonprofit organizations that plan, develop, operate, and evaluate the housing assistance and related supportive services programs in their areas. In HUD's view, this rule will help ensure the public trust in using program funds for their intended purpose in meeting the housing needs of eligible beneficiaries. The rule will also encourage the use of other mainstream health and human welfare programs for other needed support for residents of these housing assistance programs. In addition, the rule will clarify how an individual housing service plan would be developed to guide the assistance provided to beneficiaries in relation to the program's performance goals. The plans would respond to ongoing individual household needs and help the community develop a more comprehensive local assessment of the housing needs of the eligible population in this area. As a result, these encourage the efficient use of resources by determining how to best make use of HOPWA funds for eligible activities that support eligible households.

Priority: Making Government More Effective

Within the rulemaking process is a HUD-wide effort to reduce burdens on participants and program administrators by focusing on improving program outcomes and achieving performance goals. HUD is also aware of the fact that the American people demand, and are entitled to, government that serves as an effective steward of the taxpayer's money. Toward this end, HUD will reform its public housing programs to facilitate the transition of public housing to asset-based management as recommended by the congressionally mandated Harvard Cost study. That study, among other things, recommended that public housing agencies (PHAs) move to asset-based management. To facilitate this change, the study also recommended that HUD consolidate or remove unnecessary program requirements that make it difficult for PHAs to make the move to asset-based management. HUD is firmly committed to implementing the study's recommendations and providing maximum flexibility to PHAs within the parameters of current law to administer public housing programs.

HUD is also committed to overcoming regulatory barriers to affordable housing. HUD has determined that regulations such as out-of-date building codes, duplicative or time-consuming design review or approval processes, burdensome rehabilitation codes, restrictive or exclusionary zoning ordinances, unnecessary or excessive fees or taxes, and extreme environmental restrictions at all levels of government directly raise development costs in some communities by as much as 20 to 35 percent, thereby pricing many families and individuals out of those markets. For middle-income individuals such as teachers, firefighters, police officers, nurses, service sector employees and others, barrier removal is an integral component of meeting their housing needs. One of the goals of America's Affordable Communities Initiative is to help states and local governments develop comprehensive programs to remove regulatory barriers. Another goal is to remove public misconceptions about affordable housing. By educating the community and helping local communities remove regulatory barriers, HUD seeks to open doors for millions of American families who want to buy or rent an affordable home in the community of their choice. Through the following rules HUD takes additional steps in its effort to remove unnecessary barriers in the availability of affordable housing.

Regulatory Action: Streamlining Public Housing Programs

PHAs are required to annually submit to HUD a PHA Plan that outlines the their plans for the coming year. As required by section 5A of the United States Housing Act of 1937, these plans list 18 elements of a PHA's public housing and voucher programs. Among other things, HUD typically will not release a PHA's public housing capital funds unless it has approved the PHA Plan. In some instances, the PHA Plan contains an overview of the PHA's policy and plans for the coming five years, as well as the coming year.

To date, HUD has streamlined the process for submitting the PHA Plan for small PHAs and high-performing PHAs. HUD will expand this streamlining to all public housing programs in order to promote more effective governance and facilitate the transition to public housing asset-based management. HUD's intent is to more closely align public housing with the conventional real estate industry and to give PHAs maximum flexibility to administer their programs. HUD intends to remove procedural requirements not required by law, the elimination of which will allow PHAs to bring higher-income tenants into lower-income developments and lower-income tenants into higher-income developments, to avoid a concentration of low-income families as prohibited by law. HUD also intends to revise its regulations to more closely reflect statutory requirements.

Regulatory Action: Disposition of HUD-Acquired Single-Family Property

HUD is also committed to simplifying and streamlining its single-family property disposition regulations. In the course of doing business as a mortgage insurer, the Federal Housing Administration (FHA) takes ownership of some properties due to borrower default. When a default occurs, FHA lenders first try to keep the borrower in his or her home by pursuing loan loss mitigation. If these efforts are not successful, the lender forecloses on the home and conveys the property to FHA in exchange for payment of an insurance claim. FHA-foreclosed (real estate-owned (REO)) properties tend to be located in distressed communities, and they tend to be in relatively poor physical condition. The challenge for FHA is to sell these properties in a manner that protects the government's financial interest and has a positive impact on neighborhoods where REO properties are located. Over the past few years, FHA has explored new and innovative methods to improve its property disposition efforts. The regulatory changes that HUD will propose are based on the re-

procurement of management and marketing services, which provides an opportunity to improve business practices, management, and operating procedures. In reforming its property disposition program, FHA also intends to maintain its longstanding commitment to working with local governments and nonprofit organizations wishing to purchase HUD-owned single-family housing as part of a broader local strategy to provide and promote affordable housing in cities across the country. Rather than simply offering properties for sale on a property-by-property basis, HUD plans to enter into broad agreements with local governments that will agree to purchase all FHA-foreclosed properties within a specifically defined revitalization area, to be selected by both the local government and HUD. This will further focus federal and local resources on those neighborhoods most in need of public investment.

Regulatory Action: Amendments to HUD's Environmental Regulations

HUD is committed to ensuring that its funding recipients meet their responsibilities under the National Environmental Policy Act (NEPA), related environmental statutory authority, and HUD's environmental regulations, 24 CFR parts 50, 51, 55, and 58. There is, however, a need for HUD to conform its environmental regulations to recent statutory enactments, specifically the Native American Housing and Self Determination Act (NAHASDA) and the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). This new statutory authority permits HUD to expand certain regulatory exemptions and exclusions. For example, section 105(d) of NAHASDA authorizes waiving statutory environmental review requirements for the Indian Housing Block Grant program. Similarly, section 5159 of the Stafford Act allows an exemption from HUD's environmental review procedures for activities taken, or assistance provided, to substantially restore a facility to its condition prior to the disaster or emergency. As part of this effort to conform its environmental regulations to this authority, HUD will also review its environmental regulations to reduce administrative barriers and speed environmental reviews. More specifically, HUD's review will make its environmental regulations more user-friendly by removing obsolete provisions and providing other technical guidance, corrections, and conforming provisions.

The Priority Regulations that Comprise HUD's FY 2006 Regulatory Plan

A more detailed description of the priority regulations that comprise HUD's FY 2006 Regulatory Plan follows.

HUD—Office of the Secretary (HUDSEC)

PROPOSED RULE STAGE

62. AMENDMENTS TO HUD'S ENVIRONMENTAL REGULATIONS (FR–4954)

Priority:

Other Significant

Legal Authority:

12 USC 1707 note; 12 USC 1715z–13a(k); 15 USC 7001 et seq; 25 USC 4115; 25 USC 4226; 42 USC 3535(d); 42 USC 3547; 42 USC 4332; 42 USC 4852; 42 USC 5159; 42 USC 12838; 42 USC 11331 to 11388; 42 USC 12701 to 12711; 42 USC 12741 to 12756; 42 USC 12901 to 12912; 42 USC 12905(h); 42 USC 1437x; 42 USC 3601 to 3619; 42 USC 4001 to 4028; 42 USC 5301 to 5315; 42 USC 5304(g); 44 USC 101 note; 44 USC 3504 note

CFR Citation:

24 CFR 50; 24 CFR 51; 24 CFR 55; 24 CFR 58; 24 CFR 585

Legal Deadline:

None

Abstract:

This rule would make a number of revisions to HUD's environmental regulations to reduce administrative barriers and speed environmental reviews. This rule would expand HUD's regulatory waiver authority for certain environmental provisions where there is good cause and no adverse environmental impact will result. This change will allow for a more streamlined and user-friendly process for environmental review. The rule also would add an exemption to 24 CFR part 55 (floodplain management) for special projects directed to the removal of architectural barriers of properties located within floodplains. It would also exempt minor repairs or improvements, and special projects to remove architectural barriers for elderly persons and persons with disabilities. The rule would allow an exemption from environmental review procedures for an action that is taken or assistance that is provided to restore a facility to its condition prior to a disaster or emergency pursuant to section 5159 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act. In addition, the rule would make a number of minor conforming changes to HUD's environmental regulations. Finally, the rule would request public comments on proposals to allow environmental submissions and notifications to be done electronically.

Statement of Need:

HUD's environmental regulations need to be conformed to current statutory issuances providing exceptions to review under the Native American Housing Assistance and Self-Determination Act (NAHASDA) and the Robert T. Stafford Disaster Relief and Emergency Assistance Act. Further, the changes made by this proposed rule would modify existing regulatory requirements and, therefore, must be promulgated through regulation.

Summary of Legal Basis:

The changes to the NAHASDA environmental regulations are made pursuant to 25 U.S.C. 4115(d), and the regulatory changes relating to the Robert T. Stafford Act are made pursuant to 42 U.S.C. 5159. In general, HUD's environmental regulations are under the authority of the National Environmental Policy Act (NEPA) 42 U.S.C. 4321 et seq.

Alternatives:

In order to revise its environmental regulations to make them more user-friendly and remove barriers to housing, HUD is revising its environmental regulations promulgated pursuant to NEPA. Doing so requires regulation, so there is no alternative.

Anticipated Cost and Benefits:

This rule is designed to reduce the cost of development and promote the production of housing by removing unnecessary procedures while continuing to ensure that the environment is protected.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local

Agency Contact:

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Department of Housing and Urban Development
Phone: 202 708–1201

RIN: 2501–AD11

HUD—Office of Housing (OH)

PROPOSED RULE STAGE

63. DISPOSITION OF HUD–ACQUIRED SINGLE FAMILY PROPERTY AMENDMENTS (FR–4952)

Priority:

Other Significant

Legal Authority:

12 USC 1710(g); 12 USC 1710(h); 12 USC 1715z to 11a; 42 USC 3535(d); . . .

CFR Citation:

24 CFR 291

Legal Deadline:

None

Abstract:

HUD has a variety of statutory and regulatory property disposition programs. In addition to sales of unoccupied HUD-held assets, these include the following special programs: the Asset Control Area program, the Dollar Home Sales to Local Governments program, the Officer and Teacher Next Door programs, and the single-family occupied conveyance program. This rule will consolidate the requirements of these various programs to form one integrated set of procedures for property disposition.

Statement of Need:

The consolidation of the various requirements for property disposition will make for more efficient and effective disposition of HUD-acquired property for HUD and the purchaser.

Summary of Legal Basis:

The National Housing Act (NHA) at 12 U.S.C. 1710(g) authorizes the Secretary to sell HUD-held properties ''on such terms and conditions as the Secretary may prescribe.'' The NHA at 12 U.S.C. 1710(h) provides for a specific program of asset sales for revitalization purposes in specified areas, known as Asset Control Areas, at a discounted price with a preference for sale to local governments and nonprofit organizations. The NHA at 12 U.S.C. 1715z-11a provides for a specific program of sale to local governments or community development corporations of ''qualified properties'' for one dollar. ''Qualified properties'' are unoccupied or substandard properties for which at least six months have elapsed since the later of the following: the date HUD acquired the property or the date the property was determined to be unoccupied or substandard.

Alternatives:

The statutes for the Asset Control Area and Dollar Home Sales to Local Governments programs explicitly require HUD to issue regulations. Further, the changes made by this proposed rule would modify existing regulatory requirements and, therefore, must be promulgated through regulation in order to have binding effect.

Anticipated Cost and Benefits:

This rule would produce a more efficient system for HUD's property disposition program, thus lowering the costs of holding a portfolio of properties and benefiting the insurance fund by maximizing the sales of those properties.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Office of Housing
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HUD—Office of Community Planning and Development (CPD)

PROPOSED RULE STAGE

64. HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS (HOPWA) (FR–4708)

Priority:

Other Significant

Legal Authority:

42 USC 12901 et seq

CFR Citation:

24 CFR 574

Legal Deadline:

None

Abstract:

The Housing Opportunities for Persons With AIDS (HOPWA) program was authorized in 1990 by the AIDS Housing Opportunity Act (12 U.S.C. 12901 et seq.) (AHOA) to provide states and localities with the programs and resources necessary to meet the housing needs of individuals and families with HIV/AIDS. The rule proposes to adjust the formula factor that determines the allocation of 25 percent of funds based on a metropolitan area's higher-than-average incidence of cases of AIDS. In calculating the formula allocation, the proposed change would replace the one-year standard for AIDS surveillance data used to determine the high AIDS incidence to a three-year data standard. This change is intended to moderate unexpected one-year increases or declines in a grantee's formula allocation and allow for continuity in grant funding. In addition, the regulation would update the HOPWA rental assistance requirements to make use of additional provisions and create additional options for grantees for operation of rental assistance programs. The changes would implement provisions used in other HUD programs, such as the Housing Choice Voucher (Section 8) program, and thereby modernize the HOPWA regulations, which were last updated in 1994.

Statement of Need:

This rule would help ensure the public trust in using program funds for their intended purpose in meeting the housing needs of eligible beneficiaries and by encouraging the use of other mainstream health and human welfare

programs to support residents of these housing assistance programs.

Summary of Legal Basis:

The HOPWA program was authorized by AHOA ''to provide states and localities with the resources and incentives to devise long-term comprehensive strategies for meeting the housing needs of persons with acquired immunodeficiency syndrome and families of such persons.'' A final rule was published in the Federal Register on April 11, 1994 (59 FR 17194), establishing regulations for the implementation of this program at 24 CFR part 574.

Alternatives:

The changes made by this proposed rule would modify an existing regulatory requirement and, therefore, must also be promulgated through regulation. Non-regulatory alternatives (such as promulgation through a handbook or notice) would not be binding upon program participants.

Anticipated Cost and Benefits:

This rule will benefit persons with AIDS or related diseases who are low-income and their families. HOPWA funds include payments to individuals for small, short-term payments to prevent homelessness, payments of ongoing rental assistance, and the development or operation of supportive housing facilities, single-room occupancy dwellings, or community residences to meet the statutory purpose to devise long-term comprehensive strategies for meeting the housing needs of persons with AIDS.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Office of Community Planning and Development
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RIN: 2506–AC11

HUD—Government National Mortgage Association (GNMA)

PROPOSED RULE STAGE

65. GNMA: EXCESS YIELD SECURITIES (FR–4958)

Priority:

Other Significant

Legal Authority:

12 USC 1721(g); 12 USC 1723a(a); 42 USC 3535(d)

CFR Citation:

24 CFR 320

Legal Deadline:

None

Abstract:

In furthering its statutory mission of expanding affordable housing in America by linking domestic and global capital markets to the nation's housing markets, the Government National Mortgage Association (Ginnie Mae) is developing a new Excess Yield program under which Ginnie Mae will guarantee Excess Yield Securities. These securities are backed by the excess servicing income relating to one or more mortgage pools or loan packages underlying previously issued Ginnie Mae mortgage-backed securities. The Excess Yield program will allow qualifying Ginnie Mae issuers to reduce the amount of mortgage servicing rights on their balance sheets, which will in turn reduce the amount of capital they are required to hold against that asset. It will also reduce their need to use costly hedging tools to hedge against fluctuations in the value of their mortgage servicing rights. By increasing the liquidity of mortgage servicing rights for Ginnie Mae issuers, the Excess Yield program should lower the costs of, and encourage the origination of, government-insured and guaranteed single-family mortgages that back Ginnie Mae mortgage-backed securities.

Statement of Need:

The Excess Yield program is designed to further Ginnie Mae's mission and directly benefit low- and moderate-income homebuyers.

Summary of Legal Basis:

The Excess Yield Securities would be ''based on and backed by a trust or pool composed of mortgages which are insured under the National Housing Act'' and therefore eligible for guaranty as authorized by 12 U.S.C. 1721(g)(1)(ii), just as their related Ginnie Mae-guaranteed mortgage-backed securities are. Ginnie Mae expects that the servicing cash flows would be pooled and would back securities guaranteed by Ginnie Mae and upon which Ginnie Mae would charge a guaranty fee pursuant to 12 U.S.C. 1721(g)(1) and 24 CFR 320 of the implementing regulations. The guarantee fee would be no more than six basis points, as required by 12 U.S.C. 1721(g)(3)(A).

Alternatives:

The alternative would be for Ginnie Mae to take no action with respect to excess yields, and thereby not offer Ginnie Mae issuers the choice of securitizing these cash flows. Retaining the status quo would make doing business with Ginnie Mae a less attractive option for issuers, thereby undercutting Ginnie Mae's mission.

Anticipated Cost and Benefits:

The Excess Yield program would make Ginnie Mae a more attractive option for issuers of mortgage-backed securities with minimal additional implementation costs.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/14/05	70 FR 54450
NPRM Comment Period End	11/14/05	
Final Action	07/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Department of Housing and Urban Development
Government National Mortgage Association
Phone: 202 401–8970

RIN: 2503–AA18

HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

66. ● STREAMLINING PUBLIC HOUSING PROGRAMS (FR–4990)

Priority:

Other Significant

Legal Authority:

42 USC 1437c; 42 USC 1437d; 42 USC 1437e; 42 USC 1437g; 42 USC 1437r; 42 USC 3535(d)

CFR Citation:

24 CFR 903; 24 CFR 945; 24 CFR 964; 24 CFR 966

Legal Deadline:

None

Abstract:

Public Housing Agencies (PHAs) are required annually to submit a PHA Plan to HUD that outlines the PHA's plans for the coming year. This rule would revise certain program regulations to make them more consistent with HUD's overall objective to streamline public housing programs, facilitate the transition to public housing project-based management, and consider recommendations of the congressionally mandated Harvard Public Housing Cost Study concerning changes to public housing's regulatory environment.

Statement of Need:

Based on the congressionally mandated Harvard Public Housing Cost Study, which concerned changing public housing's regulatory environment and HUD's goal to consolidate or remove obsolete or unnecessary program requirements, this proposed rule would revise several sections of HUD's public housing regulations in 24 CFR parts 903, 945, 964, and subpart B of 966. The purpose of the revisions is to streamline those regulations the Department believes could impede a PHA's ability to manage its operations within the parameters of the United States Housing Act of 1937 (12 U.S.C. 1437 et seq.) (1937 Act). The rule also is designed to promote more effective governance by PHAs and provide PHAs with maximum flexibility, within the requirements of the 1937 Act, to design, manage, and operate their programs to address local needs. PHAs and local communities, through collaboration and partnership, are in the best position to create a positive living environment for their residents.

Summary of Legal Basis:

Section 5a of the United States Housing Act of 1937 (42 U.S.C. 1437c-1), which provides that each PHA shall submit a plan to HUD that contains a mission statement and statement of goals and objectives of the PHA that will enable it to serve the needs of low-income and very low-income families, and HUD's general rulemaking authority under the Department of Housing and Urban Development Act, which authorizes HUD to establish regulatory policies and procedures governing the submission of a PHA's annual plan.

Alternatives:

The changes made by this proposed rule would modify an existing regulatory requirement and, therefore, must be promulgated through regulation. Non-regulatory alternatives (such as promulgation through a handbook or notice) would not be binding upon PHAs and other program participants.

Anticipated Cost and Benefits:

This rule would support HUD's overall objective to streamline public housing programs, facilitate the transition to public housing project-based management, and consider recommendations of the congressionally mandated Harvard Cost Study. In general, this rule is directed to more closely align public housing with the conventional real estate industry, giving PHAs maximum flexibility within the parameters of current law to administer public housing programs. As a result, the rule is not anticipated to result in the imposition of new regulatory burdens on program participants nor significantly alter the costs associated with the public housing program.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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HUD—PIH

67. ● HOUSING CHOICE VOUCHER PROGRAM HOMEOWNERSHIP OPTION; ELIGIBILITY OF UNITS NOT YET UNDER CONSTRUCTION (FR–4991)

Priority:

Other Significant

Legal Authority:

42 USC 1437d; 42 USC 3535(d)

CFR Citation:

24 CFR 982

Legal Deadline:

None

Abstract:

This proposed rule would revise HUD's regulations for the homeownership option authorized under the Housing Choice Voucher program. Through the homeownership option, a public housing agency (PHA) may provide voucher assistance for an eligible family that purchases a dwelling unit for residence by the family. The current homeownership option regulations provide that, to be eligible for purchase with voucher assistance, a unit must be either an existing unit or under construction at the time the family

enters into the contract for sale. This proposed rule would permit, under certain conditions, the use of voucher homeownership assistance for the purchase of units not yet under construction at the time the family contracts to purchase the home. The revision will expand the housing choices available to families participating in the Housing Choice Voucher program.

Statement of Need:

The current housing eligibility requirements may be overly restrictive and unnecessarily prohibit voucher families from purchasing available affordable homes. For example, job growth in an area will frequently trigger the construction of new housing developments. The current eligibility prohibition deters voucher families from moving to such an area in search of employment opportunities. Further, many localities have established affordable housing requirements for new housing subdivisions mandating that a specified percentage of the homes to be constructed be set-aside for purchase by low-income families. The eligibility restriction prohibits voucher families from benefiting from these local affordable housing initiatives prior to the construction of new homes. Since few existing homes are accessible to persons with impaired mobility, the eligibility prohibition also has the potential to make it more difficult for persons with disabilities to purchase a home with voucher assistance.

Summary of Legal Basis:

Section 8(y) of the United States Housing Act of 1937 (42 U.S.C. 1437f(y)), which authorizes the homeownership option, and HUD's general rulemaking authority under the Department of Housing and Urban Development Act, authorize HUD to establish regulatory policies and procedures governing the program, including the types of homes eligible for purchase with voucher homeownership assistance.

Alternatives:

The changes made by this proposed rule would modify an existing regulatory requirement and, therefore, must also be promulgated through regulation. Non-regulatory alternatives (such as promulgation through a handbook or notice) would not be binding upon PHAs and other program participants.

Anticipated Cost and Benefits:

The proposed rule is designed to benefit voucher families by expanding the types of housing that may be purchased with voucher assistance. The rule will not result in the imposition of new regulatory burdens on program participants, nor significantly alter the costs associated with the Housing Choice Voucher program.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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DEPARTMENT OF THE INTERIOR (DOI)

Statement of Regulatory Priorities

The Department of the Interior (DOI) is the principal Federal steward of our nation's public lands and resources, including many of our cultural treasures. We serve as trustee to Native Americans and Alaska natives and also are responsible for relations with the island territories under United States jurisdiction. We manage more than 500 million acres of Federal lands, including 388 park units, 545 wildlife refuges, 24,000 miles of trails, and approximately 1.7 billion acres submerged in offshore waters. The Department protects natural, historic and cultural resources, recovers endangered species, manages water projects, manages forests and fights wildland fires, 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 almost 300 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, other groups, and individuals;
- Provide incentives for private landowners to achieve conservation goals; and
- Minimize regulatory and procedural burdens, promoting fairness, transparency, and accountability by agency regulators while maintaining performance goals.

Major Regulatory Areas

Among the Department's bureaus and offices, the Office of Surface Mining Reclamation and Enforcement (OSM) has significant regulatory responsibilities. OSM, in partnership with the States and Indian tribes, establishes and enforces environmental standards for coal mining and reclamation operations. In addition, OSM administers the abandoned mine land reclamation program, which is funded by a fee assessed on each ton of coal produced. Money from these fees is placed in a fund that, subject to appropriation, is used to reclaim lands and waters impacted by historic mining activities conducted before the enactment of the Surface Mining Control and Reclamation Act of 1977. The collection of the fee for reclamation purposes was originally scheduled to expire in 1992; however, the authority to collect the fee has been extended several times and a further extension is anticipated.

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, and 13132, DOI's regulatory programs seek to:

- Fulfill all legal requirements as specified by statutes or court orders;
- Perform essential functions that cannot be handled by non-Federal entities;
- Minimize regulatory costs to society while maximizing societal benefits; and
- Operate programs openly, efficiently, and in cooperation with Federal and non-Federal entities.

DOI bureaus 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 decision-making 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 decision making 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;
- In the Natural Resources Damage Assessment Program, de-emphasizing actions stemming from litigation while increasing outreach to involved parties and stressing cooperation and restoration of affected sites;

- A departmental effort to streamline decision-making pertaining to fuels-reduction projects under the Healthy Forests Initiative; and
- Joint counterpart pesticide regulations for EPA/FWS endangered species consultations that will allow the agencies to work together to complete the consultations (25,000 backlog) in a timely and efficient manner.

Implementing the President's National Energy Policy

The President's National Energy Policy promotes ''dependable, affordable, and environmentally sound production and distribution of energy for the future.'' The Department of the Interior plays a vital role in implementing the President's energy policy goals. The lands, 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, including several regulatory actions. The Department has diligently completed regulatory tasks assigned to it by the NEP, including the Bureau of Land Management's rule that provides a comprehensive set of regulations for managing oil and gas leases in the National Petroleum Reserve B Alaska and the Minerals Management Service's rule that provides an incentive for development of deep gas resources offshore in order to encourage drilling of these high-risk wells that provide an important new source of natural gas supply. 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 are designed to streamline permitting processes and encourage environmentally sound energy production.

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 of 2005. 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 has initiated a 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, ameliorating land and resource-management problems on public lands, and ensuring accountability and compliance with Federal laws and regulations.

Consistent with the President's Executive Order on Cooperative Conservation, the Department is continuing to work together with State and local governments, 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 of what is allowable under incidental take permits and to provide greater private landowner protections under safe harbor agreements.

The Department is also developing a uniform code of scientific conduct and policy on research. The Code describes ethical conduct for all Department employees who conduct scientific activities on behalf of the Department. The Code implements a Federal policy on research misconduct as required by the Office of Management and Budget. The policy applies to all Federal agencies and federally funded research, whether conducted in-house or by partners at universities or in non-governmental organizations. This policy meets the expectations of the Secretary regarding the conduct of scientific activities with honesty, integrity, and accuracy; to make decisions based on the best science available; and is consistent with professional codes of conduct of other organizations.

In 2002, Secretaries Norton and Veneman signed an historic agreement with 17 western governors, county commissioners and other affected parties on a plan to make communities safer from wildfires through coordinating Federal, State and local action. Under the National Fire Plan 10-year Comprehensive Strategy Implementation Plan, Federal wildfire agencies, affected States, counties, and local governments agreed to the same goals, implementation outcomes, performance measures and tasks that need to be accomplished by specific deadlines. The plan covers all phases of the fire program, including fire preparedness, suppression and prevention, hazardous fuels management, restoration of burned areas, community assistance and monitoring of progress.

In 2002, the President announced the Healthy Forests Initiative, in which he directed Federal agencies to develop administrative and legislative tools to restore forests and woodlands to more healthy, natural conditions and to assist in executing core components of the National Fire Plan. The Healthy Forests Initiative is providing public land

managers the tools to effectively manage our forests and woodlands. The initiative focuses on reducing the risk of catastrophic fire by thinning dense undergrowth and brush in priority locations that are collaboratively selected by Federal, State, tribal, and local officials and communities. In 2005, the Department, using the administrative and legislative ''tools'' provided for under the Healthy Forests Initiative and the Healthy Forests Restoration Act, plans to satisfy National Environmental Policy Act requirements on over 1,300 treatments covering approximately 222,000 acres; to date, some 164,000 acres have been treated using the tools.

The National Park Service has completed an environmental assessment to provide for a Temporary Winter Use Plan that provides for continued snowmobile and snowcoach use in Yellowstone and Grand Teton National Parks and John D. Rockefeller, Jr. Memorial Parkway for up to the next three winter seasons. This EA will allow the NPS to engage in longer-term studies and to monitor the impacts of new technology snowmobiles in the parks, as well as the effects of road grooming in the winter on bison migration in Yellowstone. The EA will require the use of cleaner, quieter snowmobiles and set caps on the numbers of machines allowed in the parks each day. The parks are working to provide a more stable winter use plan to help gateway communities develop a winter economic plan. The interim plan and longer-term studies are both intended to satisfy the issues raised by the Federal District Courts in Wyoming and the District of Columbia, respectively, that have vacated the plans previously completed by the NPS in 2001 and 2003.

The Bureau of Land Management is working on a grazing administration rule that would ensure grazing decision rules conform with the Administrative Procedure Act, compliance with recent court decisions regarding conservation use permits, require BLM to consider social and economic factors when considering changes to grazing use, and offer other improvements to grazing activities on public lands.

In December 2004, President Bush issued the Ocean Action Plan, in response to the US Ocean Commission Report. The Action Plan includes a series of proposals from across the Government that include policy proposals, legislative recommendations, and regulatory initiatives. DOI has a number of responsibilities under the Action Plan, including the issuance of the National Park Service's Ocean Park Strategy, the Dry Tortugas Management Plan and related rulemaking, creation of a National Water Quality monitoring network, as well as proposed legislation to authorize the Marine Mammal Protection Act.

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 eastern gray wolf has been delisted and an ESA section 10(j) rule for States with approved management plans (Idaho and Montana) was issued on January 6, 2005.

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 has been charged with the responsibility of developing 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. According to the law, the joint rule is to be issued within 90 days of enactment (approximately November 8). An interagency team has been assembled to develop the rule.

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 Rangeland Reform Act.

In addition, the Department completed a review of its NEPA compliance program and issued revised procedures aimed at improving public participation and reducing excess paperwork and redundancy of effort in the field. This has led to concrete reform measures covering a number of areas. They include: consensus-based management, public participation, community-based training, use of integrated analysis, adaptive management, and tiered and transferred analysis. Each of these concepts is aimed at ensuring the field staff have the tools to tailor their approach to the NEPA process to local needs and interests. Along with the departmental manual changes, policy guidance was distributed to bureaus on how to implement the major reforms.

The Recreation Enhancement Act (REA), enacted in December 2004, requires that the Forest Service and BLM establish Recreation Resource Advisory Committees (Recreation RACs). These committees will make recreation fee program recommendations on implementing or eliminating certain recreation fees, establishing a specific recreation fee site, and expanding or limiting the program. REA enables the Secretaries of Agriculture and Interior to determine the number of Recreation RACs needed for effective operation of the Act. The two agencies must determine the appropriate number and scope of Recreation RACs so that the committees can effectively review fee proposals and make recommendations. The two agencies have worked together to identify possible options for Recreation RAC configurations and have held numerous ''listening sessions'' across the country in an effort to provide an opportunity to hear what people think about various options. The agencies are

currently in the process of reviewing the feedback from these sessions.

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. On June 28, 2005, the NPS published a notice in the Federal Register announcing the Secretary's intent to establish a negotiated rulemaking advisory committee and proposing membership for the committee.

Regulatory Actions Related to the Events of September 11, 2001

The Bureau of Reclamation is responsible for protecting 348 reservoirs and more than 500 Federal dams, 58 hydroelectric plants, and over 8 million acres of Federal property. Public Law 107-69 granted Reclamation law enforcement authority for its lands. Reclamation finalized an interim rule published in April 2002 for one year that implemented this authority. It has since been extended through 2005. On September 13, 2005, Reclamation will publish a proposed rule that, when finalized, will supersede the existing public conduct rule.

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 9 park units and rulemaking actions for 6 additional units are in various 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 finalized a departmental strategic plan in 2004 in response to Congressional, OMB and other appraisals indicating that Interior's ten separate strategic planning documents were too long and lacked the appropriate agency-level focus. The strategic plan:

- Incorporated key Administration and Secretarial priorities into Interior's goals and performance measures;
- Resulted after consultation with key interested constituents on the future direction of the Department; and
- Provided more ''results-oriented'' goals for Interior programs.

Interior used the single Strategic Plan as the basis for preparing a single Departmental Annual Performance Plan beginning with the plan for FY 2004. The Interior bureaus will continue to prepare internal plans to support their budget initiatives and to meet management excellence and accountability needs. However, we plan to submit only Departmental strategic and annual plans to the Congress.

Bureaus and Offices Within DOI

The following brief descriptions summarize the regulatory functions of DOI's major regulatory bureaus and offices.

Bureau of Indian Affairs

The Bureau of Indian Affairs (BIA) is responsible for managing trust responsibilities to the Indian tribes and encouraging tribal governments to assume responsibility for BIA programs.

The 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.

Under the No Child Left Behind Act of 2001, the Secretary of the Interior established a negotiated rulemaking committee to develop proposed rules to implement several sections of the Act relating to the BIA-funded school system. The committee comprised representatives of tribes and tribally operated schools and the Federal Government. The tribal representative membership reflected the proportionate share of students from tribes served by the BIA-funded school system. This committee has negotiated rules to implement portions of the No Child Left Behind Act affecting the definition of ''Adequate Yearly Progress,'' attendance boundaries for BIA-funded schools, funding for BIA-funded schools, rights of students in the BIA-funded school system, and grants under the Tribally Controlled Schools Act. The final rule was published in the Federal Register on April 28, 2005.

Bureau of Land Management

The BLM manages about 262 million acres of land surface and about 700 million acres of Federal mineral estate. These lands consist of extensive grasslands, forests, mountains, arctic tundra, and deserts. Resources on the lands include energy and minerals, timber, forage, wild horse and burro populations, habitat for fish and wildlife species, wilderness areas, and

archaeological and cultural sites. The BLM manages these lands and resources for multiple purposes and the sustained yield of renewable resources. Primary statutes under which the BLM operates include: the Federal Land Management and Policy Act of 1976; the General Mining Act of 1872; the Mineral Leasing Act of 1920, as amended; the Recreation and Public Purposes Act; the Taylor Grazing Act; the Wilderness Act; and the Wild Free-Roaming Horses and Burros Act.

The Regulatory Program mirrors statutory responsibilities and BLM objectives including the following:

- Supporting the objectives of the Energy Policy Act of 2005 by developing regulations to 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 BLM manages and its commitment to using the best scientific and technical information to make resource management decisions.
- Understanding the needs of the public that use the BLM-managed lands and providing them with quality service.
- Committing to recover a fair return, as appropriate, for using publicly owned resources and avoiding the creation of long-term liabilities for American taxpayers.
- Resolving problems and implementing decisions in cooperation with other agencies, States, tribal governments, and the public.

In preparing regulations, BLM ensures that regulations:

- Are the product of communication, coordination, and consultation with all affected members of the public;
- Are easy for the public to understand, especially those most affected by them; and
- Are subject to periodic review to determine whether the rules are outdated, require updating to reflect statutory and policy changes, and achieve desired results.

The BLM's regulatory priorities include:

- Completion of rules to facilitate implementation of the Energy Policy Act of 2005 to encourage domestic production of energy and other alternative and renewable sources of energy;
- Finalizing the amendments to the grazing regulations to improve working relationships with permittees and lessees, protect the health of the rangelands, and increase administrative efficiency and effectiveness.
- Finalizing the amendments to the mineral resources regulations to increase many fees and to impose new fees to cover BLM's costs of processing certain documents relating to its minerals programs.
- Completing amendments to the recreation regulations to bring them into conformance with the law, including the Federal Lands Recreation Enhancement Act requirement to establish Recreation Resource Advisory Committees to make fee recommendations.

Most of BLM's regulations affect small businesses because many entities that operate on public lands meet the definition of a small business, as established by the Small Business Administration. BLM's regulations do not specifically target small businesses, and the BLM strives to ensure that its regulations do not unduly burden entities regardless of size.

Currently, BLM's mining and grazing projects often generate the greatest concern to small businesses because most livestock operators and mining companies are also considered small businesses, as classified by the SBA.

The final grazing rule that BLM intends to publish before the end of the calendar year will amend grazing regulations that BLM promulgated on February 22, 1995 (59 FR 29206). The final rule will not substantively change the existing rules. When published, the rule will rely on the regulatory flexibility analysis prepared by BLM for the 1995 final rule. At that time, BLM determined that the 1995 rule should not have a significant impact on a substantial number of small entities.

The BLM will issue a final rule to amend its mineral resources regulations to increase certain fees and to impose new fees to cover BLM's costs of processing documents relating to its minerals programs. BLM based these fee changes on statutory authorities, which authorize BLM to charge for processing costs, and on policy guidance requiring BLM to charge these fees. This rule responds to recommendations issued in audit reports by the DOI's Office of Inspector General. The final rule also reflects changes to the proposed rule required by the Energy Policy Act of 2005. Applicants for BLM authorizations are the primary beneficiaries of those authorizations. As such, the primary benefit of the rulemaking is to shift the cost of processing the affected applications from the taxpayer to the applicant.

Minerals Management Service

The 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 Minerals Leasing Act, the Outer Continental Shelf Lands Act, the Indian Mineral Leasing Act, 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, MMS published a final Federal Gas Valuation Rule on March 10, 2005 and in late 2005, MMS plans to publish a proposed rule for Indian Oil Valuation. 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 for gas produced from Federal lands and oil produced from Indian lands. Clear rules will reduce the number of disputes and lower 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, MMS published a proposed rule on March 15, 2005 to recover costs for certain services it provides to the oil and gas industry.

MMS expects to publish a final rule and an additional proposed rule on cost recovery before the end of the calendar year. These rulemakings implement the President's policy as outlined in OMB Circular 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 to recover the cost of providing the service. The Department mirrors this policy (330 DM 1.3A). MMS also published through OMM final rules to provide further guidance on deep gas royalty relief (April 29, 2005) and rules that incorporate industry safety standards for pressure vessels (February 14, 2005) and floating production facilities (July 19, 2005). Additionally, MMS plans to issue final rules in 2005 that will clarify plans and information that industry must provide MMS related to exploration and production of oil and gas on the Outer Continental Shelf. 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.

On July 29, 2005, Congress enacted energy legislation that may affect the MMS regulatory plan. In particular, Congress provided incentives for drilling ultra-deep wells in the Outer Continental Shelf, royalty relief for marginal wells, and established authority for the Department to regulate alternate sources of energy from the Outer Continental Shelf. Alternate sources of energy include wind farms. Congress directed the Secretary to promulgate regulations implementing the legislation. In compliance with the direction from Congress, MMS has added to its regulatory plan a proposed rule to implement royalty incentives for natural gas production from deep wells in the shallow waters of the Gulf of Mexico and offshore Alaska.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSM) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA) to ''strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal as an essential source of energy.''

The principal regulatory provisions contained in Title V of SMCRA set minimum requirements for obtaining a permit for surface coal mining operations, set standards for those operations, require land reclamation once mining ends, and require rules and enforcement procedures to ensure that the standards are met. Under SMCRA, OSM is the primary enforcer of SMCRA's provisions until the States achieve ''primacy;'' that is, until they demonstrate that their regulatory programs meet all the specifications in SMCRA and have regulations consistent with those issued by OSM.

When a primacy State takes over the permitting, inspection, and enforcement activities of the Federal Government, OSM changes its role from regulating mining activities directly to overseeing and evaluating State programs. Today, 24 of the 26 key coal-producing States have primacy. In return for assuming primacy, States are entitled to regulatory grants and to grants for reclaiming abandoned mine lands. In addition, under cooperative agreements, some primacy States have agreed to regulate mining on Federal lands within their borders. Thus, OSM regulates mining directly only in nonprimacy States, on Federal lands in States where no cooperative agreements are in effect, and on Indian lands.

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 (ESA) to fulfill its statutory obligation to identify and conserve species faced with extinction and to conserve certain mammals under the Marine Mammal Protection Act. The ESA dictates that the basis for determining endangered and threatened species must be limited to biological considerations. Regulations enhance the conservation of ESA-listed species and help other Federal agencies comply with the ESA. Under section 7 of the ESA, all Federal agencies must consult with the Service on actions that may jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of their critical habitats.

In designating critical habitat for listed species, the Service considers biological information and economic and other impacts of the designation. Areas may be excluded if the benefits of exclusion outweigh the benefits of inclusion, provided that such exclusion will not result in the extinction of the species. The Department is reviewing guidance for designation of critical habitat. The guidance will provide policy direction and a process for developing critical habitat designations.

Section 4(f)(1) of the ESA directs the Secretary of the Interior to develop and implement plans (known as recovery plans) for the conservation and survival of endangered and threatened species. The Service has been coordinating with the National Marine Fisheries Service to revise the joint Recovery Planning Guidance for the recovery of endangered and threatened species under the ESA. The purpose of the proposed guidance is to achieve greater consistency in the implementation of the ESA while working with partners. In addition, section 6 of the ESA pertains to cooperation with the States in the conservation of endangered and threatened species. The Department will also issue guidance to facilitate better coordination with the States and provide more opportunities for the States' direct involvement in managing endangered and threatened species.

National Park Service

The National Park Service is dedicated to conserving the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations. The Service also manages a great variety of national and international programs designed to extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.

There are 388 units in the National Park System, including national parks and monuments; scenic parkways, preserves, trails, riverways, seashores, lakeshores, and recreation areas; and historic sites associated with important movements, events, and personalities of the American past.

The NPS develops and implements park management plans, and staffs the areas under its administration. It relates the natural values and historical significance of these areas to the public through talks, tours, films, exhibits, and other interpretive media. It operates campgrounds and other visitor facilities and provides, usually through concessions, lodging, food, and transportation services in many areas.

The NPS also administers the following programs: the State portion of the Land and Water Conservation Fund; nationwide outdoor recreation coordination and information, and State comprehensive outdoor recreation planning; planning and technical assistance for the National Wild and Scenic Rivers System, the National Trails System, natural area programs, the National Register of Historic Places, national historic landmarks, historic preservation, technical preservation services, Historic American Buildings Survey; Historic American Engineering Record; Historic American Landscapes Survey; 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 is implementing its law enforcement authorization received in November 2001.

Reclamation's regulatory program is designed to ensure that its mission is carried out expeditiously, efficiently, and with an emphasis on cooperative 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 of natural resource trustees to assess appropriate restoration for injury to natural resources caused by hazardous substances. The Restoration Program is overseeing the establishment 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)

PROPOSED RULE STAGE

68. 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	11/00/05	
Supplemental NPRM Comment Period End	01/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

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Related RIN: Previously reported as 1010–AC24

RIN: 1010–AD00

DOI—MMS

69. ● RELIEF OR REDUCTION IN ROYALTY RATES – NEW DEEP GAS AND OFFSHORE ALASKA PROVISIONS

Priority:

Other Significant

Legal Authority:

43 USC 1331 et seq.

CFR Citation:

30 CFR 203

Legal Deadline:

Final, Statutory, February 3, 2006.

Abstract:

This proposed rulemaking would implement royalty incentives for natural gas production from deep wells in the shallow waters of the Gulf of Mexico and would authorize royalty relief for offshore Alaska as mandated by the Energy Policy Act of 2005 (the Act). The Act requires the deep gas incentives to be effective by February 3, 2006. The Alaska royalty suspension does not have a set date.

Statement of Need:

This rule would comply with statutory directives to enhance domestic oil and gas supply by adding new production incentives. A royalty suspension volume of 35 BCF would be created for gas produced from ultra deep (20,000 feet or more subsea) wells on shallow water leases in the Gulf of Mexico (See section 344(a) of the Act). The existing royalty suspension volumes and supplements plus the new ultra deep gas incentive would be extended to leases in the Gulf located in water depths between 200 and 400 meters of water (See section 344(b) of the Act). The Act makes pre-production royalty relief available to leases offshore Alaska when MMS determines it is necessary to promote development, increased production, or production of marginal resources (See section 346 of the Act). The rule would clarify how MMS would determine when royalty relief is appropriate.

Summary of Legal Basis:

The legal basis for rule is the Outer Continental Shelf Lands Act, 43 U.S.C. 1331 et seq. as amended by the Energy Policy Act of 2005.

Alternatives:

There are no alternatives. Congress has mandated these two incentives. Therefore MMS must publish a rule to implement the Congressional direction. MMS will include both incentives in a single rulemaking to reduce the administrative burden on the government as well as the public in its review and comment.

Anticipated Cost and Benefits:

Notification requirements by claimants for deep gas relief are insignificant relative to the benefits they will receive. The royalty relief provisions will provide significant benefits to claimants.

Risks:

No risks have been identified.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	
Final Rule	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 1010–AD31

DOI—Office of Surface Mining Reclamation and Enforcement (OSMRE)

PROPOSED RULE STAGE

70. 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 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, ''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 slop 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	06/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1029–AC04

DOI—Bureau of Land Management (BLM)

FINAL RULE STAGE

71. GRAZING ADMINISTRATION—EXCLUSIVE OF ALASKA

Priority:

Other Significant

Legal Authority:

43 USC 1181d; 43 USC 1740; 43 USC 315; 43 USC 315a to 315r

CFR Citation:

43 CFR 4100

Legal Deadline:

None

Abstract:

This rule will ensure that BLM documents its consideration of the social, cultural, environmental, and economic consequences of grazing changes; provide that changes in grazing use will be phased in under certain circumstances; allow BLM to

share title with permittees and lessees to range improvements in certain circumstances; make clear how BLM will authorize grazing if a BLM decision affecting a grazing permit is stayed pending administrative appeal; remove provisions in the present regulations concerning conservation use grazing permits; ensure adequate time for developing and successfully implementing an appropriate management action when BLM finds that rangelands do not meet standards and guidelines for rangeland health and that authorized grazing is a significant factor in not achieving one or more land health standards or not conforming with guidelines for grazing administration; and revise some administrative service charges.

Statement of Need:

This rulemaking is necessary to contribute to improving working relationships with permittees and lessees, protecting the health of the rangelands, and increasing administrative efficiency and effectiveness.

Summary of Legal Basis:

The primary laws that govern grazing on public land are the Taylor Grazing Act (TGA) of 1934, the Federal Land Policy and Management Act (FLPMA) of 1976, and the Public Rangelands Improvement Act (PRIA) of 1978.

TGA directs that occupation and use of the range be regulated to preserve the land and its resources from destruction or unnecessary injury, and to provide for the orderly use, improvement, and development of the range. FLPMA provides authority and direction for managing the public lands on the basis of multiple use and sustained yield and mandates land use planning principles and procedures for the public lands. PRIA defines rangeland as public lands on which there is domestic livestock grazing or which are determined to be suitable for livestock grazing, establishes a national policy to improve the condition of public rangelands so they will become as productive as feasible for all rangeland values, requires a national inventory of public rangeland conditions and trends, and authorizes funding for range improvement projects.

Alternatives:

The draft environmental impact statement (DEIS) on the proposed rule considered two alternatives in addition to the rule as proposed. The first alternative to the proposed rule considered in the DEIS was to continue to operate under the existing regulations. The existing regulations contain provisions that have been found unlawful by the Federal courts. They also do too little to promote cooperation between BLM and grazing permittees and lessees. They are also ambiguous at times and hard to understand.

The DEIS also considered a modified alternative with different approaches to several provisions in the proposed rule. BLM would have more discretion in phasing in changes in grazing use, be limited to five consecutive years in approving nonuse, and have discretion to use range assessments or monitoring or both to determine whether grazing management is achieving standards and conforming with guidelines. The alternative would include a prohibition of failing to comply with weed seed-free forage requirements, but would not include the current prohibition of failing to comply with Federal or State laws pertaining to resources.

In the early stages of planning this rule, BLM considered additional provisions such as Reserve Common Allotments for grazers to use when their allotments are unavailable due to fire, drought, or other factors, and authorizing grazers to lock gates on public lands temporarily. These provisions were dropped due to public comment on the advance notice of proposed rulemaking.

Anticipated Cost and Benefits:

BLM anticipates the following benefits: Increased livestock production as a result of increased forage productivity or increased ability to maintain grazing when it might otherwise be reduced; increased managerial flexibility, resulting in increased livestock output; improved environmental conditions; and potential changes in recreation values.

The major categories of costs include: BLM administrative costs (including enforcement and monitoring costs); compliance costs for permittees and lessees; environmental costs if the rule results in worsened environmental conditions.

The benefits and costs are thoroughly discussed in the Benefit-Cost/Unfunded Mandates Act Analysis and Initial Regulatory Flexibility Act Analysis dated November 14, 2003, and available in the administrative record of the rule.

Risks:

As with any new rule, the public may at first misunderstand the changes in regulatory requirements. BLM will work with the public in implementing the rule and conduct outreach meetings to explain the rule as necessary.

There is also a risk that the monitoring requirements imposed by the rule may entail increased administrative costs and the need to reallocate administrative resources. We expect this risk to be minimized because of the thresholds in the regulations that must be crossed before monitoring is required.

Timetable:

Action	Date	FR Cite
ANPRM	03/03/03	68 FR 9964
NPRM	12/08/03	68 FR 68452
NPRM Comment Period End	03/02/04	
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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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.

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.[1] However, other components do make use of the rulemaking process in certain significant respects.

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of firearms and explosives. ATF's mission and regulations are designed to:

- Curb illegal traffic in, and criminal use of, firearms, and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence;
- Facilitate investigations of violations of Federal explosives laws and arson-for-profit schemes;
- Regulate the firearms and explosives industries, including systems for licenses and permits;
- Assure the collection of all National Firearms Act (NFA) firearms taxes and obtain a high level of voluntary compliance with all laws governing the firearms industry; and
- Assist the States in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes and alcohol in avoidance of Federal and State taxes.

ATF will continue, as a priority during fiscal year 2006, to seek modifications to its regulations governing commerce in explosives. ATF continues analysis of its regulations governing storage requirements for explosives, including fireworks explosive materials. ATF plans to issue final regulations implementing the provisions of the Safe Explosives Act, title XI, subtitle C, of Public Law 107-296, the Homeland Security Act of 2002 (enacted November 25, 2002).

The Drug Enforcement Administration (DEA) is responsible for controlling abuse of narcotics and dangerous drugs, while ensuring adequate supplies for legitimate medical purposes, by regulating the aggregate supply of those drugs. However, now, the growing combination of drug trafficking and terrorism serves to call us even more urgently to action. DEA accomplishes its objectives through coordination with State, local, and other Federal officials in drug enforcement activities, development and maintenance of drug intelligence systems, regulation of legitimate controlled substances, and enforcement coordination and intelligence-gathering activities with foreign government agencies. DEA continues to develop and enhance regulatory controls relating to the diversion control requirements for controlled substances, as well as the requirements of the Comprehensive Methamphetamine Control Act of 1996 and the Methamphetamine Anti-Proliferation Act of 2000, which regulate certain chemicals to prevent them from being diverted for the production of methamphetamine.

The Federal Bureau of Prisons issues regulations to enforce the Federal laws relating to its mission: To protect society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. During the next 12 months, in addition to other regulatory objectives aimed at accomplishing its mission, the Bureau will continue its ongoing efforts to: Reduce the introduction of contraband through various means (such as clarifying drug and alcohol surveillance testing programs); improve disciplinary procedures; and improve drug abuse treatment services.

[1] As one example, the FBI published a final rule in July 2004, amending regulations implementing the National Instant Criminal Background Check System (''NICS'') pursuant to the Brady Handgun Violence Prevention Act (''Brady Act''). This rule balanced the Brady Act's mandate that the Department protect legitimate privacy interests of law-abiding firearm transferees and the Department's obligation to enforce the Brady Act and the rest of the Gun Control Act to prevent prohibited persons from receiving firearms. Changes made by the final rule regarding the amount of time that the NICS retains information about approved firearm transfers in the system's chronological log of background check transactions (''Audit Log'') were required by section 617 of H.R. 2673, the Fiscal Year 2004 Consolidated Appropriations bill, which was signed into law on January 23, 2004.

DOJ—Civil Rights Division (CRT)

PROPOSED RULE STAGE

72. 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.

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	01/00/06	
NPRM Comment Period End	07/00/06	

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

73. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN STATE AND LOCAL GOVERNMENT SERVICES (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509 to 510; 42 USC 12134; PL 101–336

CFR Citation:

28 CFR 35

Legal Deadline:

None

Abstract:

On July 26, 1991, the Department published its final rule implementing title II of the Americans With Disabilities Act (ADA). On November 16, 1999, the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) issued its first comprehensive review of the ADA Accessibility Guidelines, which form the basis of the Department's ADA Standards for Accessible Design. The Access Board published an Availability of Draft Final Guidelines on April 2, 2002, and published the ADA Accessibility Guidelines in final form on July 23, 2004. The ADA (section 204(c)) requires the Department's standards to be consistent with the Access Board's guidelines. In order to maintain consistency between ADAAG and the Standards, the Department is reviewing its title II regulations and expects to propose, in one or more stages, to adopt revised standards consistent with new ADAAG. The Department will also, in one or more stages, review its title II regulations for purposes of section 610 of the Regulatory Flexibility Act and make related changes to its title II regulations.

In addition to the statutory requirement for the rule, the social and economic realities faced by Americans with disabilities dictate the need for the rule. Individuals with disabilities cannot participate in the social and economic activities of the Nation without being able to access the programs and services of State and local governments. Further, amending the Department's ADA regulations will improve the format and usability of the ADA Standards for Accessible Design; harmonize the differences between the ADA Standards and national consensus standards and model codes; update the ADA Standards to reflect technological developments that meet the needs of persons with disabilities; and coordinate future ADA Standards revisions with national standards and model code organizations. As a result, the overarching goal of improving access for persons with disabilities so that they can benefit from the goods, services, and activities provided to the public by covered entities will be met.

The first part of the rulemaking process 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.

The Access Board has made every effort to lessen the impact of its proposed guidelines on State and local governments but recognizes that the guidelines will have some federalism effects. These affects are discussed in the Access Board's regulatory assessment, which also applies to the Department's proposed rule.

Risks:

Without this amendment to the Department's ADA regulations, regulated entities will be subject to confusion and delay as they attempt to sort out the requirements of conflicting design standards. This amendment should eliminate the costs and risks associated with that process.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/04	69 FR 58768
ANPRM Comment Period End	01/28/05	
NPRM	01/00/06	
NPRM Comment Period End	07/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Federalism:

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

Additional Information:

RIN 1190-AA46, which will effect changes to 28 CFR 35 (the Department's regulation implementing title II of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190-AA44, which will effect changes to 28 CFR 36 (the Department's regulation implementing title III of the ADA). By adopting revised ADAAG, this rulemaking will, among other things, address changes to the ADA Standards previously proposed in RINs 1190-AA26, 1190-AA36, and 1190-AA38, which have been withdrawn and merged into this rulemaking. These changes include accessibility standards for State and local government facilities that had been previously published by the Access Board (RIN 1190-AA26) and the timing for the compliance of State and local governments with the curb-cut requirements of the title II regulation (RIN 1190-AA36). In order to consolidate regulatory actions implementing title II of the ADA, on February 15, 2000, RINs 1190-AA26 and 1190-AA38 were merged into this rulemaking and on March 5, 2002, RIN 1190-AA36 was merged into this rulemaking.

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DEPARTMENT OF LABOR (DOL)

2005 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 Department works to enforce laws and regulations to ensure the health and safety of the American workforce. The vast majority of employers work hard to keep their employees and workplaces safe and secure. DOL also strives to provide employers with the knowledge and tools they need to carry out their legal obligations. Protecting America's workers is a top priority of the Secretary of Labor. The Secretary has made protecting workers through the coupling of compliance assistance and tough enforcement one of her top priorities. Her compliance assistance initiative is based on the proven success that comes when government, employers, unions and employees work together.

Compliance assistance works to prevent injuries. Educating and encouraging employers helps workers far more than enforcement alone, since no enforcement process can possibly identify every violation of the law, and fines and penalties can never fully redress losses of life, health, and economic well-being.

The Department is committed to aggressively enforcing the laws that protect employees, including the rights of workers returning to their jobs after military service. Workers also need information about protection of their health insurance and pension benefits. In addition, DOL has responsibilities beyond worker protection. The Department recognizes that workers need constant updating of skills to compete in a changing marketplace. DOL helps employers and workers bridge the gap between the requirements of new high-technology jobs and the skills of the workers who are needed to fill them.

The Secretary of Labor's Regulatory Plan for Accomplishing These Objectives

In general, DOL tries to help employees and employers meet their needs in a cooperative fashion. DOL will maintain health and safety standards and protect employees by working with the regulated community.

DOL considers the following proposals to be proactive, common sense approaches to the issues most clearly needing regulatory attention.

The Department's Regulatory Priorities

DOL has identified 14 high priority items for regulatory action. Five items address health and safety issues, which are central to DOL's mission and which represent a major focus of the Secretary. Two agencies, the Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA), are responsible for these initiatives.

MSHA administers the Federal Mine Safety and Health Act of 1977 (Mine Act). The agency is committed to ensuring safer and healthier workplaces for the nation's miners in a number of ways, and will continue to concentrate on improving existing health standards and addressing emerging health hazards in mining.

MSHA published an advance notice of proposed rulemaking (ANPRM) concerning asbestos exposure of miners, and conducted a series of public meetings in 2002 to allow early participation by interested parties in the rulemaking. A proposed rule was published in July 2005 to lower the existing permissible exposure limit (PEL) for asbestos at metal and nonmetal mines, and at surface areas of underground coal mines. MSHA used the public comments received as a result of the ANPRM, and the experience of other agencies to help develop the proposed rule. MSHA will hold public hearings to solicit additional public input before a final rule is developed.

MSHA also continues its rulemaking on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (RIN 1219-AB29). A final rule was published in June 2005 that converts the diesel particulate matter interim limit of 400 micrograms of total carbon to a more accurately measured equivalent 308 micrograms of elemental carbon. The standard includes a permissible exposure limit, establishes MSHA's longstanding hierarchy of controls required at metal and nonmetal mines, permits unlimited extensions at individual mines based on technological or economic feasibility, and eliminates the requirement for a control plan. A proposed rule was published in August 2005 that would revise the January 2006 effective date of the existing diesel particulate matter final limit to allow a 5-year phase-in of that final limit based on feasibility issues. The proposed rule also seeks input about medical evaluation before miners would be required to wear respirators and about transfer rights of miners who cannot wear respirators when their exposure to diesel particulate matter exceeds the allowable limits.

The Occupational Safety and Health Administration oversees a wide range of measures in the public and private sectors. OSHA is committed to establishing clear and sensible priorities, and to continuing to reduce occupational deaths, injuries, and illnesses.

OSHA's high-priority initiatives address health standards. The first, a revision to the Respiratory Protection Standard, will address Assigned Protection Factors for different types of respirators (RIN 1218-AA05). This action will improve respiratory protection for employees required to wear respirators and will make it easier for employers to choose the appropriate respirator for a given task. OSHA published an NPRM on June 6, 2003, and informal public hearings were held on January 28-30, 2004.

OSHA's second initiative in the area of health standards addresses worker exposures to crystalline silica (RIN 1218-AB70). This substance is one of the most widely found in workplaces, and data indicate that 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 2006.

OSHA's third health initiative addresses worker exposure to hexavalent chromium (RIN 1218-AB45). Approximately 380,000 workers are exposed to this substance in general industry, maritime, construction and agriculture. Exposure to hexavalent chromium is associated with lung cancer and dermatoses. OSHA has obtained input from small businesses about regulatory approaches through a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel, which submitted a report to the Assistant Secretary for OSHA on April 20, 2004. The proposed rule was published on October 4, 2004. A final rule is expected in January 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 2005, the Employee Benefits Security Administration (EBSA) will focus on compliance assistance for pension and group health plans through issuance of guidance. Specific initiatives for group health plans include guidance on the application of the Health Insurance Portability and Accountability Act (HIPAA) access, portability and renewability provisions (RIN 1210-AA54); and the HIPAA nondiscrimination provisions of the Employee Retirement Income Security Act (ERISA) (RIN 1210-AA77). With respect to pension plans, the Department will 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 adopting standards that will facilitate the payment of benefits from 401(k) and other defined contribution plans that have been abandoned by their sponsors (RIN 1210-AA97). In addition, the Department 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).

ERISA's requirements affect an estimated 736,000 private sector employee pension benefit plans (covering approximately 103 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 recent changes to the Trade Adjustment Assistance (TAA) program, as enacted in the Trade Act of 2002. The regulations will be issued in two parts: regulations covering TAA program benefits (RIN 1205-AB32), and regulations covering petition filing, investigations and the new Alternative TAA Program for Older Workers (RIN 1205-AB40). The proposed rules would address the many new features of the TAA program: consolidation of the TAA and NAFTA-TAA programs; rapid response services for workers to facilitate more rapid reemployment; expanded eligibility; increased benefits, including health care insurance assistance; and Alternative TAA for Older Workers program. The new regulations will be written in plain English, making them easier to read and use.

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. Revisions will be proposed to the FMLA's implementing regulations to address issues raised by the decision of the U.S. Supreme Court in *Ragsdale v. Wolverine World Wide, Inc.,* 122 S. Ct. 1155 (2002), and the decisions of other courts.

Finally, the Secretary's commitment to protecting the employment rights of service members as they return to the civilian workforce is reflected by the Veterans' Employment and Training Service's (VETS) initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA). USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA. Authoritative written guidance interpreting USERRA will ensure that our service members serve secure in the knowledge that they will be able to return to their jobs with the same pay, benefits, and status they would have attained had they not been away on military duty.

DOL—Employment Standards Administration (ESA)

PROPOSED RULE STAGE

74. FAMILY AND MEDICAL LEAVE ACT OF 1993; CONFORM TO THE SUPREME COURT'S RAGSDALE DECISION

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 2654

CFR Citation:

29 CFR 825

Legal Deadline:

None

Abstract:

The U.S. Supreme Court, in Ragsdale v. Wolverine World Wide, Inc., 122 S. Ct. 1155 (2002), invalidated regulatory provisions issued under the Family and Medical Leave Act (FMLA) pertaining to the effects of an employer's failure to timely designate leave that is taken by an employee as being covered by the FMLA. The Department intends to propose revisions to the FMLA regulations to address issues raised by this and other judicial decisions.

Statement of Need:

The FMLA requires covered employers to grant eligible employees up to 12 workweeks of unpaid, job-protected leave a year for specified family and medical reasons, and to maintain group health benefits during the leave as if the employees continued to work instead of taking leave. When an eligible employee returns from FMLA leave, the employer must restore the employee to the same or an equivalent job with equivalent pay, benefits, and other conditions of employment. FMLA makes it unlawful for an employer to interfere with, restrain, or deny the exercise of any right provided by the FMLA.

The FMLA regulations require employers to designate if an employee's use of leave is counting against the employee's FMLA leave entitlement, and to notify the employee of that designation (29 CFR section 825.208). Section 825.700(a) of the regulations provides that if an employee takes paid or unpaid leave and the employer does not designate the leave as FMLA leave, the leave taken does not count against the employee's 12 weeks of FMLA leave entitlement.

On March 19, 2002, the U.S. Supreme Court issued its decision in Ragsdale v. Wolverine World Wide, Inc., 122 S. Ct. 1155 (2002). In that decision, the Court invalidated regulatory provisions pertaining to the effects of an employer's failure to timely designate leave that is taken by an employee as being covered by the FMLA. The Court ruled that 29 CFR section 825.700(a) was invalid absent evidence that the employer's failure to designate the leave as FMLA leave interfered with the employee's exercise of FMLA rights. This proposed rule is being

prepared to address issues raised by this and other judicial decisions.

Summary of Legal Basis:

This rule is issued pursuant to section 404 of the Family and Medical Leave Act, 29 U.S.C. section 2654.

Alternatives:

After completing a review and analysis of the Supreme Court's decision in Ragsdale and other judicial decisions, regulatory alternatives will be developed for notice-and-comment rulemaking.

Anticipated Cost and Benefits:

The costs and benefits of this rulemaking action are not expected to exceed $100 million per year or otherwise trigger economic significance under Executive Order 12866.

Risks:

This rulemaking action does not directly affect risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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DOL—Employment and Training Administration (ETA)

PROPOSED RULE STAGE

75. REVISION TO THE DEPARTMENT OF LABOR BENEFIT REGULATIONS FOR TRADE ADJUSTMENT ASSISTANCE FOR WORKERS UNDER THE TRADE ACT OF 1974, AS AMENDED

Priority:

Other Significant

Legal Authority:

19 USC 2320; Secretary's Order No. 3–81, 46 FR 31117

CFR Citation:

29 CFR 90; 20 CFR 617; 20 CFR 618; 20 CFR 665; 20 CFR 671; . . .

Legal Deadline:

None

Abstract:

The Trade Adjustment Assistance Reform Act of 2002, enacted on August 6, 2002, contains provisions amending title 2, chapter 2 of the Trade Act of 1974, entitled Adjustment Assistance for Workers. The amendments, effective 90 days from enactment (November 4, 2002), make additions to where and by whom a petition may be filed, expand eligibility to workers whose production has been shifted to certain foreign countries and to worker groups secondarily affected, and make substantive changes regarding trade adjustment assistance (TAA) program benefits.

It is the agency's intention to create a new 20 CFR part 618 to incorporate the amendments and write it in plain English, while amending the WIA regulations at 20 CFR parts 665 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of nine subparts: subpart A - General; subpart B—Petitions and Determinations of Eligibility to Apply for Trade Adjustment Assistance (and Alternative TAA); subpart C—-Delivery of Services throughout the One-Stop Delivery System; subpart D—Job Search Allowances; subpart E—Relocation Allowances; subpart F—Training Services; subpart G—Trade Readjustment Allowances (TRA); subpart H—Administration by Applicable State Agencies; and subpart I—Alternative Trade Adjustment Assistance for Older Workers. Because of the complexity of the subject matter and the States' needs for definitive instructions on providing TAA benefits, the rulemaking for part 618 is divided into two parts. This notice of proposed rulemaking covers the general provisions (subpart A) and TAA benefits portions (subpart C through subpart H) of the regulations. A separate notice of proposed rulemaking will cover the two remaining subparts (subpart B and subpart I).

Statement of Need:

The Trade Adjustment Assistance Reform Act of 2002, enacted August 6, 2002, repeals the North American Free Trade Agreement-Transitional Adjustment Assistance provisions for workers affected by the NAFTA Implementation Act and adds significant amendments to worker benefits under Trade Adjustment Assistance for Workers, as provided for in the Trade Act of 1974.

The 2002 Trade Act amends where and by whom a petition may be filed. Program benefits for TAA—eligible recipients are expanded to include for the first time a health care tax credit, and eligible recipients now include secondarily affected workers impacted by foreign trade. Income support is extended by 26 weeks and by up to one year under certain conditions. Waivers of training requirements in order to receive income support are explicitly defined. Job search and relocation benefit amounts are increased. Within one year of enactment, the amendments offer an Alternative TAA for Older Workers program that targets older worker groups who are certified as TAA eligible and provides the option of a wage supplement instead of training, job search, and income support.

The Department is mandated to implement the amendments within 90 days from enactment (November 4, 2002), and it issued operating instructions in a guidance letter on October 10, 2002, and later published in the Federal Register (67 FR 69029-41). State agencies rely on the regulations to make determinations as to individual eligibility for TAA program benefits. TAA program regulations as written have been described as complicated to interpret. With the new TAA program benefit amendments contained in the Trade Act of 2002, it is imperative that the regulations be in an easy-to-read and understandable format.

Summary of Legal Basis:

These regulations are authorized by 19 U.S.C. 2320 due to the amendments to the Trade Act of 1974 by the Trade Adjustment Assistance Reform Act of 2002.

Alternatives:

The public will be afforded an opportunity to provide comments on the TAA program changes when the Department publishes the proposed rule in the Federal Register.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs of this regulatory action have not been determined at this time and will be determined at a later date.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

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DOL—ETA

76. REVISION TO THE DEPARTMENT OF LABOR REGULATIONS FOR PETITIONS AND DETERMINATIONS OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE FOR WORKERS AND ISSUANCE OF REGULATIONS FOR THE ALTERNATIVE TAA

Priority:

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

Legal Authority:

19 USC 2320; Secretary's Order No. 3–81, 46 FR 31117

CFR Citation:

29 CFR 90; 20 CFR 617; 20 CFR 618; 20 CFR 665; 20 CFR 671; . . .

Legal Deadline:

None

Abstract:

The Trade Adjustment Assistance Reform Act of 2002, enacted on August 6, 2002, contains provisions amending title 2, chapter 2 of the Trade Act of 1974, entitled Adjustment Assistance for Workers. The amendments, effective 90 days from enactment (November 4, 2002), make additions to where and by whom a petition may be filed, expand eligibility to workers whose production has been shifted to certain foreign countries and to worker groups secondarily affected, and make substantive changes regarding trade adjustment assistance (TAA) program benefits.

It is the agency's intention to create a new 20 CFR part 618 to incorporate the amendments and write it in plain English, while amending the WIA regulations at 20 CFR parts 665 and 671 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

The proposed part 618 consists of nine subparts: subpart A—General; subpart B—Petitions and Determinations of Eligibility to Apply for Trade Adjustment Assistance (and Alternative TAA); subpart C—Delivery of Services throughout the One-Stop Delivery System; subpart D—Job Search Allowances; subpart E—Relocation Allowances; subpart F—Training Services; subpart G—Trade Readjustment Allowances (TRA); subpart H—Administration by Applicable State Agencies; and subpart I—Alternative Trade Adjustment Assistance (ATAA) for Older Workers. Because of the complexity of the subject matter and the States' needs for definitive instructions on providing TAA benefits, the rulemaking for part 618 is divided into two parts. This notice of proposed rulemaking covers the petitions and determinations (subpart B) and ATAA (subpart I) of the regulations. A separate notice of proposed rulemaking will cover the remaining subparts (subpart A and subparts C through H).

Statement of Need:

The Trade Adjustment Assistance Reform Act of 2002, enacted August 6, 2002, repeals the North American Free Trade Agreement-Transitional Adjustment Assistance provisions for workers affected by the NAFTA Implementation Act and adds significant amendments to worker benefits under Trade Adjustment Assistance for Workers, as provided for in the Trade Act of 1974.

The 2002 Trade Act amends where and by whom a petition may be filed. Program benefits for TAA—eligible recipients are expanded to include for the first time a health care tax credit, and eligible recipients now include secondarily affected workers impacted by foreign trade. Income support is extended by 26 weeks and by up to one year under certain conditions. Waivers of training requirements in order to receive income support are explicitly defined. Job search and relocation benefit amounts are increased. Within one year of enactment, the amendments offer an Alternative TAA for Older Workers program that targets older worker groups who are certified as TAA eligible and provides the option of a wage supplement instead of training, job search, and income support.

The Department is mandated to implement the amendments within 90 days from enactment (November 4, 2002), and it issued operating instructions in a guidance letter on October 10, 2002, and later published in the Federal Register (67 FR 69029-41). State agencies rely on the regulations to make determinations as to individual eligibility for TAA program benefits. TAA program regulations as written have been described as complicated to interpret. With the new TAA program benefit amendments contained in the Trade Act of 2002, it is imperative that the regulations be in an easy-to-read and understandable format.

Summary of Legal Basis:

These regulations are authorized by 19 U.S.C. 2320 due to the amendments to the Trade Act of 1974 by the Trade Adjustment Assistance Reform Act of 2002.

Alternatives:

The public will be afforded an opportunity to provide comments on the TAA program changes when the Department publishes the proposed rule in the Federal Register.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs of this regulatory action have not been determined at this time and will be determined at a later date.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State

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RIN: 1205–AB40

DOL—Employee Benefits Security Administration (EBSA)

PROPOSED RULE STAGE

77. 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	03/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Federalism:

Undetermined

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RIN: 1210–AB02

DOL—EBSA

78. ● AMENDMENT OF SECTION 404(C) REGULATION DEFAULT INVESTMENTS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 1104(c); 29 USC 1135

CFR Citation:

29 CFR 2550

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulation to address the application of section 404(c)of ERISA under circumstances where a participant is automatically enrolled in a 401(k) or similar individual account plan and that participant fails to direct the investment of his or her contributions. This rulemaking also would address the extent to which fiduciary liability for investment decisions might be limited through the use of a default investment vehicle.

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. The Department has previously issued regulations under section 404(c)(1) describing the circumstances in which 404(c)(1) applies to a transaction involving a participant's or beneficiary's exercise of control over his or her account. This rulemaking would amend those regulations to respond 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 will be developed once determinations have been made with regard to the scope and nature of the regulatory guidance that will be necessary to provide for default investment options when a participant in a 401(k) or similar individual account plan fails to direct the investment of his or her account.

Anticipated Cost and Benefits:

Costs and benefits of regulatory alternatives will be estimated and taken into account in the development of the proposed regulation. Intended benefits include increases in 401(k) plan participation rates, more beneficial asset allocations of many participants' accounts, and attendant improvements in retirement security.

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.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Federalism:

Undetermined

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DOL—EBSA

FINAL RULE STAGE

79. REGULATIONS IMPLEMENTING THE HEALTH CARE ACCESS, PORTABILITY, AND RENEWABILITY PROVISIONS OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1171; 29 USC 1172; 29 USC 1191c

CFR Citation:

29 CFR 2590

Legal Deadline:

None

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended title I of ERISA by adding a new part 7, designed to improve health care access, portability and renewability. This rulemaking will provide regulatory guidance to implement these provisions.

Statement of Need:

In general, the health care portability provisions in part 7 of ERISA provide for increased portability and availability of group health coverage through limitations on the imposition of any preexisting condition exclusion and special enrollment rights in group health plans after loss of other health coverage or a life event. Plan sponsors, administrators and participants need guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Part 7 of ERISA specifies the portability and other requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 of ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Request for Information	10/25/99	64 FR 57520
Comment Period End	01/25/00	
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	

Action	Date	FR Cite
NPRM Comment Period End	03/30/05	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1210–AA54

DOL—EBSA

80. PROHIBITING DISCRIMINATION AGAINST PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS

Priority:

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

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1182; 29 USC 1191c; 29 USC 1194

CFR Citation:

29 CFR 2590.702

Legal Deadline:

None

Abstract:

Section 702 of the Employee Retirement Income Security Act of 1974, amended by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), establishes that a group health plan or a health insurance issuer may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. These provisions are also contained in the Internal Revenue Code under the jurisdiction of the Department of the Treasury, and the Public Health Service Act under the jurisdiction of the Department of Health and Human Services.

On April 8, 1997, the Department, in conjunction with the Departments of the Treasury and Health and Human Services (collectively, the Departments) published interim final regulations implementing the nondiscrimination provisions of HIPAA. These regulations can be found at 26 CFR 54.9802-1 (Treasury), 29 CFR 2590.702 (Labor), and 45 CFR 146.121 (HHS). That notice of rulemaking also solicited comments on the nondiscrimination provisions and indicated that the Departments intend to issue further regulations on the nondiscrimination rules. This rulemaking contains additional regulatory guidance under HIPAA's nondiscrimination provisions. In addition, the rulemaking contains proposed guidance on bona fide wellness programs.

Statement of Need:

Part 7 of ERISA provides that group health plans and health insurance issuers may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. Plan sponsors, administrators, and participants need additional guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Section 702 of ERISA specifies the respective nondiscrimination requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
NPRM	01/08/01	66 FR 1421
NPRM Comment Period End	04/09/01	
Second Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Comment Period End	04/09/01	
Final Rule	02/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

This item has been split off from RIN 1210-AA54.

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RIN: 1210–AA77

DOL—EBSA

81. RULEMAKING RELATING TO TERMINATION OF ABANDONED INDIVIDUAL ACCOUNT PLANS

Priority:

Other Significant

Legal Authority:

29 USC 1135; 29 USC 1002(16)(A)

CFR Citation:

29 CFR 2591

Legal Deadline:

None

Abstract:

This rulemaking will establish a procedure and standards for distributing the benefits of individual account plans that have been abandoned by their sponsoring employers or plan administrators.

Statement of Need:

Thousands of individual account plans have, for a variety of reasons, been abandoned by their sponsors, creating problems for plan participants, administrators, financial institutions (e.g., banks, insurance companies, mutual funds), the courts and the Federal Government. At present, the potential liability and costs attendant to terminating such plans and distributing the assets inhibits financial institutions and others from taking on this responsibility. Due to ongoing administrative costs and other factors, the continued maintenance of such plans is often not in the interest of the

participants and beneficiaries. This rulemaking will establish a procedure for a financial institution that holds the assets of such a plan to terminate the plan and distribute its assets to the participants and beneficiaries. The rulemaking will also include standards for determining when plans may be terminated pursuant to this procedure and for carrying out the functions necessary to distribute benefits and shut down plan operations.

Summary of Legal Basis:

Section 505 of ERISA provides that the Secretary may prescribe such regulations as the Secretary finds necessary and appropriate to carry out the provisions of title I of the Act. Section 403(d)(1) provides that, upon termination of such a plan, the assets shall be distributed generally in accordance with the provisions that apply to defined benefit plans, ''except as otherwise provided in regulations of the Secretary.'' ERISA section 3(16)(A) permits the Secretary to issue regulations designating an administrator for a plan where the plan document makes no designation and the plan sponsor cannot be identified.

Alternatives:

Alternatives will be considered following a determination of the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed, as appropriate, following a determination regarding the alternatives to be considered.

Risks:

Failure to provide guidance in this area will leave the retirement benefits of participants and beneficiaries in abandoned plans at risk of being significantly diminished by ongoing plan administrative expenses, rather than distributed to participants and beneficiaries in connection with a timely and orderly termination of the plan.

Timetable:

Action	Date	FR Cite
NPRM	03/10/05	70 FR 12046
NPRM Comment Period End	05/09/05	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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RIN: 1210–AA97

DOL—Mine Safety and Health Administration (MSHA)

FINAL RULE STAGE

82. ASBESTOS EXPOSURE LIMIT

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 56; 30 CFR 57; 30 CFR 71

Legal Deadline:

None

Abstract:

MSHA's permissible exposure limit (PEL) for asbestos applies to surface (30 CFR part 56) and underground (30 CFR part 57) metal and nonmetal mines and to surface coal mines and surface areas of underground coal mines (30 CFR part 71) and is over 20 years old. MSHA proposed a rule to lower the PEL in order to reduce the risk of miners developing asbestos-induced occupational disease. A report by the Office of the Inspector General (OIG) recommended that MSHA lower its existing permissible exposure limit for asbestos to a more protective level, and address take-home contamination from asbestos. It also recommended that MSHA use Transmission Electron Microscopy to analyze fiber samples that may contain asbestos.

Statement of Need:

Current scientific data indicate that the existing asbestos PEL is not sufficiently protective of miners' health. MSHA's asbestos regulations date to 1967 and are based on the Bureau of Mines (MSHA's predecessor) standard of 5 mppcf (million particles per cubic foot of air). In 1969, the Bureau proposed a 2 mppcf and 12 fibers/ml standard. This standard was promulgated in 1969. In 1970, the Bureau proposed to lower the standard to 5 fibers/ml, which was promulgated in 1974. MSHA issued its current standard of 2 fibers/ml in 1976 for coal mining (41 FR 10223) and 1978 for metal and nonmetal mining (43 FR 54064). During inspections, MSHA routinely takes samples, which are analyzed for compliance with its standard.

Other Federal agencies have addressed this issue by lowering their PEL for asbestos. For example, the Occupational Safety and Health Administration, working in conjunction with the Environmental Protection Agency, enacted a revised asbestos standard in 1994 that lowered the permissible exposure limit to an 8-hour time-weighted average limit of 0.1 fiber per cubic centimeter of air and the excursion limit to 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes. These lowered limits reflected 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 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, MSHA staff discussed with miners and mine operators the potential hazards of asbestos and the types of preventive measures that could be implemented to reduce exposures. The course of action MSHA takes in addressing asbestos hazards to miners will, in part, be based on these sampling results.

Anticipated Cost and Benefits:

MSHA developed a preliminary regulatory economic analysis to accompany the proposed rules.

Risks:

Miners could be exposed to the hazards of asbestos during mine operations where the ore body contains asbestos. There is also potential for exposure at facilities in which installed asbestos-containing material is present. Overexposure to asbestos causes asbestosis, 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	09/20/05	70 FR 43950
Public Hearing	10/18/05	70 FR 43950
Final Action	07/00/06	

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.

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DOL—MSHA

83. DIESEL PARTICULATE MATTER EXPOSURE OF UNDERGROUND METAL AND NONMETAL MINERS

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 57

Legal Deadline:

None

Abstract:

On January 19, 2001, MSHA published a final rule addressing diesel particulate matter (DPM) exposure of underground metal and nonmetal miners (66 FR 5706). The final rule established new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines. The rule established an interim concentration limit of 400 micrograms of total carbon per cubic meter of air that became applicable July 20, 2002, and a final concentration limit of 160 micrograms to become applicable after January 19, 2006. Industry challenged the rule and organized labor intervened in the litigation. Settlement negotiations with the litigants have resulted in further regulatory actions on several requirements of the rule. One final rule was published on February 27, 2002 (67 FR 9180). MSHA issued an advance notice of proposed rulemaking (ANPRM) on September 25, 2002 (67 FR 60199) to obtain additional information and published a notice of proposed rulemaking (NPRM) in August 2003 (68 FR 48668). MSHA issued a final rule on June 6, 2005 (70 FR 32868) that revises MSHA's existing standards addressing diesel particulate matter (DPM) exposure in underground metal and nonmetal (M/NM) mines. The rule, among other things, changes the interim concentration limit measured by total carbon (TC) to a comparable permissible exposure limit (PEL) measured by elemental carbon (EC). MSHA is developing a rule to phase in implementation of the final limit.

Statement of Need:

As a result of the first partial settlement with the litigants, MSHA published two documents in the Federal Register on July 5, 2001. One document delayed the effective date of 57.5066(b) regarding the tagging provisions of the maintenance standard; clarified the effective dates of certain provisions of the final rule; and gave correction amendments (66 FR 35518).

The second document was a proposed rule to clarify 57.5066(b)(1) and (b)(2) of the maintenance standards and to add a new paragraph (b)(3) to 57.5067 regarding the transfer of existing diesel equipment from one underground mine to another underground mine (66 FR 35521). The final rule on these issues was published February 27, 2002, and became effective March 29, 2002.

As a result of the second partial settlement agreement, MSHA proposed specific changes to the 2001 DPM final rule. On September 25, 2002, MSHA published an ANPRM. In response to commenters, MSHA proposed and finalized changes only to the interim DPM standard of 400 micrograms per cubic meter of air. MSHA also committed to proposing a rule to revise the final DPM limit of 160 micrograms per cubic meter of air.

Summary of Legal Basis:

Promulgation of this regulation is authorized by sections 101 and 103 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

This rulemaking would amend and improve health protection from that afforded by the existing standard.

Anticipated Cost and Benefits:

MSHA's preliminary economic analysis indicates that making the changes under consideration would result in a net cost savings to the mining industry.

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. We believe that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate matter. Proceeding with rulemaking on the provisions discussed above will more effectively reduce miners' exposure to DPM.

Timetable:

Action	Date	FR Cite
Final Action	02/27/02	67 FR 9180
ANPRM	09/25/02	67 FR 60199
ANPRM Comment Period End	11/25/02	
NPRM	08/14/03	68 FR 48668
NPRM Comment Period End	10/14/03	
Limited Reopening of the Comment Period	02/20/04	69 FR 7881
Limited Reopening of the Comment Period End	04/05/04	69 FR 7881

Action	Date	FR Cite
Final Action	06/06/05	70 FR 32868
Final Action Effective	07/06/05	
Second NPRM	09/07/05	70 FR 53280
Notice of Public Hearing	09/07/05	70 FR 53280
Close of Comment Period	09/07/05	70 FR 53280
Request for Data	09/07/05	70 FR 53280
Comment Period Extended	09/19/05	70 FR 55018
Change of Public Hearings Dates	09/19/05	70 FR 55018
Final Action	05/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219–AB29

DOL—Occupational Safety and Health Administration (OSHA)

PRERULE STAGE

84. 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	

Action	Date	FR Cite
Complete Peer Review of Health Effects and Risk Assessment	04/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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DOL—OSHA

FINAL RULE STAGE

85. ASSIGNED PROTECTION FACTORS: AMENDMENTS TO THE FINAL RULE ON RESPIRATORY PROTECTION

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910.134

Legal Deadline:

None

Abstract:

In January 1998, OSHA published the final Respiratory Protection standard (29 CFR 1910.134), except for reserved provisions on assigned protection factors (APFs) and maximum use concentrations (MUCs). APFs are numbers that describe the effectiveness of the various classes of respirators in reducing employee exposure to airborne contaminants (including particulates, gases, vapors, biological agents, etc.). Employers, employees, and safety and health professionals use APFs to determine the type of respirator to protect the health of employees in various hazardous environments. Maximum use concentrations establish the maximum airborne concentration of a contaminant in which a respirator with a given APF may be used.

Currently, OSHA relies on the APFs developed by NIOSH in the 1980s unless OSHA has assigned a different APF in a substance-specific health standard. However, many employers follow the more recent APFs published in an industry consensus standard, ANSI Z88.2-1992. For some classes of respirators, the NIOSH and ANSI APFs vary greatly.

This rulemaking action will complete the 1998 standard, reduce compliance confusion among employers, and provide employees with consistent and appropriate respiratory protection. On June 6, 2003, OSHA published an NPRM on Assigned Protection Factors in the Federal Register at 68 FR 34036 containing a proposed APF table, and requesting public comment. The extended comment period ended October 2, 2003, and an informal public hearing was held January 28-30, 2004.

Statement of Need:

About five million employees wear respirators as part of their regular job duties. Due to inconsistencies between the APFs found in ANSI Z88.2-1992 and in the NIOSH Respirator Decision Logic, employers, employees, and safety and health professionals are often uncertain about what respirator to select to provide protection against hazardous air contaminants.

Summary of Legal Basis:

The legal basis for this proposed rule is the determination that assigned protection factors and maximum use concentrations are necessary to complete the final Respiratory Protection standard and provide the full protection under that standard.

Alternatives:

OSHA has considered allowing the current situation to continue. Accordingly, OSHA generally enforces NIOSH APFs, but many employers follow the more recent ANSI Z88.2-1992 APFs. However, allowing the situation to continue results in inconsistent enforcement, lack of guidance for employers, and the potential for inadequate employee protection.

Anticipated Cost and Benefits:

The estimated compliance costs for OSHA's proposed APF rule are $4.6 million. The APFs proposed in this rulemaking help to ensure that the benefits attributed to proper respiratory protection under 29 CFR 1910.134 are achieved, as well as provide an additional degree of protection.

Risks:

The preamble to the final Respiratory Protection rule (63 FR 1270, Jan. 8, 1998) discusses the significance of the risks potentially associated with the use of respiratory protection. No independent finding of significant risk has been made for the APF rulemaking since it only addresses a single provision of the larger rule.

Timetable:

Action	Date	FR Cite
ANPRM	05/14/82	47 FR 20803
ANPRM Comment Period End	09/13/82	
NPRM	11/15/94	59 FR 58884
Final Rule	01/08/98	63 FR 1152
Final Rule Effective	04/08/98	
NPRM	06/06/03	68 FR 34036
NPRM Comment Period End	09/04/03	
NPRM Comment Period Extended	10/02/03	68 FR 53311
Public Hearing on 01/28/2004	11/12/03	68 FR 64036
Final Rule: Revocation of Respiratory Protection M. TB	12/31/03	68 FR 75767
Public Hearing	01/28/04	
Post–Hearing Comment and Brief Period Extended	03/30/04	69 FR 16510
Post–Hearing Comment Period End	04/29/04	
Post–Hearing Briefs End	05/29/04	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State, Tribal

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DOL—OSHA

86. OCCUPATIONAL EXPOSURE TO HEXAVALENT CHROMIUM (PREVENTING OCCUPATIONAL ILLNESS: CHROMIUM)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910

Legal Deadline:

NPRM, Judicial, October 4, 2004.

Final, Judicial, January 18, 2006.

Abstract:

In July 1993, the Occupational Safety and Health Administration (OSHA) was petitioned for an emergency temporary standard (ETS) to reduce the permissible exposure limit (PEL) for occupational exposures to hexavalent chromium (CrVI). The Oil, Chemical, and Atomic Workers International Unions (OCAW) and Public Citizen's Health Research Group (HRG) petitioned OSHA to promulgate an ETS to lower the PEL for CrVI compounds to 0.5 micrograms per cubic meter of air (ug/m3) as an eight-hour, time-weighted average (TWA). The current PEL in general industry is a ceiling value of 100 ug/m3, measured as CrVI and reported as chromic anhydride (CrO3). The amount of CrVI in the anhydride compound equates to a PEL of 52 ug/m3. The ceiling limit applies to all forms of CrVI, including chromic acid and chromates, lead chromate, and zinc chromate. The current PEL of CrVI in the construction industry is 100 ug/m3 as a TWA PEL, which also equates to a PEL of 52 ug/m3. After reviewing the petition, OSHA denied the request for an ETS and initiated a section 6(b)(5) rulemaking.

OSHA began collecting data and performing preliminary analyses relevant to occupational exposure to CrVI. However, in 1997, OSHA was sued by HRG OCAW for unreasonable delay in issuing a final CrVI standard. The 3rd Circuit, U.S. Court of Appeals ruled in OSHA's favor and the Agency continued its data collection and analytic efforts on CrVI. In 2002, OSHA was sued again by HRG and Paper, Allied-International, Chemical and Energy Workers International Union (PACE) for continued unreasonable delay in issuing a final CrVI standard. In August, 2002 OSHA published a Request for Information on CrVI to solicit additional information on key issues related to controlling exposures to CrVI and on December 4, 2002, OSHA announced its intent to proceed with developing a proposed standard. On December 24, 2002, the 3rd Circuit, U.S. Court of Appeals ruled in favor of HRG and ordered the Agency to proceed expeditiously with a CrVI standard. OSHA published a notice of proposed rulemaking on CrVI on October 4, 2004. Public hearings were held February 1-15, 2005.

Statement of Need:

Approximately 380,000 workers are exposed to CrVI in general industry, maritime, construction, and agriculture. Industries or work processes that could be particularly affected by a standard for CrVI include: Electroplating, welding, painting, chromate production, chromate pigment production, ferrochromium production, iron and steel production, chromium catalyst production, and chromium dioxide and sulfate production. Exposure to CrVI has been shown to produce lung cancer, an often fatal disease, among workers exposed to CrVI compounds. The International Agency for Research on Cancer (IARC) classifies CrVI compounds as a Group 1 Carcinogen: Agents considered to be carcinogenic in humans. The Environmental Protection Agency (EPA) and the American Conference of Governmental Industrial Hygienists (ACGIH) have also designated CrVI compounds as known and confirmed human carcinogens, respectively. Similarly, the National Institute for Occupational Safety and Health (NIOSH) considers CrVI compounds to be potential occupational carcinogens. OSHA's current standards for CrVI compounds, adopted in 1971, were established to protect against nasal irritation. Therefore, there is a need to revise the current standard to protect workers from lung cancer.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of lung cancer and dermatoses and that rulemaking is needed to substantially reduce the risk.

Alternatives:

OSHA had considered non-regulatory approaches, including the dissemination of guidance on its Web site. However, OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of CrVI and the Agency has been ordered by the U.S. Court of Appeals to move forward with a final rule.

Anticipated Cost and Benefits:

In the NPRM, OSHA preliminary estimates the cost of the proposed standards at $223 million per year. OSHA preliminarily estimates the proposed standard will prevent an average of 44 to 167 cases on cancer per year, and will have monetary benefits of $25 million to $701 million per year.

Risks:

A detailed risk analysis is included in the NPRM.

Timetable:

Action	Date	FR Cite
Request for Information	08/22/02	67 FR 54389
Comment Period End	11/20/02	
Initiate SBREFA Process	12/23/03	
SBREFA Report	04/20/04	
NPRM	10/04/04	69 FR 59305
NPRM Comment Period End	01/03/05	
Public Hearings 2/1–15/2005	02/01/05	
Final Rule	01/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local, State

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DOL—Office of the Assistant Secretary for Veterans' Employment and Training (ASVET)

FINAL RULE STAGE

87. UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT REGULATIONS

Priority:

Other Significant

Legal Authority:

38 USC 4331(a)

CFR Citation:

20 CFR 1002

Legal Deadline:

None

Abstract:

The Secretary's commitment to protecting the employment rights of service members as they return to the civilian work force is reflected by the initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA) with regard to States, local governments and private employers. USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA, although the law dates back to 1994.

Statement of Need:

The Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA), 38 U.S.C. 4301-4333, provides employment and reemployment rights for members of the uniformed services, including veterans and members of the Reserve and National Guard. Under USERRA, eligible service members who leave their civilian jobs for military service are entitled to return to reemployment with their previous employers with the seniority, status and rate of pay they would have attained had they not been away on duty. USERRA also assures that they will not suffer discrimination in employment because of their military service or obligations.

Following the attacks of September 11, 2001, the President authorized a major mobilization of National Guard and Reserve forces that has continued into 2005. In the past three years, the Department has experienced a tremendous increase in the number of inquiries about USERRA from employers and members of the Guard and Reserve. The high volume of requests for technical assistance indicates that there is a significant need for consistent and authoritative USERRA guidance. USERRA regulations will provide the Department's interpretations of the law and procedures for enforcing the law.

Summary of Legal Basis:

USERRA authorizes the Secretary of Labor, in consultation with the Secretary of Defense, to issue regulations implementing USERRA with regard to States, local governments and private employers. 38 U.S.C. 4331(a).

Alternatives:

In lieu of regulations, the Department could choose to continue its compliance assistance efforts, and could issue interpretations of USERRA in the form of a USERRA Handbook, policy memoranda or other less formal means. These would not benefit from broad-based public input, nor would they receive the same level of deference as regulations. See United States v. Mead Corp., 533 U.S. 218, 230 (2001).

Timetable:

Action	Date	FR Cite
NPRM	09/20/04	69 FR 56266
NPRM Comment Period End	11/19/04	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State

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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 Secretary Mineta's has been to increase the timeliness of DOT rulemaking actions and address the large number of old rulemakings. To implement this, the Secretary has required (1) regular meetings of senior DOT officials to ensure effective scheduling of rulemakings and timely decisions, (2) better tracking and coordination of rulemakings, (3) regular reporting, (4) early briefings of interested officials, (5) better training of staff, and (6) necessary resource allocations. The Department has achieved significant success as a result of this initiative with the number of old rulemakings as well as the average time to complete rulemakings decreasing. This is also allowing the Department to use its resources more effectively and efficiently.

The Department's regulatory policies and procedures provide a comprehensive internal management and review process for new and existing regulations and ensure that the Secretary and other appropriate appointed officials review and concur in all significant DOT rules. DOT continually seeks to improve its regulatory process. The Department's development of regulatory process and related training courses for its employees; creation of an electronic, Internet-accessible docket that can also be used to submit comments electronically; a ''list serve'' that allows the public to sign up for e-mail notification when the Department issues a rulemaking document; creation of an electronic rulemaking tracking and coordination system; the use of direct final rulemaking; and the use of regulatory negotiation are a few examples of this.

In addition, the Department continues to engage in a wide variety of activities to help cement the partnerships between its agencies and its customers that will produce good results for transportation programs and safety. The Department's agencies also have established a number of continuing partnership mechanisms in the form of rulemaking advisory committees.

The Department is also actively engaged in the review of existing rules to determine whether they need to be revised or revoked. These reviews are in accordance with section 610 of the Regulatory Flexibility Act, the Department's regulatory policies and procedures, and Executive Order 12866. This includes determining if the rules would be more understandable if they are written using a plain language approach. Appendix D to our Regulatory Agenda highlights our efforts in this area.

In addition, on January 26, 2005, the Department issued a special regulatory review notice providing the public with an additional opportunity to give comments on the Department's existing rules and regulatory agenda. The focus of the regulatory review was on (1) which existing DOT rules needed to be changed to make them more effective or (2) getting suggestions for different priorities in our agenda. In response, the Department received over sixty comments.

Over the next year, the Department will focus its efforts on the regulatory requirements enacted by the Safe, Accountable, Flexible, and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU). 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 2006, 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.

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. We are guided by our Flight Plan goals — Increased Safety, Greater Capacity, International Leadership, and Organizational Excellence. We issue 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, we 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 2005-2006 include a final rule concerning flight simulation device requirements, 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.

The remaining rulemakings included in the Aging Airplane Program are:

(1). Enhanced Airworthiness Program for Aging Systems/Fuel Tank Safety;

(2). Development of Type Certificate and Supplemental Type Certificate Holder Data for Aging Aircraft Safety Program; and

(3). Widespread Fatigue Damage Program.

Federal Highway Administration (FHWA)

The Federal Highway Administration (FHWA) carries out the Federal highway programs in partnership with State and local agencies to meet the Nation's transportation needs. The FHWA's mission is to continually improve the quality and performance of our Nation's highway system and its intermodal connectors.

Consistent with this mission, the FHWA will continue:

- with ongoing regulatory initiatives in support of its surface transportation programs;
- to implement legislation in the least burdensome and restrictive way possible; and
- 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.

Recently, the Safe, Accountable, Flexible, and Efficient Transportation Equity Act: A Legacy for Users or SAFETEA-LU was enacted. The FHWA is analyzing SAFETEA-LU to identify congressionally directed rulemakings. Additionally, the FHWA will review all FHWA regulations to ensure that they are consistent with the recently enacted legislation.

Federal Motor Carrier Safety Administration (FMCSA)

The mission of 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 through the rulemaking process is key to achieving increased safety on our Nation's highways by establishing standards for drivers, carriers, States, and others that create improved safety conditions and operating practices. In its first five years of operations, FMCSA has responded to Congressional concerns, as expressed in our enabling legislation, The Motor Carrier Safety Improvement Act of 1999 (MCSIA), over delays in timely rulemaking. There is steady progress being made, with the backlog of rules being systematically addressed.

First, FMCSA developed a directive establishing a formalized rulemaking process with ongoing oversight and involvement by senior agency leaders to lend structure and accountability to the rulemaking process. We continue to monitor the process and update the directive when additional issues are identified; a comprehensive update of this directive is scheduled to go into effect in Fall 2005.

Second, FMCSA has made significant progress in reducing the backlog and addressing longstanding and stale initiatives, including those not mandated by Congress. FMCSA has completed all of its MCSIA rulemakings, except one, and that rulemaking, ''Medical Certification as part of the Commercial Drivers License'' (RIN 2126-AA10) is among our highest priorities and is included in the Regulatory Plan. It will serve as the first step in a comprehensive update of the way that the Agency addresses the medical condition of the drivers who operate commercial motor vehicles (CMVs).

As a result of reauthorization legislation, the FMCSA's regulatory docket is increasing substantially. The Agency is committed to using its resources and personnel in the most effective manner to accomplish these additional tasks and still complete its ongoing projects. Therefore, the Agency's other entry to the Regulatory Plan continues to be the ''Unified Registration System'' rulemaking (RIN 2126-AA22), now at the final rule stage, that will create a new, unified and updated registration system that benefits both the users with simplified processes and FMCSA with better data.

In the past year, FMCSA issued a notice of proposed rulemaking and a final rule on hours of service (HOS) in response to both the concerns of the U.S. Court of Appeals for the D.C. Circuit (Public Citizen et al. v. FMCSA) and the action of Congress in extending the last previous surface transportation act to maintain the effectiveness of the April 2003 HOS final rule until September 30, 2005. Also, the Agency held several public listening sessions under the Comprehensive Safety Analysis 2010 Initiative and is analyzing the results and other input to design and improve the way FMCSA conducts compliance and enforcement operations over the coming years. FMCSA anticipates that the first results of this initiative and its associated rulemakings will contribute to the Agency's goal of decreasing CMV fatalities to no more than 1.65 per 100 million miles by the end of 2008.

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 2006, 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 SAFETEA-LU. To further improve occupant crash protection, a final rule will be published to add requirements to FMVSS No. 208 for belted occupants of small stature. Significant actions in crash avoidance will include a rulemaking notice aimed at shortening heavy truck stopping distances. Light truck fuel economy standards for Model Years 2008 and possibly beyond will be published, in accordance with statutory requirements. 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.

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 locomotive crashworthiness; (2) the development of safety standards for locomotive working conditions, including occupational noise exposure; and (3) the development and revision of certain regulations addressing the safety of rail passenger service. Recently, FRA completed a rulemaking entitled ''Performance Standards for Processor-Based Signal and Train Control Systems,'' which was based on an RSAC recommendation (for a proposed rule on the subject); published a final rule on the crashworthiness of locomotive event recorders based on the RSAC's consensus recommendations; and completed a final rule entitled ''Use of Locomotive Horns at Highway-Rail Grade Crossings.''

During calendar 2005-2006, as a part of the National Rail Safety Action Plan, FRA plans to develop and issue a proposed rule to enhance compliance with railroad operating rules, addressing the causes of many human-factor train accidents.

Federal Transit Administration (FTA)

The Federal Transit Administration (FTA) provides financial assistance to State and local governments for mass transportation purposes. The regulatory activity of FTA focuses on establishing the terms and conditions of Federal financial assistance available under the Federal transit laws.

FTA's policy regarding regulations is to:

- Implement statutory authorities in ways that provide the maximum net benefits to society;
- Keep paperwork requirements to a minimum;
- Allow for as much local flexibility and discretion as is possible within the law;
- Ensure the most productive use of limited Federal resources;
- Protect the Federal interest in local investments; and
- Incorporate good management principles into the grant management process.

As mass transportation needs have changed over the years, so have the requirements for Federal financial assistance under the Federal transit laws and related statutes. As a result of the reauthorization legislation, the FTA's regulatory activity will include a number of substantive rulemakings. A few of those rulemakings may be 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.

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.

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

88. +AGING AIRCRAFT PROGRAM (WIDESPREAD FATIGUE DAMAGE)

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 41706; . . .

CFR Citation:

14 CFR 121; 14 CFR 129

Legal Deadline:

None

Abstract:

This rulemaking would require incorporation of a program to preclude widespread fatigue damage into the FAA-approved maintenance program of each operator of large transport category airplanes. This action is the result of concern for the continued operational safety of airplanes that are approaching or have exceeded their design service goal. This rulemaking would require a limit of validity in flight cycles or hours of the structural maintenance program, where the operator must incorporate added inspections and/or

modification/replacement actions into its maintenance program to allow continued operation.

Statement of Need:

History has shown that widespread fatigue damage (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; and (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	02/00/06	

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

89. +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 44701–44702; 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 place 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	12/00/05	

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—FAA

90. +ENHANCED AIRWORTHINESS PROGRAM FOR AIRPLANE SYSTEMS (EAPAS) AND SFAR 88

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 1155; 49 USC 1372; 49 USC 40103; 49 USC 40119; 49 USC 40120; 49 USC 106(g); 49 USC 40103; 49 USC 40113; 49 USC 40119 to 40120; 49 USC 41706; 49 USC 4401; 49 USC 44111; 49 USC 44701 to 44705; 49 USC 44709 to 44713; 49 USC 44715 to 44717

CFR Citation:

14 CFR 1; 14 CFR 25; 14 CFR 91; 14 CFR 121; 14 CFR 125; 14 CFR 129; 14 CFR 1; 14 CFR 121; 14 CFR 129; 14 CFR 25; 14 CFR 91

Legal Deadline:

None

Abstract:

This rulemaking would change wiring system and fuel tank system requirements for transport category airplanes. It would organize and clarify design requirements for wire systems, by moving existing regulatory references to wiring into a single section of the regulations specifically for wiring and adding new certification rules to address aging issues in wire systems. This rulemaking would require holders of type certificates for certain transport category airplanes to conduct analyses and make necessary changes to existing Instruction for Continued Airworthiness (ICA) to improve maintenance procedures for wire systems. It would require operators to incorporate those ICA for wiring into their maintenance or inspection programs. It would also clarify requirements of certain existing operational rules for operators to incorporate ICA for fuel tank systems into their maintenance or inspection programs. The intent of this rule is to help ensure the continued safety of commercial airplanes by improving the design, installation, and maintenance of their electrical wiring systems as well as by aligning those requirements as closely as possible with the requirements for fuel tank system safety.

Statement of Need:

The proposal will address a continuing history of wire-related failures, resulting in smoke in the cabin/flight deck, fires, arcing, etc. Current maintenance practices have not been adequate to address issues of aging and degradation in wiring. Wires have not been viewed as important systems on their own.

Summary of Legal Basis:

Section 44701, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

1. Require operators to clean and inspect each airplane every C-check or every three years, causing an additional $192.5 million in cleaning and inspection costs, and an additional $104.0 million in downtime. This option would result in additional costs of $296.5 million with no commensurate increase in benefits. 2. Require electrical wiring interconnection systems training for four new groups of people (electrical/avionic engineers, individuals involved in engineering or planning work, flight deck crew, and cabin crew, in addition to maintenance workers. Training these individuals would require that operators develop additional courses. The total estimated additional cost of this alternative is approximately $381.1 million with no commensurate increase in benefits. 3. We also considered voluntary compliance with the intent of this proposal by the affected parties. Some in industry have suggested issuing advisory circulars to give guidance on changes that need to be made. However, previous voluntary safety assessments have been difficult to complete in a timely manner because they lack enforceability. Similarly, issuance of guidance material would depend on voluntary compliance, and would not be enforceable.

Anticipated Cost and Benefits:

Total costs are estimated at $474.3 million (209.2 million in present value) over 25 years. Total benefits are estimated at $755.3 million ($340.7 million in present value) over 25 years.

Risks:

The FAA estimates there may be more than 1.2 fatal events caused by electrical wiring interconnection systems (EWIS) over a 25-year period. The Poisson distribution provides a measure for this risk. Based on a mean value of 1.2 fatal EWIS events, there is a 70 percent chance there will be 1 or more occurrences of a fatal EWIS event, a 34 percent chance there will be 2 or more fatal EWIS events; and a 12 percent chance of 3 or more occurrences of fatal EWIS events.

Timetable:

Action	Date	FR Cite
NPRM	10/06/05	70 FR 58508
NPRM Comment Period End	02/03/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI31

DOT—FAA

91. +AGING AIRCRAFT SAFETY—DEVELOPMENT OF TC AND STC HOLDER DATA

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 106(g); 49 USC 40113; 49 USC 44701; 49 USC 44702; 49 USC 44704

CFR Citation:

14 CFR 25

Legal Deadline:

None

Abstract:

This rulemaking would require type certificate holders and supplemental type certificate holders to provide airplane operators with damage tolerance data for repairs, alterations, and modifications to certain airplane structure. This rulemaking is needed to support airplane operator compliance with the requirement to include damage tolerance inspections and procedures in their maintenance programs. The intended effect of this rulemaking is twofold. First, it is to ensure the continued airworthiness of airplane structure that is susceptible to fatigue cracking that could contribute to a catastrophic failure. Second, it would require that type certificate holders and supplemental type certificate holders provide needed data to support operator compliance with the Aging Airplane Safety final rule.

Statement of Need:

In several recent rules the FAA has adopted operational requirements without a corresponding requirement for design approval holders to develop and provide the necessary data and documents to support operator compliance. The difficulty encountered by operators in complying with these rules has convinced us that corresponding design approval holder requirements are necessary to enable operators to comply by the regulatory deadlines.

Summary of Legal Basis:

Section 44704, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

Issuance of guidance material would depend on voluntary compliance and would not be enforceable.

Anticipated Cost and Benefits:

Not yet determined.

Risks:

Without a regulatory requirement imposed on design approval holders, operators would have to rely on voluntary compliance by design approval holders to provide data operators needed to comply with the regulatory requirement to develop damage tolerance programs required by the Aging Airplane Safety rule.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2120–AI32

DOT—Federal Motor Carrier Safety Administration (FMCSA)

PROPOSED RULE STAGE

92. +MEDICAL CERTIFICATION REQUIREMENTS AS PART OF THE CDL

Priority:

Other Significant

Legal Authority:

PL 106–159 sec 215; 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 provide for a Federal medical certification as part of the commercial driver's license (CDL) program, as required by Section 215 of the Motor Carrier Safety Improvement Act. Incorporating medical qualification verification and documentation into State-administered CDL procedures will improve highway safety by preventing medically unqualified individuals from obtaining a CDL. It would also eliminate the requirement for CDL operators to carry their medical certificate in addition to their CDL.

Statement of Need:

This rule is required by Public Law 106-159. Section 215 of the Act requires combining the medical certification with the CDL. When applying for (or renewing) a CDL, commercial motor vehicle (CMV) drivers are not currently required to present the medical certificate or provide State licensing agencies with a copy of the medical certificate as proof of physical qualifications to operate CMVs in interstate commerce. Drivers are usually allowed to self-certify their physical qualifications by checking the appropriate box on the CDL application form. This rulemaking would require CDL holders who operate CMVs in interstate commerce to provide the actual medical certificate or identical copy to the State licensing agency, thus eliminating the States' reliance on driver self-certification.

Summary of Legal Basis:

Section 215 of the Motor Carrier Safety Improvement Action of 1999 (MCSIA) directed the Secretary of Transportation (Secretary) to ''initiate a rulemaking to provide for a Federal medical qualification certificate to be made part of commercial driver's 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:

The alternative was mandatory electronic filing of medical certificates from the medical examiner to the State. A national, automated audit system would be used to centrally monitor medical examiner performance problems, including driver physical qualification examination outcomes, in States. Each of the 51 CDL licensing jurisdictions would be required to examine a sampling of reported problems in the national data system, and meet quality control standards established by the Agency. Driver medical certification status would be available for licensing, enforcement, and employment. The States would have borne the majority of costs associated with this model.

Anticipated Cost and Benefits:

A preliminary regulatory evaluation is under development and will be released on the date 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	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Undetermined

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

FINAL RULE STAGE

93. +UNIFIED REGISTRATION SYSTEM

Priority:

Other Significant

Legal Authority:

PL 104–88; 109 Stat. 803, 888 (1995); 49 USC 13908

CFR Citation:

49 CFR 360, 365, 366, 368, 387, and 390

Legal Deadline:

Final, Statutory, January 1, 1998.

Abstract:

This rulemaking would replace three current identification and registration systems — the US DOT identification number system, the registration/licensing system, and the financial responsibility system — with a unified registration system. It would consolidate and simplify current Federal registration processes and increase public accessibility to data about interstate and foreign motor carriers, property brokers, and freight forwarders. In addition, the agency is considering how it might replace a fourth system — the single-State registration system — in a manner consistent with conditions imposed by statute.

Statement of Need:

As a result of the ICC Termination Act of 1995 [Public Law 104-88, December 29, 1995, 109 Stat. 888] (ICCTA), Congress terminated the Interstate Commerce Commission and transferred its functions concerning licensing and financial responsibility requirements to the DOT. Congress mandated that the agency consider unifying the four current systems with a single, on-line Federal system.

Summary of Legal Basis:

The ICCTA created a new 49 U.S.C. 13908 directing ''the 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 idea that it would minimize the compliance costs of this proposal. However, while reducing compliance costs (and thereby improving filing efficiency), it would also have reduced, not enhanced, the fairness of the motor carrier registration process relative to the status quo by placing higher burdens on new entrants than existing carriers. As such, it would have acted as a barrier to entry to small new entrants to the benefit of existing carriers. Conversely, we also considered exempting new entrants from these requirements, but dismissed this on the grounds that it too would have reduced the fairness of the registration process. Additionally, either option would have reduced safety relative to the proposal discussed here. 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:

Total discounted costs of the proposed rule equal $75.4 million over the 10-

year analysis period. In examining the overall burden of the NPRM to small entities, the agency countered some new (cost inducing) proposals with several actions that would reduce the filing burden of new entrant and existing motor carriers. The cost savings would partially offset the compliance costs, resulting in average total compliance costs of $48 per new entrant and $42 per existing carrier in any single year of the 10-year analysis period. Since costs are expected to reduce pre-tax profits of small entities by less than 1 percent in a given year, the agency believes the impact on small entities has effectively been minimized with the current proposal, while trying to meet its stated goals and Congress' mandate. Benefits from the proposed rule include crash-related benefits from avoided crashes as well as time/cost savings associated with a reduced filing burden and/or reduced FMCSA fees paid by motor carriers. Total first-year benefits of the proposal would be $9.3 million (discounted), while total discounted benefits are estimated at $91.4 million over the 10-year analysis period. Comments were requested on this subject in the NPRM.

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 safety; 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	
Final Action	06/00/06	

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—National Highway Traffic Safety Administration (NHTSA)

PROPOSED RULE STAGE

94. +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:

The agency is considering reducing 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	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2127–AJ37

DOT—NHTSA

95. +LIGHT TRUCK AVERAGE FUEL ECONOMY STANDARDS, MODEL YEAR 2008 AND POSSIBLY BEYOND

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

15 USC 2002; Delegation of Authority at 49 CFR 1.50

CFR Citation:

49 CFR 533

Legal Deadline:

Final, Statutory, April 1, 2006, CAFE standards must be set at least 18 months prior to the start of a model year.

Abstract:

This rulemaking would address Corporate Average Fuel Economy Standards for light trucks for model year 2008 and possibly beyond, as appropriate.

Statement of Need:

NHTSA is required by statute to establish the CAFE standard for a model year not later than 18 months before its beginning, and thus must publish the final rule for model year 2008 on or before April 1, 2006.

Summary of Legal Basis:

Section 32910(d) of Title 49 of the United States Code provides that the Administrator may prescribe regulations necessary to carry out his duties under Chapter 329, Automobile fuel economy.

Alternatives:

The agency is also considering reform of the structure of the CAFE program under Reforming the Automobile Fuel Economy Standards Program (2127-AJ17).

Anticipated Cost and Benefits:

The costs and benefits of the potential changes addressed in this action have not yet been assessed.

Risks:

Depending on how manufacturers address Federal fuel economy requirements, there is some potential effect on safety. The most recent NHTSA analysis (2003) indicated that the association between vehicle weight and overall crash fatality rates in heavier MY 1991-99 light trucks and vans was not significant. However, for three other groups of MY 1991-99 vehicles - the lighter LTVs (light trucks and vans), the heavier cars, and especially the lighter cars - fatality rates increased as weights decreased.

Timetable:

Action	Date	FR Cite
NPRM	08/30/05	70 FR 51414
NPRM Comment Period End	11/22/05	
Final Rule	04/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Energy Effects:

Statement of Energy Effects planned as required by Executive Order 13211.

URL For More Information:

dms.dot.gov

URL For Public Comments:

dms.dot.gov

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RIN: 2127–AJ61

DOT—NHTSA

FINAL RULE STAGE

96. +5TH PERCENTILE DUMMY BELTED BARRIER CRASH TEST REQUIREMENTS — STANDARD 208

Priority:

Other Significant

Legal Authority:

49 USC 322; 49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166

CFR Citation:

49 CFR 571.208

Legal Deadline:

None

Abstract:

The agency is considering an amendment to its occupant protection standard, FMVSS No. 208, to improve high speed crash protection to belted occupants of small stature who may sit in the full forward seat position. Current crash test requirements for the 5th percentile adult female dummy include a 0-48 km/h belted rigid barrier crash test. The agency is considering increasing the maximum crash test speed from 48 km/h to 56 km/h to be consistent with the 50th percentile adult male requirements that will take effect according to the second phase of the FMVSS No. 208 Advanced Air Bag Final Rule (65 FR 30680).

Statement of Need:

In May 2000, NHTSA upgraded the requirements in FMVSS No. 208 for air bags in passenger cars and light trucks, to be phased in beginning in the 2004 model year. The upgrade was designed to meet the goals of improving protection for occupants of all sizes, belted and unbelted, in moderate to high speed crashes, and of minimizing the risks posed by air bags to infants, children, and other occupants, especially in low speed crashes. The rule included a requirement that, beginning in 2007, the 50th percentile adult dummy must meet the injury criteria when subjected to a 35 mph belted rigid barrier crash. The Agency stated that there was insufficient data to incorporate the 5th percentile female dummy into the 35 mph crash, but that additional testing would be conducted to determine the feasibility of including it. That testing was completed, and NHTSA published an NPRM on August 6, 2003, proposing requirements that

the belted 5th percentile female dummy pass the injury criteria when subjected to a 35 mph rigid barrier crash. It is important to include this dummy in the requirements for FMVSS No. 208 in order to achieve the full intended benefits of advanced air bag requirements.

Summary of Legal Basis:

Section 30111, title 49 of the U.S.C., states that Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The agency will examine existing test procedures, analyze alternative approaches proposed by commenters to the NPRM, evaluate alternative international approaches, and keep abreast of the development of new occupant protection technologies specific to small stature occupants.

Anticipated Cost and Benefits:

The NPRM estimated that the proposed requirements, if adopted, could prevent between 5 and 6 small occupant fatalities per year and could also reduce two to three moderate-to-severe injuries yearly and would result in a nominal additional cost to vehicle manufacturers. Based on the comments to the NPRM, the agency is re-evaluating the benefits and costs associated with requiring a higher speed belted barrier crash test by including an evaluation of advanced air bag-equipped vehicles.

Risks:

The proposed amendment will upgrade the performance requirements of the standard such that FMVSS No. 208 will require the same level of high speed crash protection for small statured occupants as for larger occupants. The full intended benefits of the standard may not be achieved if we did not include this segment of the population.

Timetable:

Action	Date	FR Cite
NPRM	08/06/03	68 FR 46539
Final Rule	01/00/06	

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–AI98

DOT—NHTSA

97. +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:

None

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 1,440 fatal and 2,400 serious head injuries involving nearside occupants occur annually in non-rollover side crashes without full occupant ejections. ''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
NPRM Comment Period End	10/14/04	
NPRM Comment Period Extended	01/12/05	70 FR 2105
NPRM Comment Period Extended To	04/12/05	
Final Rule	03/00/06	

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

BILLING CODE 4910–62–S

DEPARTMENT OF THE TREASURY (TREAS)

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are:

- To promote prosperous and stable American and world economies, including promoting domestic economic growth and maintaining our Nation's leadership in global economic issues, supervising national banks and thrift institutions, and helping to bring residents of distressed communities into the economic mainstream.
- To manage the Government's finances by protecting the revenue and collecting the correct amount of revenue under the Internal Revenue Code, overseeing customs revenue functions, financing the Federal Government and managing its fiscal operations, and producing our Nation's coins and currency.
- To safeguard our financial systems by enforcing laws relating to Federal Government securities and developing regulations to combat money laundering.

Consistent with these missions, most regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President. Unless circumstances require otherwise, it is the policy of the Department to issue a notice of proposed rulemaking and carefully consider public comments before adopting a final rule. Also, in particular cases, the Department invites interested parties to submit views on rulemaking projects while a proposed rule is being developed, and holds public hearings to discuss proposed rules.

In response to the events of September 11, 2001, the President signed the USA PATRIOT Act of 2001 into law on October 26, 2001. Since then, the Department has accorded the highest priority to developing and issuing regulations to implement the provisions in this historic legislation that target money laundering and terrorist financing. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Financial Crimes Enforcement Network (FinCEN).

On November 26, 2002, the President signed into law the Terrorism Risk Insurance Act of 2002. The purpose of this legislation is to address disruptions in the market for terrorism risk insurance. The new law established a temporary Federal reinsurance program under which the Federal Government will share the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers. Since the Act currently is scheduled to expire on December 31, 2005, no regulatory activity is planned for the coming year.

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Order 12866, and to develop regulations that maximize aggregate net benefits to society while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Terrorism Risk Insurance Program Office

The Office of the Assistant Secretary for Financial Institutions is responsible for promulgating regulations implementing the Terrorism Risk Insurance Act of 2002 (TRIA). The Terrorism Risk Insurance Program Office, which is part of the Office of the Assistant Secretary for Financial Institutions, is responsible for operational implementation of the Act. The purposes of this legislation, which was enacted as a consequence of the events of September 11, 2001, are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections. TRIA established a temporary Federal program that provides a system of shared public and private compensation for insured losses resulting from certain types of terrorist acts.

Over the past year, the Office of the Assistant Secretary has continued the ongoing work of quickly implementing TRIA. The Office has refined regulations and procedures for filing claims under TRIA and is developing regulations for recouping the Federal share of compensation to insurers through risk-spreading premiums. If TRIA is extended beyond its scheduled expiration date of December 31, 2005, the Office will continue its ongoing work to implement the Act. If TRIA is not extended, the Office will work to close the Program.

Customs Revenue Functions

On November 25, 2002, the President signed the Homeland Security Act of 2002 (the Act), establishing the Department of Homeland Security (DHS). The Act transferred the United States Customs Service from the Department of the Treasury to the DHS, where it is now known as the Bureau of Customs and Border Protection (CBP). Notwithstanding the transfer of the Customs Service to DHS, the Act provides that the Secretary of the Treasury retains sole legal authority over the customs revenue functions. The Act also authorizes the Secretary of the Treasury to delegate any of the retained authority over customs revenue functions to the Secretary of Homeland Security. By Treasury Department Order No. 100-16, the Secretary of the Treasury delegated to the Secretary of Homeland Security authority to prescribe regulations pertaining to the customs revenue functions. This Order further provided that the Secretary of the Treasury retained the sole authority to approve any such regulations concerning import quotas or trade bans, user fees, marking, labeling, copyright and trademark enforcement, and the completion of entry or substance of entry summary including duty assessment and collection, classification, valuation, application of the U.S. Harmonized Schedules, eligibility or requirements for preferential trade programs and the establishment of recordkeeping requirements relating thereto.

During fiscal year 2006, Treasury and CBP plan to finalize several interim regulations involving the customs revenue functions not delegated to DHS. Among these are the following interim regulations that implement the trade benefit provisions of the Trade Act of 2002:

- The Andean Trade Promotion and Drug Eradication Act
- The Caribbean Basin Economic Recovery Act
- The African Growth and Opportunity Act

CBP also plans to finalize interim regulations this fiscal year to implement the preferential trade benefit provisions of the United States-Chile Free Trade Agreement Implementation Act and to issue interim regulations implementing the United States-Singapore 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 CBP will be working on finalizing this fiscal year 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 recordation of all non-U.S. works without requiring registration with the U.S. Copyright Office.

Treasury and CBP also plan to continue moving forward with amendments to improve its regulatory procedures began under the authority granted by the Customs Modernization provisions of the North American Free Trade Implementation Act (Customs Mod Act). These efforts, in accordance with the principles of Executive Order 12866, have involved and will continue to involve significant input from the importing public. CBP will also continue to test new programs to see if they work before proceeding with proposed rulemaking to permanently establish the programs.

Community Development Financial Institutions Fund

The Community Development Financial Institutions Fund (Fund) was established by the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4701 *et seq.*). The primary purpose of the Fund is to promote economic revitalization and community development through a variety of programs: the Community Development Financial Institutions (CDFI) Program, the Bank Enterprise Award (BEA) Program, and the New Markets Tax Credit (NMTC) Program.

In fiscal year 2006, the CDFI Program will comprise: (i) financial assistance awards and (ii) technical assistance grants. In addition, the Fund administers the Native American CDFI Assistance (NACA) Program, through which the Fund provides technical assistance grants and financial assistance awards to promote the development of CDFIs that serve Native American, Alaska Native, and Native Hawaiian communities.

Through the BEA Program, the Fund provides financial incentives to encourage insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs.

In addition, the Fund administers the NMTC Program in coordination with Treasury's Office of Tax Policy and the Internal Revenue Service. The NMTC Program is intended to spur investments in businesses located in low-income communities. Through the NMTC Program, taxpayers are provided a credit against Federal income taxes for qualified investments made to acquire stock or other equity interests in designated Community Development Entities (CDEs). Substantially all of the proceeds of qualified investments must in turn be used by the CDE to make qualified investments in low-income communities.

The Fund's fiscal year 2006 regulatory priority will include a revision of the regulations governing the CDFI 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 implement counter-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 and overseeing compliance examination functions delegated to other federal regulators; managing the collection, processing, storage, and dissemination of data related to the BSA; maintaining a government-wide access service to that same data, and for network users with overlapping interests; conducting analysis in support of policy makers, law enforcement, regulatory and intelligence agencies, and the financial industry; 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.

Significant rules issued during fiscal year 2005 include an interim final rule requiring dealers in precious metals, stones, or jewels to establish anti-money laundering programs, and several rules proposing imposition of special measures pursuant to Section 311 of the USA PATRIOT Act.

FinCEN's regulatory priorities for fiscal year 2006 include the following projects:

- *Due Diligence for Correspondent Accounts and Private Banking Accounts.* To the extent that a final rule has not been adopted in the fourth quarter of 2005, FinCEN expects to finalize a rule implementing Section 312 of the USA PATRIOT Act, which requires certain financial institutions to establish due diligence policies, procedures, and controls reasonably designed to detect and report money laundering through correspondent accounts and private baking accounts established or maintained for non-U.S. persons.
- *Anti-Money Laundering Programs.* Under 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 in the fourth quarter of 2005, FinCEN expects to finalize anti-money laundering program rules proposed in September 2002 for insurance companies and unregistered investment companies and rules proposed in May 2003 for investment advisers and commodity trading advisers. FinCEN expects to issue a proposed rule for loan or finance companies (including pawnbrokers). FinCEN also expects to consider issuing a proposed rule requiring certain corporate and trust service providers to establish anti-money laundering programs. 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.
- *Suspicious Activity Reporting.* To the extent that final rules have not been

adopted in the fourth quarter of 2005, the FinCEN expects to finalize several rules proposed under 31 U.S.C. 5318(g) requiring insurance companies and mutual funds to report suspicious transactions.

Other Requirements. FinCEN expects to issue a proposal to require all money services businesses, including agents, to register. FinCEN will also issue a proposed rule that would require all financial institutions that file BSA reports to do so electronically, if technically able. It will consider the need for regulatory action in conjunction with the feasibility study being prepared pursuant to the Intelligence Reform Bill concerning the issue of obtaining information about certain cross-border transmittals of funds. 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 2006 the Internal Revenue Service will accord priority to the following regulatory projects:

- *Deductibility of Subsidiary Stock Loss by Members of Consolidated Groups.* On March 14, 2003, the IRS and Treasury issued temporary regulations (Treas. Reg. § 1.1502-35T) to prevent consolidated groups from obtaining more than one tax benefit from a single economic loss. On March 3, 2005, the IRS and Treasury issued final regulations (Treas. Reg. § 1.337(d)-2) to prevent consolidated groups from avoiding the corporate tax on appreciated assets (and thereby circumventing the repeal of the General Utilities doctrine) through the recognition of noneconomic losses on subsidiary stock. The preamble to Treas. Reg. § 1.337(d)-2 stated that those regulations were an interim measure pending the proposal of another method for addressing General Utilities repeal in the consolidated return setting. During fiscal year 2006, the IRS and Treasury plan to reexamine the approach taken in both these regulations.
- *Safe Harbor Methodology for Determining the Fair Market Value of Financial Instruments that are Marked to Market.* Section 475 of the Internal Revenue Code requires dealers in stocks, debt, certain derivative financial instruments, or other securities to mark their securities to market at the end of each tax year. That is, those dealers must compute their taxable income by including their securities in inventory at their fair market value 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 2006.
- *Capitalization of Interest and Carrying Charges Properly Allocable to Straddles.* Section 1092 of the Internal Revenue Code limits loss recognition on one leg of a straddle if there is unrecognized gain with respect to one or more offsetting positions. Section 263(g) disallows a deduction for interest and carrying charges properly allocable to personal property that is part of a straddle. The IRS and Treasury expect to issue final regulations clarifying the circumstances in which a taxpayer must capitalize interest and carrying charges incurred to purchase or carry personal property that is part of a straddle. The regulations are expected to address the definition of personal property for purposes of section 263(g) of the Internal Revenue Code, the types of expenses subject to capitalization, and the operation of the capitalization rules. In addition, the regulations will indicate when the debtor's position in a debt instrument will be treated as a position in personal property that may be part of a straddle. The regulations are also expected to clarify the application of the straddle anti-abuse rules to various financial instruments and straddle transactions.
- *Deduction and Capitalization of Costs for Tangible Assets.* Section 162 of the Internal Revenue Code allows a current deduction for ordinary and necessary expenses paid or incurred in carrying on any trade or business. Under section 263(a) of the Code, no immediate deduction is allowed for amounts paid out for new buildings or for permanent improvements or betterments made to increase the value of any property or estate. 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 expenditure to repair, improve, or rehabilitate 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 December 2003, the IRS and Treasury requested public comment on rules that might be provided to clarify the application of section 263(a) to repairs and improvements to tangible property. During fiscal year 2006, the IRS and Treasury intend to propose regulations in this area.
- *Foreign Tax Credit Guidance Initiatives.* Treasury and the IRS anticipate issuing guidance under

section 901 and other provisions of the Internal Revenue Code during fiscal year 2006 to address the proper interaction of foreign income tax regimes and the U.S. foreign tax credit. The guidance will address the operation of the U.S. foreign tax credit rules in the context of foreign affiliated group structures whose income tax results are combined for foreign income tax purposes. The guidance will also address the U.S. foreign tax credit consequences of certain so-called hybrid entities that are treated as separate taxable entities for foreign, but not U.S., tax purposes. Additional guidance will provide rules relating to the effect of foreign tax redeterminations and other provisions added by the American Jobs Creation Act of 2004 (AJCA). The guidance will provide for tax treatment that is consistent with the policies of the foreign tax credit provisions and applicable law.

- *Deduction for Qualified Production Activities Income.* Section 199 of the Internal Revenue Code allows taxpayers to deduct a percentage of income derived from qualified production activities performed in the U.S. The IRS and Treasury issued Notice 2005-14 in January 2005 to provide interim guidance on issues relating to section 199, pending the issuance of regulations. During fiscal year 2006, the IRS and Treasury intend to propose regulations in this area.
- *Accuracy-Related Penalties on Understatements.* The AJCA added section 6662A to the Internal Revenue Code, which provides a new penalty for understatements with respect to reportable transactions. The AJCA also added section 6664(d) to the Code, which provides a defense to the penalty under section 6662A if the taxpayer acted with reasonable cause and in good faith. Additionally, the AJCA amended section 6662(d) of the Code 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 and clarifying the relationship between the penalty regulations and the standards of practice for tax shelter opinions adopted in the Circular 230 regulations promul gated under section 330 of title 31, United States Code.
- *Practice Before the Internal Revenue Service (Circular 230).* Section 330 of title 31, United States Code, authorizes the Secretary of the Treasury to regulate the practice of representatives before the Treasury Department. The Secretary has published these regulations in Circular 230 (31 CFR Part 10). In 2001, the IRS and Treasury issued proposed amendments to the regulations relating to practice before the IRS, which addressed general matters and proposed standards of practice for tax shelter opinions. In 2002, final regulations were issued incorporating only the non-tax shelter matters. In 2003, amendments to the standards of practice for tax shelter opinions were reproposed. Those reproposed regulations set forth best practices for tax advisors providing advice to taxpayers relating to Federal tax issues or submissions to the IRS and modified the standards for certain tax shelter opinions. In 2004, final regulations addressing covered opinions were issued along with proposed regulations addressing state and local bond opinions. Technical corrections to the tax shelter regulations were issued in 2005. During fiscal year 2006, the IRS and Treasury intend to issue additional regulations regarding practice before the IRS.
- *Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans.* Section 409A of the Internal Revenue Code was enacted by the AJCA and 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 intend to issue regulations that will clarify the application of section 409A to nonqualified deferred compensation plans.

Office of the Comptroller of the Currency

The Office of the Comptroller of the Currency (OCC) charters, regulates, and supervises national banks to ensure a safe, sound, and competitive national banking system that supports the citizens, communities, and economy of the United States. The substantive content of the OCC's regulations reflects four organizing principles that support this mission:

- The OCC's regulations help ensure safety and soundness by establishing standards that set the limits of acceptable conduct for national banks.
- The OCC's regulations promote competitiveness by facilitating a national bank's ability to develop new lines of business, subject to any safeguards that are necessary to ensure that the bank has the expertise to manage risk effectively and adapt its business practices to deal responsibly with its customers.
- Regulations can also affect national banks' ability to compete by contributing significantly to their costs. The OCC's goal is to improve efficiency and reduce burden by updating and streamlining its regulations and eliminating those that no longer contribute significantly to the fulfillment of its mission.
- The OCC's regulations help assure fair access to financial services for all Americans by removing unnecessary impediments to the flow of credit to consumers and small businesses, by encouraging national banks' involvement in community development activities, and by implementing Federal laws designed to protect consumers of financial services.

The OCC's regulatory workload and plans are affected directly by statute. One statute requiring regulatory action is the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA). The OCC, together with the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (banking agencies), is conducting a review of its regulations, pursuant to the EGRPRA. This process will continue through 2006. To date, the banking agencies' review has included: (1) issuing five notices, published in the Federal Register, that solicit comment from the industries we regulate and the public on ways to reduce regulatory burden with respect to specific categories of regulations; and (2) conducting outreach meetings with bankers and consumer groups in cities across the country for the same purpose. The review process and outreach meetings have generated a number of helpful suggestions which we, along with the other agencies, are evaluating on an ongoing basis. When these processes for obtaining input are complete, the OCC expects to be able to

determine whether revisions to any of its rules are appropriate in order to further the purposes of the EGRPRA and reduce burden. The agencies will further report to Congress on their conclusions at the end of the process, along with any suggestions for possible legislative changes.

Significant final rules issued during fiscal year 2005 include:

- *Proper Disposal of Consumer Information (12 CFR Parts 30 and 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) issued a joint rule to implement section 216 of the Fair and Accurate Credit Transactions Act of 2003. Section 216 requires the banking agencies, the National Credit Union Administration, the Securities and Exchange Commission, and the Federal Trade Commission to adopt consistent and comparable regulations, to the extent possible, requiring entities subject to their jurisdiction to properly dispose of consumer information as a means to reduce the risk of identity theft. The banking agencies issued a joint final rule on December 28, 2004 at 70 FR 77610.
- *Safety and Soundness Standards; Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (12 CFR Part 30).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration (agencies) issued an interpretation of section 501(b) of the Gramm-Leach-Bliley Act and the Interagency Guidelines Establishing Standards for Safeguarding Customer Information. This interpretation describes the agencies' expectations regarding the response programs, including customer notification procedures, that a financial institution should develop and implement to address the unauthorized access to or use of customer information that could result in substantial harm or inconvenience to a customer. A final interpretation was published on March 29, 2005 at 70 FR 15736.
- *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 to implement section 411 of the Fair and Accurate Credit Transactions Act of 2003. Section 411(a) requires the agencies to prescribe regulations that permit creditors to obtain or use medical information for certain credit eligibility purposes. Additionally, section 411(b) authorizes the agencies to issue rules to allow additional sharing of information determined by the agencies to be appropriate or necessary. The agencies issued an interim rule on June 10, 2005 at 70 FR 33958, and expect to issue a final rule in the near term.
- *Community Reinvestment Act Regulation (12 CFR 25).*The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation (agencies) issued a final rule to revise certain provisions of our rules implementing the Community Reinvestment Act (CRA). The action was taken in response to public comments we received on our February 2004 CRA proposal (69 FR 5729). The rule addresses regulatory burden imposed on smaller national banks by revising the eligibility requirements for CRA evaluation under the lending, investment, and service tests. Specifically, the rule provides a simplified lending test and a flexible and streamlined community development test for small banks with an asset size between $250 million and $1 billion. Holding company affiliation is not a factor in determining which CRA evaluation standards apply to a bank. The OCC estimates that this rule will reduce burden and costs for national banks. The agencies issued a joint final rule on August 2, 2005 at 70 FR 44256.
- *Electronic Filing and Disclosure of Beneficial Ownership Reports (12 CFR Part 11).* The Office of the Comptroller of the Currency adopted a final rule based on the interim rule, issued on September 22, 2003 at 68 FR 54981, to implement provisions enacted in the Sarbanes-Oxley Act of 2002 (Act). The Act made amendments to section 16(a) of the Securities Exchange Act of 1934, which requires the filing of beneficial ownership reports by officers, directors, and principal shareholders of issuers of securities. The OCC administers and enforces section 16(a) with respect to officers, directors, and principal shareholders of national banks. Effective July 30, 2003, the Act required that beneficial ownership reports be filed electronically and posted on the issuer's corporate website, if it has a website. The interim rule requires that beneficial ownership reports filed by officers, directors, and principal shareholders of a national bank be filed electronically pursuant to the FDIConnect system and that the reports be placed on the website of the national bank if it has a website. The OCC adopted a final rule on August 10, 2005 at 70 FR 46403.

The OCC's regulatory priorities for fiscal year 2006 include projects in the following areas:

The OCC plans to issue rules implementing the requirements of the Fair and Accurate Credit Transactions Act of 2003 as follows:

- *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 (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.

- *Fair Credit; Affiliate Marketing Regulations (12 CFR Part 41).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration (agencies) are planning to issue a rule to implement the affiliate sharing provisions of section 214 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act). The rule would implement the consumer notice and opt-out provisions of the FACT Act regarding the sharing of consumer information among affiliates for marketing purposes. The agencies issued a notice of proposed rulemaking on July 15, 2004 at 69 FR 42502.
- *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 (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 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 OCC plans to issue other rules as follows:

- *Risk-Based Capital Guidelines: Implementation of New Basel Capital Accord (12 CFR Part 3).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) plan to issue a notice of proposed rulemaking based on the *International Convergence of Capital Measurement and Capital Standards: A Revised Framework*, the new capital adequacy framework commonly known as Basel II. The banking agencies published an advance notice of proposed rulemaking (ANPR) on August 4, 2003 at 68 FR 45900 soliciting industry comments on a draft of the proposed framework for implementing the New Basel Capital Accord in the United States. In particular, the ANPR 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 ANPR 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 (12 CFR Part 3).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) plan to issue an advance notice of proposed rulemaking to amend various provisions of the capital rules for those banks that will not qualify to use the new Basel Capital Accord (Basel II) capital framework.
- *One-Year Post-Employment Restrictions for Senior Examiners (12 CFR Parts 4 and 19).* The Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (banking agencies) are issuing a joint notice of proposed rulemaking 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. The agencies issued a proposed rule on August 5, 2005 at 70 FR 45323.

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, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation (collectively, the banking agencies) continue to work together on regulations where the agencies share the responsibility to implement statutory requirements. The banking agencies are working to update capital standards to maintain, and, where necessary, improve consistency in the agencies' rules, including the *International Convergence of Capital Management and Capital Standards: A Revised Framework (Basel II).* The domestic implementation of the New Basel Capital Accord was introduced in 2003 with publication of an advanced notice of proposed rulemaking (ANPRM) and draft supervisory guidance. 68 FR 45900 (August 4, 2003). It included an introduction to the advanced internal ratings-based (IRB) approach to credit risk, and the advanced measurement approach for operational risk. The

ANPRM also specified the criteria that a banking organization must meet to use these advanced approaches. In addition, the banking agencies plan to issue an ANPR to increase the risk sensitivity of the existing risk-based capital framework that is currently applicable to all U.S. institutions.

Significant final rules issued during fiscal year 2005 include:

- *Proper Disposal of Consumer Information.* The banking agencies issued a joint rule to implement section 216 of the Fair and Accurate Credit Transactions Act of 2003. Section 216 requires the banking agencies, the National Credit Union Administration (NCUA), the Securities and Exchange Commission (SEC), and the Federal Trade Commission (FTC) to adopt consistent and comparable regulations, to the extent possible, requiring entities subject to their jurisdiction to properly dispose of consumer information as a means to reduce the risk of identity theft. The banking agencies issued a joint final rule on December 28, 2004 at 69 FR 77610.
- *Safety and Soundness Standards: Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice.* The banking agencies and the NCUA issued an interpretation of section 501(b) of the Gramm-Leach-Bliley Act and the Interagency Guidelines Establishing Standards for Safeguarding Customer Information. This interpretation describes the agencies' expectations regarding the response programs, including customer notification procedures, that a financial institution should develop and implement to address the unauthorized access to or use of customer information that could result in substantial harm or inconvenience to a customer. The interpretation was published on March 29, 2005 at 70 FR 15736.
- *Fair Credit Reporting Regulations (Medical Information):* The banking agencies and the 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 interim final rule was published on June 10, 2005 at 70 FR 33958, and the agencies expect to issue a final rule in the near term.

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.

The banking agencies also issued a joint notice of proposed rulemaking on August 5, 2005 at 70 FR 45323, 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.

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 also 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 & Integrity of Information Furnished to Consumer Reporting Agencies.* The banking agencies and the NCUA, SEC, and 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.
- *Identity Theft Detection, Prevention, and Mitigation Program for Financial Institutions and Creditors.* The banking agencies, the NCUA, and the FTC also plan to issue a proposed rule implementing section 114 and 315 of the FACT Act, which requires the agencies to develop guidelines for use in identifying patterns, pract ices, 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.

Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB) issues regulations to enforce the Federal laws relating to the manufacture and commerce of alcohol products, tobacco products, and the Federal excise tax on firearms and ammunition. TTB's mission and regulations are designed to:

- Regulate the alcohol and tobacco industries, including systems for licenses and permits;
- Assure the collection of all alcohol, tobacco, and firearms and ammunition taxes, and obtain a high level of voluntary compliance with all laws governing those industries;

- Suppress commercial bribery, consumer deception, and other prohibited practices in the alcoholic beverage industry; and
- Assist the States and other Federal agencies in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes in avoidance of State taxes.

In 2006, 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. We determined importance based on industry member numbers, revenue collected, enforcement and compliance issues identified through field audit and permit qualification, statutory changes, significant industry innovation, and other factors. The ten 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 FY 2006, proposed rules will be published on parts 19 and 28, and an advance notice of proposed rulemaking will be published on Part 25.

In addition to our modernization updates, in FY 2006 TTB will address alcohol beverage allergen and other labeling issues in regulations, with proposed rules targeted to be published the end of the fiscal year.

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 2006, BPD will accord priority to the implementation of 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.

During fiscal year 2006, FMS's regulatory priorities include the following:

- *Foreign Exchange Operations* (31 CFR Part 281): FMS plans to issue a notice of proposed rulemaking to amend 31 CFR Part 281 to establish currency conversion fees for electronic Federal payments disbursed to overseas recipients. To deliver a payment to a bank account maintained by an individual or business in a foreign country, it is necessary first to convert the payment from U.S. dollars to the local currency. FMS does not generally provide currency conversion services when disbursing payments, such as when Treasury checks are mailed abroad, and is proposing to recoup the cost of this special service from payment recipients pursuant to the authority of 31 U.S.C. 9701. We anticipate publication of the notice in the fall of 2005, with a 60 day comment period.
- *Management of Federal Agency Disbursements and Automated Clearing House (ACH)* (31 CFR Parts 208 and 210): FMS plans to issue a notice of proposed rulemaking to amend 31 CFR Parts 208 and 210 to allow Federal agencies to issue part or all of an employee's travel reimbursement to the travel card issuing bank for crediting to the employee's travel card account (''split disbursement''). Presently, 31 CFR 208.6 and 210.5 require that Federal electronic payments other than vendor payments be directed to a deposit account at the financial institution in the name of the individual. Federal employee travel accounts are not deposit accounts and therefore do not meet this requirement. Because of the benefits of split disbursement, a waiver was issued on April 25, 2005 to allow split disbursement of Federal employee travel card reimbursements, in accordance with the Secretary's waiver authority set forth at 31 CFR 208.6 and 210.5. FMS proposes to codify this waiver by creating an exception to the requirements of 31 CFR 208.6 and 210.5. We anticipate publication of the notice in the fall of 2005, with a 60 day comment period.

TREAS—Comptroller of the Currency (OCC)

PROPOSED RULE STAGE

98. IMPLEMENTATION OF A REVISED BASEL CAPITAL ACCORD (BASEL II)

Priority:

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

Legal Authority:

12 USC 93a; 12 USC 3907

CFR Citation:

12 CFR 3

Legal Deadline:

None

Abstract:

As part of 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 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.'' This rulemaking will translate the lengthy and complicated text of Basel II into the standards and requirements that will govern the largest banks in the United States.

Summary of Legal Basis:

OCC is implementing the Basel II capital framework for certain domestic financial institutions. This initiative is based on the OCC's general rulemaking authority in 12 U.S.C. 93a and its specific authority under 12 U.S.C. 3907. 12 U.S.C. 3907(a)(2) specifically authorizes 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	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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Related RIN: Split from 1557–AB14

RIN: 1557–AC91

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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.

The Department of Veterans Affairs' 2005 regulatory plan contains one rulemaking action from the Veterans Health Administration. The Veterans Health Administration rulemaking is RIN 2900-AL51 ''Enrollment—Provision of Hospital and Outpatient Care to Veterans—Subpriorities of Priority Categories 7 and 8 and Annual Enrollment Level Decision,'' which was published as an interim final rule on January 17, 2003. It amends the Department's medical regulations to protect the quality and improve the timeliness of care provided to all veterans by restricting new enrollments in higher enrollment-priority categories.

VA

FINAL RULE STAGE

99. ENROLLMENT—PROVISION OF HOSPITAL AND OUTPATIENT CARE TO VETERANS—SUBPRIORITIES OF PRIORITY CATEGORIES 7 AND 8 AND ENROLLMENT LEVEL DECISION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 104–262

CFR Citation:

38 CFR 17.36

Legal Deadline:

None

Abstract:

The Department of Veterans Affairs (VA) published in the Federal Register on January 17, 2003, an interim final rule amending VA's medical regulations at 38 CFR part 17 to establish additional subpriorities within enrollment priority categories 7 and 8 and to provide that, beginning January 17, 2003, VA will continue to treat all veterans currently enrolled in any category, and will treat new enrollees in categories 1 through 7. However, the interim final rule provided that VA will suspend the enrollment of additional veterans who are in the lowest statutory enrollment category (priority category 8). Based on the rationale set forth in the interim final rule, VA is adopting the provisions of the interim final rule as a final rule without change.

Statement of Need:

Public Law 104-262, the Veterans' Health Care Eligibility Reform Act of 1996, requires the Secretary of Veterans Affairs to make annual decisions concerning enrollment in VA's health care system in order to ensure that resources are available to provide medical services that are both timely and acceptable in quality. This document announces the enrollment decision to suspend the enrollment of additional veterans who are in the lowest statutory enrollment category (priority category 8). This also amends existing regulations to establish additional subpriorities within priority categories 7 and 8.

Summary of Legal Basis:

38 CFR 17.36(c) requires that the Secretary determine which categories of veterans are eligible to be enrolled and that the Secretary notify eligible enrollees of the determination by announcing it in the Federal Register.

Alternatives:

The Department had to consider placing additional enrollees on waiting lists and extending the waiting period for eligible enrollees seeking appointments for care as alternatives.

Anticipated Cost and Benefits:

By suspending enrollment of additional priority category 8 veterans, VA would avoid significant additional medical benefits costs and begin to bring demand in line with capacity, which will reduce the number of veterans on waiting lists. Without action to suspend new enrollment, the cost projection for FY 2003 is $23.455 billion. This is based on the projected average enrollment for FY 2003 of 6,991,405, together with the projected expenditures that would be needed to provide the medical benefits package to all enrollees. Suspending new enrollment would reduce enrollment in priority category 8 by 164,367 in FY 2003, which is expected to grow to over 520,000 by FY 2005.

Risks:

Without action to suspend new enrollment, patient safety and quality and access to care would be adversely affected.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/17/03	68 FR 2670
Interim Final Rule Effective	01/17/03	
Interim Final Rule Comment Period End	03/18/03	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For Public Comments:

www.regulations.gov

Agency Contact:

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BILLING CODE 8320–01–S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Priorities

OVERVIEW

The U.S. Environmental Protection Agency (EPA) is the leading Federal agency responsible for protecting human health and the environment. Since its creation in 1970, EPA has taken actions that have led to measurable improvements in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful chemicals and pesticides. It is EPA's goal to continue to accelerate environmental progress and to deliver better, more efficient results while maintaining our Economic Competitiveness.

To continue to build on its success, EPA is focusing on five primary principles. These principles are:

- Focusing on results;
- Committing to sound science;
- Understanding the importance of communication;
- Advancing innovation and collaboration; and,
- Investing in human capital.

EPA's first principle relates to its commitment to provide the American people with results. To do this, EPA must operate efficiently, effectively and competitively today — as well as building the necessary framework for tomorrow. The President's Management Agenda demands a focus on environmental results that are effective and enduring. By focusing on results, our nation's environment has made extraordinary gains. In the last four years alone, under the Bush Administration:

- Airborne pollutants have declined by 10 percent;
- 1200 industrial sites have been restored to productive use through the Brownfields program;
- From 2002 to 2003, toxic chemicals released into the environment have declined by 6 percent;
- And in 2004 alone, 800,000 acres of wetlands were restored or enhanced.

In order to achieve results, EPA works to make sure every Agency decision is based on sound science — the same sound science that is the basis of all its achievements and the genesis for future successes. Continuous investment in sound science is our second principle. In order to make a good, effective decision, one must consider and understand the full range of possibilities — including all of the strengths and weaknesses of an option — before reaching a conclusion. That's part of the sound science of a decision.

By expanding E-Government, the Administration and EPA is ensuring that the federal government is improving its ability to serve its citizens. Our third principle is to advance the credibility of EPA's decisions by highlighting the sound science on which all of our actions are based, and by effectively communicating to the public how and why our conclusions are reached. It is a challenge for anyone practicing good government to effectively relay your message, while still staying true to your founding values — in EPA's case, the value of sound science.

EPA has been at the forefront of advancing innovation and has also been a leader in collaborative problem solving — its fourth principle. Collaborative efforts, innovative programs, education and outreach are the proven tools for today and tomorrow. Over the Agency's 35 years, public perception of environmental stewardship has evolved from ''let the government take care of it,'' into an understanding that protecting our shared environment is each individual's responsibility. By promoting a culture of partnerships over conflicts, EPA is helping to usher in a new era of environmental protection. By involving more participants in the process, we promote a culture of environmental stewardship — both in this country and in others throughout the world.

None of these goals will be achieved without the help of EPA's dedicated staff. That is why EPA's fifth principle is an investment in human capital. The success of EPA and the health of our nation's environment is inseparable from the productivity and creativity of the Agency's professional staff. President Bush is the only president, at least in modern times, that has as a priority the development of comprehensive strategy for investing in human capital.

Helping small businesses improve environmental performance is a top priority for EPA. EPA offers a variety of services for small businesses, including a toll-free hotline, a semiannual newsletter, online expert systems, and for some sectors, compliance assistance centers that focus on the unique environmental management issues facing specific industries. EPA also maintains a Small Business Ombudsman which provides a point of contact for small businesses and ensures compliance with the Small Business Paperwork Relief Act of 2002.

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 epa.gov/regagenda.)

Rules Expected to Have a Significant Impact on a Substantial Number of Small Entities

Control of Hazardous Air Pollutants From Mobile Sources (2060-AK70)

Control of Emissions from New Locomotives and New Marine Diesel Engines less than 30 liters per Cylinder (2060-AM06)

Control of Emissions from Spark-Ignition Engines and Fuel Systems from Marine Vessels and Small Equipment (2060-AM34)

National Primary Drinking Water Regulations: Revisions to the Total Coliform Monitoring and Analytical Requirements and Additional Distribution System Requirements (2040-AD94)

National Primary Drinking Water Regulations: Radon (2040-AA94)

National Primary Drinking Water Regulations: Ground Water Rule (2040-AA97)

Lead-Based Paint Activities; Amendments for Renovation, Repair and Painting (2070-AC83)

Rule on Section 126 Petition from NC to Reduce Interstate Transport of Fine PM and O3;FIPs to Reduce Interstate Transport of Fine PM & O3;Revisions to the CAIR Rule; Revisions to the Acid Rain Program (2060-AM99)

Federal Implementation Plans to Reduce Interstate Transport of Fine Particulate Matter and Ozone (2060-AM93)

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 in national parks and other scenic areas. 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.

One of OAR's principal vehicles to mitigate particulate and ozone pollution is the program to reduce the long-range transport of the ''precursor'' pollutants that drift downwind and form particulates and ozone. The centerpiece of this program is the Clean Air Interstate Rule (CAIR), promulgated in May of 2005, which will achieve large reductions in sulfur dioxide and nitrogen oxide emissions that cause particulate and ozone pollution in the eastern half of the nation. This program will achieve its reductions via State-managed emissions-reduction programs in each of the 28 States covered by CAIR. In 2006, OAR will develop two additional rules that complement CAIR. The first of these is a Federal Implementation Plan (FIP) that will provide a backstop for CAIR in cases where the States fail to act. The second additional rule will add Delaware and New Jersey to the group of States covered by CAIR. OAR is also developing a related program to enhance scenic areas by reducing the particulate pollution that causes ''regional haze,'' restricting visibility in those areas. In 2006, this program will include a rule that will refine the definition of ''Best Available Control Techology'' (BART) for achieving pollution reductions under the program.

To complement these CAIR-related rules and help control ozone and particulate pollution, OAR is developing two additional rulemakings 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 ethanol 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 is developing implementation rulemakings for both ozone and particulates that will provide technical help and policy guidance crucial to assuring that State and local efforts achieve their pollution-control goals.

OAR also continues to assess new scientific information that underlies the National Ambient Air Quality Standards (NAAQS), which are the centerpiece of the Clean Air Act and the foundation of OAR's program. In late 2005, EPA expects to propose a rule that will announce the results of the latest review of the particulate matter NAAQS in the form of a proposed rule to either revise or reaffirm the current standard. This rule will be finalized in 2006. A companion rule on ozone will follow in 2007.

EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990. The largest part of the current effort is the ''Residual Risk'' program, which is the second phase of the regulatory program for major stationary sources of toxic air pollution and consists of evaluating the effectiveness of technology-based standards (which were developed in the first phase of the program) in reducing health risks and assessing the need for additional, more stringent standards to further reduce health risks. In 2006, we will propose to create a process by which facilities can comply with residual risk standards by demonstrating that they already pose low risks. Also in 2006, we will propose to require 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.

In March 2005, OMB issued a report entitled ''Regulatory Reform of the U.S. Manufacturing Sector.'' This report describes specific actions Federal agencies are taking to reform regulations nominated by the public. This report also includes regulatory actions that will be taken by OAR.

Office of Environmental Information

A key regulatory priority that OEI is undertaking is the enactment of burden reduction for the Toxics Release Inventory (TRI) reporting community. The TRI program collects chemical release and other waste management data on over 650 chemicals from over 24,000 facilities across the U.S. each year. To provide TRI reporters with appropriate burden relief, TRI has proposed two rulemakings to address both short-term and longer-term reporting requirement modifications while maintaining the practical utility of the TRI data. Specifically, OEI proposed the TRI Reporting Forms Modification Rule to address noncontroversial modifications to the TRI reporting requirements (i.e., Form R). The final rule was published in the **Federal Register** on July 12, 2005 (70 FR 39931). OEI published a second

regulatory proposal examining more significant reporting modifications with greater potential impact on reporting burden in September.

OEI is continuing to assess burden reduction options that are technically, practically and legally feasible in order to meet the goals and statutory obligations set forth for TRI reporting. Although the primary goal of the effort is to reduce burden associated with TRI reporting, it will also maintain EPA's commitment to providing valuable information to the public.

In addition, EPA is committed to providing electronic means to its stakeholders to meet EPA's reporting requirements, specifically through the Central Data Exchange (CDX) system. CDX is an integrated system that provides electronic reporting services to more than 30,000 users for 16 data flows in six major EPA media programs, and is on track to provide electronic reporting services for all significant environmental data collections over the next two years. CDX enables EPA and participating program offices to work with stakeholders including State, tribal and local governments and regulated industriesto enable streamlined, electronic submission of data via the Internet.

By enabling the regulated community to utilize CDX as a reporting tool, the TRI Program has seen a 43% increase in the number of reports submitted to EPA via CDX for TRI Reporting Year 2004 when compared to Reporting Year 2003. To take advantage of CDX's paperless reporting feature, TRI reporters must use the EPA-provided TRI Made-Easy (TRI-ME) Software. For Reporting Year 2004, 95 percent of all facilities used *TRI-ME* to prepare their reports. This upward trend toward greater Internet reporting via CDX is great news for the TRI program. Money saved from processing more-costly hard-copy paper submissions to TRI can now be reinvested in helpful tools and automated data quality checks to assist facilities and in ways to provide greater electronic means of accessing TRI data.

CDX also promulgated a number of new data flows, including the Office of Water's Stormwater Electronic Notice of Intent (an electronic permit application), the Office of Solid Waste and Emergency Response's Risk Management Plan WebRC (electronic updates of emergency contact information), and the Office of Prevention, Pesticides, and Toxic Substances' Lead Request for Certification (payment transactions online).

CDX is EPA's point of presence on the Environmental Exchange Network, known as the ''Node.'' Using CDX, EPA has worked with States to provide the technical specifications and exchange protocols for the Network. CDX provides support services, including node building, security and authentication and help desk. OEI is working with the major programs to deploy their data flows as node exchanges, using XML and web services. These efforts are some examples of EPA's commitment to the collection and dissemination of the highest quality of environmental information.

Office of Prevention, Pesticides, and Toxic Substances

EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) plays an important role in protecting public health and the environment from potential risk from pesticides and chemicals. In addition to the daily activities related to our licensing programs and non-rulemaking activities, OPPTS has identified several regulatory priorities for the coming fiscal year.

In 2006, OPPTS will begin 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 (ending in 2006) and reregistration program that will end in 2008. Registration review will become the Agency's program to evaluate and manage the risks posed by existing pesticides. FIFRA section 3(g) requires the Agency to establish procedural regulations for this registration review program. A proposed rule was published in July 2005, and a final rule is planned for the fourth quarter of 2006. Promulgation of a procedural regulation is a high priority and necessary in order to achieve a smooth transition into the new registration review program.

In 2005, OPPTS issued the first in a series of proposals to update and revise the regulations that provide the data requirements for the registration of pesticide products. The 2005 proposal addressed data requirements for conventional chemical pesticides. Subsequent proposals are planned for antimicrobial, biochemical, microbial pesticides, and plant-incorporated protectants. The data that is required for pesticide registrations forms the basis for the Agency's pesticide risk assessment and licensing decisions. Although the Agency has kept pace with evolving scientific understanding of pesticide risks by requiring the submission of the data needed on a case-by-case basis, the 1984 regulations have not been updated to reflect these data needs.

EPA regulations under section 18 of FIFRA allow a Federal or State agency to apply for an emergency exemption to allow an unregistered use of a pesticide for a limited time when such use is necessary to alleviate an emergency condition. By early 2006, EPA expects to finalize a 2004 proposal that will revise the regulations to improve the pesticide emergency exemption process. Two of these potential improvements are currently being tested through a limited pilot, and are based on recommendations from the States which are the primary applicants for emergency exemptions. The proposed revisions would streamline the application and review process, thereby reducing the burden to applicants and EPA, while allowing for quicker emergency response without compromising existing protections for human health and the environment.

OPPTS will 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. The Agency expects these changes will strengthen the regulations to better protect pesticide applicators and the public.

EPA has issued a proposed rule to categorically ban intentional dosing human testing for pesticides when the subjects are pregnant women or children, to formalize and further strengthen existing protections for subjects in human research conducted or supported by EPA, and to extend new protections to adult subjects in intentional dosing human studies for pesticides conducted by others who intend to submit the research to EPA. This proposal, the first of several possible Agency actions, focuses on third-party intentional dosing human studies for pesticides in response to the specific requirements of EPA's FY2006 Appropriations Act, but invites public comment on alternative approaches with broader scope. This rule is being promulgated on an accelerated schedule

because EPA is required by the FY 2006 Appropriations Act, signed by the President on August 2, 2005, to promulgate a final rule within 180 days of enactment, or by January 29, 2006.

The Agency launched the HPV Initiative in April 1998 to collect or, where necessary, develop basic screening level hazard data necessary to provide critical information about the environmental fate and potential hazards associated with high production volume (HPV) chemicals, defined as organic chemicals manufactured (including imported) at or above 1 million pounds per year based on information submitted under the 1990 Inventory Update Rule established pursuant to the Toxic Substances Control Act (TSCA). Data collected and/or developed under the HPV Initiative will provide critical basic information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action. The HPV Initiative includes a voluntary component, the HPV Challenge Program, and rulemaking under TSCA. Under the voluntary HPV Challenge Program component, to date, 368 individual companies, 104 consortia and the International Council of Chemical Associations (ICCA) have committed to sponsoring 2,244 of the estimated 2,800 HPV chemicals included in the HPV initiative. In early 2006, OPPTS expects to issue a final rulemaking under TSCA that will require testing for a number of the HPV chemicals that were not sponsored as part of the voluntary HPV Challenge Program.

Childhood lead poisoning is a pervasive problem in the United States, with approximately 310,000 young children estimated to have more than 10 ug/dl of lead in their blood (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline and various food sources, remaining lead-based paint in older houses continues to be a significant source of childhood lead poisoning. Section 402(c) of TSCA directs EPA to address renovation and remodeling activities and to revise the lead-based paint activities regulations to include renovation or remodeling activities that create lead-based paint hazards. To address these directives, the 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. Specifically, the Agency will be proposing regulatory requirements for renovation, repair and painting contractors involved in activities where, as a result of their work, lead hazards are created.

Evidence suggests that environmental exposure to man-made chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in human and wildlife populations. The Food Quality Protection Act directed EPA to develop a chemical screening program (the Endocrine Disruptor Screening Program, EDSP), using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. OPPTS is implementing recommendations from a scientific advisory committee, which was established to advise EPA on the EDSP, by developing and validating test systems for determining whether a chemical may have effects similar to those produced by naturally occurring hormones. As part of this program EPA is also designing a regulatory framework for procedures and processes to use when implementing the EDSP, and will develop an initial list of chemicals for which testing will be required. In late 2006, EPA anticipates publishing the draft procedures and processes for use in implementing the screening and testing phase of the EDSP.

As part of OMB's Regulatory Reform of the U.S. Manufacturing Sector (2005) report, commenters expressed concern that the existing TSCA section 12(b) regulations do not provide a low-level cut-off for the export notification requirements. In response to that comment, EPA committed to OMB that it would consider potential changes to the TSCA §12(b) regulation within the scope of existing statutory authority and issue a proposed amendment to address the concern expressed by January 2006. Legislation is currently still pending to address the implementation in the U.S. of the Rotterdam Convention on Prior Informed Consent (PIC), which includes export notification requirements.

In response to other commenters to the OMB 2005 Report, EPA has worked with stakeholders to address the commenters' request that EPA clarify the disposal requirements for small PCB remediation waste containing small amounts of PCBs and clarify that risk-based screening criteria can be used to determine the clean-up standards for a specific site. EPA submitted a plan to OMB in September 2005 that describes the steps it will take in FY2006 to address the requested clarifications.

EPA also agreed to conduct preliminary analysis of the use of mercury-containing switches in convenience lights and braking systems installed in new cars and identify viable non-mercury alternatives for use in TSCA rulemaking and voluntary activities. EPA is committed to making a determination on appropriate regulatory and/or voluntary approaches for addressing mercury switches and other parts in automobiles by the Fall/Winter 2005. As a result of the analysis mentioned above, EPA has made a determination to propose a TSCA Section 5 Significant New Use Rule (SNUR) in FY2006, for certain discontinued uses of mercury switches in automobiles.

Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response has a number of high priority regulatory initiatives. Two consistent themes can be found in these initiatives: Integrating a culture of innovations in all our rulemakings and reducing burden on the regulated community to focus resources on environmental results. Both of these themes directly support the Administrator's goals for land preservation and restoration and the use of innovative methods to promote environmental stewardship.

To promote innovation through rulemaking, 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.

EPA is seeking to revise the definition of solid waste in another innovation effort. For instance, EPA is looking at how to identify materials remaining in use in a continuous process in the generating industry so that they are not solid waste. The Agency is also considering other approaches that will increase the safe recycling of hazardous waste.

To reduce burden on the regulated community, Agency efforts are underway to eliminate duplicative and non-essential paperwork burden imposed by RCRA reporting and recordkeeping requirements. The regulatory changes being developed will have minimal impact on the many protections that EPA has established over the years for human health and the environment.

EPA is also considering a means to address the frequency and level of reporting nitrogen oxides under the Comprehensive Environmental Response, Compensation and Liability Act and the Emergency Planning and Community Right-to-Know Act. The Agency is considering reducing burden by either (1) using more efficiently the continuous release reporting mechanism or (2) granting an administrative reporting exemption for certain releases of nitrogen oxides.

EPA plans to issue new guidance and propose a rule concerning the Spill Prevention, Control, and Countermeasure(SPCC) Plan requirements. The guidance document will provide clarification and compliance assistance to facilities subject to SPCC. The rule will propose compliance flexibility for facilities that store small amounts of petroleum, while continuing to prevent potential discharges to navigable waters of the United States or adjoining shorelines.

All these rulemaking efforts support reform nominations mentioned in OMB's 2004 Report to Congress on the Costs and Benefits of Regulations. In addition, the rule seeking burden reduction of duplicative and non-essential paperwork burden under RCRA was also mentioned in the 2002 Report to Congress.

Office of Water

EPA's Office of Water's primary goals are to ensure that drinking water is safe; restore and maintain oceans, watersheds, and their aquatic ecosystems to protect human health; support economic and recreational activities; and provide healthy habitat for fish, plants, and wildlife. In order to meet these goals, EPA has established a number of regulatory priorities for the coming year. They include rules affecting cooling water intakes and drinking water.

On November 1, 2004, EPA proposed rules to control adverse environmental impacts associated with cooling water intakes. Many power plants and factories withdraw large volumes of water from rivers, lakes, or other water bodies to cool production equipment. As required by the Clean Water Act, EPA must ensure that the location, design, construction and capacity of these cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. The proposed rule sets standards to protect fish, shellfish and other forms of aquatic life and provides flexibility by offering several alternatives for facilities to comply. This is the third in a series of rules designed to reduce harm to aquatic life that is taken up with cooling water. This phase of rulemaking may affect certain existing manufacturing facilities and new offshore and coastal oil and gas extraction facilities that use cooling water intake structures, and whose intake flow levels exceed one of the three proposed minimum thresholds. EPA sought public comment on this proposal for 120 days. EPA intends to take final action on June 1, 2006.

Finally, EPA is developing three rules to protect the safety of drinking water. First, EPA is developing a final Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). This rule would reduce risks from microbial pathogens, especially Cryptosporidium, in public water systems that use surface water sources. LT2ESWTR provisions would target systems where current standards do not provide sufficient protection, including both filtered systems with elevated source water pathogen levels and unfiltered systems. Second, EPA plans to finalize the Ground Water Rule, a rule that addresses fecal contamination in public water systems served by ground water sources. Finally, EPA is developing a final Stage 2 Disinfectants and Disinfection Byproducts Rule to control exposure to disinfection byproducts beyond the requirements of the Stage 1 Disinfectants and Disinfection Byproducts Rule. This rule will respond to new data the Agency has received on: Disinfection byproduct occurrence; bladder, colon, and rectal cancer; and possible reproductive and developmental health effects.

EPA

PROPOSED RULE STAGE

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100. REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER

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:

NPRM, Judicial, December 20, 2005.

Final, Judicial, September 27, 2006.

Abstract:

On July 18, 1997, the EPA published a final rule revising the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) (62 FR 38652). While retaining the PM10 standard levels, new standards were added for fine particles (PM2.5) to provide increased protection against both health and environmental effects of PM. On the same day, a Presidential Memorandum (62 FR 38421) was published that, among other things, anticipated that EPA would complete the next review of the PM NAAQS by July 2002. The EPA's plans and schedule for the next periodic review of the PM NAAQS were published on October 23, 1997 (62 FR 55201). Due to the unprecedented volume of new research, the completion of the Criteria Document has been extended. As a result, the overall schedule for the review of the PM NAAQS has extended beyond the original target of July 2002. As with other NAAQS reviews, a rigorous assessment of relevant scientific information will be presented in a Criteria Document (CD) prepared by EPA's National Center for Environmental Assessment. The EPA's Office of Air Quality Planning and Standards will then prepare a Staff Paper (SP) for the Administrator which

will evaluate the policy implications of the key studies and scientific information contained in the CD and additional technical analyses and identify critical elements that EPA staff believe should be considered in reviewing the standards. The CD and SP 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 PM NAAQS review is completed, the Administrator's proposal to revise or reaffirm the PM 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 particulate matter 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 particulate matter 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 particulate matter 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 particulate matter are intended to protect against public health risks associated with morbidity or premature mortality from cardiopulmonary disease. During the course of this next review, a risk assessment will be conducted to evaluate health risks associated with retention or revision of the particulate matter standards.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	
Final Action	10/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Additional Information:

SAN No. 4255, EDocket No. OAR-2001-0017

http://docket.epa.gov/edkpub/do/EDKStaffCollectionDetailView?objectId= 0b0007d48006d9eb

URL For More Information:

http://www.epa.gov/ttn/naaqs/standards/pm/s__pm__index.html

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RIN: 2060–AI44

EPA

101. CONTROL OF HAZARDOUS AIR POLLUTANTS FROM MOBILE SOURCES

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 7521

CFR Citation:

40 CFR Part 80; 40 CFR Part 86

Legal Deadline:

None

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:

EPA has been directed by Congress under CAA section 2.2(l) to require motor vehicle and/or fuel standards. The statute requires the use of the greatest emissions reduction achievable through the use of technology. At a minimum, this applies to benzene and formaldehyde. EPA is to revise regulations ''from time to time.''

Summary of Legal Basis:

The Agency is currently negotiating a rulemaking schedule with plaintiffs stemming from a lawsuit brought by the Sierra Club and US PIRG. Recently the court ruled for the plaintiffs that EPA had a mandatory duty to meet the deadline established in the first MSAT rule (FRM in July 2004).

Alternatives:

A range of alternatives for the various fuel control options are being discussed as part of the rulemaking development process. Alternatives include more stringent standards for benzene control.

Anticipated Cost and Benefits:

There are potential significant health and welfare benefits associated with the mobile air toxics rule. Costs and benefits, including an analysis of the energy impacts as appropriate, will be developed 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	02/00/06	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

Additional Information:

SAN No. 4748;

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

102. 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 revised National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM-2.5). The rule described in this paragraph — the Implementation Rule for PM-2.5 NAAQS — will include requirements and guidance for State and local air pollution agencies to develop and submit State implementation plans (SIPs) designed to bring the areas into attainment with the 1997 standards. These SIP development activities include conducting technical analyses to identify effective strategies for reducing emissions contributing to PM-2.5 levels, and adopting regulations as needed in order to attain the standards. Ambient air quality monitoring for 1999-2001 shows that areas exceeding the standards are located throughout the eastern half of the U.S. and in California. Estimates show that compliance with the standards will prevent thousands of premature deaths from heart and lung disease, tens of thousands of hospital admissions and emergency room visits, and millions of absences from school and work every year.

Statement of Need:

This rule is needed in order to provide guidance to State and local agencies in preparing State implementation plans (SIPs) designed to bring areas into attainment with the 1997 PM-2.5 standards. The implementation requirements for nonattainment areas are generally described in subpart 1 of section 172 of the Clean Air Act. This rule provides further interpretation of those requirements for the PM-2.5 standards.

Summary of Legal Basis:

42 USC 7410 and 42 USC 7501 et seq.

Alternatives:

Alternatives will be explored as the proposal is developed.

Anticipated Cost and Benefits:

This information will be provided as the proposal is developed.

Risks:

The risks addressed by this rule are those addressed by the 1997 NAAQS rule — i.e., the health and environmental risks associated with nonattainment of the NAAQS. These risks were summarized in detail in the analyses accompanying the 1997 NAAQS rule.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	
Final Action	11/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4752;

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RIN: 2060–AK74

EPA

103. PREVENTION OF SIGNIFICANT DETERIORATION (PSD) AND NONATTAINMENT NEW SOURCE REVIEW (NSR): ALLOWABLES PLANTWIDE APPLICABILITY LIMIT (PAL), AGGREGATION, AND DEBOTTLENECKING

Priority:

Other Significant

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 51.165; 40 CFR 51.166; 40 CFR 52.21

Legal Deadline:

None

Abstract:

These rules clarify when less than significant emissions increases from

multiple activities at a single major stationary source must be considered together for the purposes of determining major new source review (NSR) applicability (aggregation). We are also changing in the way emissions from permitted emissions units upstream or downstream from those undergoing a physical change or change in the method of operation are considered when determining if a proposed project will result in a significant emissions increase (debottlenecking). The rules also provide an allowables plantwide applicability limit (PAL) option that is based on the allowable emissions from major stationary sources. A PAL is an optional approach that provides the owners or operators of major stationary sources with the ability to manage facility-wide emissions without triggering major NSR. The added flexibility of a PAL allows sources to respond rapidly to market changes consistent with the goals of the NSR program. The regulations for aggregation and debottlenecking are intended to improve implementation of the program by articulating principles for determining major NSR applicability that were previously addressed through guidance only. The purpose of the allowables PAL rule is to encourage major stationary sources to install state-of-the-art controls in exchange for regulatory certainty and flexibility.

Statement of Need:

The current New Source Review program provides for emissions from multiple projects to be aggregated (aggregation) as one single project under certain circumstances. Similarly, when making a PSD applicability calculation, emissions from units whose effective capacity and potential to emit have been increased as a result of a modification to another unit (debottlenecked units), must be included in the initial PSD applicability calculations. Specific questions regarding the application of these two terms have been addressed on a case-by-case basis. By completing this rulemaking, regulated entities and regulatory agencies will be provided an additional level of certainty in addressing applicability issues. In December 2002 we promulgated NSR rules for a Plantwide Applicability Limit (PAL) based on actual emissions that apply to existing major stationary sources. In 2005, we will propose an allowables PAL based on a facility's allowable emissions mainly for greenfield sources. If a company commits to keep its facility emissions below allowable PAL levels, then these regulations will allow the plant owners to avoid the NSR permitting process when they make changes at individual units at the plant, as long as the total emissions from the facility will not increase. This would provide flexibility for sources to respond rapidly to market changes without compromising environmental protection.

Summary of Legal Basis:

42 USC 7411(a)(4)

Alternatives:

Alternatives will be developed as the rulemaking proceeds.

Anticipated Cost and Benefits:

Cost and benefit information will be developed as appropriate as the rulemaking proceeds.

Risks:

Risk information will be developed as appropriate as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4793;

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RIN: 2060–AL75

EPA

104. 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.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 7522 to 7621

CFR Citation:

40 CFR 92 and 94

Legal Deadline:

None

Abstract:

This rule will set an additional tier of more stringent exhaust emission standards for new locomotives and new marine compression-ignition engines below 30 liters per cylinder. Pollutants to be regulated are primarily Nitrogen Oxides (NOx) and particulates. These new standards are expected to reflect the emission reductions achievable through the application of advanced emission control technologies, including high-efficiency catalytic exhaust emission control devices, and the availability and use of low-sulfur diesel fuel. Applying these technologies could result in a 90 percent reduction in exhaust emissions. The standards will build on our existing locomotive and marine diesel engine emission control programs, and will likely be modeled on our highway and nonroad diesel programs. The advanced technologies we are considering would take advantage of the fact that low-sulfur fuel for these engines will already be available as a result of previous regulation in our nonroad program.

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 U.S.C. 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. Due to the relatively small number of engines involved, it is likely that the annualized cost of the rule will be less than $100 million.

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	07/00/06	
Final Action	06/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

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RIN: 2060–AM06

EPA

105. CONTROL OF EMISSIONS FROM SPARK–IGNITION ENGINES AND FUEL SYSTEMS FROM MARINE VESSELS AND SMALL 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	01/00/06	
Final Action	01/00/07	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4882;

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RIN: 2060–AM34

EPA

106. 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. A draft rule and preamble are scheduled for completion in October 2005. Nine States were solicited for monitoring requirements data in July for use in cost/benefits analysis.

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.11 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. § 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. § 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 less 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	12/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4699.2; Split from RIN 2060-AK29.

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RIN: 2060–AN00

EPA

107. FUEL ECONOMY LABELING OF MOTOR VEHICLES: REVISIONS TO IMPROVE CALCULATION OF FUEL ECONOMY ESTIMATES

Priority:

Other Significant

Legal Authority:

15 USC. 2001–2003; 15 USC 2005–2006; 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:

Numerous studies indicate that EPA's fuel economy estimates may be overestimated, in some cases significantly so. For example, a recent Consumer Reports study found that 90 percent of the vehicles they tested fell short of EPA estimates. Some vehicles fell short of EPA's city estimate by as much as 35 to 50 percent. The American Automobile Association (AAA) has similarly undertaken fuel economy studies, indicating a similar discrepancy. Although these studies differ in their test methods and driving conditions, they do suggest that EPA's approach to estimating fuel economy can be improved to better reflect real-world driving. Bluewater Network petitioned EPA to revise the methodology for estimating fuel economy, and over 10,000 comments filed with EPA support improving the accuracy of the fuel economy labels that appear on new vehicles.

A fundamental issue is that today's test methods do not represent real-world driving conditions. For example, the highway test has a top speed of only 60 miles per hour, the city and highway tests are run at mild climatic conditions (75 deg F), acceleration rates are mild due to equipment limitations of the 1970's, and neither test is run with accessory use such as air conditioning. In the 1990's EPA added new emission tests after documenting a disconnect between existing test procedures and characteristics of real-world driving, but fuel economy tests remained unchanged. These new emission tests capture the effects of higher speeds, more aggressive acceleration rates, and the use of air conditioning at higher temperatures.

Additionally, cars and automotive technology have evolved since 1985, the last time EPA adjusted the fuel economy label methodology. The penetration of air conditioning in the automotive fleet, for example, has increased significantly. The performance and weight of automobiles has steadily increased for the last 25-30 years. Since 1985, acceleration rates have improved by 30 percent on average, average horsepower has increased by about 75 percent, and average vehicle weight has increased by about 25 percent. Driving conditions have also changed, with longer commutes and more time spent in slow, high-traffic conditions. All these factors have the potential of affecting fuel economy.

Summary of Legal Basis:

Section 774 of the Energy Policy Act of 2005 Congress 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. Section 774 directs EPA to ''. . .update or revise the adjustment factors in sections 600.209-85 and 600.209-95, of the Code of Federal Regulations, CFR Part 600 (1995) Fuel Economy Regulations for 1977 and Later Model Year Automobiles to take into consideration higher speed limits, faster acceleration rates, variations in temperature, use of air conditioning, shorter city test cycle lengths, current reference fuels, and the use of other fuel depleting features.''

Alternatives:

We are considering several broad options (note that none of these options would impact the calculation of fuel economy for Corporate Average Fuel Economy (CAFE) requirements). These include:

1. Take No Action

2. Revise Current Adjustment Factors

3. Add New Fuel Economy Tests to Current Tests

4. Propose New Test Procedures for Fuel Economy and Emissions

Anticipated Cost and Benefits:

Costs and benefits will be quantified and reported as part of the rulemaking process.

Risks:

There are no anticipated risk impacts associated with this action.

Timetable:

Action	Date	FR Cite
NPRM–	01/00/06	
Final Action–	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4962;

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RIN: 2060–AN14

EPA

108. 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	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

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RIN: 2060–AN15

EPA

109. ● 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
NPRM	03/00/07	
Final Action	12/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 5008;

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RIN: 2060–AN24

EPA

110. ● PREVENTION OF SIGNIFICANT DETERIORATION AND NONATTAINMENT NEW SOURCE REVIEW: ALTERNATIVE APPLICABILITY 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 an alternative applicability 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 alternative applicability test would be available for EGUs that are also subject to the EPA-administered Clean Air Interstate Rule (CAIR) NOx Annual Trading Program or the CAIR SO2 Trading Program. This alternative applicability test could be extended to other CAIR and non-CAIR EGUs. For existing major stationary sources, the NSR base program applicability 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 alternative NSR applicability 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.

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	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4794.2; Split from RIN 2060-AM95.

URL For More Information:

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RIN: 2060–AN28

EPA

111. ● RENEWABLE FUEL STANDARDS REQUIREMENTS FOR 2006

Priority:

Other Significant

Legal Authority:

PL 109–58, sec 1501

CFR Citation:

Not Yet Determined

Legal Deadline:

None

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. This statutory provision is subject to multiple interpretations of key terms. The ''Renewable Fuel Standard Requirements for 2006'' that we are proposing will interpret 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:

This regulation will provide certainty to the refining industry in the early part of 2006 so they understand what the requirements and obligations are for the industry in case the default standard should become effective.

Summary of Legal Basis:

The Energy Policy Act of 2005 (the Act) requires EPA to promulgate regulations that implement a renewable fuel standard (RFS) within one year of enactment. The Act also contains a provision that allows a default standard of 2.78% renewable fuels in gasoline for 2006, should EPA fail to promulgate the regulations by the required date.

Alternatives:

A range of alternatives are being discussed as part of the major RFS rulemaking development process that will follow the default standard rulemaking. Alternatives for the default rulemaking may include provisions to allow for crediting if the default standard is exceeded.

Anticipated Cost and Benefits:

There are potential significant health and welfare benefits associated with the mobile air toxics rule. Costs and benefits, including an analysis of the energy impacts as appropriate, will be developed as part of the rulemaking process.

Risks:

The rule will impose no risks beyond those inherent in the statutory requirement.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SANı 5024

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RIN: 2060–AN51

EPA

112. LEAD–BASED PAINT ACTIVITIES; AMENDMENTS FOR RENOVATION, REPAIR AND PAINTING

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 2682 ''TSCA 4 402''

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. Specifically, the Agency will be proposing 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	12/00/05	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 3557;

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:

http://www.epa.gov/oppt/lead/

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RIN: 2070–AC83

EPA

113. NOTIFICATION OF CHEMICAL EXPORTS UNDER TSCA SECTION 12(B)

Priority:

Other Significant

Legal Authority:

15 USC 2611

CFR Citation:

40 CFR 707

Legal Deadline:

None

Abstract:

Section 12(b)(2) of the Toxic Substances Control Act (TSCA) states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which submission of data is required under section 4 or 5(b), or for which a rule, action or order has been proposed or promulgated under section 5, 6, or 7, shall notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance. As part of OMB's Regulatory Reform of the U.S. Manufacturing Sector Report (2005), commenters expressed concern 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. Legislation is currently pending to address the implementation in the U.S. 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 #190, pg 10, commenter #12 available at http://www.whitehouse.gov/omb/inforeg/key__comments.html.) And then again in 2004, see #39 in OMB's Regulatory Reform of the U.S. Manufacturing Sector Report (2005).

Summary of Legal Basis:

Section 12(b)(2) of the Toxic Substances Control Act (TSCA).

Alternatives:

To be determined.

Anticipated Cost and Benefits:

Minimal, but yet to be determined.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4858;

URL For More Information:

www.epa.gov/opptintr/chemtest/12b.htm

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RIN: 2070–AJ01

EPA

114. ADMINISTRATIVE REPORTING EXEMPTION FOR CERTAIN AIR RELEASES OF NOX

Priority:

Other Significant

Legal Authority:

42 USC 9603

CFR Citation:

40 CFR 302.6(c); 40 CFR 355.40

Legal Deadline:

None

Abstract:

The Agency is considering administratively exempting from reporting requirements the releases of certain NOx emissions to air. This would eliminate reports from facilities emitting NOx where the Agency has determined that the releases pose little or no risk or to which a Federal response is infeasible or inappropriate. Requiring reports of such releases would serve little or no useful purpose and could, instead, impose a significant burden on the Federal response system and on the persons responsible for notifying the Federal Government of the release.

Statement of Need:

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This rule, if finalized, will eliminate or substantially reduce certain Federal regulatory notification requirements.

Summary of Legal Basis:

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9601 et seq., as amended by the Superfund Amendments and Reauthorization Act of 1986, gives the Federal Government broad authority to respond to releases or threats of releases of hazardous substances from vessels and facilities. The term ''hazardous substance'' is defined in section 101(14) of CERCLA primarily by reference to other Federal environmental statutes. Section 102 of CERCLA gives the U.S. Environmental Protection Agency (EPA) authority to designate additional hazardous substances. Under CERCLA section 103(a), the person in charge of a vessel or facility from which a CERCLA

hazardous substance has been released in a quantity that equals or exceeds its reportable quantity (RQ) must immediately notify the National Response Center (NRC) of the release. A release is reportable if an RQ or more is released within a 24-hour period (see 40 CFR 302.6). This reporting requirement, among other things, serves as a trigger for informing the Government of a release so that Federal personnel can evaluate the need for a Federal removal or remedial action and undertake any necessary action in a timely fashion. In addition to the reporting requirements established pursuant to CERCLA section 103, section 304 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11001 et seq., requires the owner or operator of certain facilities to immediately report releases of CERCLA hazardous substances or any extremely hazardous substances to State and local authorities (see 40 CFR 355.40).

Alternatives:

EPA is also considering the appropriateness of alternative options to address the CERCLA §103 and EPCRA §304 Reporting Requirements of Certain Unpermitted Releases of NOx to the air. Those options include; a) more efficient use of Continuous Release reporting, and b) extending the administrative reporting exemption to include all releases of NOx from combustion sources that are not the result of an accident or malfunction.

Anticipated Cost and Benefits:

The Agency estimates for industry an annual overall reduction of cost from $16,380,571 to $15,994,833 an overall reduction of $385,738 with a corresponding reduction in the hour burden from 382,890 to 376,385 a reduction of 6,505 hours. This represents an overall reduction in the likely number of respondents from 27,227 to 25,762 a reduction of 1,465 respondents.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	10/04/05	70 FR 57813
Final Action	10/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

SAN No. 4736

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RIN: 2050–AF02

EPA

115. 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 yr 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	06/00/06	

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

116. REGULATORY ACTIONS ASSOCIATED WITH THE NOTICES OF DATA AVAILABILITY ON THE SPILL PREVENTION, CONTROL, AND COUNTERMEASURE (SPCC) RULE, 40 CFR PART 112

Priority:

Other Significant

Legal Authority:

33 USC 1321

CFR Citation:

40 CFR 112

Legal Deadline:

None

Abstract:

On September 20, 2004, the Environmental Protection Agency (EPA)

issued two Notices of Data Availability (NODAs) concerning certain facilities and oil-filled and process equipment. Based on our review of the information received from the NODAs, EPA is considering additional measures to ease the compliance burden of smaller facilities and for oil-filled equipment. EPA intends to define those facilities and oil-filled equipment for which EPA plans to propose streamlined SPCC Plan requirements, and extend or otherwise address the February 2006 compliance deadline for SPCC Plan revisions for this affected universe. EPA is also considering (1) an indefinite extension of the compliance dates for a defined category of farms; (2) a definition and regulatory relief for motive power containers and airport mobile refuelers; and (3) removing the inapplicable requirements for Animal Fats and Vegetable Oils (AFVOs).

Statement of Need:

EPA is clarifying, extending and modifying the regulatory requirements for facilities subject to the SPCC rule. This is part of EPA's multi-phased strategy to address concerns with the current SPCC regulation.

Summary of Legal Basis:

The legal basis is 33 USC 1321 et seq.

Alternatives:

Undetermined at this time.

Anticipated Cost and Benefits:

Undetermined at this time.

Risks:

Undetermined at this time.

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	10/00/05	
Final Action	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 2634.3; Split from RIN 2050-AG16.

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RIN: 2050–AG23

EPA

117. 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 the Resource Conservation and Recovery Act (RCRA) when they 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, 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–	09/00/06	

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

118. 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	10/00/05	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4896;

URL For More Information:

www.epa.gov/tri

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RIN: 2025–AA14

EPA

FINAL RULE STAGE

119. INCLUSION OF DELAWARE AND NEW JERSEY IN THE CLEAN AIR INTERSTATE RULE

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7410(a)

CFR Citation:

40 CFR Part 51; 40 CFR Part 72; 40 CFR Part 73; 40 CFR Part 74; 40 CFR Part 77; 40 CFR Part 78; 40 CFR Part 96

Legal Deadline:

None

Abstract:

In the Clean Air Interstate rule(CAIR), EPA adopted a single-factor threshold of 0.20 mg/m3 contribution to PM2.5 nonattainment as the air quality element of the definition of emissions that contribute significantly to nonattainment in another state. Upon further consideration, EPA believes that this may exclude some states that should be considered to make a significant contribution if their future emissions are not reduced below presently projected levels. On May 12, 2005, we proposed to supplement the contribution threshold adopted in the CAIR with a multi-factor weight of evidence test (70 FR 25408). We published a notice of data availability on June 28, 2005 (70 FR 37068) to notify the public we had put additional

information in the docket regarding the inclusion of Delaware and New Jersey. Application of the test indicates that New Jersey and Delaware should be included in the CAIR requirements. In this action, we are responding to comments received on the proposal.

Statement of Need:

The Clean Air Act requires that a State take steps to prevent emissions from sources located within its boundaries from interfering with a downwind State's ability to meet air quality standards, or interfering with measures to protect visibility. EPA believes it is important to address interstate transport for the PM2.5 and 8-hour ozone standards prior to the time when State plans addressing nonattainment of the standards are completed, so that States can rely on upwind reductions when developing plans for attaining the standards. Analysis has shown that additional reductions in PM2.5 and ozone precursors are necessary as one part of an attainment strategy for downwind states. This rulemaking would achieve the needed reductions, either in lieu of or in combination with possible legislation such as the President's Clear Skies bill.

Summary of Legal Basis:

Clean Air Act section 110(a)(2)(D) [42 USC 7410(a)(2)(D)] requires that each State's implementation plan include the ''good neighbor'' provisions of prohibiting sources in the State from emitting air pollutants in amounts that contribute significantly to nonattainment in a downwind state, or interfere with measures to protect visibility in a Class I areas. Section 110(a)(1) [42 USC 7410(a)(1)] requires States to submit implementation plans within a specified period of time after the promulgation of a new or revised national ambient air quality standard. In addition, EPA has authority under section 110(k)(5) [42 USC 7410(k)(5)] to require States to revise existing implementation plans whenever EPA finds that those plans are inadequate to comply with any requirement. Further, section 301(a)(1) [42 USC 7601(a)(1)] confers general authority upon the EPA Administrator. These provisions of the Clean Air Act, taken together, confer authority on EPA to promulgate the present regulations.

Alternatives:

There are several alternatives to a federal interstate transport rule. The Clear Skies Act proposed by the Bush Administration will, if enacted, help reduce interstate transport of pollution from the largest emitters in the power generation sector. However, Congressional approval is not guaranteed, and all emissions sources contributing to interstate transport may not be addressed. Another alternative is to wait for States to submit plans under Clean Air Act (CAA) section 110(a), and for EPA to review these plans for compliance with the transport provisions of CAA section 110(a)(2)(D). Past experience indicates that it would be difficult for individual upwind States to adopt transport controls without EPA defining their reduction responsibilities in advance. Further, EPA is concerned that the States do not yet have the analytical tools needed to assess their contribution to transport. Another alternative is to wait for individual States to submit petitions under CAA section 126 that call for EPA to address interstate transport. In this case it would be necessary for EPA to respond by identifying the collective scope and magnitude of the interstate transport problem, and defining a collective solution. This rulemaking accomplishes this same goal, but will accomplish it earlier so that States can rely on upwind reductions when developing plans for attaining the standards.

Anticipated Cost and Benefits:

Cost and benefit calculations will be made as the rulemaking proceeds.

Risks:

The risks addressed are the health and welfare impacts resulting from nonattainment of the NAAQS for fine particulate matter and ozone, and from emissions that interfere with measures to protect visibility in Class I areas.

Timetable:

Action	Date	FR Cite
NPRM	05/12/05	70 FR 25408
NODA	06/28/05	70 FR 37068
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Energy Effects:

Statement of Energy Effects planned as required by Executive Order 13211.

Additional Information:

SAN No. 4794.1; Split from RIN 2060-AL76.

URL For More Information:

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RIN: 2060–AM95

EPA

120. RULE ON SECTION 126 PETITION FROM NC TO REDUCE INTERSTATE TRANSPORT OF FINE PM AND O3; FIPS TO REDUCE INTERSTATE TRANSPORT OF FINE PM & O3; REVISIONS TO CAIR RULE; REVISIONS TO ACID RAIN PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 52

Legal Deadline:

Final, Statutory, November 18, 2004.

NPRM, Judicial, August 1, 2005, Proposed Determinations.

Other, Judicial, August 2, 2005, Must deliver to FR NLT 1 day after signature.

Final, Judicial, March 15, 2006, Final Determination.

Abstract:

This action includes two separate but related rulemakings to address interstate transport with respect to the 8-hour ozone and fine particulate matter (PM2.5) National Ambient Air Quality Standards. In one part, EPA is responding to a petition submitted to the Agency in March 2004, by the State of North Carolina pursuant to section

126 of the Clean Air Act. The petition requests that EPA make findings that emissions of nitrogen oxides (NOx) and sulfur dioxide (SO2) from large electric generating units (EGUs) in 12 States are significantly contributing to PM2.5 nonattainment or maintenance problems in North Carolina and that NOx emissions from large EGUs in 5 States are significantly contributing to 8-hour ozone nonattainment or maintenance problems in North Carolina. NOx and SO2 are precursors to PM2.5 pollution; NOx is also a precursor to ozone pollution. If EPA makes such findings, EPA is authorized to establish Federal emissions limits for the affected sources. The second part of this rulemaking is related to EPA's Clean Air Interstate Rule (CAIR), promulgated on March 10, 2005, which addresses interstate transport of NOx and SO2. CAIR requires 28 States and the District of Columbia to revise their State implementation plans (SIPs) to reduce emissions of NOx and/or SOx. Controlling these emissions will assist the downwind areas in meeting the PM2.5 and 8-hour ozone national ambient air quality standards. To act as a ''backstop'' for CAIR, EPA is also developing Federal implementation plans (FIPs) to address interstate transport. These FIPs are the second part of the two-part rulemaking we are discussing in this abstract. The FIPs would achieve the emissions reductions required under the CAIR if a State does not have an approved SIP to do so. In the FIP actions, EPA intends to propose Federal NOx and SO2 trading programs for electric generating units. The EPA is required to promulgate a FIP within 2 years of: 1) finding that a State has failed to make the required SIP submittal, 2) finding that the submittal received does not satisfy the minimum SIP completeness criteria, or 3) disapproving a SIP in whole or in part. The EPA is required to promulgate the FIP unless EPA has approved, within the 2-year time period, a SIP that corrects the identified deficiency. In an action published on April 25, 2005, EPA notified States that they had failed to submit SIPs to address transport that were due in 2000, 3 years after EPA established the 8-hour ozone and PM2.5 standards. This current rulemaking action is also proposing certain revisions to the CAIR and the Acid Rain Program.

Statement of Need:

Clean Air Act section 110(a)(2)(D) requires that each state's implementation plan include the ''good neighbor'' provisions of prohibiting sources in the State from emitting air pollutants in amounts that contribute significantly to nonattainment, or interfere with maintenance, of a national ambient air quality standard (NAAQS) in a downwind state. Under the Clean Air Interstate Rule (CAIR), EPA determined that emissions of nitrogen oxides (NOx) and/or sulfur dioxide (SO2) from 28 States and the District of Columbia are significantly contributing to nonattainment and/or maintenance problems in downwind States with respect to the PM2.5 and/or 8-hour ozone standards. Therefore, EPA established NOx and/or SO2 emissions reductions requirements for these States to mitigate the interstate transport. The Federal implementation plans (FIPs) for the CAIR would provide a backstop to ensure that the significant emissions reductions required by the CAIR would be achieved. On March 19, 2004, EPA received a petition from the State of North Carolina filed under section 126 of the CAA. The petition, which is based largely on the analyses for proposed CAIR, requests that EPA establish control requirements for electric generating units in 13 States based on findings that emissions of NOx and SO2 from these sources are significantly contributing to PM2.5 and/or 8-hour ozone nonattainment and maintenance problems in North Carolina.

Summary of Legal Basis:

In April 2005, EPA made national findings under CAA sections 110(a)(2)(D) and 110(a)(1) that States have failed to submit SIPs required to address interstate transport with respect to the 8-hour ozone and PM2.5 NAAQS. The findings started a 2-year clock for EPA to promulgate FIPs to address the requirements of section 110(a)(2)(D). Section 126 allows States to petition EPA for a finding that major stationary sources or groups of sources in upwind States are significantly contributing to nonattainment or interfering with maintenance of a NAAQS in the petitioning State. If EPA makes the requested finding, EPA is authorized to establish emissions limitations for the affected sources. The EPA is required to respond to a section 126 petition through notice-and-comment rulemaking by a specific deadline.

Alternatives:

The proposed Federal NOx and SO2 cap and trade programs for the section 126 action and FIP would provide regulated sources with flexibility in their choice of compliance strategy. EPA is also proposing an abbreviated SIP option to allow States to submit SIPs to control specific elements of the Federal program. For the portion of the section 126 petition that has merit, EPA is proposing in the alternative to grant the petition or to deny the petition if EPA promulgates the FIP no later than the final section 126 response. In addition, EPA is proposing to withdraw section 126 or FIP control requirements in a State if the State submits and EPA approves a SIP that meets the requirements of CAIR.

Anticipated Cost and Benefits:

Costs and benefits for the proposal are based on the Regulatory Impact Analysis for the CAIR.

Risks:

The risks addressed are the health and welfare impacts resulting from nonattainment of the PM2.5 and 8-hour ozone NAAQS.

Timetable:

Action	Date	FR Cite
NPRM	08/24/05	70 FR 49708
Final Action	03/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 4956;

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RIN: 2060–AM99

EPA

121. ● REGIONAL HAZE REGULATIONS; REVISIONS TO PROVISIONS GOVERNING ALTERNATIVE TO SOURCE–SPECIFIC BEST AVAILABLE RETROFIT TECHNOLOGY (BART) DETERMINATIONS

Priority:

Other Significant

Legal Authority:

42 USC 7410; 2 USC 7414; 42 USC 7421; 42 USC 7470–7479

CFR Citation:

40 CFR 51.308(e)(2); 40 CFR 51.309; 40 CFR 51 Appendix Y (New)

Legal Deadline:

None

Abstract:

EPA published the regional haze rule on July 1, 1999 (64 FR 35714). On May 24, 2002, the D.C. Circuit Court vacated certain provisions of the regional haze rule related to best available retrofit technology (BART). The BART provisions at issue in that case were applicable on a source-by-source basis. The revisions to the haze rule to respond to that case are being finalized in the Clean Air Visibility Rule (CAVR) on June 15, 2005, under a consent decree. In a separate but related case, the D.C. Circuit vacated additional BART provisions in a decision issued on February 18, 2005. These provisions applied to BART in the context of optimal emissions trading programs. The program at issue in that case was the SO2 ''backstop'' emissions trading program developed by the Western Regional Air Partnership (WRAP), but the decision also controls all similar programs developed in the future. To address this decision, we proposed revisions to the haze provisions governing trading programs on August 1, 2005 (70 FR 44154). The proposal addresses both the particular circumstances of the WRAP and general implications of the decision for other programs. We intend to finalize this proposal by November 8, 2005, as noted in the CAVR consent decree.

Statement of Need:

This action is needed in response to the May 2002 ruling of the U.S. Court of Appeals for the D.C. Circuit (American Corn Growers et al. V. EPA, 291 F.3d 1) vacating the Best Available Retrofit Technology (BART) provisions of the regional haze rule. The Clean Air Act requires that States include BART in their visibility State Implementation Plans (SIPs). The Clean Air Act also requires that a State take steps to prevent emissions from sources located within its boundaries from interfering with a downwind State's ability to meet air quality standards, or interfering with measures to protect visibility.

Summary of Legal Basis:

Clean Air Act section 169A requires States to include BART in their visibility SIPs. Clean Air Act section 110(a)(2)(D) [42 USC 7410(a)(2)(D)] requires that each State's implementation plan include the ''good neighbor'' provisions of prohibiting sources in the State from emitting air pollutants in amounts that contribute significantly to nonattainment in a downwind state, or interfere with measures to protect visibility in a Class I areas. Section 110(a)(1) [42 USC 7410(a)(1)] requires States to submit implementation plans within a specified period of time after the promulgation of a new or revised national ambient air quality standard. In addition, EPA has authority under section 110(k)(5) [42 USC 7410(k)(5)] to require States to revise existing implementation plans whenever EPA finds that those plans are inadequate to comply with any requirement. Further, section 301(a)(1) [42 USC 7601(a)(1)] confers general authority upon the EPA Administrator. These provisions of the Clean Air Act confer authority on EPA to promulgate the present regulations.

Alternatives:

This entry comprises the action the Agency plans to take to implement the BART provisions of the Clean Air Act. This proposal addresses the elements we would expect an alternative trading program to contain in order to be approvable as an alternative to case-by-case BART.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis (RIA) for the proposed BART rule. Updated cost and benefit calculations were made for the final rulemaking.

Risks:

The risks addressed are the health and welfare impacts resulting from emissions that interfere with measures to protect visibility in Class I areas. These effects were outlined in detail in the Regulatory Impact Analysis for the proposed BART rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	08/01/05	70 FR 44154
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

San No. 4450-1. Split from RIN 2060-AJ31.

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RIN: 2060–AN22

EPA

122. ● IMPLEMENTATION RULE FOR 8–HOUR OZONE NAAQS – PHASE 2

Priority:

Other Significant

Legal Authority:

42 USC 7410; 42 USC 7501–7511f; 42 USC 7601(a)(1)

CFR Citation:

40 CFR 51; 40 CFR 50; 40 CFR 81

Legal Deadline:

None

Abstract:

This rule would provide specific requirements for State and local air pollution control agencies and tribes to prepare State implementation plans (SIPs) and Tribal Implementation Plans (TIPs) under the 8-hour national ambient air quality standard (NAAQS) for ozone, published by EPA on July 18, 1997. The Clean Air Act (CAA)

requires EPA to set ambient air quality standards and requires States to submit SIPs to implement those standards. The 1997 standards were challenged in court, but in February 2001, the Supreme Court determined that EPA has authority to implement a revised ozone standard, but ruled that EPA must reconsider its implementation plan for moving from the 1-hour standard to the revised standard. The Supreme Court identified conflicts between different parts of the CAA related to implementation of a revised NAAQS, provided some direction to EPA for resolving the conflicts, and left it to EPA to develop a reasonable approach for implementation. Thus, this rulemaking must address the requirements of the CAA and the Supreme Court's ruling. This rule would provide detailed provisions to address the CAA requirements for SIPs and TIPs and would thus affect States and Tribes. States with areas that are not attaining the 8-hour ozone NAAQS will have to develop — as part of their SIPs — emission limits and other requirements to attain the NAAQS within the timeframes set forth in the CAA. Tribal lands that are not attaining the 8-hour ozone standard may be affected, and could voluntarily submit a TIP, but would not be required to submit a TIP. In cases where a TIP is not submitted, EPA would have the responsibility for planning in those areas.

Statement of Need:

EPA is developing this rule so that States may know which statutory requirements apply for purposes of developing State Implementation Plans (SIPs) under the Clean Air Act to implement the 8-hour ozone standard. After EPA had promulgated the 8-hour standard in 1997, EPA originally set forth an approach for implementation that was challenged in court. The Supreme Court ultimately ruled against EPA. This action addresses the U.S. Supreme Court's ruling in February 2001 (Whitman v. American Trucking Assoc., 121 S.Ct.903) that stated that EPA has the authority to implement a revised ozone NAAQS but that EPA could not ignore the provisions of subpart 2 when implementing the 8-hour NAAQS. The Supreme Court identified several portions of subpart 2 that are ill-fitted to the revised NAAQS but left it to EPA to develop a reasonable implementation approach. Consequently, EPA is developing a rule to implement the 8-hour ozone NAAQS under the provisions of subpart 2 of the CAA.

Summary of Legal Basis:

Title I of the Clean Air Act

Alternatives:

EPA proposed more prescriptive and less prescriptive options for several requirements of SIPs, such as the reasonably available control technology (RACT) requirement and the reasonable further progress (RFP) requirement. The final rulemaking will provide a decision on the options for these requirements.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis for the final ozone NAAQS, and has prepared a cost analysis for the proposed implementation rule. The benefits of the rule are those associated with attainment of the ozone NAAQS including significant improvements in premature mortality, chronic asthma, chronic and acute bronchitis, upper and lower respiratory symptoms, work days lost, decreased worker productivity, visibility in urban and suburban areas, and increases in yields of commercial forests currently exposed to elevated ozone levels.

Risks:

The risks addressed by this action are the likelihood of experiencing increased health and environmental effects associated with nonattainment of the National Ambient Air Quality Standard for ozone. These effects are briefly described above in the ''costs and benefits'' section, and they were outlined in detail in the Regulatory Impact Analysis for the ozone NAAQS rulemaking. The results are summarized in the Federal Register notice for that rulemaking (62 FR 38856, July 18, 1997).

Timetable:

Action	Date	FR Cite
NPRM Phase 1 & 2	06/20/03	68 FR 32802
Final Action – Phase 2	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State, Tribal

Additional Information:

SAN No. 4625.1; Split from RIN 2060-AJ99.

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RIN: 2060–AN23

EPA

123. TEST RULE; TESTING OF CERTAIN HIGH PRODUCTION VOLUME (HPV) CHEMICALS

Priority:

Other Significant

Legal Authority:

15 USC 2603

CFR Citation:

40 CFR 790 to 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. The number of chemicals included in the first final rule may be reduced based on new information on annual production volumes, worker exposure, and commitments to the voluntary HPV Challenge Program. Subsequent test rules will require similar screening level testing for other

unsponsored HPV Challenge Program chemicals.

Statement of Need:

EPA has found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million pounds per year based on 1990 reporting for EPA's Inventory Update Rule (IUR), only 7 percent have a full set of publicly available internationally recognized basic health and environmental fate/effects screening test data. Of the over 2,800 HPV chemicals based on 1990 data, 43 percent have no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data are available. This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's right-to-know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy. It is EPA's intent to close this knowledge gap. EPA believes that for most of the HPV chemicals, insufficient data are readily available to reasonably determine or predict the effects on health or the environment from the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that a program to collect and, where needed, develop basic screening level toxicity data is necessary and appropriate to provide information in order to assess the potential hazards/risks that may be posed by exposure to HPV chemicals. On April 21, 1998, a national initiative, known as the ''Chemical Right-To-Know'' Initiative, was announced in order to empower citizens with knowledge about the most widespread chemicals in commerce— chemicals that people may be exposed to in the places where they live, work, study, and play. A primary component of EPA's Chemical Right-To-Know (ChemRTK) initiative is the voluntary HPV Challenge Program, which was created in cooperation with industry, environmental groups, and other interested parties, and is designed to assemble basic screening level test data on the potential hazards of HPV chemicals while avoiding unnecessary or duplicative testing. Data needs which remain unmet in the voluntary HPV Challenge Program, may be addressed through the international efforts or rulemaking.

Summary of Legal Basis:

These test rules will be issued under section 4(a)(1)(B) of TSCA. Section 2(b)(1) of TSCA states that it is the policy of the United States that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures [.]'' To implement this policy, TSCA section 4(a) mandates that EPA require by rule that manufacturers and processors of chemical substances and mixtures conduct testing if the Administrator finds that: (1)(A)(i) The manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment, (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture, (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is 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	01/00/06	
NPRM2	12/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 3990;

Sectors Affected:

325 Chemical Manufacturing; 32411 Petroleum Refineries

URL For More Information:

www.epa.gov/opptintr/chemtest/sect4rule.htm

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RIN: 2070–AD16

EPA

124. PESTICIDES; PROCEDURES FOR THE REGISTRATION REVIEW PROGRAM

Priority:

Other Significant

Legal Authority:

7 USC 136a(g); 7 USC 136w

CFR Citation:

40 CFR part 155

Legal Deadline:

None

Abstract:

The Agency will establish procedures to implement section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) which provides for periodic review of pesticide registrations. The goal of these regulations, which are required by FIFRA section 3(g), is to review a pesticide's registration every 15 years. The regulations will address the following procedural aspects of the program: Establishing pesticide cases for registration review; establishing schedules; assembling information to be considered during the review; deciding on the scope and depth of the review; calling in data under FIFRA sec. 3(c)(2)(B) that are needed to conduct the review; reviewing data and conducting risk assessments or benefit analyses, as needed; deciding whether a pesticide continues to meet the standard of registration in FIFRA; and public participation in the registration review process. If a pesticide does not meet the FIFRA standard, and cancellation is determined to be needed, the Agency will follow cancellation procedures in section 6 of FIFRA. This program will begin after the completion of tolerance reassessment in 2006 and before the completion of reregistration in 2008. Each pesticide will be reviewed every 15 years to assure that the it continues to meet the FIFRA standard for registration, including compliance with any new legislation, regulations or science policy.

Statement of Need:

The registration review procedural regulations are needed to implement the registration review program. This program will replace the reregistration and tolerance reassessment programs as the Agency's program for managing old chemicals. The tolerance reassessment program will end in August 2006 (statutory deadline) and the Agency expects to complete the last reregistration eligibility decision in September 2008. The registration review program will provide for systematic and routine review of pesticides to assure, among other things, that the science supporting the decision to register the pesticide continues to meet current standards.

Summary of Legal Basis:

FIFRA 3(g) requires this procedural regulation.

Alternatives:

There are no non-regulatory options that would satisfy the requirements of FIFRA 3(g).

Anticipated Cost and Benefits:

The cost of the rule to industry is estimated to be $50 million annually. Annual per company cost is an average of less than $750K.

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	04/26/00	65 FR 24586
NPRM	07/13/05	70 FR 40251
Notice of Availability	08/17/05	70 FR 48356
Final Action	09/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 4170, EDocket No. OPP-2004-0404;

Sectors Affected:

32519 Other Basic Organic Chemical Manufacturing; 32551 Paint and Coating Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32561 Soap and Cleaning Compound Manufacturing

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RIN: 2070–AD29

EPA

125. PESTICIDES; EMERGENCY EXEMPTION PROCESS REVISIONS

Priority:

Other Significant

Legal Authority:

7 USC 136p; 7 USC 136w

CFR Citation:

40 CFR 166

Legal Deadline:

None

Abstract:

EPA regulations under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) allow a Federal or State agency to apply for an emergency exemption to allow an unregistered use of a pesticide for a limited time when such use is necessary to alleviate an emergency condition. This action will revise the regulations to improve the pesticide emergency exemption process. Two of these potential improvements are currently being tested through a limited pilot, and are based on recommendations from the States

which are the primary applicants for emergency exemptions. The proposed revisions would streamline the application and review process, thereby reducing the burden to applicants and EPA, while allowing for quicker emergency response without compromising existing protections for human health and the environment.

Statement of Need:

In 1996, stakeholders, including States and Federal agencies, identified a number of issues related to improving the emergency exemption process. States and Federal agencies are the only applicants for emergency exemptions. Representatives of States have recommended modifications to the current process for application, review and approval of emergency exemptions. If adopted, the changes would reduce unnecessary burden to both applicants and EPA, and expedite decisions on applications (which is critical in emergency situations).

Summary of Legal Basis:

FIFRA sec. 18 authorizes EPA to temporarily exempt States from the requirements of registration to alleviate an emergency condition.

Alternatives:

EPA has analyzed several measures for streamlining or improving the emergency exemption process, and has received considerable comment, both formally and informally, from stakeholders, including specific recommendations from a group representing States' interests. Since the modifications would generally constitute regulatory relief, and are not expected to cause any adverse economic impact, options with varying cost do not apply.

Anticipated Cost and Benefits:

EPA has assessed the potential economic impacts of the proposed improvements and found that they would reduce burdens and costs to States and Federal agencies that apply for emergency exemptions, as well as reduce burden to EPA. The Agency estimates an annual cost reduction of $820,000 for applicants and $120,000 for EPA, for a total of $940,000. Indirect benefits may accrue to users of pesticides under emergency exemptions if changes result in faster review and approval, or greater availability of pesticides.

Risks:

In general, the measures being considered are primarily intended to reduce burdens for States and EPA and achieve efficiencies in the program. No impact on risk is anticipated.

Timetable:

Action	Date	FR Cite
Notice: Limited Pilot	04/24/03	68 FR 20145
NPRM	09/03/04	69 FR 53866
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4216, EDocket No. OPP-2004-0038;

Sectors Affected:

9241 Administration of Environmental Quality Programs

URL For More Information:

http://www.epa.gov/opprd001/section18/

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RIN: 2070–AD36

EPA

126. PROTECTIONS FOR TEST SUBJECTS IN HUMAN RESEARCH

Priority:

Other Significant

Legal Authority:

5 USC 301; 7 USC 136w(a)(1); 21 USC 346a(e)(1)(C); 42 USC 300v–1(b)

CFR Citation:

40 CFR 26

Legal Deadline:

Final, Statutory, January 29, 2006, HR 2361, Department of Interior, Environment, and Related Agencies Appropriations Act of 2006, 08/02/05.

Abstract:

In early September 2005, EPA proposed a rulemaking to ban intentional dosing human testing for pesticides when the subjects are pregnant women or children, to formalize and further strengthen existing protections for subjects in human research conducted or supported by EPA, and to extend new protections to adult subjects in intentional dosing human studies for pesticides conducted by others who intend to submit the research to EPA. This proposal, the first of several possible Agency actions, focuses on third-party intentional dosing human studies for pesticides, but invites public comment on alternative approaches with broader scope. This proposed rule would significantly strengthen the ethical framework for conducting and reviewing human studies, especially intentional dosing human studies for pesticides. With respect to human research conducted by EPA (''first-party research''), or by others with EPA's support (''second-party research''), this proposed rule would (1) categorically prohibit any intentional dosing studies involving pregnant women or children as subjects; and (2) adopt the Department of Health and Human Services (HHS) regulations that provide additional protections to pregnant women and children as subjects of other than intentional dosing studies. With respect to human research conducted by third-parties—i.e., by others without any support from EPA or other Federal Government agencies—the proposed rule would: (1) Categorically prohibit any third-party intentional dosing studies for pesticides involving pregnant women or children as subjects; (2) extend the provisions of the Federal Policy for the Protection of Human Subjects of Research (the ''Common Rule'') to all other third-party intentional dosing human studies intended for submission to EPA under the pesticide laws; (3) require, before testing is initiated, submission to EPA of protocols and related information for proposed research covered by this extension of the Common Rule; and (4) require information about the ethical conduct of covered human studies when the results of the research are submitted to EPA. In addition, the proposed rule would (1) establish an independent Human Studies Review Board to review proposals for covered

intentional dosing human research and reports of completed research; (2) specify measures EPA would consider to address non-compliance with the provisions of a final rule along the lines of this proposal; (3) define the ethical standards EPA would apply in deciding whether to rely on relevant, scientifically sound data derived from intentional dosing human studies for pesticides, and (4) forbid EPA to rely in its decision-making under the pesticide laws on human research involving intentional exposure of pregnant women or children. The pace of rule development has accelerated in response to the FY 2006 Appropriations Act, signed by the President on August 2, 2005, which requires the Agency to promulgate a final rule within 180 days of enactment, or by January 29, 2006.

Statement of Need:

In July 1998, the Agency stated that it had not used any human study data for final decisions under the FQPA. The Agency subsequently convened a special joint subcommittee of the FIFRA Scientific Advisory Panel and the EPA Science Advisory Board to advise on this policy. The subcommittee completed its report in September 2000 without reaching consensus on many issues. In December 2001 the Agency sought the advice of the National Academy of Sciences on remaining scientific and ethical issues. At the same time, the Agency issued an interim policy, committing, subject to certain exceptions, not to consider or rely on any third party studies involving intentional dosing of human subjects with toxicants for the purpose of defining or quantifying their effects until a final policy is in place, and clarifying that this interim policy applies across all Agency programs. The Agency's interim policy was challenged in a lawsuit filed in early 2002. In May 2003 the Agency published an Advance Notice of Proposed Rulemaking on the subject of the acceptability of human studies, posing an array of questions in response to which many comments and suggestions were received. The ANPR also restated the Agency's intention to issue proposed rules for comment. In June 2003, the U.S. Court of Appeals vacated the December 2001 interim policy on the ground that it constituted an improperly promulgated ''rule.'' The Court further stated that, as a consequence, the Agency's ''previous practice of considering third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide,'' was reinstated ''until it is replaced by a lawfully promulgated regulation.'' In February 2004, the NAS released their report, making many recommendations now under review by the Agency. Some of the Academy's recommendations could only be implemented through rulemaking. On August 2, 2005, the President signed into law Pub. L. 109-54, the Department of Interior, Environment, and Related Agencies Appropriations Act, 2006, which provides appropriated funds for the Environmental Protection Agency and other Federal departments and agencies. Section 201 addresses EPA activities regarding third-party intentional dosing human toxicity studies using pesticides. Specifically, Section 201 provides: ''None of the funds made available by this Act may be used by the Administrator of the Environmental Protection Agency to accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject. The Administrator shall allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule. Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and shall establish an independent Human Subjects Review Board. The final rule shall be issued no later than 180 days after enactment of this Act.''

Summary of Legal Basis:

With respect to pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C 136 et seq.), a licensing statute, requires applicants for registration to provide a ''full description of tests made and the results thereof'' and further authorizes EPA to call in data to maintain a registration under FIFRA sec. 3(c)(2)(B). FIFRA sec. 25(a) provides general rulemaking authority to implement these data requirements, and also to interpret FIFRA sec. 12(a)(2)(P), which makes it unlawful to conduct tests using human subjects unless the subjects volunteer for such tests and are fully informed. Section 408(e) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a) authorizes the Administrator to issue regulations establishing general procedures and requirements. EPA has broad authority under 5 U.S.C. 301 and 42 U.S.C. 300v-1(b).

Alternatives:

Although several options were considered over the years, it is important to note that the FY 2006 Appropriations Act, signed by the President on August 2, 2005, specifically directs the Agency to promulgate a rule to address third party intentional dosing human toxicity studies for pesticides. In the Economic Analysis that was prepared for the proposed rule, EPA identified a range of options for which potential impacts have been evaluated and presented. The first option involved continuing current practice, but this option is not viable given the recent congressional mandate to promulgate a rule. The second option would extend the requirements of the Common Rule to third-party human research only when it involved intentional exposure studies for the purpose of identifying or quantifying a toxic effect. The third option would extend the requirements of the Common Rule to all third-party intentional exposure human studies intended for submission under FIFRA or FFDCA, and the fourth option would extend the requirements of the Common Rule to all third-party human research intended for submission under the pesticide laws. All of the latter three options include a requirement on third parties to submit protocols for review prior to initiating the types of human research covered by the Common Rule. Finally, options 2 - 4 include a provision prohibiting the Agency and third parties from conducting covered human research with pregnant women or children as subjects.

Anticipated Cost and Benefits:

The Agency has conducted a preliminary analysis of the benefits of a proposed rulemaking in qualitative terms. These benefits included greater protections for test subjects, and a corresponding reduction in their risks, to the extent that affected researchers are not already following the Common Rule. The general public will benefit from the proposed rule because the rule will strengthen the protections for human subjects and reinforce the Agency's strong commitment to base its decisions on scientifically sound information. The benefits to sponsors of third-party human research include a better understanding of the standards

that EPA will apply in determining whether to rely on the results of their studies, and thus, the opportunity to design and perform studies that are more likely to meet EPA standards, leading to more efficient Agency reviews. The preliminary analysis also estimates the potential costs of the proposed rule to third parties and to EPA for implementing the new requirements. In general, EPA believes that most, if not all, third-party research intended for submission to EPA that involves intentional exposure of human subjects already complies with the Common Rule or an equivalent international standard. For purposes of this analysis, EPA assumed that current practice was in full compliance with the Common Rule. In contrast, EPA assumed that other types of third-party human research do not comply with the Common Rule, although it is likely that many responsible for such research are aware of and do follow Common Rule principles relating to informed consent and IRB review. After reviewing the history of EPA's consideration of research involving human subjects in its various program offices, EPA estimates that the proposed rule would affect only a limited number of third-party studies involving human subjects each year. EPA also collected data on the cost per study of compliance with the Common Rule. These costs include preparing documents to support review by an IRB and the expense associated with the IRB review. These costs are very minor relative to the overall cost of conducting the studies. For EPA, the costs are associated with the review of protocols and the review of completed human studies to determine whether they complied with the Common Rule. For all of the options, the potential costs of the proposed rule to third party researchers and EPA are estimated to be very low, both because the number of affected studies is relatively small and because the costs of compliance with the Common Rule are low. Where the option simply reflects the current practice (option 1) the added total incremental costs to third-party sponsors of human research are zero. EPA assumes that currently the pesticide industry is already spending $159,000 to $196,000 annually to comply with the Common Rule for intentional exposure human studies and the Agency is currently spending $113,000 a year to review, on a case-by-case basis, the ethical aspects of such studies. Option 2 would add an estimated total annual incremental cost to third parties of $7,532, and an estimated annual cost to EPA of $220,894. Option 3 would add an estimated total annual incremental cost to third parties of $16,140, and an estimated annual cost to EPA of $327,630. Option 4 would add an estimated total annual incremental cost to third parties of $202,700 to $242,796, and an estimated annual cost to EPA of $601,134. The proposed rule, if finalized as proposed, is estimated to result in a total annual incremental cost to third parties of approximately $16,000, and an estimated annual cost to EPA of approximately $328,000.

Risks:

To the extent that affected researchers are not already following the Common Rule, this rulemaking will provide greater protections for test subjects, and thereby provide a corresponding reduction in potential risks to these individuals.

Timetable:

Action	Date	FR Cite
ANPRM	05/07/03	68 FR 24410
Notice	02/08/05	70 FR 6661
NPRM	09/12/05	70 FR 53838
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Federal

Additional Information:

SAN No. 4610, EDocket No. OPP-2003-0132;

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

URL For More Information:

www.epa.gov/oppfead1/guidance/human-test.htm

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RIN: 2070–AD57

EPA

127. RCRA BURDEN REDUCTION INITIATIVE

Priority:

Other Significant

Legal Authority:

42 USC 6907; 42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925; 42 USC 6926; 42 USC 6927; 42 USC 6930; 42 USC 6934; 42 USC 6935; 42 USC 6937; 42 USC 6938; 42 USC 6939; 42 USC 6944; 42 USC 6949(a); 42 USC 6974; PL 104–13

CFR Citation:

40 CFR 261.38; 40 CFR 264.16; 40 CFR 264.52; 40 CFR 264.56; 40 CFR 264.73; 40 CFR 264.98 et seq; 40 CFR 265.16; 40 CFR 265.52; 40 CFR 265.56; 40 CFR 265.73; 40 CFR 265.98 et seq; 40 CFR 266.103; 40 CFR 261.4; 40 CFR 268.7; 40 CFR 268.9

Legal Deadline:

None

Abstract:

EPA plans to reduce the burden imposed by the RCRA reporting and recordkeeping requirements to help meet the Federal Government-wide goal established by the Paperwork Reduction Act (PRA). In June 1999, EPA published a Notice of Data Availability (NODA) in the Federal Register (64 FR 32859) to seek comment on a number of burden reduction ideas to eliminate duplicative and nonessential paperwork. After reviewing the comments received on the NODA, EPA proposed (67 FR 2518,

1/17/02) to implement many of these ideas. EPA issued a notice (68 FR 61662; 10/29/03) seeking further input on a number of changes we proposed. EPA plans to finalize this burden reduction effort.

Statement of Need:

The Paperwork Reduction Act of 1995 establishes a Federal Government-wide goal to reduce the paperwork and reporting burden it imposes. The RCRA Burden Reduction Initiative Proposed Rulemaking makes the regulatory changes necessary to meet this goal.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

Reducing recordkeeping and reporting will require changes in our regulations. There was no alternative to doing a rulemaking. The Agency sought opinions from the regulated community on various burden reduction possibilities.

Anticipated Cost and Benefits:

Our preliminary cost benefit analyses for the final rule shows a savings of between 38,800 and 54,000 burden hours. The total annual cost savings under the final rule ranges from approximately $3.1 million to $4 million. The rule will have minimal impact on the protectiveness of the RCRA regulations. It will eliminate or streamline paperwork requirements that are unnecessary.

Risks:

The rule will have no risk impacts.

Timetable:

Action	Date	FR Cite
NODA 1	06/18/99	64 FR 32859
NPRM	01/17/02	67 FR 2518
NODA 2	10/29/03	68 FR 61662
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4084; Applicable SIC codes: Chemicals and Allied Products (28), Primary Metal Industries (33), Fabricated Metals (34), Industrial Machinery and Equipment (35), Electrical Equipment (36), Transportation Equipment (37), Other Manufacturing, Transportation and Utilities (40-49), Wholesale Trade (50-51), Services (70-89) and Other SIC Groups

Sectors Affected:

325 Chemical Manufacturing; 334 Computer and Electronic Product Manufacturing; 332 Fabricated Metal Product Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 562 Waste Management and Remediation Services

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RIN: 2050–AE50

EPA

128. REVISIONS TO THE DEFINITION OF SOLID WASTE

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6903 ''RCRA Section 1004''

CFR Citation:

40 CFR 261.2

Legal Deadline:

None

Abstract:

Under RCRA, to be a hazardous waste, a material must also be a solid waste. EPA's framework for determining whether a material is a solid waste is based on what the material is, and how it's managed (e.g., how it is used, reused, etc.). For materials being recycled, RCRA jurisdiction is complex and the history of legal decisions related to the definition of solid waste is extensive. Primarily, in response to American Mining Congress v. EPA, 824 F. 2d 1177(D.C. Cir. 1987) (''AMC I'') and one of the most recent decisions, the Association of Battery Recyclers v. EPA 208 F.3d 1047 (2000) (''ABR''), EPA has proposed to revise the definition of solid waste. We specifically address materials undergoing reclamation. In the context of reclamation, we discuss options for how to identify materials that remain in use in a continuous process in the generating industry and thus are not solid wastes. In addition, we proposed criteria for determining whether or not hazardous secondary materials are recycled legitimately.

Statement of Need:

EPA is revising the definition of solid waste to increase recycling and as a response to several court decisions.

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 currently 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 final 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
Final Action	11/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4670; Listed in the 2005 OMB report, Regulatory Reform of the U.S. Manufacturing Sector. EPA and OMB

have determined that this reform has potential merit and justifies further action.

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RIN: 2050–AE98

EPA

129. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUND WATER RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300 g–1 ''SDWA 1412 (b)(8)''; 42 USC 300j–4 ''SDWA 1445''

CFR Citation:

40 CFR 141; 40 CFR 142

Legal Deadline:

Other, Statutory, Not later than promulgation of the Stage 2 Disinfection Byproducts Rule (currently scheduled for December 2005).

Abstract:

EPA proposed a targeted risk-based regulatory strategy for all public water systems served by ground water in May of 2000. The proposed requirements provide a meaningful opportunity to reduce public health risk for a significant number of people served by ground water sources from the exposure to waterborne pathogens from fecal contamination. The proposed strategy addresses risks through a multiple-barrier approach that relies on five major components: periodic sanitary surveys of ground water systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a requirement for correction of significant deficiencies and fecal contamination through the following actions: Eliminate the source of contamination; correct the significant deficiency; provide an alternative source water, or provide a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses; and compliance monitoring to insure disinfection treatment is reliably operated where it is used. The final rule will establish a risk-based strategy as was described in the proposed (May 2000) rulemaking. However, the proposed design has been improved in the draft final rule to provide greater flexibility for States and systems implementing the rule.

Statement of Need:

Public water systems (PWSs) that use ground water as their sole source of water, as opposed to surface water PWSs, are not federally regulated as to treatment for microorganisms. There is data that indicates that a number of ground water PWSs are contaminated with microorganisms of fecal origin that can and have caused illness.

Summary of Legal Basis:

Section 1412(b)(8) of the Safe Drinking Water Act requires that EPA develop regulations specifying the use of disinfectants for ground water systems as necessary and ''. . .(as part of the regulations) promulgate criteria. . .to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water.''

Alternatives:

EPA considered four regulatory alternatives in the development of the GWR proposal: The proposed regulatory alternative (multi-barrier option), the sanitary survey option, the sanitary survey and triggered monitoring option, and the across-the-board disinfection option. All options include the sanitary survey provision. The sanitary survey option would require the primary agency to perform surveys every 3 to 5 years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring options adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multi-barrier option, which was proposed by EPA, adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive, results in a routine source water fecal indicator monitoring requirement. The multi-barrier option and the sanitary survey and triggered monitoring options are targeted regulatory approaches designed to identify wells that are fecally contaminated or are at a high risk for contamination. These across-the-board disinfection options would require all systems to install treatment instead of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

Anticipated Cost and Benefits:

EPA estimates the cost of the proposed GWR will be $183 million dollars per year (using a 3% discount rate). More than half of the estimated costs are for corrective actions which systems will be required to take to fix or prevent fecal contamination. The remainder of the costs are due to increased scope and frequency of sanitary surveys, hydrogeologic sensitivity assessments and source water monitoring. System costs are expected to be $162 million per year for implementation of the GWR. States are expected to incur costs of $21 million per year. Cost estimates do not include land acquisition, public notification or the potential cost of illness due to exposure to disinfection by-products. The total estimated value of these benefits is $205 million per year, $139 million from avoided illness and $66 million from avoided deaths. These benefits are monetized based on a cost of illness and a value of statistical life. These estimates do not include pain and suffering associated with viral and bacterial illness avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality.

Risks:

EPA estimates that currently over 200,000 illnesses and 18 deaths occur each year due to viral and bacterial contamination of public ground water systems. Children, the elderly and the immunocompromised are particularly sensitive to the waterborne pathogens and account for between 20 and 30 percent of the illnesses and deaths. As

proposed, the GWR is expected to reduce the total number of illness by 115,000 and the total number of deaths by 11 each year. The GWR in conjunction with the Surface Water Treatment Rule (SWTR), the Total Coliform Rule (TCR), the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Filter Backwash Rule (FBR) and the Long Term Enhanced Surface Water Treatment Rules (LT1ESWTR & LT2ESWTR) will provide protections to the consumers of public water supply systems from waterborne pathogens.

Timetable:

Action	Date	FR Cite
NPRM	05/10/00	65 FR 30194
Final Action	04/00/06	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN No. 2340; Statutory deadline for final rule: Not later than the Administrator promulgates a Stage II rulemaking for disinfection byproducts (currently scheduled for July 2005).

Sectors Affected:

22131 Water Supply and Irrigation Systems

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EPA

130. NATIONAL PRIMARY DRINKING WATER REGULATIONS: LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300f; 42 USC 300g–1; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

None

Abstract:

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will control risk from microbial pathogens, specifically cryptosporidium, in drinking water. It is being developed simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR), which will address risk caused by the use of disinfectants in drinking water. This rule could affect all public water systems that use surface water as a source. Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the LT2ESWTR, EPA has analyzed a significant body of new survey data on microbial pathogens in source and finished waters, as well as data on parameters which could serve as indicators of microbial risk. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, has provided a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was previously available. EPA has also used significant new data on the efficiency of treatment processes for the removal and inactivation of microorganisms, as well as new information on the pathogenicity of certain microbes, to determine effective regulatory requirements for controlling microbial risk. On March 30, 1999, EPA established a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an agreement in principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is to reduce health risks posed by Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoa which causes cryptosporidiosis, a severe gastrointestinal disease. While cryptosporidiosis is generally self limiting in healthy individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of Cryptosporidium in drinking water sources through the Information Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems has an unacceptably high risk for Cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for Cryptosporidium through monitoring and prescribe an appropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

Summary of Legal Basis:

Section 1412(b)(7)(A) of SDWA authorizes the Administrator to promulgate a national primary drinking water regulation that requires the use of a treatment technique in establishing a maximum contaminant level if the Administrator makes a finding that it is not feasible to ascertain the level of the contaminant. The MCLG for Cryptosporidium is zero and it is not feasible for public water systems to measure Cryptosporidium concentrations in treated water. Consequently, under Section 1412(b)(1)(A), the Administrator may establish a treatment technique for Cryptosporidium if this presents a meaningful opportunity for health risk

reduction. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule ''concurrently with'' the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

Alternatives:

EPA is considering various rule scenarios to reduce risk from Cryptosporidium. These scenarios include treatment requirements that would apply to all systems, such as requiring all conventional plants to achieve 2-log inactivation of Cryptosporidium. Alternative scenarios have involved assigning systems to bins based on mean Crypto source water concentrations. Additional treatment requirements would then depend on the bin to which a system was assigned. Issues associated with the binning approach include: amount of monitoring necessary to assign systems to bins, appropriate Crypto concentrations to demarcate bin boundaries, and appropriate level of additional treatment for a given bin. EPA is exploring analyses that evaluate the impact of these issues on costs and benefits. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the LT2ESWTR, as proposed, will have an annual cost of $73 to $111 million per year. The majority of people (approximately 67%) are served by public water systems that use a surface water or ground water under the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. EPA estimates that the proposed LT2ESWTR would prevent up to 1,020,000 cases of cryptosporidiosis annually with an economic benefit of up to $1.4 billion. In addition, EPA has recently identified UV light as a technology that can achieve high levels of Cryptosporidium inactivation at relatively low cost.

Risks:

Approximately 67 percent of consumers are served by drinking water systems that use surface water sources or ground water under the direct influence of surface water. Survey data indicate that Cryptosporidium is prevalent in drinking water sources and current levels of treatment may not be adequate to control highly resistant pathogens like Cryptosporidium. Cryptosporidiosis is a potentially fatal disease in people with weak immune systems, such as infants, the elderly, people with AIDS, and people taking immune suppressing drugs like cancer and transplant patients. By requiring additional treatment for those systems with the highest concentrations of Cryptosporidium in their source waters, EPA expects to significantly reduce current risk.

Timetable:

Action	Date	FR Cite
NPRM	08/11/03	68 FR 47639
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

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

Additional Information:

SAN No. 4341;

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD37

EPA

131. NATIONAL PRIMARY DRINKING WATER REGULATIONS: STAGE 2 DISINFECTION BYPRODUCTS RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300f; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141–142; 40 CFR 9

Legal Deadline:

Final, Statutory, July 14, 2003.

Abstract:

This Regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that will be promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process, although the impacts may be limited to community water systems (CWSs) and non-transient non-community water systems (NTNCWSs). Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the Stage 2 DBPR, EPA analyzed a significant body of new survey data on source water quality parameters, treatment data and disinfection byproduct occurrence. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was previously available. EPA also used new information on the health effects of exposure to DBPs to determine effective regulatory requirements for controlling risk. On March 30, 1999, EPA reconvened a committee of stakeholders under the Federal Advisory Committee Act

(FACA) to assist in the development of these rules; an Agreement in Principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Stage 2 Disinfectants/Disinfection Byproducts Rule (DBPR) is to reduce potential health risks posed by disinfection byproducts (DBPs). Certain DBPs have been shown in laboratory tests to be carcinogens or to cause adverse reproductive and developmental health effects. In addition, epidemiology studies have indicated that exposure to chlorinated water may increase the risk of bladder cancer, miscarriage, and certain developmental defects. The Stage 2 DBPR is designed to reduce peak events in DBP exposure in order to mitigate these potential health risks.

Summary of Legal Basis:

Section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than July 14, 2003. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule concurrently with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

Alternatives:

EPA is considering various rule scenarios to achieve reductions in disinfection byproduct exposure. These alternatives include: decreasing the standard set in the Stage 1 DBPR (0.080 mg/L total trihalomethanes (TTHM) and 0.060 mg/L the sum of 5 haloacetic acids (HAA5)) by half and maintaining a running annual average compliance calculation; maintaining 80/60 TTHM/HAA5 standards but revising the compliance calculation to a stricter locational running annual average; setting the 80/60 TTHM/HAA5 standard as a never to be exceeded maximum; and revising the standard for bromate which is currently 0.010 mg/L. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the Stage 2 DBPR will have an annual economic impact of $59-65 million. Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants and potentially exposed to DBPs. Thus, a large number of people will benefit from the Stage 2 DBPR.

Risks:

Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Due to the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health. EPA estimates that the Stage 2 DBPR will decrease exposure to DBPs on average but, more importantly, the rule will significantly reduce exposure to peak occurrences of DBPs.

Timetable:

Action	Date	FR Cite
NPRM	08/18/03	68 FR 49548
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

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

Additional Information:

SAN No. 4342;

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD38

BILLING CODE 6560–50–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

Statement of Regulatory and Deregulatory Priorities

The mission of the Equal Employment Opportunity Commission (EEOC, Commission or Agency) is to ensure equality of opportunity in employment by vigorously enforcing six Federal statutes. These statutes are: Title VII of the Civil Rights Act of 1964, as amended (prohibits employment discrimination on the basis of race, color, sex, religion, or national origin); the Equal Pay Act of 1963, as amended; the Age Discrimination in Employment Act of 1967 (ADEA), as amended; title I of the Americans with Disabilities Act of 1990, as amended, and sections 501 and 505 of the Rehabilitation Act of 1973, as amended (disability); and the Government Employee Rights Act of 1991, which extends protections against employment discrimination to certain employees who were not previously covered.

The item in this Regulatory Plan involves amending regulations governing age discrimination in employment to exempt from the prohibitions of the Age Discrimination in Employment Act (ADEA) the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits. This rule 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.

EEOC

FINAL RULE STAGE

132. 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	01/00/06	

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.

Agency Contact:

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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 Governmentwide policy for construction and operation of buildings, procurement and distribution of supplies, travel and transportation, acquisition, electronic commerce, management of advisory committees, and utilization and disposal of real and personal property.

GSA's fiscal year 2006 regulatory priority is to complete conversion of the Federal Property Management Regulations to the Federal Management Regulation (FMR).

GSA is writing the FMR so that its contents are consistent and sensible, and limit the regulatory burden placed on Government officials and the public. GSA has adopted a question and answer, plain language format for its regulations to make them easier to read and understand. Non-regulatory guidance is being moved into other, less formal publications such as customer service guides.

As necessary, GSA will prepare its regulations so that they address national health and security concerns.

BILLING CODE 6820–27–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 U.S.C. 2451 et seq., which laid the foundation for NASA's mission. The Act authorizes NASA, among other things, to conduct space activities devoted to peaceful purposes for the benefit of humankind; to preserve the leadership of the United States in aeronautics and space science and technology; and to expand knowledge of the Earth and space. To carry out this mission, NASA is authorized to conduct research for the solution of problems of flight within and outside the Earth's atmosphere; to develop, construct, test, and operate aeronautical and space vehicles for research purposes; to operate space transportation systems, including the Space Shuttle and the International Space Station; and to perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with human-tended, robotic, and expendable vehicles and arranges for the most effective utilization of the scientific and engineering resources of the United States with other nations engaged in aeronautical and space activities for peaceful purposes.

NASA was created to pursue activities in space devoted to peaceful purposes and the benefit of all humankind. Our mission isto explore, discover, and understand the Earth's origins and the phenomena in the atmosphere and space that affect life. We are pursuing a *Vision for Space Exploration*that will advance U.S. scientific, security, and economic interests through a robust robotic and human space exploration program that will take us throughout the solar system and beyond. We will redefine what is''possible,'' and develop innovative technologies to protect our planet and improve human life. We will promote international and commercial partnerships to further science, security, and safety. And, we will lead the world into a new understanding of our planet, our solar system, and the universe around us.

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 FAR changes that are promulgated. 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 2006. 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 2006.

The second priority is to revise our records declassification regulation in 36 CFR part 1260 to reflect changes in the Executive Order governing declassification of national security classified information (E.O. 12958, as amended, Classified National Security Information). Our regulations in part 1260 establish procedures for the automatic declassification of records in NARA's legal custody and revise requirements for reclassification of information as provided for in the Executive Order. NARA serves the public and Federal agencies by specifying the declassification process we use.

Our third priority regulatory action is reviewing and updating our NHPRC grants program regulations in 36 CFR part 1206. The NHPRC grants program participates in the Grants.gov eGovernment Initiative, and our review will ensure that the regulations reflect that participation. The NHPRC makes grants to preserve and to deliver historical records for use by the American people. The Commission each year receives over 150 applications requesting over $15 million of which less than $10 million is available to award.

NARA does not have any planned regulatory actions that relate to the events of September 11, 2001.

Regulations of Particular Concern to Small Businesses

NARA completed a revised regulation specifying facility standards for records storage facilities that house Federal records(RIN 3095-AB31) in fiscal year 2005.

NARA

PROPOSED RULE STAGE

133. FEDERAL RECORDS MANAGEMENT

Priority:

Other Significant

Legal Authority:

44 USC 2104(a); 44 USC ch 21; 44 USC ch 29; 44 USC ch 33

CFR Citation:

36 CFR 1220 to 1238

Legal Deadline:

None

Abstract:

As part of its initiative to redesign Federal records management, NARA is revising its records management regulations in 36 CFR ch. XII, subchapter B to ensure that the regulations are appropriate, effective, and clear. During fiscal year 2006, we will publish several rules relating to the redesign.

Statement of Need:

NARA's records management program was developed in the 20th century in a paper environment. This program has not kept up with a Federal Government that creates and uses most of its records electronically. Today's Federal records environment requires different management strategies and techniques. The revision of NARA's records disposition policies, processes, and tools is identified in our Strategic Plan as a key strategy to meet the primary goal that ''essential evidence will be created, identified, appropriately scheduled, and managed for as long as needed.'' Without effective records management, records needed to document citizens' rights, actions for which Federal officials are responsible, and the historical experience of our Nation will be at risk of loss, deterioration, or destruction.

Summary of Legal Basis:

Under the Federal Records Act, the Archivist of the United States is responsible for: 1) Providing guidance and assistance to Federal agencies to ensure adequate and proper documentation of the policies and transactions of the Federal Government and ensuring proper records disposition (44 U.S.C. 2904); 2) approving the disposition of Federal records (44 U.S.C. ch. 33); and 3) preserving and making available the Federal records of continuing value that have been transferred to the National Archives of the United States (44 U.S.C. ch. 21).

The Federal Records Act also makes the heads of Federal agencies responsible for making and preserving records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and is designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities (44 U.S.C. 3101). Agency heads must also have an active, continuing records management program (44 U.S.C. 3102).

Alternatives:

None.

Anticipated Cost and Benefits:

The revision of NARA's records disposition policies and processes, of which this regulation review is a part, is intended to reduce the burden on agencies and NARA in the area of records disposition activities.

Risks:

None.

Timetable:

Action	Date	FR Cite
Begin Review	09/17/02	
ANPRM	03/15/04	69 FR 12100
ANPRM Comment Period End	05/14/04	
NPRM	11/00/05	

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 (OPM) is the human resources and personnel manager for the President and the Federal Government. The primary focus of OPM's regulatory efforts in the coming year will continue to be the modernization and improvement of human resources management to support the President's goal of creating a Government that is citizen-centered, results-oriented and market-based. To this end, OPM's primary regulatory objective is to implement improvements to human resources management that will enable the Federal Government to recruit, manage, develop, and retain the high-quality, diverse workforce that departments and agencies require to carry out their respective missions.

The *President's Management Agenda* recognizes the critical role that human resources management must play in reforming Government by identifying the Strategic Management of Human Capital as the first of its five core Governmentwide initiatives. OPM is the managing partner on this Presidential initiative and has aggressively implemented a program to assist other agencies in achieving success in this area through aligning human resources management practices with agency missions and objectives. OPM will continue implementing this initiative by way of collaboration, coordination, and regulation as necessary and appropriate during the coming year.

National Security Personnel System

The 2004 National Defense Authorization Act (NDAA) authorizes the creation of a National Security Personnel System (NSPS) at the Department of Defense (DoD). OPM has collaborated extensively with DoD to identify the regulatory requirements needed to establish a flexible and contemporary human resources management system as called for in the statute. The NSPS must be fair and credible, adhere to merit principles, honor veterans' preference, protect against prohibited personnel practices, and include a performance management system that incorporates pay for performance. In addition, the Act permits the establishment of a new labor relations system and a new employee appeals process, and grants flexibilities in recruitment and assignment actions and in the adjustment of overall agency staff. The NSPS is vital to DoD's national security mission and will remain a regulatory priority for OPM in the year ahead.

Working for America Act (WFAA)

OPM and OMB have drafted legislation that they anticipate will be introduced in Congress sometime in the fall of 2005. This legislation will modernize certain elements of existing civil service law covering Federal employees in departments and agencies not covered by statutes already enacted for the Departments of Defense and Homeland Security. If enacted, over the course of the next year OPM would begin to develop regulations to define in greater detail the parameters of these new statutory authorities(i.e., for the governmentwide classification, pay, and performance appraisal systems, as well as for any other new human resources authorities enacted into law) and to provide a plan for fairly and effectively implementing new human resources management authorities through a system of robust coordination, certification, oversight, and evaluation.

Compensation Reform

Because compensation reform is a necessary element of improving the management of human capital —a central goal of the *President's Management Agenda* —OPM anticipates making promulgation of compensation reform regulations a priority in 2006, including the final regulations on recruitment, relocation, and retention incentives; compensatory time for travel; annual leave accrual for SES members; and annual leave creditable service enhancements.

e-Government

OPM has been designated as the managing partner on 5 of the 24 e-Government initiatives in the *President's Management Agenda*. Specifically, OPM is the managing partner for Recruitment One Stop, e-Clearance, e-Training, e-Payroll, and e-Enterprise HR Integration (e-EHRI). These initiatives will require promulgation of new or modified regulations. In addition, OPM has been designated the managing partner of the Human Resources Line of Business (HR LOB). The objective of HR LOB is to create a framework for a Governmentwide, modern, cost effective, standardized, and interoperable Human Resources solution that provides common core functionality and maximizes automation of processes to support the strategic management of human capital. The current suite of e-Government initiatives managed by OPM will be transitioned and integrated into the HR LOB. This initiative will also require promulgation of new or modified regulations in 2005-2006.

No FEAR Regulations

In July 2003, the President delegated responsibility for promulgating regulations pursuant to title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 to OPM. The provisions of title II relate to reimbursement of the Treasury Department's judgment fund, notice and training for applicants and employees, and reporting requirements by agencies. Regulations concerning reimbursement of the judgment fund were promulgated on an interim final basis on January 22, 2004. Regulations concerning notice and training for applicants and employees were promulgated as proposed regulations on February 28, 2005. At the request of Congress and stakeholder groups, the comment period for the regulations was extended from April 2005 to June 2005. After working with the EEOC, the Office of Special Counsel, the Department of Justice and the Department of Treasury, OPM expects to promulgate the remaining provisions of title II of the Act, the regulations for the annual report and comprehensive study before the end of this calendar year.

Human Resources (HR) Flexibilities

In FY 2005 OPM continued to modernize the civil service and hiring process. OPM issued the following proposed and interim regulations in support of this endeavor which we anticipate will be finalized in FY 2006. The Direct Hire for Acquisition Positions regulation will allow non-DoD agencies to recruit and directly hire individuals into certain Federal acquisition positions.The Employment of Persons with Disabilities regulation supports the President's New Freedom Initiative and will provide agencies the authority to determine whether these individuals can receive an excepted appointment. The Student Career Experience Program regulations enhance the value of work experience and academic performance as credits towards a permanent appointment. The Veterans Recruitment Appointment regulations broaden eligibility criteria for obtaining a noncompetitive appointment. The salary offset (dual compensation) waivers regulation amends the criteria under which OPM may grant dual compensation (salary off-set) waivers on a case-by-case basis, or delegate waiver authority to agencies in emergency situations posing a direct

threat to life or property or in unusual non-emergency situations.

Human Capital Management

The Chief Human Capital Officers Act established a new chapter 14, Agency Chief Human Capital Officers, within title 5, U.S. Code, as well as a requirement for OPM to establish by regulation systems for assessing the management of human capital in Federal agencies. Provisions of the NDAA established a related requirement for agencies to conduct annual employee surveys under regulations issued by OPM. In the coming year, OPM will be addressing these and related general human capital management requirements through implementing regulations.

Combined Federal Campaign (CFC)

OPM is in the process of issuing a proposed regulation for the Combined Federal Campaign (CFC) which will require all CFC applicant charities to certify that they are in compliance with all statutes, executive orders, and regulations restricting or prohibiting U.S. persons and entities from engaging in transactions and dealings with countries, entities, or individuals subject to economic sanctions administered by the U.S. In addition, OPM is exploring other possible regulatory changes concerning participation criteria.

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 31,000 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 trusteed by the PBGC, and recoveries from the companies formerly responsible for the trusteed plans.

To carry out these functions, the PBGC must issue regulations interpreting such matters as the termination process, establishment of procedures for the payment of premiums, and assessment and collection of employer liability. 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). At the end of fiscal year 2004, the program had a record $23 billion deficit, and Congress was considering proposals by the Administration and others to improve funding of plans and restore the financial health of the insurance program.

*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, went into a deficit position in FY 2003, which improved slightly in 2004. The Administration will be examining the multiemployer program to determine what changes, if any, may be needed to strengthen it.

Regulatory Objectives and Priorities

PBGC 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. PBGC also attempts to minimize administrative burdens on plans and participants.

The PBGC regulatory priorities are focused on changes to improve transparency and to simplify filing with PBGC by increasing use of electronic filing. PBGC policymaking gives consideration to the special needs and concerns of small business.

Improve Transparency of Information

PBGC has been moving forward to improve transparency of information to plan participants, investors, and PBGC, to better inform them and to encourage more responsible funding of pension plans. In March 2005, 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. PBGC also is developing proposed amendments to the regulation that requires notice to PBGC of certain events that threaten plan funding. In addition, PBGC is developing proposed amendments to improve the accuracy of plan funding information that certain underfunded plans are required to provide in an annual Participant Notice.

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 March 2005, PBGC issued a proposed rule that would require electronic filing of premium information for plans with 500 or more participants for plan years beginning after 2005 and for all plans for plan years beginning after 2006. The PBGC would grant case-by-case exemptions for filers that demonstrated good cause. On-line filers will have a choice of using private-sector software that meets PBGC's published standards or using PBGC's software. Electronic premium filing will simplify filers' paperwork, improve accuracy of PBGC's premium records and database, and enable more prompt payment of premium refunds.

Plan actuarial and employer financial information required to be reported to 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 will reduce the filing burden, improve accuracy, and better enable PBGC to monitor and manage risks posed by these plans.

Relief for Small Businesses

A large percentage of the plans insured by the PBGC are small or maintained by small employers. The PBGC takes the special needs and concerns of small entities into account in developing its regulatory policies. For example, mandatory electronic filing of premiums would apply a year 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.

The PBGC will continue to review its regulations to look for further simplification opportunities. The PBGC's regulatory plan for October 1, 2005, to September 30, 2006, consists of one significant regulatory action.

PBGC

FINAL RULE STAGE

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134. ALLOCATION OF ASSETS IN SINGLE–EMPLOYER PLANS; VALUATION OF BENEFITS AND ASSETS

Priority:

Other Significant

Legal Authority:

29 USC 1302(b)(3); 29 USC 1341; 29 USC 1301(a); 29 USC 1344; 29 USC 1362

CFR Citation:

29 CFR 4044, subpart B

Legal Deadline:

None

Abstract:

The PBGC proposes to amend its benefit valuation and asset allocation regulations by adopting more current mortality tables and otherwise simplifying and improving its valuation assumptions and methods.

Statement of Need:

The PBGC's regulations prescribe rules for valuing a terminating plan's benefits for several purposes, including (1) determining employer liability and (2) allocating assets to determine benefit entitlements. The PBGC's interest assumption for valuing benefits, when combined with the PBGC's mortality assumption, is intended to reflect the market price of single-premium, nonparticipating group annuity contracts for terminating plans. In developing its interest assumptions, the PBGC uses data from surveys conducted by the American Council of Life Insurers. The PBGC currently uses a mortality assumption based on the 1983 Group Annuity Mortality Table in its benefit valuation and asset allocation regulations (29 CFR parts 4044 and 4281).

In May 1995, the Society of Actuaries Group Annuity Valuation Table Task Force issued a report that recommends new mortality tables for a new Group Annuity Reserve Valuation Standard and a new Group Annuity Mortality Valuation Standard. In December 1996, the National Association of Insurance Commissioners adopted the new tables as models for determining reserve liabilities for group annuities. The PBGC is considering incorporating these tables into its regulations and making other modifications.

Summary of Legal Basis:

The PBGC has the authority to issue rules and regulations necessary to carry out the purposes of title IV of ERISA.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Cost estimates are not yet available. However, the PBGC expects that this regulation will not have a material effect on costs.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/97	62 FR 12982
ANPRM Comment Period End	05/19/97	
NPRM	03/14/05	70 FR 12429
NPRM Comment Period End	05/13/05	
Final Action	11/00/05	
Final Action Effective	12/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

URL For More Information:

www.pbgc.gov/regs

URL For Public Comments:

www.pbgc.gov/regs

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RIN: 1212–AA55

BILLING CODE 7708–01–S

SMALL BUSINESS ADMINISTRATION (SBA)

Statement of Regulatory Priorities

Overview

The Small Business Administration's (SBA) mission is to maintain and strengthen the Nation's economy by enabling the establishment and viability of small businesses and by assisting in economic recovery of communities after disasters. In order to accomplish this mission, SBA focuses on improving the economic environment for small businesses; bridging the competitive opportunity gap facing small business entrepreneurs; and providing financial assistance for the restoration of homes and businesses affected by disasters.

SBA is committed to:

- Working with its financial partners to improve small businesses' access to capital through SBA's loan and venture capital programs;
- Providing technical assistance to small businesses 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;
- Measuring outcomes, such as revenue growth, job creation, business longevity, and recovery rate after a disaster, to ensure that SBA's programs and services are delivered efficiently and effectively.

SBA's regulatory actions reflect the goals and objectives of the agency and are designed to provide the small business and residential communities with the information and guidance they need to succeed as entrepreneurs and restore their homes or other property after a disaster. All of SBA's rules concern small businesses and programs that promote small businesses. 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, facilitating small business involvement in innovative manufacturing through modernization of the Small Business Innovation & Research and Small Business Technology Transfer programs, and promoting Federal contracting opportunities through the implementation of the Women-Owned Small Business Federal Contract Assistance program.

SBA

PROPOSED RULE STAGE

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135. SMALL BUSINESS LENDING COMPANY AND LENDER OVERSIGHT REGULATIONS

Priority:

Other Significant

Legal Authority:

15 USC 634(b)(6); 15 USC 634(b)(7); 15 USC 634(b)(14); 15 USC 636(a); 15 USC 636(m); 15 USC 650; 15 USC 687(f); 15 USC 697(a); 15 USC 697e(c)(8)

CFR Citation:

13 CFR 120.460; 13 CFR 120.470; 13 CFR 120.1000 et seq.

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; among other things.

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, sec. 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	12/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

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SBA

FINAL RULE STAGE

136. SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM POLICY DIRECTIVE

Priority:

Other Significant

Legal Authority:

15 USC 638; PL 107–50

CFR Citation:

None

Legal Deadline:

Final, Statutory, February 15, 2002, Small Business Technology Transfer Program Reauthorization Act of 2001, enacted 10/15/2001, requires publication of policy directive modifications.

Abstract:

This Policy Directive would fulfill SBA's statutory obligation to provide guidance to the participating Federal agencies for the general operation of the Small Business Technology Transfer (STTR) Program. In particular, the Policy Directive would: (1) clarify STTR data rights pertaining to STTR Phase I, II, and III awards; (2) require the establishment of a STTR Program database that would be accessible to the Government and the public; (3) require participating agencies to increase the amount of their extramural budget reserved for STTR from 0.15 percent to 0.3 percent; (4) permit agencies to increase the dollar value of STTR Phase II awards from $500,000 to $750,000; (5) permit agencies to approve a shorter or longer duration of time for award performance; and (6) to incorporate language implementing Executive Order 13329, ''Encouraging Innovation in Manufacturing;'' among other things.

Statement of Need:

In 1992, Congress enacted the Small Business Technology Transfer Act of 1992 (STTR Act), Public Law No. 102-564 (codified at 15 U.S.C. 638). The STTR Act established the Small Business Technology Transfer Program (STTR Program) as a pilot program that required Federal agencies with extramural budgets for research or research and development (R/R&D) in excess of $1 billion per fiscal year to enter into funding agreements with small business concerns (SBCs) that engage in a collaborative relationship with a research institution. The purpose of the STTR Program is to stimulate a partnership of ideas and technologies between innovative SBCs and research institutions. The program assists the small business and research communities by developing commercially viable technologies. The STTR Program is a phased process, uniform throughout the Federal Government, of soliciting proposals and awarding funding agreements for R/R&D to meet stated agency needs or missions. The STTR Act requires the U.S. Small Business Administration (SBA) to ''issue a policy directive for the general conduct of the STTR Programs within the Federal Government.'' (15 U.S.C. 638(p)(1)). SBA published its first STTR Policy Directive in 1993 (58 FR 42607-42620, August 10, 1993). This Policy Directive fulfilled SBA's statutory obligation to provide guidance to the participating Federal agencies for the general operation of the STTR Program. Federal agencies participating in the STTR Program (STTR agencies) are obligated to follow the guidance provided by this Policy Directive. Each agency is required to review its rules, policies, and guidance on the STTR Program to ensure consistency with this Policy Directive and to make any necessary changes in accordance with each agency's normal procedures. This is consistent with the statutory authority provided to the SBA concerning the STTR Program.

On February 24, 2004, the President signed Executive Order (Order) 13329, ''Encouraging Innovation in Manufacturing.'' This Order specifically requires the Small Business Administration (SBA) to: (1) establish, after consultation with the Director of the Office of Science and Technology Policy (Director), formats and schedules for submission of reports by the heads of departments and agencies; (2) issue to departments and agencies guidelines and directives (in addition to the formats and schedules) as the Administrator determines from time to time are necessary to implement the Order, after such guidelines and directives are submitted to the President, through the Director, for approval and are approved by the President. In addition, the heads of the agencies and departments with one or more SBIR or STTR programs are required: (1) to the extent permitted by law and in a manner consistent with the mission of that department or agency, to give high priority within such programs to manufacturing-related research and development to advance innovation, including innovation in manufacturing; and 2) to submit reports annually to the Administrator of the SBA and the Director concerning the efforts of such departments or agencies in implementing this Order.

Summary of Legal Basis:

In 1992, Congress enacted the Small Business Technology Transfer Act of 1992 (STTR Act), Public Law No. 102-564 (codified at 15 U.S.C. 638). Congress has since amended the STTR Act, most recently with the enactment of the Small Business Technology Transfer Program Reauthorization Act of 2001 (Reauthorization Act), Public Law No. 107-50. The Reauthorization Act extends the STTR Program through September 30, 2009, and changed its status from a pilot program to a permanent one. The President signed Executive Order 13329, ''Encouraging Innovation in Manufacturing'' in 2004.

Alternatives:

There are no alternatives since it is mandated by law to issue a policy directive for the general conduct of the program.

Anticipated Cost and Benefits:

This directive does not impose any new substantive costs to small businesses or to the Federal Government. Instead, the directive ensures that the Federal agencies and departments are assisting the private sector consistent with the directive. The Small Business Technology Transfer Program Reauthorization Act of 2001 benefits small businesses by requiring participating agencies to increase the amount of their extramural budget to be reserved for the STTR Program from 0.15 percent to 0.3 percent and permits agencies to increase the dollar value of STTR Phase II awards from $500,000 to $750,000.

Risks:

This policy directive poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
Notice of Proposed Policy Directive	06/16/03	68 FR 35748
Comment Period End	07/16/03	
Final Action	11/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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SBA

137. SMALL BUSINESS INNOVATION RESEARCH (SBIR) POLICY DIRECTIVE

Priority:

Other Significant

Legal Authority:

15 USC 638(j)(1)

CFR Citation:

None

Legal Deadline:

None

Abstract:

On May 19, 2005, SBA proposed amendments to the Small Business Innovation and Research (SBIR) Program Policy Directive. Those amendments reflected the requirements that Executive Order 13329, ''Encouraging Innovation in Manufacturing,'' February 24, 2004, imposed on SBA and Federal agencies participating in the SBIR Program (70 FR 28975). In accordance with the Executive Order, SBA intends to issue guidelines on implementing the Executive Order, including requiring participating agencies to (1) give high priority to SBIR projects that are focused on manufacturing-related R&D in a manner consistent with their missions and the purpose of the SBIR program; (2) develop an action plan for implementing the order; and (3) report to SBA annually on these implementation plans.

Statement of Need:

On February 24, 2004, the President signed Executive Order (Order)13329 ''Encouraging Innovation in Manufacturing.'' This Executive order specifically requires the Small Business Administration (SBA) to: 1) establish, after consultation with the Director of the Office and Science and Technology Policy (Director), formats and schedules for submission of reports by the heads of departments and agencies; 2) issue to departments and agencies guidelines and directives (in addition to the formats and schedules) as the Administrator determines from time to time are necessary to implement the Order, after such guidelines and directives are submitted to the President, through the Director, for approval and are approved by the President. In addition, the heads of the agencies and departments with one or more SBIR or STTR programs are required: 1) to the extent permitted by law and in a manner consistent with the mission of that department or agency, to give high priority within such programs to manufacturing-related research and development to advance innovation including innovation in manufacturing and 2) to submit reports annually to the Administrator of the SBA and the Director concerning the efforts of such departments or agencies in implementing this Order.

Summary of Legal Basis:

In 1982, Congress enacted the Small Business Innovation Development Act of 1982 (SBIDA), Public Law 97-219 (codified at 15 U.S.C. 638), which established the Small Business Innovation Research Program (SBIR Program). SBIDA requires the SBA to ''issue Policy Directives for the general conduct of the SBIR programs within the Federal Government.'' (15 U.S.C. 638(j)(1)) In December of 2000, Congress enacted the Small Business Innovation Research Program Reauthorization Act of 2000 (Reauthorization Act), Public Law 106-554. The Reauthorization Act extends the SBIR Program through September 30, 2008. SBA published its first Policy Directive, Policy Directive No. 65-01, 22 years ago (47 FR 52966, November 24, 1982). The last SBIR Policy Directive amendments were published 2 years ago (67 FR 60072-60098, September 24, 2002).

Alternatives:

There are no practical alternatives that accomplish the objectives established by Executive Order 13329. An alternative to amending the SBIR Policy Directive that was considered was to issue a Special Policy Information Notice (SPIN) to the participating SBIR agencies and departments. SPINs have been used in the past in order to provide clarifying guidance on existing definitions or policy matters to the participating SBIR agencies and departments. As Executive Order 13329 was a new Presidential initiative, a SPIN was not deemed the appropriate medium for providing guidance to the participants. Amending the Policy Directives was identified as the method for effective implementation of Executive Order 13329.

Anticipated Cost and Benefits:

The amendments to the Policy Directive do not impose any new substantive costs to small businesses. Further, implementing the Executive order does not impose any substantive cost to the Federal Government. Instead, implementing this Executive Order ensures that the Federal agencies and departments are assisting the private sector in its manufacturing innovation efforts.

Risks:

The amendments to the SBIR Policy Directive and the implementation of Executive Order 13329 pose no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
Notice of Proposed Policy Directive	05/19/05	70 FR 28975
Other/Comment Period End	06/20/05	
Notice of Final Policy Directive	11/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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BILLING CODE 8025–01–S

SOCIAL SECURITY ADMINISTRATION (SSA)

Statement of Regulatory Priorities

The Social Security Administration (SSA) administers the retirement, survivors, and disability insurance programs under title II of the Social Security Act (the Act), 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 21 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 the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173), the Social Security Protection Act of 2004 (Pub. L. 108-203) and the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108-458).

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 12 initiatives that address disability.

We are amending our administrative review process for benefit claims under title II of the Social Security Act (the Act) based on disability, and for applications for supplemental security income (SSI) payments based on disability or blindness under title XVI of the Act. We expect that the changes we are making will improve the accuracy and timeliness of decision-making throughout the disability determination process.

We are including several initiatives that address issues involving attempts by disabled individuals to return to the workforce. A final rule will revise several areas of our regulations on the Ticket to Work program to improve the support of disabled individuals who want and need assistance to return to the workforce. Another proposed rule would, among other changes, require us to issue a receipt when an individual receiving disability benefits reports a change in work activity or earnings. This rule would also include home schooling as a form of regular school attendance for purposes of the Student Earned Income Exclusion and reflects provisions of the Social Security Protection Act of 2004. A final rule will establish time limits and other criteria for individuals receiving disability benefits who wish to initiate plans to achieve self-support. We are including two proposed rules concerning the continuing disability review (CDR). One would explain the standards we use to evaluate the work activity of an individual receiving disability benefits, and when we will conduct a CDR. The other would amend our regulation to suspend disability benefits when a beneficiary fails to cooperate with our request for information during a CDR.

We are including a final rule that will clarify how we make a finding regarding medical equivalence.

A proposed 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 and cardiovascular disorders, and two proposed rules on immune system disorders and evaluating mental disorders. 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 are developing proposed rules that reflect provisions of the Social Security Protection Act of 2004 intended to strengthen our oversight of the representative payee program.

The Debt Collection Improvement Act of 1996, as amended by the Foster Care Independence Act of 1999, provided SSA with new tools for our efforts in collecting debts, including the use of administrative wage garnishment. We are developing a proposed rule on Federal salary offset that will enable us to collect qualifying, delinquent title II and XVI debts owed by former beneficiaries who are currently employed by the Federal government.

A proposed rule would prohibit title II benefits to persons fleeing prosecution, custody, or confinement after conviction, and to persons violating probation or parole. This proposed rule reflects a provision of the Social Security Protection Act of 2004.

A proposed rule will enhance the integrity of SSA's enumeration processes for assigning Social Security Numbers by reducing the opportunity for fraud. It would limit the number of Social Security Number cards an individual can obtain. This proposed rule reflects provisions of the Intelligence Reform and Terrorism Prevention Act of 2004.

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.

A final rule will enhance our program integrity efforts by expanding our civil monetary penalties program. Included, among other activities, would be solicitations or mailings by outside individuals or entities that mislead the public into believing that SSA either approves, endorses, or authorizes the solicitations or mailings. This final rule reflects provisions of the Social Security Protection Act of 2004.

Simplify the SSI Program

We are including a proposed rule that would reflect several provisions of the Social Security Protection Act of 2004, including simplifying the calculation of infrequent and irregular income, and other changes.

Implement Medicare Legislation

SSA does not have overall responsibility for the Medicare program under title XVIII of the Social Security Act. However, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 directs SSA to assist in administering portions of the Medicare program. We are including in the Plan two proposed rules that would implement the legislation.

First, we expect to finalize rules concerning Medicare Prescription Drug

premium and cost-sharing subsidies (Medicare part D).

Second, we propose rules on reduction of premium subsidies for the Supplementary Medical Insurance Benefit program (Medicare part B).

SSA

PROPOSED RULE STAGE

138. FEDERAL SALARY OFFSET (WITHHOLDING A PORTION OF A FEDERAL EMPLOYEE'S SALARY TO COLLECT A DELINQUENT DEBT OWED TO THE SOCIAL SECURITY ADMINISTRATION) (721P)

Priority:

Other Significant

Legal Authority:

42 USC 404; 42 USC 405; 42 USC 902; 42 USC 1383; 5 USC 5514

CFR Citation:

20 CFR 422

Legal Deadline:

None

Abstract:

This initiative would enable the Social Security Administration (SSA) to collect from Federal salaries qualifying, delinquent title II and title XVI overpayment debts and administrative debts owed by individuals who are currently Federal employees. The debt collection would be accomplished by the partial reduction of the employee's disposable salary.

Statement of Need:

This regulation is required by 5 U.S.C. 5514(b) and by regulations of the Department of the Treasury (Treasury) and the Office of Personnel Management (OPM) in order for SSA to participate in the Federal Salary Offset program. Treasury's regulation is 31 CFR 285.7; OPM's regulation is 5 CFR 550.1104.

Summary of Legal Basis:

SSA's use of the Federal Salary Offset program is authorized by 42 U.S.C. 404(f), 42 U.S.C. 1383(b) and 5 U.S.C. 5514.

Alternatives:

None. SSA must have regulations, approved by OPM, in order to use Federal salary offset to collect debts owed by Federal employees. See 5 U.S.C. 5514(b), 5 CFR 550.1104, and 31 CFR 285.7.

Anticipated Cost and Benefits:

Administrative costs are to be determined.

Risks:

At this time we have not identified any risks associated with the proposal.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	
Final Action	08/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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SSA

139. EXEMPTION OF WORK ACTIVITY AS A BASIS FOR A CONTINUING DISABILITY REVIEW (TICKET TO WORK AND WORK INCENTIVES IMPROVEMENT ACT OF 1999) (725P)

Priority:

Other Significant

Legal Authority:

42 USC 421(m)

CFR Citation:

20 CFR 404.903; 20 CFR 404.1574; 20 CFR 404.1575; 20 CFR 404.1590; 20 CFR 404.1592a; 20 CFR 404.1594; 20 CFR 416.974; 20 CFR 416.990; 20 CFR 416.994; 20 CFR 416.1403

Legal Deadline:

None

Abstract:

We are proposing to amend our regulations to explain how we will implement section 221(m) of the Social Security Act (the Act). We are also proposing to amend our regulation to eliminate the use of the secondary substantial gainful activity amount for evaluating work done by an employee prior to January 2001. Section 221(m) affects our rules for when we will conduct a continuing disability review if a beneficiary works and receives benefits under title II of the Act based on disability. (We interpret this section to include beneficiaries who receive both title II disability benefits and Supplemental Security Income (SSI) payments based on disability.) It also affects the way we evaluate work activity when deciding if a beneficiary has engaged in substantial gainful activity, and affects the standards we use when we determine whether disability continues or ends.

Statement of Need:

This regulation is necessary to clarify how SSA will implement section 221(m) of the Social Security Act, which prohibits starting continuing disability reviews for certain beneficiaries based on work activity, and limits the use of the work activity of certain beneficiaries as evidence that the individual is no longer disabled.

Summary of Legal Basis:

This regulation implements section 221(m) of the Social Security Act, which was added by section 111 of Public Law 106-170.

Alternatives:

None.

Anticipated Cost and Benefits:

Over a five year period, this regulation will result in a net administrative cost of about $10 million and an SSA workyear savings of 420 workyears. The estimates for program costs are $165 million in the first five years.

Risks:

At this time we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	10/11/05	70 FR 58999
NPRM Comment Period End	12/12/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

140. REVISED MEDICAL CRITERIA FOR EVALUATING IMMUNE SYSTEM DISORDERS (804P)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

We 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 11 years old. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings do not reflect state-of-art medical knowledge and technology.

Anticipated Cost and Benefits:

We anticipate that if finalized, these proposed rules 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	12/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

141. 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	06/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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SSA

142. AMENDMENTS TO THE TICKET TO WORK AND SELF–SUFFICIENCY PROGRAM (967P)

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 411.210; 20 CFR 411.325; 20 CFR 411.350 to 411.370; 20 CFR 411.385 to 411.395; 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 proposed rules are intended to amend the final rules implementing the Ticket to Work and Self-Sufficiency Program under section 1148 of the Social Security Act: To expand beneficiary eligibility to receive tickets under this program; to clarify the rules for assignment of a beneficiary's ticket to a State vocational rehabilitation (VR) agency; to revise the rules for payment when a beneficiary receives services from both a State VR agency and an employment network (EN); and, consistent with the Commissioner's authority in section 1148(h) of the Act, to revise the rules for milestone and outcome payments, in increase the incentives for providers of employment services, vocational rehabilitation services, and other support services to participate in this program.

Statement of Need:

This proposed regulatory action is 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:

None.

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 Period End	12/29/05	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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SSA

143. REPRESENTATIVE PAYMENT; POLICIES AND ADMINISTRATIVE PROCEDURE FOR IMPOSING PENALTIES FOR FALSE OR MISLEADING STATEMENTS OR WITHHOLDING OF INFORMATION (2422P)

Priority:

Other Significant

Legal Authority:

42 USC 405(j); 42 USC 1007; 42 USC 1383(a)(2); PL 108–203, sec 102; PL 108–203, sec 103; PL 108–203, sec 104; PL 108–203, sec 105; PL 108–203, sec 106; PL 108–203, sec 201

CFR Citation:

20 CFR 404.459; 20 CFR 404.2022; 20 CFR 404.2035; 20 CFR 404.2040a; 20 CFR 404.2041(f); 20 CFR 404.2065; 20 CFR 408.665; 20 CFR 416.622; 20 CFR 416.635; 20 CFR 416.640a; 20 CFR 416.641(f); 20 CFR 416.665; 20 CFR 416.1340

Legal Deadline:

None

Abstract:

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries judged incapable of managing or directing someone else to manage their benefits. Congress determined that improvements to the representative payment procedures were needed to assure program integrity. These proposed regulations are required to further our program integrity efforts.

In order to reflect and implement section 201 of Public Law 108-203 we propose regulations for imposing penalties for withholding of information when the person knows or should know that the failure to provide the information is misleading.

Statement of Need:

These proposed regulations, which reflect certain provisions of Public Law 108-203, would modify existing representative payee procedures by: (1) Expanding the scope of disqualification to prohibit an individual from serving as representative payee if he or she is convicted of offenses resulting in imprisonment for more than one year or is fleeing to avoid prosecution, custody, or confinement after conviction; (2) requiring annual certifications from nongovernmental fee for service organizational payees that they are licensed and bonded; (3) requiring a fee for service representative payee to forfeit their fee for the months during which funds were misused; (4) requiring a representative payee to receive benefits in person at a local social security field office if they fail to provide an annual accounting of benefits; and (5) explaining financial requirements for representative payees.

Public Law 108-203 also provides for SSA to impose a penalty on any person who knowingly withholds information that is material for use in determining any right to or the amount of monthly benefits under title II or XVI.

Summary of Legal Basis:

These proposed regulations implement sections 102 to 106, and 201 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

The net administrative cost, which is attributable to Public Law 108-203 and not to these regulations, is estimated to be $20 million and 250 workyears over 5 years.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Organizations

Government Levels Affected:

None

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RIN: 0960–AG09

SSA

144. ISSUANCE OF WORK REPORT RECEIPTS, PAYMENT OF TWP MONTHS AFTER A FRAUD CONVICTION, CHANGES TO THE SEIE, & EXPANSION OF THE REENTITLEMENT PERIOD FOR CHILDHOOD DIB BENEFITS (2502P)

Priority:

Other Significant

Legal Authority:

42 USC 402; 42 USC 403; 42 USC 404(a); 42 USC 404(e); 42 USC 405(a) to 405(d); 42 USC 405(h); 42 USC 405 note; 42 USC 416(1); 42 USC 421(a); 42 USC 421(i); 42 USC 421 note; 42 USC 422(c); 42 USC 423(e); 42 USC 425; 42 USC 428(a) to 428(e); 42 USC 902(a); 42 USC 902(5); 42 USC 902 note; 42 USC 1320 a–8a; 42 USC 1320 b–17; 42 USC 1381; 42 USC 1382; 42 USC 1382 note; 42 USC 1382a(b); 42 USC 1383

CFR Citation:

20 CFR 404.351; 20 CFR 404.401a; 20 CFR 404.471; 20 CFR 404.903; 20 CFR 404.1588; 20 CFR 404.1592; 20 CFR 416.708(c); 20 CFR 416.1112(c)(3); 20 CFR 416.1403; 20 CFR 416.1861

Legal Deadline:

None

Abstract:

We are proposing to amend our rules to reflect and implement sections 202, 208, 420A and 432 of the Social Security Protection Act of 2004 (the SSPA). Section 202 of the SSPA requires us to issue a receipt each time you or your representative report a change in your work activity or give us documentation of a change in your earnings if you receive benefits based on disability under title II or title XVI of the Social Security Act (the Act) until such time as the Commissioner implements a centralize computer file. Section 208 changes the way we pay benefits during the trial work period if you are convicted by a Federal court of fraudulently concealing your work activity. Section 420A allows you to be re entitled to childhood disability benefits at any time if your previous entitlement to childhood disability benefits terminated because of the performance of substantial gainful activity. Section 432 changes the way we decide if you are eligible for the student earned income exclusion. We also propose to change the SSI student policy to include home schooling as a form of regular school attendance when

determining eligibility for the student earned income exclusion.

Statement of Need:

This regulation is necessary to implement the program improvements established in the SSPA. The regulation will improve our service to individual beneficiaries who attempt to work and improve our ability to protect the programs from certain types of fraud.

Summary of Legal Basis:

This regulation implements Sections 202, 208, 420A and 432 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

The administrative impact of these proposed rules is estimated to be negligible (i.e., less than $2 million or 25 workyears). Any administrative impact would be attributable to Public Law 108-203 and not to these regulations.

Risks:

At this time we have not identified any risks to this proposal.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	
Final Action	07/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG10

SSA

145. MEDICARE PART B INCOME–RELATED MONTHLY ADJUSTMENT AMOUNT (2101P)

Priority:

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

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1395r(i); PL 108–173

CFR Citation:

20 CFR 418 (New)

Legal Deadline:

None

Abstract:

We propose to add to our regulations a new part 418 that would include our rules applicable to reduction of premium subsidies for beneficiaries who have income above a threshold amount. Section 811 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 amends section 1839 of the Act. Starting in 2007, the new subsection 1839(i) requires that Medicare part B enrollees with income above a threshold amount specified in the law receive a reduced part B premium subsidy. The statute establishes four income ranges above the threshold, and prescribes a percentage adjustment of premiums for each range. As income increases, the premium subsidy decreases. In effect, the Medicare Part B premium will increase for individuals with income above the threshold. All beneficiaries will continue to receive some subsidy of the Medicare Part B premium. The income threshold in 2007 is $80,000 ($160,000 for an individual who files a joint income tax return). The premium adjustments will be phased in over a five year period from 2007 through 2011. After 2007, the threshold amount and all of the income range amounts will be annually adjusted for inflation.

Statement of Need:

Regulations required by statute.

Summary of Legal Basis:

Section 1839(i) of the Social Security Act.

Alternatives:

None. The Social Security Act directs the Commissioner to establish regulations to implement this provision. The statute requires the Commissioner to establish regulations regarding temporary use of tax year data from a year other than the year ordinarily used to determine premium adjustments, establishment of premium adjustments for Medicare Part B when IRS tax data is not available, and specification of ''life-changing events'' that meet the standard for use of more recent tax year data, and a methodology for making such adjustments.

Anticipated Cost and Benefits:

The Medicare Part B income-related premium subsidy reduction was established to produce Federal savings in the Medicare program. The Congressional Budget Office estimates that this provision will produce $13.3 billion in savings from 2007 through 2013.

Risks:

None identified.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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SSA

146. NONPAYMENT OF BENEFITS TO FUGITIVE FELONS AND PROBATION OR PAROLE VIOLATORS (2222P)

Priority:

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

Legal Authority:

42 USC 402; 42 USC 404(a); 42 USC 404(e); 42 USC 405(a); 42 USC 405(c);

42 USC 423(e); 42 USC 424a; 42 USC 902(a)(5); 42 USC 902(a)(5); 48 USC 1801

CFR Citation:

20 CFR 404.471(new); 20 CFR 416.202; 20 CFR 416.1339

Legal Deadline:

None

Abstract:

These regulations will propose rules for nonpayment of title II benefits to persons avoiding prosecution, custody or confinement after conviction and to persons violating probation or parole. We will also propose rules for establishing that good cause exists for continuing to pay such benefits for titles II and XVI.

Statement of Need:

Public Law 108-203, the Social Security Protection Act of 2004, extends the fugitive felon nonpayment provision to title II beneficiaries under section 202(x) of the Social Security Act, effective January 2005, if an outstanding warrant exists for 30 continuous days or more. It also provides a good cause exception that, if met, provides for the continued payment of titles II and XVI benefits. The good cause exception requires the Commissioner to apply good cause if a court finds the person not guilty, charges are dismissed, a warrant for arrest is vacated, there are similar exonerating circumstances identified by the court, or the individual establishes that he or she was the victim of identity fraud and the warrant was issued on such basis. Public Law 108-203 also gives the Commissioner the discretionary authority to establish good cause based on mitigating factors if the criminal offense is nonviolent and not drug-related, and in the case of probation or parole violators, if the underlying offense is nonviolent and not drug-related.

Summary of Legal Basis:

Section 203 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

There are no anticipated costs and benefits resulting from this regulatory action. Any program savings from nonpayment to fugitive felons will be the result of implementing Public Law 108-203.

Risks:

The fugitive felon provision of title XVI of the Act has been the subject of litigation. Future litigation over the program is anticipated with respect to the term ''fleeing to avoid'' and our interpretation of the effective date provision of section 203 of the SSPA. In addition, the discretionary good cause exceptions to the titles II and XVI provisions may be perceived as either bestowing an unjust benefit on felons or being unnecessarily restrictive.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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SSA

147. CHANGES TO THE INCOME AND RESOURCES PROVISIONS FOR SSI BASED ON SECTIONS 430, 435, AND 436 OF THE SOCIAL SECURITY PROTECTION ACT (SSPA) OF 2004 (2482P)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 1381a; 42 USC 1382; 42 USC 1382a; 42 USC 1382b; 42 USC 1382c(f); 42 USC 1382j

CFR Citation:

20 CFR 416.1111; 20 CFR 416.1112; 20 CFR 416.1123; 20 CFR 416.1124; 20 CFR 416.1161; 20 CFR 416.1210; 20 CR 416.1250 (New)

Legal Deadline:

None

Abstract:

The proposed regulations are required to implement legislation, specifically sections 430, 435 and 436 of Public Law 108-203, the Social Security Protection Act of 2004, which was enacted March 2, 2004.

Statement of Need:

These regulations, which reflect certain sections of Public Law 108-203, modify existing Supplemental Security Income (SSI) policies under Title XVI of the Social Security Act (the Act) by: (1) Changing the calculation of infrequent or irregular income from a monthly to a quarterly basis and excluding the first $60 dollars of unearned income and the first $30 dollars of earned income from such infrequent or irregular income; (2) excluding from income any interest or dividend income earned on a countable resource or a resource excluded under a Federal statute other than the Act; (3) excluding from income, gifts used to pay tuition, fees or other necessary educational expenses at any educational institution, including vocational and technical training; (4) excluding from resources for 9 months beginning the month after the month of receipt, any portion of grants, scholarships, fellowships or gifts used to pay tuition, fees or other necessary educational expenses at any educational institution; and (5) under the discretionary authority of the Commissioner of Social Security (the Commissioner), considering wages and unearned income from the Uniformed Services to be received in the month in which the compensation was earned rather than paid both for eligible individuals and deemors. We also propose to apply the preceding changes to how we count the income and resources of ineligible spouses and parents.

Summary of Legal Basis:

These regulations implement sections 430, 435 and 436 of Public Law 108-203.

Alternatives:

The only alternative was not to apply the exclusions in sections 430, 435 and 436 of the SSPA to the deeming process. Section 1614(f) of the Act grants the Commissioner the discretion to waive the deeming of income and resources from an ineligible spouse or parent to an eligible individual when the Commissioner determines that deeming would be inequitable under

the circumstances. However, extending these exclusions to the deeming process is consistent with the SSI program's longstanding policy of treating the income and resources of spouses and parents comparably to the income and resources of the eligible individual.

Anticipated Cost and Benefits:

The net administrative savings of section 430, 435 and 436 of the SSPA, which is attributable to Public Law 108-203 and not to these regulations, is estimated to be about $4 million and 50 workyears over 5 years.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	09/06/05	70 FR 52949
NPRM Comment Period End	11/07/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG13

SSA

148. CONTINUING DISABILITY REVIEW FAILURE TO COOPERATE PROCESS (2763P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 402; 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(i); 42 USC 422(c); 42 USC 423; 42 USC 425; 42 USC 902(a)(5); 42 USC 1382; 42 USC 1382c; 42 USC 1382h; 42 USC 1383(a); 42 USC 1383(c); 42 USC 1383(d)(1)

CFR Citation:

20 CFR 404.1587; 20 CFR 404.1596; 20 CFR 416.992

Legal Deadline:

None

Abstract:

We propose to amend our regulations to provide that we will suspend your disability benefits before we make a determination during a continuing disability review (DR) under title II of the Social Security Act (the Act) when you fail to comply with our request for necessary information. Should you remain non-compliant for a period of one year following your suspension, we will then terminate your disability benefits. We are proposing these revisions to conform out title II policy to our current title XVI policy. Although our current title XVI regulations provide for the suspension and termination of payments after 12 months, we are proposing to amend these regulations by restating this policy in the CDR regulatory provisions.

Statement of Need:

The regulatory changes are being proposed to conform our title II procedures for determining whether you continue to meet the disability requirements to our current title XVI procedures.

Summary of Legal Basis:

This proposed change is not required by statute or court order.

Alternatives:

A change in the statute is not necessary in order to implement this change.

Anticipated Cost and Benefits:

The proposed rules will have a negligible administrative savings per year (i.e., less than $2 million or 25 workyears).

The Office of the Chief Actuary estimated that net savings for FY 2006 through FY 2010 would be $48 million. However, there is the possibility that the new procedure could impact the number of beneficiaries who fail to cooperate, which could result in smaller savings or even a net cost, but there is no reliable empirical evidence with which to investigate this possibility.

Risks:

The only risk may be if beneficiaries complain that their benefits have stopped. However, since a beneficiary who meets the other factors of entitlement only has to cooperate in order to have their benefits resumed the risk appears to be minimal.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	
Final Action	07/00/06	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

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SSA

149. PROHIBITION OF ENTITLEMENT ON EARNINGS RECORDS 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 noncitizen workers who

were originally assigned a Social Security number (SSN) on or after January 1, 2004. Under this law, a noncitizen 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 noncitizen worker must have been issued an SSN for work purposes at any time on or after January 1, 2004; or

• The noncitizen worker must have been admitted to the U.S. 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 a noncitizen 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 noncitizen 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 noncitizen workers, it also affects the entitlement of any person seeking a benefit on the record of a noncitizen who is subject to this law.

A noncitizen worker who was properly assigned an 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 SSA has 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	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

150. • LIMITING REPLACEMENT OF SOCIAL SECURITY NUMBER CARDS (965P)

Priority:

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

Legal Authority:

42 USC 405; 42 USC 432; 42 USC 902(a)(5); 42 USC 1320b–1; 42 USC 1320b–13; PL 108–458, sec 7213(a)(1)(A)

CFR Citation:

20 CFR 422.103 to 422.110

Legal Deadline:

None

Abstract:

The proposed rule will revise our regulations to indicate that replacement SSN cards will be limited to three per year and ten per lifetime. The Commissioner will allow certain exceptions to these limits on a case-by-case basis in compelling circumstances. Furthermore, when determining these limits, SSA will not consider replacement SSN cards issued for the purpose of changing the numberholder's (NH) name or for changes in alien status that result in a necessary change to a restrictive legend on the SSN card, because we believe these situations satisfy the compelling circumstances test. We want to ensure the accuracy of our records by encouraging number holders to report name changes and changes in alien status.

Statement of Need:

We are codifying the statutory change in our rules. These revisions of our regulations facilitate the implementation of Section 7213(a)(1)(A) of the Intelligence Reform and Terrorism Prevention Act (IRTPA) of 2004. Previously, there have never been any limits placed on the number of cards an individual receives over the course of a year or a lifetime other than a protocol in our electronic records that prevents the issuance of a replacement SSN card within seven days of a previous issuance.

Summary of Legal Basis:

The revision to our regulations are needed to implement Section 7213(a)(1)(A) of IRTPA.

Alternatives:

None.

Anticipated Cost and Benefits:

Administrative costs are estimated to be negligible (i.e., less than $2 million or 25 workyears). Any costs attributable to this regulation are due to the legislation and not to the regulation itself.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG25

SSA

151. ● AGE AS A FACTOR IN EVALUATING DISABILITY (3183P)

Priority:

Other Significant

Legal Authority:

42 USC 405(a); 42 USC 423; 42 USC 1382c; 42 USC 902(a)(5)

CFR Citation:

404.1562; 404.1563; 404.1568; 404P appendix 2; 416.962; 416.963; 416.968

Legal Deadline:

None

Abstract:

We are proposing to 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 proposed 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 proposed changes would not affect the rules under part 404 of our regulations for individuals age 55 or older who have statutory blindness. They also would 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	10/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG29

SSA

152. ● ADMINISTRATIVE REVIEW PROCESS FOR ADJUDICATING INITIAL DISABILITY CLAIMS (3203F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 401(j); 42 USC 404(f); 42 USC 405(a); 42 USC 405(b); . . .

CFR Citation:

20 CFR 404.903; 20 CFR 404.1502; 20 CFR 404.1503; 20 CFR 404.1512; . . .

Legal Deadline:

None

Abstract:

In order to improve the accuracy, consistency, and timeliness of decision making throughout its disability determination process, we propose to change its four-step administrative review process for benefit claims filed under title II of the Social Security Act (Act) based on disability, and for applications filed for supplemental security income (SSI) payments based on disability or blindness under title XVI of the Act. We expect that the proposed changes will significantly reduce our current disability case processing times, increase decisional consistency and accuracy, and ensure that the right determination or decision is made as early in the disability determination process as possible.

Statement of Need:

Over the years, the Social Security and SSI disability programs have grown in size and complexity, and there has been significant growth in the number of claims filed for disability benefits each year. During the early years of the Social Security disability program, the number of claims filed each year was measured in the hundreds of thousands. Currently, more than two and a half million individuals apply for Social Security and SSI benefits based on disability each year. That volume will grow even more in future years as baby boomers move into their disability-prone years. In light of these factors, the need to make substantial changes in our disability determination process has become a high priority.

Summary of Legal Basis:

These proposed rules are based on the broad authority the Commissioner of Social has under sections 205(a), 1631(d)(1) and 702(b)(5) of the Act to promulgate rules and regulations governing the administration of the disability determination process.

Alternatives:

We could maintain the current four-step administrative review process and rely on our transition to an electronic disability process—one usually referred to as eDib—to reduce current processing times and improve the efficiency of the current disability determination process. In an electronic disability process, applications, claimant information and medical evidence that have been processed in paper form in the past are processed in electronic form instead. eDib provides opportunities to manage and process workloads in ways that have not existed until now. However, eDib alone is not enough to improve the current process to the level that we deem necessary.

Anticipated Cost and Benefits:

To be determined.

Risks:

Maintaining the status quo likely would result in the General Accountability Office (GAO) continuing to designate modernizing federal disability programs, including our disability programs, as a high-risk area. The GAO has listed this as a high-risk area since 2003 (refer to GAO-05-207, High-Risk Series, An Update, January 2005).

Timetable:

Action	Date	FR Cite
NPRM	07/27/05	70 FR 43589
NPRM Comment Period End	10/25/05	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

FINAL RULE STAGE

153. EVIDENTIARY REQUIREMENTS FOR MAKING FINDINGS ABOUT MEDICAL EQUIVALENCE (787F)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1525 to 404.1527; 20 CFR 404.1529; 20 CFR 416.925; 20 CFR 416.926; 20 CFR 416.926a; 20 CFR 416.927; 20 CFR 416.929

Legal Deadline:

None

Abstract:

This notice of proposed rulemaking will clarify that we will consider the medical severity of the individual's impairment, based on all relevant evidence in the case record when we make a finding regarding medical equivalence. These rules will clarify our medical equivalence policy in light of the decision in Hickman v. Apfel, 187 F.3d 683 (7th Cir. 1999).

Statement of Need:

We developed these proposed rules to restore consistency in our regulatory language and to clarify the language in 20 CFR 404.1526 and 20 CFR 416.926 of our regulations, the rules we use for making findings about medical equivalence to listings in the Listing of Impairments.

Summary of Legal Basis:

Administrative—not required by statute or court order.

Alternatives:

We considered not making the language in 20 CFR 404.1526 and 20 CFR 416.926 consistent. However, because determining medical equivalence is the same under title II and title XVI, we believe it is important that the language in the two sections be consistent. We also considered not making the other clarifying revisions in the NPRM. However, because the court in Hickman v. Apfel, 187 F.3d 683 (7th Cir. 1999) interpreted our statement in 20 CFR 416.926(b) that ''[w]e will always base our decision about whether your impairment(s) is medically equal to a listed impairment on medical evidence only'' differently from what we intended, we believe the proposed revisions are necessary to clarify our intent. We intend the phrase ''medical evidence only'' in this regulation section only to exclude consideration of the vocational factors of age, education, and work experience. The proposed revisions make the language in the two sections identical and clarify our intent of how medical equivalence is to be determined in response to the Hickman decision.

Anticipated Cost and Benefits:

The administrative cost of this regulation is estimated to be negligible (i.e., less than $2 million or 25 workyears) since the proposed rules are simply a clarification of our current longstanding policy on determining medical equivalence.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	06/17/05	70 FR 35188
NPRM Comment Period End	08/16/05	
Final Action	08/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AF19

SSA

154. REVISED MEDICAL CRITERIA FOR EVALUATING IMPAIRMENTS OF THE DIGESTIVE SYSTEM (800F)

Priority:

Economically 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 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. The current listings are now over 15 years old. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings do not reflect state-of-the-art medical knowledge and technology.

Anticipated Cost and Benefits:

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	02/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AF28

SSA

155. REVISED MEDICAL CRITERIA FOR EVALUATING CARDIOVASCULAR DISORDERS (826F)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

Sections 4.00 and 104.00, Cardiovascular Impairments, of appendix 1 to subpart P of our regulation (20 CFR 404.1501 through 404.1599) describe those impairments that are considered severe enough to prevent a person from doing any gainful activity, or for a child claiming SSI payments under title XVI, that causes marked and severe functional limitations. We will revise 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 and uses the same medical criteria as the old-age, survivors, and disability insurance program.

Statement of Need:

These regulations are necessary because the current rules are now over ten years old. These rules will update the medical criteria and provide more information about how we evaluate cardiovascular impairments. They ensure that determinations of disability have a sound medical basis, that claimant 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 proposing only some of the revisions. However, we believe that all of these revisions are necessary because of the medical advances that have been made in treating and evaluating these types of impairments. These revisions also provide more information for our adjudicators to aid them in the evaluation of cardiovascular impairments; a number of the changes codify in our regulations guidance we have already provided to our adjudicators in other instruction we provided after we published the current rules.

Anticipated Cost and Benefits:

We anticipate that when finalized, these rules will result in negligible program and administrative costs.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	09/16/04	69 FR 55874
NPRM Comment Period End	11/15/04	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 0960–AF48

SSA

156. RULES FOR HELPING BLIND AND DISABLED INDIVIDUALS ACHIEVE SELF–SUPPORT (506F)

Priority:

Other Significant

Legal Authority:

42 USC 1383b(d)

CFR Citation:

20 CFR 416.1180; 20 CFR 416.1181; 20 CFR 416.1226

Legal Deadline:

None

Abstract:

We will amend our regulations to explain how we implement section 203 of the Social Security Independence and Program Improvements Act of 1994 (Public Law 103-296). Section 203 of this law amended section 1633 of the Social Security Act to require us to establish by regulations criteria for time limits and other criteria related to plans to achieve self-support (PASS). The law requires that the time limits take into account the length of time that a person needs to achieve his or her occupational goal, within a reasonable period, and other factors as determined by the Commissioner to be appropriate.

Statement of Need:

This regulation is necessary to implement the changes in section 1633 of the Social Security Act regarding time limits and other criteria deemed necessary by the Commissioner.

Summary of Legal Basis:

42 U.S.C. 1383b authorizes the Commissioner to promulgate regulations for the purpose of establishing criteria for time-limits and other criteria deemed necessary related to the PASS program.

Alternatives:

None.

Anticipated Cost and Benefits:

We estimate that the administrative impact would be negligible.

Risks:

At this time we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	07/11/05	70 FR 39689
NPRM Comment Period End	09/09/05	
Final Action	04/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Previously reported as 0960–AE17

RIN: 0960–AG00

SSA

157. MEDICARE PART D SUBSIDIES (1024F)

Priority:

Other Significant

Legal Authority:

PL 108–173; 42 USC 405; 42 USC 902(a)(5); 42 USC 1395w–101; 42 USC 1395w–114; 42 USC 1395w–115

CFR Citation:

20 CFR 418.3001 (new); 20 CFR 418.3005 (new); 20 CFR 418.3010 (new); 20 CFR 418.3101 (new); 20 CFR 418.3105 (new); 20 CFR 418.3110 (new); 20 CFR 418.3115 (new); 20 CFR 418.3120 (new); 20 CFR 418.3123 (new); 20 CFR 418.3125 (new); 20 CFR 418.3201 (new); 20 CFR 418.3205 (new); 20 CFR 418.3210 (new); 20 CFR 418.3215 (new); 20 CFR 418.3220 (new); 20 CFR 418.3225 (new); 20 CFR 418.3230 (new); 20 CFR 418.3301 (new); 20 CFR 418.3305 (new); 20 CFR 418.3310 (new); 20 CFR 418.3315 (new); 20 CFR 418.3320 (new); 20 CFR 418.3325 (new); 20 CFR 418.3330 (new); 20 CFR 418.3335 (new); 20 CFR 418.3340 (new); 20 CFR 418.3345 (new); 20 CFR 418.3350 (new); 20 CFR 418.3401 (new); 20 CFR 418.3405 (new); 20 CFR 418.3410 (new); 20 CFR 418.3415 (new); 20 CFR 418.3420 (new); 20 CFR 418.3425 (new); 20 CFR 418.3501 (new); 20 CFR 418.3505 (new); 20 CFR 418.3510 (new); 20 CFR 418.3515 (new); 20 CFR 418.3601 (new); 20 CFR 418.3605 (new); 20 CFR 418.3610 (new); 20 CFR 418.3615 (new); 20 CFR 418.3620 (new); 20 CFR 418.3625 (new); 20 CFR 418.3630 (new); 20 CFR 418.3635 (new); 20 CFR 418.3640 (new); 20 CFR 418.3645 (new); 20 CFR 418.3650 (new); 20 CFR 418.3655 (new); 20 CFR 418.3665 (new); 20 CFR 418.3670 (new); 20 CFR 418.3675 (new); 20 CFR 418.3680 (new)

Legal Deadline:

None

Abstract:

We will add to our regulations a new part 418 to contain rules that we will apply when we evaluate applications for premium and cost-sharing subsidies under the Medicare program. We will include a new subpart D, Medicare part D Subsidies, to this part. This new subpart will contain the rules that we use to determine eligibility for premium and cost-sharing subsidies under the Medicare part D program, which was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. (Medicare part D is a program for voluntary prescription drug coverage effective January 1, 2006.) These final rules will describe: What the new subpart is about; how we determine whether you are eligible for premium and cost-sharing subsidies; how we redetermine your eligibility for a subsidy; how you apply for a subsidy; how we evaluate your income and resources; when your eligibility for premium and cost-sharing subsidies terminates; how you may report changes in your circumstances; and how you can appeal a determination we make under the part D subsidy program.

Statement of Need:

SSA is responsible for determining premium and cost-sharing subsidy eligibility for the new Medicare Prescription Drug Benefit. The provision will be implemented in January 2006.

Summary of Legal Basis:

Section 1860D-14 of the Social Security Act provides for premium and cost-sharing subsidies for certain low-income individuals, and directs the Social Security Administration to develop a simplified application process.

Alternatives:

None.

Anticipated Cost and Benefits:

The Centers for Medicare and Medicaid Services (CMS) has developed detailed cost estimates for implementation of the Prescription Drug Benefits program. These costs are explained in a CMS Notice of Proposed Rulemaking (CMS-4068P; 69 FR 46632; 08/03/2004). The administrative costs are estimated to be about $1 billion over the 5-year period from fiscal year (FY) 2004 through FY 2008. The benefit of developing agency regulations for a simplified subsidy application are that many beneficiaries with incomes below 150 percent of the poverty level, and limited resources, will be able to get help with paying premiums and cost-sharing for Medicare part D coverage.

Risks:

There are inherent risks in any form of public benefit which requires means-testing. The risks for the prescription drug benefit premium and cost-sharing subsidy program are increased by the requirement that SSA use a simplified application process.

Timetable:

Action	Date	FR Cite
NPRM	03/04/05	70 FR 10558
NPRM Comment Period End	05/03/05	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AG03

SSA

158. CIVIL MONETARY PENALTIES, ASSESSMENTS, AND RECOMMENDED EXCLUSIONS (2362F)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5); 42 USC 1320a–8; 42 USC 1320b–10

CFR Citation:

20 CFR 498.100 TO 498.104; 20 CFR 498.106; 20 CFR 498.109; 20 CFR 498.114; 20 CFR 498.128

Legal Deadline:

None

Abstract:

These final regulations will amend the existing regulations for the implementation of section 1129 of the Social Security Act (42 U.S.C. 1320a-8) to:

(1) Reflect the expanded authority under section 1129 to impose a civil monetary penalty and assessment, as applicable, for fraud or similar fault involved in the receipt of benefits under title VIII of the Social Security Act; and (2) add as new categories for civil monetary penalty and assessment under section 1129 (i) representative payees with respect to wrongful conversion, and (ii) individuals who withhold the disclosure of material facts to the SSA if the person knows or should know that withholding of such disclosure is misleading.

These final regulations will also amend the existing regulations for the implementation of section 1140 of the Social Security Act (42 U.S.C. 1320b-10) to: (1) Require an advertiser or direct marketer who offers to assist an individual in obtaining products or services for a fee, that SSA otherwise provides free of charge, to include a written notice on the solicitation/mailing that the product or service is available from SSA free of charge; and (2) expand the list of terms in section 1140 that encompass the scope of words or phrases that the statute prohibits from being used in a misleading manner.

Statement of Need:

These final regulations are necessary to reflect and implement the amendments to sections 1129 and 1140 of the Social Security Act (42 U.S.C. 1320A-8 and 42 U.S.C. 1320b-10) made by Public Laws 106-169 and 108-203.

Summary of Legal Basis:

These final regulations will reflect and implement section 251(b)(6) of Public Law 106-169 and sections 111, 201, 204, and 207 of Public Law 108-203.

Alternatives:

None.

Anticipated Cost and Benefits:

Cost—The administrative cost impact of this rule is attributable to enacted legislation and not to the regulation itself, and will be negligible (i.e., less than $2 million or 25 workyears).

Benefits—These final regulations are intended to enhance our program integrity efforts.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/23/05	70 FR 14603
NPRM Comment Period End	05/23/05	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

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 2006, the Commission's significant rulemaking activities will involve addressing risks of fire associated with ignition of upholstered furniture and of mattresses and bedding. The emphasis on this rulemaking activity in the Commission's FY 2006 regulatory plan is consistent with the Commission's statutory mandate and its criteria for setting priorities.

CPSC

PROPOSED RULE STAGE

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159. 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. The staff is currently analyzing comments and preparing alternatives for Commission consideration.

CPSC is also considering possible impacts of flame-retardant chemical use on worker safety and the environment. At the CPSC staff's request, the National Institute for Occupational Safety and Health studied potential worker exposure to and risks from certain flame-retardant chemicals that may be used by textile and furniture producers to comply with an upholstered furniture flammability standard. NIOSH preliminarily concluded that significant worker health effects were unlikely. CPSC staff is also working with the Environmental Protection Agency to (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-friendly flame retardants under a Design for the Environment industry/government partnership.

Statement of Need:

For 1995-1999, an annual average of approximately 6,600 residential fires in which upholstered furniture was the first item to ignite resulted in an estimated 460 deaths, 1,110 civilian injuries, and about $130 million in property damage that could be addressed by a flammability standard. The total annual societal cost attributable to these upholstered furniture fire losses was approximately $2.75 billion. This total includes fires ignited by small open-flame sources and cigarettes.

Summary of Legal Basis:

Section 4 of the Flammable Fabrics Act (FFA) (15 U.S.C. 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is ''needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage.'' The Commission's regulatory proceeding could result in several actions, one of which could be the development of a mandatory standard requiring that upholstered furniture sold in the United States meet mandatory labeling requirements, resist ignition, or meet other performance criteria under test conditions specified in the standard.

Alternatives:

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of upholstered furniture; (2) The Commission could issue mandatory requirements for labeling of upholstered furniture, in addition to, or as an alternative to, the requirements of a mandatory flammability standard; and (3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result.

Anticipated Cost and Benefits:

The estimated annual cost of imposing a mandatory standard to address ignition of upholstered furniture will depend upon the test requirements imposed by the standard and the steps manufacturers take to meet those requirements. Again, depending upon the test requirements, a standard may reduce cigarette and small open flame-ignited fire losses, the annual societal cost of which was $2.75 billion for 1995-1999. Thus, the potential benefits of a mandatory standard to address the risk of ignition of upholstered furniture could be significant, even if the standard did not prevent all such fires.

Risks:

The estimated average annual cost to society from all residential fires associated with upholstered furniture was $2.75 billion for 1995-1999. Societal costs associated with upholstered furniture fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs.

Timetable:

Action	Date	FR Cite
ANPRM	06/15/94	59 FR 30735
ANPRM Comment Period End	08/15/94	
Staff Briefing of Commission on NPRM	12/18/97	
Commission Voted To Defer Action Pending Results of Toxicity Hearing	03/02/98	
Commission Hearing May 5 & 6, 1998 on Possible Toxicity of Flame Retardant Chemicals	03/17/98	63 FR 13017
NAS Study Completed (Required by Congress)	07/10/00	
Staff Sent Briefing Package to Commission	11/01/01	
Meeting Notice	03/20/02	67 FR 12916
Staff Held Public Meeting	06/18/02	
Second Day of Public Meeting	06/19/02	
Staff Sent Analysis of Information From Public Meeting to the Commission	02/06/03	
Staff Sent Regulatory Options to Commission	07/12/03	
Notice of September 24 Public Meeting	08/27/03	68 FR 51564
Commission Decision	10/17/03	
ANPRM	10/23/03	68 FR 60629
ANPRM Comment Period End	12/22/03	
Staff Held Public Meeting	10/28/04	
Staff Held Public Meeting	05/18/05	
Staff Sends Briefing Package to Commission	01/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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CPSC

FINAL RULE STAGE

160. PROPOSED STANDARD TO ADDRESS OPEN–FLAME IGNITION OF MATTRESSES/FOUNDATION SETS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

15 USC 1193, Flammable Fabrics Act; 5 USC 801

CFR Citation:

16 CFR 1633

Legal Deadline:

None

Abstract:

On October 11, 2001, the Commission published an advance notice of proposed rulemaking (ANPRM) to begin a proceeding for development of a flammability standard to address risks of death, injury, and property damage from fires associated with ignition of mattresses/bedding by small open-flame sources such as lighters, candles, or matches. This ANPRM was issued after the Commission staff conducted a field investigation study of these incidents and worked with industry members to improve consumer information programs and conducted research to define and measure the fire hazard presented by mattress/bedding ignitions in residential fires.

The Commission also received four petitions from the Children's Coalition for Fire-Safe Mattresses proposing: (1)

an open flame standard similar to the full-scale test set forth in California Technical Bulletin 129; (2) an open flame standard similar to the component test set forth in British Standard 5852; (3) a warning label for mattresses warning of polyurethane foam fire hazards; and (4) a permanent, fire-proof mattress identification tag. The Commission granted the first two petitions and denied the others.

The Commission staff reviewed public comments on the ANPRM and continued working with the Sleep Products Safety Council (representing manufacturers and suppliers to the industry), the National Institute of Standards and Technology, the State of California Bureau of Home Furnishings, and others to complete the development of an appropriate test method and criteria for a standard to address open flame ignition of mattresses. In 2004, the staff prepared a decision package for Commission consideration, including a draft proposed standard with supporting materials, draft notice of proposed rulemaking (NPRM), and possible options to separately address the bedclothes contribution to mattress fires. On December 22, 2004, the Commission voted to publish the NPRM for mattresses (and to separately address bedclothes by publishing an ANPRM for bedclothes). The staff will evaluate public comments received on the NPRM and prepare a briefing package for Commission decision on publishing a final mattress standard.

Statement of Need:

Based on national fire estimates for the years 1995-1999, ignition of mattresses and bedding resulted in an estimated 18,500 residential fires, 440 civilian deaths, 2,160 civilian injuries, and $259.5 million in property loss annually that could be addressed by a flammability standard. Since mattress fires often involve the ignition source of burning bedding, initially ignited by a smaller source, a standard incorporating an ignition source representing burning bedding could address deaths and injuries from these fires.

Summary of Legal Basis:

Section 4 of the Flammable Fabrics Act (FFA) (15 U.S.C. 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is ''needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage.'' The Commission's regulatory proceeding could result in the development of a mandatory standard requiring that mattresses sold in the United States meet mandatory labeling requirements and performance criteria limiting the size of the fire produced when a mattress is exposed to a large ignition source representing burning bedclothes.

Alternatives:

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of mattresses;

(2) The Commission could issue mandatory requirements for labeling of mattresses, in addition to, or as an alternative to, the requirements of a mandatory flammability standard; or

(3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result.

Anticipated Cost and Benefits:

The estimated annual cost of imposing a mandatory standard to address ignition of mattresses by open-flame sources will depend upon the performance requirements imposed by the standard and the steps manufacturers take to meet those requirements. A standard incorporating an ignition source representing burning bedclothes could address deaths and injuries from fires caused by smoking materials, traditional small open flame sources, as well as other heat sources.

Risks:

The estimated total cost to society from all residential fires associated with mattresses/bedding was about $3 billion in 1999. Societal costs associated with mattress/bedding fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs.

Timetable:

Action	Date	FR Cite
ANPRM	10/11/01	66 FR 51886
ANPRM Comment Period End	12/10/01	
Staff Sends Briefing Package to Commission	11/01/04	
Staff Briefs Commission on NPRM Draft	12/09/04	
Commission Decision	12/22/04	
NPRM	01/13/05	70 FR 2470
Public Hearing	03/03/05	
NPRM Comment Period End	03/29/05	
Staff Sends Briefing Package to Commission	01/00/06	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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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 2006 that would be required to be included in a regulatory plan.

The Finance Board's highest regulatory priorities during 2006 continue to be to ensure the safety and soundness of the Bank System and to ensure that the Banks fulfill their housing finance and community investment mission. In furtherance of these statutory mandates, the Finance Board expects to consider regulations that will:

- More clearly delineate the responsibilities and the accountability of the board of directors for governance of a Bank, thereby strengthening the role of the boards in the Banks' operations;
- Streamline the Finance Board's review of new business activities proposed by a Bank to more clearly focus the regulatory review process on ensuring that a new product, service, or activity will not endanger the continued safe and sound operation of the Bank;
- Streamline the community support requirements to eliminate unnecessary regulatory burden, while preserving the statutory intent of ensuring that members' access to long-term advances reflects such factors as their record of performance under the Community Reinvestment Act and their record of lending to first-time homebuyers;
- Improve the operations and efficiency of the Affordable Housing Program by more clearly delineating the Banks' responsibilities for program administration and for satisfying the statutory directive that the subsidy benefit very low-income, low-income, and moderate-income households.
- 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 basic vision. The Commission's vision is to administer the shipping statutes as effectively as possible to provide fairness and efficiency in the United States maritime commerce. The Commission's regulations are designed to implement each of the statutes the Agency administers in a manner consistent with this vision in a way that minimizes regulatory costs, fosters economic efficiencies, and promotes international harmony.

The Ocean Shipping Reform Act of 1998 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 rules and 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.

The Commission also oversees the financial responsibility of passenger vessel operators to indemnify passengers and other persons in cases of death or injury and to indemnify passengers for nonperformance of voyages. The Commission has received a number of comments in response to its rulemaking proposal to update the nonperformance coverage requirements to correspond more closely with current industry conditions. Included among these submissions is a request that the Commission consider a report providing an update on developments in the industry. The Commission is continuing its review of this request as well as the other matters submitted in this proceeding.

The principal objective or priority of the Agency's current regulatory plan will be to continue to assess major existing regulations for continuing need, burden on the regulated industry, and clarity. The Commission 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. The Commission, however, is also charged with the responsibility of issuing and enforcing regulations under a number of statutes. Pursuant to the FTC Act, for example, the Commission currently has in place thirteen trade regulation rules. The Commission also has adopted a number of voluntary industry guides. Most of the regulations and guides pertain to consumer protection matters and are generally intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions.

Industry Self-Regulation and Compliance Partnerships With Industry

The Commission continues to be committed to protecting 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. Privacy, information security, and information sharing continue to be at the forefront of the Commission's consumer protection program:

1. During November 2004, the Commission convened an E-mail Authentication Summit, co-sponsored by the National Institute of Standards and Technology at the Commerce Department. Since then, the Commission has been encouraging the development of a compatible authentication standard that would provide accountability for email communication.
2. 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.
3. The Commission held a 2004 public workshop on spyware—which can surreptitiously install itself on a personal computer and wreak havoc—and 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.
4. The Commission has also undertaken efforts to educate consumers about the risks associated with downloading and using peer-to-peer file-sharing software programs. A March 2005 ''Cyber Security Tip'' warns consumers that use of such 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.
5. 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.

Additionally, in 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 a self-regulatory system that rates or labels 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. 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, although the Commission found that violent R-rated movies and M-rated games were still being advertised in media with large teen audiences. The recording industry 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 Commission also noted that there remained 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, even though the movie theater industry has made real progress in this area, and to a lesser extent so have game retailers. 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/2004/07/040708kidsviolencerpt.pdf. Most recently, the Commission has issued consumer education materials to assist parents in understanding video game ratings.

The Commission also supports 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 also continues to encourage companies in the alcohol industry to engage in self-regulation to ensure that advertising for products containing alcohol is not directed at underage youths. The Commission has worked and will continue to work with industry to facilitate compliance with the improved 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://ftc.gov/os/2003/09/alcohol08report.pdf.

In addition, in the weight loss product advertising area, the Commission has consistently proposed a strengthened self-regulatory response from the industry and more media responsibility to address the widespread problem of blatantly false efficacy claims. Specifically, the Commission authorized the release of a media reference guide to assist media in identifying facially false weight-loss claims. Federal Trade Commission Staff, *Red Flag: A Reference Guide for Media on Bogus Weight Loss Claim Detection* (2003), available at: http://www.ftc.gov/bcp/online/pubs/buspubs/redflag.pdf. 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 supported a joint effort by the Electronic Retailing Association and the Better Business Bureau's National Advertising Review Council to develop a self-regulatory, rapid review process, the Electronic Retailing Self-Regulation Program, that could promptly address deceptive infomercial claims.

In a related area, the Commission and the Department of Health and Human Services (HHS) jointly sponsored a workshop during June 2005 that examined marketing, self-regulation, and childhood obesity (materials are available at http://www.ftc.gov/bcp/workshops/foodmarketingtokids/). The workshop brought together a wide range of speakers to examine ways, including self-regulation, to best promote competition among marketers of healthy foods and the dissemination of good information so that consumers can make healthy food choices.

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, 50 companies have been granted ''leniency'' for self-reported minor violations of FTC textile regulations.

The Commission has also engaged industry in compliance partnerships in at least two areas involving the funeral and franchise industries. Specifically, the Commission's Funeral Rule Offender Program, conducted in partnership with the National Funeral Directors Association, is designed to educate funeral home operators found in violation of the requirements of the Funeral Rule, 16 CFR part 453, so that they can meet the rule's disclosure requirements. Approximately 226 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, seventeen companies have agreed to participate in the program.

Rulemakings Required by Statute

In 2003, the Congress enacted several laws requiring the Commission to undertake rulemakings and studies. These include at least 25 new rulemakings and eight studies required by the Fair and Accurate Credit Transactions Act of 2003, Pub. L. No. 108-159 (FACTA or the FACT Act); the rulemakings and reports required by the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, Pub. L. No. 108-187 (CAN-Spam Act); and the rulemaking pursuant to the Federal Deposit Insurance Corporation Improvements Act of 1991, Pub. L. 102-242. These rulemakings are proceeding according to schedule and are detailed more extensively in the Unified Agenda. 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 requires the Commission to complete two rulemakings while authorizing other discretionary rulemaking actions. Pursuant to this statute the Commission is 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 is required to complete this rulemaking within two years of enactment. The statute also requires the Commission to issue labeling requirements for ceiling fans concerning the electricity used by the fans to circulate air in a room. The statute also amends 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.

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). The comment period closed on October 12, 2005.

Ten-Year Review Program

In 1992, the Commission implemented a program to review its rules and guides regularly. The Commission's review program is patterned after provisions in the Regulatory Flexibility Act, 5 USC 601-612. Under the Commission's program, however, rules have been reviewed on a ten-year schedule as resources permit. For many rules this has resulted in more frequent reviews than is generally required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, in that it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a ''significant economic impact upon a substantial number of small entities.'' 5 USC 610. The program's goal is to ensure that all of the Commission's rules and guides remain beneficial and in the public interest. It complies with the Small Business Regulatory Enforcement Act of 1996, Pub. L. 104-121. This program is consistent with the Administration's ''smart'' regulation agenda to streamline regulations and reporting requirements and Section 5(a) of Executive Order 12866, 58 FR 51735 (Sept. 30, 1993).

As part of its continuing ten-year plan, the Commission examines the effect of rules and guides on small businesses and on the marketplace in general. These reviews often lead to the revision or rescission of rules and guides to ensure that the Commission's consumer protection and competition goals are achieved efficiently and at the least cost to business. In a number of instances, the Commission has determined that existing rules and guides were no longer necessary nor in the public interest. As a result of the review program, the Commission has repealed 48 percent of its trade regulation rules and 57 percent of its guides since 1992.

Calendar Year 2005 Reviews

All of the matters currently under review pertain to consumer protection and are intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions. During early 2005, the Commission announced its ten-year schedule of review and that it would initiate the review of two rules during 2005: (1) the Deceptive Advertising as to Sizes of Viewable Pictures Shown by Television Receiving Sets Rule (the Picture Tube Rule), 16 CFR part 410, and (2) the Children's Online Privacy Protection Rule (COPPA Rule), 16 CFR part 312. 70 FR 2074 (Jan. 12, 2005). On April 7, 2005, the Commission requested comments on the applicability and use of the Picture Tube Rule, particularly in light of an array of new types of televisions now available to consumers. 70 FR 17623. The notice asked nine specific questions about the rule that the public may wish to address. The comment period ended on June 6, 2005, and staff plans to forward its recommendation to the Commission in late 2005. A regulatory review of the COPPA rule was also required by the COPPA statute within five years after the rule became effective. On Apr. 22, 2005, the Commission requested comments about the implementation of the COPPA Rule. 70 FR 21107. The comment period ended on June 27, 2005, and staff plans to forward recommendations to the Commission by the end of 2005.

Ongoing Reviews

It is expected that during 2006, the Commission will issue separate notices requesting comments both on the Statement of General Policy or Interpretations under the Fair Credit Reporting Act (also known as FCRA Commentary) and for the Guides Concerning the Use of Endorsements and Testimonials in Advertising. Other reviews are continuing.

First, for the Telemarketing Sales Rule (TSR), 16 CFR part 310, the Commission published an NPRM on November 17, 2004, proposing to permit prerecorded message telemarketing when there is an established business relationship between the caller and a consumer as long as a consumer has the opportunity to make a do not call request at the outset of the message. At the same time, and in response to a request for reconsideration on the FTC's calculation of call abandonment rates on a daily basis, the NPRM also requested comments and factual information supporting a requested switch from the current policy of measuring the 3% abandoned call ratio from a per day calculation to an average of calls abandoned over a 30-day period. The NPRM also stated that, pending completion of the rulemaking, the FTC would not enforce the TSR's current call abandonment provisions against callers who engage in prerecorded message telemarketing when there is an established business relationship provided they comply with the proposed requirements. The comment period closed on January 10, 2005, and staff anticipates forwarding its recommendation to the Commission by October 2005.

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 the end of 2005.

Third, for the Hart-Scott-Rodino Premerger Notification Rules (HSR Rules), Bureau of Competition staff anticipates forwarding a recommendation to the Commission by the end of 2005 to update the base year used in Item 5 of the Premerger Notification Form Response from 1997 to 2002. In addition, the Commission published an NPRM proposing to amend 16 CFR part 803 of the HSR Rules to address the issue of stale filings and to permit filing parties to provide Internet links to certain documents in lieu of paper copies. 70 FR 47733 (Aug. 15, 2005).

Fourth, for the rulemaking on Privacy of Consumer Financial Information, 16 CFR part 313, the Commission and banking agencies published an ANPRM and requested public comments on a variety of subjects including the goals, language, and mandatory or permissible aspects of privacy notices. 68 FR 75164 (Dec. 30, 2003). Since the issuance of rules in 2000 in accordance with 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 agencies are reviewing comments and continuing to work together to determine the next steps.

Fifth, 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 2006.

Sixth, 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 the end of 2005.

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. Staff anticipates forwarding its recommendation to the Commission by early 2006.

Final Actions

First, since publication of the 2004 Regulatory Plan, the Commission has taken final actions on several rulemakings. For the Children's Online Privacy Protection Rule (COPPA Rule), 16 CFR part 312, the Commission issued a final rule, 70 FR 21104, effective April 21, 2005, extending a previously published temporary e-mail verification provision until the conclusion of the Commission's rule review. That provision allows operators of websites and online services that collect personal information from children only for internal use to obtain verifiable parental consent via e-mail plus an additional step to verify that the person consenting is the child's parent.

Second, the Commission is actively issuing rules required to implement the Fair and Accurate Credit Transactions Act (FACTA or Fact Act). These rulemakings are sometimes conducted in conjunction with other federal financial regulatory agencies.

1. The Commission issued final model notices on November 30, 2004, 69 FR 69776, summarizing consumers' identity theft rights and mounting a public education campaign regarding consumers' new identity theft rights.
2. The Commission published a Final Fraud Alerts Rule on November 3, 2004. 69 FR 63922. This rule defines certain terms that are relevant to consumers' new identity theft rights including: ''identity theft'' and ''identity theft report''; the duration of an ''active duty alert''; and the ''appropriate proof of identity'' for purposes of sections 605A (fraud alerts and active duty alerts), 605B (consumer report information blocks), and 609(a)(1) (truncation of Social Security numbers) of the FCRA, as amended by the FACT Act.
3. The Commission, in consultation with the banking agencies and the NCUA, published a final rule on January 31, 2005, that enhances notices to consumers about their right to opt out of prescreened solicitations. 70 FR 5022.
4. The Commission, in coordination with the banking agencies, NCUA, and the SEC, also issued a rule concerning the proper disposal of credit report information and records. 69 FR 68690 (Nov. 24, 2004). The Disposal Rule was effective on June 1, 2005.

5. On April 27, 2005, the Commission, in consultation with the Federal banking agencies and NCUA, issued notice of its publication of guidance *Take Charge: Fighting Back Against Identity Theft*, which is available at www.consumer.gov/idtheft or by writing to FTC, Consumer Response Center, Room 130-B, 600 Pennsylvania Avenue, NW, Washington, DC 20580. This document contains model forms and describes procedures that identity theft victims may use for contacting and informing creditors and consumer reporting agencies of the fraud.

Third, for the rulemaking implementing the Controlling the Assault of Non-Solicited Pornography and Marketing Act (the CAN-SPAM Act), the Commission announced the final rule defining the relevant criteria to facilitate the determination of the primary purpose of an electronic message on December 16, 2004, which was published in the Federal Register on Jan. 19, 2005, 70 FR 3110. The rule became effective on March 28, 2005.

Fourth, for the HSR Rules, the Commission issued a Final Rule to reconcile, as far as practical, the current disparate treatment of corporations, partnerships, limited liability companies, and other types of non-corporate entities under the rules. *See* 70 FR 11502 (Mar. 8, 2005). Among other things, the amendments addressed acquisitions of interests in unincorporated entities; formations of unincorporated entities; and the application of certain exemptions, including the intraperson exemption.

Fifth, the Commission issued amendments to the R-Value Rule for home insulation, 16 CFR part 460, requiring disclosures that will make it easier to ensure that the correct amount of loose-fill insulation is installed in homes; update the required tests for some insulation products; delete disclosures for insulation products no longer sold; and eliminate duplicative disclosure requirements for sellers of do-it-yourself home insulation. 70 FR 31258 (May 31, 2005). The amendments will become effective on Nov. 28, 2005.

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 April 22, 2005. 70 FR 20848. The comment period ended on June 1, 2005. The Commission published final fee changes for the National Do-Not-Call Registry on July 27, 2005, with an effective date of September 1, 2005. 70 FR 43273.

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. As stated above, since 1992 the Commission has repealed 48 percent of its trade regulation rules and 57 percent of its industry guides that existed in 1992 because they had ceased to serve a useful purpose. In sum, the Commission's regulatory actions are aimed at efficiently and fairly promoting the ability of ''private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.'' Executive Order 12866, section 1.

Rulemakings that Respond to Public Regulatory Reform Nominations

During March 2002, OMB requested public nominations for regulatory reforms. The Office of Information and Regulatory Affairs (OIRA) conducted a preliminary review of the public comments received and found five FTC activities that one or more commenters had nominated for reform. In a March 7, 2003 letter, the FTC responded that the agency systematically reviews all regulations and guides on a ten-year basis and explained how the agency had already reviewed or was about to review the activity at issue or why some of the other activities were not good candidates for reform as contemplated by the Smarter Regulations Report. 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 or the Commission). The stated purpose of the Commission is to regulate the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments. It is the Commission's intention to provide regulation of Indian gaming to adequately shield it from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players.

The regulatory priorities for the next fiscal year reflect the Commission's commitment to upholding the principles of IGRA. The gaming industry changes rapidly with advancements in machine technology. It is crucial for the vitality of Indian gaming that regulators have the ability to respond quickly to these changes. To that end, the Commission has decided that the development of technical standards and game classifications for gaming machines and related gaming systems is an important initiative for the promotion and protection of tribal gaming.

Additionally, the Commission will be continuing to make technical amendments to the minimal internal control standards. These amendments will correct isolated problems that have been brought to the Commission's attention by tribal gaming operators and regulators.

The Commission has been innovative in using active outreach efforts to inform its generic policy development and its rulemaking efforts. For example, the Commission has had great success in using regional meetings, both formal and informal, with tribal governments to gather views on current and proposed Commission initiatives. The Commission anticipates that these consultations with regulated tribes will play an important role in the development of technical standards.

NIGC

PROPOSED RULE STAGE

161. 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	11/00/05	
Fourth NPRM	To Be	Determined

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

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NIGC

162. 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	05/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Federalism:

Undetermined

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NIGC

163. 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. 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	05/00/06	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Federalism:

Undetermined

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