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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'' (58 FR 51735; October 4, 1993) 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, as part of their submissions to the fall edition of the Unified Agenda, agencies prepare 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 all of these requirements. This publication contains the plans of 27 Federal agencies and the unified agendas of these and 34 other Federal agencies.

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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 3039, Washington, DC 20405, (202) 482-7340. You may also send comments to us by e-mail at:

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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 27 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 61 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 E.O. 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 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. The agendas do not contain regulations that were excluded under Executive Order 12866, such as those 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 within it or to confine their regulatory activities to those regulations that appear in this publication.

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 12866

Executive Order 12866 entitled ''Regulatory Planning and Review'' (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'' (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'' (May 22, 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. If the issuing agency believes that a rule may be major, it indicates this under the ''Priority'' heading of the entry. 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. The Center provides a table of contents that appears in the Agenda after the agency preamble. For each agency that requests it, the table of contents includes a section listing entries that the agency is reporting as withdrawn, duplicate, merged, or transferred. Following the table of contents is a description of each 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 in the rulemaking process.

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 in their rulemaking process.

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 appears in this publication as the start of a new rulemaking cycle.

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 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 entries 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 entries that agencies believe may have effects on levels of government.

- Index E lists entries 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 E.O. 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 an agency believes that a rule may be ''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, the agency indicates this 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 12/00/02 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 one or more persons 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 Info — one URL directing the reader to an Internet site that provides more information about the RIN entry.

URL for Public Comments — one URL directing the reader to an Internet site that accepts public comments on the RIN entry.

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'' issued on May 18, 2001 (66 FR 28355; May 22, 2001).

Related RINs— one or more, past or current RIN(s) 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** may 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 E.O. 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. The agency issues an ANPRM before it develops a detailed proposed rule. The 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, and each title covers 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 — 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 105-4 is the fourth public law of the 105th 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 rulemaking cycle listed in **The Regulatory Plan** and the Unified Agenda, as directed by E.O. 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

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, and each title covers 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, Washington, DC 20402-9325, (202) 512-1800.

Copies of individual agency materials may be available directly from the agency. 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 October 1995 are also available in electronic form. You can search the Agenda and the Plan on the World Wide Web at:

http://reginfo.gov

You may also search the Plan and the Agenda on the Government Printing Office's GPO Access, which is accessible through:

http://www.access.gpo.gov

Dated: October 30, 2002.

Ronald C. Kelly,

Executive Director.

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The Regulatory Plan

THE INTRODUCTION TO THE FALL 2002 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, food safety, transportation safety, quality health care, equal employment opportunity, energy security, educational quality, 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.

Citizen-centered service is a vital element of the President's Management Agenda and The Regulatory Plan is a vital piece of this initiative. The Regulatory Plan is published as part of the fall edition of the Unified Agenda of Federal Regulatory and Deregulatory Actions. The Regulatory Plan serves as a statement of the Administration's regulatory and deregulatory policies and priorities. The purpose of The Regulatory 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 take in the coming year.

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 ''smarter regulatory process'' that adopts new rules when markets fail to serve the public interest, simplifies and modifies existing rules to make them more effective and/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.

Smart regulatory policy is not uniformly pro-regulation or anti-regulation. It starts, of course, 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) in order to design regulations that achieve their ends in the most efficient and economical way — the smartest way. This means bringing to bear on the regulatory problem sound economic principles, the highest quality information, and the best possible science. This is not always an easy task — science and economics may point in very different directions for example — and does not mean the rote application of quantified data to reach policy decisions. In making regulatory decisions, we expect agencies to consider other attributes and factors that cannot be integrated readily in a benefit-cost framework, such as fairness and privacy, as well as benefit and cost items that can be quantified and expressed in monetary units. However, smart regulation is the result of the careful use of all available data and the application of broad principles established by the President.

In pursuing this goal of establishing a smarter regulatory system, the Bush Administration has increased the level of public involvement and trans-

parency in its review and clearance of new and existing regulations. First, OMB has solicited public suggestions for improving the quality of existing regulations. In OMB's draft 2002 Report to Congress on the Costs and Benefits of Regulation, OMB asked for public comment on a number of regulatory issues, including: (1) regulatory programs that need to be extended, modified or rescinded, (2) issues of regulatory analysis that need to be refined in OMB's formal guidance documents to agencies, and (3) ideas for new regulatory priorities that we can suggest to agencies in the form of prompt letters. This year, OMB has made every effort to publicize the public comment period, and at the President's request, OMB for the first time made available an electronic comment form. As a result, the public provided over 1700 comments, compared with 71 comments for last year's report. OMB is in the process of reviewing these comments and identifying candidates for reform. The results of this review will be published in our final report to Congress and shared with the agencies.

Second, OIRA has enhanced the transparency of OMB's regulatory review process to the public. By consulting the Web site, for example, the public can find information on rules that are formally under review at OMB, rules that have recently been cleared, and rules have been returned to agencies for reconsideration. OIRA has also increased the amount of information available on the OIRA Web site. 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 Presidents Management Council (September 20, 2001) on Presidential review of agency rulemaking by OIRA.

Third, the Bush Administration has 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 have now issued guidelines in effect as of October 1, 2002, under the Information Quality Law to ensure the ''quality, objectivity, utility, and integrity'' of all Federal information. 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. OMB worked toward this October 1 deadline for over a year, developing its Government-wide guidelines for the agencies, providing interpretive memos, organizing working groups, and meeting with agencies to give views on what the agency-specific guidelines should say.

In addition, under the agency guidelines, ''affected persons'' can petition if they believe that scientific, technical, economic, statistical or other information does not meet these standards and if necessary appeal a denial of such a petition. While OMB agreed with agencies to meld the information complaint resolution process into their established notice-and-comment rulemaking procedures, OMB ensured that substantive standards of quality, the information quality standards provided in both the OMB and agency guidelines, would remain applicable to any information disseminated in support of a regulation. Through the combination of ongoing agency commitment, public interaction with the agencies, and OMB oversight, the underlying information and resulting analyses that agencies rely upon in developing regulations should become ever ''smarter'' and more reliable.

Fourth, early OMB involvement is under way to increase the impact of OMB's analytical perspective. The OIRA Administrator has devised the ''prompt letter'' to agencies as a new way to suggest promising regulatory priorities. The prompt letter highlights issues that may warrant the attention of regulators. These prompt letters are not meant to have legal authority but are designed to bring issues to the attention of agencies in a transparent manner that permits public scrutiny and debate. Prompt letters may highlight regulations that should be pursued, rescinded, revised, or further investigated.

For example, OIRA's first set of prompts has suggested lifesaving opportunities at FDA, NHTSA, OSHA and EPA. In a letter to FDA, OIRA suggested that priority should be given to completing a promising rulemaking started in the previous Administration, a consumer labeling rule that would require food companies to report the trans-fatty acid content of foods. Trans-fats are now recognized as a significant contributor to coronary heart disease. 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.

In addition to increasing the level of public involvement and transparency in its review of regulations, the Bush Administration has aggressively sought coordination of Federal agencies to stimulate and foster the development of ''smarter'' regulations.

OIRA, for example, played a key role in implementing the Card Memorandum, a January 20, 2001, directive from the President's Chief of Staff, Andrew H. Card, Jr., to agency heads initiating the first regulatory action taken by the Bush Administration. As OMB discussed in its 2001 Report to Congress on the Costs and Benefits of Regulations, agencies conducted numerous reviews of new and pending regulations pursuant to the Card memo and a subsequent OMB memorandum to agencies. OIRA provided oversight of these agency actions. The 2002 Regulatory Plan continues OIRA's effort to ensure coordination across Federal agencies in pursuing regulatory policies.

Improvements Made to the 2002 Regulatory Plan

The Administration has modified the format and content of agencies' regulatory plans for the fall 2002 publication. Since The Regulatory Plan is integral in enhancing quality of Federal regulations, OMB instituted a number of changes to ensure that the public is provided with the information needed to understand and comment on the Federal regulatory agenda. Specifically, the 2002 Regulatory Plan has been modified to highlight several themes. These include:

1. Regulations that are related to the events of September 11, 2001.
2. Regulations that are of particular concern to small businesses.
3. Regulations that were among the 71 nominated by the public as reform candidates last year. (See OMB's 2001 Report to Congress on the Costs and Benefits of Regulations.)
4. Issues that have been the subject of an OIRA ''prompt letter.''

The regulatory improvements proposed in the 2002 Regulatory Plan may be incremental but promise to have a powerful positive long-run effect on the quality of Federal regulation. 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 Administration's 2002 Regulatory Priorities

The Administration's regulatory priorities can be grouped into five national policy objectives: (1) strengthening economic performance; (2) reducing barriers to the growth of small businesses, (3) improving public health and safety, (4) enhancing environmental protection, and (5) ensuring homeland security. The Administration is committed to pursuing regulatory actions that achieve each of these goals. Below are examples of regulatory priorities in the upcoming year that address each objective.

Strengthening Economic Performance

One of the Administration's primary goals is to strengthen the country's economic performance. Agencies across the Federal Government are actively pursuing this goal through regulatory changes. The Department of Housing

and Urban Development will undergo rulemakings on simplifying and improving the process of obtaining mortgages to reduce settlement costs to consumers. The rule simplifies the mortgage application process and allows a greater understanding of the upfront and long-term costs of a mortgage. The rule should strengthen market competition among mortgage providers and ultimately lower costs to consumers.

Similarly, the Department of Transportation will begin a review of its Computer Reservations System Regulations. The Department regulates computer reservations systems owned by airlines or airline affiliates that are used by travel agencies. The current rules are designed to prevent the systems from unreasonably prejudicing the competitive position of other airlines and to ensure that travel agencies can provide accurate and unbiased information to the public. The Department is reexamining its rules to see whether they should be readopted and, if so, whether they should be changed in response to greater use of the Internet in airline reservations and ticketing and changes in the industry

Reducing Barriers to the Growth of Small Business

This Administration has endeavored to encourage the growth of small businesses in our economy. As President George W. Bush has noted, ''Wealth is created by Americans — by creativity and enterprise and risk-taking. But government can create an environment where businesses and entrepreneurs and families can dream and flourish.'' For example, the Small Business Administration will pursue rulemaking on the HUBZone Empowerment Contracting Program. This regulation will address eligibility requirements for small business concerns owned by Native American tribal governments and community development corporations and the addition of new HUBZone areas called redesignated areas.

Improving Public Health and Safety

The Federal Government's role in improving public health and safety is broad in scope. The Administration's 2002 regulatory priorities include a Department of Labor rulemaking on child labor, Regulations, Orders and Statements of Interpretation. This regulation will set forth the permissible industries and occupations in which 14- and 15-year-olds may be employed, and specify the number of hours in a day and in a week, and time periods within a day, that such minors may be employed.

The Department of Energy is addressing a different area of health and safety in its regulatory proposal to examine radiation protection of the public and the environment. This regulation will set forth 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 include a dose limitation system for the protection of the public and reporting and monitoring requirements.

The Department of Health and Human Services' Food and Drug Administration (FDA) will issue a rule on Food Labeling Requirements for Trans-Fatty Acids. This rule will specify how trans-fatty acids, which have been shown to have adverse health consequences, should be labeled on food products.

Enhancing Environmental Protection

Environmental protection is an integral consideration in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade. These factors are similarly considered in establishing environmental policy. The Administration is dedicated to enhancing environmental protection through smart regulations, based on the best scientific data available.

The Environmental Protection Agency (EPA) is considering a new rulemaking to reduce the particulate matter and nitrogen oxide emissions from diesel-

powered non-road vehicles and equipment. Non-road engines emit significant amounts of fine particles and nitrogen oxide emissions; these pollutants are associated with a variety of adverse health effects, ranging from lost work days and greater numbers of hospital admissions to premature mortality. The proposal will evaluate not only new emission control devices that would be required for new engines, but also the reductions in sulfur levels that are likely to be needed to enable the control systems to operate effectively. This comprehensive systems approach is similar to that taken for the heavy-duty diesel highway rule for trucks and buses that takes effect in the 2006-2007 timeframe. EPA plans to publish a formal proposal for public comments early next year.

EPA will also propose two companion rules designed to protect drinking water against the risks of both microbial pathogens and the disinfectants that are used to control them. The rules will enhance existing monitoring and treatment requirements to ensure that risks from disinfection byproducts, which have been linked to various adverse health effects, are minimized, without compromising the important protection they provide against pathogens.

Ensuring Homeland Security

After the shocking terrorist attacks of September 11, 2001, the American public looked to the Federal Government to take action not only to prevent future security threats but also to provide relief for individuals affected by the tragedies. In response, the Federal Government revisited its current practices and procedures and sought solutions to address these concerns. Several agencies, including the Departments of Justice, Transportation, Labor, Health and Human Services, Commerce, the Office of Personnel Management, Small Business Administration, and the Office of Management and Budget, issued new regulations.

The Administration will continue to pursue regulatory actions necessary to ensure homeland security. The Department of Transportation proposes to examine limitations on the issuance of commercial drivers' licenses with a hazardous materials endorsement. This rule will implement section 1012 of the USA Patriot Act. It would prohibit States from issuing licenses to operate motor vehicles transporting hazardous materials unless DOT has determined that the operator does not pose a security risk.

The Department of Justice's Immigration and Naturalization Service (INS) will pursue rulemaking related to manifest requirements under section 231 of the Act. This rule will implement section 402 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107-173), which requires the submission of arrival and departure manifests electronically in advance of an aircraft or vessel's arrival in or departure from the United States. This rule also proposes to require manifest data on certain passengers and voyages previously exempt from this requirement. The information required in this rule will assist in the efficient inspection of passengers and crew members and is necessary for the effective enforcement of the immigration laws as part of the larger entry-exit system.

The Food and Drug Administration in the Department of Health and Human Services will issue four rules implementing the Bioterrorism Act of 2002. These rules include one that will authorize FDA to order the detention of food if there is credible evidence that it will create a threat of serious adverse health consequences to humans or animals. Another rule will require the maintenance of records to allow FDA to identify the previous source and subsequent recipient of food including its packaging. FDA will use this information to assess credible threats to human or animal health.

The Administration is committed to: (1) strengthening economic performance; (2) reducing barriers to the growth of small businesses; (3) improving public health and safety; (4) enhancing environmental protection; and (5) ensuring homeland security. Smarter regulatory policies, created through public participation, transparency, and cooperation across Federal agencies, seek to

accomplish these five national objectives. Each of the following department or agency's plans is a reflection of these objectives and provides information of regulatory priorities in the context of specific programs and initiatives.

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Department of Agriculture

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
1	Livestock Mandatory Reporting Program--Lamb Amendment (LS-01-08)	0581-AB98	Proposed Rule
2	National Dairy Promotion and Research Program (DA-02-03)	0581-AC16	Proposed Rule
3	Chronic Wasting Disease in Elk and Deer; Interstate Movement Restrictions and Payment of Indemnity	0579-AB35	Proposed Rule
4	Foot-and-Mouth Disease; Payment of Indemnity	0579-AB34	Final Rule
5	Biological Agents and Toxins	0579-AB47	Final Rule
6	Multi-Family Housing (MFH)	0575-AC13	Proposed Rule
7	Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages	0584-AC90	Proposed Rule
8	Food Stamp Program: Simplification and State Flexibility	0584-AD22	Proposed Rule
9	FSP: High Performance Bonuses	0584-AD29	Proposed Rule
10	FSP: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002	0584-AD30	Proposed Rule
11	FSP: Quality Control Provisions of the Farm Security and Rural Investment Act of 2002	0584-AD31	Proposed Rule
12	FSP: Employment and Training Program Provisions of the Farm Security and Rural Investment Act of 2002	0584-AD32	Proposed Rule
13	Child and Adult Care Food Program: Improving Management and Program Integrity	0584-AC24	Final Rule
14	Performance Standards for Bacon	0583-AC49	Proposed Rule
15	Egg and Egg Products Inspection Regulations	0583-AC58	Proposed Rule
16	Elimination of Chilling Time and Temperature Requirements for Ready-To-Cook Poultry **(Section 610 Review)**	0583-AC87	Proposed Rule
17	Emergency Regulations To Prevent Meat Food and Meat Products That May Contain the BSE Agent From Entering Commerce	0583-AC88	Proposed Rule
18	Performance Standards for Ready-To-Eat Meat and Poultry Products	0583-AC46	Final Rule
19	Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems	0583-AC51	Final Rule
20	Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products	0583-AC60	Final Rule

Department of Defense

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
21	Programmatic Regulations for the Comprehensive Everglades Restoration Plan	0710-AA49	Final Rule

Department of Education

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
22	Reauthorization of the Educational, Research, Development, Dissemination, and Improvement Act of 1994 **(Section 610 Review)**	1850-AA57	Proposed Rule
23	Reauthorization of Title I of the Elementary and Secondary Education Act of 1965 **(Section 610 Review)**	1810-AA91	Final Rule
24	Reauthorization of the Individuals With Disabilities Education Act **(Section 610 Review)**	1820-AB54	Proposed Rule

Department of Energy

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
25	Energy Efficiency Standards for Residential Furnaces, Boilers, and Mobile Home Furnaces	1904-AA78	Prerule
26	Energy Efficiency Standards for Electric Distribution Transformers	1904-AB08	Prerule
27	Energy Efficiency Standards for Commercial Central Air Conditioning Units and Heat Pumps Rated 65-240 kBtus/Hr	1904-AB09	Prerule
28	Radiation Protection of the Public and the Environment	1901-AA38	Final Rule

Department of Health and Human Services

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
29	Control of Communicable Diseases	0920-AA03	Proposed Rule
30	Possession, Use, and Transfer of Select Agents	0920-AA08	Final Rule
31	Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97	Proposed Rule
32	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910-AB88	Proposed Rule
33	Control of Salmonella Enteritidis in Shell Eggs During Production and Retail	0910-AC14	Proposed Rule
34	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910-AC25	Proposed Rule
35	Bar Code Label Requirements for Human Drug Products	0910-AC26	Proposed Rule
36	Administrative Detention	0910-AC38	Proposed Rule
37	Establishment and Maintenance of Records to Identify Immediate Previous Source and Immediate Subsequent Recipient of Foods	0910-AC39	Proposed Rule
38	Registration of Food and Animal Feed Facilities	0910-AC40	Proposed Rule
39	Establishment of Prior Notification Requirement for All Imported Food Shipments	0910-AC41	Proposed Rule
40	Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications	0910-AC48	Proposed Rule
41	Labeling for Human Prescription Drugs; Revised Format	0910-AA94	Final Rule
42	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims	0910-AB66	Final Rule
43	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV (Lookback)	0910-AB76	Final Rule
44	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910-AC35	Final Rule
45	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) **(Section 610 Review)**	0938-AG82	Proposed Rule
46	National Standard for Identifiers of Health Plans (CMS-6017-P)	0938-AH87	Proposed Rule
47	Health Insurance Reform: Claims Attachments Standards (CMS-0050-P)	0938-AK62	Proposed Rule
48	Organ Procurement Organization Conditions for Coverage (CMS-3064-P)	0938-AK81	Proposed Rule
49	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities that Provide Inpatient or Residential Care (CMS-2130-P)	0938-AL26	Proposed Rule
50	Prospective Payment System for Psychiatric Hospitals (CMS-1213-P)	0938-AL50	Proposed Rule
51	Revisions to the Medicare Appeals Process (CMS-4004-P)	0938-AL67	Proposed Rule
52	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities--Update for FY 2004 (CMS-1469-P)	0938-AL90	Proposed Rule
53	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS-1471-P)	0938-AL91	Proposed Rule
54	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS-1476-P)	0938-AL96	Proposed Rule
55	Revisions to Average Wholesale Price Methodology (CMS-1229-P)	0938-AM12	Proposed Rule
56	Electronic Medicare Claims Submission (CMS-0008-P)	0938-AM22	Proposed Rule
57	Revision of Medicare/Medicaid Hospital Conditions of Participation (CMS-3745-F)	0938-AG79	Final Rule
58	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F)	0938-AH99	Final Rule
59	Security Standards (CMS-0049-F)	0938-AI57	Final Rule
60	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (QAPI) (CMS-3050-F)	0938-AK40	Final Rule
61	Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-F)	0938-AK60	Final Rule
62	Health Insurance Reform: Modifications to Standards for Electronic Transactions (CMS-0003-F)	0938-AK64	Final Rule
63	Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS-1470-N)	0938-AL89	Final Rule
64	Application of Emergency Medical and Treatment Act (EMTALA) (CMS-1063-F)	0938-AM34	Final Rule

Department of Housing and Urban Development

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
65	Participation in HUD Programs by Faith-Based Organizations; Providing for Equal Treatment for All HUD Program Participants (FR-4782)	2501-AC89	Proposed Rule
66	The Secretary of HUD's Regulation of Fannie Mae and Freddie Mac (FR-4790)	2501-AC92	Proposed Rule

Department of Housing and Urban Development (Continued)

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
67	Disposition of HUD-Owned Single Family Assets in Asset Control Areas (FR-4471)	2502-AH40	Proposed Rule
68	FHA Appraiser Watch Initiative (FR-4744)	2502-AH81	Proposed Rule
69	Appraiser Qualifications for Placement on FHA Single Family Appraiser Roster (FR-4620)	2502-AH59	Final Rule
70	RESPA--Improving the Process for Obtaining Mortgages (FR-4727)	2502-AH85	Final Rule
71	Project-Based Voucher Program (FR-4636)	2577-AC25	Proposed Rule
72	Changes to the Public Housing Assessment System (PHAS)(FR-4707)	2577-AC32	Proposed Rule
73	Streamlining and Deregulation of Public Housing Agency Plans (FR-4788)	2577-AC40	Proposed Rule
74	Deregulation for Small Public Housing Agencies (FR-4753)	2577-AC34	Final Rule

Department of the Interior

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
75	Snowmobile Regulations; Yellowstone and Grand Teton National Parks and John D. Rockefeller Memorial Parkway	1024-AD09	Final Rule
76	Relief or Reduction in Royalty Rates -- Deep Gas Provisions	1010-AD01	Proposed Rule
77	Valuation of Oil from Indian Leases	1010-AD00	Final Rule

Department of Justice

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
78	Nondiscrimination on the Basis of Disability in Public Accommodations and Commercial Facilities **(Section 610 Review)**	1190-AA44	Proposed Rule
79	Nondiscrimination on the Basis of Disability in State and Local Government Services **(Section 610 Review)**	1190-AA46	Proposed Rule
80	Carrier Arrival and Departure Electronic Manifest Requirements	1115-AG57	Proposed Rule
81	Revision of the Regulations Concerning F, J, and M Nonimmigrant Classifications	1115-AG55	Final Rule

Department of Labor

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
82	Defining and Delimiting the Term ''Any Employee Employed in a Bona Fide Executive, Administrative, or Professional Capacity'' (ESA/W-H)	1215-AA14	Proposed Rule
83	Family and Medical Leave Act of 1993	1215-AB35	Proposed Rule
84	Child Labor Regulations, Orders, and Statements of Interpretation (ESA/W-H)	1215-AA09	Final Rule
85	Senior Community Service Employment Program	1205-AB28	Proposed Rule
86	Trade Adjustment Assistance for Workers	1205-AB32	Proposed Rule
87	Labor Certification Process for the Permanent Employment of Aliens in the United States	1205-AA66	Final Rule
88	Rulemaking Relating to Notice Requirements for Continuation of Health Care Coverage	1210-AA60	Proposed Rule
89	Regulations Implementing the Health Care Access, Portability, and Renewability Provisions of the Health Insurance Portability and Accountability Act of 1996	1210-AA54	Final Rule
90	Prohibiting Discrimination Against Participants and Beneficiaries Based on Health Status	1210-AA77	Final Rule
91	Blackout Notice Regulation	1210-AA90	Final Rule
92	Blackout Notice Civil Penalty	1210-AA91	Final Rule
93	Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners	1219-AB29	Prerule
94	Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust	1219-AB14	Proposed Rule
95	Determination of Concentration of Respirable Coal Mine Dust	1219-AB18	Proposed Rule
96	Asbestos Exposure Limit	1219-AB24	Proposed Rule
97	Assigned Protection Factors: Amendments to the Final Rule on Respiratory Protection	1218-AA05	Proposed Rule
98	Fire Protection in Shipyard Employment (Part 1915, Subpart P) (Shipyards: Fire Safety)	1218-AB51	Proposed Rule
99	Occupational Exposure to Crystalline Silica	1218-AB70	Proposed Rule
100	Standards Improvement (Miscellaneous Changes) for General Industry, Marine Terminals, and Construction Standards (Phase II)	1218-AB81	Proposed Rule

Department of Labor (Continued)

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
101	Update and Revision of the Exit Routes Standard	1218-AB82	Final Rule

Department of Transportation

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
102	Computer Reservations System Regulations Comprehensive Review	2105-AC65	Proposed Rule
103	Salvage and Marine Firefighting Requirements; Vessel Response Plans for Oil (USCG-1998-3417)	2115-AF60	Final Rule
104	Flight Crewmember Duty Period Limitations, Flight Time Limitations, and Rest Requirements	2120-AF63	Proposed Rule
105	Improved Flammability Standards for Thermal/Acoustic Insulation Materials Used in Transport Category Airplanes	2120-AG91	Final Rule
106	Certification of Airports	2120-AG96	Final Rule
107	Hours of Service of Drivers; Driver Rest and Sleep for Safe Operations **(Rulemaking Resulting From a Section 610 Review)**	2126-AA23	Final Rule
108	Limitations on Issuance of Commercial Driver's License With Hazardous Materials Endorsement	2126-AA70	Final Rule
109	Frontal Offset Protection	2127-AH73	Proposed Rule
110	Standards for Development and Use of Processor-Based Signal and Train Control Systems	2130-AA94	Final Rule
111	Pipeline Safety: Pipeline Integrity Management in High-Consequence Areas (Gas Transmission Pipeline Operators)	2137-AD54	Proposed Rule

Department of the Treasury

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
112	Revision of Brewery Regulations and Issuance of Regulations for Taverns on Brewery Premises (Brewpubs)	1512-AB37	Proposed Rule
113	Commerce in Explosives (Including Explosives in the Fireworks Industry) **(Rulemaking Resulting From a Section 610 Review)**	1512-AB48	Proposed Rule

Department of Veterans Affairs

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
114	Payment or Reimbursement for Emergency Treatment Furnished at Non-VA Facilities	2900-AK08	Final Rule

Environmental Protection Agency

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
115	Pesticides; Emergency Exemption Process Revisions	2070-AD36	Prerule
116	Endocrine Disruptor Screening Program; Priority Setting Criteria	2070-AD59	Prerule
117	Sustainable Futures; Voluntary Pilot Project Under the TSCA New Chemical Program	2070-AD60	Prerule
118	Clean Water Act Definition of Waters of the United States	2040-AB74	Prerule
119	NESHAP: Plywood and Composite Wood Products	2060-AG52	Proposed Rule
120	NESHAP: Reciprocating Internal Combustion Engine	2060-AG63	Proposed Rule
121	NESHAP: Industrial, Commercial, and Institutional Boilers and Process Heaters	2060-AG69	Proposed Rule
122	NESHAP: Surface Coating of Automobiles and Light-Duty Trucks	2060-AG99	Proposed Rule
123	Transportation Conformity Amendments: Response to March 2, 1999, Court Decision	2060-AI56	Proposed Rule
124	Control of Emissions from Spark Ignition Marine Vessels and Highway Motorcycles	2060-AJ90	Proposed Rule
125	Implementation Rule for 8-hour Ozone NAAQS	2060-AJ99	Proposed Rule

Environmental Protection Agency (Continued)

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
126	Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel	2060-AK27	Proposed Rule
127	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Routine Maintenance, Repair, and Replacement	2060-AK28	Proposed Rule
128	Endocrine Disrupter Screening Program; Implementing the Screening and Testing Phase	2070-AD61	Proposed Rule
129	Modifications to RCRA Rules Associated With Solvent-Contaminated Shop Towels and Wipes	2050-AE51	Proposed Rule
130	Revision of Wastewater Treatment Exemptions for Hazardous Waste Mixtures	2050-AE84	Proposed Rule
131	Increase Metals Reclamation from F006 Waste Streams	2050-AE97	Proposed Rule
132	Revisions to the Definition of Solid Waste	2050-AE98	Proposed Rule
133	NPDES Permit Requirements for Municipal Sanitary and Combined Sewer Collection Systems, Municipal Satellite Collection Systems, Sanitary Sewer Overflows, and Peak Excess Flow Treatment Facilities	2040-AD02	Proposed Rule
134	National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule	2040-AD37	Proposed Rule
135	National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule	2040-AD38	Proposed Rule
136	Minimizing Adverse Environmental Impact from Cooling Water Intake Structures at Existing Facilities Under Section 316(b) of the Clean Water Act, Phase 3	2040-AD70	Proposed Rule
137	Watershed Rule: Total Maximum Daily Load (TMDL) Program Revisions	2040-AD82	Proposed Rule
138	Withdrawal of Total Maximum Daily Load (TMDL) Program Revisions	2040-AD84	Proposed Rule
139	Overview of Rulemakings for the Purpose of Reducing Interstate Ozone Transport	2060-AJ20	Final Rule
140	Control of Emissions of Air Pollution From New Marine Compression-Ignition Engines At or Above 30 Liters per Cylinder	2060-AJ98	Final Rule
141	Management of Cement Kiln Dust (CKD)	2050-AE34	Final Rule
142	Standardized Permit for RCRA Hazardous Waste Management Facilities	2050-AE44	Final Rule
143	Office of Solid Waste Burden Reduction Project	2050-AE50	Final Rule
144	National Primary Drinking Water Regulations: Groundwater Rule	2040-AA97	Final Rule
145	Effluent Guidelines and Standards for the Metal Products and Machinery Category, Phases 1 and 2	2040-AB79	Final Rule
146	National Pollutant Discharge Elimination System Permit Regulation and Effluent Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs)	2040-AD19	Final Rule
147	Minimizing Adverse Environmental Impact From Cooling Water Intake Structures at Existing Facilities Under Section 316(b) of the Clean Water Act, Phase 2	2040-AD62	Final Rule
148	Cross-Media Electronic Reporting (ER) and Recordkeeping Rule	2025-AA07	Final Rule

Equal Employment Opportunity Commission

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
149	Coordination of Retiree Health Benefits With Medicare and State Health Benefits	3046-AA72	Proposed Rule

National Archives and Records Administration

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
150	Federal Records Management	3095-AB16	Prerule

Pension Benefit Guaranty Corporation

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
151	Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets	1212-AA55	Proposed Rule

Railroad Retirement Board

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
152	Application for Annuity or Lump Sum	3220-AB55	Proposed Rule
153	Account Benefits Ratio	3220-AB56	Proposed Rule
154	Requests for Reconsideration and Appeals Within the Board	3220-AB03	Final Rule

Small Business Administration

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
155	Small Business Lending Companies Regulations	3245-AE14	Proposed Rule
156	HUBZone Empowerment Contracting Program	3245-AE66	Final Rule

Social Security Administration

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
157	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
158	Administrative Wage Garnishment (To Repay a Debt Owed to the Social Security Administration) (724P)	0960-AE92	Proposed Rule
159	Evidence Requirement for Assignment of Social Security Administration Numbers (SSNs) and Assignment of SSNs for Nonwork Purposes (751P)	0960-AF05	Proposed Rule
160	Claimant Identification Pilot Projects (937P)	0960-AF79	Proposed Rule
161	Representative Payment Under Titles II, VIII, and XVI of the Social Security Act (949P)	0960-AF83	Proposed Rule
162	Removal of Clothing from the Definitions of Income and In-Kind Support and Maintenance, Exclusions of One Automobile and Household Goods and Personal Effects Under SSI from Resources (950P)	0960-AF84	Proposed Rule
163	OASDI and SSI; Administrative Review Process; Video Teleconferencing Appearances Before Administrative Law Judges of the Social Security Administration (737F)	0960-AE97	Final Rule
164	Revised Medical Criteria for Evaluating Impairments of the Digestive System (800F)	0960-AF28	Final Rule
165	Access to Information Held by Financial Institutions (815F)	0960-AF43	Final Rule
166	New Disability Claims Process--Roles of State Agency (816F)	0960-AF44	Final Rule

National Indian Gaming Commission

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
167	Freedom of Information Act Procedures (Amendments)	3141-AA21	Proposed Rule
168	Debt Collection	3141-AA25	Final Rule

DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

The Department of Agriculture will implement the recently enacted Farm Security and Rural Investment Act of 2002 (Farm Bill) through the promulgation of regulations to ensure the viability of the Nation's domestic farm economy and promote and maintain the world's safest, most abundant, and most affordable food supply. USDA is also actively engaged in the Nation's homeland security and will promulgate regulations that protect the food supply from all sources of potential threats.

Farm Bill implementation will be a high priority in 2003 as new regulations are issued and farmers, ranchers, and other USDA customers participate in new and existing Federal farm programs over the next 6 years through direct payments, counter-cyclical payments, and marketing loans. While the Farm Bill and other future legislative initiatives are implemented, the Department is working to reduce the regulatory burden on program participants through focusing as much as possible on outcome-based regulation through implementing more efficient and simplified information collections and the continued migration to efficient electronic services and capabilities.

- USDA will develop new regulations and review existing ones that address the potential threats posed by domestic outbreaks of exotic animal diseases such as Foot-and-Mouth Disease (FMD) and Bovine Spongiform Encephalopathy (BSE).
- In the area of food safety, the Department will continue to refine existing regulations to assist industry in implementing a consistent, science-based process control system that yields the best outcomes. Further, USDA is developing new regulations that address emerging and exotic threats to the safety of the Nation's meat, poultry, and egg products supply.
- The Department is also improving regulations that serve rural communities. Regulations are being streamlined and simplified so that they will be more customer friendly, while providing for more efficient and effective program management.
- Nutrition programs are being improved to strengthen dietary quality for children and low-income participants, while also improving the efficiency and integrity of program operations.

Reducing Paperwork Burden on Farmers

The Department 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. The Government Paperwork Elimination Act (GPEA) is leading all agencies in the Department to evaluate how they conduct business and migrate toward electronically oriented methods. The Farm Service Agency, Natural Resources Conservation Service, Rural Development, and Risk Management Agency are also working to implement the Freedom to E-File Act. Freedom to E-File directs the agencies, to the maximum extent practicable, to modify forms into user-friendly formats with user instructions and permits those forms to be downloaded and submitted via facsimile, mail, or similar means. As a result, producers should have the capability to electronically file forms and all other documentation if they so desire. Underlying these efforts will be analyses to identify and eliminate redundant data collections and streamline collection instructions. The end result of implementing both of these pieces of legislation will be better service to our customers so that they can choose when and where to conduct business with USDA.

The Role of Regulations

The programs of the Department are diverse and far reaching, as are the regulations that attend their delivery. Regulations codify how the Department 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 the 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 departmental programs has accompanying regulatory needs, often with a significant impact. The Farm Security and Rural Investment Act of 2002, Public Law 107-171, has had considerable regulatory consequences. This key legislation affects most agencies of USDA and resulted in the addition of new programs, the deletion of others, and modification to still others. In addition, the Agricultural Risk Protection Act of 2000, Public Law 106-224, provides further assurances that agricultural programs will continue to achieve long-term improvements, particularly in reforms to the crop insurance programs. This legislation also provides for improvements in market loss and conservation assistance, crop and livestock disease pest protection, marketing program enhancements, child nutrition program measures, pollution control, and research and development for biomass.

Major Regulatory Priorities

Seven agencies are represented in this regulatory plan as well as the Rural Development mission area. They include the Farm Service Agency, the Food and Nutrition Service, the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, the Natural Resources Conservation Service, and the Rural Housing Service. This document represents summary information on prospective significant regulations as called for in Executive Order 12866. A brief comment on each of the seven agencies and Rural Development appears below, which summarizes the Agency mission and its key regulatory priorities. The Agency summaries are followed by the regulatory plan entries.

Farm Service Agency

Mission: The Farm Service Agency's (FSA) mission is to stabilize farm income; to assist owners and operators of farms and ranches to conserve and enhance soil, water, and related natural resources; to provide credit to new or

existing farmers and ranchers who are temporarily unable to obtain credit from commercial sources; and to help farm operations recover from the effects of disaster, as prescribed by various statutes.

Priorities: FSA's priority for 2003 will be to fully implement the new Farm Bill, the Farm Security and Rural Investment Act of 2002. The 2002 Farm Bill, which was enacted on May 13, 2002, governs Federal farm programs for the next 6 years. Among its major provisions is to provide income support for wheat, feed grains, upland cotton, rice, and oilseeds through three programs: Direct payments, counter-cyclical payments, and marketing loans. Support for peanuts is changed from a price support program with marketing quotas to a program with marketing loans, counter-cyclical payments, direct payments, and a quota buyout. These are entirely new programs that require complete revision of the existing program regulations. FSA will develop and issue the regulations and make program funds available to eligible clientele in as timely a manner as possible. As these and future changes required by Administration initiatives and new legislation are made, the Agency's focus will be to implement the changes in such a way as to provide benefits while minimizing program complexity and regulatory burden for program participants. Opportunities will be taken to clarify, simplify, and reduce confusion whenever possible. However, the Agency's ability to promote new policy initiatives when implementing these regulations is limited, due to the need to adhere to legislative intent. Therefore, due to their economic magnitude, they are noted here to acknowledge their significance in the overall USDA regulatory plan but are not further listed in the body of the plan that appears below.

The 2002 Farm Bill exempts most of the new programs from the requirements of the Paperwork Reduction Act of 1995. However, FSA is still committed to the Act's goal of reducing the information collection burden on the public. New information collections are being designed to minimize our customers' time and cost to participate in the programs, while maintaining program integrity. In addition, FSA is streamlining its existing farm loan-making and servicing regulations and reducing the information collection burden associated with the programs. FSA plans to reduce the number of CFR parts containing its farm loan program regulations by approximately 70 percent. FSA also hopes to achieve a significant reduction in the total number of CFR pages by removing administrative provisions and internal policy and eliminating duplicative material. Furthermore, FSA intends to improve the clarity of the farm loan program regulations by following the guidelines established in the Plain Language in Government Writing Initiative.

As part of this project, all farm loan program regulations and internal Agency directives will be completely rewritten.

FSA has completed the streamlining of the Guaranteed Loan Program, the Indian Tribal Land Acquisition Loan Program, the Emergency Loan Program, and portions of the Direct Loan Program. The balance of the Direct Loan Program will be published in two separate rulemaking packages. Two proposed rules, one streamlining the loan-making process for farm ownership and operating loans and servicing of direct loans and another streamlining special loan programs, including boll weevil eradication, drainage and irrigation, and grazing association, will be published by the end of 2002.

Finally, FSA continues to be a full participant in the USDA Electronic Access Initiative and continues to work with other USDA county-based agencies to implement the Government Paperwork Elimination Act as we migrate to an environment where a greater proportion of information exchange and transaction processing occurs through off-site alternatives. Key components include: Providing farm program information, availability, and eligibility requirements electronically; providing on-line information collection and transaction processing capability; and developing information collection and management partnerships to integrate information collection and sharing mechanisms among service providers. In a continuing effort to accomplish these goals, all FSA information collections, forms, and procedures are reviewed for their applicability to electronic submission and collection. FSA has identified and made accessible on-line approximately 143 forms used by farm program and farm loan program customer groups. Approximately 90 of these forms are available for electronic submission. The agency intends to provide full electronic access and submission capabilities to the commodity operations customer group by October 2003.

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' 2003 regulatory plan supports the broad goals and objectives in the Agency's strategic plan, which include:

- *Improved nutrition of children and low-income people.* This goal represents FNS' efforts to improve nutrition by providing access to program benefits (Food Stamps, WIC food vouchers, school lunch, and other child nutrition programs and commodities), including nutrition education, quality meals, and other benefits. It includes three major objectives: 1) Improve food security, which reflects nutrition assistance benefits issued to program eligibles; 2) improve the healthfulness of program participants' food choices, which represents efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion; and 3) improve nutritional quality of meals, food packages, commodities, and other program benefits, which represents efforts to ensure that program benefits meet appropriate nutrition standards and help to effectively improve nutritional intakes for program participants.
- In support of this goal, FNS plans to propose rules implementing provisions of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), as well as under other authorities, that will give States additional new flexibility by streamlining complex rules, simplifying program administration, supporting work, and improving access to benefits. This includes provisions to restore food stamp eligibility to certain legal immigrants who have lived in this country for at least 5 years, as well as immigrant children and disabled without a waiting period. Other changes will be implemented to reduce reporting burden on working families.
- The Agency also plans a proposed rule to amend regulations governing food packages provided in WIC to improve their variety and consistency with the *Dietary Guidelines for*

Americans and to increase the nutritional adequacy of food packages for those with special medical needs.

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

In support of this goal, FNS plans to propose rules implementing provisions of Public Law 107-171 that give States substantial new flexibility by streamlining some of the Food Stamp Program's complex rules, making it easier to administer, less error prone, and more accessible to those eligible for its benefits. Another proposed rule implementing this law will offer most States some relief from current sanction rules related to Food Stamp payment errors, allowing them to focus on program improvements, and will introduce new incentives to reward States for high performance on a variety of important program outcomes. FNS also plans to publish a final rule making changes in Child and Adult Care Food Program (CACFP) designed to improve management and financial integrity in this important 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 safe and not adulterated or misbranded.

Priorities: FSIS is reviewing its regulations to eliminate duplication of and inconsistency with its own and other agencies' regulations and to improve the consistency of the regulations with the Agency's pathogen reduction and hazard analysis and critical control point (PR/HACCP) regulations. HACCP is a science-based process control system for producing safe food products. FSIS-inspected meat and poultry establishments are required to develop and implement HACCP plans incorporating the controls the establishments have determined are necessary and appropriate to produce safe products. Under the HACCP regulations, the establishments are able to tailor their control systems to their particular needs and processes and to take advantage of the latest technological innovations.

FSIS is continuing to revise its numerous command-and-control regulations, which prescribe the exact means establishments must use to ensure the safety of their products. Some of these regulations specify precise time-and-temperature combinations for processing meat, poultry, or egg products. Others require the prior approval by FSIS of equipment and procedures, in effect assigning to the Agency the responsibility for determining the means used by establishments to comply with the regulations. As a general matter, such command-and-control regulations are incompatible with HAACP because they deprive plants of the flexibility to innovate and they undercut the clear delineation of responsibility for food safety.

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

Following are some of the Agency's recent and planned initiatives to convert command-and-control regulations to performance standards, to streamline and simplify the regulations, and to make the meat, poultry products, and egg products inspection regulations more consistent with the pathogen reduction and HACCP systems final rule:

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

FSIS has proposed a rule to establish food safety performance standards for all processed ready-to-eat meat and poultry products and for partially heat-treated meat and poultry products that are not ready-to-eat.

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

In addition, FSIS will be proposing to require shell egg packers and 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 pasteurized shell eggs and egg products. Further, the Agency will be proposing to remove requirements for approval by FSIS of egg-product plant drawings, specifications, and equipment prior to use, and to end the system for pre-marketing approval of labels for egg products.

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 planning to propose stand-by emergency procedures for dealing with any occurrences of bovine spongiform encephalopathy (BSE), known as mad-cow disease, to prevent any meat or meat products of animals affected by BSE from entering commerce. To date, no cases of BSE have been found in the United States herd. Any final rule that may be developed after the proposal would become effective when and if a native case of BSE is detected in the United States.

Post-September 11, 2001, initiatives: FSIS has not proposed new regulations in response to the September 11, 2001, events. The Agency has, however, issued non-regulatory security guidelines for food plants within the Agency's jurisdiction.

Small business concerns: Nearly all FSIS regulations affect small businesses in some way because the majority of FSIS-inspected establishments and other FSIS-regulated entities are small businesses. FSIS makes available to small and very small establishments technical materials and guidance on how to comply with FSIS regulations.

The Agency's post-September 11, 2001, security guidance materials were prepared with small food producing establishments in mind.

Animal and Plant Health Inspection Service

Mission: The major part of the mission of the Animal and Plant Health Inspection Service (APHIS) is to protect U.S. animal and plant resources from destructive pests and diseases. APHIS conducts programs to prevent the introduction of exotic pests and diseases into the United States and monitors and manages pests and diseases existing in this country. These activities enhance agricultural productivity and competitiveness and contribute to the national economy and the public health.

Priorities: APHIS is reviewing its existing regulations and developing new regulatory initiatives to ensure that a comprehensive framework is in place to address the threats posed by exotic and endemic animal diseases. Prompted in part by recent outbreaks of foot-and-mouth disease elsewhere in the world, APHIS plans to amend its regulations for the cooperative control and eradication of animal diseases to ensure their adequacy with regard to the valuation of animals and materials, as well as the payment of indemnity, should an outbreak of foot-and-mouth disease occur in the United States. APHIS has also published, or is developing, proposed and final rules pertaining to the group of neurological diseases known as transmissible spongiform encephalopathies, which includes scrapie (a disease of sheep and goats), bovine spongiform encephalopathy (BSE, which affects cattle), and chronic wasting disease (a disease of deer and elk). In addition, APHIS, in coordination with the Department's Food Safety Inspection Service, and with input from the public, is considering various options for addressing the disease risks that may be presented by nonambulatory animals and dead stock should BSE be introduced into the United States. APHIS is also working in conjunction with the Centers for Disease Control and Prevention to establish regulations for the possession, use, and transfer of biological agents and toxins that could pose a severe disease or pest risk to animals and plants or their products. In addition, APHIS plans to strengthen its regulations for the importation of plants and plant products, including unmanufactured wood, in response to new pest detections and the adoption, recently, of an international standard for treatment of solid wood packing material.

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

Agricultural Marketing Service

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

Priorities: (A) The recently enacted Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) amended the Dairy Production and Stabilization Act of 1983 (the authorizing legislation for the National Dairy Promotion and Research Program (NDP&RP). The 2002 Farm Bill requires that the NDP&RP be amended to provide for: (1) Implementation of a mandatory 15-cent per hundred weight assessment on dairy products imported into the 48 contiguous States; (2) importer representation on the National Dairy Board; (3) importer voter eligibility during referenda; (4) the definition of imported dairy products to include casin; and (5) the order must be implemented in a manner consistent with the U.S. trade obligations. A proposed rule providing interested parties an opportunity to submit comments on the implementation of the mandatory assessment on imported dairy products will be published fall 2002.

(B) Livestock Mandatory Reporting-Lamb Amendments. These proposed amendments to the lamb reporting requirements are necessary to ensure that consistent, accurate, and easily understood information on the marketing of domestic and imported boxed lamb cuts is available to producers, packers, and other lamb market participants. AMS believes that the lamb industry would be better served by decreasing the lamb importer threshold to 2,500 metric tons of lamb meat products and redefining carlot of boxed lamb cuts to increase the ability to report import product and to reduce the volume of inappropriate or incompatible data submitted. AMS is presently working on burden-related issues placed on importers with the Office of Management and Budget. The Agency expects to have the proposed rule ready for departmental review by late fall.

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

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 2003 will be to implement fully the conservation provisions of the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), while continuing to meet the needs of landowners and land users who participate in non-Farm Bill programs. The 2002 Farm Bill was enacted on May 13, 2002, and governs Federal farm programs for the next 6 years. Title II of the 2002 Farm Bill reauthorized and made amendments to existing conservation programs, authorized new conservation programs, and expanded the overall funding for conservation.

The changes made by title II necessitate the revisions of existing regulations and the promulgation of proposed and final regulations to implement new programs. The 2002 Farm Bill exempts administration of title II from the requirements of the Paperwork Reduction Act of 1995. However, NRCS is still committed to the Act's goal of reducing the information collection burden on the public. New information collections are being designed to minimize program participants' time and cost to participate in the programs, while maintaining program integrity. NRCS is also committed to compliance with the Government Paperwork Elimination Act and the Freedom to E-File Act, which require Government agencies in general and NRCS in particular to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. NRCS is designing its program forms to allow the public to conduct business with NRCS electronically.

The NRCS plans to publish the following proposed or final rules during FY 2003:

1. Conservation of Private Grazing Land (CPGL) Final Rule
2. Environmental Quality Incentives Program (EQIP) Proposed Rule and Final Rule
3. Technical Service Provider Assistance (TSPA) Interim Final Rule and Final Rule
4. Conservation Security Program (CSP) Proposed Rule and Final Rule
5. Farmland Protection Program (FPP) Proposed Rule and Final Rule
6. Emergency Watershed Protection (EWP) Program Proposed Rule and Final Rule
7. Highly Erodible Land and Wetland Conservation (HEL/WC) Final Rule
8. Categorical Minimal Effects (CME) Final Rule

The rulemaking for EQIP, EWP, and HEL/WC consist of changes being made to current regulations. The remainder of the rulemaking involves the creation of new regulatory provisions. NRCS will develop and issue the regulations and make program funds available to program participants in as timely a manner as possible. Opportunities will be taken to clarify, simplify, and reduce confusion whenever possible.

Rural Development

Mission: Enhance the ability of rural communities to develop, to grow, and to improve their quality of life by targeting financial and technical resources in areas of greatest need through activities of greatest potential.

Priorities: Rural Development priorities for 2003 will include timely implementation of the 2002 Farm Bill sections for which it is responsible. In addition to the regulations identified in the regulatory agenda, there are several sections of titles VI and IX of the Farm Bill for which work plans are being developed for future regulatory action.

Rural Housing Service

Mission: As part of USDA Rural Development, Rural Housing Service (RHS) works to improve the quality of life in rural areas. RHS helps rural communities and individuals by providing loans and grants for housing and community facilities. The Agency provides funding for single-family homes, apartments for low-income persons or the elderly, housing for farm laborers, childcare centers, fire and police stations, hospitals, libraries, nursing homes, and schools.

Priorities: A key priority for RHS is to identify ways to improve customer service, ensure borrower accountability and performance, and streamline the administration of its Multi-Family Housing (MFH) programs. These programs include the section 515 Rural Rental Housing (RRH) loan program, the section 514/516 Farm Labor Housing loan and grant programs, and the section 521 Rental Assistance (RA) program.

The new regulation substantially updates the current regulations and programs to current industry practices. Many of the current regulations had not been substantially updated for over 15 years. The new regulation consolidates the 13 current regulations that govern the programs. The new regulation and three handbooks substantially reduce the number of pages published in the Code of Federal Regulations.

Prior USDA Office of Inspector General (OIG) program audits identified weaknesses in the regulations that let some program participants commit program fraud, waste, and abuse. The new regulation was developed to correct such problems.

Significant automation initiatives have been implemented since the current regulations were written. The regulation addresses the permanent implementation of several pilot automation projects along with other innovative e-Government improvements.

The regulation focuses on the challenge of the Agency's aging portfolio. Areas such as conducting comprehensive needs analyses, reserve account administration, financial statement standards, and tenant quality of life issues are addressed.

As part of the regulatory process, RHS has solicited input from MFH program stakeholders, including borrowers (who are also owners of the projects), management agents, tenant representatives, State housing finance agencies, accounting firms, and the USDA, Office of Inspector General (OIG). The Agency has held several stakeholders meetings on issues that needed to be considered before proposing to revise the regulations. Stakeholders concurred with RHS that the MFH regulations were in need of a substantial revision, particularly with regard to asset management, housing preservation, and financial reporting.

USDA—Agricultural Marketing Service (AMS)

PROPOSED RULE STAGE

1. LIVESTOCK MANDATORY REPORTING PROGRAM—LAMB AMENDMENT (LS-01-08)

Priority:

Other Significant

Legal Authority:

7 USC 1621

CFR Citation:

7 CFR 59

Legal Deadline:

None

Abstract:

The Agricultural Marketing Service is amending the Livestock Reporting Act of 1999 regulations. The amendments would: (1) Amend regulations requiring lamb packers to report negotiated purchases of live lamb and sales of carcass lamb; (2) adjust requirements for reporting of imported and domestic boxed lamb sales; and (3) make adjustments to input data collection forms. The Act was implemented April 2, 2001, and requires packers to report purchase and sales transactions for cattle, swine, sheep, boxed beef, and lamb meat.

Statement of Need:

These proposed amendments and adjustments to the lamb reporting requirements of the Livestock Mandatory Reporting (LMR) regulations are necessary to ensure that consistent, accurate, and easily understood information on the marketing of domestic and imported boxed lamb cuts is available to producers, packers, and other lamb market participants. The amendment is intended to address problems that have occurred in the collection and publishing of lamb market information in the period since the implementation of the LMR on April 2, 2001.

Summary of Legal Basis:

The Livestock Mandatory Act of 1999 (Act) was enacted into law on October 22, 1999 (Pub. L. 106-78; 113 Stat. 1188; 7 U.S.C. 1635-1636(h)) as an amendment to the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.). The Act gives the Secretary of Agriculture (Secretary) the latitude to require mandatory reporting

of market information on lamb transactions.

Alternatives:

None.

Anticipated Cost and Benefits:

The Agricultural Marketing Service believes that the lamb industry would be better served by decreasing the lamb importer threshold to 2,500 metric tons of lamb meat products and redefining carlot of boxed lamb cuts to increase the ability to report import product and reduce the volume of inappropriate or incompatible data.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	

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.

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USDA—AMS

2. ● NATIONAL DAIRY PROMOTION AND RESEARCH PROGRAM (DA-02-03)

Priority:

Other Significant

Legal Authority:

7 USC 450 et seq

CFR Citation:

7 CFR 1150

Legal Deadline:

NPRM, Statutory, November 2002, Proposed Rule necessary for industry input.

Final, Statutory, February 2003, Final Rule to be issued after 60-day comment period.

Abstract:

Recently enacted Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) amended the Dairy Production and Stabilization Act of 1983 (the authorizing legislation for the National Dairy Promotion and Research Program) concerning implementation of mandatory 15-cent per hundred weight assessment on dairy products imported into the 48 contiguous States and other related amendments.

Statement of Need:

The National Dairy Promotion and Research Program must be amended to conform with the recently enacted Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), which amended the Dairy Promotion and Research Programs. The amendments relate to implementation of a mandatory 15-cent per hundred weight assessment on dairy products imported into the 48 contiguous States and other related amendments.

Summary of Legal Basis:

The Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) mandated changes to the National Dairy Promotion and Research Program.

Alternatives:

None.

Anticipated Cost and Benefits:

The incremental costs associated with the assessments collection on imported dairy products by U.S. Customs will be paid from the assessments collected. It is estimated that the fees will range between $30,000-$40,000 monthly after start-up. The annual assessment collected will be approximately $9 million.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	02/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—Animal and Plant Health Inspection Service (APHIS)

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8316

CFR Citation:

9 CFR 55; 9 CFR 81

Legal Deadline:

None

Abstract:

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

Statement of Need:

CWD has been confirmed in free-ranging deer and elk in a limited number of counties in northeastern Colorado and southeastern Wyoming and has also been diagnosed in farmed elk herds in South Dakota, Nebraska, Oklahoma, Montana, and Colorado. This project includes an interim rule to establish indemnity for voluntary depopulation of CWD-affected herds, followed by a proposed rule to establish a voluntary certification

program and interstate movement restrictions on captive elk and deer. APHIS believes that establishing restrictions on the interstate movement of infected and exposed farmed elk and deer, coupled with the payment of some level of indemnity for infected and exposed animals, will encourage producers who are not yet engaging in surveillance activities to begin doing so. To date, the level of support from States and the farmed cervid industry for such a program has been high. Without a Federal program in place to depopulate infected and exposed animals, the movement of infected animals into new herds and States with no known infection will continue or may even accelerate. APHIS needs to take action to document the prevalence of the disease and to prevent its further spread.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/08/02	67 FR 5925
Interim Final Rule Comment Period End	04/09/02	
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

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–AB35

USDA—APHIS

FINAL RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8317

CFR Citation:

9 CFR 53

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

property as a result of foot-and-mouth disease.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	05/01/02	67 FR 21934
NPRM Comment Period Extended	06/28/02	67 FR 43566
NPRM Comment Period End	07/01/02	
NPRM Comment Period End	07/31/02	
Final Rule	04/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

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–AB34

USDA—APHIS

5. ● BIOLOGICAL AGENTS AND TOXINS

Priority:

Other Significant

Legal Authority:

7 USC 8401

CFR Citation:

7 CFR 331; 9 CFR 121

Legal Deadline:

None

Abstract:

In accordance with the Agricultural Bioterrorism Protection Act of 2002, APHIS has established, by regulation, an initial list of biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health or to animal or plant products. The Act requires that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of the interim rule, notify the Secretary of such possession. The interim rule establishes APHIS' initial list of biological agents and toxins and provides guidance on the manner in which the required notice is to be provided. A second interim rule, also required by the Act, will follow this interim rule and will establish regulations regarding the possession, use, and transfer of listed biological agents and toxins.

Statement of Need:

The second interim rule referred to in the abstract is required under section 212 of the Public Health Security and Bioterrorism Response Act of 2002 (Pub. L. 107-188), which requires the Secretary of Agriculture to establish regulations by interim rule for the possession, use, and transfer of biological agents and toxins that she determines has the potential to pose a severe threat to animal or plant health or to animal or plant products. Among other things, the regulations must require registration with the Secretary and include appropriate safeguard and security measures, including data base checks by the Attorney General of individuals and facilities seeking to register with the Secretary. The Act imposes a deadline of December 9, 2002, for the promulgation of the regulations and requires an effective date of February 12, 2003.

Summary of Legal Basis:

The President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 on June 12, 2002. Title II of Public Law 107-188 ''Enhancing Controls on Dangerous Biological Agents and Toxins'' (sections 201 through 231) provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201-204) and the Department of Agriculture (subtitle B, sections 211-213) and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). Subtitle D (section 231) provides for criminal penalties regarding certain biological agents and toxins. For the Department of Health and Human Services, the Centers for Disease Control and Prevention has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling

that role for the Department of Agriculture.

Alternatives:

APHIS' Veterinary Services and Plant Protection and Quarantine programs have had regulations in place for some years that require prior authorization from APHIS for the importation or interstate movement of certain animal disease agents and plant pests. Those regulations further require that appropriate safeguards be applied to the handling and containment of those animal disease agents and plant pests. While the biological agents and toxins that the Secretary has determined have the potential to pose a severe threat to animal or plant health or to animal or plant products have historically fallen within the scope of the existing regulations, those regulations do not contain the individual/facility registration requirements, physical security, and other considerations that the Public Health Security and Bioterrorism Response Act of 2002 requires the Agency to address in the second interim rule.

Anticipated Cost and Benefits:

APHIS is currently preparing a regulatory flexibility analysis and cost/benefit analysis to accompany the second interim rule. Among the costs we anticipate will be examined in those analyses are the costs associated with compliance with the administrative requirements of the rule (e.g., salary costs associated with the time needed to complete required forms), as well as costs that may be incurred in the course of making any necessary upgrades to the physical, computer, and biological security capabilities of facilities that possess, use, or transfer listed biological agents and toxins. The regulations are intended to increase the security over such agents and toxins and establish a comprehensive national data base of the location and characterization of those agents and toxins and the identities of those in possession of them. These enhanced security measures will prevent the use in domestic or international terrorism of those biological agents and toxins, thus protecting human, animal, and plant health and preventing the economic impacts that would be associated with the release of those agents and toxins.

Risks:

The regulations will include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism).

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/12/02	67 FR 52383
Interim Final Rule Effective	08/12/02	
Interim Final Rule Comment Period End	10/11/02	
Second Interim Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Federal

Additional Information:

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

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USDA—Rural Housing Service (RHS)

PROPOSED RULE STAGE

6. MULTI-FAMILY HOUSING (MFH)

Priority:

Other Significant

Legal Authority:

5 USC 301; 42 USC 1490a; 7 USC 1989; 42 USC 1475; 42 USC 1479; 42 USC 1480; 42 USC 1481; 42 USC 1484; 42 USC 1485; 42 USC 1486

CFR Citation:

7 CFR 1806 subpart A; 7 CFR 1955 subpart B; 7 CFR 1955 subpart C; 7 CFR 1956 subpart B; 7 CFR 1965 subpart B; 7 CFR 1965 subpart E; 7 CFR 1930 subpart C; 7 CFR 1944 subpart D; 7 CFR 1944 subpart E; 7 CFR 1951 subpart C; 7 CFR 1951 subpart D; 7 CFR 1951 subpart K; 7 CFR 1951 subpart N; 7 CFR 1955 subpart A

Legal Deadline:

None

Abstract:

The Rural Housing Service (RHS) proposes to consolidate regulations pertaining to section 515 Rural Rental Housing, section 514 Farm Labor Housing Loans, section 516 Farm Labor Housing Grants, and section 521 Rental Assistance Payments. Fourteen published regulations will be reduced to one regulation and handbooks for program administration. This will simplify loan origination and portfolio management for applicants, borrowers, and housing operators, as well as Rural Development field staff. This will also provide flexibility for program modifications to reflect current and foreseeable changes. It will also reduce regulations that address solely internal Agency program administration. Finally, the regulation will be more customer friendly and responsive to the needs of the public.

Statement of Need:

The new regulation for the program known as the Multi-Family Housing Loan and Grant Programs will be more user friendly for lenders, borrowers, and Agency staff. These changes are essential to allow for improved service to the public and for an expanded program with increased impact on rural housing opportunities without a corresponding expansion in Agency staff. The regulations will be shorter, better organized, and more simple and clear. Many documentation requirements will be eliminated or consolidated into more convenient formats.

Summary of Legal Basis:

The existing statutory authority for the MFH programs was established in title V of the Housing Act of 1949, which gave authority to the RHS (then the Farmers Home Administration) to make

housing loans to farmers. As a result of this Act, the Agency established single-family and multifamily housing programs. Over time, the sections of the Housing Act of 1949 addressing MFH have been amended a number of times. Amendments have involved issues such as the provision of interest credit, broadening definitions of eligible areas and populations to be served, participation of limited profit entities, the establishment of a rental assistance program, and the imposition of a number of restrictive use provisions and prepayment restrictions.

The MFH program, as it exists today, began in the 1960s. Its first loans were primarily for small rental projects. In the mid-sixties, the program expanded and changed from making small rural rental housing loans to individuals to making larger loans to organizations, such as limited partnerships. Regulations for the program have been amended several times over the years to reflect statutory changes and to revise the Agency's procedures for administering the program. The most recent significant regulatory revisions took place after the Appropriations Act of 1997 directed the Agency to implement six reforms to the MFH program. This was accomplished with the publication of a final rule for the reforms on December 23, 1997. Reforms addressed such items as equity skimming, review of other Government assistance, the maximum loan terms, and the use of a Notice of Funding Availability and competitive process to award funds for new projects.

Statistics show that the MFH program fills a significant need for rural Americans. Two primary types of households occupy RHS-financed, section 515 rental housing—elderly households who have decided that they prefer renting over continued ownership of their own dwellings and younger female and male headed households that do not have sufficient resources available to purchase their own home. Additionally, the sections 514/516 Farm Labor Housing loan and grant programs are the only Federal programs available for the provision of housing to farmworkers, one of the most chronically underhoused populations within America.

Alternatives:

The proposed rule is important to all program participants, beneficiaries, and agency staff. Any budgetary impacts of the regulation are minor and reflect good business practices rather than policy shifts. Funding for major program needs as rehabilitation, preservation, and future new construction may be addressed through the budget process rather than publication of the rule. To not publish the rule will substantially restrict RHS' ability to effectively administer the programs and cost the Agency significant credibility with the public and oversight organizations.

If the Agency were not to publish the proposed rule, the 25 percent reduction in Government burden not achieved would be significant. During the past 6 years, the number of staff-years assigned MFH functions has decreased approximately 25 percent. RHS' limited staff resources could be utilized more effectively on activities that would improve program performance by decreasing and simplifying the paperwork for the MFH program.

Current regulations include standards for physical condition, maintenance, and reserve levels to address the physical condition of the property. However, projects are experiencing physical maintenance problems due to their average age. One of the sources of this problem is that project reserves are inadequate to cover ongoing capital needs. Current regulations require that borrowers contribute initially 1 percent annually of total development costs toward a reserve for project improvements until a total of 10 percent is reached. While borrowers are permitted to request adjustments to their reserve contributions, there is no systematic provision for reevaluating reserves over the life of the project. A recent study found that while an average MFH project has accumulated $5,000 in reserves per unit at the end of 10 years and maintained at that level thereafter, the full cost of rehabilitation is likely to be close to $16,000 per unit. When rehabilitation is needed and the reserve is inadequate to meet the need, the project owner usually applies for a subsequent loan, which, if received, requires that rents be increased. In recent years, RHS has been experiencing a growing number of requests for subsequent loans and rent increases to cover costs of rehabilitation, while funding for such loans has been limited. For example, the President's budget for 2002 provides funding to rehabilitate 4,115 units, which is consistent with the funding received in recent years. However, at that rate, it will take more than 109 years to cycle once through the entire portfolio.

Consistently, RHS is taking several steps to link reserve levels more closely to projects' capital needs. The proposed rule allows a life cycle costs analysis to be used to establish the initial reserve amount needed to meet the capital needs for new projects. For existing projects, the proposed rule requires that any servicing action that involves additional agency funds must take into account physical needs of the project, based on a capital needs assessment. The proposed rule also allows borrowers with existing projects to include the cost of capital needs assessments in their budgets, which is expected to focus attention on the use of such assessments. Alternatively, by not publishing the proposed rule, properties financed under the programs may deteriorate.

Anticipated Cost and Benefits:

Based on analysis of the proposed rule, the following impacts may occur, some of which could be considered significant:

There would be cost savings due to reduced paperwork, estimated to be about $1.8 million annually for the public and about $10.1 million for the Government.

Rents for about half the 459,000 units in MFH projects would likely be increased by an average of about $15 per month. This estimate combines the impacts on rents of two different changes—an increase in reserve requirements for project improvements from $5,000 to $10,000 per unit and a change in RHS' policies relating to the investment of funds in reserves accounts. The latter change is expected to increase interest earnings on reserve accounts from 2 percent currently earned to 6 percent, with 25 percent of the earnings becoming eligible to be taken out of the accounts for owners to pay taxes and the rest remaining for improvements.

Government costs for rental assistance payments would increase by at least $23 million annually, and those for section 8 project-based assistance would increase by about $4 million annually.

Tenants of an estimated 79,500 units, about half the 159,000 units that do not receive rental assistance payments or similar assistance from HUD, would have to pay higher rents of about 5 percent. This amounts to an annual cost of about $14 million for these tenants. Most of these tenants are expected to remain in the projects because rents would remain competitive.

Increasing the reserve requirements would provide additional funds for improving projects. However, the full impact of this change is not expected to be reached until 10 years after it is implemented. Thus, projects that are in need of immediate rehabilitation will likely remain short of adequate funds for making needed improvements in the near term. Only a substantial increase in funding for rehabilitation loans would help resolve this problem.

Allowing project improvement needs to be considered in RHS' servicing actions could result in increased write-downs of the $12 billion MFH portfolio. This potential impact cannot be easily estimated.

Project owners who have or soon will meet the 20-year restriction on the use of their projects for low-income housing will have a clearer picture of RHS' policies in trying to maintain these projects in the program. In particular, establishment of a 15-month limit on waiting for incentives to be offered to them to stay in a program should help them make decisions on either staying in the program or prepaying their loans and possibly converting the projects to other uses.

Risks:

The risk associated with this regulatory initiative is that some program participants may be faced with increased replacement reserve requirements without sufficient cashflow in the property to make the deposits. The Agency believes that the need to adequately address project physical replacement needs offsets this risk. The Agency also believes that for the three-quarters of the properties that have deep tenant subsidies, this impact will be mitigated as rents can be increased in those situations without impacting the affordability of the units to eligible program beneficiaries.

The primary risk to the Agency is if the proposed rule is not implemented. Without the streamlining, program improvements and focus on current industry practices, including the increased use of third-party funds to rehabilitate program properties that are included in the regulation, the underlying assets for the loans and grants made under the programs will deteriorate as the properties age. This will cause a decrease in the ability of the Agency to provide safe, decent, and sanitary housing to program beneficiaries.

The loans made to recipients will become undersecured as the properties' values decrease. Lastly, there will be a greater propensity of borrowers to elect to either default on their loans or to pay off loans and remove their properties from the stock of affordable housing.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	02/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 0575–AC13

USDA—Food and Nutrition Service (FNS)

PROPOSED RULE STAGE

7. 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 246

Legal Deadline:

None

Abstract:

This proposed rule will amend regulations governing the WIC food packages to disallow low-iron WIC formulas in food packages 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; make technical adjustments in all of the food packages to accommodate newer packaging and physical forms of the WIC foods; add vegetables as a food category in Food Packages III-VII for women and children; require that State agencies make available the full maximum foods allowed in each package; revise the criteria for developing State agency proposals for alternative food packages to accommodate participant food preferences more effectively; revise the purpose, content, and requirements for Food Package III; and address general provisions that apply to all the food packages. These revisions will improve the likelihood that WIC recipients achieve the food servings recommendations of the Dietary Guidelines for Americans and nutritional recommendations, providing WIC participants with a wider variety of foods, accommodating newer packaging and physical forms of WIC foods, and providing WIC State agencies with greater flexibility in prescribing food packages, especially to accommodate participants with hardships or cultural/food preferences. (99-006)

Statement of Need:

While WIC has been successful in many areas, obesity and inappropriate dietary patterns have become equal, if not greater, problems for many in WIC's target population. WIC food packages and nutrition education are the chief means by which WIC affects the dietary quality and habits of participants. Results of a recent WIC study found that the supplemental food package is consistently ranked by pregnant and postpartum women as the leading positive attribute of the program. Therefore, revised food packages, which will foster greater consistency with the Dietary Guidelines for Americans, are an appropriate response to further increase the positive effects of the program among the WIC eligible population.

The overarching objective of this rule is to improve disease prevention and nutritional status by improving dietary quality and nutritional adequacy of the WIC food packages by:

1. Improving the manner in which the nutrients lacking in the target population's diet are provided by revising food packages to reflect more closely the Dietary Guidelines for Americans as represented by the diet recommendations of the Food Guide Pyramid; and

2. Increasing the nutritional adequacy of the WIC food packages for medically needy participants.

Summary of Legal Basis:

The WIC Program was established to provide nutritious supplemental foods, nutrition education, and referrals to related health and social services to low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, infants, and children up to age 5. Section 17 of the Child Nutrition Act of 1966 (as amended, 42 U.S.C. 1786) clearly established the WIC Program as a supplemental nutrition program designed to provide nutrients determined by nutritional research to be lacking in the diets of the WIC target population. WIC law requires that, to the extent possible, the fat, sugar, and salt content of WIC foods be appropriate. The law gives substantial latitude to the Department in designing WIC food offerings but obligates the Department to prescribe foods that effectively and economically supply the target nutrients.

Alternatives:

None.

Anticipated Cost and Benefits:

None.

Risks:

This rule is intended to improve the nutritional status and dietary patterns of the WIC target population, as a response to the threat of increasing risk factors for nutrition-related diseases—obesity, diabetes, coronary heart disease, stroke, and cancer, to name a few—in the WIC eligible population.

Timetable:

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

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

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

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RIN: 0584–AC90

USDA—FNS

8. FOOD STAMP PROGRAM: SIMPLIFICATION AND STATE FLEXIBILITY

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

7 USC 2011 to 2036

CFR Citation:

7 CFR 272; 7 CFR 273

Legal Deadline:

None

Abstract:

This action will 1) propose to streamline the regulations by removing unnecessary or redundant provisions and reorganizing several sections; 2) propose to increase State flexibility by moving overly prescriptive regulations; 3) re-propose several provisions that were proposed in a previous rule, the Noncitizen Eligibility Certification Provisions (NECP) of Public Law 104-193, as amended by Public Laws 104-208, 105-33, and 105-185, published on February 29, 2000, but were not accepted in the final NECP rule published on November 21, 2001; 4) propose to remove or revise several provisions that were finalized in the NECP final rule; and 5) propose to incorporate current policy from the Food Stamp Program's Policy Interpretation Response System (PIRS). (01-018)

Statement of Need:

This rule is discretionary in nature. However, it simplifies the food stamp regulations and allows State flexibility in administering the program.

Summary of Legal Basis:

The legal basis for this rule is Public Law 104-193, as amended by Public Laws 104-208, 105-33, and 105-185.

Alternatives:

This rule is discretionary in nature; therefore it is not mandatory that we publish it.

Anticipated Cost and Benefits:

Undetermined

Risks:

The FSP provides nutrition assistance to millions of Americans nationwide—working families, eligible non-citizens, and elderly and disabled individuals. Many low-income families don't earn enough money and many elderly and disabled individuals don't receive enough in retirement or disability benefits to meet all of their expenses and purchase healthy and nutritious meals. The FSP serves a vital role in helping these families and individuals achieve and maintain self-sufficiency and purchase a nutritious diet. This rule is intended to simplify the regulations and allow State flexibility in administering the program, thus decreasing barriers to access benefits.

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	
NPRM Comment Period End	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

Undetermined

URL For Public Comments:

http://www.fns.usda.gov/fsp/

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RIN: 0584–AD22

USDA—FNS

9. ● FSP: HIGH PERFORMANCE BONUSES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 107-171

CFR Citation:

7 CFR 272; 7 CFR 275

Legal Deadline:

None

Abstract:

This action will propose implementation of the high performance bonuses as provided for in the Farm Security and Rural Investment Act of 2002 for States that demonstrate high or improved performance in administration of the Food Stamp Program. This action will propose the measurement criteria for fiscal year 2005 and beyond. (02-006)

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

Undetermined

Risks:

The law mandates that we codify the performance measures for the high performance bonuses for FY 2005 and beyond. If we did not publish this proposed rule, we would be unable to publish a final rule, thus making us out of compliance with a legislative mandate.

Timetable:

Action	Date	FR Cite
NPRM	08/00/03	
NPRM Comment Period End	10/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

Undetermined

URL For More Information:

http://www.fns.usda.gov/fsp

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USDA—FNS

10. ● 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 proposed rule will amend Food Stamp Program regulations to implement the food stamp eligibility and certification provisions of Public Law 107-171, the Farm Security and Rural Investment Act of 2002. The rule allows States, at their option, to treat legally obligated child support payments to a non-household member as an income exclusion rather than a deduction (as provided in current law); allows a State option to exclude certain types of income that are not counted under the State's Temporary Assistance for Needy Families (TANF) cash assistance or Medicaid programs; replaces the current, fixed standard deduction with a deduction that varies according to household size and is adjusted annually for cost-of-living increases; allows States to simplify the Standard Utility Allowance (SUA) if the States elect to use the SUA rather than actual utility costs for all households; allows States to use a standard deduction from income of $143 per month for homeless households with some shelter expenses; allows States to disregard reported changes in deductions during certification periods except for changes associated with a new residence or earned income until the next recertification; increases the resource limit for households with a disabled member from $2,000 to $3,000 consistent with the limit for households with an elderly member; allows States to exclude certain types of resources that the State does not count for TANF or Medicaid (section 1931); allows USDA to approve alternate methods for issuing food stamp benefits during disasters when reliance on electronic benefit transfer systems (EBT) is impracticable; allows States to extend semiannual reporting of changes to all households not exempt from periodic reporting; requires State agencies that have a website to post applications on these sites in the same languages that the State uses for its written applications; allows States to extend from the current 3 months up to 5 months the period of time households may receive transitional food stamp benefits when they lose TANF cash assistance; and restores food stamp eligibility to qualified aliens who are otherwise eligible AND who (1) are receiving disability benefits regardless of date of entry (current law requires them to have been in the country on 8/22/96)—effective FY 2003, (2) are under 18 regardless of date of entry (current law limits eligibility to children who were in the country on 8/22/96)—effective FY 2004 and beyond, or (3) have lived in the U.S. continuously for 5 years as a qualified alien beginning on date of entry—effective April 2003. (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 proposed rule deals with changes required by Public Law 107-171, the Farm Security and Rural Investment Act of 2002. The Department has limited discretion in implementing

provisions of that law. Most of the provisions in this rule are effective October 1, 2002, and must be implemented by State agencies prior to publication of this rule.

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	
NPRM Comment Period End	11/00/03	
Final Action	12/00/04	
Final Action Effective	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

Undetermined

URL For Public Comments:

http://www.fns.usda.gov/fsp/

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RIN: 0584–AD30

USDA—FNS

11. ● FSP: QUALITY CONTROL PROVISIONS OF THE FARM SECURITY AND RURAL INVESTMENT ACT OF 2002

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 proposed rule will implement quality control changes to the Food Stamp Act required by sections 4118 and 4119 of the Farm Security and Rural Investment Act of 2002 in 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. (02-008)

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 proposed rule deals with changes required by Public Law 107-171, the Farm Security and Rural Investment Act of 2002. The Department has limited discretion in implementing provisions of that law. The provisions in this rule are effective for fiscal year 2002 quality control review period and must be implemented by FNS and State agencies during fiscal year 2002.

Anticipated Cost and Benefits:

The provisions of this rule will eliminate enhanced funding for low payment error rates and revise the quality control sanction and liability requirements. The provisions of Public Law 107-171 implemented by this rule will save $190 million over 5 years through elimination of the current enhanced funding system. This savings will be partially offset by costs of implementing a new performance system. The costs for the new performance system are estimated to be $144 million.

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. The provisions of this rule will eliminate enhanced funding for low payment error rates. It will significantly revise the system for determining State agency liabilities and sanctions for high payment error rates.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	
NPRM Comment Period End	04/00/03	
Final Action	01/00/04	
Final Action Effective	02/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local, Federal

Federalism:

Undetermined

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USDA—FNS

12. ● 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 proposed rule will implement 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	09/00/03	
NPRM Comment Period End	11/00/03	
Final Action	12/00/04	
Final Action Effective	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Federal

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USDA—FNS

FINAL RULE STAGE

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

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

7 CFR 226

Legal Deadline:

None

Abstract:

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

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

In developing the proposal, the Agency considered various alternatives to minimize burden on State agencies and institutions while ensuring effective program operation. Key areas in which alternatives were considered include State agency reviews of institutions and

sponsoring organization oversight of day care homes.

Anticipated Cost and Benefits:

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

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/12/00	65 FR 55103
NPRM Comment Period End	12/11/00	
Interim Final Rule	06/00/03	
Interim Final Rule Effective	07/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local

Federalism:

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

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USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

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14. PERFORMANCE STANDARDS FOR BACON

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq; 21 USC 451 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 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 bacon. FSIS is proposing to replace these provisions with an upper limit for nitrite and a performance standard that establishments producing pumped bacon must meet. To meet the proposed performance standard, the process used 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 bacon with an upper limit for nitrite and a performance standard. The proposed performance standard concerns limiting the presence of volatile nitrosamines in pumped bacon. These proposed changes are necessary to make the regulations concerning pumped 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. 601-695) a meat or meat food product is adulterated ''if it bears or contains any poisonous or deleterious substance which 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 bacon, they may be produced when the pumped 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 of ingoing curing accelerators that are used in the production of pumped 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 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 bacon, FSIS does not anticipate that this proposed rule would result in any significant costs or benefits. Pumped bacon processing establishments whose HACCP plans do not address nitrosamines as hazards reasonably likely to occur may incur some costs. Also, establishments that choose to test their products for nitrosamines 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 product with wide consumer appeal.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 0583–AC49

USDA—FSIS

15. EGG AND EGG PRODUCTS INSPECTION REGULATIONS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 1031 to 1056

CFR Citation:

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

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) is proposing to require shell egg packers and egg products plants 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 pasteurized shell eggs and egg products. 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 and 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.

The actions being proposed are part of FSIS' regulatory reform effort to improve FSIS' 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 and 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 shell egg packers and egg products plants to develop and implement HACCP systems and sanitation SOPs. FSIS also is proposing pathogen reduction performance standards that would be applicable to pasteurized 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 shell egg and 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 shell egg and 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. 1031-1056). 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, the shell egg and 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 six States and the Commonwealth of Puerto Rico under which they provide inspection services to egg processing plants under Federal jurisdiction. FSIS reimburses the States for staffing costs and expenses for full-time State inspectors. HACCP implementation may result in a reduction of staffing resource requirements in the States and a corresponding reduction of the Federal reimbursement. As a result, some States may decide to stop providing inspection services and convert to Federal inspection of egg products plants.

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

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

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

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

Risks:

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

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State

Federalism:

Undetermined

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USDA—FSIS

16. ELIMINATION OF CHILLING TIME AND TEMPERATURE REQUIREMENTS FOR READY-TO-COOK POULTRY (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

21 USC 451 to 470

CFR Citation:

9 CFR 381.66

Legal Deadline:

None

Abstract:

FSIS is proposing to eliminate the time and temperature requirements for chilling ready-to-cook poultry carcasses and giblets. The Agency is taking this action because the requirements are inconsistent with the Agency's Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) System regulations, with its final rule further restricting retained water in raw meat and poultry, and with the Agency's regulatory reform program. Moreover, because of these regulations, the meat and poultry industries receive disparate regulatory treatment: No regulations that apply to the chilling of poultry apply to the chilling of meat. This proposal responds to longstanding petitions by 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. 451-470).

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 fifth alternative.

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 unavoidable for food-safety purposes. They would be able to operate with a wider range of chilling temperatures consistently 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	06/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

17. EMERGENCY REGULATIONS TO PREVENT MEAT FOOD AND MEAT PRODUCTS THAT MAY CONTAIN THE BSE AGENT FROM ENTERING COMMERCE

Priority:

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

Legal Authority:

21 USC 601 et seq

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

FSIS is proposing to amend the meat inspection regulations to add emergency regulations to prevent meat and meat food products that may contain the bovine spongiform encephalopathy (BSE) agent from entering commerce. The emergency regulations would become effective when, and if, BSE is diagnosed in native cattle in the United States. FSIS may also propose to issue certain regulations in the absence of BSE as preventive measures. The proposed regulations provide for periodic review by FSIS to determine their effectiveness and to evaluate the need to modify or remove some measures or impose additional measures.

Statement of Need:

FSIS is proposing to amend the meat inspection regulations to add provisions to prevent meat and meat products that may contain the BSE agent from entering commerce in the event that BSE is diagnosed in native cattle in the U.S. Any final rule that is developed as a result of this proposal will become effective if, and when, a native case of BSE is detected in the U.S.

BSE is a chronic, degenerative, neorological disorder of cattle. Worldwide, there have been more than 185,000 cases since the disease was first diagnosed in 1986 in Great Britain. There have been no cases of BSE detected in the United States despite 10 years of active surveillance for the disease. 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. Like BSE, vCJD has not been detected in the United States. Both BSE and vCJD are always fatal.

Although BSE has not been detected in the U.S., USDA policy in regard to BSE has been to be proactive and preventive. Therefore, FSIS is proposing these regulations so that the Agency will have an immediate regulatory response in the event that BSE is detected in the U.S. Once finalized, the proposed measures will be incorporated in the meat inspection regulations but would only become effective if, and when, BSE is detected in native cattle. The proposed regulations would: (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) impose restrictions on the use of the vertebral column as a source material in the production of meat produced using advanced meat recovery systems (AMRS) and in the production of ''Mechanically Separated (Beef)'' (MS(Beef)) meat food product; (5) 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 (6) prescribe requirements for the sanitation or disposal of plant equipment that may be contaminated with the BSE agent. The proposed regulations provide for periodic review by FSIS to determine their effectiveness and to evaluate the need to modify or remove some measures or impose additional measures.

Summary of Legal Basis:

Under the Federal Meat Inspection Act (21 U.S.C. 601-695), 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 proposed requirements, 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. Publishing a proposed rule will inform the public of the type of regulatory response it can expect from FSIS when, and if, BSE is detected in native cattle.

In addition to the proposed requirements, FSIS is considering taking actions prior to the detection of BSE in the U.S. to minimize human exposure to materials from cattle that could potentially contain the BSE agent. The measures under consideration are targeted at the materials of cattle that are most likely to contain the BSE agent, if such animals have been infected with BSE, and those cattle that have consumed feed prohibited by Food and Drug Administration's (FDA) regulations (i.e., mammalian meat and bone meal in ruminant feed).

Anticipated Cost and Benefits:

If issued as a final rule, this proposal would 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 and systems used to produce MS (Beef) product 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. would affect 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, if issued as a final rule, this proposal 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 proposed rule may benefit the meat industry by helping to restore confidence in the domestic meat supply when, and if, a native case of BSE is detected in the U.S. 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 proposed 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 proposed 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 will use the findings of the risk assessment to evaluate the level of risk reduction associated with the proposed measures.

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, if BSE were detected in the U.S., additional measures to reduce the risk of human exposure to the BSE agent are necessary to protect public health.

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0583–AC88

USDA—FSIS

FINAL RULE STAGE

18. PERFORMANCE STANDARDS FOR READY-TO-EAT MEAT AND POULTRY PRODUCTS

Priority:

Economically Significant

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 451 et seq; 21 USC 601 et seq

CFR Citation:

9 CFR 317; 9 CFR 381; 9 CFR 430

Legal Deadline:

None

Abstract:

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

FSIS also proposed requirements intended to reduce the incidence of Listeria in ready-to-eat meat and poultry products. First, FSIS proposed to require establishments that produce ready-to-eat meat and poultry products to conduct environmental testing for Listeria to verify that they are controlling the presence of L. monocytogenes within their processing environments. Establishments that have developed and implemented HACCP controls for L. monocytogenes would be exempt from these testing requirements.

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 601-695) and the Poultry Product Inspection Act (21 U.S.C 451-470) 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 requirements for Listeria testing, FSIS considered: End-product testing; mandatory post-lethality interventions for L. monocytogenes; mandatory food-contact surface testing for all establishments that produce read-to-eat products; redesignation of hotdogs and other ready-to-eat products as not-ready-to-eat; and requiring ''use-by'' date labeling on certain ready-to-eat products.

Anticipated Cost and Benefits:

If the proposed regulations could achieve a complete elimination of listeriosis that results from the consumption of contaminated RTE meat and poultry products, the expected annual reduction in listeriosis cases and deaths would range from 1,660 cases and 331 deaths (based on the draft FDA-FSIS risk assessment and on 100 percent program effectiveness) to 167 cases and 35 deaths (based on two independent CDC studies and on 100 percent program effectiveness). FSIS is uncertain about the effectiveness of its proposed testing requirements in reducing listeriosis and therefore unable to adequately quantify a range of benefits. FSIS intends to use comments and data received during the comment period and at the planned technical conference to refine the proposed regulations and to better estimate benefits. It is of course unlikely that the proposed regulations could achieve complete elimination of the listeriosis that results from contaminated meat and poultry, but FSIS believes that the benefits of the regulations would exceed the total costs of all of the proposed provisions.

The two main provisions of the proposed rule are: (1) Mandatory in-plant testing for Listeria and (2) Salmonella and E. coli performance standards firms must employ as measures of process control. Much of the costs of these actions are associated with first-year, one-time validation pertaining to the achievement of the performance standards and with the incorporation of new information into plants' HACCP plans. These initial costs are projected at over $6.5 million, while annual recurring costs are estimated at $6.2 million. Benefits are expected to result from less contaminated product entering commercial channels due to increased sanitation efforts and in-plant verification through testing.

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

Action	Date	FR Cite
NPRM Comment Period End	09/10/01	
Final Action	06/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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USDA—FSIS

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

Priority:

Other Significant

Legal Authority:

21 USC 601 to 695

CFR Citation:

9 CFR 301.2; 9 CFR 318.24 (Revision); 9 CFR 320.1(b)(10)

Legal Deadline:

None

Abstract:

In 1994, the Food Safety and Inspection Service (FSIS) amended its regulations to recognize that products resulting from advanced meat/bone separation machinery comes within the definition of meat when recovery systems are operated to assure that the characteristics and composition of the resulting product are consistent with those of meat. Subsequent compliance problems and other concerns have made it apparent that the regulations are inadequate to prevent misbranding and economic adulteration. Therefore, FSIS is developing a rule to clarify the regulations and supplement the rules for assuring compliance.

Statement of Need:

In 1998, FSIS proposed to clarify the meat inspection regulations regarding mechanically separated meat contained in a final rule issued in December 1995. The rule would replace the present compliance program parameters with non-compliance criteria for bone and bone-related material. The rule would require, as a prerequisite to labeling or using product derived by mechanically separating skeletal muscle tissue from cattle and swine bones as meat, that establishments implement and document procedures for ensuring that their production process is in control. The proposed rule was published in 1998.

FSIS intends to implement more rigid measures for central nervous system tissue and prohibiting the use of vertebral columns in the AMR final product unless the establishment can demonstrate effective process control to ensure that no spinal cord and dorsal root ganglia will be present in the final AMR product. Current FSIS policy prohibits the presence of spinal cord in AMR products but not the presence of DRG or the use of vertebral columns. In January 2002, FSIS began the first of two surveys on AMR products derived from non-vertebral and vertebral beef and pork columns.

Summary of Legal Basis:

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

Alternatives:

No action.

Anticipated Cost and Benefits:

Although the 1998 proposed rule was determined to be not economically significant, FSIS restudied the projected costs using data from various FSIS data bases and other sources to develop an improved estimate of the benefits and costs of implementing the final rule. To date, it appears that the final rule will not be economically significant, but data evaluation continues. The benefit of enforcing the misbranding provisions will ensure that the product does not contain materials not consistent with boneless, comminuted meat.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/13/98	63 FR 17959
NPRM Comment Period End	06/12/98	
Final Action	09/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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USDA—FSIS

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

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq; 21 USC 451 et seq

CFR Citation:

9 CFR 317; 9 CFR 381

Legal Deadline:

None

Abstract:

FSIS has proposed to amend the Federal meat and poultry products inspection regulations to require 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. FSIS proposed to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products 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.

In this rule, FSIS also proposed to amend its regulations to extend mandatory labeling to single-ingredient ground or chopped products. Under this proposal, individual retail packages of ground or chopped meat and ground or chopped poultry products would bear nutrition labeling. The Agency has determined that ground or chopped products are different from other single-

ingredient products in several important respects. Thus, FSIS proposed to make nutrition labeling requirements for ground or chopped products consistent with those for multi-ingredient products.

Finally, FSIS has proposed to 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 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 has proposed to 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 believes that these products would be misbranded.

FSIS has also proposed to amend its regulations to require nutrition labels on the packages of all ground or chopped meat and poultry products. The Agency has determined that single-ingredient, ground or chopped products are different from other single-ingredient products in several important respects. Thus, FSIS has proposed to make nutrition labeling requirements for all ground or chopped products consistent with those for multi-ingredient products.

Finally, FSIS has proposed to 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 proposed this provision because many consumers have become accustomed to this labeling on ground beef products and because FSIS believed 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. 601-695) and the Poultry Products Inspection Act (21 U.S.C. 451-470).

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 would include the equipment for making labels, labor, and materials used for labels for ground or chopped products. FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products should be negligible. Retail establishments would have the option of providing nutrition information through point-of-purchase materials. These materials are available for a nominal fee through the Food Marketing Institute. Also, FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site.

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.

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	07/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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BILLING CODE 3410–90–S

DEPARTMENT OF COMMERCE (DOC)

Statement of Regulatory and Deregulatory Priorities

The mission of the Department of Commerce (Commerce) is to promote job creation, economic growth, technological competitiveness and sustainable development, and improved living standards for all Americans by working in partnership with business, universities, communities, and workers to:

- Build for the future and promote U.S. 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 Commerce mission statement, containing our three strategic themes, provides the vehicle for understanding Commerce'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.

Commerce 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.

Commerce 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, national security, 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 needs of the Nation, according to the priorities of the President and the Congress. The President's priorities for Commerce range from issues concerning the economy, the environment, and national security. For example, the President directs Commerce to promote electronic commerce activities; encourage open and free trade; represent American business interests abroad; assist small businesses to expand and create jobs; and regulate the export of goods and technology that may compromise national security. 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.

Commerce 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. Commerce completes these activities all the while preserving national security. For example, Commerce works to implement export controls on dual-use goods and technology to prevent the proliferation of weapons of mass destruction and to limit the U.S. transactions of terrorists and those who support them.

Commerce encourages development in every community, clearing the way for private-sector growth by building or 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, Commerce 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.

Commerce'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 this information, businesses can undertake the new ventures, investments, and expansions that make our economy grow.

Commerce 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.

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

The Department's 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 Commerce's programs and activities do not involve regulation. Of Commerce's 12 primary operating units, only 2—the Bureau of Industry and Security (BIS) and the National Oceanic and Atmospheric Administration (NOAA)—plan significant preregulatory or regulatory actions for this Regulatory Plan year. However, none of these significant actions rise to the level of ''most important'' of Commerce's ''significant regulatory actions'' planned for the Regulatory Plan year.

Though not principally a regulatory agency, Commerce 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 Commerce Department 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 down-sized, 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 Commerce's goal of promoting stewardship by providing assessments of the global environment.

Recognizing that economic growth must go hand-in-hand with environmental stewardship, Commerce, 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. Commerce is where business and environmental interests intersect, and the classic debate on the use of natural resource 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 be guided by a comprehensive understanding of the environment. Commerce, 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) rulemaking concerns 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 Council (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. Most of these rulemakings will be minor, involving only the opening or closing of a fishery under an existing FMP. While no one Magnuson-Stevens Act rulemaking is among the Department's most important significant regulatory actions, and, therefore, none is specifically described below, the sum of these actions, and a few of the individual actions themselves, are highly significant.

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 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 Commerce'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, which has become especially important in light of the tragic events of September 11, 2001. 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.

One of the most important updates to the EAR came as a result of the acts of terrorism committed on September 11, 2001. The President's Executive Order 13224, entitled ''Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism,'' directs agencies to, among other things, block property and interests in property of persons listed in the Annex of the Executive Order. This action was taken to ensure the continued preservation of national security, foreign policy, and the economy of the United States. To implement EO 13224, the EAR was updated to implement license requirements on all exports and reexports to persons designated in, or pursuant to, the Executive order.

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.

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 7 DoD field activities. It has over 1,400,000 military personnel and 670,000 civilians assigned as of May 31, 2002, 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 impacted 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 plans to issue just two significant regulations this year, the probability of developing conflicting regulations is low. Conversely, DoD is impacted 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 world-wide 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.''

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

The Department of Defense promulgated two acquisition regulations relating to the events of September 11, 2001. Defense Federal Acquisition Regulation Supplement (DFARS) Case 2001-D018, Performance of Security Functions, implements section 1010 of the USA Patriot Act. An interim rule was published in the **Federal Register** on March 14, 2002. Section 1010 provides an exception to the prohibition on contracting for security functions at a military installation or facility. The exception applies during the period of time that the United States Armed Forces are engaged in Operation Enduring Freedom and the 180 days thereafter. The interim rule was finalized without change on August 30, 2002 (67 FR 55730).

Federal Acquisition Regulation (FAR) Case 2002-003, Temporary Emergency Procurement Authority, implements section 836 of the Fiscal Year (FY) 2002 National Defense Authorization Act. Section 836 increases the

micropurchase threshold and the simplified acquisition threshold for purchases during FY 2002 and 2003 that facilitate the defense against terrorism or biological or chemical attack against the United States. The section also specifies that the procurement of biotechnology property or services to facilitate the defense against terrorism or biological or chemical attack shall be treated as procurement of commercial items. The interim rule was published in the **Federal Register** on August 30, 2002, as part of Federal Acquisition Circular (FAC) 2001-009 (67 FR 56120-56122).

Suggestions From the Public for Reform—Status of DoD Item

In the draft report on costs and benefits published May 2, 2001, the Office of Information and Regulatory Affairs asked the public to recommend specific proposals for regulatory reform. Of the 71 suggestions involving 17 agencies, one specifically addressed the Army Corps of Engineers' Regulatory Program. The nationwide permits were classified as priority 3 in appendix A of the report, ''Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities.''

In the January 15, 2002, issue of the **Federal Register** (67 FR 2019-2095), the Army Corps of Engineers reissued 43 nationwide permits and 26 general conditions, with minor modifications. The Corps also issued one new nationwide permit general condition. The implementing regulations for the nationwide permit program are found at 33 CFR part 330. The most recent substantive modifications to 33 CFR part 330 were published in the **Federal Register** on November 22, 1991 (56 FR 59110). On February 14, 1997, the Corps removed appendix A (which contained the text of the nationwide permits) from the Code of Federal Regulations at 33 CFR part 330 (see 62 FR 6877). The nationwide permits are not classified as regulations. They are permits to authorize certain minor activities in waters of the United States that result in minimal adverse effects on the aquatic environment, individually and cumulatively. Nationwide permits cannot be issued for a period of more than 5 years and must be reviewed prior to reissuance to ensure compliance with section 404(e) of the Clean Water Act and other applicable laws. Although the permits and general conditions are not regulations, the Corps coordinated the reissue package with the Office of Management and Budget, who subsequently vetted the submission with other Federal agencies interested in the Army's Regulatory Program. The 43 nationwide permits and 27 general conditions that were published on January 15, 2002, reflect the result of this interagency coordination.

Specific Priorities

For this regulatory plan, there are three specific DoD priorities, all of which reflect the established regulatory principles. One of these, ''U.S. Army Corps of Engineers, Directorate of Civil Works,'' will have one significant regulatory action as defined by E.O. 12866. 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 three 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, and installations and the environment.

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

Preserve the Quality of Water and the Quality and Quantity of Wetlands

During Fiscal Year (FY) 2003, the U.S. Army Corps of Engineers is proposing one significant regulation as defined by Executive Order 12866. Although not economically significant, the ''Programmatic Regulations for the Comprehensive Everglades Restoration Plan'' has been classified as significant (''other significant'') because of the novel legal and policy issues that have arisen and will continue to arise over the 30-year implementation period. The Office of the Assistant Secretary of the Army (Civil Works) and the Corps have completed one regulation.

The U.S. Army Corps of Engineers was directed by Congress in section 601 of the Water Resources Development Act of 2000 (Public Law 106-541, 114 Stat. 2680) to develop a Comprehensive Everglades Restoration Plan (Plan) to restore and preserve south Florida's natural ecosystem, while enhancing water supplies and maintaining flood protection. To guide the development of the Plan, Congress also directed the Secretary of the Army, after notice and opportunity for public comment, to develop and implement Programmatic Regulations within 2 years (not later than December 11, 2002). The Programmatic Regulations will establish a process for developing project implementation reports, project cooperation agreements, and project operating manuals that will ensure the goals and the objectives of the Plan are achieved. The regulations also will establish procedures for developing and using any new information resulting from ecosystem changes or unforeseen circumstances in accordance with the principles of adaptive management contained in the Plan. Finally, the Programmatic Regulations will facilitate the re-establishment of and protection of the natural system consistent with the interim and final goals of the Plan while providing thorough evaluation points during the 30-year project implementation schedule. The Office of Management and Budget (OMB) is facilitating development of the rule. OMB vetted the draft with appropriate Federal agencies and held several interagency meetings before clearing the draft for publication in the **Federal Register** in August 2002. The final Programmatic Regulations require the concurrence of the Governor of Florida and the Secretary of the Interior, and the consultation with the Seminole Tribe of Indians of Florida, the Miccosukee Tribe of Indians of Florida, the Administrator of the Environmental Protection Agency, and the Secretary of Commerce. Additionally, other Federal, State, and local agencies will continue to assist in promulgating the Programmatic Regulations to ensure that the goals and purposes of the Plan are achieved.

The Office of the Assistant Secretary of the Army (Civil Works) and the U.S. Army Corps of Engineers completed one regulation in 2002. On April 20, 2001, the Corps proposed revisions to the Clean Water Act (Act) regulatory definitions of ''Fill Material'' and ''Discharge of Fill Material'' (65 FR 21292). On May 9, 2002, the Corps in conjunction with the U.S. Environmental Protection Agency (EPA), issued a final rule in the **Federal Register** (67 FR 31129) revising the Clean Water Act regulatory definitions of ''fill material'' and ''discharge of fill material.'' Revising the rule was necessary in order to clarify those pollutants that are regulated by the Corps under section 404 of the Act.

Section 404 of the Clean Water Act requires a permit from the U.S. Army Corps of Engineers for discharges of dredged or fill material to waters of the

United States. The Environment Protection Agency and the Corps' regulations implementing section 404 previously contained differing definitions of the term ''fill material.'' In particular, the Corps regulations defined fill material as being used for the ''primary purpose'' of replacing an aquatic area with dry land or changing the bottom elevation of a waterbody. In contrast, EPA's definition of fill material looked to whether the effect is to replace waters of the U.S. with dry land or change the bottom elevation of waterbodies and did not contain a ''primary purpose'' test as found in the Corps regulations. In order to clarify what constitutes ''fill material'' for purposes of section 404 and provide improved regulatory certainty, the Corps and EPA have implemented the final rule under which both agencies have adopted identical, effect-based definitions of the terms ''fill material'' and ''discharge of fill material.''

National Historic Preservation Act—Army's Regulatory Program

More than 20 years ago, 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 for the Army's Regulatory Program. Over the years, there have been significant changes in policy, and the Act was amended in 1992, leading to the publication in December 2000 of new implementing regulations, at 36 CFR part 800, developed by the Advisory Council on Historic Preservation (ACHP). Thus, on March 8, 2002, the Corps published a notice in the **Federal Register** (67 FR 10822), requesting comments on the implementation of the Army's regulatory program in view of the new ACHP regulations at 36 CFR part 800. Thirty-nine comments were received in response to this notice. The Corps Regulatory Program currently uses 33 CFR part 325, appendix C, to comply with the National Historic Preservation Act and other laws that address historic properties. In Fiscal Year 2003, the Corps may propose changes to 33 CFR part 325, appendix C, to bring the regulation into conformance with the new Advisory Council on Historic Preservation's regulations at 36 CFR part 800.

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 its attention on implementing and institutionalizing initiatives that may include additional changes to existing and recently modified regulations to ensure that the Department is achieving the outcomes it desires (continuous process improvement).

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

- Consider FAR and Defense Federal Acquisition Regulation Supplement (DFARS) changes to facilitate timely contract closeout.
- Consider policies and procedures to provide contractors an adequate share of savings from cost efficiencies and rationalization over a not-to-exceed 5-year period.
- Revise the FAR to provide for electronic listing of acquisition vehicles available for use by more than one agency.
- Rewrite DFARS part 225, Foreign Acquisition, to improve clarity and make procedures less complex, particularly for evaluation of foreign offers and customs duty. The rewrite also proposes to implement the determination of the Under Secretary of Defense (AT&L) that for procurements subject to the Trade Agreements Act, it would be inconsistent with the public interest to apply the Buy American Act to U.S.-made end products that are substantially transformed in the United States.
- Rewrite FAR part 27, Patents, Data and Copyrights, to clarify, streamline, and update guidance and clauses on patents, data, and copyrights.
- 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.
- Revise the FAR part 45, Government Property, to organize and streamline the property disposal procedures and to incorporate into the FAR the DoD deviations relating to Government property rental and special tooling.

Defense Installations and the Environment

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

Restoration Advisory Boards

Section 324(a) of Public Law 104-106, which amended section 2705 of title 10, United States Code, requires the Secretary of Defense to ''prescribe regulations regarding the establishment, characteristics, composition, and funding of restoration advisory boards.'' Section 324(a) also stated that DoD's issuance of regulations shall not be a precondition to the establishment of Restoration Advisory Boards (RABs) (amended section 2705(d)(2)(B)).

The Department of Defense recognizes the importance of public involvement at military installations and formerly used defense sites that require environmental restoration. RABs provide an expanded opportunity for stakeholder input into the environmental restoration process at operating and closing DoD installations. They also act as a forum for the discussion and exchange of restoration program information between agencies and the community, as well as providing an opportunity for RAB members to review progress and participate in a dialogue with the installation's decisionmakers.

In August 1996, the Department proposed and requested public comments on regulations regarding the characteristics, composition, funding, and establishment of Restoration Advisory Boards. The Boards were not subject to the Federal Advisory Committee Act (FACA), because DoD did not want to subject community members to the FACA requirements, such as financial disclosure. The General Services Administration did not agree that RABs are not subject to FACA. DoD continued its RABs but did not publish a final rule.

In the fall of 2001, the RAB regulations were raised in a case before the 9th Circuit. On the RAB rule issue,

the Judge indicated that he would dismiss without prejudice and give the Department of Defense 18 months to promulgate a rule. The Judge was not inclined to grant the plaintiff's request that he order DoD to promulgate the rule, stating that the plaintiff could bring the matter back to the Court if the Department of Defense had not completed the rulemaking in 18 months. Accordingly, DoD is preparing a new RAB rule to meet this requirement and plans on publishing the rule by the middle of 2003.

Munitions Response Site Prioritization Protocol

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

The proposed rule will be called the ''Munitions Response Site Prioritization Protocol'' and will assign a relative response priority for all sites addressed under the Military Munitions Response Program (MMRP) category of the Defense Environmental Restoration Program (DERP). The protocol will be a qualitative methodology used to sequence environmental restoration activities. The tool will make use of limited data and reflect the overall conditions at the site. It will be used to assign a relative priority based on an evaluation of factors relating to safety and environmental hazard potential.

The proposed Munitions Site Prioritization Protocol Rule is being developed by a defense working group with input from other Federal agencies and State members of the Munitions Response Committee in consultation with tribal representatives. A notice was published in the **Federal Register** in March 2002 announcing DoD's intent to develop the protocol and requesting input from the public on the factors promulgated by Congress. Working documents are on the World Wide Web and the Department continues to meet with State and tribal representatives. DoD intends to prepare, in consultation with the States and Indian tribes, a proposed and final protocol according to the requirements. Currently a draft proposed protocol is being prepared. Meetings are scheduled to discuss it with the States and tribes prior to publication.

DOD

FINAL RULE STAGE

21. PROGRAMMATIC REGULATIONS FOR THE COMPREHENSIVE EVERGLADES RESTORATION PLAN

Priority:

Other Significant

Legal Authority:

PL 106-541

CFR Citation:

33 CFR 385

Legal Deadline:

Final, Statutory, December 11, 2002.

Abstract:

The U.S. Army Corps of Engineers was directed by Congress in section 601 of the Water Resources Development Act of 2000 (Public Law 106-541, 114 Stat. 2680) to develop a Comprehensive Everglades Restoration Plan (Plan) to restore and preserve south Florida's natural ecosystem, while enhancing water supplies and maintaining flood protection. To guide the development of the Plan, Congress also directed the Secretary of the Army, after notice and opportunity for public comment, to develop and implement Programmatic Regulations within 2 years (NLT December 11, 2002). The Programmatic Regulations will establish a process for developing project implementation reports, project cooperation agreements, and project operating manuals that will ensure the goals and the objectives of the Plan are achieved. The regulations also will establish procedures developing and using any new information resulting from ecosystem changes or unforeseen circumstances in accordance with the principles of adaptive management contained in the Plan. Finally, the Programmatic Regulations will facilitate the re-establishment and protection of the natural system consistent with the interim and final goals of the Plan while providing thorough evaluation points during the 30-year project implementation schedule.

Statement of Need:

The Programmatic Regulations will fulfill the intent of Congress to establish explicit guidance on how this project, and its constituent parts, will be developed and implemented, with full public and agency participation.

Summary of Legal Basis:

Specifically, the Programmatic Regulations will implement the following sections of the Water Resources Development Act of 2000:

Section 601(h)(3)(A), requires Programmatic Regulations to be completed not later than 2 years after enactment;

Section 601(h)(3)(B), the Secretary of the Interior and the Governor shall provide the Secretary of the Army with a written statement of concurrence or nonconcurrence not later than 180 days after the end of the comment period;

Section 601(h)(3)(C), the regulations shall establish a process for the development of project implementation reports, project cooperation agreements, and operating manuals; ensure that new information resulting from changed or unforeseen circumstances, new science or technical information developed through adaptive management are integrated into the implementation of the Plan; and ensure the protection of the natural system consistent with the goals and purposes of the Plan;

Section 601(h)(3)(D), all project implementation reports approved before the date of promulgation of the Programmatic Regulations shall be consistent with the Plan;

Section 601(h)(3)(E), at least every 5 years the Secretary of the Army shall review the Programmatic Regulations for consistency with Plan goals and purposes.

Alternatives:

None.

Anticipated Cost and Benefits:

There are no economic costs, per say, attributed to the promulgation of the Programmatic Regulations. The regulations will help ensure that the $8 billion estimated Federal investment will result in ecosystem restoration benefits identified as individual projects are developed and implemented over a 30-year construction period.

Risks:

There are no risks associated with the Programmatic Regulations. Promulgation of the regulations will help ensure that the Army Corps of Engineers follows agreed upon project development and implementation

procedures, designed to achieve the environmental restoration and protection benefits outlined in the Plan. Although no regulatory impacts with other Federal, Tribal, State, or local regulations have been identified to date, the Corps will take comments on impacts as part of the public and agency comment period, and address them in the final regulations. The draft Programmatic Regulations have been drafted so as not to conflict with existing laws and regulations. Any oversights will be corrected in the final version.

Timetable:

Action	Date	FR Cite
NPRM	08/02/02	67 FR 50540
NPRM Comment Period End	10/01/02	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal, Local

Agency Contact:

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DEPARTMENT OF EDUCATION (ED)

Statement of Regulatory and Deregulatory Priorities

General

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

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

http://www.ed.gov

More than 773,600 people take advantage of these resources every week. 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 and local governments, neighborhood groups, schools, colleges, special education and rehabilitation service providers, professional associations, advocacy organizations, business, and labor.

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

OMB's 2001 Report to Congress on the Costs and Benefits of Regulations identified as needing changes — (priority 1) — the Department's title IV regulations promulgated under the authority of the Higher Education Act. These regulations were recently negotiated with the financial aid, higher education, and other related community members through the negotiated rulemaking process and will reduce administrative burden for program participants, provide benefits to students and borrowers, and protect taxpayers' interests.

We are streamlining information collections, reducing burden on information providers involved in our programs, and making information maintained by us easily available to the public. We are looking into coordinating similar information collections across programs as one possible approach to reduce overlapping or inconsistent paperwork requirements. To the extent permitted by statute, we'll revise regulations to eliminate barriers that inhibit coordination across programs (such as by creating common definitions). This should help reduce the frequency of reports and eliminate unnecessary data requirements.

Recently, we have piloted two new Internet-based software applications, e-Application and e-Reports. These enable applicants, grantees, and grant teams to process applications and file performance reports online. We have received positive feedback from participants in the pilot programs. Our goal over time is to encourage applicants and grantees to make electronic commerce, or the process of conducting business over the Internet, their preferred method of doing business.

New Initiatives

The Secretary's initiatives include One-ED, a new way of doing business for the Department of Education. One-ED represents the culmination of a series of changes that will transform the Department into a flexible, high-performing, high-integrity workplace focused on program outcomes and management reform. One-ED provides an integrated, 5-year human capital, strategic sourcing and restructuring plan that builds on the President's Management Agenda and the Department's Strategic Plan, Culture of Accountability Report and Blueprint for Management Excellence, by providing employee learning and achievement opportunities.

Some One-ED changes involve employees learning new skills so that staff can help the Department's partners achieve key education outcomes. Creating One-ED also means making organization structure changes to coordinate policymaking and avoid duplication. One-ED clients and partners will find knowledgeable people arrayed in a structure that is easy to access and navigate.

Moving to One-ED also involves re-engineering work processes; i.e., changing how Department staff performs its work by reducing paperwork, introducing technology, and removing unnecessary steps. In some cases, through competitions and cost comparisons, the Department may find it less costly to provide high quality services by contracting with private sector organizations. In such cases, re-training and restructuring may become necessary.

Also, the Department of Education and the National Council of Negro Women (NCNW) have joined forces to ignite a movement in communities across the country to close the achievement gap between African American students and their peers. The Partnership for Academic Achievement will leverage the new provisions of the No Child Left Behind Act of 2001 in conjunction with the tremendous outreach network of NCNW to improve academic achievement dramatically, reducing the difference in the gap between white and African American National Assessment of Educational Progress performance at the proficient level.

Principles for Regulating

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

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

Whether to Regulate:

- When essential to promote quality and equality of opportunity in education.

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

How to regulate:

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

Regulatory and Deregulatory Priorities for the Next Year

Reauthorization of the Elementary and Secondary Education Act of 1965 reflected President Bush's No Child Left Behind plan for reforming our public schools. Our priorities include amending existing regulations in 34 CFR chapter II (Office of Elementary and Secondary Education) to make the No Child Left Behind plan a reality and to implement various changes in statutes as they are enacted.

Reauthorization of the Individuals with Disabilities Education Act (IDEA), parts C and D, will make changes needed to improve implementation of the early intervention program for infants and toddlers with disabilities under part C, and the effectiveness of the National Activities under part D. The Secretary solicited public comment on the reauthorization of IDEA using the underlying framework of the President's principles of education reform to ensure that no child is left behind.

Reauthorization of the Educational, Research, Development, Dissemination, and Improvement Act of 1994 will make changes needed to ensure that activities carried out by the Office of Educational Research and Improvement meet the highest standards of professional excellence.

ED—Office of Educational Research and Improvement (OERI)

PROPOSED RULE STAGE

22. • REAUTHORIZATION OF THE EDUCATIONAL, RESEARCH, DEVELOPMENT, DISSEMINATION, AND IMPROVEMENT ACT OF 1994 (SECTION 610 REVIEW)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

20 USC 6001 et seq

CFR Citation:

34 CFR ch VII

Legal Deadline:

None

Abstract:

These regulations would implement changes made by the anticipated reauthorization of the Educational, Research, Development, Dissemination, and Improvement Act of 1994. This action is a notice that if regulations are necessary, ED would review the regulations in 34 CFR chapter VII under section 610 of the Regulatory Flexibility Act (5 U.S.C. 610). The purpose of this review would be to determine if these regulations should be continued without change, or should be amended or rescinded, to minimize any significant economic impact upon a substantial number of small entities. We would request comments on the continued need for the regulations; the complexity of the regulations; the extent to which they overlap, duplicate, or conflict with other Federal, State, or local government regulations; and the degree to which technology, economic conditions, or other relevant factors have changed since the regulations were promulgated.

Statement of Need:

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

Summary of Legal Basis:

New legislation.

Alternatives:

In addition to implementing the anticipated reauthorization of the Educational, Research, Development, Dissemination, and Improvement Act of 1994, the purpose of this review would be to determine whether there are appropriate alternatives.

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1850–AA57

ED—Office of Elementary and Secondary Education (OESE)

FINAL RULE STAGE

23. REAUTHORIZATION OF TITLE I OF THE ELEMENTARY AND SECONDARY EDUCATION ACT OF 1965 (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

PL 107-110

CFR Citation:

34 CFR 200

Legal Deadline:

Final, Statutory, July 8, 2002.

Abstract:

These regulations would implement changes made by the reauthorization of title I of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001. This action is a notice that ED is reviewing the regulations in 34 CFR part 200 under section 610 of the Regulatory Flexibility Act (5 U.S.C. 610). The purpose of this review is to determine if these regulations should be continued without change, or should be amended or rescinded, to minimize any significant economic impact upon a substantial number of small entities. We are requesting comment on the continued need for the regulations; the complexity of the regulations; the extent to which they overlap, duplicate, or conflict with other Federal, State, or local government regulations; and the degree to which technology, economic conditions, or other relevant factors have changed since the regulations were promulgated.

Statement of Need:

These regulations are necessary to implement new legislation. The Department is also completing its review of these regulations under section 610(c) of the Regulatory Flexibility Act. In developing any regulations, the Department will seek to reduce regulatory burden and increase flexibility to the maximum extent possible.

Summary of Legal Basis:

New legislation.

Alternatives:

In addition to implementing the reauthorization of title I of the Elementary and Secondary Education Act of 1965, the purpose of reviewing these regulations is to determine whether there are appropriate alternatives.

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	08/06/02	67 FR 50986
NPRM Comment Period End	09/05/02	
Final Action	11/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Agency Contact:

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RIN: 1810–AA91

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

PROPOSED RULE STAGE

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

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

20 USC 1400 to 1487

CFR Citation:

34 CFR ch III

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

New legislation.

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1820–AB54

BILLING CODE 4000–01–S

DEPARTMENT OF ENERGY (DOE)

Statement of Regulatory and Deregulatory Priorities

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

- Foster a secure and reliable energy system that is environmentally and economically sustainable;
- Provide responsible stewardship of the Nation's nuclear weapons;
- Clean up the Department's facilities;
- 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 of Energy's regulatory plan reflects the Department's continuing commitment to enhance safety, cut costs, reduce regulatory burden, and increase responsiveness to the public. While not primarily a major Federal regulatory agency, the Department's regulatory activities are essential to achieving its critical mission and to implementing major initiatives in the President's National Energy Plan.

Energy Efficiency Program for Consumer Products and Commercial Equipment

On May 23, 2002, the Department published a final rule that amended the existing energy conservation standards for central air conditioners and heat pumps by raising the minimum energy efficiency levels by 20 percent for most units. As part of this action, the Department withdrew a final rule, published on January 22, 2001, that would have established even higher standards. DOE determined the higher standards in the January 22 final rule, which was the only DOE regulation among the 23 identified as priority 1 reform candidates in OMB's 2001 Report to Congress on the Costs and Benefits of Regulations, were not economically justified under the Energy Policy and Conservation Act. DOE estimates that the revised standards will still save consumers $2 billion and reduce energy consumption by an amount equivalent to 516 million barrels of oil through the year 2030. By the year 2020, the new standards will eliminate the need for three 400 megawatt coal—fired powerplants and nineteen 400 megawatt gas-fired powerplants. In addition, the energy consumption thus avoided will reduce cumulative greenhouse gas emissions by 24 million metric tons of carbon, or an amount equal to that produced by approximately 2 million cars every year.

The Department's ongoing rulemaking activities related to energy efficiency standards and determinations have been categorized as high, medium, or low priority. On August 21, 2002, the Department released its most recent priority-setting report, ''Appliance Standards Program — The FY 2003 Priority Setting Summary Report and Actions Proposed.'' These priorities, established with significant input from the public, are reflected in the rulemaking schedules set forth in The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions. The complete report can be viewed online at the following website: http://www.eren.doe.gov/buildings/codes__standards/reports/priority__setting/priority__setting.html

During the coming year, the Department expects to revise the energy efficiency standards for residential furnaces, boilers, and mobile home furnaces; electric distribution transformers; and commercial unitary air conditioners and heat pumps rated 65-240 kBtu's/hr. Additional information and timetables for these high priority actions can be found below. In addition, the Department will begin the preliminary analyses required to revise the standards for packaged terminal air conditioners and heat pumps, oil- and gas-fired commercial packaged boilers, and tankless gas-fired instantaneous water heaters.

The Department plans to publish final rules concerning test procedures for dishwashers, residential central air conditioners and heat pumps, electric distribution transformers, commercial warm air furnaces and air conditioning equipment, package boilers, and commercial water heaters. Information and timetables concerning these actions, medium and low priority standards rulemakings, and other test procedures can be found in the Department's regulatory agenda, which appears elsewhere in this issue of the **Federal Register**.

Nuclear Safety Regulations

The Department is committed to openness and public participation as it addresses one of its greatest challenges—managing the environment, health, and safety risks posed by its nuclear activities. A key element in the management of these risks is to establish the Department's expectations and requirements relative to nuclear safety and to hold its contractors accountable for safety performance. The 1988 Price-Anderson Amendments Act revisions to the Atomic Energy Act of 1954 (AEA) provide for the imposition of civil and criminal penalties for violations of DOE nuclear safety requirements. As a result, new nuclear safety requirements were initiated with the publication of four notices of proposed rulemaking for review and comment in 1991. The Department's nuclear safety procedural regulations (10 CFR part 820) were published as a final rule in 1993. The Department's substantive nuclear safety requirements (10 CFR parts 830 and 835) were finalized in 2001 and 1998, respectively. The remaining action, 10 CFR part 834, Radiation Protection and the Environment, is scheduled for publication by the end of fiscal year 2003.

DOE—Energy Efficiency and Renewable Energy (EE)

PRERULE STAGE

25. ENERGY EFFICIENCY STANDARDS FOR RESIDENTIAL FURNACES, BOILERS, AND MOBILE HOME FURNACES

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 6295

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, January 1, 1994.

Abstract:

The Energy Policy and Conservation Act, as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and generally requires DOE to undergo 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 furnaces, boilers and mobile home furnaces.

Statement of Need:

This rulemaking is required by statute. 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:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and certain commercial equipment. The EPCA generally requires DOE to undergo rulemakings, at specified times, to determine whether the standard for a covered product should be made more stringent.

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

Without appliance standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions such as CO2 and NOx. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may 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	02/00/03	
NPRM	02/00/04	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local

Agency Contact:

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RIN: 1904–AA78

DOE—EE

26. ENERGY EFFICIENCY STANDARDS FOR ELECTRIC DISTRIBUTION TRANSFORMERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6317

CFR Citation:

10 CFR 430

Legal Deadline:

None

Abstract:

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

This is the initial review of the statutory standards for electric distribution transformers.

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
Determination Notice	10/22/97	62 FR 54809
ANPRM	03/00/03	
NPRM	03/00/04	
Final Action	10/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 1904–AB08

DOE—EE

27. ENERGY EFFICIENCY STANDARDS FOR COMMERCIAL CENTRAL AIR CONDITIONING UNITS AND HEAT PUMPS RATED 65-240 KBTUS/HR

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 6293

CFR Citation:

10 CFR 431

Legal Deadline:

None

Abstract:

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

This is the initial review of the statutory standards for these products.

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
Screening Workshop	10/01/01	66 FR 43123
ANPRM	04/00/03	
NPRM	04/00/04	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 1904–AB09

DOE—Departmental and Others (ENDEP)

FINAL RULE STAGE

28. 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 included a dose limitation system for protection of the public; requirements for liquid discharges; reporting and monitoring requirements; and residual radioactive material requirements.

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/25/93	58 FR 16268
Second NPRM	08/31/95	60 FR 45381
Final Action	09/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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RIN: 1901–AA38

BILLING CODE 6450–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

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

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

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

Since September 11, 2001, the Department has placed a renewed emphasis on taking action to prepare and protect all Americans from acts of terrorism and other public health emergencies. The Department is also moving aggressively to issue regulations addressing health care, foods and drugs, and the Medicare and Medicaid programs. In addition, consistent with the Secretary's priorities, the Department has taken important actions to enhance coordination of regulations across all its components.

Given the size and scope of the Department's responsibilities, effective program regulations are critical. Yet too often, excessive regulation can be more of a hindrance than a help. Programs can become caught in a web of mandates, rules and paperwork, and those whom the programs were intended to serve fail to receive the help they need. Last year, Secretary Thompson established a Secretary's Advisory Committee on Regulatory Reform (Advisory Committee), to provide recommendations regarding potential regulatory changes. The Advisory Committee has held public hearings across the country, in an effort to identify unnecessarily burdensome rules. The Advisory Committee's specific recommendations will be issued later this year.

FY 2003 Regulatory Themes

The Secretary has adopted four overarching regulatory themes for FY 2003:

- Improving the Department's ability to respond to emergencies and disasters;
- Reducing medical errors and enhancing patient safety;
- Protecting America's consumers; and
- Reducing unnecessary and counter-productive regulations.

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

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

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

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

- A final rule required under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) governing the possession, use and transfer of certain biological agents and toxins known as ''select agents;''
- A proposed rule emanating from the Bioterrorism Act establishing registration requirements for all facilities engaged in manufacturing, processing, packing, or holding food for U.S. consumption;
- A proposed rule based on the Bioterrorism Act requiring the establishment and maintenance of certain records regarding food products; and
- A proposed rule under the Bioterrorism Act authorizing the FDA to detain the release or shipment of food if it is determined that such acts would present a serious health threat.

Reducing Medical Errors and Enhancing Patient Safety

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

- A proposed rule requiring human drug products to have a scanable bar code that will reduce medication errors;
- A proposed rule to enhance and make more timely the safety reporting on drugs and biologics;
- A final rule to strengthen requirements that hospitals maintain policies and procedures to assess and improve the quality of the medical care they provide;
- A final rule requiring that drug labels contain a toll-free number in order to report adverse events;
- A final rule requiring improvements in the format and content requirements of the ''professional'' labeling of drug products, enabling health care practitioners to prescribe drugs more safely.

Protecting America's Consumers

Consumer health and safety is a major concern for the public and the Secretary. Consumers are inundated each year with an availability of new ingestible products and ingredients. Providing consumers with information about these products is a matter of great interest to the Secretary. Every year, tens of thousands of Americans become sick and some die from food borne pathogens, and the size of vulnerable

populations (e.g., the elderly and those with compromised immune systems) is growing. The Secretary is especially interested in identifying opportunities that exist to make patient care and the food supply safer.

Regulations under this theme include:

- A proposed rule controlling the manufacturing and packaging of dietary supplements;
- A final rule to require that amounts of trans fatty acids be included in food labeling because such information has significant potential to reduce the risk of coronary heart disease;
- A proposed rule to strengthen safety requirements for the storage and distribution of eggs.

Reducing Unnecessary and Counterproductive Regulations

The Secretary's Advisory Committee on Regulatory Reform is addressing HHS' priority of reducing regulatory burden on consumers, beneficiaries, health care providers, and other stakeholders. In addition to conducting the series of public meetings mentioned above, the Advisory Committee has reviewed an array of Departmental regulations, with the goal of identifying reforms that would maintain or enhance program performance while reducing burdens and costs. Proposed ways to accomplish these objectives include: a) clarifying and simplifying regulations; b) eliminating unnecessary paperwork; c) improving the quality and timeliness of information for consumers, beneficiaries, and providers; d) increasing flexibility in Federal health programs; and e) promoting collaboration and coordination among and between HHS agencies and other public and private stakeholders.

Regulations under this theme include:

- A proposed rule under which current requirements for Medicare reimbursement for services to persons with End Stage Renal Disease would be completely overhauled and simplified;
- A final rule to clarify the responsibilities of Medicare hospitals that provide emergency room treatment;
- A final rule to reduce the cost of drugs by eliminating a current practice that allows manufacturers to repeatedly obtain 30-month stays in order to block the approval of generic versions of their drugs;
- A variety of other actions resulting from the recommendations of the Advisory Committee.

Public Comments and Reactions

The Secretary welcomes comments not only on specific regulations as they are published in the Federal Register, but also on the themes he has established for 2003, as well as the regulatory principles noted above. Such comments, as well as ideas and specific suggestions for regulatory improvements and initiatives, should be sent to Secretary Tommy G. Thompson, c/o Ann C. Agnew, Executive Secretary to the Department, Room 603, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

TITLES OF ALL PRIORITY REGULATIONS, BY THEME

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

- Possession, Use, and Transfer of Select Agents
- Registration Requirements for Food Facilities
- Establishment and Maintenance of Records Regarding Food Products
- Detainment of Food
- Control of Communicable Diseases through Quarantine
- Prior Notification Requirement for All Imported Food Shipments

1. Reducing Medical Errors and Enhancing Patient Safety

- Bar Code Label Requirements for Human Drug Products
- Safety Reporting on Drugs and Biologics
- Hospital Conditions of Participation
- Quality Assurance/Performance Improvement Program
- Toll-free Number for Reporting Adverse Drug Events
- Use of Restraint and Seclusion in Medicare and Medicaid Facilities
- Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Risk of Transmitting Hepatitis C Virus
- ''Professional'' Labeling for Prescription Drugs

Protecting America's Consumers

- Manufacturing and Packaging of Dietary Supplements
- Food Labeling: Trans Fatty Acids
- Medicare: Review of National Coverage Determinations
- Control of Salmonella Enteriditis in Shell Eggs
- Exception from General Requirements for Informed Consent

1. Reducing Unnecessary and Counterproductive Regulations

- Application of the Emergency Medical Treatment and Labor Act
- End Stage Renal Disease Conditions for Coverage
- 30-Month Stays on Approvals of New Drug Applications
- A variety of actions resulting from the recommendations of the Advisory Committee

Also included in the Plan, are other regulatory actions entitled as follows, which would update or otherwise improve the Medicare program.

- Hospital Conditions of Participation
- Security Standards for Electronic Health Information
- Organ Procurement Organizations' Conditions for Coverage
- Revisions to the Medicare Appeals Process
- Revisions to Average Wholesale Price Methodology
- Electronic Claims Submission
- National Standard for Identifiers of Health Plans
- National Standard for Identifiers for Health Care Providers
- Prospective Payment System for Psychiatric Hospitals
- FY 2004 Changes—Hospital Inpatient Prospective Payment System
- FY 2004 Changes—Hospital Outpatient Prospective Payment System
- 2004 Physician Fee Schedule Changes
- Establishment of a Prospective Payment System for Skilled Nursing Facilities

HHS—Centers for Disease Control and Prevention (CDC)

PROPOSED RULE STAGE

29. CONTROL OF COMMUNICABLE DISEASES

Priority:

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

Legal Authority:

42 USC 216; 42 USC 243; 42 USC 264; 42 USC 271

CFR Citation:

42 CFR 70; 42 CFR 71

Legal Deadline:

None

Abstract:

This proposal updates existing regulations related to prevention of the introduction, transmission, or spread of communicable diseases from foreign countries to the U.S. and from State to State. The regulation addresses the process by which persons infected with, or who have been exposed to, modern communicable diseases should be quarantined, surveillance of quarantined persons, and requirements for carriers (e.g., airlines, etc.) to maintain passenger manifests for a determined period of time.

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 bioterrorist events, it is important to assure procedures reflect new threats and uniform ways to contain them.

The existing regulations are outdated and do not address some communicable diseases that currently pose a public health threat.

Summary of Legal Basis:

Section 264 of the U.S. Code, title 42 authorizes the Surgeon General, with the approval of the Secretary, to make and enforce regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or its possessions, or from one State or possession into any other State or possession.

Alternatives:

In the absence of this regulation, uniform application of procedures for the quarantine of individuals exposed to or infected with a communicable disease would be unavailable.

Anticipated Cost and Benefits:

It is anticipated that there will be a cost to carriers to maintain passenger manifests for an extended period of time. However, these costs are undetermined.

Risks:

This rule would allow for improvements to existing quarantine procedures and clarify due process procedures.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State

Federalism:

Undetermined

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RIN: 0920–AA03

HHS—CDC

FINAL RULE STAGE

30. • POSSESSION, USE, AND TRANSFER OF SELECT AGENTS

Priority:

Other Significant

Legal Authority:

PL 107-188

CFR Citation:

42 CFR 72; 42 CFR 72.6

Legal Deadline:

Final, Statutory, December 9, 2002.

Abstract:

On June 12, 2002, President George W. Bush signed Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Title II, subtitle B of the Bioterrorism Act repeals, expands, and incorporates the Secretary's current authority to regulate the transfer of certain biological agents and toxins (select agents) as provided in section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Pub. L. 104-132) (42 U.S.C. 262 note) and that Act's implementing regulations (42 CFR 72.6). The Bioterrorism Act specifies that the Secretary develop and biennially review the list of select agents. Safety procedures must be established and enforced for the possession, use, and transfer of listed agents and toxins, and access to select agents is limited to those individuals and entities that pass background checks administered by the Attorney General. The Bioterrorism Act exempts certain information from disclosure under the Freedom of Information Act, including information that would identify the location of regulated entities or their security measures. Subtitle C of the Bioterrorism Act outlines the required interagency coordination between the Department of Health and Human Services and the Department of Agriculture regarding agents that are regulated by both departments (overlap agents).

CDC is currently in the rulemaking process that will culminate in the publication of an interim final rule on or before December 9, 2002. To date, CDC has published a notice of proposed data collection submitted for public comment and recommendations (Fed Reg. vol. 67, no. 127; Tuesday, July 2, 2002); a notice of OMB approval of data collection (Fed Reg, vol. 67, no 151; Tuesday, August 6, 2002); and a notice of preliminary guidance for notification of possession of select agents (Fed. Reg., vol. 67, no. 164; Friday, August 23, 2002).

Statement of Need:

Statutorily required by subtitles A and C of title II of the Bioterrorism Act, Public Law 107-188.

Summary of Legal Basis:

Subtitles A and C of title II of the Bioterrorism Act, Public Law 107-188.

Alternatives:

On June 12, 2002, the President signed the Bioterrorism Act into law. Section 202 (a) of the Bioterrorism Act requires that all persons possessing, using, or transferring agents or toxins deemed a threat to public health to notify the Secretary of the Department of Health and Human Services (HHS). Since this is a mandate from Congress, the only alternative for this regulation would be to have HHS go back to Congress to request reconsideration.

Anticipated Cost and Benefits:

Modest internal cost implications for HHS/CDC can be foreseen at this time, but the potential costs to entities and individuals required to register under provisions of this rulemaking are currently unknown. CDC has issued a task order for support for the agency's responsibilities for the rulemaking and

related requirements of the Bioterrorism Act. The contractor implementing this task order will conduct an analysis of all anticipated costs of the rulemaking. The economic impact information resulting from this analysis will be set out in the preamble of the interim final rule.

Risks:

By establishing and enforcing standards for the possession, use, and transfer of potentially lethal biological agents and toxins, the regulation will serve as a preventive mechanism against bioterrorism, which complements some of the Department's other bioterrorism related activities.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

31. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

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

CFR Citation:

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

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

Manufacturers of human drug and biological products currently have limited incentives to invest capital and resources in standardized global safety reporting systems because individual firms acting alone cannot attain the economic gains of harmonization. This proposed rule would harmonize FDA's safety reporting requirements with certain international initiatives, thereby providing the incentive for manufacturers to modify their safety reporting systems. Initial investments made by manufacturers to comply with the rule are likely to ultimately result in substantial savings to them over time.

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

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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HHS—FDA

32. 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 (FDA) announced in an advance notice of proposed rulemaking (ANPRM) of February 6, 1997 (62 FR 5700), its plans to consider developing regulations establishing current good manufacturing practices (CGMP) for dietary supplements and dietary ingredients. The ANPRM was published in order for FDA to solicit comments on whether it should initiate action to establish CGMP regulations, and if so, what constitutes CGMP for these products. FDA announced that this effort was in response to the section of the Federal Food, Drug and Cosmetic Act (the Act) that provides authority to the Secretary of Health and Human Services to promulgate CGMP regulations and to a submission from the dietary supplement industry asking that FDA consider an industry-proposed CGMP framework as a basis for CGMP regulations. The ANPRM 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; which have the identity and provide the quantity of dietary ingredients declared in labeling; and which meet the quality specifications that the supplements are represented to meet.

Statement of Need:

FDA intends to publish a proposed 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 CGMP 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 CGMP are end-product testing and Hazard Analysis Critical Control Points (HACCP). In the ANPRM, FDA asked for public comment on approaches to ensure that dietary supplements and dietary ingredients are not adulterated during the manufacturing process. The agency asked whether HACCP may be a more effective approach than a comprehensive CGMP, and 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. FDA has considered the information it received in response to the ANPRM and from other sources, such as public meetings and small business outreach meetings, in its consideration of whether CGMP or other approaches are most appropriate.

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	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

33. CONTROL OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION AND RETAIL

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

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

CFR Citation:

21 CFR 16; 21 CFR 116; 21 CFR 118

Legal Deadline:

None

Abstract:

The President's Council on Food Safety was established in August 1998 to improve the safety of the food supply through science-based regulations and well-coordinated inspection, enforcement, research, and education programs. The Council has identified egg safety as one component of the public health issue of food safety that warrants immediate Federal, interagency action.

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

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

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

Because egg safety is a farm-to-table effort, FDA intends to include in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at certain retail establishments. In addition, the agency plans to propose specific requirements for certain retail establishments that serve populations most at risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

Statement of Need:

FDA is proposing regulations as part of the farm-to-table safety system for eggs outlined by the President's Council on Food Safety in its Egg Safety Action Plan to require that shell egg producers implement SE risk reduction plans at the farm and that retail establishments institute certain egg relevant provisions of the 1999 Food Code. FDA intends to propose these regulations because of the continued reports of outbreaks of foodborne illness and death caused by SE that are associated with the consumption of shell eggs. The agency believes these regulations can have significant effect in reducing the risk of illness from SE-contaminated eggs and will contribute significantly to the interim public health goal of the Egg Safety Action Plan of a 50 percent reduction in egg-related SE illness by 2005.

Summary of Legal Basis:

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

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

Moreover, the use of shell eggs or egg products that have been treated to destroy SE or through cooking of untreated eggs in retail establishments will significantly contribute to the reduction of egg-related SE illnesses.

Alternatives:

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

meetings in its consideration of the various alternatives.

Anticipated Cost and Benefits:

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

Risks:

Any potential for contamination of eggs with SE and its subsequent survival or growth must be considered a very serious risk because of the possibility that such contamination, survival, and growth could cause widespread foodborne illness, including some severe long-term effects and even loss of life. FDA made a decision to publish a proposed rule to require that shell egg producers have on-farm SE risk reduction plans and that retail establishments institute certain egg relevant provisions of the 1999 Food Code, based on a considerable body of evidence, literature, and expertise in this area. In addition, this decision was also based on the USDA risk assessment on SE in shell eggs and egg products and the identified public health benefits associated with controlling SE in eggs at the farm and retail levels.

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0910–AC14

HHS—FDA

34. EXCEPTION FROM GENERAL REQUIREMENTS FOR INFORMED CONSENT; REQUEST FOR COMMENTS AND INFORMATION

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360bbb; 21 USC 360c; 21 USC 360d; 21 USC 360e; 21 USC 360f; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 381

CFR Citation:

21 CFR 50.23

Legal Deadline:

None

Abstract:

FDA is proposing to clarify its regulations about the exception from the general requirement for informed consent in life-threatening situations necessitating the use of a test article. This proposal will explain how the informed consent provisions would apply during emergencies, including a response to chemical or biological terrorism, requiring the use of investigational in vitro diagnostic devices regulated by FDA.

Statement of Need:

The agency is proposing this action because of concern that confusion exists about how to apply the informed consent rules during a potential emergency, including a chemical or biological terrorism event. This confusion could delay the immediate use of investigational products thus threatening the rights, welfare, or lives of subjects.

Summary of Legal Basis:

FDA has already determined that the statutory authority provided in the Federal Food, Drug and Cosmetic Act (the Act) allows a limited exception to requiring informed consent in life-threatening situations such as those considered here. Section 505(i) of the Act requires informed consent except where it is not feasible or it is contrary to the best interests of the human beings involved. The Act also provides specifically for an exception from informed consent for investigational devices. Section 520(g)(3)(D) of the Act requires informed consent of the subject unless the clinical investigator determines in writing that: 1) there exists a life-threatening situation involving the human subject of such testing which necessitates the use of such device; 2) it is not feasible to obtain informed consent from the subject; and 3) there is not sufficient time to obtain such consent from his or her representative. Further, a licensed physician uninvolved in the testing must agree with this three-part determination before using the product, unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to get such concurrence.

Alternatives:

The other option available to the agency is to work within the existing regulatory scheme. FDA believes that this option may result in improper or no diagnosis, and improper treatment or no treatment for persons with life-threatening illnesses because the health professionals may not use these investigational products.

Anticipated Cost and Benefits:

The minimal burdens imposed by this rule are offset by the fact that, in the absence of this rule, the sponsor may be required to obtain informed consent, which is just as burdensome, if not more so. The rule would permit use

of investigational products without which patients' lives might be threatened. Because of uncertainty about the nature or extent of any chemical or biological terrorism event, FDA cannot estimate the extent of the benefits of this rule.

Risks:

The primary risk addressed by this rule is the risk that patients may go untreated or may be improperly treated because health professionals may not use an investigational product in the absence of informed consent. FDA cannot determine the extent of this risk without knowing the nature or extent of any chemical or biological terrorism event.

Timetable:

Action	Date	FR Cite
NPRM	04/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0910–AC25

HHS—FDA

35. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS

Priority:

Economically Significant. Major under 5 USC 801.

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 201.25; 21 CFR 601.67

Legal Deadline:

None

Abstract:

This regulation is one component of the Secretary's initiative to reduce medical errors. The proposal would require human drug products and biological products and possibly other products to have a bar code. The bar code would contain certain information about the product, and when used in conjunction with bar code scanners and computer equipment, would help reduce the number of medication errors.

Statement of Need:

In 1999, the Institute of Medicine (IOM) report titled, ''To Err Is Human: Building a Safer Health System,'' cited studies and articles estimating that between 44,000 and 98,000 Americans may die each year due to medical mistakes made by health care professionals, with most deaths attributable to medication errors. The report also indicated that, between 1983 and 1993, the medication error rate leading to a patient's death may have increased by over 2.5 times. While later medical articles have questioned the IOM's estimates, other studies have indicated that, regardless of the medication error rate, many medication errors are or were preventable.

Medication errors are a significant economic cost to the United States. An article published in 1995 estimated the direct cost of preventable drug-related mortality and morbidity to be $76.6 billion, with drug-related hospital admissions accounting for much of the cost. The authors suggested that indirect costs, such as those relating to lost productivity, might be two to three times greater than the direct costs, making the total cost of all preventable drug-related mortality and morbidity range from $138 to $182 billion. Another article, published in 2001, used updated cost estimates derived from current medical and pharmaceutical literature to revise the $76.6 billion estimate to exceed $177.4 billion; hospital admissions accounted for $121.5 billion in costs, and long-term care admissions accounted for another $32.8 billion.

Various organizations and health professional associations have advocated the use of bar codes as a method for reducing medication errors. For example, if a health professional could use a bar code scanner to compare the bar code on a human drug product to a specific patient's drug regimen, the health professional would be able to verify that the patient is receiving the right drug, at the right dose, at the right time. Most organizations and associations have recommended that the bar code contain, at a minimum, a unique numerical code identifying the manufacturer, product, and package size or type. In addition, some have advocated including the lot number and expiration date.

Thus, FDA is considering proposing to require certain medical products to be bar coded. The bar code would contain certain information about the product, such as its National Drug Code number. The agency is considering whether to require other information, such as the drug's expiration date and lot number, to make it easier to identify expired drugs and recalled drugs that may not be safe and effective for use. The bar code, when used in conjunction with bar code scanners and computer equipment, will enable health professionals to decrease the medication error rate.

Summary of Legal Basis:

Section 502 of the Federal Food, Drug, and Cosmetic Act (the Act) considers a drug to be misbranded unless it bears a label containing (in part) the name of the manufacturer and the drug's name (see sections 502(b) and 502(e)(1)(A) of the Act).

Section 501(a)(1) of the Act considers a drug to be adulterated if, among other things, the methods used in, or the facilities and controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the drug meets the requirements of the Act as to safety and ''has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess....''

Section 701(a) of the Act, in turn, authorizes FDA to issue regulations for the efficient enforcement of the Act.

A bar code requirement for human drug products and biological products would be consistent with, and aid in the efficient enforcement of, sections 501 and 502 of the Act. For example, if the bar code merely contained the drug's National Drug Code number, the bar code would identify the manufacturer

and the drug, and this would be consistent with sections 502(b) and 502(e)(1)(A) of the Act. If the bar code contained other information, such as lot number and expiration date (pieces of information required under FDA's good manufacturing practice regulations (see 21 CFR 211.130 and 211.137), this would be consistent with section 501(a)(1) of the Act.

Therefore, using its general rulemaking authority at section 701(a) of the Act, the agency has sufficient authority to propose requiring human drug products to have a bar code.

Alternatives:

FDA considered a voluntary bar coding program, but this would be akin to a ''no action'' alternative as many products are not bar coded or not coded in a manner that would help health professionals. A voluntary bar coding system might also lead to the adoption of multiple incompatible bar coding formats on human drug products and biological products, thereby deterring hospitals and health care professionals from buying bar code scanners and computer equipment.

FDA also considered decreasing the amount of information it might require on the bar code. This would decrease bar coding costs to drug manufacturers and labelers, but also decrease the usefulness of the bar code and its ability to reduce medication errors.

Anticipated Cost and Benefits:

FDA is continuing to examine the potential costs and benefits associated with bar coding. The anticipated costs may vary greatly depending on the amount of information required in a bar code and the products to be bar coded. FDA's preliminary estimate is that the rule would cost between $500 million and $1.4 billion over a 10-year period; the wide range in the cost estimate reflects the agency's uncertainty as to the costs associated with various pieces of information that might go into a bar code, what products should be bar coded, and possible changes in labeling operations.

The rule's principal benefit would be a reduction in the number of medication errors, including reduced mortality and morbidity. As stated earlier, medication error costs have been estimated in the billions of dollars, and the agency is trying to determine the extent to which medication errors would be reduced.

Risks:

There is a possible risk that some manufacturers and repackagers, if required to bar code individual unit dose packages, would eliminate such types of packaging and only supply their products in bulk containers. Individual unit dose packages are convenient for hospitals, health professionals, and patients, but are more expensive to produce, and bar coding may increase production costs. Consequently, a manufacturer or repackager who wanted to reduce its expenses might decide to reduce the number of packages, particularly individual unit dose packages, that would be subject to a bar coding requirement.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AC26

HHS—FDA

36. ● ADMINISTRATIVE DETENTION

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

PL 107-188, sec 303

CFR Citation:

21 CFR 1

Legal Deadline:

None

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 303 of the Bioterrorism Act authorizes the Secretary, through FDA, to order the detention of food if an officer or qualified employee finds credible evidence or information indicating an article of food presents a threat of serious adverse health consequences or death to humans or animals. The Act requires the Secretary, through FDA, to issue final regulations to expedite court actions (i.e., seizures and injunctions) on perishable foods.

FDA intends to implement section 303 of the Act by proposing a regulation to provide for: 1) a detention procedure; 2) expedited procedures for enforcement actions with respect to perishable foods; and 3) an appeals procedure for detained goods.

Statement of Need:

The events of September 11, 2001 highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was signed into law on June 12, 2002. The proposed regulation would implement section 303 of the Bioterrorism Act.

Summary of Legal Basis:

The Bioterrorism Act, section 303, amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding section 304(h), which authorizes the Secretary to order the detention of domestic and imported food and specifies an appeals process that includes an opportunity for an informal hearing. Section 303 of the Bioterrorism Act also amends section 301 of the FFDCA by making it a prohibited act to transfer an article of food in violation of a detention order or to remove or alter any required mark or label identifying the article as detained. Furthermore, section 303 of the Bioterrorism Act amends section 801 of the FFDCA to provide for temporary holds at ports of entry.

Alternatives:

FDA's decision to promulgate a regulation is based primarily on clear statutory directive to establish regulations, and also on need. The Bioterrorism Act, section 303, clearly states that the Secretary must provide by regulation for procedures for instituting enforcement actions with

respect to perishable foods on an expedited basis.

Section 303 of the Bioterrorism Act also specifies an appeals process that requires the Secretary, after providing for an informal hearing, to confirm or terminate a detention order within five days of an appeal. Section 201(x) of the FFDCA defines ''informal hearing'' and describes the requirements necessary for informal hearings. 21 CFR part 16 of FDA's regulations outlines FDA's informal hearing procedures in greater detail. Part 16 provides no requirements or limitations on the length of the informal hearing. FDA proposes to adopt part 16 with minor modifications (e.g., limiting length of hearing, delegating Secretary's duties as presiding officer to an FDA official in a regulation tailored to the administrative detention provisions in the Bioterrorism Act. If FDA were to include the minor modifications in a guidance document, FDA would not be able to enforce legally the new provisions because guidance documents are not binding (21 CFR 10.115(d)). If FDA chose simply to follow part 16, we would run the risk of not providing the presiding officer sufficient time to consider and weigh the evidence for the informal hearing within the statutory timeframes.

Anticipated Cost and Benefits:

Administrative detention actions on imports would generate two types of costs: 1) enforcement costs, including marking or labeling, transporting, and storing detained or held products in secure facilities, as necessary, and the cost of preparing and administering detention appeal hearings; and 2) the loss of product value during the detention period (in the case of products that we detain or hold but that turn out to be non-violative) and firms' costs for preparing for detention appeal hearings. In those cases in which we could have used other means to detain the relevant goods (i.e., collaboration with states or Customs, or our own existing authority to detain imports, shell eggs, and infant formula), only the net change in these costs would be relevant to this rule. We do not have sufficient information to estimate these costs at this time. However, annual costs would probably be fairly small because we would only use these procedures under rare, extraordinary circumstances. In addition to potentially reducing enforcement costs, product value loss, and firms' appeals hearing preparation costs relative to current methods of detention, this rule would generate benefits by improving our ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism would advance the development, organization, and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the ability to address credible threats of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0910–AC38

HHS—FDA

37. ● ESTABLISHMENT AND MAINTENANCE OF RECORDS TO IDENTIFY IMMEDIATE PREVIOUS SOURCE AND IMMEDIATE SUBSEQUENT RECIPIENT OF FOODS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

PL 107-188, sec 306

CFR Citation:

21 CFR 1

Legal Deadline:

Final, Statutory, December 12, 2003.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 306, directs the Secretary, through FDA, to issue final regulations establishing recordkeeping requirements by December 12, 2003.

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. The regulations will require the establishment and maintenance of records, for not longer than two years, that would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. This section does not extend to recipes for food, financial data, pricing data, personnel data, research data, and sales data (other than shipment data regarding sales). Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. In addition, the Secretary is directed to take appropriate measures to ensure that effective procedures are in place to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by FDA pursuant to these regulations.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the

security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law on June 12, 2002. The proposed regulations would implement section 306 of the Bioterrorism Act.

Summary of Legal Basis:

Section 306 of the Bioterrorism Act amended the Federal Food, Drug and Cosmetic Act by adding section 414(b), which authorizes the Secretary to establish by regulation requirements for the creation and maintenance of records. In addition, section 306 of the Bioterrorism Act also amends section 301 of the Federal Food, Drug and Cosmetic Act by making the failure to establish or maintain any record, as required by the new regulations, a prohibited act.

Alternatives:

None, based on clear statutory authority to establish regulations.

Anticipated Cost and Benefits:

The records provisions will impose a substantial cost on industry. Using the 1999 Country Business Patterns (CBP) database from the U.S. Census and recordkeeping cost estimates based on other FDA regulations (and assuming no small establishment exemptions), a rough first estimate is that the current provisions will affect approximately 500,000-600,000 establishments and will cost the food industry approximately $400 million in the first year and approximately $150 million every year thereafter.

The provisions will improve substantially FDA's ability to respond to outbreaks from deliberate and accidental contamination of food. FDA will use data collected by the Center for Disease Control (CDC) and FDA on past outbreaks to estimate the benefit of improved documentation in standard tracing investigations. Of the 1,344 food-borne illness outbreaks CDC identified in 1999, only 368 (27 percent) had a confirmed etiology. A host of factors contribute to the inability to identify the cause of an outbreak, but many investigations are hampered by the lack of adequate records identifying the production history of foods. Unfortunately, it is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring. Instead, to get an idea of the cost of a food disaster, we will look at the costs of some severe food-borne illness outbreaks.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism would advance the development, organization, and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the ability to address credible threats of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AC39

HHS—FDA

38. • REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

PL 107-188, sec 305

CFR Citation:

21 CFR 1

Legal Deadline:

Final, Statutory, December 12, 2003.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 305, directs the Secretary, through FDA, to issue a final regulation establishing registration requirements by December 12, 2003. The statute is self-implementing on this date if FDA does not issue a final regulation by December 12, 2003.

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 415 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), directs the Secretary to require any facility engaged in manufacturing, processing, packing, or holding food for consumption by humans or animals in the United States to be registered with the Secretary through FDA. Section 415 directs the Secretary, through FDA, to promulgate final regulations implementing the requirements by December 12, 2003. The owner, operator, or agent in charge of the facility must submit the registration. Foreign facilities must include the name of the United States agent for the facility. The registration must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. If FDA determines it is necessary through guidance, the registration must include the general food category (as identified under 21 CFR 170.3) of foods manufactured, processed, packed, or held at the facility. The registrant is required to notify the Secretary of changes to the registration in a timely manner. Upon receipt of the completed registration form, FDA is to notify the registrant of receipt of the registration and assign a unique registration number to the facility. The Secretary is also required to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, ''facility'' includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from the registration requirement are farms, restaurants, retail food establishments,

nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in 21 CFR 123.3(k)). Foreign facilities required to register include only those from which food is exported to the United States without further processing or packaging outside the United States. The Bioterrorism Act provides that if a foreign facility attempts to import food into the United States without having registered, the food will be held at the port of entry until the foreign facility has registered.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was signed into law on June 12, 2002. Regulations are needed to implement the new statutory provisions.

Summary of Legal Basis:

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) amends the FFDCA by adding section 415, which directs the Secretary to establish by regulation requirements for the registration of food and animal feed facilities. Section 305 amends section 301 of the FFDCA by making the failure to register in accordance with section 415 a prohibited act. Section 305 also amends section 801 of the FFDCA by requiring food offered for import to be held at the port of entry until the foreign facility attempting to import the food has registered.

Alternatives:

None, based on clear statutory directive to establish regulations.

Anticipated Cost and Benefits:

Costs: Requiring registration for domestic and foreign facilities that manufacture, process, pack, or hold food will create costs for facilities to register and for FDA to set up and administer a database of firms. Industry costs are primarily a function of the number of firms affected and the amount of labor needed to register those firms. FDA estimates that 158,618 domestic establishments and 100,000 foreign establishments covered by the statute and proposed regulation will bear a cost of approximately $8.5 million in the first year. In subsequent years, new establishments will enter the industry. FDA estimates the number of new entrants each year will be equal to 10 percent of the current number of firms, for a recurring annual cost of $850,000. FDA's costs will include labor hours, hardware, software, and mailing costs for creating and administering a database. We estimate the costs to the agency for setting up the database and registering the first year registrants to be $17.4 million. This includes four FDA FTEs, contractor development of the database, hardware, software, industry outreach, and a firewall. We estimate costs for maintaining the database and adding new establishments to be $13.8 million in the second year. Total first year costs will be $25.9 million and second year costs will be $14.7 million. All of these cost estimates are preliminary and uncertain.

Benefits: These provisions will improve FDA's ability to respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. It is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring. Instead, to get an idea of the cost of a food disaster, we will look at the costs of some severe, foodborne illness outbreaks.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism would advance the development, organization, and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the ability to address credible threats of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AC40

HHS—FDA

39. ● ESTABLISHMENT OF PRIOR NOTIFICATION REQUIREMENT FOR ALL IMPORTED FOOD SHIPMENTS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

PL 107-188, sec 307

CFR Citation:

Not Yet Determined

Legal Deadline:

Final, Statutory, December 12, 2003.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notification requirements for all imported food shipment by December 12, 2003. If FDA fails to issue final regulations by this date, the statute is self-executing on this date, and requires FDA to receive prior notice of not less than 8 hours, nor more than 5 days until final regulations are issued.

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. Section 801(m) requires notification to FDA prior to the entry of imported food. The required prior notice would

provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation would identify the parties responsible for providing the notice and explain the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be held at the port of entry until proper notice is provided.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), was signed into law on June 12, 2002. The proposed regulations would implement section 307 of the Bioterrorism Act.

Summary of Legal Basis:

Section 307 of the Bioterrorism Act amended the FFDCA by adding section 801(m), which authorizes the Secretary through FDA to establish by regulation requirements for the notification to FDA prior to the entry of imported food. In addition, section 307 of the Bioterrorism Act also amends section 301 of the FFDCA by making the offering of a food for import or the importing of a food without prior notification, as required by the new regulations, a prohibited act.

Alternatives:

None, based on clear statutory directive to establish regulations.

Anticipated Cost and Benefits:

The prior notification provision is an economically significant regulatory action, mainly because so many shipments are affected. For calendar year 2002, FDA estimates that about 4.7 million human and animal food and dietary supplements line items will be imported into U.S. commerce by airplane, train, vessel, and truck.

For those importers who currently do not notify FDA until their actual arrival (or later) at a point of entry, this proposed rule will create a burden as it would require a change in their current methods of operation. Prior notice requirements will also create some additional burdens if FDA requires more imported articles to be held for FDA inspection.

FDA costs will include the labor hours, hardware, and software costs for updating the present OASIS system. Technology costs will likely increase further if FDA has to create a stand alone system instead of working through U.S. Customs Service's ACE system to meet the statutory deadlines. FDA costs may also include hiring additional inspectors to certify the receipt of prior notice and clear the food to enter into U.S. commerce, and storing goods, if FDA has to take custody.

The provisions will improve substantially FDA's ability to examine imported food for deliberate and accidental contamination. The purpose of the prior notification of imported food shipments is to allow the FDA to determine whether there is any credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and to receive and review the prior notification, and appropriately respond. It is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism would advance the development, organization and enhancement of public health prevention systems and tools. The magnitude of the risks addressed by such systems and tools is at least as great as the other risk reduction efforts within HHS' jurisdiction. These regulations will improve the ability to address credible threats of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Federalism:

Undetermined

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RIN: 0910–AC41

HHS—FDA

40. ● APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG: PATENT LISTING REQUIREMENTS AND APPLICATION OF 30-MONTH STAYS ON APPROVAL OF ABBREVIATED NEW DRUG APPLICATIONS

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 3321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a; 21 USC 356b; 21 USC 356c; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation:

21 CFR 314.52(a)(3); 21 CFR 314.53(b); 21 CFR 314.53(c)(1); 21 CFR 314.53(c)(2); 21 CFR 314.95(a)(3)

Legal Deadline:

None

Abstract:

The final rule would clarify the types of patents for which information must or must not be submitted to FDA. The final rule would also revise the patent declaration to make it more detailed. The rule would also revise the regulations regarding the approval date for certain abbreviated new drug applications or ''505(b)(2) applications'' by stating that there is only one opportunity for a 30-month stay in the approval date of an ANDA or 505(b)(2) application.

Statement of Need:

In recent years, FDA has seen new drug application (NDA) applicants submit

patent information to FDA shortly before other patents for the drug are to expire. Disputes have arisen whether the later-filed patents are appropriately submitted to FDA. The Federal Trade Commission (FTC) has also asked FDA to clarify whether NDA applicants can or should list various types of patents at FDA. The FTC has also issued a report questioning whether NDA applicants have used later-filed patents to seek unwarranted delays in the approval of generic drugs.

Summary of Legal Basis:

The principal legal authority for this rule is found at sections 505 and 701 of the Federal Food, Drug, and Cosmetic Act (the Act). Section 505(b) of the Act describes the contents of an NDA and 505(b)(2) application, including the patent listing and patent certification requirements. Section 505(j) of the Act describes the contents of an ANDA, including patent certification requirements. Both sections 505(b) and 505(j) of the Act also describe the 30-month stay of approval dates for ANDA's and 505(b)(2) applications if the ANDA or 505(b)(2) application applicant had certified that a patent was invalid or would not be infringed, and a timely suit for patent infringement ensued. Section 701(a) of the Act gives FDA the authority to issue regulations for the efficient enforcement of the Act.

Alternatives:

With respect to patent listing, one alternative would be to remain silent and defer to NDA applicants as to the appropriateness of any particular patent. This alternative, however, would not deter the submission of inappropriate patent information and could lead to unnecessary patent disputes between patent owners, NDA holders, and ANDA or 505(b)(2) application applicants.

As for the 30-month stay, there are alternative arguments to justify a single 30-month stay, but those alternative theories could also result in no notice to the patent owner or NDA holder and no opportunity for even a single 30-month stay. Such results would be contrary to the Act's desire to balance generic drug approvals against a need to preserve incentives for innovation. Another alternative would be to continue allowing multiple 30-month stays, but this would have the effect of delaying the introduction of generic drugs into the market.

Anticipated Cost and Benefits:

The one-year benefits of the regulation will include the increase in revenues to generic firms and the savings to consumers from the earlier availability of less expensive pharmaceuticals. The estimated total one-year benefit is approximately $3.2 billion. Adjusting this benefit to account for the expected increase in baseline pharmaceutical expenditures, the total benefit for the years 2002 through 2011 is expected to be approximately $53.9 billion.

Eliminating multiple 30-month stays per ANDA will prevent delays in generic drug competition. Generic drug companies gain through additional sales, and, to the extent that generic prices are lower than innovator prices, consumers benefit from the ''price gap.'' While the quantified benefits do exceed the quantified costs, this rule has the additional important benefit of preserving the balance struck in the Hatch-Waxman amendments.

Risks:

The regulation would deter misuse of the patent listing and patent certification process to obtain unwarranted, multiple 30-month delays in the approval of an ANDA or 505(b)(2) application. Court decisions indicate that ANDA applicants and 505(b)(2) applicants have no private right of action to have inappropriate patents removed from FDA's lists, and the FTC report suggests that some patents submitted to FDA have been inappropriately listed.

Timetable:

Action	Date	FR Cite
NPRM	10/24/02	67 FR 65448
NPRM Comment Period End	12/23/02	
Final Rule	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HHS—FDA

FINAL RULE STAGE

41. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

Priority:

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

Unfunded Mandates:

Undetermined

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

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 drug and biologic products, 21 CFR 201.56 and 201.57. The regulation would require that professional labeling include a section containing highlights of prescribing information, and a section containing an index to prescribing information; reorder currently required information and make minor changes to its content, and establish minimum graphical requirements for professional labeling. The regulation would also eliminate certain unnecessary statements that are currently required to appear on prescription drug labels and move

certain information to professional labeling.

Statement of Need:

The current format and content requirements in sections 201.56 and 201.57 were established 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 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 product labeling.

FDA took numerous steps to evaluate the usefulness of prescription drug labeling for its principal audience 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 prescription drug labeling is used by health care practitioners, what labeling information is most important to practitioners, and how professional labeling should be revised to improve its usefulness to prescribing practitioners.

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

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

Summary of Legal Basis:

The agency has broad authority under sections 201, 301, 501, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321, 331, 351, 352, 353, 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262) to regulate the content and format of prescription drug labeling to help ensure that products 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) only if, among other things, it contains the information required, in the format specified, by sections 201.56 and 201.57.

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

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

Alternatives:

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

Anticipated Cost and Benefits:

The expected benefits from the final rule include reduced time needed for health care professionals to read or review labeling for desired information, increased effectiveness of treatment, and a decrease in adverse events resulting from avoidable drug-related errors. For example, the proposed revised format is expected to significantly reduce the time spent on reading labeling by highlighting often used information at the beginning of labeling and facilitating access to detailed information.

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	

Action	Date	FR Cite
NPRM Comment Period Reopening End	06/22/01	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

42. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

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 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; ...

CFR Citation:

21 CFR 101

Legal Deadline:

None

Abstract:

Section 403(q) of the Federal Food, Drug, and Cosmetic Act, which was added by the Nutrition Labeling and Education Act of 1990 (NLEA), requires that the label or labeling of food products bear nutrition information. Among other things, section 403(q) of the Act authorizes the Food and Drug Administration (FDA) to add or delete nutrients that are to be declared on the labels or labeling of food products by regulation if it finds such action necessary to assist consumers in maintaining healthy dietary practices. FDA issued final regulations implementing NLEA in 1993. FDA subsequently received a citizen petition requesting that FDA amend its regulations on food labeling to require that the amount of trans fatty acids be listed in the nutrition label and be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disqualifying levels and disclosure levels. In response to this petition and based on new evidence, FDA proposed the actions requested in the petition on November 17, 1999 (64 FR 62746). In addition, FDA proposed to define the claim ''trans fat free.''

Statement of Need:

FDA intends to publish a final rule amending its nutrition labeling regulations to incorporate requirements for trans fatty acids in labeling for several reasons. First, this final rule responds, in part, to a citizen petition on trans fatty acids in food labeling from the Center for Science in the Public Interest. Also, recent research shows that dietary trans fatty acids raise low density lipoprotein cholesterol (LDL-C), the major diet related risk factor for coronary heart disease (CHD). Finally, the information on trans fatty acids in nutrition labeling is needed to assist consumers in maintaining healthy dietary practices.

Summary of Legal Basis:

The NLEA (Pub. L. 101-535) amended the Federal Food, Drug, and Cosmetic Act (the Act) to provide, among other things, that certain nutrients and food components be included in nutrition labeling. Sections 403(q)(2)(A) and (q)(2)(B) of the Act provide the agency with authority to, by regulation, add or delete nutrients included in the food label or labeling if the agency finds that such action will assist consumers in maintaining healthy dietary practices.

Alternatives:

FDA proposed, in the November 1999 proposal, that when trans fatty acids are present in a food, the declaration of saturated fat must bear a symbol that refers to a footnote at the bottom of the nutrition label that states the number of grams of trans fatty acids present in a serving of the product, i.e., ''Includes _____ g trans fat.'' In addition to the proposed option, the agency considered a variety of other options for the declaration of trans fatty acids in the Nutrition Facts panel. The other options were: (1) include trans fatty acids with saturated fat and call the total value ''saturated fat;'' (2) include trans fatty acids with saturated fat and call the total value ''saturated fat,'' and add an asterisk after the term ''saturated fat'' when the food contains trans fatty acids that refers to a footnote stating ''Contains _____ g trans fat;'' (3) include trans fatty acids with saturated fat and call the total value ''saturated + trans fat;'' and (4) list trans fatty acids separately under saturated fat.

Anticipated Cost and Benefits:

FDA has estimated the benefits of the proposed rule in the range of $25 to $50 billion compared with costs in the range of $400 to $900 million (discounted at 7 percent for 20 years). The value of the benefits were estimated based on CHD morbidity and mortality prevented. The costs were estimated based on a formula that included costs for testing, decisionmaking, information panel reprinting, relabeling of the principal display panels, and product reformulation.

Risks:

The American Heart Association estimates that CHD causes 1.1 million heart attack cases annually, with 33 percent of them fatal. FDA used these estimates as the baseline to estimate the number of cases and fatalities prevented by this rule. The agency estimated the rule would annually prevent 6,300 to 17,100 cases of CHD and 2,100 to 5,600 deaths, using three different methods to estimate these benefits. Thus, the labeling changes resulting from this rule are expected to reduce the risk of CHD, preventing, at a minimum, 6,300 cases of CHD and 2,100 deaths annually.

Timetable:

Action	Date	FR Cite
NPRM	11/17/99	64 FR 62746
NPRM Comment Period Reopened	12/05/00	65 FR 75887
NPRM Comment Period End	01/19/01	
Final Rule	03/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

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

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

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

CFR Citation:

21 CFR 606; 21 CFR 610

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69377
NPRM Comment Period End	02/14/01	
Final Action	04/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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Related RIN: Related To 0910-AB26

RIN: 0910–AB76

HHS—FDA

44. TOLL-FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Priority:

Other Significant

Legal Authority:

21 USC 355a

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 this final rule to issue within one year of the date of its enactment on January 4, 2002.

Alternatives:

This final 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
Interim Final Rule	01/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—Centers for Medicare & Medicaid Services (CMS)

PROPOSED RULE STAGE

45. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS-3818-P) (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

42 USC 1395rr

CFR Citation:

42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412 to 414; 42 CFR 489; 42 CFR 494

Legal Deadline:

None

Abstract:

This proposed rule would revise the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

Statement of Need:

The proposed rule is a complete overhaul of the current ESRD conditions for coverage in order to reduce unnecessary process and procedural requirements and focus on the patient and the results of the care provided to the patient. The proposed conditions for ESRD facilities would include, among other things, new infection control guidelines; updated water quality standards; new fire safety standards; as well as patient assessment, care planning, quality improvement, and electronic data reporting provisions that reflect the current advances in dialysis technology and standard care practices. The ESRD conditions were last published in their entirety in 1976.

Summary of Legal Basis:

Section 1881 [42 U.S.C. 1395rr] of the Social Security Act (the Act) authorizes benefits for individuals who have been determined to have end stage renal disease as provided in section 226A. Section 1881(b) of the Act authorizes payments on behalf of such individuals to providers of services and renal dialysis facilities ''which meet requirements as the Secretary shall by regulation prescribe.'' ESRD conditions for coverage may be revised as needed under the Secretary's rulemaking authority in section 1881.

Alternatives:

Retain the current conditions. CMS has undertaken various quality improvement initiatives, e.g., the Dialysis Facility Compare website and the CMS Clinical Performance Measures Project that have improved beneficiaries' quality of care. However, these initiatives lack the potential impact of an overall regulatory change.

Anticipated Cost and Benefits:

Undetermined.

Risks:

Failure to update would leave CMS with ESRD conditions for coverage that are over 26 years old and do not reflect current medical practices or scientific advances in the field.

Timetable:

Action	Date	FR Cite
NPRM	05/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

46. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (CMS-6017-P)

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments.

Legal Authority:

42 USC 1320d to 1320d-8

CFR Citation:

45 CFR 160; 45 CFR 162

Legal Deadline:

Final, Statutory, February 21, 1998.

Abstract:

This proposed rule would implement a standard identifier to identify health plans that process and pay certain electronic health care transactions. It would implement one of the requirements for administrative simplification in section 262 of the Health Insurance Portability and Accountability Act of 1996.

Statement of Need:

This rule would implement the national health plan identifier, one of the requirements for administrative simplification in section 262 of the Health Insurance Portability and Accountability Act of 1996.

Summary of Legal Basis:

Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, August 21, 1996, sec. 1173).

Alternatives:

Three alternatives were considered:

Option 1: Federal and State Medicaid Agencies Cost : $38.1M

Option 2: Private Organizations Cost : $38.1M

Option 3: Registry Cost : $34.9M

Duration: Every option is required to complete the enumeration process within two years of the promulgation and effective date of the final rule for all health plans, except that small health plans have three years to comply.

Option 1: Two or more coordinating entities will share responsibility for enumerating health plans. The entities would consist of Federal and State Medicaid programs.

Option 2: Same as option one, except that coordinating entities would consist of private organizations.

Option 3: CMS, acting through a contractor, would be the single entity enumerating all health plans and maintaining the registry.

Decision: The Secretary has selected option three, not only because its costs are lower, but also because it would result in less burden on organizations in coordinating enumeration, less confusion for health plans, better quality control of data control, and better management of the enumeration process.

Anticipated Cost and Benefits:

A benefit/cost analysis was conducted with three contribution rates of PlanID toward overall HIPPA cost savings. Given a 1 percent contribution rate, the PlanID project shows a net present value of over $12.8 million and a benefit/cost ratio of 1.45. For 5 and 15 percent rates, the net present values are $179.2 million and $595.3 million, respectively, and the benefit cost ratios are 7.23 and 21.69, respectively. These values indicate that the implementation of the PlanID project will result in a considerable positive return on investment.

Risks:

There are three categories of risk:

Technical and Operational—physical/logical system

Schedule—delays/slippage

Cost/Budget—cost overruns, funding shortfalls, unexpected funding needs

An assessment and mitigation of risks was conducted as part of the information technology documentation. The subsequent risk analysis determined the project to be a low risk endeavor.

Timetable:

Action	Date	FR Cite
Proposed Rule	02/00/03	

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.

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HHS—CMS

47. HEALTH INSURANCE REFORM: CLAIMS ATTACHMENTS STANDARDS (CMS-0050-P)

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments.

Legal Authority:

42 USC 1320d-2(a)(2)(B)

CFR Citation:

45 CFR 162

Legal Deadline:

Final, Statutory, August 21, 1998.

Abstract:

This rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act (HIPAA) of 1966. It

would be used to transmit clinical data, beyond those data contained in the claims standard, to help establish medical necessity for coverage.

Statement of Need:

The Administrative Simplification subtitle of HIPAA requires the Secretary of Health and Human Services to adopt standards for electronically requesting and supplying additional information to support submitted claims data. This rule stipulates the requirements necessary to comply with the law.

Summary of Legal Basis:

The Administrative Simplification provisions of HIPAA require the Secretary to establish standards that additionally support information attached to claims.

Alternatives:

In the absence of this regulation, claims attachments in electronic form would be left with the private industry to develop. This action may create an inconsistent standard use of electronic claims attachments within the health care industry.

Anticipated Cost and Benefits:

As the effect of any one of the HIPAA standards is affected by the implementation of other standards, it is misleading to discuss the impact of one standard by itself. Therefore, an Impact Analysis on the total effect of all standards was published in the proposed rule concerning the national provider identifier (HCFA-0045-P), which was published on May 7, 1998 (63 FR 25320).

Risks:

Failure to publish this rule would mean that no standard for electronic claims attachments would be established for use within the health care system. Lack of a standard for electronic claims attachments would decrease the amount of savings in health care costs.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Federal, Tribal

Federalism:

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

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HHS—CMS

48. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS-3064-P)

Priority:

Other Significant

Legal Authority:

42 USC 1320b-8(b)(1)(A)(i); 42 USC 273(b)(2)

CFR Citation:

42 CFR 486.301

Legal Deadline:

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

Abstract:

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

Statement of Need:

This proposed rule contains new conditions for coverage for OPOs, including new performance standards. This proposed rule would also increase the rectification cycle for OPOs from two years to four years.

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 in order 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 rectified 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 (section 701 of Pub. L. 106-505, 42 U.S.C. section 273(b)(1)(D)) amended section 371(b) of the PHS Act to require CMS to increase the certification cycle for OPOs from two years to four years and promulgate new performance standards for OPOs.

Alternatives:

CMS is considering various alternatives in the development of performance measures and additional conditions for coverage, and will solicit public comments in order to identify additional alternatives.

Anticipated Cost and Benefits:

While this rule is expected to improve OPO performance and organ donations, CMS is uncertain at this time about the rule's economic impact on OPOs.

Risks:

Failure to publish new outcome performance standards would violate section 701 of Public Law 106-505, which amended the Public Health Service Act.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/01	66 FR 67109
Proposed Rule	02/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

49. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS-2130-P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

Children's Health Act of 2000

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This proposed rule would implement provisions of the Children's Health Act (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Statement of Need:

In recent years, media, government, and consumer reports of deaths and injuries occurring due to the use of restraint or seclusion have heightened concern about these mechanisms as interventions. However, concern about use is nothing new; the appropriate use of restraint and seclusion has been debated and regulated in various health care settings for many years. Researchers have examined the use of restraint and seclusion, related injuries and deaths, and potential alternatives to address safety and care concerns while posing less inherent risk to the individual. Patient advocates have lobbied for reduced and more highly regulated use. Health care facilities and professionals have examined mechanisms for reduction, and some have implemented training programs to promote safe application and use. However, reports of injuries and deaths have brought concerns about care and safety to the forefront. The issue has gained national attention, with a call for regulation across health care settings.

Several highly publicized newspaper articles and Federal reports are considered the impetus for this regulation. The CHA established a significant collaboration of several important children's health bills. CMS has responsibility for part H, which established certain requirements related to the rights of residents of certain facilities receiving Federal funds. The CHA establishes for certain facilities common definitions, staff training standards, reporting requirements, and strict enforcement criteria.

Summary of Legal Basis:

The Children's Health Act of 2000 (Pub. L. 106-310), section 3207, part H.

Alternatives:

No other regulatory alternatives were considered. However, in some form current regulations exist for hospitals and residential treatment facilities, while nursing homes and ICFs/MR utilize survey guidelines. The CHA's intent is to develop consistency in requirements across all Federally funded patient or residential care facilities. The statutory language required that regulations be promulgated within one year of its enactment. This NPRM, CMS-2130-P, is currently one year behind its mandated time of publication.

Anticipated Cost and Benefits:

The anticipated benefits include the increase in staff education and training that leads to alternative usage of restraint or seclusion as a means of intervention and less traumatic experiences for beneficiaries within the given facilities, more involvement with developing alternative treatment mechanisms for staff and clients, alike. The regulation creates a change in facility practices and policies on the use of restraint or seclusion as a treatment mechanism. The regulation will create standard criteria for all patients or residential care facilities that receive Federal funds, which will establish an industry wide effect on beneficiaries who are receiving services within these Federal facilities. The regulation creates consistent criteria for staff training, and defining and reporting on restraint or seclusion.

The anticipated cost is based on regulations that will affect more than 31,800 Medicare and Medicaid funded facilities. However, at this time, the extent of potential facilities affected is unattainable until comments are received from other HHS agencies. It is estimated that the cost will be roughly $500 million/yr for Federal Medicaid, and $2.5 - 3 billion for all payors. However, the NPRM will request comments on actual staff training and reporting costs, it is assumed this cost will decrease since the majority of facilities currently have training and reporting requirements.

Risks:

The risks in implementing this regulation are: 1) increase in cost for facilities in staff training (However, facilities that currently utilize restraint or seclusion as a form of intervention, have some general staff training requirements. The CHA will only expand the content of this training.); 2) increased possibility of facilities having their Federal funding status placed in jeopardy due to non-compliance with regulations (Industry may raise concern that the CHA's enforcement aspect is too harsh. For nursing homes, argument may occur that the CHA's enforcement goes against the intent of Congress and its OBRA '87 language to devise other alternative sanctions besides termination from the Medicare or Medicaid programs.); and 3) concern from facilities that currently do not have any regulations governing the use of restraints or seclusion (e.g., nursing homes, hospice inpatient facilities, and critical access hospitals. However, nursing homes have requirements in their survey guidance materials.)

And the risks in not implementing the regulation are: 1) increase in cost for facilities in staff training (However, facilities that currently utilize restraint or seclusion as a form of intervention, have some general staff training requirements. The CHA will only expand the content of this training.); 2) increased possibility of facilities having their Federal funding status placed in jeopardy due to non-compliance with regulations (Industry may raise concern that the CHA's enforcement aspect is too harsh. For nursing homes, argument may occur that the CHA's enforcement goes against the intent of Congress and its

OBRA '87 language to devise other alternative sanctions besides termination from the Medicare or Medicaid programs.); and 3) concern from facilities that currently do not have any regulations governing the use of restraints or seclusion (e.g., nursing homes, hospice inpatient facilities, and critical access hospitals. However, nursing homes have requirements in their survey guidance materials.)

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0938–AL26

HHS—CMS

50. PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS (CMS-1213-P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

PL 106-113, sec 124

CFR Citation:

Not Yet Determined

Legal Deadline:

NPRM, Statutory, October 1, 2002, per section 124 of Public Law 106-113.

Abstract:

This proposed rule would set forth a prospective payment system (PPS) for psychiatric hospitals.

Statement of Need:

This proposed rule will set forth a PPS for psychiatric hospitals and distinct part units. It would replace the current TEFRA payment mechanism that is outdated and problematic for psychiatric facilities.

Summary of Legal Basis:

Section 124 of BBRA mandated implementation of an inpatient psychiatric facility (IPF) PPS.

Alternatives:

An IPF PPS is required by statute.

Anticipated Cost and Benefits:

The statute requires us to implement this PPS in a budget neutral fashion, however there will be CMS administrative costs associated with its implementation.

Risks:

Redistributional effects inherent in a new payment system may adversely affects certain classes of facilities.

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State, Local, Federal

Federalism:

Undetermined

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RIN: 0938–AL50

HHS—CMS

51. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS-4004-P)

Priority:

Other Significant

Legal Authority:

Sec 521 of BIPA

CFR Citation:

42 CFR 426

Legal Deadline:

NPRM, Statutory, October 1, 2002, Statutory effective date 10/01/2002.

Abstract:

This proposed rule will also incorporate recommendations from an SSA/HHS workgroup to improve the Administrative Law Judge (ALJ) hearing process. ALJs within the SSA who conduct hearings for Medicare fee-for-service and managed care cases are currently governed by the SSA disability regulations. These regulations apply to disability cases and not to Medicare. In an effort to improve the integrity of the appeals process, CMS has recognized the need to develop regulations that are specific to the adjudication of Medicare cases.

Statement of Need:

Section 521 of the Benefits Improvement and Protection Act of 2000 (BIPA) requires the Secretary to promulgate regulations implementing new claims appeal procedures that are scheduled to take effect by October 1, 2002. Although we are unable to meet this deadline, we anticipate publishing a proposed rule in October, 2002. Subsequently, a final rule will be needed to implement the changes required by the statute.

Summary of Legal Basis:

Section 521 of BIPA amended section 1869 of the Social Security Act to require significant revisions to Medicare claims appeal procedures. Section 1869(a)(1) specifically directs the Secretary to promulgate regulations implementing the required changes.

Alternatives:

Promulgation of this regulation is required by statute, therefore there is no alternative.

Anticipated Cost and Benefits:

We anticipate that the new appeals process created by this regulation will decrease the number of appeals requested, reduce the length of time required to adjudicate an appeal, improve the integrity of the appeals process, and improve the accuracy and consistency of appeals decisions. These changes will benefit Medicare providers, suppliers, and beneficiaries. The new appeal procedures should not impose any additional costs on these groups but fully implementing the changes required by the statue is anticipated to generate administrative costs for HHS exceeding $100 million.

Risks:

Failure to implement this regulation by the statutory effective date will expose CMS to potential lawsuits.

Timetable:

Action	Date	FR Cite
Proposed Rule	11/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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HHS—CMS

52. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS-1469-P)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

Sec 1888(e) of the Social Security Act

CFR Citation:

42 CFR 413.330 to 413.350

Legal Deadline:

NPRM, Statutory, April 1, 2003.

Final, Statutory, July 31, 2003, final rule to be published before August 1, 2003.

Abstract:

This annual proposed rule updates the payment rates used under the SNF PPS beginning October 1, 2003.

Statement of Need:

The Medicare SNF PPS was established by section 4432 of the Balanced Budget Act of 1997 (BBA). The PPS applies to all costs (routine, ancillary, and capital) of covered SNF services furnished to beneficiaries under part A of the Medicare program, effective for cost reporting periods beginning on or after July 1, 1998. Annual updates to the PPS rates are required by section 1888(e) of the Social Security Act (the Act), as amended by the Medicare, Medicaid, and SCHIP Balanced Budged Refinement Act of 1999 (BBRA), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), relating to Medicare payments and consolidated billing for SNFs.

Summary of Legal Basis:

Section 1888(e)(4)(H) requires that annual updates to the SNF PPS rates be published in the Federal Register before August 1 of each year, to be effective on the first day of the fiscal year.

Alternatives:

None.

Anticipated Cost and Benefits:

Section 1888(e) of the Act established the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section also specifies that the base year cost date to be used in computing the Resource Utilization Group III (RUG-III) payment rates must be from FY 1995. The Act also requires that a number of elements be incorporated into the SNF PPS, such as case-mix classification methodology, the Minimum Data Set (MDS) assessment schedule, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates. Payment for SNF care prospectively has a direct, positive impact on the Medicare program by controlling the increase in costs for services provided by SNFs. Operating under a PPS also has a beneficial impact on the efficient management and planning capability of individual SNFs.

Risks:

Failure to update the SNF PPS by October 1, 2002 would place us in violation of the Act. Moreover, failure to meet the publication deadline imposed by the Act would also constitute a violation.

Timetable:

Action	Date	FR Cite
Proposed Rule	04/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

53. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS-1471-P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1395L; BBA'97; BBRA'99; BIPA'00

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This rule would revise the Medicare hospital outpatient department prospective payment system for the January 1, 2004 update.

Statement of Need:

Annual updates to the hospital outpatient prospective payment systems rates are required by section 1833 of the Social Security Act (the Act), as amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), relating to Medicare payments for hospital outpatient department patient prospective payment systems.

Summary of Legal Basis:

Section 1833(t) of the Act sets forth a system of payment for hospital outpatient department services furnished to Medicare beneficiaries based on prospectively set rates.

Alternatives:

None.

Anticipated Cost and Benefits:

Undetermined.

Risks:

Failure to update the hospital outpatient department prospective payment systems would place us in violation of the Act. Moreover, failure to meet the publication deadline imposed by the Act would also constitute a violation.

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—CMS

54. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2004 (CMS-1476-P)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1395W-4

CFR Citation:

42 CFR 410; 42 CFR 414

Legal Deadline:

None

Abstract:

Revisions to payment policies under the physician fee schedule for calendar year 2004.

Statement of Need:

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' This section provides for three major elements: 1) a fee schedule for the payment of physicians' services; 2) a sustainable growth rate for the rates of increase in Medicare expenditures for physicians' services; and 3) limits on the amounts that nonparticipating physicians can charge beneficiaries. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense.

Summary of Legal Basis:

Section 6102 of the Omnibus Reconciliation Act of 1989 (Pub. L. 101-239) amended the Act by adding section 1848, ''Payment for Physicians' Services,'' which requires Medicare to pay for physicians' services under a fee schedule. Section 4644 of the Balanced Budget Act of 1997 (Pub. L. 105-33) amended section 1848(b)(1) of the Act by requiring that we publish fee schedules that establish payment amount of all physicians' services before November 1 of the preceding year, each year.

Alternatives:

None.

Anticipated Cost and Benefits:

The statute 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 this threshold is exceeded, we would make adjustments to the conversion factor (the dollar amount that converts relative values into a payment amount for a physician's service) to preserve budget neutrality. Because changes to RVUs must be budget neutral, if we increase a service's RVUs, we must reduce the overall multiplier (or the actual RVUs) that converts the RVUs to a dollar amount.

Risks:

Failure to establish payment amounts for physicians' services would place us in violation of section 1848 of the Act.

Timetable:

Action	Date	FR Cite
NPRM	05/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—CMS

55. • REVISIONS TO AVERAGE WHOLESALE PRICE METHODOLOGY (CMS-1229-P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

1842(o)

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This rule would propose revisions to the source and methodology for determining the average wholesale price (AWP) of drugs covered by Medicare incident to a physician's service.

Statement of Need:

Studies by the Department of Justice, GAO, OIG, and others indicate that the current method of calculating AWP results in payments that are significantly higher than the providers' acquisition costs for Medicare-covered drugs. These revisions are intended to pay more appropriately for Medicare-covered drugs. A revision of AWP was included in the President's FY 2003 budget.

Summary of Legal Basis:

1842(o) requires that Medicare pay 95 percent of the average wholesale price for drugs not otherwise paid on a cost

or prospective payment basis. The definition of AWP is left to the Secretary to interpret.

Alternatives:

None.

Anticipated Cost and Benefits:

We anticipate significant savings for the program and beneficiaries from using a revised definition of AWP.

Risks:

Without this regulation, Medicare will continue to make payments that are significantly higher than market prices and providers' acquisition costs for Medicare-covered drugs.

Timetable:

Action	Date	FR Cite
Proposed Rule	05/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—CMS

56. ● ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS-0008-P)

Priority:

Other Significant

Legal Authority:

PL 107-105

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This proposed rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

Statement of Need:

Needed to state how we will implement the Administrative Simplification Compliance Act (ASCA), Public Law 107-105. It requires the electronic submission of Medicare claims, although the Secretary has the authority to grant waivers. This requirements applies to claims on or after October 16, 2003.

Summary of Legal Basis:

Public Law 107-105

Alternatives:

If we do nothing, it demonstrates the Department's lack of commitment to HIPAA and its enforcement.

Anticipated Cost and Benefits:

Will have an impact on the Medicare contractors budget but the magnitude is unknown at this time. A presumed benefit is that providers will choose to switch to electronic claims submissions.

Risks:

Providers may choose not to participate in Medicare.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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HHS—CMS

FINAL RULE STAGE

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57. REVISION OF MEDICARE/MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION (CMS-3745-F)

Priority:

Other Significant

Legal Authority:

42 USC 1395x; 42 USC 1302; 42 USC 1395(cc); 42 USC 1395hh; 42 USC 13206-8

CFR Citation:

42 CFR 416; 42 CFR 482; 42 CFR 485; 42 CFR 489

Legal Deadline:

None

Abstract:

This final rule will revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care, and how the outcomes of that care reflect a cross-functional view of how patients experience care and treatment in the hospital setting.

Statement of Need:

The purpose of the hospital conditions of participation is to protect patient health and safety and help assure that quality care is furnished to all hospital patients. Hospitals must meet the conditions of participation in order to participate in Medicare or Medicaid. Revised conditions are necessary to ensure that our regulations focus primarily on the actual quality of care furnished to patients, and the outcomes of that care, rather than on procedural compliance. These changes are intended to give hospitals the flexibility needed to achieve high-quality outcomes in the most cost-effective manner.

In addition, the regulations are intended to promote a cross-functional, interdisciplinary approach to hospital performance, instead of an approach geared towards evaluating each department of a hospital as a stand-alone entity. This approach is in line with current best practices in hospitals, in which patients routinely encounter many caregivers and services that often cut across department lines.

Summary of Legal Basis:

Section 1861(e) of the Social Security Act (the Act) provides that a hospital participating in the Medicare program must meet certain specified requirements. In addition, section 1861(e)(9) of the Act specifies that a hospital also must meet such requirements that the Secretary finds are necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in regulations the requirements that a hospital must meet to participate in Medicare. These requirements are set forth in regulations at 42 CFR part 482, ''Conditions of Participation for Hospitals.'' Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii), hospitals generally are required to meet the Medicare conditions of participation in order to participate in Medicaid.

Alternatives:

CMS considered the possibility of revising individual sections of the current hospital regulations. However, we determined that the best means of achieving the systematic changes needed in the regulations was to revise the hospital conditions in their entirety. The specific areas that are likely to form the core of the revised requirements include patient rights, patient assessment, patient care, quality assessment and improvement, and information management.

Anticipated Cost and Benefits:

There would not be significant costs associated with this final rule. The benefits that would be derived from the rule are discussed in the Statement of Need section, above.

Risks:

By revising these regulations to focus on the quality of the actual care given to an individual and the effectiveness of that care for the individual patient, we hope to reduce risks to beneficiaries' health and safety. Revised procedures can better focus on ensuring that the care being given to a patient is the care that is actually necessary and effective for that patient. No quantitative estimates of risk reductions are available yet.

Timetable:

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66726
NPRM Comment Period End	03/20/98	
Final Action	09/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Federalism:

Undetermined

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HHS—CMS

58. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS-0045-F)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1320D-2(b)(1)

CFR Citation:

42 CFR 160; 42 CFR 162

Legal Deadline:

Final, Statutory, February 21, 1998.

Abstract:

This final rule establishes a standard unique ID for all health care providers under the Health Insurance Protability and Accountability Act (HIPAA) of 1966 (Pub. L. 104-191). The rule implements administrative simplification initiatives that have a national scope beyond Medicare and Medicaid.

Statement of Need:

HIPAA creates a new part C, entitled ''Administrative Simplification,'' to title XI of the Social Security Act. One of the standards for health identifiers that is mandated by part C is a standard unique health care provider identifier, to be used in the health care system. This regulation announces the adoption of the National Provider Identifier (NPI) as the standard unique health care provider identifier. It also provides information on how health care providers will be assigned NPIs and defines the requirements of health plans, health care providers, and health care clearinghouses with respect to obtaining and using this standard. Implementation of the NPI and the other Administrative Simplification standards will increase the efficiency of the processing of standard transactions within the health care system.

Summary of Legal Basis:

Currently, health plans assign identification numbers to their member health care providers. Different health plans assign different numbers to the same health care providers. The identifiers are frequently not standard within a health plan or across health plans. This results in health care providers having different identification numbers for different health programs, often having multiple billing numbers issued within a single health program. This complicates the health care providers' claims submissions and other transactions and increases the costs incurred by health care providers in conducting those transactions.

The Administrative Simplification provisions of HIPAA were designed to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of the standard unique health care provider identifier and other standards and requirements to facilitate the electronic transmission of certain health information.

Alternatives:

This regulation announces the NPI as the standard unique health care provider identifier. The NPI is a 10-position all numeric identifier, with a check-digit in the tenth position. There is no intelligence in the number. This design and our assignment strategy will allow more than 200 million NPIs to be issued. The NPI meets the principles established by the Department of Health and Human Services (HHS) for designation as a national standard. This final regulation defines ''health care provider'' in terms of the entities that will receive NPIs.

Health care providers will be enumerated by a federally directed registry (the enumeration contractor). The enumeration contractor will use the National Provider System (NPS) to uniquely identify a health care provider and issue it an NPI. The NPS will be developed by CMS. Health care providers must supply updates to their

NPS data to the enumeration contractor within 30 days of the effective dates of the changes.

The NPS will establish the National Provider File (NPF), which will contain information collected from health care providers in order to assign them NPIs. The NPS will assign a single, unique NPI to a health care provider. Upon the dissolution of an organization health care provider or the death of a individual health care provider, the NPS will deactivate the NPI that had been issued to that health care provider and will not assign a deactivated NPI to any other health care provider.

Anticipated Cost and Benefits:

Our analysis of the costs and savings of the HIPAA Administrative Simplification standards is an aggregate impact of all the standards. Assessing the impact of each standard independently would inflate the costs and would yield inaccurate results. While each individual standard is beneficial, the standards as a whole have a synergistic effect on savings. A difficulty in this analysis was the fact that we have no historical experience in assessing the costs and benefits of such a sweeping change. The costs of implementing the standards specified in HIPAA are primarily one-time or short-term costs related to conversion. These costs will be incurred during the first three years of implementation. Benefits will accrue almost immediately, but will not exceed costs for health care providers until after the third year of implementation. After the third year, the benefits will continue to accrue into the fourth year and beyond. The impact analysis for the costs and benefits associated with all the Administrative Simplification standards indicates that the combined net savings for health plans and health care providers would amount to $1.5 billion dollars after five years.

Risks:

This rule will formally establish the standard for the unique health care provider identifier and will communicate the requirements for health plans, health care providers, and health care clearinghouses in implementing this standard.

Failure to publish this rule would jeopardize the benefits of administrative simplification. Payers would continue to maintain their own system of enumerating providers, and providers would need to maintain systems to store the different identifiers. Additional costs would thus be incurred.

Timetable:

Action	Date	FR Cite
NPRM	05/07/98	63 FR 25320
NPRM Comment Period End	07/06/98	
Final Action	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

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

Additional Information:

None

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HHS—CMS

59. SECURITY STANDARDS (CMS-0049-F)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

PL 104-191; 42 USC 1320d-2(d)

CFR Citation:

45 CFR 162

Legal Deadline:

Final, Statutory, February 21, 1998.

Abstract:

This final rule is being jointly developed by CMS and the Department of Commerce. This final rule adopts standards for the security of certain electronic, individually identifiable health information of health plans, health care clearinghouses, and certain health care providers. It implements administrative simplification initiatives that have a national scope beyond the Medicare and Medicaid programs.

Statement of Need:

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1966 required the Department to adopt standards for security.

Currently, no standard measures exist in the health care industry that address all aspects of the security of electronic health information while it is being stored or transmitted between entities.

The use of the security standards will improve the Medicare and Medicaid programs, and other Federal health programs and private health programs, and the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information.

Summary of Legal Basis:

This final rule implements some of the requirements of the Administrative Simplification subtitle of HIPAA.

Alternatives:

Existing security standards do not encompass all the requirements set forth in the law.

Anticipated Cost and Benefits:

Although we cannot determine the specific economic impact of the standards in this final rule (and individually each standard may not have a significant impact), we are unable to estimate the cost of implementing the security standards as implementation needs will vary dependent upon each entity's risk assessment and upon what is already in place. In addition, it is important to recognize that security is not a one-time project, but rather an on-going, dynamic process. However, the overall impact analysis makes clear that, collectively, all the HIPAA standards will have a significant impact of over $100 million on the economy. We believe that the overall Administrative Simplification costs will be offset by future savings.

Implementation of the security standards will provide confidentiality, integrity and availability protections to certain personaly identifiable health information. The synergistic effect of the employment of the security standards will also enhance all aspects of HIPAA's Administrative Simplification requirements.

Risks:

The security of electronic protected health information is, and has been for some time, a basic business

requirement that health care entities ignore at their peril. Instances of ''hacking'' and other security violations may be widely publicized, and can seriously damage an institution's community standing. Appropriate security protections are crucial for encouraging the growth and use of electronic data interchange.

Timetable:

Action	Date	FR Cite
NPRM	08/12/98	63 FR 43242
NPRM Comment Period End	10/13/98	
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

Undetermined

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HHS—CMS

60. HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (QAPI) (CMS-3050-F)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh

CFR Citation:

42 CFR 482.21

Legal Deadline:

None

Abstract:

This final rule addresses provisions relating to the development and implementation of a QAPI program and its components. It imposes several requirements that are designed to increase patient safety and track the methodologies and/or programs or both used to increase patient safety.

Statement of Need:

In 1999, reports of deaths and serious injuries to patients associated with medical errors were published in a report issued by the Institute of Medicine (IOM) entitled, ''To Err is Human: Building a Safer Health System.'' This report generated much media, public, Congressional, and Departmental concern for patient health and safety, estimating that up to 98,000 Americans die each year as a result of preventable medical errors.

The Quality Interagency Coordination Task Force (QuiC), evaluated the recommendations in the IOM report and to respond with a strategy to identify patient safety issues and stimulate the reduction of medical errors by 50 percent over the next 5 years, as recommended by the IOM. This regulation will serve to accomplish this goal.

Summary of Legal Basis:

Hospitals must meet certain conditions in order to participate in the Medicare program that are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the CoPs in Medicare. 42 U.S.C. 1302 and 42 U.S.C. 1395hh authorizes promulgation of regulations in the interest of the health and safety of individuals who are furnished services in the institution.

Alternatives:

We considered adding requirements that were more prescriptive in nature. However, in response to public comments, and in recognition that this requirement will apply to hospitals of varying size, operating in wide ranges of localities, serving diverse populations, we opted not to utilize this approach. Development of more detailed strategies and policies to comply with the requirement will be left to the discretion of each hospital.

Anticipated Cost and Benefits:

Hospitals are currently required to have a quality assurance program and we believe that the costs associated with the QAPI program are similar to the costs associated with their existing quality assurance program. Therefore, we do not anticipate the implementation of the final rule to result in any significant increase in costs to hospitals or the Medicare and Medicaid programs. The information requirements contained within the regulations are comparable to those of JCAHO and are necessary safeguards against patient safety.

Given the variability of QAPI programs, it would be difficult to define the extent to which this would affect individual hospitals. CMS has allowed maximum flexibility in meeting these requirements, and Medicare hospitals have existing requirements for QA programs. We do, however, recognize that hospitals will have an increased minimal burden associated with the writing of internal policies and procedures that encompass all aspects of this requirement. Also, hospitals must continue to track incidents and analyze their causes, in addition to the new requirement of implementing preventive actions and mechanisms of learning. Accredited JCAHO hospitals should not experience increased burden associated with the requirement for performance projects; however, CMS' assessment of the rule's possible burden implications for these hospitals is currently under review. Also, the 1,485 non-accredited hospitals will now be required to perform improvement projects that measure, analyze, and track quality indicators or other aspects of performance. We have minimized the burden to these facilities by allowing projects to be representative of the hospitals complexity of services and resources.

Risks:

This final rule is intended to encourage the emphasis of patient safety in hospitals, and serves as the first step toward providing the framework for and bringing to the forefront of medical practice, increased patient safety and accountability. The knowledge gained from QAPI and patient safety programs will lead to better health care for Medicare's more than 39 million beneficiaries.

Given the substantial media, public, Congressional, and Departmental concern regarding patients' health and safety, we believe that this final rule should be published as soon as possible. The QAPI CoP provides the framework to implement the Administration's initiatives, thereby addressing preventable medical errors and patient safety in hospitals.

Timetable:

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66725
NPRM Comment Period End	02/17/98	
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

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HHS—CMS

61. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS-3063-F)

Priority:

Other Significant

Legal Authority:

Sec 522 of the BIPA 2000

CFR Citation:

42 CFR 405

Legal Deadline:

NPRM, Statutory, October 1, 2001, The effective date for regulation changes is 10/01/01.

Abstract:

This final rule would announce a new process for beneficiaries to appeal national and local coverage determinations (LCDs).

Statement of Need:

Implementation of an LCD and national coverage determination (NCD) appeals process is required by section 522 of the Benefits Improvement and Protections Act (BIPA). The effective date for this section was October 1, 2001, so expeditious implementation of the regulation is crucial.

Summary of Legal Basis:

An appeal process for LCDs and NCDs is mandated by section 522 of BIPA.

Alternatives:

Because of the complex nature of the proposed processes, the agency opted to implement through a Notice of Proposed Rulemaking (NPRM) in order to grant the public an opportunity to comment on these complex processes. Though other approaches would not have granted such an opportunity to comment, alternatives could have also included not writing a regulation, or implementing via another mechanism, such as a Federal Register Notice. The agency decided that the processes were too complex to implement via anything other than an NPRM.

Anticipated Cost and Benefits:

The Medicare program would incur certain administrative costs associated with coverage determination reviews, the cost of being a party to coverage determination reviews, and the cost of reevaluating policies. A potential benefit for beneficiaries includes providing another avenue for beneficiaries to challenge NCDs (this time to a third party), and a new mechanism to challenge LCDs, as mandated by section 522 of BIPA.

Risks:

Risks include receiving so many comments from the public, or comments that are sufficiently complex, that thorough review of the comments would further delay implementation of a final rule.

Timetable:

Action	Date	FR Cite
Proposed Rule	08/22/02	67 FR 54534
Comment Period End	10/21/02	
Final Action	07/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—CMS

62. HEALTH INSURANCE REFORM: MODIFICATIONS TO STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0003-F)

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

Social Security Act, sec 1871

CFR Citation:

45 CFR 162

Legal Deadline:

None

Abstract:

This rule finalizes provisions applicable to electronic data transaction standards, adopts implementation specifications for health care entities and others, and responds to public comments received on two related proposed rules published on May 31, 2002 in the Federal Register.

Statement of Need:

The Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires the Secretary of Health and Human Services to adopt standards for electronic transactions. This rule modifies previous adopted standards as a result of the Designated Standard Maintenance Organization (DSMO) process. The modifications in this rule are required by the health care industry for initial implementation of the HIPAA transactions standards.

Summary of Legal Basis:

The Administrative Simplification provisions of HIPAA require the Secretary to establish standards of electronic transactions for health plans, health care clearing houses, and certain health care providers.

Alternatives:

In the absence of this final rule, the health care industry would be unable to implement the adopted standard transactions.

Anticipated Cost and Benefits:

The estimated costs and benefits of this rule would not change the impact of the Standard for Electronic Transaction final rule published on August 17, 2000 (65 FR 50312). It would loosen the financial burden on the health care industry.

Risks:

Modifying standards established in the Standard for Electronic Transaction final rule (65 FR 50312), as a result of the DSMO process, will allow the health care industry to be in compliance with regulations under HIPAA. This rule would enable providers, health plans, and clearinghouses to utilize a consistent set of electronic standards that are in compliance throughout the entire health care community.

Timetable:

Action	Date	FR Cite
Proposed Rule	05/31/02	67 FR 38044
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

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HHS—CMS

63. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS-1470-N)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Sec 1886(d) of the Social Security Act

CFR Citation:

42 CFR 412 to 413; 42 CFR 485; 42 CFR 489

Legal Deadline:

NPRM, Statutory, April 1, 2003.

Final, Statutory, August 1, 2003.

Abstract:

This notice would revise the Medicare acute hospital inpatient prospective payment systems for operating and capital market costs to implement changes arising from our continuing experience with these systems. These changes apply to discharges occurring on or after October 1, 2003.

Statement of Need:

Annual updates to the hospital inpatient prospective payment system rates are required by section 1886 of the Social Security Act (the Act), as amended by the Medicare, Medicaid, and SCHIP Balanced Budged Refinement Act of 1999 (BBRA), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), relating to Medicare payments for hospital inpatient prospective payment systems.

We are proposing to revise the Medicare hospital inpatient prospective payment systems for operating and capital costs to describe proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services. These changes would be applicable to discharges occurring on or after October 1, 2003. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the prospective payment systems.

Summary of Legal Basis:

Section 1886(d) of the Social Security Act sets forth a system of payment for the operating costs of the acute care hospital inpatient system under Medicare part A based on prospectively set rates. Section 1866(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system.

Section 1886(e)(5)(B) requires that annual updates to the hospital inpatient prospective payment systems rates be published in the Federal Register before August 1 of each year, to be effective on the first day of the fiscal year (FY).

Alternatives:

None.

Anticipated Cost and Benefits:

The cost and benefits of this regulation will depend upon the market basket projection by the Office of the Actuary. Under current law, the update for FY 2003 will be market basket minus .55 percentage points. A one percent change in payments under the inpatient prospective payment system represents an approximately $760 million change.

Risks:

Inadequately paying for the services hospitals furnish to Medicare beneficiaries has the potential to affect a beneficiary's access to care and the quality of care furnished to a beneficiary. Therefore, we will carefully assess the impacts of all of the changes we implement through this regulation to mitigate these risks.

Failure to update the hospital inpatient prospective payment systems by October 1, 2003 would place us in violation of the Act. Moreover, failure to meet the publication deadline imposed by the Act would also constitute a violation.

Timetable:

Action	Date	FR Cite
Notice	05/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0938–AL89

HHS—CMS

64. ● APPLICATION OF EMERGENCY MEDICAL AND TREATMENT ACT (EMTALA) (CMS-1063-F)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

Not Yet Determined

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This final rule regulation would clarify special responsibilities of Medicare hospitals that offer services for treatment of emergency medical conditions, to promote consistent application of the Emergency Treatment and Labor Act to situations not discussed in current regulations.

Statement of Need:

Revised regulations are needed to clarify the responsibilities of Medicare participating hospitals with respect to individuals who come to the hospital emergency department and request examination or treatment of a medical condition. The regulations would announce the agency's final position on proposals published on May 9, 2002 (67 FR 31404).

Summary of Legal Basis:

The legal basis of this regulation are sections 1866(a)(1)(I) and 1867 of the Social Security Act (42 U.S.C. 1385cc and 42 U.S.C. 1395dd).

Alternatives:

None feasible. If the regulations are not published in final, uncertainty among physicians and hospitals about their responsibilities will continue and increase.

Anticipated Cost and Benefits:

We are unable to provide objective dollar estimates of the impact of the regulations. We expect that publication of the regulations will enable hospitals and physicians to act in more focused and efficient ways to meet their statutory responsibilities, thus increasing the quality and availability of emergency care.

Risks:

Some physicians and hospitals may continue to have some concerns about these requirements, even after the publication of clarifying regulations. However, if current regulations are not clarified, hospitals and physicians will have continued uncertainty as to their statutory responsibilities, and patients with emergency medical conditions may face greater difficulty in receiving needed care in a timely manner.

Timetable:

Action	Date	FR Cite
Final Action	11/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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Related RIN: Related To 0938-AL23

RIN: 0938–AM34

BILLING CODE 4150–24–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The Regulatory Plan for the Department of Housing and Urban Development for fiscal year 2003 highlights the Department's most significant regulations and policy initiatives, as established by Secretary Martinez, for the upcoming fiscal year. As the Federal agency responsible for national policy and programs that address the housing needs of Americans, encourage community development, and enforce fair housing laws, HUD plays a significant role in communities throughout America. HUD touches the lives of individuals and families by helping to expand homeownership and affordable housing, and suitable living environments for all Americans. HUD's commitment to expand homeownership is achieved by underwriting homeownership for lower- and moderate-income families through its mortgage insurance programs, and by enforcing fair housing laws that operate to eliminate housing discrimination. HUD also provides housing and other essential support to a wide range of individuals and families with special needs, including homeless individuals, the elderly, persons with disabilities, and people living with HIV/AIDS.

From the beginning of his administration, Secretary Martinez has called on HUD to focus on activities that support the Department's core mission of providing affordable housing, expanding homeownership opportunities, and promoting economic growth in our Nation's communities. Consistent with that direction, HUD's regulatory plan for fiscal year 2003 builds upon the successes of the previous fiscal year through regulations that are designed to expand homeownership opportunities, that reform the home buying process by improving and simplifying the process of financing or refinancing homes, that strengthen HUD's oversight of Federal Housing Administration-approved mortgage lenders, and that combat predatory lending practices.

HUD is also committed to supporting its core community and economic development programs. Across America, faith-based and community-based organizations at the grassroots level share HUD's commitment and mission by providing critically important charitable services. In fiscal year 2003, HUD will comprehensively examine its programs to eliminate regulatory requirements that hinder these organizations from being able to fully participate in HUD programs and contribute to HUD's mission.

Consistent with the Secretary's direction, 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: Ensuring the Equal Participation of Faith-Based Organizations in HUD's Efforts To Enhance Communities

Faith-based and other community organizations are indispensable in meeting the needs of poor Americans and distressed neighborhoods. HUD believes, however, that faith-based organizations have not been effectively utilized in assisting the Federal Government to address those needs. Faith-based organizations have a strong history of providing vital community services, such as assisting the homeless and preventing homelessness, counseling individuals and families on fair housing rights, providing the elderly with housing opportunities, increasing homeownership and rental housing opportunities, developing first-time homeownership programs, developing affordable and accessible housing, creating economic development programs, and supporting the residents of public housing facilities.

HUD's goal is to remove any restrictions in regulations or the appearance of restrictions so that faith-based and non-faith-based organizations can participate equally in HUD's programs. This removal of restrictions will ultimately make HUD programs more effective, efficient and accessible by expanding opportunities for all organizations to participate in developing creative solutions for their own communities.

Regulatory Action: Faith-Based Organizations: Providing for Equal Treatment of All HUD Program Participants

HUD believes that there is no need to single out faith-based organizations for special instructions or conditions before allowing them to participate in HUD programs. This proposed rule would remove regulatory language that appears to impose, or in fact imposes, special conditions or requirements on faith-based organizations. HUD's objective is to ensure that its programs are neutral with regard to the religious character of a grant-recipient organization, thereby ensuring that faith-based organizations have equal opportunity to participate in HUD programs. Programs that will be affected by this proposed rule include Community Development Block Grants; HOPE for Homeownership of Single Family Homes; Housing Opportunities for Persons with AIDS; Emergency Shelter Grants; Shelter Plus Care; Supportive Housing; Youthbuild; and Community Development Block Grants for Indian Tribes and Alaska Native Villages.

Priority: Establishing Housing Goals for Fannie Mae and Freddie Mac

Under the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, HUD is required to establish housing goals for Fannie Mae and Freddie Mac (collectively, the Government Sponsored Enterprises or GSEs). The current goals, promulgated by regulation in 2000, cover the calendar years 2001 through 2003. The Secretary is therefore establishing new goals for future years. The new goals may be higher than the current goals; in the past, each new set of goals has in fact been higher than its predecessor. The purpose of the housing goals is to ensure that the two GSEs more fully address the housing finance needs of low- and moderate-income families and residents of underserved areas, and thereby to more fully realize their public purposes.

Regulatory Action: The Secretary of HUD's Regulation of Fannie Mae and Freddie Mac (Government Sponsored Entities)

Through this rule, HUD will issue new housing goal levels for the purchase of mortgages by Fannie Mae and Freddie Mac for calendar years 2003 and beyond. The Department is required by statute to establish housing goals for the GSEs. The new goals to be established by this rule will have the benefit of increasing homeownership opportunities and affordable housing units for very low-, low- and moderate-income families, and will ensure that the GSEs carry out their statutory responsibilities.

Priority: Expanding Homeownership — Making the Home Purchase Process Less Complicated and Less Costly

Homeownership plays a vital role in creating strong communities, generating wealth for families, and providing financial security for millions of Americans. Homeownership also helps to strengthen families and to provide a positive, stable environment for children. In brief, homeownership has a positive and pronounced effect on the

nation's economy. Yet every day Americans enter into mortgage loans, the largest investment most families will ever make, without the clear and useful information they receive with almost any other major purchase. Under the leadership of Secretary Martinez, HUD is determined to simplify the home buying process, and in doing so, expand homeownership to thousands of American first-time homebuyers. HUD is committed to streamlining the home mortgage finance process and making loan shopping and settlement simpler, so consumers have the information necessary to make informed decisions regarding mortgage costs.

Regulatory Action: RESPA: Simplifying and Improving the Process of Obtaining Mortgages To Reduce Settlement Costs to Consumers

The objective of this rule is to simplify and improve the process of obtaining home mortgages and reduce settlement costs for consumers by creating a more ''transparent'' settlement process to facilitate consumers' understanding of the true costs of a mortgage and the functions of an originator. Specifically, the proposed rule would: (1) address the issue of loan originator compensation, namely the problem of lender payments to mortgage brokers, by fundamentally changing the way in which these payments in brokered mortgage transactions are recorded and reported to consumers; (2) significantly improve HUD's Good Faith Estimate (GFE) settlement cost disclosure and HUD's related RESPA regulations to make the GFE firmer and more usable, to facilitate shopping for mortgages, to make mortgage transactions more transparent, and to prevent unexpected charges to consumers at settlement; and (3) remove regulatory barriers to allow guaranteed packages of settlement services and mortgages to be made available to consumers, and to permit consumers to shop for financing and further reduce settlement costs.

Priority: Expanding Homeownership — Through Revitalization of Communities

HUD is committed to expanding homeownership opportunities, particularly among racial and ethnic minorities and families with disabilities. Homeownership helps families establish strong roots, which in turn strengthens communities. One way in which HUD will expand homeownership opportunities for minorities is through implementation of section 204 of the National Housing Act, as recently amended. The stated purpose of this authority is to make HUD-held single family homes and formerly insured mortgages on single family properties, referred to as eligible assets, available for sale in a manner that promotes the revitalization of certain areas through expanded homeownership opportunities. Through this authority, HUD together with local government and nonprofit organizations can revitalize distressed areas and increase homeownership opportunities.

Regulatory Action: Disposition of HUD-Owned Single Family Assets in Asset Control Areas

This proposed rule would make available HUD-held single family homes and mortgage assets for sale to governmental and nonprofit organizations, among others, for use in homeownership programs to revitalize certain areas. By statute, governmental and nonprofit organizations are to be given preference. Under this program, revitalization areas would be identified by applying specified economic and housing criteria. Eligible purchasers would be able to establish an Asset Control Area within a revitalization area identified by the Secretary, and would commit by contract to purchase all HUD-owned single family homes or mortgages that become available in that area for a time frame specified by the contract. These purchasers would then make available the assets in accordance with a HUD-approved plan to encourage homeownership and revitalize the area.

Priority: Expanding Homeownership — Enhancing Accountability in the Home Purchase Process

HUD is committed to continuing its efforts to reduce predatory lending practices and enhance accountability in the home purchase process. Predatory lending, whether undertaken by creditors, brokers or home improvement contractors, involves engaging in deception or fraud, manipulating the borrower through aggressive sales tactics, or taking unfair advantage of a borrower's lack of understanding about loan terms. These practices are combined with loan terms that, alone or in combination, are abusive or make the borrower more vulnerable to abusive practices. While no one set of abusive lending practices or terms characterizes a predatory mortgage loan, a loan can be predatory when lenders or brokers undertake one or more of the following practices: charge borrowers excessive, often hidden fees; successively refinance loans at no benefit to the borrower; make loans without regard to a borrower's ability to repay; and engage in high-pressure sales tactics or outright fraud and deception. In addition, faulty appraisals, whether intentional or unintentional, are a significant part of this problem and contribute to the inability of homebuyers to make monthly mortgage payments and to the instability of neighborhoods. Vulnerable populations, including elderly and low-income individuals, and low-income or minority neighborhoods may be targeted by these unscrupulous lenders. As a result, predatory lending threatens homeownership by placing on borrowers loans that are so expensive or have such high rates that borrowers are unable to pay and risk default. This significantly undercuts HUD's efforts to revitalize communities and expand homeownership.

To date, HUD has issued several regulations directed to curbing predatory lending practices, such as the rule prohibiting property flipping, the rule establishing criteria for house inspectors to be placed on and removed from the FHA Inspector Roster, and the rule to clarify the responsibilities of lenders in the FHA appraisal process. Additional rules designed to enhance lender accountability and strengthen FHA's oversight of mortgage transactions are planned for fiscal year 2003, and include the following:

Regulatory Action: FHA Appraiser Watch Initiative

Through the Appraiser Watch Initiative, HUD plans to establish and monitor a performance standard that appraisers must meet to maintain their status on the FHA Appraiser Roster. This rule will cover approximately 25,000 individuals who conduct appraisals on FHA-insured single family homes. The Appraiser Watch Initiative is modeled on FHA's Credit Watch Termination Initiative and would provide for an electronic, fully computerized Appraiser Watch monitoring system. The rule would permit an appraiser to be removed from the FHA Appraiser Roster if the rate of defaults and claims on closed mortgages linked to the appraiser exceeds a rate established by HUD. Under the terms of this approach, FHA would notify appraisers before removing them from the FHA Appraiser Roster. Any appraiser who receives such notice would be permitted to meet with HUD officials and present evidence that factors beyond his or her control contributed to the excessive rates. The proposal would also make provisions for appraisers to be reinstated to the roster.

Regulatory Action: Appraiser Qualifications for Placement on Single Family Appraiser Roster

This rule is designed to strengthen the integrity of FHA appraisals by requiring that appraisers have, at a minimum, the professional credentials required by the Appraiser Qualifications Board of the Appraisal Foundation. This rule helps ensure that homebuyers seeking FHA-insured mortgages receive an accurate and complete appraisal of the homes they seek to purchase.

Priority: Improving the Quality of Public and Assisted Housing

A central HUD objective is to help low-income working families acquire skills that will move them toward self-sufficiency. Combined with this objective, it is HUD's goal to improve the quality of the housing opportunities provided to families in public and assisted housing. To do this, HUD will focus on improving the management accountability and physical conditions of public and assisted housing through the following regulations.

Regulatory Action: Deregulation of Small Public Housing Agencies (PHAs)

Although HUD has an obligation to monitor and regulate the use of Federal housing funds in order to ensure that taxpayer dollars are well spent, HUD is also mindful that compliance with its regulatory requirements may impose administrative burdens on PHAs and divert scarce resources. The cost of excessive regulation is especially problematic for small entities, in this case small PHAs, because they often possess the fewest staff and technical resources. In response to the limitations faced by many small PHAs, HUD is undertaking efforts to alleviate the regulatory and other administrative burdens Departmental requirements impose on small PHAs, while still requiring basic accountability. HUD believes that deregulating small PHAs will alleviate burden, and better enable them to focus on their core mission of providing safe, decent, and affordable housing to the neediest American families.

This final rule would simplify and streamline HUD's regulatory requirements for small PHAs that administer the public housing and voucher assistance programs under the United States Housing Act of 1937. Specifically, the final rule would further streamline the PHA Annual Plan requirements for certain small PHAs. The final rule will also deregulate the assessment and scoring of small PHAs under the Public Housing Assessment System (PHAS) and the Section 8 Management Assessment Program (SEMAP), consistent with its basic regulatory responsibilities. In addition to the changes that solely concern small PHAs, this final rule would also streamline HUD's review of the annual plans submitted by all PHAs (large and small). The final rule follows publication of an August 12, 2002, proposed rule, and takes into consideration the public comments received on the proposed rule.

Regulatory Action: Simplification of PHA Planning Requirements

This rule would streamline various aspects of the PHA Plan requirements to eliminate redundancies and unnecessary reporting requirements that do not relate to PHAs' strategic planning efforts, and are burdensome to PHAs and HUD. The rule would retain aspects of the current process that bolster resident participation and ensure the public's access to PHA records and documents.

PHA strategic planning involving residents and the community can be accomplished in a manner that is less dictated from Washington and involves fewer elements of bureaucratic compliance. The current PHA Plan statute requires eighteen specific Plan elements and a HUD approval process that in many respects does not affect the substance of the Plans. The proposal would deregulate various elements of the PHA Plan now requiring HUD approval, leaving these to local discretion. The rule would allow and encourage PHAs to focus on performance rather than form and process.

Regulatory Action: Improve the Public Housing Assessment System

This rule will propose changes to the Public Housing Assessment System (PHAS) and the regulations implementing that system. The PHAS, established in 1998, assesses the management performance of public housing agencies and resident management corporations in four critical areas of public housing operations: the physical condition of public housing; the financial condition; the management operations; and the satisfaction of the residents with the housing and services. The Department has met with public housing agencies, residents, representatives of these groups and other interested parties, to solicit input on how the PHAS can be improved. As a result of these meetings, the Department will publish a proposed rule for public comment incorporating some of the proposed changes from the stakeholders and seeking additional suggestions and proposals from the public. Improvements made to the PHAS will in turn promote maintaining affordable rental housing.

Regulatory Action: Project-Based Voucher Program

The Project-Based Voucher Program replaces the former and long-term Project-Based Certificate Program and provides PHAs with flexibility in administering the program that will assist PHAs in increasing housing opportunities. The Project-Based Program was authorized by law in 1998, as part of the statutory merger of the certificate and voucher tenant-based programs. In 2000, the Congress substantially revised the project-based voucher law. The statutory revisions of 2000 made a number of changes to the program including permitting a PHA to pay project-based assistance for a term of up to 10 years, permitting a PHA to provide project-based assistance for existing housing that does not need rehabilitation, as well as for newly constructed or rehabilitated housing, and allowing a family to move from a project-based voucher unit after one year and transfer to the PHA's tenant-based voucher program. Initial guidance on the new law was provided to PHAs and residents in January 2001. This rulemaking begins the process of providing the more permanent regulatory framework for this new program.

The Priority Regulations That Comprise HUD's FY 2003 Regulatory Plan

A more detailed description of the priority regulations that comprise HUD's FY 2003 regulatory plan follows.

HUD—Office of the Secretary (HUDSEC)

PROPOSED RULE STAGE

65. ● PARTICIPATION IN HUD PROGRAMS BY FAITH-BASED ORGANIZATIONS; PROVIDING FOR EQUAL TREATMENT FOR ALL HUD PROGRAM PARTICIPANTS (FR-4782)

Priority:

Other Significant

Legal Authority:

42 USC 3535(d), 42 USC 12701 to 12839;42 USC 5301 to 5320; 42 USC 12891, 42 USC 12901 to 12912; 42 USC

11376; 42 USC 11403 to 114706, 42 USC 11389; 42USC 8011

CFR Citation:

24 CFR 92; 24 CFR 570; 24 CFR 572; 24 CFR 574; 24 CFR 576; 24 CFR 582; 24 CFR 583; 24 CFR 585; 24 CFR 1003; ...

Legal Deadline:

None

Abstract:

This rule would revise those HUD regulations that appear to deter or preclude the participation of faith-based organizations in HUD programs. Faith-based organizations are welcome participants in HUD programs. They are eligible to participate in HUD programs and are subject to the same HUD and other Federal requirements to which all other program participants are subject. The rule therefore would clarify that the prohibitions against discriminating on the basis of religion and engaging in efforts to advance religion in the provision of HUD-funded activities are applicable to all HUD program participants and not just one category of participants. The rule would also clarify that faith-based organizations participating in HUD programs may consider religion as a factor in hiring, consistent with Title VII of the Civil Rights Act of 1964. The rule would amend the regulations for the following HUD programs: (1) HOME Investment Partnerships; (2) Community Development Block Grants (CDBG); (3) Hope for Homeownership of Single Family Homes (HOPE 3); (4) Housing Opportunities for Persons with AIDS(HOPWA); (5) Emergency Shelter Grants (ESG); (6) Shelter Plus Care; (7) Supportive Housing; (8) Youthbuild; and (9) Community Development Block Grants for Indian Tribes and Alaska Native Villages (ICDBG).

Statement of Need:

HUD regulations must treat all program participants fairly. The regulations should ensure that all grantees use HUD funds for the purposes specified in the regulations, and only those purposes, and under the conditions specified in the regulations. Consistent with recent judicial decision, this rule would ensure that HUD programs are neutral with regard to the religious character of participating organizations.

Summary of Legal Basis:

The statutes establishing the various programs amended by this proposed rule and HUD's general rulemaking authority under the Department of Housing and Urban Development Act authorize HUD to establish regulatory policies and procedures for the operation of these programs. This authority includes the establishment of eligibility requirements for organizations seeking to participate in HUD's programs, the conditions for receipt of funding, and the eligible uses of the HUD funds.

Alternatives:

The changes made by this rule would modify regulatory requirements and, therefore, must also be promulgated through regulation. Nonregulatory alternatives (such as promulgation through HUD notice or handbook) would not be binding upon HUD program participants.

Anticipated Cost and Benefits:

This rule would remove regulatory language that appears to present barriers to equal participation by faith-based organizations in HUD's programs. The anticipated benefit is that the rule would help to ensure equal opportunity for all organizations to participate as partners in HUD's programs.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	
NPRM Comment Period End	04/00/03	
Final Action	08/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

None

Agency Contact:

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Office of the Secretary
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RIN: 2501–AC89

HUD—HUDSEC

66. ● THE SECRETARY OF HUD'S REGULATION OF FANNIE MAE AND FREDDIE MAC (FR-4790)

Priority:

Other Significant

Legal Authority:

12 USC 1451 et seq; 12 USC 1716 to 1723h; 12 USC 4501 to 4641; 28 USC 2641 note; 42 USC 3535(d); 42 USC 3601 to 3619

CFR Citation:

24 CFR 81

Legal Deadline:

None

Abstract:

Through this rule, the Department will propose housing goals for the purchase of mortgages by Fannie Mae and Freddie Mac (collectively, the Government Sponsored Enterprises, or GSEs) for calendar year 2004 forward and make any necessary revisions to HUD's GSE rules to ensure that the GSEs meet the laws' requirements and carry out their public missions. In accordance with the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (FHEFSSA), this rule would establish new goals for the GSEs' purchase of mortgages financing low- and moderate-income housing, special affordable housing, and housing in central cities, rural areas, and other underserved areas. This rule would clarify, as necessary, HUD's guidelines for counting different types of mortgage purchases toward those goals. The current housing goals apply through 2003. The Secretary of HUD has general regulatory power over each GSE and is required to make such rules and regulations as shall be necessary to ensure that the purposes of FHEFSSA and the GSEs' charters are accomplished. HUD's current GSE regulations implement FHEFSSA's provisions and include fair housing, new program approval, reporting and access to information requirements. This rule will propose any necessary revisions to HUD's rules to implement FHEFSSA and carry out the Secretary's regulatory responsibilities.

Statement of Need:

In the absence of new goals, the goals already established for 2003 remain in place, but the Secretary intends to establish goals for 2004 and later years, with the objective of ensuring that the two enterprises fully address the housing finance needs of very low-,

low- and moderate-income families and residents of underserved areas, and thus realize more fully their public purposes. FHEFSSA sets forth the Secretary's responsibilities regarding the GSEs and the GSEs' charters specify their public missions. Under FHEFSSA, the Secretary must make necessary rules and regulations to ensure that the purposes of FHEFSSA and the GSEs' Charters are accomplished.

Summary of Legal Basis:

The Department is required to establish housing goals for the GSEs pursuant to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 et seq.). HUD also has general regulatory power over each GSE (12 U.S.C. 4541) and is required to make such rules and regulations as are necessary to ensure that the purposes of FHEFSSA and the GSEs' charters are accomplished. (See 12 USC 4501-4641.)

Alternatives:

The Department considered the alternative of leaving the housing goals unchanged. However, HUD takes very seriously its obligations under the law to establish the housing goals using the most current data and information.

The alternative of leaving other provisions of the GSE rules unchanged also has been considered but it is not evident that the existing rules will ensure that the purposes of the law are accomplished.

Anticipated Cost and Benefits:

This rule will have the benefit of increasing homeownership opportunities and affordable housing units for low- and moderate-income families and underserved communities from 2004 and beyond and it will ensure that the GSEs otherwise carry out their responsibilities under FHEFSSA. However, there is no indication that these objectives would be costly for the GSEs. HUD's analyses have consistently indicated that meeting housing goals will have little impact on the GSEs' financial returns or on the safety and soundness of GSE operations. Additionally, increased GSE activity in the affordable lending arena has not adversely affected traditional portfolio lenders.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	
NPRM Comment Period End	08/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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RIN: 2501–AC92

HUD—Office of Housing (OH)

PROPOSED RULE STAGE

67. DISPOSITION OF HUD-OWNED SINGLE FAMILY ASSETS IN ASSET CONTROL AREAS (FR-4471)

Priority:

Other Significant

Legal Authority:

12 USC 1710(h); 42 USC 3535(d)

CFR Citation:

24 CFR 291

Legal Deadline:

NPRM, Statutory, September 15, 2002.

Abstract:

This rule would implement a new program to make available HUD-held single family assets for sale to governmental organizations and nonprofits for use in homeownership programs to revitalize certain areas. Under the new program, HUD would identify revitalization areas by applying specified economic and housing criteria. Eligible purchasers, that is, units of general local government and nonprofit organizations, may establish an Asset Control Area within a revitalization area and commit by contract to purchase all HUD-owned single family homes or mortgages that become available in that area for a time frame specified by the contract. By statute, these purchasers are to be given preference. The entities would then make available the assets pursuant to a HUD-approved plan to encourage homeownership and revitalize the area.

Statement of Need:

The authorizing statute requires HUD to issue regulations for this program through rulemaking in accordance with the procedures established under section 553 of title 5, United States Code.

Summary of Legal Basis:

Section 602 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1999 (Pub.L. 105-276) added a new subsection (h) to section 204 of the National Housing Act to authorize this program.

Alternatives:

Administration of this program under a generally applicable rule will provide all interested parties with a level playing field and notice of what requirements must be followed in order to participate. This is more efficient than proceeding on a case-by-case basis.

Anticipated Cost and Benefits:

The costs of this rule will mainly be borne by the Department, since the discounts offered on eligible assets could represent a loss to the Mutual Mortgage Insurance Fund. The benefits are those related to the revitalization of, and increased homeownership within, the designated areas.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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RIN: 2502–AH40

HUD—OH

68. FHA APPRAISER WATCH INITIATIVE (FR-4744)

Priority:

Other Significant

Legal Authority:

12 USC 1701 to 1715z-18; 42 USC 3535(d)

CFR Citation:

24 CFR 200

Legal Deadline:

None

Abstract:

This rule would establish HUD's regulations for the Federal Housing Administration (FHA) Appraiser Watch Initiative. Modeled on FHA's Credit Watch Termination Initiative, the proposed rule would provide for an electronic, fully computerized Appraiser Watch monitoring system. The Appraiser Watch Initiative establishes and monitors a performance standard that appraisers must meet to maintain their status on the Appraiser Roster. An appraiser may be removed from the Roster if the rate of defaults and claims on closed mortgages linked to the appraiser exceeds the rate established in this rule.

Statement of Need:

This rule is needed to increase appraiser accountability and address the role of faulty appraisals in the misuse of FHA insurance to underwrite bad loans that lead to defaults and foreclosed homes. Such defaulted properties contribute to neighborhood destabilization and decline. Faulty appraisals, whether intentional or not, are a significant part of this problem and contribute to the inability of homebuyers to make monthly mortgage payments and to the instability of neighborhoods.

Summary of Legal Basis:

The National Housing Act and HUD's authority under the Department of Housing and Urban Development Act authorize HUD to provide a home financing system through the insurance of mortgages that would maintain and expand homeownership opportunities, particularly for first-time homebuyers and low-income families.

Alternatives:

Individual fact-finding investigations and adjudications on a case-by-case basis as presently conducted, and which will continue on an ongoing basis, are lengthy and time-consuming proceedings. The Department is planning to adopt a streamlined approach to increase appraiser accountability modeled on its successful Credit Watch Initiative.

Anticipated Cost and Benefits:

Anticipated costs are mainly those of information collection and recordkeeping requirements related to establishing an electronic, fully computerized Appraiser Watch monitoring system. The anticipated benefit is an increase in sound appraisals and a corresponding decrease in defaults, foreclosures, and FHA losses.

Risks:

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

Timetable:

Action	Date	FR Cite
ANPRM	07/23/02	67 FR 48344
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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RIN: 2502–AH81

HUD—OH

FINAL RULE STAGE

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69. APPRAISER QUALIFICATIONS FOR PLACEMENT ON FHA SINGLE FAMILY APPRAISER ROSTER (FR-4620)

Priority:

Other Significant

Legal Authority:

12 USC 1701 to 1715z-18; 42 USC 3535(d)

CFR Citation:

24 CFR 200

Legal Deadline:

None

Abstract:

This rule makes several regulatory changes designed to strengthen the licensing and certification requirements for placement on the Federal Housing Administration (FHA) Appraiser Roster. First, the rule requires that appraisers on the Appraiser Roster must have credentials that are based on the minimum licensing/certification standards issued by the Appraiser Qualifications Board of the Appraisal Foundation. The rule also clarifies that an appraiser may be removed from the Appraiser Roster if the appraiser loses his or her license or certification in any State due to disciplinary action, even if the appraiser continues to be licensed or certified in another State. Finally, the rule provides that an appraiser whose license or certification in any State has expired, or has been revoked, suspended or surrendered as a result of a State disciplinary action, will be automatically suspended from the Appraiser Roster until HUD receives evidence demonstrating renewal or that the State-imposed sanction has been lifted. The final rule follows publication of a November 30, 2001, proposed rule and takes into consideration the public comments received on the proposed rule.

Statement of Need:

HUD's Appraiser Roster lists those appraisers who are eligible to perform FHA single family appraisals. HUD maintains the Appraiser Roster to provide a means by which HUD can ensure the competency of appraisers performing FHA appraisals. The Appraiser Roster is an important part of the FHA Single Family Mortgage

Insurance program because accurate appraisals are vital to the success of the program and HUD's ability to protect the FHA Insurance Fund. The changes made by this final rule are necessary to help ensure that homebuyers seeking FHA-insured mortgages receive accurate and complete appraisals of the homes they seek to purchase.

Summary of Legal Basis:

The National Housing Act and HUD's authority under the Department of Housing and Urban Development Act authorize HUD to provide a home financing system through the insurance of mortgages that would maintain and expand homeownership opportunities, particularly to first-time homebuyers and low-income families. This authority includes the regulation of appraisers participating in the FHA single family mortgage insurance programs.

Alternatives:

HUD has established codified placement and removal procedures for the FHA Appraiser Roster. The changes made by this final rule would modify these requirements and, therefore, must also be promulgated through regulation. Furthermore, nonregulatory alternatives (such as promulgation through mortgagee letter) would not be binding upon appraisers.

Anticipated Cost and Benefits:

This rulemaking will strengthen the FHA Appraiser Roster licensing and certification requirements. The anticipated benefit is that the rule will enhance the accuracy and integrity of FHA appraisals, thereby reducing opportunities for fraud and predatory lending abuses conducted with the collusion of unscrupulous appraisers, such as property flipping.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	11/30/01	66 FR 60128
NPRM Comment Period End	01/29/02	
Final Action	01/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HUD—OH

70. RESPA—IMPROVING THE PROCESS FOR OBTAINING MORTGAGES (FR-4727)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

12 USC 2601; 42 USC 3535(d)

CFR Citation:

24 CFR 3500 et seq

Legal Deadline:

None

Abstract:

This rule would establish a new framework for borrower disclosures under RESPA that would: (1) address the issue of mortgage broker compensation, specifically the problem of lender payments to mortgage brokers, by fundamentally changing the way in which such lender payments in brokered mortgage transactions are recorded and reported to borrowers; (2) significantly improve HUD's Good Faith Estimate (GFE) settlement cost disclosure, and amend HUD's related RESPA regulations, to make the GFE firmer and more usable, to facilitate shopping for mortgages, and to avoid unexpected charges to borrowers at settlement; and (3) remove regulatory barriers to allow guaranteed packages of settlement services and mortgages to be made available to borrowers, to make borrower shopping for mortgages easier and further reduce settlement costs.

Statement of Need:

The rule is needed to simplify and improve the process of obtaining a home mortgage to lower costs for consumers. The current disclosure requirements under RESPA have not been substantially revised in decades. Under current rules, there is confusion concerning the role of the mortgage broker and how the broker is compensated. Recent developments have only heightened the need for greater clarity. The GFE does not result in reliable estimates for consumers nor does it facilitate shopping to lower costs. Current rules present regulatory impediments to offering consumers simpler guaranteed packages of mortgages and settlement services to make shopping for a mortgage even easier and to lower settlement costs further. There have been continuing changes to the home mortgage process in the marketplace including new products and greater accessibility of mortgage information through the Internet. If properly addressed by Government, these and other factors can result in price reductions for consumers.

Summary of Legal Basis:

The Secretary is authorized to prescribe such rules and regulations as may be necessary to achieve the purpose of the Act under the Real Estate Settlement and Procedures Act of 1974 (12 USC 2617).

Alternatives:

As noted above, the Department has not updated the disclosure requirements in decades. The Department tried to bring some clarity to the process through two policy statements: a Statement of Policy on Lender Payments to Mortgage Brokers issued on March 1, 1999, and a Clarification of the 1999 Statement of Policy, issued on October 17, 2001. Nonregulatory alternatives were considered and acted upon, but it was determined that the changes in the marketplace and recent judicial decisions call for new regulations on the part of HUD.

Anticipated Cost and Benefits:

Because the Nation's home mortgage market is a billion-dollar industry, there are costs and benefits associated with this rule that were described in detail in the Initial Economic Analysis that accompanied the proposed rule. The Economic Analysis identifies a wide range of benefits, costs, efficiencies, transfers and market impacts. The effects on consumers from improved borrower shopping could be substantial as a result of this rulemaking. Similarly, increased competition associated with packaging could result in large reductions in settlement service costs and associated income transfers from service providers who are earning ''economic rents'' in today's system to borrowers, who would most likely be the ultimate

beneficiaries of more competition among settlement service providers. Entities that would suffer revenue losses under this rulemaking are usually those who now overcharge uninformed borrowers, or are high-cost producers, or are benefiting from the current system's restrictions on competition.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	07/29/02	67 FR 49134
NPRM Comment Period End	10/28/02	
Final Action	01/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

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RIN: 2502–AH85

HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

71. PROJECT-BASED VOUCHER PROGRAM (FR-4636)

Priority:

Other Significant

Legal Authority:

42 USC 1437f(o); 42 USC 3535(d)

CFR Citation:

24 CFR 983

Legal Deadline:

None

Abstract:

The Project-Based Voucher Program replaces the Project-Based Certificate Program that was in existence for many years. Under the Project-Based Voucher Program, HUD pays rental assistance for eligible families to live in specific housing developments or units. A public housing agency (PHA) that administers a tenant-based housing choice voucher program may ''project-base'' up to 20 percent of voucher units funded by HUD. The Project-Based Program was authorized by law in 1998, as part of the statutory merger of the certificate and voucher tenant-based programs. In 2000, the Congress substantially revised the project-based voucher law. The law made a number of changes including permitting a PHA to pay project-based assistance for a term of up to 10 years, permitting a PHA to provide project-based assistance for existing housing that does not need rehabilitation, as well as for newly constructed or rehabilitated housing, and allowing a family to move from a project-based voucher unit after one year and transfer to the PHA's tenant-based voucher program.

Statement of Need:

This rule will implement the requirements for the new Section 8 Project-Based Voucher program. The regulations will provide the appropriate notice of the legal framework for the program, and clear and uniform guidance for program operation for PHAs and the residents that the PHAs serve.

Summary of Legal Basis:

The statute is not self-implementing. Regulations are needed to present the legal framework for the program. The Secretary is authorized under the U.S. Housing Act of 1937 and the Department of Housing and Urban Development Act to prescribe such rules and regulations as may be necessary to effectively administer Department programs.

Alternatives:

This is a new program that provides assistance for housing and replaces a previous HUD program. Effective and fair administration of the program necessitates a permanent legal framework rather than informal and sporadic HUD notices.

Anticipated Cost and Benefits:

The new law and the regulations to be implemented by HUD provide additional flexibility to PHAs to manage their project-based voucher programs, and also provide more housing choices to the individuals and families served by the PHA.

Risks:

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

Timetable:

Action	Date	FR Cite
Notice	01/16/01	66 FR 3605
NPRM	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local

Agency Contact:

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RIN: 2577–AC25

HUD—PIH

72. CHANGES TO THE PUBLIC HOUSING ASSESSMENT SYSTEM (PHAS)(FR-4707)

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

24 CFR 902

Legal Deadline:

None

Abstract:

Through this rule, the Department will be revising the regulations that govern the Public Housing Assessment System (PHAS). This rule will incorporate the input of public housing stakeholder groups in the public housing assessment process, and solicit additional input from the public.

Statement of Need:

The Department has agreed to consider changes to the current PHAS regulations based on consultation with public housing stakeholders including industry representatives, resident groups and other interested Federal and congressionally chartered agencies.

Summary of Legal Basis:

The Secretary of HUD is directed under section 6(j) of the United States Housing Act of 1937 (42 U.S.C. 1437 et seq.) to develop and publish in the Federal Register indicators to assess the management performance of public housing agencies and resident management corporations.

Alternatives:

The current interim scoring methodologies provide the Department with a fully implemented assessment system while the amended PHAS regulation is being developed. Other alternatives that have been considered, such as utilizing the Management Indicator (MASS) only, fail to meet the Department's strategic goal of ensuring that public housing agencies provide decent, safe and sanitary housing.

Anticipated Cost and Benefits:

This rule will have the benefit of promoting the success of PHAS by ensuring the buy-in of public housing stakeholder groups in the public housing assessment process. The new proposed rule is in the development phase; therefore, accurate cost estimates cannot be provided at this time.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 2577–AC32

HUD—PIH

73. ● STREAMLINING AND DEREGULATION OF PUBLIC HOUSING AGENCY PLANS (FR-4788)

Priority:

Other Significant

Legal Authority:

42 USC 1437c-1; 42 USC 3535(d)

CFR Citation:

24 CFR 903

Legal Deadline:

None

Abstract:

This rule would simplify and streamline the regulations for the Public Housing Agency (PHA) Plans to eliminate redundancies and unnecessary reporting requirements that do not relate to the strategic planning efforts of PHAs. The rule would also deregulate certain components of the PHA Plans that currently require HUD approval, leaving these policies to the local discretion of individual PHAs. The rule would retain those PHA Plan requirements that bolster resident participation in the strategic planning of PHAs and that ensure the public's access to PHA records and documents. The regulatory changes will alleviate administrative burden on both PHAs and HUD. The changes will also further the goals of the PHA Plan process by enabling PHAs to focus their resources on strategic planning and performance, rather than on the forms and processes required under the current PHA Plan regulations.

Statement of Need:

The PHA Plans provide an easily identifiable source by which program participants and other members of the public may locate basic PHA policies and requirements concerning its operations, plans and services. The current PHA Plan regulations, however, impose several requirements on PHAs that are duplicative or administratively burdensome. For example, the regulations establish eighteen specific elements that must be addressed by PHAs and a HUD approval process that in many respects does not affect the substance of the Plans. Moreover, other statutory and HUD regulatory requirements facilitate and encourage successful PHA planning. For example, HUD has implemented management assessment systems for public housing and tenant-based assistance, and PHAs are statutorily required to include a resident on their governing boards. Accordingly, HUD has determined that PHA strategic planning involving residents and the community can be accomplished in a manner that is less dictated by the Federal Government and involves fewer elements of bureaucratic compliance.

Summary of Legal Basis:

Section 5A of the United States Housing Act of 1937 (42 U.S.C. 1437c-1), which establishes the PHA Plan process, 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 content, submission and approval of the PHA Plans.

Alternatives:

The changes contained in this rule would modify regulatory requirements and therefore, must also be promulgated through regulation. Nonregulatory alternatives (such as promulgation through HUD Notice) would not be binding upon PHAs.

Anticipated Cost and Benefits:

This rule simplifies and streamlines regulatory requirements for PHAs that are required to prepare and submit Annual and 5-Year PHA Plans. The anticipated benefit is that the rule will alleviate the administrative burden imposed on PHAs, thereby freeing limited resources that may be better used in strategic planning efforts and in the provision of housing assistance for poor families.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	02/00/03	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

State, Local

Agency Contact:

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HUD—PIH

FINAL RULE STAGE

74. DEREGULATION FOR SMALL PUBLIC HOUSING AGENCIES (FR-4753)

Priority:

Other Significant

Legal Authority:

42 USC 1437a; 42 USC 1437c; 42 USC 1437d(j); 42 USC 1437f; 42 USC 3535(d)

CFR Citation:

24 CFR 902; 24 CFR 903; 24 CFR 985

Legal Deadline:

None

Abstract:

This rule simplifies and streamlines HUD's regulatory requirements for small public housing agencies (PHAs) that administer the public housing and voucher assistance programs under the United States Act of 1937 (1937 Act). Specifically, the rule will further streamline the PHA Annual Plan requirements for certain small PHAs. HUD also proposes to deregulate the assessment and scoring of small PHAs under the Public Housing Assessment System (PHAS) and the Section 8 Management Assessment Program (SEMAP), consistent with its basic regulatory responsibilities. In addition to the changes that solely concern small PHAs, this rule will also streamline HUD's review of the Annual Plans submitted by all PHAs (large and small). This final rule follows publication of an August 14, 2002, proposed rule and takes into consideration the public comments received on the proposed rule.

Statement of Need:

Although HUD has an obligation to monitor and regulate the use of Federal housing funds in order to ensure that taxpayer dollars are well spent, HUD is also mindful that compliance with its regulatory requirements may impose administrative burdens on PHAs and divert scarce resources. The cost of excessive regulation is especially problematic for small PHAs, because they often possess the fewest staff and technical resources. The changes made by this final rule will alleviate administrative burden, and better enable small PHAs to focus on their core mission of providing decent, safe, and affordable housing for the neediest American families.

Summary of Legal Basis:

The 1937 Act and HUD's authority under the Department of Housing and Urban Development Act authorize HUD to establish regulatory policies and procedures for the operation of the Federal public and assisted housing programs authorized by the 1937 Act.

Alternatives:

The changes made by this final rule would modify regulatory requirements and, therefore, must also be promulgated through regulation. Nonregulatory alternatives (such as promulgation through HUD Notice) would not be binding upon PHAs.

Anticipated Cost and Benefits:

This rule simplifies and streamlines regulatory requirements for small PHAs that administer HUD's public housing and voucher assistance programs. The anticipated benefit is that the rule will alleviate the administrative burden imposed on small PHAs, thereby freeing limited resources that may be better used for the provision of housing assistance for poor families.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	08/14/02	67 FR 53276
NPRM Comment Period End	09/13/02	
Final Action	01/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local

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BILLING CODE 4210–01–S

DEPARTMENT OF THE INTERIOR (DOI)

Statement of Regulatory Priorities

The Department of the Interior (DOI) is the principal Federal steward of our Nation's public lands and resources, including many of our cultural treasures. We serve as trustee to Native Americans and Alaska natives and also are responsible for relations with the island territories under United States jurisdiction. We manage more than 450 million acres of Federal lands, including 385 park units, 538 wildlife refuges, 24,000 miles of trails, and approximately 1.7 billion acres submerged in offshore waters. The Department recovers endangered species, manages water projects, fights wildland fires, leases public lands for coal, oil and gas production to meet the Nation's energy needs, educates children in Indian schools and provides recreational opportunities for almost 300 million visitors annually in our national parks. To fulfill these responsibilities, the Department generates scientific information relating to land and resource management.

The Department is committed to achieving its stewardship objectives in partnership with States, communities, landowners, and others through consultation, cooperation, and communication.

We will review and update the Department's regulations and policies to ensure that they are effective, efficient, and promote accountability. Special emphasis will be given to regulations and policies that:

- Adopt performance-based approaches focusing on achieving results in the most cost-effective and timely manner;
- Incorporate the best available science, and utilize peer review where appropriate;
- Promote partnerships with States, other groups and individuals;
- Provide incentives for private landowners to achieve conservation goals; and
- Minimize regulatory and procedural burdens, promoting fairness, transparency, and accountability by agency regulators while maintaining performance goals.

Major Regulatory Areas

Among the Department's bureaus and offices, the Office of Surface Mining Reclamation and Enforcement (OSM) has a significant concentration of regulatory responsibilities. OSM, in partnership with the States and Indian tribes, sets and enforces environmental standards during coal mining and reclamation operations. Other DOI bureaus rely on regulations to implement legislatively mandated programs that focus on the management of natural resources and public or trust lands. Some of these regulatory activities include:

- Management of migratory birds and preservation of certain marine mammals and endangered species;
- Management of dedicated lands, such as national parks, wildlife refuges, and American Indian trust lands;
- Management of public lands open to multiple use;
- Leasing and oversight of development of Federal energy, minerals, and renewable resources;
- Management of revenues from American Indian and Federal minerals;
- Fulfillment of trust and other responsibilities pertaining to American Indian tribes;
- Natural resource damage assessments; and
- Management of financial and nonfinancial assistance programs.

Regulatory Policy

How DOI Regulatory Procedures Relate to the Administration's Regulatory Policies

Within the requirements and guidance in Executive Orders 12866, 12630, and 13132, DOI's regulatory programs seek to:

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

DOI bureaus have taken the initiative in working with other Federal agencies, non-Federal government agencies, and public entities to make our regulations easier to comply with and understand. Regulatory improvement is a continuing process that requires the participation of all affected parties. We strive to include all affected entities in the decisionmaking process and to issue rules efficiently. To better manage and review the regulatory process, we have revised our internal rulemaking and information quality guidance. Results have included:

- Increased bureau awareness of and responsiveness to the needs of small businesses and better compliance with the Small Business Regulatory Enforcement Fairness Act (SBREFA);
- A Departmentwide effort to evaluate the economic effects of planned rules and regulations;
- Issuance of new guidance in the Departmental Manual to ensure the use of plain language;
- Issuance of new guidance in the Departmental Manual to ensure that Departmental National Environmental Policy Act reforms are institutionalized; and
- In the Natural Resources Damage Assessment Program, deemphasizing actions stemming from litigation while increasing outreach to involved parties and stressing cooperation and restoration of affected sites.

We are committed to improving the regulatory process through the use of plain language. Simplifying regulations has resulted in a major rewrite of the regulations for onshore oil and gas leasing and operations in an easily understandable form that: (a) puts previously published rules into one location in a logical sequence; (b) eliminates duplication by consolidating existing regulations and onshore orders and national notices to lessees; (c) incorporates industry standards by reference; and (d) implements performance standards in some of the operating regulations. 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.

Implementing the President's National Energy Policy

The President's National Energy Policy promotes ''dependable, affordable, and environmentally sound production and distribution of energy for the future.'' The Department of the Interior plays a vital role in implementing the President's energy policy goals. The lands and facilities managed by the Department account for nearly 30 percent of all the energy produced in the United States, and undeveloped conventional and renewable energy resources on these lands suggest that this share will increase in the future.

The Department is taking over 100 actions to implement the President's energy policy, including several regulatory actions. The Bureau of Land Management recently completed a final rule that provides a comprehensive set of regulations for managing oil and gas leases in the National Petroleum Reserve — Alaska. The Minerals Management Service will soon propose a rule that would provide an incentive for development of deep gas resources offshore in order to encourage drilling of these high-risk wells and help tap into an important new source of natural gas supply. The Office of Surface Mining will propose regulations that will create a stable regulatory environment in order to encourage the development of better mining and reclamation practices that will reduce environmental damages associated with coal operations, while maintaining coal production. These and other regulatory actions within the Department are designed to streamline permitting processes and encourage environmentally sound energy production.

Encouraging Responsible Management of the Nation's Resources

The Department's mission includes protecting and providing access to our Nation's natural and cultural heritage and honoring our trust responsibilities to tribes. We are committed to this mission and to applying laws and regulations fairly and effectively. The Department's priorities include protecting public health and safety, restoring and maintaining public lands, ameliorating land and resource-management problems on public lands, and ensuring accountability and compliance with Federal laws and regulations.

The Department is continuing to work together with State and local governments, landowners, conservation groups, and the business community to conserve species and habitat. Building on successful approaches such as habitat conservation plans, safe harbor agreements, and candidate conservation agreements, the Department is reviewing its policies and regulations to identify opportunities to streamline the regulatory process where possible, consistent with protection of wildlife, and to enhance incentive-based programs to encourage landowners and others to implement voluntary conservation measures. For example, the Fish and Wildlife Service is developing 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 Service will be publishing a proposed rule to facilitate projects that improve habitat for listed species.

The Department is also developing a uniform code of scientific conduct and policy on research. The code describes ethical conduct for all Department employees who are engaged in conducting scientific activities on behalf of the Department. The primary reason for developing the code is to implement a new Federal policy on research misconduct as required by the Office of Science and Technology Policy. The new policy applies to all Federal agencies and federally funded research, whether conducted in-house or by partners at universities or in nongovernmental organizations. This new 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.

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

The National Park Service is completing a Supplemental Environmental Impact Statement regarding snowmobile management in Yellowstone and Grand Teton National Parks and John D. Rockefeller, Jr. Memorial Parkway. Although a final decision is not expected until spring 2003, the NPS has made preliminary indications that snowmobile use will continue at some level in all three units. In order to continue this use, the NPS will likely require the use of new snowmobile engine technology in machines entering the parks. The new technology will likely improve air quality associated with the use of older machines and unlimited numbers of users. The subsequent changes to the existing rules will also likely reduce adverse economic impact projected to result from completely prohibiting the use of snowmobiles in all three parks.

The Bureau of Land Management is working on a grazing administration rule that would ensure grazing decision rules conform with the Administrative Procedure Act, are in 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.

Minimizing Regulatory Burdens

We are using the regulatory process to ease the burdens on various entities throughout the country while improving results. For instance, the Endangered Species Act (ESA) allows for the delisting of threatened and endangered species if they no longer need the protection of the ESA. We have identified approximately 40 species for which delisting or downlisting (reclassification from endangered to threatened) may be appropriate.

We use performance standards in a variety of regulations to improve compliance and achievement of regulatory goals. These allow the affected entity to choose the most economical method to accomplish a goal provided it meets the requirements of the regulations. An example of this is Minerals Management Service's (MMS) training rule, which will allow companies with operations in the Outer Continental Shelf (OCS) to select their own training courses or programs for employees. The new rule will allow lessees and contractors to properly train the employees by any method they choose as long as the employees are competent. We anticipate that this will result in new and innovative training techniques and allow companies added flexibility in tailoring their training to employees' specific duties.

Over the last year, the Department's bureaus have worked extensively with the Federal Energy Regulatory Commission, along with the Departments of Commerce and Agriculture, to establish new licensing procedures that will reduce both the cost and time of obtaining a FERC hydropower license. In September 2002 the above agencies published a Federal Register notice inviting the public to comment on the new draft licensing procedures, and the agencies will be conducting public meetings around the

country throughout this fall. Over the course of the next year, the Department will be working closely with FERC and the other agencies in drafting new regulations that should embody many of the aspects of the agencies' draft new procedures.

Encouraging Public Participation and Involvement in the Regulatory Process

The Department is encouraging increased public participation in the regulatory process to improve results by ensuring that regulatory policies take into account the knowledge and ideas of our customers, regulated community, and other interested participants. The Department is reaching out to communities to seek public input on a variety of regulatory issues. For example, every year FWS establishes migratory bird hunting seasons in partnership with ''flyway councils,'' which are made up of State fish and wildlife agencies. As the process evolves each year, FWS holds a series of public meetings to give other interested parties, including hunters and other groups, opportunities to participate in establishing the upcoming season's regulations.

Similarly, the Bureau of Land Management (BLM) uses Resource Advisory Councils (RACs) made up of affected parties to help prepare land management plans and regulations that it issues under the Rangeland Reform Act.

We encourage public consultation during the regulatory process. For example:

- OSM is continuing its outreach to interested groups to improve the substance and quality of rules and, to the greatest extent possible, achieve consensus on regulatory issues;
- The Bureau of Indian Affairs is developing its roads program rule using the negotiated rulemaking process. Because of the importance of the roads program to the individual tribes and because of the varying needs of the tribal governments, the negotiated rulemaking process will result in a rule that better serves the diverse needs of the Native American community;
- The National Park Service has granted cooperating agency status to three states and several local governments surrounding Yellowstone and Grand Teton National Parks to participate in the development of a sustainable winter use management plan that will include two phases of snowmobile regulations during 2002 and 2003.

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 will finalize an interim rule published in April 2002 that implements this authority.

Rules of Particular Interest to Small Businesses

The National Park Service snowmobiling rule for Yellowstone and Grand Teton National Parks and the John D. Rockefeller Memorial Parkway is of great interest to small business in the area of the parks, in particular those who rent snowmobiles. If, as discussed above, snowmobile use does continue in all three units, those small businesses and others will benefit.

The Future of DOI

Interior has developed a draft Departmentwide strategic plan in response to congressional, OMB and other appraisals indicating that Interior's ten separate strategic planning documents are too long and lack the appropriate agency-level focus. Interior also intends to use the single Strategic Plan as the basis for preparing a single Departmentwide Annual Performance Plan beginning with the plan for FY 2004. The Interior bureaus will continue to prepare internal plans to support their budget initiatives and to meet management excellence and accountability needs. However, in the future we plan to submit only Departmentwide strategic and annual plans to the Congress. Finally, the process of developing the new strategic plan provides the Secretary with an opportunity to:

- Incorporate key Administration and Secretarial priorities into Interior's goals and performance measures;
- Consult with key interested constituents on the future direction of the Department; and
- Make Interior programs more ''results-oriented'' and accountable to citizens.

Bureaus and Offices Within DOI

The following brief descriptions summarize the regulatory functions of DOI's major regulatory bureaus and offices.

Office of the Secretary, Natural Resource Damage Assessment and Restoration Program

The regulatory functions of the Natural Resource Damage Assessment and Restoration Program (Restoration Program) stem from requirements under section 301(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). Section 301(c) requires the development of natural resource damage assessment rules and the biennial review and revisions, as appropriate, of these rules. Rules have been promulgated for the optional use of natural resource trustees to assess compensation for damages to natural resources caused by hazardous substances. The Restoration Program is overseeing the study and possible promulgation of additional rules pursuant to section 301(c)(2) and the review and possible revision of the existing rule in compliance with section 301(c)(3).

In undertaking DOI's responsibilities under section 301(c), the Restoration Program is striving to meet three regulatory objectives: (a) make the regulation user-friendly through the use of plain language so that the assessment and restoration process can be followed by all interested parties; (b) move towards a restoration approach for determining compensation rather than monetizing economic damages, and (c) facilitating negotiated settlements rather than litigation over natural resource damages.

Bureau of Indian Affairs

The Bureau of Indian Affairs (BIA) is responsible for managing trust responsibilities to the Indian tribes and encouraging tribal governments to assume responsibility for BIA programs.

The Bureau's rulemaking and policy development processes are designed to foster public and tribal awareness of the standards and procedures that directly affect them. The processes also encourage the public and the tribes to participate in developing these standards and procedures. The goals of BIA regulatory policies are to: (a) ensure consistent policies within BIA that result in uniform interactions with the tribal governments, (b) facilitate tribal involvement in managing, planning, and evaluating BIA programs and services, and (c) ensure continued protection of tribal treaties and statutory rights.

Bureau of Land Management

The Bureau of Land Management manages about 262 million acres of land

surface and about 700 million acres of Federal mineral estate. These lands consist of extensive grasslands, forests, mountains, arctic tundra, and deserts. Resources on the lands include energy and minerals, timber, forage, wild horse and burro populations, habitat for fish and wildlife, wilderness areas, and archeological and cultural sites. BLM manages these lands and resources for multiple purposes and the sustained yield of renewable resources. Primary statutes under which the agency must operate include: the Federal Land Policy and Management Act of 1976; the General Mining Law of 1872; the Mineral Leasing Act of 1920, as amended; the Recreation and Public Purposes Act; the Taylor Grazing Act; and the Wild, Free-Roaming Horses and Burros Act.

The regulatory program mirrors statutory responsibilities and agency objectives. Agency objectives include:

- 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 historical resources;
- Understanding the arid, semi-arid, arctic, and other ecosystems we manage and committing to using the best scientific and technical information to make resource management decisions;
- Understanding the needs of the public that use BLM-managed lands and providing them with quality service;
- Committing to recovering a fair return for using publicly owned resources and avoiding the creation of long-term liabilities for American taxpayers; and
- Resolving problems and implementing decisions in cooperation with other agencies, States, tribal governments, and the public.

The regulatory program contains its own objectives. These include preparing regulations that:

- Are the product of communication, coordination and consultation with all affected members of the public;
- Are understandable to the general public, especially those to whom they are directly applicable; and
- Are subject to periodic review to determine whether BLM still needs them, whether they need to be updated to reflect statutory and policy changes, and whether they are achieving desired results.

The regulatory priorities of BLM include:

- Completing the revision of oil and gas leasing and operations regulations in order to make the program more efficiently serve the regulated public;
- Completing the updating and consolidation of the regulations on locating, filing, and maintaining mining claims and mill and tunnel sites in order to remove unnecessary and outdated provisions, reorder the regulations more logically, and make them easier to read and follow;
- Completing the revision of the regulations on administration of rights-of-way on the public lands in order to increase cost recovery to levels that properly compensate BLM for our administrative and monitoring costs and to raise the cap on strict liability for right-of-way holders to a reasonable level in light of costs for environmental cleanup; and
- Completing the revision of the regulations on disclaimers of interest in public lands in order to remove claims on titles to lands in which the Federal Government no longer has an interest.

None of these specific priorities is based on recent legislation. They derive from programmatic needs and awareness of national budget constraints.

Minerals Management Service

The Minerals Management Service (MMS) has two major responsibilities. The first is timely and accurate collection, distribution, accounting for, and auditing of revenues owed by holders of Federal onshore, offshore, and tribal land mineral leases in a manner that meets or exceeds Federal financial integrity requirements and recipient expectations. The second is management of the resources of the Outer Continental Shelf in a manner that provides for safety, protection of the environment, and conservation of natural resources. These responsibilities are carried out under the provisions of the Federal Oil and Gas Royalty Management Act, the Minerals Leasing Act, the Outer Continental Shelf Lands Act, the Indian Mineral Leasing Act, and other related statutes.

Our regulatory philosophy is to develop clear, enforceable rules that support the missions of each program. For the Offshore Minerals Management program, as authorized by the Deep Water Royalty Relief Act (DWRRA) (Pub. L. 104-58), we plan to issue a final regulation to revise current regulations at 30 CFR part 203. The new rule would provide temporary incentives in the form of royalty suspension volumes for deep wells (at least 15,000 feet below sea level) in the Gulf of Mexico, that explore for or produce gas. We will also continue to review rules and issue amendments in response to new technology and new industry practices.

We also plan to continue our review of existing regulations and to issue rules to refine the Minerals Revenue Management (MRM) regulations in chapter II of 30 CFR. MRM is in the process of issuing regulations to: (1) revise its oil valuation regulations for Indian leases; (2) codify provisions in the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996; and (3) implement new financial and compliance procedures resulting from a major reengineering initiative.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSM) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA) to ''strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal as an essential source of energy.''

The principal regulatory provisions contained in title V of SMCRA set minimum requirements for obtaining a permit for surface coal mining operations, set standards for those operations, require land reclamation once mining ends, and require rules and enforcement procedures to ensure that the standards are met. Under SMCRA, OSM is the primary enforcer of SMCRA's provisions until the States achieve ''primacy,'' that is, until they demonstrate that their regulatory programs meet all the specifications in SMCRA and have regulations consistent with those issued by OSM.

When a primacy State takes over the permitting, inspection, and enforcement activities of the Federal Government, OSM then changes its role from regulating mining activities directly to overseeing and evaluating State programs. Today, 24 of the 26 key coal-producing States have primacy. In return for assuming primacy, States are entitled to regulatory grants and to grants for reclaiming abandoned mine lands. In addition, under cooperative agreements, some primacy States have agreed to regulate mining on Federal lands within their borders. Thus, OSM regulates mining directly only in nonprimacy States, on Federal lands in States where no cooperative agreements are in effect, and on Indian lands.

SMCRA charges OSM with the responsibility of publishing rules as necessary to carry out the purposes of the Act. The fundamental mechanism for ensuring that the purposes of SMCRA are achieved is the basic policy and guidance established through OSM's permanent regulatory program and related rulemakings. This regulatory framework is developed, reviewed, and applied according to policy directives and legal requirements.

Litigation by the coal industry and environmental groups is responsible for some of the rules now being considered by OSM. Others are the result of efforts by OSM to address areas of concern that have arisen during the course of implementing OSM's regulatory program, and one is the result of legislation.

OSM has sought to develop an economical, safe, and environmentally sound program for the surface mining of coal by providing a stable, consistent regulatory, results-focused framework. At the same time, however, OSM has recognized the need: (a) to respond to local conditions; (b) to provide flexibility to react to technological change; (c) to be sensitive to geographic diversity; and (d) to eliminate burdensome recordkeeping and reporting requirements that over time have proved unnecessary to ensure an effective regulatory program.

Major regulatory objectives regarding the mining of surface coal include:

- Regulatory certainty so that coal companies know what is expected of them and citizens know what is intended and how they can participate; and
- Continuing consultation, cooperation, and communication with interest groups during the rulemaking process in order to increase the quality of the rulemaking, and, to the greatest extent possible, reflect consensus on regulatory issues.

U.S. Fish and Wildlife Service

The mission of the U.S. Fish and Wildlife Service is 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 our 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 international partners.
- *Habitat conservation—a network of lands and waters.* Cooperating with others, FWS strives to conserve an ecologically diverse network of lands and waters—of various ownerships—providing habitats 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 habitat conservation strategy uses an ecosystem approach to focus on the interaction and balance of people, lands and waters, and fish and wildlife.
- *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 affording the public hands-on experiences through volunteer conservation activities on Service lands.
- *Partnerships in natural resources.* FWS supports and strengthens partnerships with tribal, State, and local governments and others in their efforts to conserve and enjoy fish, wildlife, and plants and habitats. 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 and programs. The Service works continually with foreign and State governments, affected industries and individuals, and other interested parties to minimize any burdens associated with Service-related activities. The Service attempts to ensure a balance between any possible public burdens and adequate protection for the natural resource.

The Service implements and enforces regulations that govern public access, use, and recreation on more than 500 national wildlife refuges and in national fish hatcheries. The Service authorizes those uses that are compatible with the purpose for which each area was established, are consistent with State and local laws where practical, and afford the public appropriate economic, recreational, and conservation opportunities.

The Service 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.

The Service enforces regulations to fulfill its statutory obligation to identify and conserve species faced with extinction. The Endangered Species Act (ESA) dictates that the basis for determining endangered species is limited to biological considerations. Regulations enhance the conservation of listed species and certain marine mammals. Regulations also help other Federal agencies comply with the ESA, which prohibits them from conducting activities that would jeopardize the existence of endangered species or adversely modify critical habitat of listed species. In designating critical habitat, 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.

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. In carrying out its assistance programs, the Service administers regulations to help interested parties obtain Federal assistance and also to help assistance recipients comply with applicable laws and Federal requirements.

National Park Service

The National Park Service is dedicated to conserving the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations. The Service also manages a great variety of national and international programs designed to help extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.

There are 385 units in the National Park System, including national parks and monuments; scenic parkways, preserves, trails, riverways, seashores, lakeshores, and recreation areas; and historic sites associated with important movements, events, and personalities of the American past.

The National Park Service develops and implements park management plans and staffs the areas under its administration. It relates the natural values and historical significance of these areas to the public through talks, tours, films, exhibits, and other interpretive media. It operates campgrounds and other visitor facilities and provides, usually through concessions, lodging, food, and transportation services in many areas. The National Park Service also administers the following programs: the State portion of the Land and Water Conservation Fund, Nationwide Outdoor Recreation coordination and information and State comprehensive outdoor recreation planning, planning and technical assistance for the National Wild and Scenic Rivers System, and the National Trails System, natural area programs, the National Register of Historic Places, national historic landmarks, historic preservation, technical preservation services, Historic American Buildings survey, Historic American Engineering Record, and interagency archeological services.

The National Park Service maintains regulations that help manage public use, access, and recreation in units of the National Park System. The Service provides visitor and resource protection to ensure public safety and prevent degradation of resources. The regulatory program develops and reviews regulations, maintaining consistency with State and local laws, to allow these uses 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.

DOI—National Park Service (NPS)

FINAL RULE STAGE

75. • SNOWMOBILE REGULATIONS; YELLOWSTONE AND GRAND TETON NATIONAL PARKS AND JOHN D. ROCKEFELLER MEMORIAL PARKWAY

Priority:

Other Significant

Legal Authority:

16 USC 1; 16 USC 3; 16 USC 9a; 16 USC 460(q); 16 USC 462(k)

CFR Citation:

36 CFR 7.13; 36 CFR 7.21; 36 CFR 7.22

Legal Deadline:

Final, Judicial, November 15, 2002.

Abstract:

This is a multiphase rule with the next phase legally due to be published by November 15, 2002. This phase will delay, for one year, certain provisions of the existing snowmobile and snowcoach regulations at the parks. The next phase will implement any new provisions for snowmobile management that arise from the record of decision due to be issued in spring 2003. It is expected that those provisions will become effective before the winter use season of 2003-2004.

Statement of Need:

The rulemaking is necessary as a result of legal action taken by the International Snowmobile Manufacturers Association (ISMA) and others in June 2001. The NPS agreed to reevaluate the impacts of the existing regulations on local economies and to analyaze and incorporate provisions for new technology snowmobile engines into the existing Winter Use Management Plan.

Summary of Legal Basis:

The National Park Service entered into a settlement agreement with ISMA and others in June 2001. This agreement was a result of a lawsuit initiated by ISMA disputing provisions of the snowmobile regulations written at the end of the Clinton administration. The settlement agreement required publication of a final rule, if necessary, by November 15, 2002.

Alternatives:

The only alternative to these regulations would be to allow provisions of the existing regulations for the parks to go into effect for the winter use season 2002-2003. The result would be a 50 percent reduction in snowmobiles allowed into Yellowstone and Grand Teton National Parks with each entrance station being allotted a set number of users to enter per day.

Anticipated Cost and Benefits:

This rule would delay adverse economic impacts from the existing rule for one year. There may be economic benefits resulting from the proposed extension. In the draft supplemental environmental impact statement (DSEIS) the NPS estimated that in 2003-2004, the economic outputs and employment impacts of implementing actions under this rule are: in the five-county, greater Yellowstone area, an estimated loss of $15.9 to $21.1 million; in the three-State area surrounding the parks, a variance of a possible $18.4 million loss to a $7.0 million increase. Increased winter visitation from new visitors to the park under existing regulations could substantially offset estimated losses and employment reductions from current visitors.

Risks:

If the rulemaking were not to proceed, the gateway communities surrounding Yellowstone and Grand Teton National

Parks would experience a decrease in snowmobile use of 50 percent beginning this winter use season. Allowing the existing regulations to become effective would cause adverse economic impacts on the local communities and potentially to the surrounding three-State area.

Timetable:

Action	Date	FR Cite
NPRM	03/29/02	67 FR 15145
Final Action	11/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1024–AD09

DOI—Minerals Management Service (MMS)

PROPOSED RULE STAGE

76. ● RELIEF OR REDUCTION IN ROYALTY RATES — DEEP GAS PROVISIONS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

43 USC 1331 et seq

CFR Citation:

30 CFR 203

Legal Deadline:

None

Abstract:

Declines in outer continental shelf production from existing fields need to be offset by new sources to keep up with growing demand. Very little of the deep gas potential in shallow water areas of the Gulf of Mexico has yet been explored. Extensive infrastructure already exists in shallow water, unlike in deep water, so new production could reach market quickly. Because the most prospective tracts in shallow water are already under lease, most of the deep gas potential in shallow water may already have been acquired. This rule proposes temporary incentives in the form of royalty suspension volumes for deep wells (at least 15,000 feet below significant energy action level) on existing leases that explore for or produce gas.

Statement of Need:

Very little of the deep gas potential in shallow water areas of the Gulf of Mexico has yet been explored. Extensive infrastructure already exists in shallow water, unlike in deep water, so new production could reach market quickly. Because the most productive

tracts in shallow water are already under lease, most of the deep gas potential in shallow water may already have been acquired. This rule would accelerate exploration and production of deep gas by providing temporary incentives in the form of royalty suspension volumes for deep wells on existing leases that explore for or produce gas.

Summary of Legal Basis:

The OCS Lands Act is the basis for our regulations on suspending or lowering royalties on ''producing'' OCS leases. The Deep Water Royalty Relief Act, which amended the OCS Lands Act, is the basis for regulations to reduce or eliminate royalty on ''non-producing'' leases in the Gulf of Mexico west of 87 degrees, 30 minutes West longitude. It gives the Secretary of the Interior this authority to (1) promote development or increased production on producing and non-producing leases, or (2) encourage production of marginal resources on producing and non-producing leases.

Alternatives:

There are two alternatives — providing incentives only through the lease sale process, or through an application process. Reserving the deep gas incentive only for new leases issued in future sales

will not encourage exploration and production of much of the deep gas potential that underlies existing leases. Many of the best blocks have not been through a sale in decades. Also, new leases would be less able to use the existing infrastructure than existing leases so additional gas production would be delayed. Granting royalty relief on a case-by-case basis to existing leases would better protect against unnecessary royalty relief but is unlikely to encourage much additional production. The unavoidable complexity and delays in a system like we use in the discretionary deep water royalty relief program would discourage many lessees and delay the desired activity by those that would apply.

Anticipated Cost and Benefits:

Costs of this program to the federal government are the foregone royalties associated with drilling and production of deep gas that would have occurred even if no royalty suspension incentives were offered. We estimate that recipients of deep gas royalty relief will earn an average of 350 Bcf of gas royalty relief each year from activity that would have taken place without the program.

This rule's royalty benefits derive from the extra gas production (i.e., gas produced in excess of the royalty suspension volumes) from discoveries induced by the program incentives and resulting drilling. We estimate this benefit to be, on average, 370 Bcf of gas each year, yielding a net annual royalty benefit of 20 Bcf.

The additional gas production resulting from this rule also offers an important timing benefit. We do not expect significant gas production from deep water for another 10-15 years. We estimate that this rule will result in twice as many deep wells drilled each year of the program producing 1 to 2 Tcf more gas production in shallow water. The additional gas volumes will help offset declines in other OCS gas production until deep water gas comes on stream, thereby moderating gas prices and reducing the need for gas imports and consumption of dirtier fuels.

Risks:

The risk of not offering royalty relief provided in this rulemaking

action is that some deep gas resources in shallow water will not be

developed, at least not during a period when growing demand and declines in traditional sources for natural gas will lead to volatile prices.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
NPRM Comment Period End	01/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1010–AD01

DOI—MMS

FINAL RULE STAGE

77. • 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 1001 et seq; 30 USC 1701 et seq; 30 USC 351 et seq; 30 USC 181 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	
Supplementary Proposed Rule	01/05/00	65 FR 10436
ANPRM Comment Period End	03/19/00	
NPRM Comment Period Extended	03/20/00	
Final Action	10/00/03	
Final Action Effective	01/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Tribal

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Related RIN: Previously reported as 1010-AC24

RIN: 1010–AD00

BILLING CODE 4310–RK–S

DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The first and overriding priority of the Department of Justice is to prevent, detect, disrupt, and dismantle terrorism while preserving constitutional liberties. To fulfill this mission, the Department is devoting all the resources necessary and utilizing all legal authorities to eliminate terrorist networks, to prevent terrorist attacks, and to bring to justice those who kill Americans in the name of murderous ideologies. It is engaged in an aggressive arrest and detention campaign of lawbreakers with a single objective: To get terrorists off the street before they can harm more Americans. In addition to using investigative, prosecutorial, and other law enforcement activities, the Department is also using the regulatory process to enhance its ability to prevent future terrorist acts and safeguard our borders while ensuring that America remains a place of welcome to foreigners who come here to visit, work, or live peacefully.

Accordingly, the Department has issued immigration regulations: (1) to register and more closely monitor certain nonimmigrants from designated countries; reinvent the processes for monitoring the admission and status of foreign students; (2) to provide for a uniform policy on the safeguarding of information relating to INS detainees; and (3) to establish greater control over the visitor visa process. In addition, the Department has also issued regulations to prevent dissemination by selected inmates of information that could endanger the national security and regulations authorizing immigration judges to issue protective orders and seal records relating to law enforcement or national security information. (These and other completed and ongoing antiterrorism regulatory actions are described in a separate section of this Statement below.)

Immigration

Although the Congress is currently considering legislation to restructure the immigration agencies, this Statement presents the Department's past and current efforts to improve the enforcement and administration of the immigration laws. The Department will continue to advance the President's antiterrorism objectives with regulatory initiatives that support law enforcement activities and increase border security along with its immigration mission responsibilities. The INS administers regulations governing the admission of legal immigrants and temporary visitors, apprehension and deportation of illegal aliens, alien employment authorization and verification, asylum, and naturalization.

The Department's top regulatory initiatives are described below, but many of the Agency's key initiatives occur either outside of the rulemaking process or supplement it. Although this regulatory agenda focuses on strengthening homeland security, the Department is pursuing an aggressive agenda, through both regulations and systems development, to enhance the delivery of immigration services.

Strengthening Immigration Enforcement

During the next 12 months, the Department will continue to implement rulemakings focused on supporting the President's homeland defense initiatives. In addition to regulations published as a result of the events of September 11, 2001, the Agency is pursuing rulemaking to implement three major components of the President's directive on Homeland Security: (1) control and tracking of foreign students and exchange visitors; (2) an improved entry-exit system that will track the arrivals and departures of foreign visitors who come to the United States. The Attorney General has also mandated that one aspect of this system will include additional registration requirements for certain nonimmigrants from countries of concern to the United States for national security reasons; and (3) a surrender requirement for aliens removed from the United States.

- Tracking Foreign Students and Exchange Visitors

In response to the first component of the President's directive, the Service is implementing section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA). Section 641 requires the Service to collect current information, on an ongoing basis, from schools and exchange programs relating to nonimmigrant foreign students and exchange visitors during the course of their stay in the United States. In addition, the USA PATRIOT Act, Public Law 107-56, amended section 641 to require full implementation and expansion of Student and Exchange Visitor Information System (SEVIS) prior to January 1, 2003. Furthermore, the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107-173) (Border Security Act) adds to and clarifies the collection of student and school information and specifically requires an educational institution to report any failure of an alien to enroll not later than 30 days after registration deadline. The Service is promulgating several regulations focused on addressing control issues for over 500,000 international students attending colleges and universities in the United States and a similar number of exchange visitors entering the United States through the Department of State's (DOS) ''J'' visa program.

The Service has embarked on a series of regulatory and nonregulatory initiatives to improve the tracking of foreign students. A key component of this initiative is the creation of SEVIS, an Internet-based system through which schools must submit current information on nonimmigrant students (F and M visa) and exchange visitors (J visa) and their dependents (F-2, M-2, and J-2). SEVIS enables schools and program sponsors to transmit electronic information and event notifications, via the Internet, to the Service and DOS throughout a student's or exchange visitor's stay in the United States. SEVIS will be informed of status events for international students and exchange visitors including, but not limited to, entry/exit data, changes of address, program extensions, employment notifications, and changes in program of study. SEVIS will also provide system alerts, event notifications, and reports to the end-user schools and programs, as well as for Service and DOS offices. SEVIS will be mandatory after January 30, 2003, for all institutions wishing to bring F/M/J aliens into the United States.

Also, on December 21, 1999, the Service published a proposed rule at 64 FR 71323 establishing a fee and a fee collection system allowing the Service to collect the fee authorized by section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA). The interim final rule currently under expedited development differs from the earlier proposed rule in several ways. First, Public Law 106-396 amended section 641 of IIRIRA to provide that the Attorney General, rather than schools, is to collect the fee. Second, Congress appropriated startup funds for the program after the publication of the proposed rule. Accordingly, the forthcoming final rule will reflect a lower fee, based on a new fee study, which does not recapture those startup funds already appropriated. Finally, the Service will build into the final rule additional flexibility regarding the means and methods of payment. The interim final rule will make compliance easier than what was initially proposed.

In addition, INS published on August 27, 2002, at 67 FR 54941, an interim rule governing F and M nonimmigrants. This rule clarifies that nonimmigrant aliens who reside outside the U.S. and regularly commute across a land border to study may do so on a part-time basis within the F or M nonimmigrant category. These changes are being made to facilitate and legitimate part-time study along border communities while ensuring that all applicable requirements and safeguards are met. (INS No. 2220-02, RIN 1115-AG75)

- Entry-Exit System and Special Registration Requirements for Certain Nonimmigrants

Congress has mandated that, by 2005, the Department must complete deployment of an entry-exit system that integrates the available alien arrival and departure data that exists in the Department and DOS systems. This system also must include the arrival and departure data for any visitor who transits through the air and seaports and is admitted under the Visa Waiver Program. In addition, recent legislation requires that visas and other entry travel documents issued on or after October 26, 2004, be machine readable and contain biometrics and that INS deploy machines to read those documents at all ports-of-entry by that date. The entry-exit system must capture arrival and departure data from these biometric documents. The Administration is also planning to make the entry-exit system as comprehensive as possible to include arrival and departure information that is not currently recorded by existing systems.

As part of this initiative, the Service will promulgate regulations to implement the provisions of section 217(h) of the Immigration and Nationality Act (INA) concerning electronic passenger manifest requirements for carriers who transport Visa Waiver Program applicants, as well as the provisions of section 402 of the Border Security Act that requires submission of arrival and departure manifests electronically in advance of a commercial aircraft or vessel's arrival in or departure from the United States. The rule also proposes to require manifest data on certain passengers, crew, and voyages previously exempt from this requirement.

In addition, the Service and DOS plan to promulgate complementary regulations under section 212 of the INA that will remove the current visa and passport waivers for permanent residents of Canada and Bermuda who are citizens of approximately 55 other countries. Although these regulations are being promulgated for national security and related reasons, and not strictly for purposes of the entry-exit system, the system will be improved as a result of the arrival/departure data that will now be available on these previously document-exempt visitors to the U.S.

- Surrender Requirement for Aliens Ordered Removed from the U.S.

In an effort to streamline the removal process, the Service will promulgate a rule that requires aliens who become subject to a final order of removal to surrender themselves to the Service 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 Service 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.

Concurrently, the Service has launched an initiative to address the fact that hundreds of thousands of aliens who already have final removal orders have not departed the United States. Such aliens, termed absconders, are the subject of the Service's sub-regulatory Absconder Apprehension Initiative (AAI), which is designed to enhance the ability of the Service's limited workforce to apprehend absconders. In the AAI, the Service has begun reviewing the files of absconders to enter appropriate records into the National Crime Information Center (NCIC) data base so that they may be apprehended when encountered by Federal, State, or local law enforcement officials. This effort supplements efforts being undertaken by the Service to use recent resource enhancements to apprehend those absconders whom the Service can locate.

Strengthening Immigration Services

In addition to the initiatives to strengthen homeland security as set forth above, the Service plans to re-engineer its regulations that govern nonimmigrant classes and admission requirements. These regulations are codified in 8 CFR 214 and have grown in size and complexity during the past 15 years as Congress has added at least 10 new nonimmigrant classes and expanded the requirements and restrictions on many of the existing classes. The regulatory outline for part 214 has become extremely complicated. This initiative provides for a comprehensive reorganization, streamlining, and rewriting of 8 CFR part 214. There are a number of other planned regulatory actions focused on improving benefit processing and adjudication services that are delineated in DOJ's unified agenda. For example, the following key regulatory initiatives are being pursued.

- Proposed Rule, INS No. 2134-01, RIN 1115-AG21, Removal and Adjustment Procedures for Victims of Trafficking and Certain Criminal Activities. This rule proposes that certain victims of severe forms of trafficking and victims of certain crimes who have been granted T or U nonimmigrant status may apply for adjustment to permanent resident status.
- Proposed Rule, INS No. 2170-01, RIN 1115-AG39, New Classification for Victims of Certain Criminal Activity; Eligibility for the U Nonimmigrant Status. This proposed action establishes the application requirements for a new nonimmigrant status ''U.'' The U classification is for non-United States citizens/Lawful Permanent Residents who are victims of certain crimes and who cooperate with an investigation or prosecution of such crimes. There is a limit of 10,000 principals per year.
- Proposed Rule, INS No. 2228-02, RIN 1115-AG78, Petitions for Aliens to Perform Temporary Nonagricultural Services of Labor (H-2B). This action proposes to make significant changes to the regulations affecting H-2B nonimmigrant classification. The proposed changes are aimed to increase the usefulness of the H-2B nonimmigrant classification program for U.S. employers by eliminating certain regulatory barriers, by adding protections for foreign workers, and by increasing the Government efficiency and coordination.
- Proposed Rule, INS No. 2080-00, RIN 1115-AE73, Certificates for Certain Health Care Workers. This rule proposes to implement the foreign health care worker certification requirements by providing that all

immigrants and nonimmigrants, including nonimmigrants changing status, who are coming to the U.S. for the primary purpose of performing labor in a health care occupation, obtain health care worker certification and present this certificate to a consular officer and/or the INS.

Regulations Published or Being Developed Because of September 11, 2001

INS

- Final Rule, Registration and Monitoring of Certain Nonimmigrants (INS 2216-02, RIN 1115-AG70). This regulation broadened the special registration requirements for nonimmigrant aliens from certain designated countries, and other nonimmigrant aliens whose presence in the United States requires closer monitoring, to require that they provide specific information at regular intervals to ensure their compliance with the terms of their visas and admission and to ensure that they depart the United States at the end of their authorized stay. (67 FR 52584, 8-12-02)
- Interim Rule, Custody Procedures (INS 2171-01, RIN 1115-AG40). This rule changes the period of time after an alien's arrest within which the INS must make a determination whether the alien will be continued in custody or released on bond or recognizance and whether to issue a notice to appear and warrant of arrest. This rule provides that unless voluntary departure has been granted, the INS must make such determinations within 48 hours of arrest, except in the event of emergency or other extraordinary circumstance in which case the INS must make such determinations within an additional reasonable period of time. (66 FR 48334, 9-20-01)
- Interim Rule, Release of Information Regarding INS Detainees in Non-Federal Facilities (INS No. 2203-02, RIN 1115-AG67). This rule governs disclosure by any State or local government entity or by any privately operated facility of the name or other information relating to any immigration detainee being housed or otherwise maintained or provided service on behalf of the INS. This rule establishes a uniform policy on the public release of information on INS detainees. (67 FR 19508, 4-22-02)
- Proposed Rule, Limiting the Period of Admission for B Nonimmigrant Aliens (INS No. 2176-01, RIN 1115-AG43). This proposed action eliminates the minimum admission of B-2 visitors for pleasure, reducing the maximum admission period of B-1 and B-2 visitors from 1 year to 6 months. It will establish greater control over a B visitor's ability to extend status or to change status to that of nonimmigrant student. (67 FR 18605, 4-12-02)
- Interim Rule, Requiring Change of Status from B to F-1 or M-1 Nonimmigrant Prior to Pursuing a Course of Study (INS No. 2195-01, RIN 1115-AG60). This rule eliminates the current provisions allowing a B-1 or B-2 nonimmigrant visitor for business or pleasure to begin attending school without first obtaining approval of a change of nonimmigrant status request from the INS. This change ensures that no B nonimmigrant is allowed to enroll in school until the alien has applied for, and the INS has approved, a change of nonimmigrant status to that of F-1 or M-1 nonimmigrant student. (67 FR 18061, 4-12-02)
- Proposed Rule, Limiting the Number of Transit Without Visa (TWOV) Stops in the United States to One (INS No. 2194-02, RIN 1115-AG59). This proposed action limits the number of transit stops in the United States for those passengers participating in the TWOV program from two stops to one stopover. Current regulations allow an alien to be transported in transit through the United States to another foreign country without first obtaining a nonimmigrant visa from the DOS overseas, provided the carrier and the INS have entered into an immediate and continuous transit agreement pursuant to section 233(c) of the INA.
- Interim Rule, Additions to the List of Countries whose Citizens or Nationals are Ineligible for TWOV Privileges to the United States under the TWOV Program (INS No. 2199-02, RIN 1115-AG16). This rule will rescind standing waivers for certain countries because the Attorney General acting jointly with DOS has determined that it is in the best interests of the United States that nationals of these countries be required to obtain a visa before traveling to the United States.

Bureau of Prisons

- RIN 1120-AB08 ''National Security; Prevention of Acts of Violence and Terrorism'' (BOP 1116). This rule imposed special administrative measures with respect to specified inmates, where it has been determined to be necessary to prevent the dissemination either of classified information that could endanger the national security or of other information that could lead to acts of violence and terrorism.

Civil Division

- RIN 1105-AA79 ''September 11th Victim Compensation Fund of 2001'' (CIV 104). Shortly after the attacks the President signed the ''September 11th Victim Compensation Fund of 2001'' (the ''Fund'') into law. This Act authorized compensation to any individual (or the personal representative of a deceased individual) who was physically injured or killed as a result of the terrorist-related aircraft crashes on that day. The Department implemented this Act by an Interim rule (published on December 21, 2001, as required by statute), and then provided clarifications and other changes in a final rule (published on March 13, 2002.)

Executive Office for Immigration Review

- RIN 1115-AG41 ''Review of Custody Determinations.'' This rule amended EOIR regulations to expand an existing regulatory provision for a temporary automatic stay of an immigration judge's decision to order an alien's release in any case in which a district director has ordered that the alien be held without bond or has set a bond of $10,000 or more. The detention of an alien during the pendency of proceedings ensures removal by preventing the alien from fleeing and protects the public from potential harm.
- RIN 1125-AA38 ''Protective Orders in Immigration Administrative Proceedings'' (EOIR 133). In this post-September 11, 2001, era, the highest priority of the Department is to prevent, detect, disrupt, and dismantle terrorism while preserving constitutional liberties. Disclosures of sensitive information could allow terrorists to discern patterns in an investigation, enabling them to evade detection in the future. Accordingly, the Department published the rule ''Protective Orders in Immigration Administrative Proceedings'' authorizing immigration judges to issue protective orders and seal records relating to law enforcement or national security information.

Foreign Terrorist Tracking Task Force

- RIN 1105-AA80 ''Screening of Aliens and Other Designated Individuals Seeking Flight Training'' (OAG 104). Also, after September 11th, Congress

enacted the ''Aviation and Transportation Security Act'' (Pub. L. 107-71) to enhance air safety by prohibiting certain flight schools from training aliens without the prior notification of the Attorney General. Relevant components of the Department (including FBI, INS, and the Foreign Terrorist Tracking Task Force) consulted with the FAA and representatives of the aviation industry to coordinate the Department's implementation of this notification program. Two temporary Federal Register Notices were published (on January 16, 2002, and on February 8, 2002) to provide relief for flight schools who were prohibited from furnishing recurrent training to aliens who were pilots in order to relieve the financial burden imposed by the Act imposed on the aviation industry. The Department published a proposed rule on June 14, 2002, to implement notification procedures for all prospective alien pilots.

The Department of Justice's regulatory priorities focus in particular on four regulatory initiatives in the areas of immigration and civil rights. However, in addition to these four specific initiatives, 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 antiterrorism and law enforcement priorities.

Drug Enforcement Administration

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. Nearly one-third of the organizations on the State Department's list of Foreign Terrorist Organizations appear also on the Department's list of targeted United States drug suppliers. 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 and to the requirements of the Comprehensive Methamphetamine Control Act of 1996 (MCA) and the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), which regulate certain drug products that are being diverted for the illicit production of methamphetamine. DEA has determined that proceeds from an illegal drug operation in the United States (that was diverting regulated drug products for the production of methamphetamine in violation of the diversion control requirements and the MCA and MAPA) have been funneled to Middle East terrorist groups like Hezbollah.

Civil Rights

The Department and its Civil Rights Division are deeply committed to the rigorous enforcement of this Nation's civil rights laws. In keeping with that commitment, although not a part of the regulatory process, since September 11, 2001, the Civil Rights Division has been and remains committed to the investigation and prosecution of incidents involving violence or threats of violence against people of Middle-Eastern origin, including Arab Americans, Muslim Americans, Sikh Americans, and South-Asian Americans. The Division is also actively involved in outreach efforts to individuals and organizations to provide information about Government services to vulnerable communities.

Additionally, the Division will review and update its regulations implementing the Americans with Disabilities Act of 1990 (ADA), as well as issue a rule pertaining to the Department's authority to review police departments for a pattern or practice of unlawful conduct under the Violent Crime Control and Law Enforcement Act of 1994.

The Department is planning to make revisions in 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 proposed by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) 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 has been engaged in a multiyear effort to revise and amend its accessibility guidelines. The goals of this project have been: 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 has proposed and/or adopted 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 the changes previously proposed by the Access Board.

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 two parts. The first part will be a proposed rule adopting the Access Board's revised and amended guidelines as enforceable standards, which 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 second part will be an advanced notice of proposed rulemaking seeking public comment on two discreet sets of issues: (i) the Department's interpretation of the new ADAAG and (ii) the section 610 review of the ADA regulations under SBREFA.

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.

Pursuant to the Violent Crime Control and Law Enforcement Act of 1994, 42 U.S.C. section 14141 (section 14141), the Attorney General is authorized to file lawsuits seeking court orders to reform police departments engaging in a pattern or practice of conduct that deprives persons of rights, privileges, or immunities secured by the Constitution or laws of the United States. To date, the Department of Justice has conducted reviews of police departments pursuant to section 14141 using informal procedures. The Department plans to issue a rule to formalize the procedures by which the Department reviews police departments for a pattern or practice of unlawful conduct.

DOJ—Civil Rights Division (CRT)

PROPOSED RULE STAGE

78. 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 is currently in the process of revising ADAAG, and it published a Notice of Proposed Rulemaking (NPRM) on November 16, 1999. 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 the revisions proposed by the Access Board 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 adoption of revised ADAAG will also serve to address changes to the ADA Standards previously proposed in RIN 1190-AA26 and RIN 1190-AA38, which have been withdrawn. These changes will include technical specifications for facilities designed for use by children and accessibility standards for State and local government facilities that have 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 first stage 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 ADAAG as the ADA Standards for Accessible Design and 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.

The Access Board has prepared a regulatory assessment, which includes a cost impact analysis for certain accessibility elements and a discussion of the regulatory alternatives considered. A summary of the Board's regulatory assessment is published at

64 FR 62282 (November 16, 1999). That assessment will also apply to the Department's proposed rule.

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
NPRM	01/00/03	
NPRM Comment Period End	03/00/03	

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

79. 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 ADA (section 204(c)) requires the Department's standards to be consistent with the Access Board's guidelines. Therefore, the Department will publish a Notice of Proposed Rulemaking (NPRM) proposing to adopt the revisions proposed by the Access Board. 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 timetable set forth below refers to the notice of proposed rulemaking that the Department will issue as the first stage 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, this notice will propose to eliminate the Uniform Federal Accessibility Standards (UFAS) as an alternative to the ADA Standards for Accessible Design and to adopt revised ADAAG as the ADA Standards.

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.

The Access Board has prepared a regulatory assessment, which includes a cost impact analysis for certain accessibility elements and a discussion of the regulatory alternatives considered. A summary of the Board's regulatory assessment is published at 64 FR 62282 (November 16, 1999). That assessment will also apply to the Department's proposed rule.

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
NPRM	01/00/03	
NPRM Comment Period End	03/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

State, Local

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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RIN: 1190–AA46

DOJ—Immigration and Naturalization Service (INS)

PROPOSED RULE STAGE

80. CARRIER ARRIVAL AND DEPARTURE ELECTRONIC MANIFEST REQUIREMENTS

Priority:

Other Significant

Legal Authority:

PL 107-173; PL 106-96; 8 USC 1101; 8 USC 1103; 8 USC 1182; 8 USC 1221; 8 USC 1228; 8 USC 1229

CFR Citation:

8 CFR 231

Legal Deadline:

Final, Statutory, January 1, 2003.

Public Law 107-173, the Visa Waiver Permanent Program Act (VWPPA), sets a mandatory deadline of October 1, 2002.

Abstract:

There are four principal laws that require the Attorney General to develop an automated and integrated entry/exit data system for aliens:

1. The Immigration and Naturalization Service Data Management Improvement Act (DMIA), Public Law 106-21;

2. The Visa Waiver Permanent Program Act (VWPPA), Public Law 106-396;

3. The USA PATRIOT Act, Public Law 107-56; and

4. The Enhanced Border Security and Visa Entry Reform Act (Border Security Act), Public Law 107-173.

Implementation of the relevant provisions in these four laws together will result in the Entry/Exit System. One of the basic legislative mandates is that the system integrate the available alien arrival and departure data that exist in any Department of Justice (DOJ) or Department of State (DOS) data base or system. This necessarily must include the systems that incorporate carrier manifest data on passengers and crew members who are entering or leaving the U.S. via air or sea. Section 231 of the Immigration and Nationality Act (INA) and 8 CFR part 231 state the requirements for carrier manifests.

In section 402 of the Border Security Act, Congress amended the manifest requirements in INA, section 231. The Border Security Act requires the submission of arrival and departure manifests electronically in advance of a commercial aircraft or vessel's arrival in or departure from the United States not later than January 1, 2003. Promulgation of regulations to implement this law will provide the Service with advance notification of information necessary for the identification of passengers and crewmembers on commercial carriers. The contents of the electronic arrival and departure manifest include: (1) complete name; (2) date of birth; (3) citizenship; (4) sex; (5) passport number and country of issuance; (6) country of residence; (7) United States visa number, date, and place of issuance, where applicable; (8) alien registration; (9) United States address while in the United States; and (10) such other information the Attorney General, in consultation with the Secretary of State and the Secretary of Treasury determines as being necessary for the identification of the persons transported and for the enforcement of the immigration laws and to protect safety and national security.

In October 2000, Congress also amended section 217 of the INA to make the Visa Waiver Pilot a permanent program. The VWPPA also added a specific requirement for a ''fully automated entry and exit control system'' covering all aliens who enter the United States under the VWP at airports and seaports. The requirements for this system are both narrower and broader, in different respects, than the DMIA automated system requirements. The VWP entry/exit system will be incorporated into the broader Entry/Exit System mandated by DMIA. In addition, the VWPPA states that no alien arriving by air or sea may be granted a visa waiver under INA, section 217, on or after October 1, 2002, unless the carrier is submitting passenger information electronically to the VWP entry/exit system, as required by the Attorney General. The Service is separately promulgating regulations to amend 8 CFR part 217 to implement the electronic manifest requirements for VWP purposes.

Statement of Need:

The INS is pursuing rulemaking to aid in implementing a major component of the President's directive on Homeland Security: An improved entry/exit system that will track the arrival and departures of foreign visitors who come to the United States. The carrier electronic manifest regulations are necessary to implement the statutory requirements of the Border Security Act and VWPPA. In addition, collection of this electronic arrival/departure manifest information will be incorporated into the Entry/Exit system that is mandated in DMIA, the USA PATRIOT Act, and the Border Security Act. Failure to fully implement these regulations could result in adverse consequences to national security because INS would not have advance notification of the arrival and departure of foreign visitors and therefore would be unable to check their names against relevant law enforcement data bases. The historical record reveals that Congress has a strong interest in documenting the arrival and departure of aliens, and recent legislation demonstrates that relief from this requirement is unlikely. Therefore, the Immigration and Naturalization Service must immediately begin development of an entry/exit system, which includes the electronic manifest information and that meets the will of Congress.

Summary of Legal Basis:

See Statement of Need. These actions are required by the statute as explained in the Statement of Need.

Alternatives:

Public Law 107-173 statutorily amends section 231 of the Immigration and Nationality Act and requires that commercial carriers submit electronic arrival and departure manifests to the INS. The only means of implementing this change is through rulemaking.

Anticipated Cost and Benefits:

The enactment of section 402 of Public Law 107-173 reflects Congress' desire to ensure that commercial air and sea carriers submit to immigration officials passenger and crew information in such timeframes and in such a format so as to maximize the Government's efforts to (1) timely identify persons being transported to and from the United States, (2) enforce the immigration laws, and (3) protect public safety and national security. In addition to strengthening homeland security, the INS has focused on reengineering its regulations that govern nonimmigrant and admission requirements. The INS will continue to advance the President's objectives with regulatory initiatives that are focused on minimizing regulatory burdens on the public and increasing the efficiency of the Agency operations. The President's FY 2003 budget has allocated $362 million for the development of the entry/exit system. The INS is in the process of developing a project plan and estimated costs and benefits of different alternatives for utilizing this funding.

The INS is in the process of reengineering its inspections process with automated inspections systems for low-risk travelers. Commercial air carriers operating passenger flights have been required to electronically submit many of the data elements to the U. S. Customs Service in advance of arrival since December 21, 2001, and therefore, the INS plans to build upon these existing concepts to benefit the business community and the public.

Risks:

This regulatory action is critical for complete and clear implementation of the provisions of the recent legislation discussed above. The regulation will clarify the confusion that exists in the immigration and business community as to the scope and applicability of many of these provisions and will thus prevent the public from taking actions, which may unintentionally trigger adverse immigration consequences. Delay in this rulemaking or failure to promulgate will perpetuate confusion among the public and lead to members of the public unwittingly incurring adverse immigration consequences. Failure to implement these regulations in a timely manner may jeopardize national security and increase the costs to implement new alternative inspections methods. Finally, and not insignificantly, failure to publish the amended section 231 regulations will result in INS and DOJ not being in compliance with the laws as passed by Congress. As with any major program, implementation of the new electronic manifest requirements is not without some challenges.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
NPRM Comment Period End	01/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

INS No. 2182-01

Sectors Affected:

481 Air Transportation

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Related RIN: Related To 1115-AG73, Related To 1115-AG68

RIN: 1115–AG57

DOJ—INS

FINAL RULE STAGE

81. REVISION OF THE REGULATIONS CONCERNING F, J, AND M NONIMMIGRANT CLASSIFICATIONS

Priority:

Other Significant

Legal Authority:

5 USC 552, 552(a); 8 USC 1101, 1103, 1201, 1252 note, 1252(b), 1304, 1356; 31 USC 9701; EO 12356; 8 USC part 2; ...

CFR Citation:

8 CFR 103; 8 CFR 214

Legal Deadline:

None

Abstract:

This rule lays the foundation for the implementation of the Student and Exchange Visitor Information System (SEVIS), an Internet-based system that provides tracking and monitoring functionality, with access to accurate and current information on nonimmigrant students and exchange visitors. There are three principal laws that require the Attorney General to develop an automated system to track foreign students and exchange visitors:

1. Section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA);

2. Section 416 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT ACT); and

3. Section 501 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act).

IIRIRA requires the Service to collect current information, on an ongoing basis, from schools and exchange programs relating to nonimmigrant foreign students and exchange visitors during their course of stay in the United States. In addition, the USA PATRIOT Act amended section 641 of IIRIRA to require full implementation and expansion of SEVIS prior to January 1, 2003. Furthermore, the Border Security Act clarifies the collection of information required by SEVIS and adds the specific requirement that educational institutions report any failure of an alien to enroll not later than 30 days after the registration deadline of the institution. Finally, Presidential Directive No. 2 and the findings released by the Office of the Inspector General have also had a significant impact on the direction of the student program at the Service.

While this rule implements SEVIS and its requirements, SEVIS is only one component of the Service's Student and Exchange Visitor Program (SEVP). Further rulemakings are a necessary part of the overall reengineering process and success of SEVP, which encompasses the review and registration of all schools and exchange programs in SEVIS prior to January 30, 2003, subsequent recertifications every 2 years, and the student fee regulation mandated by Congress in IIRIRA to pay for the operation and maintenance of SEVIS.

As part of this ongoing program, the Service published an interim rule at 67 FR 44344 (July 1, 2002) allowing schools that met certain criteria to preliminarily enroll in SEVIS beginning on July 1, 2002. In early fall, the Service will publish another rule that will require all schools to apply for certification in SEVIS in order to be able to begin accepting or continue accepting foreign students after the SEVIS mandatory compliance date. Additionally, the Service will publish a rule describing the recertification, withdrawal, and denial process for SEVIS. Finally, the Service will reintroduce a rule for the collection of the fee for all F, J, and M nonimmigrants.

Statement of Need:

This regulation is necessary to implement the statutory requirements of IIRIRA, the USA PATRIOT ACT, and the Border Security Act. Failure to implement will result in adverse consequences to national security. The historical record reveals that Congress has a strong interest in monitoring foreign students and exchange visitors for the duration of their stay in the United States.

Additionally, the climate of the current administration as evidenced by Presidential Directive No. 2 and the findings of the Office of the Inspector General demonstrate that the student program is a high priority. Therefore, the Service must steadfastly continue to improve upon the SEVP program, implement the process to monitor foreign students and exchange visitors, as well as to complete the process by which all schools and programs use SEVIS prior to the acceptance of any foreign students or exchange visitors.

Summary of Legal Basis:

See Abstract and Statement of Need. These actions are required by statute as explained in the Abstract and the Statement of Need.

Alternatives:

None.

Anticipated Cost and Benefits:

This regulation implements the new processes and requirements for the electronic exchange and update of information. In 1994, the Service began conducting a comprehensive review and analysis of the foreign student program, both upon admission to the United States and on a continuing basis. Based on these findings, the Service established a plan to reengineer the business process.

Currently, updates to nonimmigrant student and exchange visitor information (e.g., change of address, extensions, curricular practical training) are submitted by the Service or the educational institution or exchange program to the Service via a paper copy. A significant amount of time lapses as the paperwork is routed and data entered by a contractor.

The utilization of SEVIS gives the schools and program sponsors the ability to make real-time updates without routing paperwork to a contractor. The SEVIS process reduces the risk of paperwork being lost or sent to an incorrect address and eliminates the risk of inaccurate information being entered by the data entry contractor. The elimination of the contractor will result in a monetary savings as the current data entry costs associated with the existing process average $800,000 per year. Finally, the information is stored electronically in SEVIS, thus reducing the need to store paper copies during and after routing and data entry, by both the Service and the educational institutions and sponsors.

Risks:

This regulatory action is critical for complete and clear implementation of the provisions of the legislation as well as the overall student program. The regulation will clarify for designated school officials and others in the education community the scope, applicability, and process for the exchange of student and school information and will prevent actions which may unintentionally trigger adverse immigration consequences.

Delay in this rulemaking or failure to promulgate will cause the Service to miss the dates mandated by Congress.

Timetable:

Action	Date	FR Cite
NPRM (INS 2185-02)	05/16/02	67 FR 34862
NPRM Comment Period End	06/16/02	
Interim Final Rule (INS 2211-02)	07/01/02	67 FR 44343
Interim Final Rule Comment Period End	07/31/02	
Final Action (INS 2185-02)	11/00/02	
Final Action (INS 2211-02)	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

INS No. 2185-02 (See also RIN 1115-AF56, INS No. 1991-99, which amends Service regulations to establish a fee for F, J, and M nonimmigrants. See also RIN 1115-AG71 ''Requiring Certification of Service Approved Schools for Enrollment in SEVIS.)

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BILLING CODE 4410–BP–S

DEPARTMENT OF LABOR (DOL)

2002 Regulatory Plan

Executive Summary: Making Worker Protections Work

A new culture of responsibility is being built at the Department of Labor (DOL) whereby its employees will be responsible for helping the regulated community understand DOL's exhaustive list of rules and regulations. The Department understands that before any business or other regulated entity can comply with DOL's rules, they must be understandable and communicated clearly.

Since its creation in 1913, the Department of Labor has been guided by the idea that employers must be held responsible for the protection of their employees — protection of their wages, pensions, safety and health. In turn, the Department of Labor recognizes that it is responsible for helping employers and others understand and comply with their responsibilities under the Department's many laws and regulations.

The Department has always known that the vast majority of employers work hard to keep their employees and workplaces safe and secure and that employers who knowingly neglect or abuse their employees are a very small minority. DOL must provide this vast majority who want to comply with the knowledge and tools they need to carry out their legal responsibilities and obligations. To ensure DOL does this, the Secretary has made protecting workers through compliance assistance 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 to ensure that worker protections work.

As an essential part of this initiative, the Department of Labor is making the information it provides, including new or revised regulations, clearer, more helpful and more accessible. DOL has developed compliance materials in plain language, as well as online programs that answer questions and direct users to information that is easy to understand. DOL also is using its Web site, e-mail, toll-free numbers (e.g., the Call Center), and partnerships to convey this information when and where it is needed. And employers know that requesting compliance assistance materials through any of these means will not lead to referrals for investigation.

DOL's goal is to touch every workplace in a positive way, through sharing information and offering a helping hand. DOL will emphasize prevention, relying on the use of common-sense standards of safety and fairness to prevent workers from being harmed physically or economically. Education and encouragement of employers will help 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.

DOL has responsibilities beyond worker protection. It recognizes that the emerging 21st century economy presents challenges to workers at all skill levels and in all walks of life. Those who have been laid off from jobs because their companies could not adapt to technological changes or foreign competition, or those workers who are disabled, who did not get a full education, or who made a wrong turn at some point in their lives, cannot be left behind. Some of these workers, especially young workers, need training in basic skills and help in becoming acclimated to working life. Other workers need assistance in learning new skills or in obtaining advanced schooling.

At the same time, high-technology industries are creating job opportunities unheard of even a decade ago. DOL must help employers and workers bridge the gap between the requirements of those jobs and the skills of the workers who are needed to fill them. Workers who can keep their skills up to date throughout their careers have more productive and more rewarding economic futures.

The Secretary of Labor's Regulatory Plan for Accomplishing These Objectives

The balance between labor and management that underlies the country's labor laws is a crucial source of stability in our economy, and the need for labor and management to work together has become increasingly evident in recent years. For these reasons, any change in the regulations that implement the country's labor laws must be carefully considered, and the views of all affected parties must be taken into account.

In general, DOL will try to help employees and employers meet their needs in a cooperative fashion, with a minimum of rulemaking. However, to reflect changes in technology and business practices, to implement new laws and clarify existing rules in light of new laws and legal interpretations, and to rewrite rules in plain language, DOL needs to engage in rulemaking.

In doing so, DOL will craft proposals that are responsive to workers' needs yet understanding of employers' desire for the least burdensome regulatory alternative. These proposals will span an entire range of work environments, from traditional settings that have well-defined conditions and locations of work, to newly emerging settings that are more flexibly structured in terms of schedules and workplaces.

Similarly, the skills needed by today's workforce are more varied than at any time in our country's history, and they continue to change at a rapid rate. Changes in the financial marketplace, as well as in compensation and benefit arrangements, present both challenges and opportunities for today's workers.

The following proposals represent what DOL believes to be a balanced plan for protecting workers in their current jobs and preparing them for future employment while making it easier for the regulated community to play its part. DOL considers these proposals to be proactive, common-sense approaches to the issues most clearly needing regulatory attention.

The Department's Regulatory Priorities

DOL has identified 20 high-priority items for regulatory action. Nine of them 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 demonstrates its commitment to ensuring safer and healthier workplaces for the Nation's miners in a number of ways, but Government intervention alone cannot eliminate occupational deaths, injuries and illnesses in mining. The commitment of miners and mine operators is also needed. MSHA will continue to concentrate on improving existing health standards and addressing emerging health hazards in mining.

While levels of respirable coal dust have been significantly reduced over the years, some miners continue to develop coal workers' pneumoconiosis. MSHA intends to reopen the record for the

rulemaking on the Determination of Concentration of Respirable Coal Mine Dust (RIN 1219-AB18), and repropose Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust (RIN 1219-AB14). The former rule would permit MSHA to determine the level of mine dust on the basis of a single sample. The latter rule would help assure that operators' dust control plans are effective under typical mining conditions. These rules work in tandem to address miners' exposure to respirable coal dust.

MSHA is considering lowering the permissible exposure limit (PEL) for asbestos at metal and nonmetal and coal mines, addressing take-home contamination, and reevaluating the method used for sample analysis (RIN 1219-AB24). MSHA conducted a series of public meetings earlier this year to allow early participation in the rulemaking by interested parties. MSHA will be evaluating those comments as it prepares a notice of proposed rulemaking.

In response to litigation and a partial settlement agreement regarding its final rule on Diesel Particulate Matter, MSHA has initiated a rulemaking on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (RIN 1219-AB29). MSHA will address several provisions of the final standard, including changing the diesel particulate matter surrogate from total carbon to elemental carbon for the concentration limits, addressing the diesel particulate matter control plan, and revising requirements regarding the use of personal protective equipment and administrative controls to comply with the concentration limits.

The Occupational Safety and Health Administration administers a wide range of measures throughout the public and private sectors. OSHA is committed to establishing clear and sensible priorities, reducing occupational deaths, injuries, and illnesses, and simplifying its recordkeeping requirements.

Three of OSHA's high-priority initiatives address health standards. The first, Standards Improvement, will streamline a number of such health standards by removing language that is outdated, duplicative, unnecessary or inconsistent (RIN 1218-AB81). These changes will reduce the amount of time and effort needed to understand and comply with these standards.

The second, 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, as well as making it easier for employers to choose the appropriate respirator for a given task.

OSHA's third initiative in the area of health standards addresses worker exposure to Crystalline Silica (RIN 1218-AB70). This substance is one of the most widely found in workplaces, and data have indicated that exposure to it may cause a debilitating respiratory disease called silicosis. Exposure also has been linked to cancer. OSHA is collecting information to determine what regulatory action might be appropriate to address these occupational health concerns.

OSHA has two initiatives in the area of safety standards. The first concerns Fires in Shipyards (RIN 1218-AB51). A negotiated rulemaking committee completed its work earlier this year, and recommended regulatory actions to address this issue. Fires in shipyards claim an average of one life a year, as well as causing 110 lost-workday ''heat/burn'' injuries, and more than three times that many total injuries. This rule will provide a comprehensive approach to dealing with fires in shipyard environments to help prevent these deaths and injuries.

OSHA's second safety initiative addresses requirements for Exit Routes, formerly known as Means of Egress (RIN 1218-AB82). OSHA has rewritten these important provisions in plain language to help ensure they are properly understood and implemented.

Protection of pension and health benefits continues to be a priority of the Secretary of Labor. As a member of the President's Task Force to strengthen retirement security, the Secretary played a major role in formulating legislative proposals to give workers better information about their pension rights, increased freedom to choose where to invest their retirement savings, and expanded access to investment advice. Two of these proposals were enacted as part of the Sarbanes-Oxley Act of 2002.

Consistent with the Secretary's priorities, the Pension and Welfare Benefits Administration (PWBA), which administers the Employee Retirement Income Security Act (ERISA), will focus on implementation of the recently enacted retirement security amendments to ERISA relating to the timely notification of participants and beneficiaries of periods during which they will be unable to direct investments in their 401(k) plan (RIN 1210-AA90) and civil penalties for failures to provide these notices (RIN 1210-AA91).

PWBA's regulatory program also will focus on compliance assistance to group health plans through issuance of guidance, as well as model forms and notices. Specific initiatives include guidance for group health plans on the application of the continuation of coverage notice provisions (RIN 1210-AA60); access, portability and renewability provisions (RIN 1210-AA54); and nondiscrimination provisions of ERISA (RIN 1210-AA77).

ERISA's requirements affect an estimated 730,000 private sector employee pension benefit plans (covering approximately 99 million participants); an estimated 2.5 million group health benefit plans (covering 131 million participants and dependents); and 3.4 million other welfare benefits plans (covering approximately 190 million participants).

The Secretary's emphasis on meeting the needs of the 21st century workforce is reflected in the first regulatory initiative developed by the Employment and Training Administration (ETA). ETA will issue regulations reflecting recent changes to the Trade Adjustment Assistance (TAA) program, as enacted in the Trade Act of 2002 (RIN 1205-AB32). The proposed rule would address the many new features of the TAA program: consolidation of the TAA and NAFTA-TAA programs; immediate services to workers to facilitate more rapid reemployment; expanded eligibility; increased benefits, including health care assistance; and an Alternative TAA Program for older workers. The new regulations will be in plain English, making them easier to read and use.

ETA's second regulatory initiative also focuses on meeting the needs of our workforce by improving the quality of employment services provided to low-income senior citizens under the Older Americans Act (RIN 1205-AB28). These individuals often need assistance in developing skills and obtaining work experience so that they can obtain unsubsidized work. This rule will also improve performance accountability and enhance the ability of the States to coordinate services.

In its third initiative, ETA proposes to reengineer the permanent labor certification process (RIN 1205-AA66). ETA's goals are to make fundamental changes that will streamline the process; save resources; improve the

effectiveness of the program; and better serve the Department of Labor's customers.

Finally, the Employment Standards Administration (ESA) has set forth three priority regulatory initiatives. Among the statutes enforced by the Wage and Hour Division is the Fair Labor Standards Act (FLSA), which sets requirements for payment of minimum wages and overtime pay to more than 100 million employees. It also defines conditions for the employment of minors.

The Wage and Hour Division's first initiative updates the child labor rules issued under the FLSA to address changes in the nature of the workplace and situations in which minors may operate certain kinds of machinery (RIN 1215-AA09). While young workers need employment experiences that will help them gain the skills needed to find and hold good jobs later in life, they also need to focus on obtaining high-quality educations, and ensuring that their work hours are reasonable will help them do so.

The Wage and Hour Division's second initiative revises and clarifies the criteria that define the minimum wage and overtime exemptions for ''executive,'' ''administrative,'' ''professional,'' and ''outside sales'' employees under the FLSA (RIN 1215-AA14). These regulations were nominated for reform in a public comment on OMB's 2001 Report to Congress on the Costs and Benefits of Regulations. The issues of concern raised by various interested parties are being carefully examined in the development of proposed changes. Changes to these rules will help employers meet their obligations voluntarily and enhance workers' understanding of their rights and benefits.

The Wage and Hour Division's third initiative pertains to regulations issued under the Family and Medical Leave Act (FMLA) that were also nominated as a reform candidate in OMB's 2001 Report to Congress on 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.

DOL—Employment Standards Administration (ESA)

PROPOSED RULE STAGE

82. DEFINING AND DELIMITING THE TERM ''ANY EMPLOYEE EMPLOYED IN A BONA FIDE EXECUTIVE, ADMINISTRATIVE, OR PROFESSIONAL CAPACITY'' (ESA/W-H)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

29 USC 213(a)(1)

CFR Citation:

29 CFR 541

Legal Deadline:

None

Abstract:

These regulations set forth the criteria for exemption from the Fair Labor Standards Act's minimum wage and overtime requirements for ''executive,'' ''administrative,'' ''professional,'' and ''outside sales employees.'' To be exempt, employees must meet certain tests relating to duties and responsibilities and be paid on a salary basis at specified levels. A final rule increasing the salary test levels was published on January 13, 1981 (46 FR 3010), to become effective on February 13, 1981, but was indefinitely stayed on February 12, 1981 (46 FR 11972). On March 27, 1981, a proposal to suspend the final rule indefinitely was published (46 FR 18998), with comments due by April 28, 1981. As a result of numerous comments and petitions from industry groups on the duties and responsibilities tests, and as a result of case law developments, the Department concluded that a more comprehensive review of these regulations was needed. An ANPRM reopening the comment period and broadening the scope of review to include all aspects of the regulations was published on November 19, 1985, with the comment period subsequently extended to March 22, 1986.

The Department has revised these regulations since the ANPRM to address specific issues. In 1991, as the result of an amendment to the Fair Labor Standards Act (FLSA), the regulations were revised to permit certain computer systems analysts, computer programmers, software engineers, and other similarly skilled professional employees to qualify for the exemption, including those paid on an hourly basis if their rates of pay exceed 6 1/2 times the applicable minimum wage. Also, in 1992 the Department issued a final rule which modified the exemption's requirement for payment on a ''salary basis'' for otherwise exempt public sector employees.

Statement of Need:

These regulations contain the criteria used to determine if an employee is exempt from the FLSA as an ''executive,'' ''administrative,'' ''professional,'' or ''outside sales'' employee. The existing salary test levels used in determining which employees qualify as exempt were adopted in 1975 on an interim basis. These salary level tests are outdated and offer little practical guidance in applying the exemption. In addition, numerous comments and petitions have been received from industry groups regarding the duties and responsibilities tests in the regulations, requesting a review of these regulations.

These regulations have been revised to deal with specific issues. In 1991, as the result of an amendment to the FLSA, the regulations were revised to permit certain computer systems analysts, computer programmers, software engineers, and other similarly skilled professional employees to qualify for the exemption, including those paid on an hourly basis if their rates of pay exceed 6 1/2 times the applicable minimum wage. Also in 1991, the Department undertook separate rulemaking on another aspect of the regulations, the definition of ''salary basis'' for public-sector employees. Because of the limited nature of these revisions, the regulations are still in need of updating and clarification.

Summary of Legal Basis:

These regulations are issued under the statutory exemption from minimum wage and overtime pay provided by section 13(a)(1) of the Fair Labor Standards Act, 29 USC 213(a)(1), which requires the Secretary of Labor to issue regulations that define and delimit the terms ''any employee employed in a bona fide, executive, administrative, or professional capacity... or in the capacity of outside salesman...'' for purposes of applying the exemption to employees who meet the specified criteria.

Alternatives:

The Department will involve affected interest groups in developing regulatory alternatives. Following completion of these outreach and consultation activities, full regulatory alternatives will be developed.

Although legislative proposals have been introduced in Congress to address certain aspects of these regulations, the Department continues to believe revisions to the regulations are the appropriate response to the concerns raised. Alternatives likely to be considered range from particular changes to address ''salary basis'' and salary level issues to a comprehensive overhaul of the regulations that also addresses the duties and responsibilities tests.

Anticipated Cost and Benefits:

Some 19 to 26 million employees are estimated to be within the scope of these regulations. Legal developments in court cases are changing the guiding interpretations under this exemption and creating law without considering a comprehensive analytical approach to current compensation concepts and workplace practices. Clear, comprehensive, and up-to-date regulations would provide for central, uniform control over the application of these regulations and ameliorate many concerns. In the public sector, State and local government employers contend that the rules are based on production workplace environments from the 1940s and 1950s that do not readily adapt to contemporary government functions. The Federal Government also has concerns regarding the manner in which the courts and arbitration decisions are applying the exemption to the Federal workforce. Resolution of confusion over how the regulations are to be applied in the public sector will ensure that employees are protected, that employers are able to comply with their responsibilities under the law, and that the regulations are enforceable. Preliminary estimates of the specific costs and benefits of this regulatory action will be developed once the various regulatory alternatives are identified.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
Indefinite Stay of Final Rule	02/12/81	46 FR 11972
Proposal To Suspend Rule	03/27/81	46 FR 18998
ANPRM	11/19/85	50 FR 47696
Extension of ANPRM Comment Period	01/17/86	51 FR 2525
ANPRM Comment Period End	03/22/86	
NPRM	01/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

State, Local, Federal

Federalism:

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

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RIN: 1215–AA14

DOL—ESA

83. ● FAMILY AND MEDICAL LEAVE ACT OF 1993

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	01/00/03	
NPRM Comment Period End	03/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1215–AB35

DOL—ESA

FINAL RULE STAGE

84. CHILD LABOR REGULATIONS, ORDERS, AND STATEMENTS OF INTERPRETATION (ESA/W-H)

Priority:

Other Significant

Legal Authority:

29 USC 203(e)

CFR Citation:

29 CFR 570

Legal Deadline:

None

Abstract:

Section 3(l) of the Fair Labor Standards Act requires the Secretary of Labor to issue regulations with respect to minors between 14 and 16 years of age ensuring that the periods and conditions of their employment do not interfere with their schooling, health, or well-being. The Secretary is also directed to designate occupations that are particularly hazardous for minors 16 and 17 years of age. Child Labor Regulation No. 3 sets forth the permissible industries and occupations in which 14- and 15-year-olds may be employed, and specifies the number of hours in a day and in a week, and time periods within a day, that such minors may be employed. The Department has invited public comment in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders, and whether changes are needed in some of the applicable hazardous occupation orders. Comment has also been solicited on whether revisions should be considered in the permissible hours and time-of-day standards for 14- and 15-year-olds. Comment has been sought on appropriate changes required to implement school-to-work transition programs. Additionally, Congress enacted Public Law 104-174 (August 6, 1996), which amended FLSA section 13(c) and requires changes in the regulations under Hazardous Occupation Order No. 12 regarding power-driven paper balers and compactors, to allow 16- and 17-year-olds to load, but not operate or unload, machines meeting applicable American National Standards Institute (ANSI) safety standards and certain other conditions. Congress also passed the Drive for Teen Employment Act, Public Law 105-334 (October 31, 1998), which prohibits minors under age 17 from driving automobiles and trucks on public roads on the job and sets criteria for 17-year-olds to drive such vehicles on public roads on the job.

Statement of Need:

Because of changes in the workplace and the introduction of new processes and technologies, the Department is undertaking a comprehensive review of the regulatory criteria applicable to child labor. Other factors necessitating a review of the child labor regulations are changes in places where young workers find employment opportunities, the existence of differing Federal and State standards, and the divergent views on how best to correlate school and work experiences. Under the Fair Labor Standards Act, the Secretary of Labor is directed to provide by regulation or by order for the employment of youth between 14 and 16 years of age under periods and conditions which will not interfere with their schooling, health and well-being. The Secretary is also directed to designate occupations that are particularly hazardous for youth between the ages of 16 and 18 years or detrimental to their health or well-being. The Secretary has done so by specifying, in regulations, the permissible industries and occupations in which 14- and 15-year-olds may be employed, and the number of hours per day and week and the time periods within a day in which they may be employed. In addition, these regulations designate the occupations declared particularly hazardous for minors between 16 and 18 years of age or detrimental to their health or well-being.

Public comment has been invited in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders or necessitate revision to some of the existing hazardous orders. Comment has also been invited on whether revisions should be considered in the permissible hours and time-of-day standards for the employment of 14- and 15-year-olds, and whether revisions should be considered to facilitate school-to-work transition programs. When issuing the regulatory proposals (after review of public comments on the advance notice of proposed rulemaking), the Department's focus was on assuring healthy, safe and fair workplaces for young workers, and at the same time promoting job opportunities for young people and making regulatory standards less burdensome to the regulated community.

Summary of Legal Basis:

These regulations are issued under sections 3(l), 11, 12, and 13 of the Fair Labor Standards Act, 29 USC sections 203(l), 211, 212, and 213 which require the Secretary of Labor to issue regulations prescribing permissible time periods and conditions of employment for minors between 14 and 16 years old so as not to interfere with their schooling, health, or well-being, and to designate occupations that are particularly hazardous or detrimental to the health or well-being of minors under 18 years old.

Alternatives:

Regulatory alternatives developed based on recent legislation and the public comments responding to the advance notice of proposed rulemaking included specific proposed additions or modifications to the paper baler, teen driving, explosive materials, and roofing hazardous occupation orders, and proposed changes to the permissible cooking activities that 14- and 15-year-olds may perform in retail establishments.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of this regulatory action indicated that the rule was not economically significant. Benefits will include safer working environments and the avoidance of injuries with respect to young workers.

Risks:

The child labor regulations, by ensuring that permissible job opportunities for working youth are safe and healthy and not detrimental to their education as required by the statute, produce positive benefits by reducing health and productivity costs employers may otherwise incur from higher accident and injury rates to young and inexperienced workers. Given the limited nature of the changes in the proposed rule, a detailed assessment of the magnitude of risk was not prepared.

Timetable:

Action	Date	FR Cite
Final Action	11/20/91	56 FR 58626
Final Action Effective	12/20/91	
ANPRM	05/13/94	59 FR 25167
ANPRM Comment Period End	08/11/94	59 FR 40318
NPRM	11/30/99	64 FR 67130
NPRM Comment Period End	01/31/00	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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DOL—Employment and Training Administration (ETA)

PROPOSED RULE STAGE

85. SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM

Priority:

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

Legal Authority:

42 USC 3056(b)(2)

CFR Citation:

20 CFR 641

Legal Deadline:

None

Abstract:

The Employment and Training Administration will implement new regulations to govern the Senior Community Service Employment Program (SCSEP) under title V of the Older Americans Act Amendments of 2000. SCSEP is the only federally sponsored job creation program targeted to low-income older Americans. The program subsidizes part-time community service jobs for low-income persons age 55 years and older who have poor employment prospects. Approximately 100,000 program enrollees annually work in a wide variety of community service jobs, including nurse's aides, teacher aides, librarians, clerical workers and day care assistants. The Department of Labor allocates funds to operate the program to State agencies on aging and to national organizations.

Proposed regulations will improve integration of SCSEP with the broader workforce investment system and introduce performance measures and sanctions.

Statement of Need:

As the baby boom generation ages, the demand for employment and training services and income support for low-income older persons will increase. Low-income seniors generally must continue working and many may not be able to find employment without work experience and additional training. The basic goals of the SCSEP are to provide community service employment for older workers with few skills and little work experience, and to move many of those seniors into unsubsidized employment. The Employment and Training Administration will issue regulations and other guidance, provide technical assistance, and establish performance standards that will drive State and national grantees' efforts towards the program's goals.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 502(b)(2) of Pub. L. 106-501 of the Older Americans Act Amendments of 2000.

Alternatives:

The public provided comments on changes to the statute due to the Older Americans Act Amendments of 2000 during Town Hall meetings held throughout the country in spring 2001. The public also will be afforded an opportunity to comment on the Department's plans for implementing the Amendments in a notice of proposed rulemaking that will be published 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	01/00/03	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

Undetermined

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DOL—ETA

86. ● TRADE ADJUSTMENT ASSISTANCE FOR WORKERS

Priority:

Other Significant

Legal Authority:

19 USC 2320

CFR Citation:

20 CFR 617; 29 CFR 90

Legal Deadline:

None

Abstract:

The Trade 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 amendments regarding trade adjustment assistance (TAA) program benefits.

Additionally, a final rule implementing the 1988 Amendments to the TAA program was published in the Federal Register on January 6, 1994. Although published as a final rule, comments were requested on several material changes, which were not included in the proposed rule. Comments were received and will be considered and included in the final rule implementing the amendments under the Trade Act of 2002.

Furthermore, it is the agency's intention to rewrite both 20 CFR 20 part 617 and 29 FR 29 part 90 in plain English.

Statement of Need:

The Trade 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 Department is mandated to implement the amendments in 90 days from enactment, November 4, 2002. 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 Program for Older Workers that targets older worker groups at firms who are certified as TAA eligible and provides the option of a wage supplement instead of training, job search, relocation and income support.

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 the Trade Act of 2002 amendments to the Trade Act of 1974.

Alternatives:

The public will be afforded an opportunity to provide comments on the TAA program changes when the Department publishes the interim final 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	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Federal

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DOL—ETA

FINAL RULE STAGE

87. LABOR CERTIFICATION PROCESS FOR THE PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES

Priority:

Other Significant

Legal Authority:

29 USC 49 et seq; 8 USC 1182(a)(5)(A), 1189(p)(1)

CFR Citation:

20 CFR 656

Legal Deadline:

None

Abstract:

The Employment and Training Administration (ETA) is in the process of reengineering the permanent labor certification process. ETA's goals are to make fundamental changes and refinements that will streamline the process, save resources, improve the effectiveness of the program and better serve the Department of Labor's (DOL) customer.

Statement of Need:

The labor certification process has been described as being complicated, costly and time consuming. Due to the increases in the volume of applications received and a lack of adequate resources, it can take up to 2 years or more to complete processing an application. The process also requires substantial State and Federal resources to administer and is reportedly costly and burdensome to employers as well. Cuts in Federal funding for both the permanent labor certification program and the U.S. Employment Service have made it difficult for State and Federal administrators to keep up with the process. ETA, therefore, is taking steps to improve effectiveness of the various

regulatory requirements and the application processing procedures, with a view to achieving savings in resources both for the Government and employers, without diminishing protections now afforded U.S. workers by the current regulatory and administrative requirements.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 212(a)(5)(A) of the Immigration and Nationality Act.

Alternatives:

Regulatory alternatives are now being developed by the Department. The public will be afforded an opportunity to comment on the Department's plans for streamlining the permanent labor certification process in a notice of proposed rulemaking which will be published in the Federal Register.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits have not been determined at this time. Preliminary estimates will be developed after a decision is made as to what regulatory amendments are necessary and after the implementing forms and automated systems to support a streamlined permanent labor certification process have been developed.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	05/06/02	67 FR 30465
NPRM Comment Period End	07/05/02	67 FR 30466
Final Rule	01/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State, Federal

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DOL—Pension and Welfare Benefits Administration (PWBA)

PROPOSED RULE STAGE

88. RULEMAKING RELATING TO NOTICE REQUIREMENTS FOR CONTINUATION OF HEALTH CARE COVERAGE

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 1135; 29 USC 1166

CFR Citation:

29 CFR 2590

Legal Deadline:

None

Abstract:

This rulemaking will provide guidance concerning the notification requirements pertaining to continuation coverage under the Employee Retirement Income Security Act of 1974 (ERISA). Section 606 of ERISA requires that group health plans provide employees notification of the continuation coverage provisions of the plan and imposes notification obligations upon plan administrators, employers, employees, and qualified beneficiaries relating to certain qualifying events.

Statement of Need:

Part 6 of title I of ERISA requires that group health plans provide employees with notice of the continuation of health care coverage provisions of the plan; it imposes notification requirements upon employers, employees, plan administrators, and qualified beneficiaries in connection with certain qualifying events. The public needs guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Section 606 of ERISA specifies the respective notification requirements for employers, employees, plan administrators, and qualified beneficiaries in connection with group health plan provisions relating to continuation of health care coverage. Section 606(a) of ERISA specifically refers to regulations to be issued by the Secretary of Labor clarifying these requirements. Section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Alternatives:

Regulatory alternatives will be developed once determinations have been made with regard to the scope and nature of the regulatory guidance which is needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed once decisions are reached regarding the alternatives to be considered.

Risks:

Failure to provide guidance to the public concerning their notification obligations under section 606 of ERISA may complicate compliance by the public with the law and may reduce the availability of continued health care coverage in certain commonly encountered situations.

Timetable:

Action	Date	FR Cite
ANPRM	09/23/97	62 FR 49894
ANPRM Comment Period End	11/24/97	
NPRM	03/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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DOL—PWBA

FINAL RULE STAGE

89. REGULATIONS IMPLEMENTING THE HEALTH CARE ACCESS, PORTABILITY, AND RENEWABILITY PROVISIONS OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1171; 29 USC 1172; 29 USC 1191c

CFR Citation:

29 CFR 2590

Legal Deadline:

Other, Statutory, April 1, 1997, Interim Final Rule.

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended title I of ERISA by adding a new part 7, designed to improve health care access, portability and renewability. This rulemaking will provide regulatory guidance to implement these provisions.

Statement of Need:

In general, the health care portability provisions in part 7 of ERISA provide for increased portability and availability of group health coverage through limitations on the imposition of any preexisting condition exclusion and special enrollment rights in group health plans after loss of other health coverage or a life event. Plan sponsors, administrators and participants need guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Part 7 of ERISA specifies the portability and other requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 of ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Alternatives:

Regulatory alternatives will be considered after determining the scope and nature of additional regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Determinations on the anticipated costs and benefits will be developed once determinations have been made with regard to the alternatives to be developed.

Risks:

Failure to provide guidance concerning Part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Request for Information	10/25/99	64 FR 57520
Comment Period End	01/25/00	
Final Rule	03/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1210–AA54

DOL—PWBA

90. 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 1194; 29 USC 1182; 29 USC 1191c

CFR Citation:

29 CFR 2590.702

Legal Deadline:

None

Abstract:

Section 702 of the Employee Retirement Income Security Act of 1974, amended by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), establishes that a group health plan or a health insurance issuer may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. These provisions are also contained in the Internal Revenue Code under the jurisdiction of the Department of the Treasury, and the Public Health Service Act under the jurisdiction of the Department of Health and Human Services.

On April 8, 1997, the Department, in conjunction with the Departments of the Treasury and Health and Human Services (collectively, the Departments) published interim final regulations implementing the nondiscrimination provisions of HIPAA. These regulations can be found at 26 CFR 54.9802-1 (Treasury), 29 CFR 2590.702 (Labor), and 45 CFR 146.121 (HHS). That notice of rulemaking also solicited comments on the nondiscrimination provisions and indicated that the Departments intend to issue further regulations on the nondiscrimination rules. This rulemaking contains additional regulatory interim guidance under HIPAA's nondiscrimination provisions. In addition, the rulemaking contains proposed guidance on bona fide wellness programs.

Statement of Need:

Part 7 of ERISA establishes 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.

Alternatives:

Regulatory alternatives will be considered after determining the scope and nature of additional regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Determinations on the anticipated costs and benefits will be developed once determinations have been made with regard to the alternatives to be developed.

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
Second Interim Final Rule	01/08/01	66 FR 1378
NPRM Comment Period End	04/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Rule	04/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

This item has been split off from RIN 1210-AA54 in order to provide focused guidance on section 702 of ERISA, which prohibits discrimination against participants and beneficiaries by group health plans and health insurance issuers based on health status.

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RIN: 1210–AA77

DOL—PWBA

91. • BLACKOUT NOTICE REGULATION

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

PL 107-204; 29 USC 1135; 116 Stat 745 (29 USC 1132)

CFR Citation:

29 CFR 2520

Legal Deadline:

Other, Statutory, October 13, 2002, Interim Final Rule, PL 107-204.

Abstract:

This regulation will provide guidance with respect to the requirement that plan administrators furnish advance notice of blackout periods affecting individual account plans pursuant to section 101(i) of ERISA, as added by section 306 of the Sarbanes-Oxley Act of 2002.

Statement of Need:

The Sarbanes-Oxley Act of 2002 (the Act), amended ERISA by adding a new section 101(i), which requires plan administrators to notify individual account plan participants in advance of any period during which their ability to give investment directions will be suspended. The Act also added a new section 502(c)(7) to ERISA authorizing the Secretary of Labor to assess civil penalties against a plan administrator who fails or refuses to provide the required notice. The Act specifically requires the Secretary of Labor to provide regulatory guidance to the public with regard to new section 101(i) and establishes deadlines for the issuance of such guidance.

Summary of Legal Basis:

The Act requires the Secretary to issue regulatory guidance by October 13, 2002, and a model notice by January 1, 2003. Section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Alternatives:

The Department will develop regulatory alternatives after determining the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Determinations on the anticipated costs and benefits will be developed once determinations have been made with regard to the alternatives to be developed.

Risks:

Failure to provide the regulatory guidance mandated by the Act would contravene the provisions of law. Moreover, failure to issue such guidance would increase the potential risks of loss to plan participants and beneficiaries, and deprive plan administrators of information they need to enable them to comply with the new notice requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/21/02	67 FR 64765
Interim Final Rule Comment Period End	11/20/02	
Interim Final Rule Effective	01/26/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1210–AA90

DOL—PWBA

92. ● BLACKOUT NOTICE CIVIL PENALTY

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

PL 107-204; 29 USC 1135; 29 USC 1021(b)(1)

CFR Citation:

29 CFR 2560

Legal Deadline:

Final, Statutory, October 13, 2002.

Abstract:

These regulations will provide guidance with respect to the requirement that plan administrators furnish advance notice of blackout periods affecting individual account plans pursuant to section 101(i) of ERISA, as added by section 306 of the Sarbanes-Oxley Act of 2002, as well as the related civil penalty provisions.

Statement of Need:

The Sarbanes-Oxley Act of 2002 (the Act), amended ERISA by adding a new section 101(i), which requires plan administrators to notify individual account plan participants in advance of any period during which their ability to give investment directions will be suspended. The Act also added a new section 502(c)(7) to ERISA authorizing the Secretary of Labor to assess civil penalties against a plan administrator who fails or refuses to provide the required notice. The Act specifically requires the Secretary of Labor to provide regulatory guidance to the public with regard to new section 101(i) and establishes deadlines for the issuance of such guidance.

Summary of Legal Basis:

The Act requires the Secretary to issue regulatory guidance by October 13, 2002, and a model notice by January 1, 2003. Section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Alternatives:

The Department will develop regulatory alternatives after determining the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Determinations on the anticipated costs and benefits will be developed once determinations have been made with regard to the alternatives to be developed.

Risks:

Failure to provide the regulatory guidance mandated by the Act would contravene the provisions of law. Moreover, failure to issue such guidance would increase the potential risks of loss to plan participants and beneficiaries, and deprive plan administrators of information they need to enable them to comply with the new notice requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/21/02	67 FR 64774
Interim Final Rule Comment Period End	11/20/02	
Interim Final Rule Effective	01/26/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 1210–AA91

DOL—Mine Safety and Health Administration (MSHA)

PRERULE STAGE

93. ● DIESEL PARTICULATE MATTER EXPOSURE OF UNDERGROUND METAL AND NONMETAL MINERS

Priority:

Other Significant

Legal Authority:

30 USC 811

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. The final rule established new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines. The rule establishes an interim concentration limit of 400 micrograms of total carbon per cubic meter of air that became applicable July 20, 2002, and a final concentration limit of 160 micrograms to become applicable after January 19, 2006. This rule has been legally challenged and settlement negotiations with the litigants have resulted in further regulatory action on several requirements in the January 19, 2001 final rule. Several of the actions have been completed. This new rulemaking will address the remaining issues. MSHA issued an ANPRM to obtain additional information and to develop a proposed rule thereafter.

Statement of Need:

Several entities legally challenged the January 19, 2001 final rule. As a result of 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 evidence and the tagging provisions of the maintenance standards; clarified the effective dates of certain provisions of the final rule; and gave correction amendments.

The second document was a proposed rule to clarify 57.5066(b)(1) and (b)(2) of the maintenance standards and to add a new paragraph (b)(3) to 57.5067 regarding the transfer of existing diesel equipment from one underground mine to another underground mine. The final rule on these issues was published February 27, 2002, and became effective March 29, 2002.

Also as part of the settlement agreement, MSHA agreed to conduct joint sampling with industry and labor at 31 underground mines to determine existing concentration levels of DPM; assess the performance of the SKC sampler and the NIOSH Analytical Method 5040; assess the feasibility of achieving compliance with the standard's concentration limit at the 31 mines; and, to assess the impact of

interferences on the sample in the metal and nonmetal underground mining environment before the limits established in the final rule became effective. Sampling and date analyses are completed and the final report is being developed.

MSHA also agreed to reenter rulemaking on several other provisions. The following provisions will constitute the basis for this new rulemaking:

57.5060(a) and (b) - changing the diesel particulate matter surrogate from total carbon to elemental carbon for both the interim and final concentration limits;

57.5060(d) - permitting miners to work in areas where diesel particulate matter exceeds the applicable concentration limit;

57.5060(e) - prohibiting the use of personal protective equipment to comply with the concentration limits;

57.5060(f) - prohibiting the use of administrative controls to comply with the concentration limits;

57.5061(b) - changing reference of total carbon to elemental carbon;

57.5061(c) - deleting reference to ''area'' and ''occupational'' sampling for compliance;

57.5062 - addressing the diesel particulate matter control plan.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

This rulemaking action is a result of the parties' settlement negotiations. This action will not decrease protection for miners.

Anticipated Cost and Benefits:

MSHA will develop a preliminary economic analysis to accompany the proposed rule.

Risks:

Several epidemiological studies have found that exposure to diesel exhaust presents potential health risk to workers. These potential adverse health effects range from headaches and nausea to respiratory disease and cancer. In the confined space of the underground mine 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 reduce miners exposure to DPM.

Timetable:

Action	Date	FR Cite
ANPRM	09/25/02	67 FR 60199
ANPRM Comment Period End	11/25/02	
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 1219–AB29

DOL—MSHA

PROPOSED RULE STAGE

94. VERIFICATION OF UNDERGROUND COAL MINE OPERATORS' DUST CONTROL PLANS AND COMPLIANCE SAMPLING FOR RESPIRABLE DUST

Priority:

Other Significant

Legal Authority:

30 USC 811

CFR Citation:

30 CFR 70; 30 CFR 75; 30 CFR 90

Legal Deadline:

None

Abstract:

Our current regulations require that all underground coal mine operators develop and follow a mine ventilation plan for each mechanized mining unit that we approve. However, we do not have a requirement that provides for verification of each plan's effectiveness under typical mining conditions. Consequently, plans may be implemented by mine operators that could be inadequate to control respirable dust. The proposed rule provides for MSHA to verify the effectiveness of mine ventilation plans to control respirable dust under typical mining conditions. For longwall mine operators, we proposed to permit the limited use of either approved loose-fitting powered air purifying respirators (PAPRs) or verifiable administrative controls as a supplemental means of compliance if we have determined that further reduction in respirable dust levels cannot be achieved using all feasible engineering controls. Furthermore, MSHA proposed to assume responsibility for all compliance sampling for respirable dust in underground coal mines as required under 30 CFR parts 70 and 90. However, given significant public comments, MSHA will repropose this rule.

Statement of Need:

Respirable coal mine dust levels in this country are significantly lower than they were two decades ago. Despite this progress, there continues to be concern about the respirable coal mine dust sampling program and its effectiveness in maintaining exposure levels in mines at or below the applicable standard. Our regulations require that all underground coal mine operators develop and follow a mine ventilation plan approved by us. The dust control portion of the mine ventilation plan is the key element of an operator's strategy to control respirable dust in the work environment. Although such plans are required to be designed to control respirable dust, there is no current requirement that provides for verification of each proposed plan's effectiveness under typical mining conditions. Consequently, plans may be implemented that may be inadequate to control respirable dust. Therefore, we proposed to revoke existing operator respirable dust sampling and to implement new regulations that would require each underground coal mine operator to have a verified ventilation plan. MSHA would verify the effectiveness of the mine ventilation plan for each mechanized mining unit in controlling respirable dust under typical mining conditions.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 101 of the

Federal Mine Safety and Health Act of 1977.

Alternatives:

In developing the proposed rule, we considered alternatives related to typical production levels, the use of appropriate dust control strategies, use of supplemental controls for mining entities other than longwalls, and the level of protection of loose-fitting powered air purifying respirators (PAPRS) in underground coal mines.

Anticipated Cost and Benefits:

Benefits sought are reduced dust levels over a miner's working lifetime by the elimination of overexposures to respirable coal mine dust on each and every production shift. Additional benefits include reduced health care costs and disability and black lung benefit payments. There would be a cost savings for mine operators when MSHA completely takes over compliance and abatement sampling for respirable dust. We developed cost estimates and made them available for public review.

Risks:

Respirable coal mine dust is one of the most serious occupational hazards in the mining industry. Occupational exposure to excessive levels of respirable coal mine dust can cause black lung and silicosis, which are potentially disabling and can cause death. We are pursuing both regulatory and non-regulatory actions to eliminate these diseases through the control of coal mine respirable dust levels in mines and the reduction of miners' exposure.

Timetable:

Action	Date	FR Cite
NPRM	07/07/00	65 FR 42122
Notice of Hearings; Close of Record	07/07/00	65 FR 42186
Extension of Comment Period; Close	09/08/00	65 FR 49215
NPRM	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

This rulemaking is related to RIN 1219-AB18 (Determination of Concentration of Respirable Coal Mine Dust).

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RIN: 1219–AB14

DOL—MSHA

95. DETERMINATION OF CONCENTRATION OF RESPIRABLE COAL MINE DUST

Priority:

Other Significant

Legal Authority:

30 USC 811

CFR Citation:

30 CFR 72

Legal Deadline:

None

Abstract:

The National Institute for Occupational Safety and Health and the Mine Safety and Health Administration jointly proposed that a single, full-shift measurement (single sample) will accurately represent the atmospheric condition to which a miner is exposed. The proposed rule addresses the U.S. Court of Appeals' concerns raised in National Mining Association v. Secretary of Labor, 153 3d 1264 (11th Cir. 1998). MSHA is supllmenting the record with additional data and will reopen the record for comments.

Statement of Need:

Respirable coal mine dust levels in this country are significantly lower than they were over two decades ago. Despite this progress, there continues to be concern about our current sampling programs' ability to accurately measure and maintain respirable coal mine dust exposure at or below the applicable standard on each shift. For as long as miners have taken coal from the ground, many have suffered respiratory problems due to their occupational exposures to respirable coal mine dust. These respiratory problems affect the current workforce and range from mild impairment of respiratory function to more severe diseases, such as silicosis and pulmonary massive fibrosis. For some miners, the impairment of their respiratory systems is so severe, they die prematurely. Since there is a clear relationship between a miner's cumulative exposure to respirable coal mine dust and the severity of the resulting respiratory conditions, it is imperative that each miner's exposure not exceed the applicable standard on each and every shift.

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 requirements of this rule (single sample) will work in tandem with those of the proposed rule (RIN 1219-AB14) in which MSHA proposed to verify the effectiveness of ventilation plans as well as conduct all compliance sampling in underground coal mines. However, given significant public comments, MSHA will repropose RIN 1219-AB14 - Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust.

Anticipated Cost and Benefits:

Benefits sought are reduced dust levels over a miner's working lifetime by the elimination of overexposures to respirable coal mine dust on each and every production shift. Additional benefits include reduced health care costs and disability and black lung benefit payments.

Risks:

Respirable coal mine dust is one of the most serious occupational hazards in the mining industry. Occupational exposure to excessive levels of respirable coal mine dust can cause workers' pneumoconiosis and silicosis, which are potentially disabling and can cause death. We are pursuing both regulatory and nonregulatory actions to eliminate these diseases through the control of coal mine respirable dust levels in mines and reduction of miners' exposure.

Timetable:

Action	Date	FR Cite
NPRM	07/07/00	65 FR 42068
Notice of Hearings; Close of Record	07/07/00	65 FR 42185
Extension of Comment Period; Close	09/08/00	65 FR 49215
Reopen Record for Comments	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

This rulemaking is related to RIN 1219-AB14 (Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust).

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RIN: 1219–AB18

DOL—MSHA

96. 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. Current scientific data indicate that this existing PEL is not adequate to protect miners' health. MSHA is considering rulemaking to lower the PEL in order to reduce the risk of miners developing asbestos-induced occupational disease. A recent 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 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 at the end of 1978 for metal and nonmetal mining (43 FR 54064). Since enactment of the Mine Act, MSHA has conducted regular inspections at both surface and underground operations at metal and nonmetal mines. During these 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 and the excursion limit to an eight (8) hour time-weighted average limit of 0.1 fiber per cubic centimeter of air and to 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes. These lowered limits reflected increased asbestos-related disease risk to asbestos-exposed workers.

Alternatives:

The Agency has increased sampling efforts in an attempt to determine current miners' exposure levels to asbestos, including taking samples at all existing vermiculite, taconite, talc, and other mines to determine whether asbestos is present and at what levels. Since the spring of 2000, MSHA has taken almost 900 samples at more than 40 operations employing more than 4,000 miners. During those sampling events, the MSHA staff also discussed with the miners and mine operators the potential hazards of asbestos and the types of preventive measures that could be implemented to reduce exposures. The course of action MSHA takes in addressing asbestos hazards to miners will, in part, be based on these sampling results.

Anticipated Cost and Benefits:

MSHA will develop a preliminary economic analysis to accompany any proposed rule that may be developed.

Risks:

There is concern that 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 mesothelioma and other forms of cancers, such as cancers of the digestive system, as well as asbestosis.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/02	67 FR 15134
Notice of Public Meetings	03/29/02	
Notice of Change to Public Meetings	04/18/02	67 FR 19140
ANPRM Comment Period End	06/27/02	
NPRM	09/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

The Office of the Inspector General's ''Evaluation of MSHA's Handling of Inspections at the W.R. Grace & Company Mine in Libby, Montana,'' was issued in March 2001.

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RIN: 1219–AB24

DOL—Occupational Safety and Health Administration (OSHA)

PROPOSED RULE STAGE

97. ASSIGNED PROTECTION FACTORS: AMENDMENTS TO THE FINAL RULE ON RESPIRATORY PROTECTION

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910.134

Legal Deadline:

None

Abstract:

In January 1998, OSHA published the final Respiratory Protection standard (29 CFR 1910.134), except for reserved provisions on assigned protection factors (APFs) and maximum use concentrations (MUCs). APFs are numbers that describe the effectiveness of the various classes of respirators in reducing employee exposure to airborne contaminants (including particulates, gases, vapors, biological agents, etc.). Employers, employees, and safety and health professionals use APFs to determine the type of respirator to protect the health of employees in various hazardous environments. Maximum use concentrations establish the maximum airborne concentration of a contaminant in which a respirator with a given APF may be used.

Currently, OSHA relies on the APFs developed by NIOSH in the 1980s unless OSHA has assigned a different APF in a substance-specific health standard. However, many employers follow the more recent APFs published in the industry consensus standard, ANSI Z88.2-1992. For some classes of respirators, the NIOSH and ANSI APFs vary greatly.

When OSHA published the final Respiratory Protection standard in 1998, it reserved for later rulemaking those provisions of the standard dealing with APFs and MUCs. This rulemaking action will complete the 1998 standard, reduce compliance confusion among employers, and provide employees with consistent and appropriate respiratory protection.

Statement of Need:

About 5 million employees wear respirators as part of their regular job duties. Due to inconsistencies between the APFs found in the current industry consensus standard (ANSI Z88.2-1992) and in the NIOSH Respirator Decision Logic, employers, employees, and safety and health professionals are often uncertain about what respirator to select to provide protection against hazardous air contaminants. Several industry and professional groups have asked OSHA to proceed with this rulemaking to resolve these inconsistencies and provide reliable protection of employees' health in cases where respirators must be worn.

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 of that standard.

Alternatives:

OSHA has considered allowing the current situation to continue, in which OSHA generally enforces NIOSH APFs but many employers follow the more recent consensus standard APFs. However, allowing the continuation of this situation results in inconsistent enforcement, lack of guidance for employers, and the potential for inadequate employee protection.

Anticipated Cost and Benefits:

The scope of the proposed APF table is still under development, and estimates of the costs and benefits have not yet been completed.

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 will be 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	02/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State, Local, Tribal, Federal

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RIN: 1218–AA05

DOL—OSHA

98. FIRE PROTECTION IN SHIPYARD EMPLOYMENT (PART 1915, SUBPART P) (SHIPYARDS: FIRE SAFETY)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 655

CFR Citation:

29 CFR 1915, subpart P

Legal Deadline:

None

Abstract:

The rule will update and revise an important but outdated part of OSHA's shipyard rules. The original rule was adopted by OSHA in 1971 and has remained unchanged since then. A negotiated rulemaking committee was convened on October 15, 1996. Members of the committee included: OSHA, State government, Federal agency, small and large shipyard employers, and maritime and firefighter union representatives. The committee completed work in February 2002, and recommended proposal requirements to OSHA. The Agency has developed an NPRM based on their recommendations.

Statement of Need:

Fires in the shipyard environment may cause death and serious injuries in this 100,000-employee workforce. Updating OSHA's outdated shipyard

requirements for fire extinguishers, sprinkler systems, detection systems, alarm systems, and fire brigades will facilitate compliance by employers and employees and reduce these fire-related injuries and fatalities.

Summary of Legal Basis:

The legal basis for this proposed rule is a preliminary determination that an unacceptable risk of fire-related injuries and fatalities exists in the shipyard industry.

Alternatives:

OSHA has considered but rejected the alternative of allowing the existing rule to remain in place, because the Agency believes that doing so would contribute to the unacceptable number of fire-related accidents occurring in shipyards every year.

Anticipated Cost and Benefits:

Detailed cost and benefits estimates are being prepared for the NPRM.

Risks:

A risk analysis is incldued in the NPRM.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 1218–AB51

DOL—OSHA

99. OCCUPATIONAL EXPOSURE TO CRYSTALLINE SILICA

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910; 29 CFR 1915; 29 CFR 1917; 29 CFR 1918; 29 CFR 1926

Legal Deadline:

None

Abstract:

Crystalline silica is a significant component of the earth's crust, and many workers in a wide range of industries are exposed to it, usually in the form of respirable quartz or, less frequently, cristobalite. Chronic silicosis is a uniquely occupational disease resulting from exposure of employees over long periods of time (10 years or more). Exposure to high levels of respirable crystalline silica causes acute or accelerated forms of silicosis that are ultimately fatal. The current OSHA permissible exposure limit (PEL) for general industry is based on a formula recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1971 [PEL=10mg/cubic meter/(%silica + 2), as respirable dust]. The current PEL for construction and maritime (derived from ACGIH's 1962 Threshold Limit Value) is based on particle counting technology, which is considered obsolete. NIOSH and ACGIH recommend a 50ug/m3 exposure limit for respirable crystalline silica.

Both industry and worker groups have recognized that a comprehensive standard for crystalline silica is needed to provide for exposure monitoring, medical surveillance, and worker training. The American Society of Testing Materials (ASTM) recently published a final recommended standard to address 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.

In developing a proposed standard, OSHA is currently considering several options ranging from proposing comprehensive standards simultaneously for general industry, construction, and maritime, to focusing the proposal on one or more specific issues, such as modernizing the construction and maritime PELs or standardizing sampling and employee exposures. OSHA is continuing to coordinate closely with the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) in collecting and developing information for a proposed standard.

Statement of Need:

Over 2 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 operation, 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. 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. 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 recently 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 rulemaking 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 nonregulatory approaches, including initiation of a Special Emphasis Program on silica in October 1997, sponsorship with NIOSH and MSHA of the National Conference to Eliminate Silicosis, and dissemination of guidance information on its Web site. OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of crystalline silica. The Agency is currently evaluating several options for the scope of the rulemaking.

Anticipated Cost and Benefits:

The scope of the proposed rulemaking is still under development, and estimates of the costs and benefits have not yet been developed.

Risks:

A detailed risk analysis has not yet been completed for this rule.

Timetable:

Action	Date	FR Cite
Initiate SBREFA Process or Initiate	06/00/03	
NPRM	11/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

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RIN: 1218–AB70

DOL—OSHA

100. STANDARDS IMPROVEMENT (MISCELLANEOUS CHANGES) FOR GENERAL INDUSTRY, MARINE TERMINALS, AND CONSTRUCTION STANDARDS (PHASE II)

Priority:

Other Significant

Legal Authority:

29 USC 655(b)

CFR Citation:

29 CFR 1910, subpart Z; 29 CFR 1910.1001 to 1910.1052; 29 CFR 1910.142; 29 CFR 1910.178; 29 CFR 1910.219; 29 CFR 1910.261; 29 CFR 1910.265; 29 CFR 1910.410; 29 CFR 1917.92; 29 CFR 1926.1101; 29 CFR 1926.1127; 29 CFR 1926.1129; 29 CFR 1926.60; 29 CFR 1926.62

Legal Deadline:

None

Abstract:

The Occupational Safety and Health Administration (OSHA) is proposing to remove or revise provisions in its health standards that are out of date, duplicative, unnecessary, or inconsistent. The Agency is proposing these changes to reduce the burden imposed on the regulated community by these requirements. In this document, substantive changes are proposed for standards that will revise or eliminate duplicative, inconsistent, or unnecessary regulatory requirements without diminishing employee protections. Phase I of this Standards Improvement process was completed in June 1998 (63 FR 33450). OSHA plans to initiate Phase III of this project at a future date to address problems in various safety standards.

Statement of Need:

Some of OSHA's standards are out of date, duplicative, unnecessary, or inconsistent. The Agency needs to periodically review its standards and make needed corrections. This effort results in standards that are easier for employers and employees to follow and comply with, and thus enhances compliance and worker protection.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary finding that the OSHA standards need to be updated to bring them up to date, reduce inconsistency, and remove unneeded provisions.

Alternatives:

OSHA has considered updating each standard as problems are discovered, but has determined that it is better to make such changes to groups of standards so it is easier for the public to comment on like standards. OSHA has also considered the inclusion of safety standards that need to be updated. However, the Agency has decided to pursue a separate rulemaking for safety issues because the standards to be updated are of interest to different stakeholders.

Anticipated Cost and Benefits:

This revision of OSHA's standards is a deregulatory action. It will reduce employers' compliance obligations.

Risks:

The project does not address specific risks, but is intended to improve OSHA's standards by bringing them up do date and deleting unneeded provisions. The anticipated changes will have no negative effects on worker safety and health.

Timetable:

Action	Date	FR Cite
NPRM	10/31/02	67 FR 66493
NPRM Comment Period End	12/20/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 1218–AB81

DOL—OSHA

FINAL RULE STAGE

101. UPDATE AND REVISION OF THE EXIT ROUTES STANDARD

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 5 USC 353

CFR Citation:

29 CFR 1910.35; 29 CFR 1910.36; 29 CFR 1910.37; 29 CFR 1910.38

Legal Deadline:

None

Abstract:

Many Occupational Safety and Health Administration (OSHA) standards were adopted under section 6(a) of the Occupational Safety and Health Act (OSH Act; 29 U.S.C. 655(a)). This section of the OSH Act authorized the Agency, in its first 2 years of existence, to adopt national consensus standards without prior notice and comment. The versions of the consensus standards OSHA adopted are now typically well over 30 years old and have been superseded by newer ones. In addition, many of these old standards were written in technical jargon and were hard for many employers and employees to understand. To address these problems, OSHA is revising OSHA's exit routes (also known as means of egress) standard. The revisions rewrite the standard in simple, easy-to-understand language that will be easier for employers and employees to follow.

Statement of Need:

The standard being revised in this initiative is one of OSHA's oldest and most difficult to understand. The Agency has identified the exit routes standard as a standard in need of revision because it is out of date and unnecessarily complex, and stakeholders have recommended that the standard be updated quickly. OSHA also believes that revising the standard will lead to better voluntary compliance and fewer disputes about violations. With OSHA's limited resources, any effort that can substantially increase opportunities for compliance without sacrificing employee safety and health protection will have long-term benefits.

Summary of Legal Basis:

The legal basis for the final rule is that by making these OSHA standards easier to understand and comply with, the Agency will increase compliance and reduce work-related injuries and deaths.

Alternatives:

The alternative considered — leaving the outdated standard on the books — has been rejected because doing so would not encourage compliance or enhance safety.

Anticipated Cost and Benefits:

The final standard for exit routes will have no economic impacts because this revision will not increase employers' obligations or reduce employee protections.

Risks:

Employees can be injured or killed if they are not able to exit an area safely when a fire or other emergency occurs.

Timetable:

Action	Date	FR Cite
NPRM	09/10/96	61 FR 47712
Public Hearing	04/29/97	62 FR 9402
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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DEPARTMENT OF TRANSPORTATION (DOT)

Statement of Regulatory Priorities

The Department of Transportation (DOT) consists of eleven operating administrations, the Bureau of Transportation Statistics and the Office of the Secretary, each of which has statutory responsibility for a wide range of regulations. For example, DOT regulates safety in the aviation, motor carrier, railroad, mass transit, motor vehicle, maritime, 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. It regulates the construction and operation of bridges over navigable waters, the prevention of oil pollution, and the security of commercial aviation and passenger vessels. 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, security, 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.

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 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.

Throughout the Department, we are 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.

Office of the Secretary of Transportation (OST)

The Office of the Secretary (OST) oversees the regulatory process for the Department. OST implements the Department's regulatory policies and procedures and is responsible for ensuring the involvement of top management in regulatory decisionmaking. Through the General Counsel's office, OST is also responsible for ensuring that the Department complies with Executive Order 12866 and other legal and policy requirements affecting rulemaking, including new statutes and Executive orders. Although OST's principal role concerns the review of the Department's significant rulemakings, this office has the lead role in the substance of projects concerning aviation economic rules and those affecting the various elements of the Department.

OST provides guidance and training regarding compliance with regulatory requirements and process for use by personnel throughout the Department. OST also plays an instrumental part in the Department's efforts to improve our economic analyses, risk assessment, and regulatory flexibility analyses.

OST also leads and coordinates the Department's response to Administration and congressional proposals that concern the regulatory process. The General Counsel's Office works closely with representatives of other agencies, the Office of Management and Budget, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

During fiscal year 2003, OST expects to substantially complete work on a CRS final rule. OST also expects to publish two NPRMs to implement provisions of the Aviation Investment and Reform Act for the 21st Century, signed into law in April 2000. One NPRM will seek to amend 14 CFR part 382, DOT's Air Carrier Access Act (ACAA) implementing rule, to cover foreign carriers operating to and from the United States or code sharing with the U.S. carriers. Another NPRM will propose to require air carriers to file with DOT detailed information on the disability-related complaints they receive to be used for enforcement, educational and other relevant purposes by DOT, disabled air travelers and Congress. OST also expects to substantially complete work on a final rule on the reporting requirements during FY 2003.

Transportation Security Administration (TSA)

The TSA was established on November 19, 2001, by the Aviation and Transportation Security Act (ATSA) (Pub. L. 107-71). Under ATSA, TSA is responsible for civil aviation security, as well as security in other modes of transportation regulated by the DOT. TSA's regulatory priorities for 2002-2003 are to continue to issue rulemakings necessary to meet the requirements of ATSA, including rules needed to address new security vulnerabilities that may arise. TSA also will undertake a review of its rules to eliminate duplicative and unnecessary requirements.

United States Coast Guard (USCG)

The United States Coast Guard's statutory responsibilities include

protecting the marine environment, enforcing U.S. laws and international treaties, performing search and rescue, and ensuring marine safety and security.

The majority of the regulatory actions issued by the Coast Guard are classified as routine and frequent because they apply to a specific location and most take effect for a limited time. These actions allow local Coast Guard units to respond quickly to ensure safety and security for our ports and waterways.

From its headquarters in Washington, DC, the Coast Guard issues approximately 20 regulations annually. These regulations set national standards or respond to specific statutory mandates. The Marine Safety Council, a board of senior Coast Guard Leaders, approves each of these rulemaking projects, monitors the Coast Guard's regulatory program, and advises the Commandant on regulatory matters. The following are significant aspects of the Coast Guard's regulatory program:

- The Coast Guard continues using a plain language format for its notices and regulations. Plain language updates will be an important part of the Coast Guard's review of all regulations under the Regulatory Flexibility Act. The Coast Guard recognizes that this format facilitates better understanding of regulations and promotes more public participation.
- Another way the Coast Guard encourages early public involvement in rulemaking is through public meetings and the ongoing work of 10 advisory committees. In addition, public comments are requested on existing rules identified for analysis each year and identified in Appendix D of the fall agenda. The Coast Guard is a staunch supporter of the Department of Transportation Docket Management System (DMS). DMS provides electronic docketing for all Coast Guard headquarters rulemaking projects. The public can view agency documents and public comments on each rulemaking project. DMS is located at http://dms.dot.gov/.
- As part of its response to the terrorist attacks of September 11, 2001, the Coast Guard conducted a public workshop on Maritime Security in January 2002. The public comments from this workshop have helped guide our work on security plans for ports, waterfront facilities (including passenger facilities), passenger vessels and high-consequences vessels, and identification credentials for persons on vessels and in waterfront facilities. Since September 11, 2001, the Coast Guard has created more than 100 security zones to protect vessels and waterfront facilities. We are also working to enhance our maritime domain awareness capabilities.
- Recognizing that it should issue only necessary regulations tailored to impose the least burden on society, the Coast Guard has developed a broad Prevention Through People Program, which develops and encourages a wide variety of voluntary actions by industry and individuals to improve marine safety. To support this effort, the Coast Guard has developed several Quality Partnerships.
- Finally, to ensure that all regulations are necessary, each agenda item specifies how it supports at least one of the five goals of the Coast Guard's Strategic Plan — maritime safety, protection of natural resources, maritime security, maritime mobility, and national defense. As indicated by the project in our regulatory plan, our post-September 11, 2001, emphasis on maritime security and national defense has not prevented us from addressing our other strategic goals. Our regulatory plan is structured to help us achieve the Commandant's new direction emphasizing readiness, people and stewardship.

Federal Aviation Administration (FAA)

The FAA issues regulations to provide a safe, secure, and efficient global aviation system for civil aircraft. In an effort to make sure their rules are concise and easy to understand, the FAA reexamined the use of plain language in its regulations. The result of this review was revisions to 14 CFR part 11, which delineates the process for rulemaking changes. This rulemaking effort is only the first of several planned revisions to the regulations. Other actions include:

- Supporting the FAA's Safety Agenda on Safer Skies. This agenda is based on a comprehensive review of the causes of aviation accidents and is designed to bring about a five-fold (80 percent) reduction in fatal accidents. The reformed rulemaking process supports this agenda by ensuring that appropriate resources are available to support those rulemaking projects identified as the agency's highest priority. Projects related to controlled flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decisionmaking, and cabin safety are some of the focus areas identified that may result in rulemaking, advisory and guidance materials.
- Continuing to involve the aviation community early in the regulatory process. The Aviation Rulemaking Advisory Committee completed numerous reports and recommendations, leading to the publication of nine regulatory actions and issuance of several advisory circulars and other guidance materials. The FAA Aging Transport Nonstructural Systems Plan addresses concerns with potential safety issues associated with problems that may develop in transport category airplanes systems as a result of wear and degradation in service. One important component of the plan is use of the Aging Transport Nonstructural Systems Rulemaking Advisory Committee to provide a mechanism for public input to FAA activities. The FAA will receive recommendation from the Committee in the form of regulations, guidance materials and training requirements supporting enhanced airworthiness for airplane systems.
- Continuing to harmonize the U.S. aviation regulations with those of other countries. The harmonization of the U.S. regulations with the European Joint Aviation Regulations (JAR) is the FAA's most comprehensive long-term rulemaking effort. The differences worldwide in certification standards, practices 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 operators. Harmonization and standardization should help the U.S. aerospace industry remain internationally competitive. While the overall effort to achieve this is global, it will be accomplished by many small, individual, nonsignificant rulemaking projects. The FAA has published 39 regulations based on recommendations of ARAC that will lead to harmonizing FAA regulations and Joint Aviation Requirements.
- Continuing to recognize the needs of small entities by complying with the Small Business Regulatory Enforcement Fairness Act and addressing small entity concerns whenever appropriate in rulemaking documents. In response to the Act, the FAA has established a Small Entity Contact, a Web site on FAA's home

page, a toll-free number, and an e-mail address for receipt of inquiries.

- Ensuring that the congressional mandates for rulemaking deadlines established by the FAA Reauthorization Act of 1996 are met. One mandate is the issuance of a final rule 16 months after the close of the comment period on the proposed rule.

Top regulatory priorities for 2002-2003 include a duty limitations and rest requirements proposal to ensure that pilots are sufficiently rested for duty, and final rules concerning certification of airports and thermal acoustic insulation flammability and fractional ownership.

Federal Highway Administration (FHWA)

The FHWA anticipates that its priority for fiscal year 2003 will be continuing implementation of the Transportation Equity Act for the 21st Century (TEA-21), which reauthorizes the surface transportation programs administered by the FHWA. The FHWA will continue to implement this legislation in the least burdensome and restrictive way possible consistent with the FHWA's mission. The FHWA will continue to pursue regulatory reform in areas where project development can be streamlined or accelerated, duplicative requirements can be consolidated, recordkeeping requirements can be reduced or simplified, and the decisionmaking authority of our State and local partners can be increased.

Federal Motor Carrier Safety Administration (FMCSA)

The FMCSA was established on January 1, 2000, by the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L. 106-159). As required by MCSIA, FMCSA has developed a strong Safety Action Plan to guide it toward the goal of reducing the number of fatalities resulting from crashes involving large trucks. Setting new performance standards for vehicles, drivers, and motor carriers through regulation will raise the bar for safety in commercial operations. The FMCSA now is responsible for most of the functions of the former Office of Motor Carriers in the Federal Highway Administration. Several regulatory initiatives are required by MCSIA. Over the next year, FMCSA is committed to developing an effective and efficient regulatory program that meets the expectations of Congress, its stakeholders and partners, and the general public. FMCSA's regulatory program will assist the agency in meeting one of the stated goals of MCSIA to reduce the number and severity of large-truck involved crashes through expedited completion of rulemaking proceedings.

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 motor vehicle information to consumers, and improving automotive fuel efficiency. NHTSA pursues policies that encourage the development of nonregulatory approaches when feasible in meeting its statutory mandates. It issues new standards and regulations or amendments to existing standards and regulations when appropriate. For example, during FY 2003, NHTSA's implementation of the TREAD Act will remain a high priority. 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.

In addition to numerous programs that focus on the safety and performance of the motor vehicle, the Agency is engaged in a variety of programs to improve driver behavior. These programs emphasize the human aspects of motor vehicle safety and recognize the important role of the States in this common pursuit. This goal is accomplished through a number of means, including encouraging initiatives in such areas as safety belt use, child safety-seat use, activities aimed at combating impaired driving and aggressive driving, and consumer information activities.

NHTSA's regulatory program includes safety improvements that address significant numbers of fatalities and injuries and that are of the most concern to the public. Within this context, an important regulatory priority is offset frontal protection.

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 requires cooperative action by all affected parties. In order to foster an environment of collaborative rulemaking, FRA established the Railroad Safety Advisory Committee (RSAC). The purpose of RSAC is to develop consensus recommendations for regulatory action on issues referred to it by FRA. Where consensus is achieved, and FRA believes it serves 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 RSAC's recommendations.

The RSAC has met on a quarterly basis so far and currently has working groups addressing the following tasks: (1) the development of regulations governing roadway maintenance equipment; (2) the review of FRA regulations for their applicability to historic railroads; (3) the development of safety standards for locomotive crashworthiness; (4) the development of safety standards for locomotive working conditions; (5) the development of locomotive event recorder accident survivability standards; (6) the development of regulations governing the use of processor-based signal and train control systems; (7) the revision of FRA's accident/incident reporting regulations to ensure conformity with OSHA's revised occupational injury and illness reporting regulations; and (8) the revision of FRA's blue signal protection requirements for workers performing certain duties on, under or between rolling equipment.

In addition to RSAC, FRA continues to use collaborative rulemaking to address passenger safety issues. FRA established a working group to address Passenger Equipment Safety Standards and published a final rule in the first phase of this rulemaking initiative in May 1999 based on its recommendations. FRA also employed a working group to develop Passenger Train Emergency Preparedness regulations. FRA continues to conduct research related to the second phase of the rule, and expects to convene a reconstituted working group on Passenger Safety Standards in late 2002. FRA also engaged in extensive public outreach to develop regulations regarding the use of train whistles and published an NPRM in January 2000.

Federal Transit Administration (FTA)

The Federal Transit Administration (FTA) provides financial assistance to

State and local governments for mass transportation purposes. The regulatory activity of FTA focuses on establishing the terms and conditions of Federal financial assistance available under the Federal transit laws.

FTA's policy regarding regulations is to:

- Implement statutory authorities in ways that provide the maximum net benefits to society;
- Keep paperwork requirements to a minimum;
- Allow for as much local flexibility and discretion as is possible within the law;
- Ensure the most productive use of limited Federal resources;
- Protect the Federal interest in local investments; and
- Incorporate good management principles into the grant management process.

As mass transportation needs have changed over the years, so have the requirements for Federal financial assistance under the Federal transit laws and related statutes. FTA's regulatory priorities for 2002-2003 are to continue to issue rulemakings required under the Transportation Equity Act for the 21st Century (TEA-21), to amend existing regulations as needed, and to update existing regulations for plain language.

Maritime Administration (MARAD)

MARAD administers Federal laws and programs designed to promote and maintain a U.S. merchant marine capable of meeting the Nation's shipping needs for both national security and domestic and foreign commerce.

MARAD's regulatory objectives and priorities reflect the Agency's responsibility of ensuring the availability of adequate and efficient water transportation services for American shippers and consumers. To advance these objectives, MARAD issues regulations, which are principally administrative and interpretive in nature, when appropriate, in order to provide a net benefit to the U.S. maritime industry.

MARAD's regulatory priorities are to update existing regulations and to reduce unnecessary burden on the public.

Research and Special Programs Administration (RSPA)

The Research and Special Programs Administration (RSPA) has responsibility for rulemaking under two programs. Through the Associate Administrator for Hazardous Materials Safety, RSPA administers regulatory programs under Federal hazardous materials transportation law and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990. Through the Associate Administrator for Pipeline Safety, RSPA administers regulatory programs under the Federal pipeline safety laws and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990.

In the area of hazardous materials transportation, the regulatory priority is to clarify through rulemaking the applicability of regulations to the loading, unloading, and storage of hazardous materials incidental to their movement in commerce. Clarifying the applicability of the regulations will facilitate compliance with them and also clarify when other requirements of Federal, State, local, and tribal governments apply.

Bureau of Transportation Statistics (BTS)

The Bureau of Transportation Statistics (BTS) is responsible for collecting, compiling, analyzing, and making accessible information on the Nation's transportation systems; identifying needs for new information and analysis and implementing programs to meet those needs; and enhancing the quality and effectiveness of the Department's statistical programs through research, the development of guidelines, coordination with related information-gathering activities conducted by other Federal agencies, and the promotion of improvements in data acquisition, archiving, dissemination, and use.

BTS's Office of Airline Information (OAI) collects airline financial and operating statistical data, covering both passenger and cargo traffic. This information gives the Government consistent and comprehensive economic and market data on individual airline operations and is used, for instance, in supporting policy initiatives, negotiating international bilateral aviation agreements, awarding international route authorities, and meeting international treaty obligations. The aviation, travel, and tourism communities value this information for a variety of purposes, such as conducting analyses of on-time performance, denied boardings, market trends, and economic analyses.

During FY 2003, BTS will continue its efforts to develop a reporting system that would allow relevant causal information to be disseminated to the traveling public. This reporting system would enable the Department to better identify the causes of delays and evaluate its efforts to mitigate such causes. BTS' goal is to publish a final rule concerning airline delays and cancellations during FY 2003.

BTS' long-range regulatory priority in the aviation area is to conduct a complete review and modernization of the Passenger Origin and Destination Survey. BTS can make significant improvements by providing data to meet the needs of DOT and other users in a way that takes advantage of the information revolution and matches the dramatically changing airline industry.

BTS, in conjunction with the Office of the Secretary, is in the process of performing a zero-base review of the financial and traffic data to determine what, if any, revisions can be made to the current data collections to ensure that these collections fully support the Department's mandated aviation responsibilities. Moreover, the review will seek to identify potential savings to the affected air carriers and the Government that can be accomplished through the application of advanced information technologies to the collection, processing, validation, and dissemination of aviation data. BTS's review and modernization of the Passenger Origin and Destination Survey will be incorporated as part of this zero-base review.

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—Office of the Secretary (OST)

PROPOSED RULE STAGE

102. +COMPUTER RESERVATIONS SYSTEM REGULATIONS COMPREHENSIVE REVIEW

Priority:

Other Significant

Legal Authority:

49 USC 41712; 49 USC 40101(a); 49 USC 40113(a); 49 USC 40105

CFR Citation:

14 CFR 255; 14 CFR 399

Legal Deadline:

Final, Statutory, December 31, 1997.

Abstract:

The Department regulates computer reservations systems owned by airlines or airline affiliates that are used by travel agencies. The current rules are designed to prevent the systems from unreasonably prejudicing the competitive position of other airlines and to ensure that travel agencies can provide accurate and unbiased information to the public. The Department is reexamining its rules to see whether they should be readopted and, if so, whether they should be changed in response to greater use of the Internet in airline reservations and ticketing and changes in the industry. The Department is also reviewing its policies on the requirements for advertising fares by airline travel agencies that charge fees for brokering airline tickets. As part of this action, we will be looking at ways to lessen impacts on small entities.

Statement of Need:

The Department's existing rules require the Department to reexamine whether the rules are necessary and effective. In addition, two developments since the Department's last review of rules necessitate a reexamination. Those developments are the growing role of the Internet in airline distribution and the decline in airline control of the systems. A number of airlines obtain a large share of their bookings from their own Web sites, online travel agencies account for a significant share of all airline bookings, and the two largest systems operating in the United States are not owned by any airline.

Summary of Legal Basis:

The Department has the authority under 49 U.S.C. 41712 to prohibit unfair and deceptive practices and unfair methods of competition in the sale of air transportation by airlines and ticket agents. The Department accordingly may prohibit conduct by airlines and ticket agents that is likely to cause deception or violate the antitrust laws or antitrust principles. The original CRS rules were affirmed in United Air Lines v. CAB, 766 F.2d 1107 (7th Cir. 1985).

Alternatives:

The Department will consider alternatives ranging from allowing some or all of the rules to expire at their sunset date to readopting the rules with some additional provisions. The Department has issued two advance notices of proposed rulemaking asking for comment on whether the rules remain necessary in light of the developments in airline distribution and the systems' declining airline control and on whether rules are necessary for governing the sale of airline services through the Internet. The rules can be phased out or eliminated, along with comment on whether the rules should be strengthened in several respects raised by the comments on the advance notices of proposed rulemaking.

Anticipated Cost and Benefits:

The Department will include a preliminary regulatory evaluation in its notice of proposed rulemaking.

Risks:

The Department found in its last overall review of the rules that the systems had the ability and potential incentives to engage in conduct that could prejudice airline competition and cause consumers and their travel agents to receive misleading and inaccurate information on airline services. Systems could also engage in practices that would deny airlines and travel agencies a reasonable opportunity to use alternative electronic services that would provide information and booking capabilities. The rules may also impose costs on the systems and airlines. The Department will ask for comment on whether the risks still exist and, if so, whether the costs imposed by the rules outweigh the benefits provided by the rules.

Timetable:

Action	Date	FR Cite
ANPRM	09/10/97	62 FR 47606
Notice Extending Comment Period	10/30/97	62 FR 58700
Request for Comments	11/07/97	62 FR 60195
ANPRM Comment Period End	11/10/97	
Extended Comment Period End	12/09/97	
Notice Extending Reply Comment Period	01/23/98	63 FR 3491
Extended Comment Period End	02/03/98	
SANPRM	07/24/00	65 FR 45551
SANPRM Comment Period End	09/22/00	
SANPRM Reply Comment Period End	10/23/00	
NPRM	01/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

The extensions for the existing rule are under RINs 2105-AC75 and 2105-AD00 and AD09.

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RIN: 2105–AC65

DOT—U.S. Coast Guard (USCG)

FINAL RULE STAGE

103. +SALVAGE AND MARINE FIREFIGHTING REQUIREMENTS; VESSEL RESPONSE PLANS FOR OIL (USCG-1998-3417)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

33 USC 1321

CFR Citation:

33 CFR 155

Legal Deadline:

None

Abstract:

Current vessel response plan regulations require that the owners or operators of vessels carrying groups I through V petroleum oil as a primary cargo identify in their response plans a salvage company with expertise and equipment, and a company with firefighting capability that can be deployed to a port nearest to the vessel's operating area within 24 hours of notification (groups I-IV) or a discovery of a discharge (group V). Numerous requests for clarification revealed widespread misunderstanding and confusion regarding the regulatory language, which will make the implementation of this requirement difficult. Based on comments received after the Vessel Response Plan final rule publication (61 FR 1052; January 12, 1996) and during a Coast Guard hosted workshop, the Coast Guard intends to better define the terms ''salvage expertise and equipment'' and ''vessel firefighting capability'' requirements and will reconsider the 24-hour deployment requirement which was scheduled to go into effect on February 18, 1998. Therefore, the Coast Guard suspended the effective dates of the 24-hour deployment requirements as published in the final rule. The Coast Guard will continue with this project to better define the requirements. This rulemaking supports the Coast Guard's strategic goals of maritime safety and protection of the natural resources. This rulemaking is also significant because it concerns a matter of substantial public interest or controversy.

Statement of Need:

This rulemaking is intended to reduce the impact of oil spills from vessels.

Summary of Legal Basis:

The statutory authority for this rulemaking is 33 U.S.C. 1321.

Alternatives:

The Coast Guard hosted a workshop to solicit comments from the public on potential alternatives to the salvage and marine firefighting requirements contained in the vessel response plan rule.

Anticipated Cost and Benefits:

Undetermined

Risks:

Response plans are required by statute. A response plan will not prevent a discharge of oil, but it may help minimize the discharge and resulting damage to the environment. We estimate the provisions included in the salvage and firefighting requirements will prevent approximately 85,000 barrels of oil from entering the water during the next 25 years. As a point of reference, we further estimate the eleven major Oil Pollution Act of 1990 rulemakings will prevent approximately 1.2 million barrels of oil from entering the water over that same period. Consequently, the salvage and firefighting rulemaking represents a significant portion of the benefits to sociey of OPA 90.

Timetable:

Action	Date	FR Cite
Final Rule - Partial Suspension	02/12/98	63 FR 7069
Final Rule - Partial Suspension	01/17/01	66 FR 3876
NPRM	05/10/02	67 FR 31868
Public Meeting 7/9/02, 7/17/02, 7/25/02	06/12/02	67 FR 40254
Public Meeting 9/26/02	08/07/02	67 FR 51159
NPRM Comment Period Extended	08/07/02	
NPRM Comment Period End	10/18/02	
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Partial suspension of regulations created through the Vessel Response Plan final rule, docket no. 91-034, RIN 2115-AD81. The project was originally titled ''Salvage and Firefighting Equipment; Vessel Response Plans.'' The change was made in order to distinguish this project from other similarly titled projects within the Coast Guard.

URL For More Information:

http://dms.dot.gov

URL For Public Comments:

http://dms.dot.gov

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Related RIN: Related To 2115-AD81

RIN: 2115–AF60

DOT—Federal Aviation Administration (FAA)

PROPOSED RULE STAGE

104. +FLIGHT CREWMEMBER DUTY PERIOD LIMITATIONS, FLIGHT TIME LIMITATIONS, AND REST REQUIREMENTS

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 44101; 49 USC 44701 to 44701; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44712; 49 USC 44713; 49 USC 44715; 49 USC 44716 to 44717; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912

CFR Citation:

14 CFR 121; 14 CFR 135

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulations on duty period limitations, flight time limitations, and rest requirements for flight crewmembers engaged in air transportation. The FAA proposes additional changes in response to comments received on the NPRM. The changes are necessary to ensure that the rules will continue to provide the minimum level of safety. This rulemaking responds to public and congressional interest in regulating flight crewmember rest requirements, NTSB Safety Recommendations, petitions for rulemaking, and scientific data. This action is considered significant because of substantial public interest.

Statement of Need:

The aviation community requires 24-hour activities to meet operational demands. Growth in long-haul,

regional, overnight cargo, and short-haul domestic operations is increasing. Therefore, shift work, night work, irregular work schedules, and time-zone changes will continue to be commonplace.

With this growth, the scientific knowledge about sleep, sleep disorders, circadian physiology, fatigue, and performance decrements has also grown. Some of the scientific knowledge has indicated that aviators experience performance-impairing fatigue from sleep loss resulting from current flight and duty practices.

In addition, industry and individuals have told the FAA that the current regulations are confusing and difficult to enforce. Therefore, a second purpose of the rulemaking is to establish consistent and clear duty-period limitations and rest requirements for all types of operations.

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:

One obvious alternative would be to continue with the current rules; however, these regulations are rapidly becoming obsolete. As a second alternative, one commenter asked that the FAA develop a standard and then allow each carrier to design a rest/duty program that would meet that standard while accommodating differences in operations. While this works for certain rules, such as training regulations where the standard is training to proficiency, there is no way to apply this application to individual pilots on a daily basis.

Anticipated Cost and Benefits:

Undetermined.

Risks:

Although there has been only one identifiable accident due to pilot fatigue, fatigue is increasingly becoming the focus of possible causes following all accidents. Pilot reports of being fatigued to the point of incapacity are not uncommon, and intuitively, it is reasonable, given the sheer volume of air traffic, to expect fatigue to be a factor in future accidents if the regulations are not corrected.

Timetable:

Action	Date	FR Cite
NPRM	12/20/95	60 FR 65951
NPRM Comment Period End	03/19/96	
NPRM Comment Period Extended to 6/19/96	03/20/96	61 FR 11492
SNPRM	11/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Project Number: AFS-94-443R

ANALYSIS: Regulatory Evaluation, 12/20/95, 60 FR 65951

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RIN: 2120–AF63

DOT—FAA

FINAL RULE STAGE

105. +IMPROVED FLAMMABILITY STANDARDS FOR THERMAL/ACOUSTIC INSULATION MATERIALS USED IN TRANSPORT CATEGORY AIRPLANES

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 44701; 49 USC 44702; 49 USC 44704

CFR Citation:

14 CFR 25

Legal Deadline:

None

Abstract:

This document proposes upgraded flammability standards that specifically address flame propagation and entry of an external fire into the airplane (burnthrough) under realistic fire scenarios. The proposed standards are intended to reduce the incidence and severity of cabin fires, particularly those ignited in inaccessible areas where thermal/acoustic insulation materials are typically installed. Also the proposed standards would provide an increased level of safety with respect to post-crash fires by delaying the entry of such a fire into the cabin, thereby providing additional time for evacuation and enhancing survivability. The new standards would apply to new type designs, and newly manufactured airplanes entering parts 91, 121, 125, and 135 service. This action is significant because of substantial public interest.

Statement of Need:

Service history and laboratory testing demonstrate that the current flammability requirements applicable to thermal/acoustic insulation materials may not be providing the intended protection against the spread of fires. Additionally, the FAA considers that increased protection against external fire penetrating the fuselage can be provided by proper selection of the same material. These new test methods would not only provide for increased in-flight fire safety, by reducing the flammability of thermal/acoustic insulation blankets, but would provide increased time for evacuation during externally fed, post-crash fires by increasing fuselage burnthrough resistance.

Summary of Legal Basis:

49 USC 4401 empowers the Administrator to prescribe regulations and minimum standards in the interest of safety for aircraft and equipment.

Alternatives:

The FAA considered several options to identify the least intrusive and most cost-effective alternative to increase the level of safety for insulation materials. The alternatives considered were as follows: (1) Utilize the industry test instead of the requirements proposed; this would not screen out certain types of materials shown to propagate a fire under more realistic conditions, but would screen out the worst performers. (2) Limit replacement of insulation materials to only certain parts of the airplane; it is not feasible to specify areas of the airplane that are more crucial than others. This would be an economic consideration that would not address safety issues. (3) Change the

effectivity or compliance times to reduce the number of airplanes affected; the proposal will be designed to optimize costs versus benefits in this regard. Changes to either would be less than optimal. (4) Propose some combination of the above. Other combinations would either reduce the level of safety or be less cost effective.

Anticipated Cost and Benefits:

The total cost of this rule is $68.0 million, or $36.5 million discounted to present value if only blanket material changes are made to the aircraft. If manufacturers need to make configuration changes to the aircraft as well as material changes to their drawings, the FAA estimates that total costs would be $103.1 million or $68.2 million discounted to present value. The FAA is unable to quantify the benefits for this rule. However, preventing the loss of one airplane and its passengers over the 20-year period is not likely. Assuming such a loss would occur at the midpoint of the analysis, or in 2009, with 169 passengers, the nondiscounted loss would be $455.5 million, or $231.5 million discounted to present value (again, assuming society's willingness to pay $2.7 million to avoid a fatality). This loss does not include the value of the airplane. Even without loss of life, as several of the incidents show, a hull loss could exceed tens of millions of dollars. The FAA therefore has determined that this proposed rule would be cost beneficial.

Risks:

The FAA is aware of several events in which the flammability characteristics of thermal/acoustic insulation material may have been a contributing factor of airplane fires. The FAA initiated investigations and research to determine the appropriateness of applying existing Bunsen burner flammability criteria to thermal/acoustic insulation, as typically installed in concealed and inaccessible areas. This rule is necessary to decrease the risk of fires on airplanes and to improve airplane fire safety.

Timetable:

Action	Date	FR Cite
NPRM	09/20/00	65 FR 56992
NPRM Comment Period End	01/18/01	
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Project Number: ANM-99-086R.

Analysis: Regulatory Evaluation 12/00/2002.

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RIN: 2120–AG91

DOT—FAA

106. +CERTIFICATION OF AIRPORTS

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 44101; 49 USC 44701 to 44706; 49 USC 44709 to 40711; 49 USC 44713; 49 USC 44716 to 44717; 49 USC 44719; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912; 49 46105

CFR Citation:

14 CFR 121; 14 CFR 139

Legal Deadline:

None

Abstract:

This action proposes to revise the current airport certification regulation and to establish certification requirements for airports serving scheduled air carrier operations in aircraft with 10 to 30 seats. In addition, changes are proposed to address National Transportation Safety Board recommendations and petitions for exemptions and rulemaking. A section of an air carrier operation regulation also would be amended to conform with proposed changes to airport certification requirements. The FAA believes that these proposed revisions are necessary to ensure safety in air transportation and to provide a comparable level of safety at all certificated airports. This action is significant because of substantial public interest.

Statement of Need:

The last major revision to the airport certification regulation occurred in 1987, and since then, industry practices and technology have changed. To respond to such changes, the FAA is proposing to revise the regulation to clarify and update several requirements. Additionally, with the passage of the 1996 FAA Reauthorization Act, Congress provided the FAA the necessary authority to certificate airports serving scheduled air carrier operations with 10- to 30-seat aircraft, except in the State of Alaska (in addition to existing authority to regulate airports serving air carrier operations using aircraft with more than 30 seats). To achieve a comparable level of safety at all covered airports, FAA now proposes to exercise this authority and amend the regulation to incorporate airports serving smaller air carrier aircraft into the FAA's airport certification program. Also, the 2000 FAA Reauthorization Act (P.L. 106-181) mandates publication of the NPRM within 60 days of the Act's enactment; and publication of the final rule within one year of the close of comment period for airports serving smaller air carrier aircraft.

Summary of Legal Basis:

FAA has general and specific authority to regulate airports as set out in 49 USC 106(g) and 44701.

Alternatives:

The FAA has considered several alternative approaches to this proposed rulemaking and has attempted to minimize the potential economic impact of the proposal, especially the impact on small entities. In addition, this action fulfills the FAA's responsibility to meet deadlines established by Congress to certificate airports serving scheduled air carrier operations with 10- to 30-seat aircraft, except for the State of Alaska. The FAA considered alternatives based on two issues. Issue 1 was the revision of 14 CFR 139, and Issue 2 was the certification of airports serving scheduled operations of small air carrier aircraft with 10 to 30 passenger seats. The FAA determined that it was necessary to revise 14 CFR 139 and that the revised part 139 should include the certification of airports serving scheduled air carrier operations with 10- to 30-passenger seat aircraft.

Anticipated Cost and Benefits:

Most of the costs of this proposed rule are associated with the proposed improvements to safety and operational

requirements. Most of these costs result from the expansion of ARFF services. The present value of the total cost of the rule over a 10-year period is approximately $46 million, which includes training, additional emergency response protection, wildlife management, and an updated airport certification manual that better reflects current best practices. With the tremendous cost of aviation accidents, the proposed rule provides the potential for enhanced safety for a reasonable cost. The expected benefit of this proposed rule is an enhanced level of safety resulting in reduced fatalities, injuries, and property damage at airports with scheduled air carrier operations, particularly operations in aircraft configured with 10 to 30 passenger seats. The cost of a single accident of a 30-seat scheduled passenger aircraft is greater than the total cost of the proposal. Other benefits of this proposal include provisions for snow and ice control, wildlife management, and training.

Risks:

The purpose of this rulemaking is to expand and enhance the safety benefits of the current regulation by providing, to the extent possible, a comparable level of safety at all airports used by air carriers.

Timetable:

Action	Date	FR Cite
NPRM	06/21/00	65 FR 38636
Correction	08/21/00	65 FR 50669
NPRM Comment Period Extended	08/22/00	65 FR 50945
NPRM Comment Period End	09/19/00	
NPRM Comment Period End	11/03/00	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Project Number: AAS-97-072R.

ANALYSIS: Regulatory Evaluation, 06/21/00

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RIN: 2120–AG96

DOT—Federal Motor Carrier Safety Administration (FMCSA)

FINAL RULE STAGE

107. +HOURS OF SERVICE OF DRIVERS; DRIVER REST AND SLEEP FOR SAFE OPERATIONS (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

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 31136; 49 USC 31502; PL 74-255; PL 84-939; PL 98-554; PL 103-311; PL 104-59; PL 104-88; PL 106-159

CFR Citation:

49 CFR 1.73; 49 CFR 395

Legal Deadline:

Final, Statutory, November 5, 1999, PL 104-88, sec 408(b).

Abstract:

This action would revise the regulations for commercial motor vehicle driver rest requirements and duty-period limitations for safe highway transportation. A broad rulemaking was required by the ICC Termination Act of 1995 (ICCTA), Pub. L. 104-88. There is substantial public and congressional interest in the regulation of medium- and heavy-duty truck and bus drivers' sleep, off-duty, and working periods of time. This action is one of the 23 ''high priority'' rule reform nominations in the 2001 cost benefit report.

Statement of Need:

Growth in long-haul, regional, overnight, local, for-hire and private carriage operations has kept pace with the growth of the U.S. economy. The scientific knowledge about sleep, sleep disorders, circadian physiology, fatigue, and performance decrements has also grown. The agency intends to incorporate as much of the scientific knowledge as possible into the regulations.

Summary of Legal Basis:

Section 408 of the ICC Termination Act of 1995 (Pub. L. 104-88, December 29, 1995) requires the Federal Highway Administration (functions transferred to the Federal Motor Carrier Safety Administration under Pub. L. 106-159) to issue a final rule dealing with a variety of fatigue-related issues pertaining to commercial motor vehicle safety (including 8 hours of continuous sleep after 10 hours of driving, loading and unloading operations, automated and tamper-proof recording devices, rest and recovery cycles, fatigue and stress in longer combination vehicles, fitness for duty, and other appropriate regulatory and enforcement countermeasures for reducing fatigue-related incidents and increasing driver alertness).

The FY 2001 Department of Transportation Appropriations Act, Pub. L. 106-346, included language prohibiting the Department from adopting a final rule before October 1, 2001.

Alternatives:

FMCSA received more than 53,000 comments on the NPRM. The agency is committed to fully exploring all issues and concerns of stakeholders; eight public hearings were held in May, June and July 2000; and three additional roundtables were held in September and October 2000. The roundtables drew broad public participation and elicited in-depth discussion and exchange of supporting data on critical issues, including issues surrounding the economic analyses and assumptions used by the agency. This will help FMCSA identify any necessary changes to the proposal that would address stakeholders' divergent concerns and support the development of a successful rule.

Anticipated Cost and Benefits:

FMCSA has placed a Preliminary Regulatory Evaluation of the NPRM in the docket.

Risks:

Driver reports of being fatigued to the point of incapacity are not uncommon, and it is reasonable to expect fatigue to be a factor in future crashes if the regulations are not corrected. FMCSA has established a goal to reduce by 50 percent over ten years the number of

fatalities from crashes involving any commercial motor vehicle.

Timetable:

Action	Date	FR Cite
ANPRM	11/05/96	61 FR 57251
Notice of Meeting	02/11/97	62 FR 6161
ANPRM Comment Period End	03/31/97	
NPRM	05/02/00	65 FR 25540
Notice of Hearing	05/05/00	65 FR 26166
Notice of Hearing	05/22/00	65 FR 32070
Notice of Change in Hearing Structure	05/26/00	65 FR 34132
NPRM; Correction	05/31/00	65 FR 34904
Notice of Hearing	06/12/00	65 FR 36809
Comment Period Extended	06/19/00	65 FR 37956
Comment Period Extended; Roundtable Meetings	08/15/00	65 FR 49780
NPRM Comment Period End	12/15/00	
Final Action	03/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

State, Local, Federal

Federalism:

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

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RIN: 2126–AA23

DOT—FMCSA

108. +LIMITATIONS ON ISSUANCE OF COMMERCIAL DRIVER'S LICENSE WITH HAZARDOUS MATERIALS ENDORSEMENT

Priority:

Other Significant

Legal Authority:

49 USC 5103a; PL 107-56, sec 1012

CFR Citation:

49 CFR 383

Legal Deadline:

None

Abstract:

This rule would amend the Federal Motor Carrier Safety Regulations to prohibit States from issuing, renewing, transferring, or upgrading a commercial driver's license to transport hazardous materials unless and until the U.S. Department of Justice first conducts a background records check of the applicant and the U.S. Department of Transportation determines that the applicant does not pose a security risk which would warrant denial of the hazardous materials endorsement. This interim final action is required by section 1012 of the USA PATRIOT Act of 2001. This action is considered significant because of significant public interest in security issues since the events that occurred on September 11, 2001.

Statement of Need:

National security and intelligence officials continue to warn that future terrorist attacks against civilian targets are possible. One potential method could include obtaining hazardous materials for malicious purposes. This action responds to the requirement of section 1012 of the USA PATRIOT Act which is intended to make obtaining a hazardous materials endorsement difficult for those intending to do harm to the United States.

Summary of Legal Basis:

In response to the events of September 11, 2001, Congress passed the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Pub. L. 107-56, October 26, 2001, 115 Stat. 272). Section 1012 of the USA PATRIOT Act (115 Stat. 396) amended the Hazardous Materials Transportation Act (49 U.S.C. chapter 51) by adding new section 5103a(a)(1), Limitation on issuance of hazmat licenses. Further, section 1012(b) of the USA PATRIOT Act amended the fitness and testing standards of the Commercial Motor Vehicle Safety Act of 1986, which created the Commercial Driver's License (CDL) Program (49 U.S.C. 31305(a)(5)(C)).

Alternatives:

The purpose of section 1012 of the USA PATRIOT Act is to obstruct potential terrorists from gaining access to hazardous materials. If other, less costly methods were available to attain the same end, they would be employed. However, FMCSA does not believe any such alternatives exist.

Anticipated Cost and Benefits:

This rule will not have a significant impact on a substantial number of small entities because the impact of the rule will be gradual. Nonetheless, a regulatory analysis was prepared and placed in the docket.

Risks:

A failure to require background records checks of hazardous materials drivers could pose a national security risk.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State

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RIN: 2126–AA70

DOT—National Highway Traffic Safety Administration (NHTSA)

PROPOSED RULE STAGE

109. +FRONTAL OFFSET PROTECTION

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 establishing a Federal motor vehicle safety standard for high-speed frontal offset crash testing. The frontal offset test is a crash test for automobiles and light trucks in which the subject vehicles are run into a deformable honeycomb barrier. The barrier contacts only 40 percent of the front of the vehicle, simulating an off-center frontal collision. The agency is considering adding the offset test to the frontal occupant protection standard to measure vehicle structural integrity and reduce the number and severity of lower-body injuries.

Statement of Need:

While the Federal motor vehicle safety standards already contain a frontal crash test, injuries and fatalities still occur in various types of frontal crashes. The European Union determined that the best test for frontal occupant protection would be an offset test with belted test dummies. As part of the House of Representatives Conference Report 104-785, to accompany H.R. 3675, the National Highway Traffic Safety Administration was directed on September 16, 1996, to conduct research ''...toward establishing a Federal motor vehicle safety standard for frontal offset crash testing.'' Such a standard would be largely harmonized with the European Union frontal crash standard. Subsequent research results with the 50th percentile male and the 5th percentile female Hybrid III dummies suggest that additional safety benefits would be provided under the offset test conditions.

Summary of Legal Basis:

Section 30111, title 49 of the United States Code, states the Secretary shall prescribe motor vehicle safety standards. As part of the House of Representatives Conference Report 104-785, to accompany H.R. 3675, the National Highway Traffic Safety Administration was directed on September 16, 1996, to conduct research ''...toward establishing a Federal motor vehicle safety standard for frontal offset crash testing.''

Alternatives:

The agency will focus on existing test procedures. However, the agency is working through the national and international biomechanical engineering community to develop better test devices such as improved dummy legs. Comments will be sought on the best dummy designs in the agency's proposal.

Anticipated Cost and Benefits:

The agency is evaluating the benefits and costs associated with requiring an offset frontal crash test procedure in FMVSS No. 208. Additional vehicle crash tests with advanced lower-leg instrumentation and new injury criteria are being conducted to develop comprehensive benefits estimates. The agency is also studying the societal costs associated with long-term lower-leg impairment.

Risks:

Current motor vehicles provide numerous occupant protection systems, such as safety belts and strategically placed energy absorption materials such as foam padding. However, an estimated 3,300 people per year are killed and 400,000 people per year are injured in frontal offset crashes. While lower-extremity injuries are rarely fatal, they do account for substantial societal costs associated with long-term impairment.

NHTSA is also examining whether implementing a new offset test might create disbenefits in other crash modes such as side impacts.

Timetable:

Action	Date	FR Cite
NPRM	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

In December 2001, the Office of Management and Budget (OMB) sent a prompt letter to NHTSA suggesting that it give higher priority to this rulemaking. NHTSA advised OMB that it is making offset frontal crash protection one of its highest safety rulemaking priorities.

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Related RIN: Related To 2127-AI39

RIN: 2127–AH73

DOT—Federal Railroad Administration (FRA)

FINAL RULE STAGE

110. +STANDARDS FOR DEVELOPMENT AND USE OF PROCESSOR-BASED SIGNAL AND TRAIN CONTROL SYSTEMS

Priority:

Other Significant

Legal Authority:

49 USC 20103

CFR Citation:

49 CFR 234; 49 CFR 236; 49 CFR 209

Legal Deadline:

None

Abstract:

Consistent with congressional mandate, FRA has continued its commitment to supporting Positive Train Control (PTC) technology development, testing and compatibility; and promoting deployment of PTC technology in the near future. In September 1997, FRA initiated joint fact-finding efforts through the Railroad Safety Advisory Committee (RSAC) Working Group on PTC. The advice and recommendations of RSAC formed the basis of an NPRM that would facilitate introduction of advanced technology, including systems that support PTC functions. The NPRM addresses technical standards for all processor-based signal and train control products, amending 49 CFR part 236. The comment period ended 11/08/01, and FRA is now preparing a final rule.

Statement of Need:

Current FRA regulations do not adequately address the use of signal and train control technology that is

processor-based. In fact, application of current regulations to processor-based systems can create unnecessarily burdensome requirements. Recently, use of this technology has begun to increase on the general system of North American railroads, placing new demands on agency resources to ensure the safety objectives contemplated by the current regulations are achieved. The existence of Federal regulations addressing this subject matter would further encourage safe use of the technology, which would reduce the risk of train-to-train collisions, better enforce speed restrictions, and increase the level of protection to roadway workers and their equipment. These improvements will likely result in fewer fatalities, injuries, and economic damage associated with such risks. Given the potential for substantial safety benefits that this program represents, this initiative is extremely important to the agency.

Summary of Legal Basis:

FRA is issuing this rule pursuant to its general rulemaking authority (49 U.S.C. 20103(a)). Currently, railroads may discontinue or materially alter a signal system initially required by the Secretary of Transportation only with approval from the Secretary (49 U.S.C. 20502). Exercise of both of these powers has been delegated to the FRA Administrator (49 C.F.R. 1.49).

Alternatives:

Currently, FRA accepts waiver applications from railroads that seek relief from FRA safety regulations in order to test new signal and train control equipment. Since FRA must consider the safety ramifications of each application on a case-by-case basis, this procedure can take years.

Prior to this action, FRA considered: (1) leaving the existing regulatory requirement as is, and (2) adopting a single standard for the design of processor-based signal and train control systems. However, agency inaction would hinder introduction of new, safer technology into railroad signal and train control; elimination of all railroad signal and train control system regulation would be a total abdication of the agency's statutory duties; and a single design standard would inhibit innovative signal and train control system designs.

Anticipated Cost and Benefits:

The proposed rule would provide flexible performance standards for the design of processor-based signal and train control systems, but would not mandate their usage. FRA believes that a railroad would adopt such a system under one or more of the following conditions: (1) the new system is safer; (2) the new system is less expensive; and (3) continued maintenance of the existing system is no longer feasible. The rule would ensure that any replacement system is at least as safe as the current system. Concerning existing processor-based systems, the rule would require railroads to adopt a software management plan, which will ensure proper software configuration, resulting in decreased risk of train accidents due to signal malfunction. FRA has not quantified these benefits because of the difficulties in estimating how many systems are likely to be affected by this rule, what the incremental cost would be, and when the benefits would accrue.

Most of the costs of this proceeding are associated with safety documentation required to demonstrate compliance with the performance standard. As with many performance standards, this rule would require substantial safety documentation from the railroad to demonstrate compliance, both up front and during the life cycle of the system. It appears that the primary cost involved in this rule would be the product risk assessment, a one-time expense presently incurred by product suppliers. For current processor-based systems, railroads face the cost of implementing a software management control plan, which is less expensive than attempting to satisfy current requirements, which did not contemplate the use of processor-based technology.

Overall, it appears that the benefits of the rule would outweigh the costs.

Risks:

The risk category addressed by the proposed rule is that of accidents that occur due to improper train operations and certain types of vandalism. Types of accidents that may be prevented include train-to-train collisions, derailments due to excessive train speed, and trains penetrating the work limits of roadway workers.

Timetable:

Action	Date	FR Cite
NPRM	08/10/01	66 FR 42351
NPRM Comment Period End	11/08/01	
Final Rule	06/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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DOT—Research and Special Programs Administration (RSPA)

PROPOSED RULE STAGE

111. +PIPELINE SAFETY: PIPELINE INTEGRITY MANAGEMENT IN HIGH-CONSEQUENCE AREAS (GAS TRANSMISSION PIPELINE OPERATORS)

Priority:

Other Significant

Legal Authority:

49 USC 5121; 49 USC 60102 to 60104; 49 USC 60108, 60117, 60118, 60124; 49 CFR 1.53

CFR Citation:

49 CFR 192

Legal Deadline:

None

Abstract:

An October 21, 1999, notice announced a public meeting to consider the need for additional safety and environmental regulations for gas transmission lines, hazardous liquid pipelines, and distribution pipelines in high-density population areas, commercially navigable waterways, and areas unusually sensitive to environmental damage. The public meeting was held on November 18-19, 1999 in Herndon, Virginia. The meeting was to determine the extent to which operators now have integrity management programs, to explore effective ways to promote their development and implementation by all operators, and to discuss mechanisms to confirm the adequacy of such operator-developed programs. Participants in the meeting discussed

a practical definition of high-consequence areas, as well as the need, if any, for increased inspection, enhanced damage prevention, improved emergency response, and other measures to prevent and mitigate pipeline leaks and ruptures in these areas. Comments from the public were due by January 17, 2000.

A final rule was published to require validation/testing of the integrity of certain hazardous liquid pipelines in high-consequence areas (RIN 2137-AD45).

Consideration of a similar gas rule is underway. A public meeting was held on February 12-14, 2001 to present information on integrity requirements for gas transmission pipelines. Additional information was requested June 27, 2001 (66 FR 34318). Rulemakings addressing gas transmission line high-consequence areas, direct assessment, and overall integrity management program will be published in 2002.

Statement of Need:

This action would address risks that have evolved as a growing economy brought people closer and closer to pipelines that are constructed in once rural areas. This action would provide added protection to areas where a gas release could do the greatest harm to people, and increase the public's assurance about the safety of pipelines.

In addition, this action would address four recommendations from the National Transportation Safety Board (NTSB): (1) require periodic testing and inspection to identify corrosion and other time-dependent damage; (2) establish criteria to determine appropriate intervals for inspections and tests, including safe service intervals between pressure testing; (3) determine hazards to public safety from electric resistance welded (ERW) pipe and take appropriate regulatory action; and (4) expedite requirements for installing automatic or remote-operated mainline valves on high-pressure lines to provide for rapid shutdown or failed pipeline segments.

Summary of Legal Basis:

Section 60102 of title 49, United States Code, provides broad authority to address pipeline operations and maintenance. In addition, paragraph (f) of that section requires that the Department prescribe, if necessary, additional standards requiring the periodic inspection of pipelines in high-density population areas, to include any circumstances when an instrumented internal inspection device, or similarly effective inspection method, should be used to inspect the pipeline (49 U.S.C. 60102(f)(2)). Paragraph (j) of that section requires that the Department prescribe standards on the circumstances where an operator of a gas transmission pipeline facility must use remote control valves to shut off the flow of natural gas in the event of a rupture of an interstate natural gas pipeline facility. (49 U.S.C. 60102(j)).

Alternatives:

The Office of Pipeline Safety considered several alternatives to provide the necessary increased level of protection to high consequence areas. These alternatives were: (1) no action; (2) prescriptive requirements for inspection and repair of pipelines in high consequence areas; (3) requiring pipeline operators to develop integrity management programs providing for inspection and testing based on risk factors and integration of information related to pipeline risk; and (4) requiring pipeline operators to develop integrity management programs providing for expedited inspection and testing.

Anticipated Cost and Benefits:

RSPA has estimated the following costs and benefits from the gas integrity management rulemaking and they have been subjected to peer review by the technical advisory committee charged by statute with reviewing the costs and benefits of proposed regulation.

For option 3, costs for the first year are estimated at $250M; for years 2-10 at $90M/year; and years 11-20 at $65M. In addition to a large amount of qualitative benefits, quantified benefits are estimated to be on order of $40 million annually.

Risks:

In conjunction with the existing pipeline safety requirements, this action creates a protective superstructure through more comprehensive assessment, repair, preventive, and mitigative actions in those areas (high consequence areas) where a failure would do the greatest damage. This assessment process will produce better information about problems that may have been missed and creates checks and balances to assure that the best use is made of available information to correct the problems.

Timetable:

Action	Date	FR Cite
NPRM - Integrity Management Program	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Docket No. RSPA-00-7666.

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RIN: 2137–AD54

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DEPARTMENT OF THE TREASURY (TREAS)

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are:

- To promote prosperous and stable American and world economics, 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 and collecting the correct amount of revenue under the Internal Revenue Code and customs laws, financing the Federal Government and managing its fiscal operations, and producing our Nation's coins and currency; and
- To safeguard our financial systems, protect our Nation's leaders, and secure a safe and drug-free America by enforcing laws relating to counterfeiting, Federal Government securities, firearms and explosives, money laundering, border security, foreign commerce in goods and financial instruments, and smuggling and trafficking in contraband; protecting the President, Vice President, certain foreign diplomatic personnel, and others; and training Federal, State, and local law enforcement officers.

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, 2002, the President signed the USA PATRIOT Act of 2001 into law on October 26, 2001. Over the past year, the Department of the Treasury has accorded the highest priority to developing and issuing regulations to implement the provisions in this historic legislation that target money laundering and terrorist financing. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Financial Crimes Enforcement Network (FinCEN). Also over the past year, the U.S. Customs Service has undertaken important regulatory initiatives to enhance our Nation's border security. These efforts will also continue during the coming year and are reflected in the regulatory priorities of the U.S. Customs Service.

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.

Financial Crimes Enforcement Network

The regulations of the Financial Crimes Enforcement Network (FinCEN) constitute the core of Treasury's anti-money laundering initiatives and are an essential component of Treasury's anti-narcotics effort. FinCEN's regulations implement the Bank Secrecy Act (BSA), as amended in October 2001 by the USA PATRIOT Act. The BSA authorizes the Secretary of the Treasury to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, or regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures. FinCEN is working closely with the Treasury Offices of the General Counsel, Enforcement, and Financial Institutions to develop regulations to implement the amendments to the BSA made by the USA PATRIOT Act that target money laundering and terrorist financing.

FinCEN's regulatory priorities for fiscal year 2003 include the following projects, all of which are related to the events of September 11, 2001:

- *Due Diligence for Correspondent Accounts and Private Banking Accounts*. This final rule would implement 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 banking accounts established or maintained for non-U.S. persons.
- *Foreign Shell Banks and Recordkeeping for Foreign Banks with U.S. Correspondent Accounts*. This final rule would implement section 313 of the USA PATRIOT Act, which prohibits certain financial institutions from providing correspondent accounts in the United States to foreign shell banks (banks without a physical presence in any country) and requires certain financial institutions to take reasonable steps to ensure that correspondent accounts are not being used indirectly by foreign shell banks. The final rule would also implement section 319(b) of the USA PATRIOT Act, which requires certain financial institutions that provide correspondent accounts to a foreign bank to maintain records of the foreign bank's owners and agent in the United States designated to accept service of legal process regarding the correspondent account.
- *Anti-Money Laundering Programs*. These final and proposed rules would implement section 352 of the USA PATRIOT Act, under which financial institutions must adopt anti-money laundering programs. FinCEN expects to finalize rules proposed in April 2002 for banks and other depository institutions, casinos, securities broker-dealers, futures commission merchants, mutual funds, operators of credit card systems, and money services businesses. FinCEN also expects to issue a series of proposed rules for other financial institutions.
- *Customer Identification and Verification Procedures*. These final and proposed rules would implement section 326 of the USA PATRIOT Act, which mandates regulations requiring financial institutions to implement reasonable procedures for verifying the identity of customers opening an account, maintaining records of the information used to verify customer identity, and consulting lists of known or suspected terrorists or terrorist organizations. These procedures are required to be part of a financial institution's anti-money laundering program. FinCEN expects to finalize rules proposed in July 2002 for banks and other depository institutions, securities broker-dealers, futures commission merchants, and mutual funds and to publish proposed rules for other financial institutions.
- *Suspicious Activity Reporting*. FinCEN expects to issue a proposed rule to implement section 356(b) of the USA PATRIOT Act, which requires futures commission

merchants to report suspicious transactions.

United States Customs Service

The United States Customs Service (Customs) is responsible for, among other things, administering laws concerning the importation of goods into the United States. This includes inspecting imports, collecting applicable duties, overseeing the activities of persons and businesses engaged in importing, and enforcing the laws concerning smuggling and trafficking in contraband. During the past fiscal year, due to the events of September 11, 2001, Customs also stressed its role in border security and in defending our nation's homeland. The regulatory priorities of Customs for fiscal year 2003 are: to continue to facilitate procedures for legitimate commercial transactions; to provide further obstacles to the flow of narcotics and other contraband into the United States; and to help secure the nation's borders from the introduction into this country of terrorists and weapons of terrorism. Customs also expects a regulatory priority to be amending its regulations to reflect its anticipated transition from the Department of the Treasury to the Department of Homeland Security.

During fiscal year 2002, Customs issued the following rules relating to border security:

- *Passenger and Crew Manifests Required for Passenger Flights in Foreign Air Transportation to the United States*. This interim rule requires that each air carrier, foreign and domestic, operating a passenger flight in foreign air transportation to the United States electronically transmit to Customs in advance of arrival a passenger and crew manifest that contains certain specified information.
- *Passenger Name Record Information Required for Passengers on Flights in Foreign Air Transportation To or From the United States*. This interim rule requires that each air carrier must provide Customs with electronic access to Passenger Name Record information contained in the carrier's automated reservation system and/or departure control system that sets forth the identity and travel plans of any passengers on flights in foreign air transportation either to or from the United States.
- *Access to Customs Security Areas at Airports*. This interim rule enhances the security environment at airports in Customs security areas at airports that accommodate international air commerce.
- *Presentation of Vessel Cargo Declaration to Customs Before Cargo Is Laden Aboard Vessel at Foreign Port for Transport to the United States*. This notice of proposed rulemaking would require that vessel carriers destined for the United States provide advance and accurate presentation of manifest information to Customs prior to cargo being loaded on the vessels at foreign ports and encourages electronic presentation of the advance information.

During fiscal year 2003, Customs plans to continue issuing regulations to enhance border security. In addition to finalizing the proposed rule and interim rules described above, Customs plans to issue rules that require advance manifesting for other modes of transportation pursuant to the Trade Act of 2002.

During fiscal year 2002, Customs developed and issued several rules to implement various provisions of the Tariff and Suspension Act of 2000 concerning the importation of goods into the United States. Customs published proposed rules on the following subjects:

- *Single Entry for Split Shipments*. This proposed rule would establish procedures to allow a single entry for a split shipment.
- *Single Entry for Unassembled or Disassembled Entities Imported on Multiple Conveyances*. This proposed rule would allow for a single entry to cover multiple portions of a single entity which, due to its size or nature, arrives in the United States on separate conveyances.
- *Prototypes Used Solely for Product Development, Testing, Evaluation, or Quality Control Purposes*. This proposed rule would establish procedures for allowing the duty-free entry of prototypes that are to be used exclusively in product development, testing, evaluation, or quality control.

Customs plans to finalize these proposals during fiscal year 2003.

Customs also plans to continue moving forward with amendments to improve its regulatory procedures that 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. Customs will also continue to test new programs to see if they work before proceeding with proposed rulemaking to permanently establish the programs.

Consistent with the Customs Mod Act, Customs will accord priority to several projects to foster the development of a more automated environment to expedite the entry and release of imported merchandise, and the processing of merchandise for export. These regulations will benefit the importing and exporting public by streamlining the work of Customs officers and the trade community through improved efficiency and reduced paperwork and administrative costs. Among these projects are:

- *Liquidations*. Customs intends to propose regulations allowing paperless procedures for extension and suspension of liquidation notices, improving and clarifying the administrative process, and simplifying the regulations pertaining to liquidations and extensions and suspensions of liquidations.
- *Entry Reconciliation*. Customs will continue to develop through testing a ''reconciliation'' process that will allow the delayed submission to Customs of information that is undetermined at the time an entry summary or an import summary statement is required to be submitted. After Customs is satisfied with the testing, regulations will be proposed to allow reconciliation on a permanent basis.
- *Remote Location Filing*. Customs will continue to develop through testing the procedures that will allow electronic filing of entries with Customs from locations in the United States other than the port of arrival of the merchandise or the place at which the merchandise is examined. Remote location filing will provide entry filers (such as brokers and couriers) with greater flexibility and will allow Customs to make more efficient use of its resources. After Customs is satisfied with the testing, regulations will be proposed to allow remote location filing on a permanent basis.

In addition, Customs also plans to undertake several other regulatory actions that will affect the traveling and importing public, customs brokers, carriers, and commercial importers.

Internal Revenue Service

The Internal Revenue Service (IRS), 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 IRS 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 2003, the IRS will accord priority to the following regulatory projects:

- *Deduction and Capitalization of Costs To Create Intangible Assets.* Section 162 of the Internal Revenue Code allows a current deduction for ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business. Under section263(a) of the Internal Revenue Code, however, no immediate deduction is allowed for expenditures to acquire or create property with a useful life that extends substantially beyond the taxable year. Such expenditures are capital expenditures that generally may be deducted only in future taxable years as the property is used in the taxpayer's trade or business. In recent years, there has been much uncertainty and controversy regarding whether expenditures that produce or enhance intangible assets or benefits are currently deductible under section 162, or are capital expenditures under section 263(a). The IRS and Treasury intend to publish proposed regulations that clarify the circumstances in which taxpayers must capitalize expenditures to produce or enhance intangible assets or benefits. As a first step in this process, the IRS and Treasury issued an advance notice of proposed rulemaking on January 24, 2002, describing and explaining rules that they expect to propose in the regulations and requesting public comment on these rules.
- *R&E Credit.* Section 41 of the Internal Revenue Code provides a credit for increasing research expenditures. The R&E Credit has been the subject of significant controversy between the Internal Revenue Service and taxpayers. In December 2001, the IRS and Treasury issued proposed regulations that clarify the types of research expenditures eligible for the credit. After a full review of the comments received from taxpayers, the IRS and Treasury expect to issue further guidance in FY 2003.
- *Abusive Tax Avoidance Transactions.* In February 2000, the IRS and Treasury issued temporary regulations requiring taxpayers to disclose potentially questionable transactions on their returns and requiring promoters to register, and maintain lists of investors for, similar types of transactions. The Treasury issued its Enforcement Proposals for Abusive Tax Avoidance Transactions on March 20, 2002, and, among other things, indicated that these rules would be revised based on the disclosures that had been made under the existing temporary regulations. New regulatory guidance will be issued revising the definition the types of transactions covered by these rules. In addition, in January 2001, the IRS and Treasury issued proposed Circular 230 regulations governing practice before the IRS. In July 2002, a number of these proposed changes were finalized. Additional guidance covering opinion standards for certain types of transactions will be issued in FY 2003.
- *Qualified Tuition Programs.* Section 529 of the Internal Revenue Code provides tax-deferred growth on college savings that are contributed to a section 529 program. Congress made significant amendments to section 529 in the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA). Earnings on college savings in a section 529 program are excluded from the gross income of a student if used to pay qualified higher education expenses. The IRS and Treasury expect to issue regulations that will clarify various rules and definitions. Regulations are necessary because many taxpayers use a Qualified Tuition Program to save for college.
- *Losses on Consolidated Group Member Stock.* In response to Rite Aid v. United States, 255 F.3d 1357 (Fed. Cir. 2001), the IRS and Treasury will propose regulations to implement Notice 2002-11, 2002-7 I.R.B. 526, and Notice 2002-18, 2002-12 I.R.B. 644, which address the repeal of the General Utilities doctrine and duplication of losses if the stock of a member of a consolidated group is sold.
- *Cash Balance Pension Plans.* The IRS and Treasury will issue proposed regulations concerning approaches for cash balance plans to use to comply with the prohibition on discrimination on the account of age that is contained in the Internal Revenue Code, ERISA, and the Age Discrimination in Employment Act. A cash balance plan is a type of defined benefit plan under which benefits are calculated using a hypothetical account balance to which annual pay credits and interest credits are made. This proposed regulation will also address the circumstances in which a conversion from a traditional defined benefit pension plan to a cash balance plan is discriminatory on the account of age.
- *Split-Dollar Life Insurance Arrangements.* A split-dollar life insurance contract is an arrangement used to share or ''split'' the costs and benefits of a whole life insurance policy between two parties. Split-dollar insurance contracts usually arise in compensation-related and corporation-shareholder contexts, but have also been used in gift contexts. In a typical split-dollar insurance contract, an employer (the policy sponsor) agrees to contribute all or a significant portion of the premiums on a policy insuring the life of a key executive. Proposed regulations issued in July 2002 provide two mutually exclusive regimes to tax split-dollar life insurance arrangements for Federal income, employment, and gift tax purposes. Under the economic benefit regime, the owner of the life insurance contract is treated as providing current life insurance protection and other taxable economic benefits to the nonowner of the contract. Under the loan regime, the nonowner of the life insurance contract is treated as lending premium payments to the owner of the contract. If the loan from the non-owner does not provide for sufficient interest, the loan is a below-market loan, and is subject to imputations under section 7872 of the Internal Revenue Code as implemented by the proposed regulations. The IRS and Treasury

intend to issue additional guidance regarding the taxation of split-dollar life insurance arrangements in FY 2003.

- *Cost Sharing Arrangements.* Under existing regulations, affiliates within a multinational group may enter into so-called cost sharing arrangements and share the costs of developing intangibles in exchange for rights to exploit the resulting intangibles. Group affiliates that contribute pre-existing intangibles to the R&D effort must receive arm's length compensation (known as the buy-in) from the other affiliates participating in the arrangement. A number of technical issues have arisen that raise serious concerns that the cost sharing regulations are not operating in practice as intended. Treasury and the IRS anticipate issuing proposed amendments to the cost sharing regulations addressing these issues during FY 2003. In addition, Treasury and IRS anticipate following up the July 2002 issuance of proposed regulations addressing the treatment of stock option compensation under cost sharing arrangements with the issuance in FY 2003 of final regulations reflecting any revisions that may be appropriate in light of comments to be received on those proposed regulations.
- *Cross-Border Services.* Under existing regulations, if an affiliate within a multinational group provides services for other group affiliates' benefit, it must receive arm's length compensation (in certain cases cost reimbursement) from such other affiliates. A number of technical issues have arisen that raise serious concerns that the services regulations are not operating in practice as intended. Treasury and the IRS anticipate issuing proposed amendments to the services regulations addressing these issues during FY 2003.
- *Notices to Plan Participants.* Both the Internal Revenue Code and the Employee Retirement Income Security Act (ERISA) impose certain requirements on retirement plan administrators to provide notices to plan participants and beneficiaries about the plan benefits for which they are eligible. The IRS and Treasury will finalize guidance under section 204(h) of ERISA and section 4980F of the Internal Revenue Code on the requirements of the administrator of certain qualified retirement plans to provide notices to plan participants and others of certain reductions in the rate of future benefit accruals under the plan and the elimination or reduction of early retirement benefits or retirement-type subsidies. This guidance is needed in order to assist plan administrators in complying with their obligations and to ensure that participants receive the timely, understandable, and accurate notices required by the statute. In addition, the IRS and Treasury will revise existing regulations dealing with disclosure requirements to participants when a defined benefit pension plan offers participants a choice between a subsidized early retirement pension and a lump sum payment that does not include the subsidy. The new rules respond to complaints that employers are failing to warn participants that the lump sum distribution from the retirement plan that a participant may choose to receive is worth considerably less than the subsidized retirement annuity that is available to the participant.
- *Excess Parachute Payments.* Section 280G of the Internal Revenue Code imposes an excise tax on payments made to employees on account of a change in control of a corporation and denies the corporation the tax deduction for such payments. The IRS and Treasury will finalize proposed regulations that detail the way in which these rules work.
- *Nonwritten Consents To Disclose Return Information.* Prior to 1996, a taxpayer's request or consent to disclose his or her return information was required to be in written form. In 1996, section 1207 of the Taxpayer Bill of Rights II amended section 6103(c) of the Internal Revenue Code by removing the requirement that a request or consent authorizing the Service to disclose tax information to a third party designated by the taxpayer be in writing. Section 6103(c) provides that the Secretary may disclose returns or return information to a taxpayer's designee, subject to such requirements and procedures as the Secretary may prescribe by regulation. Temporary regulations were published in January 2001 authorizing the IRS to accept nonwritten requests or consents for disclosure in certain circumstances, providing parameters for developing consents applicable to the electronic filing program, easing the burden on taxpayers in combined Federal-State return filing programs, and clarifying the requirements for written consents. In FY 2003, the IRS and Treasury intend to issue final regulations regarding these important procedures.
- *New Markets Tax Credit.* Section 45D of the Internal Revenue Code, enacted as part of the Community Renewal Tax Relief Act of 2000, provides a credit for qualified equity investments in qualified community development entities that have received a new markets tax credit allocation. Temporary and proposed regulations were issued in December 2001, which provide guidance for taxpayers claiming the new markets tax credit under section 45D. The IRS and Treasury intend to issue additional guidance during FY 2003 in response to public comments that have been received.

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 new statutes. Possible statutory changes are not addressed in this regulatory plan, but may affect some of the planned rules directly, and likely would affect how the OCC prioritizes its regulatory workload.

Important final rules issued during fiscal year 2002 include:

- *Capital; Treatment of Recourse, Direct Credit Substitutes and Residual Interests in Asset Securitizations (12 CFR Part 3).* This rulemaking, issued jointly with the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision, amended the agencies' regulatory capital standards to change the treatment of certain recourse obligations, direct credit substitutes, residual interests, and other positions in securitized transactions that expose banking organizations to credit risk. This final rule amended the agencies' regulatory capital standards to align more closely the risk-based capital treatment of recourse obligations and direct credit substitutes, to vary the capital requirements for positions in securitized transactions (and certain other credit exposures) according to their relative risk, and required capital commensurate with the risks associated with residual interests.
- *Capital; Nonfinancial Equity Investments (Merchant Banking) (12 CFR Part 3).* This rulemaking, issued jointly with the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation, amended the agencies' capital guidelines to establish special minimum capital requirements for equity investments in nonfinancial companies. The new capital requirements, which apply symmetrically to equity investments of banks and bank holding companies, impose a series of marginal capital charges on covered equity investments that increase with the level of a banking organization's overall exposure to equity investments relative to the organization's Tier 1 capital.
- *Capital; Claims on Securities Firms (12 CFR Part 3).* This rulemaking, issued jointly with the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision, amended the agencies' risk-based capital standards with regard to the risk weighting of claims on, and claims guaranteed by, qualifying securities firms. This rule reduced the risk weight applied to certain claims on, and claims guaranteed by, qualifying securities firms in countries that are members of the Organization for Economic Cooperation and Development from 100 percent to 20 percent under the agencies' risk-based capital rules. This rule implemented a change made to the Basel Accord.
- *Operating Subsidiaries of Federal Branches and Agencies (12 CFR Parts 5 and 28).* This rulemaking provided that a Federal branch or agency may establish, acquire, or maintain an operating subsidiary in generally the same manner that a national bank may acquire or establish an operating subsidiary.
- *International Banking Activities: Capital Equivalency Deposits (12 CFR Part 28).* This rulemaking revised certain requirements regarding capital equivalency deposit arrangements to increase flexibility for and reduce burden on certain Federal branches and agencies, based on a supervisory assessment of the risks presented by the particular institution.
- *Electronic Activities (formerly Electronic Banking) (12 CFR Part 7).* This rulemaking facilitated national banks' ability to conduct business using electronic technologies, consistent with safety and soundness. The rule groups together new and revised regulations addressing: national banks' exercise of their Federally authorized powers through electronic means; the location, for purposes of the Federal banking laws, of a national bank that engages in activities through electronic means; and the disclosures required when a national bank provides its customers with access to other service providers through hyperlinks in the bank's Web site or other shared electronic ''space.''
- *Prohibition Against Use of Interstate Branches Primarily for Deposit Production (12 CFR Part 25).* This rulemaking, issued jointly with the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation, amended the regulatory prohibition against branches being used as deposit production offices to include any bank or branch of a bank controlled by an out-of-State bank holding company, including a bank consisting only of a main office. The rulemaking implemented section 109 of the Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994 to effectuate the amendment contained in section 106 of the Gramm-Leach-Bliley Act of 1999.
- *Debt Cancellation Contracts and Debt Suspension Agreements (12 CFR Part 37).* The OCC published a final rule that addresses debt cancellation contracts and debt suspension agreements. The purposes of the customer protections are to facilitate customers' informed choice about whether to purchase debt cancellation contracts and debt suspension agreements, based on an understanding of the costs, benefits, and limitations of the products and to discourage inappropriate or abusive sales practices. The final rule also promotes safety and soundness by requiring national banks that provide these products to maintain adequate loss reserves.

The OCC's regulatory priorities for fiscal year 2003 include projects in the following areas:

- *Implementation of a Revised Basel Capital Accord (formerly Domestic Capital Framework) (12 CFR Part 3).* The OCC plans to initiate one or more rulemakings to revise its regulatory capital requirements to take account of expected revisions to the 1988 Basel Accord. These rulemakings, which will be undertaken jointly with the other Federal banking agencies, will address the implementation of provisions of the revised Accord such as the internal ratings-based approach, as well as other revisions to the U.S. domestic capital framework that are appropriate in light of the revised Accord.
- *Capital; Securities Borrowing Transactions (12 CFR Part 3).* This final rule generally would lower the capital requirements for certain qualifying securities borrowing transactions by permitting the collateralized portion of the securities borrowing transactions to be subject to the market risk capital requirements at 12 CFR part 3, appendix B, as opposed to the risk-based capital requirements at 12 CFR part 3, appendix A. Among other things, in order to qualify for the lower market risk capital requirement under this joint interim rule, a bank must be subject to the market risk capital requirements, and the securities borrowing transaction must result in a receivable that arises from the posting of the cash collateral. Only the portion of the receivable

collateralized by the market value of the securities borrowed qualifies for the lower market risk capital requirement; noncollateralized portions must continue to be risk weighted under the risk-based capital guidelines.

- *Community Reinvestment Act Regulations (12 CFR Part 25).* The OCC, along with the other Federal banking agencies, published an advance notice of proposed rulemaking soliciting comments on ways to improve the CRA regulation. Based on the comments received, the OCC and other agencies will consider the need for changes to the CRA rules and will propose such changes as are deemed appropriate.
- *Implementation of Sections 1204-1206 of the Financial Regulatory Relief and Economic Efficiency Act of 2000 (the Act) (12 CFR Parts 5 and 7).* The OCC intends to initiate a rulemaking to implement the authority vested in national banks by the Act to reorganize into a holding company through a share exchange and to merge with a subsidiary or affiliate. The rulemaking may make other changes as well.
- *Fair Credit Reporting Act (12 CFR Part 41).* The OCC, along with the other Federal banking agencies, intends to publish a revised notice of proposed rulemaking to implement the affiliate-sharing provisions of the Fair Credit Reporting Act. This rulemaking would clarify the notice and opt-out obligations arising from the sharing of consumer information with affiliates.
- *Change in Business Plans (12 CFR Part 5).* The OCC intends to seek comment on a proposed rule that would require national banks to notify the OCC of material changes in business plans.
- *Suspension and Debarment of Accounts (12 CFR Part 19).* The OCC, along with the other Federal banking agencies, intends to issue proposed rules implementing the agencies' authority to suspend or debar accountants and accounting firms from performing the annual independent audits that are required by section 36 of the Federal Deposit Insurance Act (12 U.S.C. 1831m).

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, proactive approach to supervision.

OTS continues to work with the other Federal banking agencies on regulations where the agencies share the responsibility to implement statutory requirements. The agencies are working to update capital standards to maintain, and, where necessary, improve consistency in the agencies' rules. Regulatory projects in this area include the following:

- *Implementation of a Revised Basel Capital Accord.* The OTS plans to initiate one or more rulemakings to revise its regulatory capital requirements to take account of expected revisions to the 1988 Basel Accord. These rulemakings, which will be undertaken jointly with the other Federal banking agencies, will address the implementation of provisions of the revised Accord such as the internal ratings-based approach, as well as other revisions to the U.S. domestic capital framework that are appropriate in light of the revised Accord.

OTS and the other Federal banking agencies anticipate reproposing a rule implementing provisions of the Fair Credit Reporting Act (FCRA) concerning information sharing with affiliates. The agencies informed those institutions potentially affected by the rulemaking that any final rule would not apply to privacy notices sent before the effective date of the final FCRA rule.

The banking agencies are considering changes to the Community Reinvestment Act (CRA) rules, based upon the comments received on the joint advance notice of proposed rulemaking seeking comments on how to improve the CRA regulations, and will propose such changes as are deemed appropriate.

The banking agencies are considering rules on the corporate governance of depository institutions and on the ability of accountants and other professionals to provide audit services and practice before the agencies.

OTS has proposed regulations codifying certain interpretations affecting the fiduciary activities of savings associations and providing recordkeeping requirements for securities transactions. OTS is also considering possible amendments to its regulations governing directors and officers of savings associations.

Bureau of Alcohol, Tobacco and Firearms

The Bureau of Alcohol, Tobacco and Firearms (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of alcohol products, tobacco products, firearms and explosives. ATF's missions 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 alcohol, tobacco, firearms, and explosives industries, including systems for licenses and permits;
- Assure the collection of all alcohol, tobacco, 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 in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes in avoidance of State taxes.

In 2003, ATF is initiating a multiyear plan to revise its regulations in plain language. As resources permit, the ATF will update and revise regulations to be more clear and concise, using the principles of plain language. ATF began the groundwork for this priority in 2002 by starting recodifications in Title 27. These changes reorganize ATF regulations into a more logical sequence. The plain language revisions will make ATF rules more accessible to small businesses and to the public.

ATF will continue, as a priority during fiscal year 2003, 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 regulations in response to closing loopholes in purchasing explosives materials, as directed by legislation now pending or contemplated.

Bureau of the Public Debt

The Bureau of the Public Debt (BPD) administers regulations:

- Governing transactions in government securities by Government securities brokers and dealers under the Government Securities Act of 1986 (GSA).
- Implementing Treasury's borrowing authority, including rules governing the sale and issue of savings bonds, marketable Treasury securities, and State and local government securities.
- Setting out the terms and conditions by which Treasury may redeem (buy back) outstanding, unmatured marketable Treasury securities through debt buyback operations.
- Governing the acceptability and valuation of all collateral pledged to secure deposits of public monies and other financial interests of the Federal Government.

Treasury's GSA rules govern financial responsibility, the protection of customer funds and securities, recordkeeping, reporting, audit, and large position reporting for all Government securities brokers and dealers, including financial institutions. During fiscal year 2003, BPD will give priority to the issue of final amendments to Treasury's Large Position Rules that pertain to very large positions in certain Treasury securities. The modifications will improve the information available to Treasury concerning the causes of market shortages. A proposed rule was published for comment on this matter in July 2002.

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 2003, BPD will accord priority to rewriting the Uniform Offering Circular in plain language. This will communicate the auction rules in a more direct and effective manner. BPD will also give priority to any further regulatory action the Department deems appropriate regarding the net long position reporting. An advance notice of proposed rulemaking was published in April 2002 soliciting comments on the timing and reporting of the net long position in Treasury auctions.

Financial Management Service

The Financial Management Service (FMS) issues regulations to improve the quality of Government financial management and to administer its payments, collections, debt collection, and Governmentwide accounting programs.

During fiscal year 2003, FMS' regulatory priorities will include several ongoing initiatives in the following areas:

- *Payment of Federal Taxes and the Treasury Tax and Loan Program (TT&L) (31 CFR Part 203*). FMS expects to revise this rule to support operational changes to the system used for the collection of corporate withholding taxes. FMS will streamline this rule and write it in plain language.
- *Automated Clearing House (ACH) (31 CFR Part 210*). FMS will continue to update this rule, which establishes standards for Federal Government payments and collections via the ACH system. FMS will revise this rule in order to stay current with private industry rules and to facilitate the continued expansion of electronic commerce.
- *Checks Drawn On the United States Treasury (31 CFR Part 240).* FMS intends to propose revisions to its rule governing the indorsement and payment of checks drawn on the United States Treasury. The proposed revisions will relate to, among other things, finality of payment, liability for checks bearing material defects or alterations, and the use of powers of attorney.
- *Debt Collection Improvement Act of 1996 (DCIA) (31 CFR Part 285*). FMS plans to issue general rules governing the offset of Federal Government payments to collect delinquent non-tax debt owed to Federal agencies. These rules will clarify the policies and procedures applicable to the collection of debt through the Treasury Offset Program and will facilitate full implementation of the program.

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 investments in, and assistance to, community development financial institutions (CDFIs), principally through the CDFI Program. In FY 2003, the CDFI Program will comprise three components: the Core/Intermediary Component, the Small Capitalization Component, and the Technical Assistance Component. In addition, the Fund administers the Native American CDFI Technical Assistance Program, which provides capacity building grants to promote the development of CDFIs that serve Native American, Alaska Native and Native Hawaiian communities, and the Bank Enterprise Award (BEA) Program, which encourages insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs.

In addition, the Fund administers the New Markets Tax Credit (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. Under 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 2003 regulatory priority will focus on the NMTC Program, by developing guidance and/or regulations regarding aspects of the administration and operation of the program. In the last quarter of FY 2002, the Fund is developing revisions to the regulations that govern the CDFI Program and the BEA Program.

TREAS

PROPOSED RULE STAGE

112. REVISION OF BREWERY REGULATIONS AND ISSUANCE OF REGULATIONS FOR TAVERNS ON BREWERY PREMISES (BREWPUBS)

Priority:

Other Significant

Legal Authority:

26 USC 5051 to 5057; 26 USC 5401 to 5418; 27 USC 205

CFR Citation:

27 CFR 7; 27 CFR 25

Legal Deadline:

None

Abstract:

ATF intends to streamline regulations applying to breweries. ATF will eliminate obsolete regulatory provisions. A formula system for manufactured beer products will replace statements of process attached to the brewers notice. The annual notice for small brewers to pay the reduced rate of tax will be eliminated. Separate regulations for brewpubs will be added to part 25. A section will be added to part 25 to authorize and regulate the alternating use of brewery premises by different brewers. Regulations authorizing the operation of brew-on-premises facilities will be added to part 25.

Statement of Need:

ATF intends to streamline its regulations applying to the brewing industry. These changes will simplify brewery reports and operations and eliminate obsolete regulatory provisions. Specific changes would include the implementation of a formula system for the breweries to replace the statement of process; the establishment of a separate subpart containing simplified regulations for brewpubs; authorizing alternating brewery premises among different proprietors; eliminating the annual notice to pay the reduced rate of tax for most breweries; authorizing brewers to file the Brewer's Report of Operations on a quarterly basis; and authorizing many brewers to take inventories quarterly rather than monthly. The rule will also propose minimum production standards for beer thereby reducing formula filings and a revised statement of net contents requirement for certain container sizes.

Summary of Legal Basis:

ATF has undertaken this review of brewery regulations as part of the President's Regulatory Initiative. These regulations are issued under the general authority of the Secretary of the Treasury to promulgate regulations to implement the Internal Revenue Code and the Federal Alcohol Administration Act.

Alternatives:

Not applicable. ATF believes that industry will support these regulatory changes because they will streamline regulatory requirements applying to the brewing industry.

Anticipated Cost and Benefits:

The proposed regulations will benefit the brewing industry by reducing required inventories, notices, and other submissions to ATF.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	03/00/03	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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TREAS

113. COMMERCE IN EXPLOSIVES (INCLUDING EXPLOSIVES IN THE FIREWORKS INDUSTRY) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

5 USC 552(a); 31 USC 9303; 31 USC 9304; 40 USC 304(k); 18 USC 847; 18 USC 921 to 930; 18 USC 1261; 19 USC 1612; 19 USC 1613; 19 USC 1618; 26 USC 7101; 26 USC 7322 to 7326; 31 USC 9301

CFR Citation:

27 CFR 55

Legal Deadline:

None

Abstract:

Pursuant to section 610 of the Regulatory Flexibility Act, ATF published a notice on January 10, 1997, seeking public comments on whether it should revise its regulations, codified at 27 CFR part 55, governing Commerce in Explosives (Including Explosives in the Fireworks Industry). Based on comments received, ATF plans to initiate a rulemaking to revise these regulations in 2002.

Statement of Need:

This notice of proposed rulemaking will address many of the issues in part 55, Commerce in Explosives, especially the issues in requirements for explosives, including fireworks explosive materials. Pursuant to the periodic review requirements of the Regulatory Flexibility Act (5 U.S.C. 610), ATF published on January 10, 1997 a general notice initiating the review of a final rule published in 1990 concerning the storage of fireworks explosives materials. The 1990 rule, which was issued as a result of the number and severity of explosions occurring on the premises of special fireworks plants, amended certain regulations codified at 27 CFR part 55, generally concerning the recordkeeping and storage of fireworks explosive materials. The regulations also codified two fireworks-related rulings issued in 1979 and 1985, and the provisions of Public Law 99-308 relating to black powder. As a result of the public comments received in response to the General Notice and further study of this issue, ATF will issue a notice of proposed rulemaking covering this and related commerce and storage of explosives issues.

Summary of Legal Basis:

18 U.S.C. 847 grants the Secretary of the Treasury broad discretion to promulgate regulations necessary for the importation, manufacture, distribution, and safe storage of explosives materials. 18 U.S.C. 846 authorizes the Secretary to prescribe precautionary measures to prevent the recurrence of accidental explosions in which explosive materials were involved. The General Notice and upcoming notice of proposed rulemaking are also being issued pursuant to section 610 of the Regulatory Flexibility Act (5 U.S.C. 610), which requires an agency to review within 10 years of publication rules for which an agency prepared a final regulatory flexibility analysis addressing the impact of the rule on small businesses or other small entities.

Alternatives:

Alternatives will be examined in the context of public comments to the notice of proposed rulemaking.

Anticipated Cost and Benefits:

Unknown at this time.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
General Notice of Regulatory Review	01/10/97	62 FR 1386
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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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.

A new priority undertaken at VA includes a comprehensive effort to review, reorganize, and rewrite the existing VA regulations contained in part 3 of 38 CFR. The goal of the Regulation Rewrite Project is to improve the clarity and logical consistency of these regulations in order to better inform veterans and their family members of their entitlements.

The Department of Veterans Affairs' 2002 regulatory plan contains one rulemaking action from the Veterans Health Administration. The Veterans Health Administration rulemaking is RIN 2900-AK08 ''Payment or Reimbursement for Emergency Treatment Furnished at Non-VA Facilities,'' which amends the Department's medical regulations by establishing a mechanism for payment or reimbursement for certain non-VA emergency services furnished to veterans for nonservice-connected conditions.

VA

FINAL RULE STAGE

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114. PAYMENT OR REIMBURSEMENT FOR EMERGENCY TREATMENT FURNISHED AT NON-VA FACILITIES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

38 USC 501; 38 USC 1725; PL 106-117

CFR Citation:

38 CFR 17

Legal Deadline:

NPRM, Statutory, May 22, 2000, 180 days after effective date of PL 106-117.

Abstract:

This document amends the Department of Veterans Affairs medical regulations by establishing a mechanism for payment or reimbursement for certain non-VA emergency services furnished to veterans for nonservice-connected conditions. This amendment is necessary to implement provisions of ''The Veterans Millennium Health Care and Benefits Act.''

Statement of Need:

Public Law No. 106-117 ''The Veterans Millennium Health Care and Benefits Act'' requires this amendment to implement its provisions.

Summary of Legal Basis:

38 U.S.C. 1725 authorizes VA to establish provisions for payment or reimbursement for certain non-VA emergency services furnished to Veterans for nonservice-connected conditions.

Alternatives:

The alternatives that the Department had to consider are the amount of reimbursement and the location where claimants can file a claim.

Anticipated Cost and Benefits:

Cost projection for FY 2001 is $66 to $75 million. The FY 2003 budget, in accordance with section 1725 of title 38, will provide an updated estimate of the full year impact of this legislation expected to be incurred in FY 2003.

Risks:

None.

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	05/29/00	66 FR 36467
Interim Final Rule	07/19/01	66 FR 36467
Interim Final Rule Comment Period End (Information Collection)	07/19/01	
Interim Final Rule Effective (38 CFR 17.004)	07/19/01	
Interim Final Rule Comment Period End	09/10/01	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 2900–AK08

BILLING CODE 8320–01–S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Priorities

OVERVIEW

Since 1970 the U.S. Environmental Protection Agency (EPA) has had the major Federal responsibility for protecting the quality of the American environment and controlling the effects of pollution on public health. EPA fulfills these responsibilities using a combination of tools, and over the past three decades EPA's actions have led to measurable improvements in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful pesticides.

In the year ahead EPA will continue its regulatory and nonregulatory activities in order to further protect the Nation's air, water, and land from the harmful effects of pollution. In particular, the Agency will focus its attention on the President's Clear Skies Initiative, the protection of specific watersheds and the strengthening of urban economies through the enhanced cleanup of brownfields.

But in one particular area EPA's responsibilities have changed substantially over the past year, and they will continue to change in the year ahead. After the terrorist attacks of September 11, 2001, EPA — like the rest of the nation — reordered its priorities so that it could sharply increase the services it provides in terms of both preventing future terrorist attacks and cleaning up the effects of such attacks, should any occur in the future. The response to future terrorism and its potential effects on human health and environmental quality is now one of EPA's top priorities. This new priority is affecting the structure of EPA's programs, the Agency's budget, and its regulatory agenda.

EPA also has made assistance to small businesses a top priority both in terms of the direct services it provides to those businesses and the consideration it gives them when developing regulations. The Agency is committed to fulfilling the President's pledge that ''...we're going to do everything we can to clean up the regulatory burden on small businesses.''

EPA continues to give a high priority to fresh thinking and innovation in its efforts to protect human health and the environment. Innovative methods of achieving environmental goals are being incorporated into EPA's regulations, and they are an important part of the Agency's regulatory agenda in each of its program offices.

Moreover, EPA's innovations extend beyond regulations and into a range of voluntary partnerships with industry, State governments, and local communities, partnerships that are leading to measurable environmental improvements. Although those partnerships often support activities that generate environmental benefits beyond those required by environmental regulations, many of them also result in more effective and less burdensome regulations. Like EPA's emphasis on innovation, partnerships involving individual facilities and whole industries cut across all of EPA's program offices.

Water Infrastructure Security

EPA's response to the terrorist attacks of September 11, 2001, and its subsequent homeland security efforts have not involved the need to promulgate new regulations.

The responsibility and authority provided to the Agency with respect to certain public drinking water systems under the Public Health Security and Bioterrorism Response Act, signed into law on June 12, 2002, may require the promulgation of a codification rule or other regulation.

Assistance to Small Businesses

Because of the crucial role played by small businesses in sustaining the health of the national economy, EPA has undertaken several activities that make it easier for those businesses to understand and fulfill their environmental responsibilities. Those activities constitute a strategically important priority in EPA's regulatory agenda, and in many cases they provide assistance that goes beyond EPA's formal regulatory responsibilities, while encouraging small businesses to improve their environmental performance beyond what is required by regulation.

In particular, the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA) give small businesses the opportunity to participate early in the development of certain regulations so that their special needs are given full consideration. For rules that may have a significant effect on small businesses, EPA solicits input from those businesses and considers alternatives that minimize adverse impacts. All of EPA's activities under SBREFA and RFA have a high priority on the Agency's regulatory agenda.

EPA also will encourage wider use of self-certification for small businesses, a system that is starting to become a reality in several states. Under this sector-based program, industrywide environmental performance standards are established with annual certifications of compliance. This system eases the regulatory burden on small businesses while improving and rewarding compliance with regulation. EPA's emphasis on small-business assistance extends to all of its program offices.

Regulatory Innovation

Innovation has been an important priority at EPA for the past several years, and it will be a priority into the future, because it has demonstrated its potential for improving environmental quality beyond what is possible with traditional regulations. As EPA develops its regulations, the Agency will continue to include economic incentives, compliance assistance, and other types of mechanisms that have proven capable of motivating better environmental performance by individuals, communities, businesses, and industry sectors. EPA also will support environmental technology innovation by ensuring that environmental regulations encourage and provide the flexibility for use of innovative technologies. Regulatory flexibility, cost reduction, information transfer, and technology development are all key parts of EPA's emphasis on regulatory innovation, and they will be evident in EPA's efforts to develop a number of regulations, including those related to Clear Skies.

Voluntary Partnerships

For the past several years EPA has placed a high priority on working as partners with both individual facilities and whole industries to help them improve their environmental performance. In many cases, these partnerships — such as Energy Star and WasteWise — support industry efforts to reduce pollution in ways that are not required by Federal regulation. But voluntary partnerships between EPA and regulated businesses also are directly affecting the quality of the Agency's regulations. For example, by working closely with trade associations, the Agency has been able to develop regulations that meet environmental goals while still being responsive to the special needs or circumstances of particular industries. Because EPA/private sector partnerships hold so much potential for improving regulations, they will continue to be a

priority for the Agency's regulatory agenda.

HIGHLIGHTS OF EPA'S REGULATORY PLAN

Office of Air and Radiation

EPA's Office of Air and Radiation (OAR) remains committed to taking advantage of the flexibility granted by the Clean Air Act that enables companies, States, and communities to meet clean air goals with cost-effective approaches. Consequently, this flexibility is a major priority in OAR's regulatory agenda for the coming year.

In 1997 the Agency established new, more stringent national ambient air quality standards for ozone and particulate matter (PM) based on new scientific information indicating that new standards were needed to protect public health with an adequate margin for safety. In 1999 a panel of the D.C. Circuit Court, in a 2 to 1 decision, held that the statutory provision authorizing issuance of such standards constituted an impermissible delegation of authority, as interpreted by EPA, and therefore was unconstitutional. On appeal to the United States Supreme Court, this decision was reversed in a unanimous vote. On remand, the same panel of the D.C. Circuit upheld all of the challenged standards for PM and ozone. The Agency now is working on an implementation program for ozone to respond to different aspects of the court decisions. The Agency also is proceeding with the next legislatively mandated review of the standards. In addition, in response to a recommendation from the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), OAR is collaborating with OIRA to identify specific types of health research that would be useful in enhancing OAR's ability to quantify the health benefits from future reductions in human exposure to particulate matter.

To date, EPA's air toxics program has focused primarily on reducing emissions from large industrial sources through technology-based standards. Since 1990, the Agency has issued standards affecting 77 different industries, such as petroleum refineries and chemical manufacturing plants. When fully implemented, these standards will reduce more than one million tons of toxic air emissions per year. Through other efforts such as phasing lead out of gasoline, EPA also has significantly reduced air toxics from cars and trucks.

OAR will continue to set technology-based standards for large industries. The rules listed in this year's regulatory plan — covering industrial boilers, institutional/commercial boilers, wood manufacturing, reciprocating engines, combustion turbines, and automobile painting operations — are among the most significant remaining categories to be regulated under this program. While working on these standards, OAR is beginning to evaluate those sources with standards already in place to determine if the remaining risk from those sources warrants additional regulation.

OAR also is implementing an Urban Air Toxics Strategy, which focuses on 33 air toxics that pose the greatest risk to the largest number of urban areas. This strategy presents OAR's plan, both nationally and locally, to reduce these toxic emissions. Finally, to better understand and measure risks from air toxics, OAR is conducting important health research while improving emissions inventories, modeling capability, and monitoring networks.

To assist States in meeting clean air goals, OAR is proceeding with Federal programs aimed at achieving large, cost-effective reductions in particulate matter (PM) and ozone-forming nitrogen oxide (NOX) emissions. OAR also is working to develop a rule to control emissions from off-road vehicles such as construction equipment. In addition, OAR is in the final stages of completing a rulemaking to help States reduce airborne ozone concentrations resulting from the windblown transfer of NOX emissions from the Midwest to the East Coast.

Of these actions, one supports nominations of reform candidates in public comments responding to OMB's 2001 Report to the Congress on the costs and Benefits of Regulations. This action is the rulemaking entitled Review of the National Ambient Air Quality Standards for Particulate Matter, which supports the nomination to revise this standard.

Office of Water

EPA's Office of Water (OW) has established six regulatory priorities for the coming year. They include rules affecting cooling-water intakes, industrial and municipal wastewater pollution, concentrated animal feeding operations (CAFOs), the Total Maximum Daily Load (TMDL) program, Clean Water Act (CWA) jurisdiction, and drinking water.

EPA intends to issue two rules to minimize the adverse environmental impacts associated with cooling-water intakes. As the name implies, certain industrial operations require large volumes of water to be drawn in from a surface water body in order to regulate the operating temperature of equipment. Given the makeup of the regulated community, entities that own or operate steam electric power plants would bear most of the costs of these rules. The expected benefits would be significant reductions in aquatic organisms killed or injured by impingement (being pinned against screens or other parts of a cooling-water intake structure) or entrainment (being drawn into cooling water systems and subjected to thermal, physical, or chemical stresses).

EPA also will issue two regulations to help control industrial and municipal wastewater pollution. First, for the metal products and machinery industry, EPA expects to issue effluent limitations to reduce the discharge of millions of pounds of conventional and toxic pollutants. These reductions would achieve significant improvements in water quality. Second, EPA expects to propose a rule to better control sanitary sewer overflows (SSOs). EPA estimates that about 60,000 SSOs discharge untreated sewage to the environment yearly, exposing the public to health risks (primarily from pathogens in untreated sewage). The proposed rule would clarify the existing prohibition of these overflows, improve public notification and reporting, and provide guidelines for planning and managing sewer systems. It also would ensure that several thousand ''satellite'' sewer collection systems are covered by permit requirements.

CAFOs present significant risks to water quality through runoff from animal feeding facilities and farmland where manure has been spread. EPA will revise existing regulations to better control these risks. The revisions will control the discharge and runoff of excess nutrients and other pollutants and, in turn, improve surface water quality.

EPA plans to propose to withdraw the July 2000 TMDL program revisions and, at the same time, to propose a rule establishing a new framework for accomplishing the water quality planning and management provisions of the Total Maximum Daily Load (TMDL) program. EPA believes this framework, based on the watershed approach, will allow more jurisdictions — i.e., States, territories, and tribes — to use the program to contribute more effectively to improving the Nation's water quality. The proposal recognizes that the major responsibility for water quality management resides with these jurisdictions. The goal of the proposal is to provide jurisdictions with a tailored

yet flexible approach to water quality management that meets the unique needs and situation of each jurisdiction and of local communities, while ensuring that progress is made towards restoring the Nation's waters so they attain and maintain water quality standards. EPA's proposal revitalizes and strengthens the Continuing Planning Process (CPP) as a focus for a variety of jurisdictions' water quality planning and implementation activities. The proposed new framework seeks to increase TMDL program flexibility and enhance stakeholder participation, promote opportunities for trading, and increase efficiencies in establishing, approving, and implementing TMDLs.

EPA intends to undertake joint proposed rulemaking with the Department of the Army to amend the regulatory definition of waters subject to the CWA. The existing regulations contain language asserting jurisdiction over isolated intrastate waters, but a January 9, 2001, U.S. Supreme Court opinion limits use of that regulatory provision. The revisions of the regulations will address the Court's decision, improve regulatory clarity, and provide more specificity regarding the scope of CWA jurisdiction.

Finally, EPA is developing three rules to protect the safety of drinking water. First, EPA is developing a proposed Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) to 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 also 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 proposed 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 and possible reproductive and developmental health effects.

Office of Prevention, Pesticides, and Toxic Substances

The Food Quality Protection Act (FQPA) overhauled U.S. pesticides laws, enhancing protections related to pesticide residues in food by requiring aggregate and cumulative risk assessments, with a special emphasis on children and infants. EPA is currently working on the Pesticide Tolerance Reassessment Program, a ten-year program to reevaluate the safety of all pesticide residues in food. Under this program, EPA has completed reassessment of two-thirds of the tolerances for pesticide residues in foods. Implementation of FQPA has required an increase of the activities of the Scientific Advisory Panel (SAP) established under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Significant risk-assessment methodology issues continue to be addressed by the SAP, including drinking water assessment methodologies, approaches for conducting cumulative and aggregate risk assessments, use of 10x safety factors, and guidelines for assessing protein plant pesticides. The SAP also jointly sponsored with the EPA Science Advisory Board several meetings on ethical considerations related to the testing of human subjects, and the Agency has asked the National Academy of Science to evaluate the ethics of testing human subjects.

The Agency will be announcing revisions to its pesticide emergency exemption program, under which States and other Federal agencies may obtain permission to temporarily use a pesticide not in accordance with registration requirements under emergency conditions. In response to State concerns, EPA already has reduced the review time for emergency exemptions significantly. Other changes that EPA is considering have the potential for further streamlining the exemption program and allowing more flexibility.

Evidence suggests that environmental exposure to manmade chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in human and wildlife populations. FQPA directed EPA to develop a chemical screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. In October 1996, EPA chartered a scientific advisory committee to advise it on establishing a program to carry out the legislated directive. The advisory committee recognized that there currently were no validated test systems for determining whether a chemical may have an effect in humans that is similar to an effect produced by naturally occurring hormones.

EPA is in the process of developing and validating the screens and tests that the advisory committee recommended, and designing a framework for regulatory information. As part of this process, EPA is developing priority-setting criteria to be used by the Agency to identify the initial list of chemicals for which testing will be required. The proposed criteria will be published in the Federal Register in December 2002 for public comment. The final criteria will be published in the Federal Register approximately six months later.

Bioengineering is on the cutting edge of an emerging technology with new and different products rapidly being developed and introduced into commerce. A Plant-Incorporated Protectant (PIP) is a bioengineered pesticidal substance produced and used by the living plant to protect itself from pests, typically insects, viruses, and fungi. EPA regulates the domestic manufacture, sale, and use of pesticides, including PIPs, under FIFRA and FFDCA to assure that any pesticide residue in/on a food product is safe. The Agency sets appropriate residue limits and assures that there is no adverse affect to the environment from the PIP.

Through the voluntary High Production Volume (HPV) Challenge Program, certain international efforts, and rulemaking under the Toxic Substances Control Act (TSCA), basic data related to the environmental fate and potential hazards associated with HPR chemicals, i.e., organic chemicals manufactured (including imported) at or above 1 million pounds per year, based on information submitted under the 1990 Inventory Update Rule (TSCA) will be collected or, where necessary, developed. When combined with information about exposure and uses, this data will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate action.

EPA received commitments from 357 companies, individually or through 106 consortia, and the International Council of Chemical Associations (ICCA) to sponsor 2,214 of the estimated 2,800 HPV chemicals included in the voluntary HPV Challenge Program.

As an integrated approach for addressing the widespread problems associated with toxic pollutants that persist and bioaccumulate in the environment, EPA launched the Persistent, Bioaccumulative, and Toxic (PBT) pollutants program in November 1998. The goal of the program is to further reduce risks to human health and the environment from existing and

future exposure to PBT pollutants such as mercury, PCBs, and dioxin through the use of chemical- specific action plans. Through this program, the Agency is committed to create an enduring cross-office system that will address the cross-media issues associated with priority PBT pollutants.

To encourage the application of pollution prevention principles during the development of new chemicals submitted as premanufacture notices (PMNs) under TSCA section 5, EPA has initiated a new and innovative voluntary pilot project entitled Sustainable Futures. The goal of this pilot project is to encourage pollution prevention and the development of inherently low-hazard chemicals. Also, the Agency seeks to gain additional data and experience regarding the pollution prevention, risk reduction, and source reduction benefits of use of hazard, exposure, and risk screening methodologies such as EPA's Pollution Prevention Framework in new product development efforts.

Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) is planning regulatory actions to reduce risks to human health and the environment, reduce burden on the regulated community, encourage recycling and reuse, and standardize certain aspects of recordkeeping programs. All these actions will be taken under the Resource Conservation and Recovery Act (RCRA), the Federal law governing waste management.

During the 1990s EPA determined that additional control is needed for cement kiln dust, a high-volume material byproduct of the cement manufacturing process that potentially contains hazardous constituents such as lead, cadmium and chromium. EPA is assessing regulatory approaches for waste management of cement kiln dust.

EPA also is taking steps to encourage recycling and reuse. EPA is considering modifying RCRA rules that impact the management of solvent-contaminated shop towels and wipes. This effort would encourage pollution prevention and recycling of hazardous solvents, make management standards more consistent with the risks these materials pose, and clarify existing Federal policies regarding these materials.

Under RCRA, wastewater treatment sludge from electroplating operations is listed as hazardous waste (waste code F006). F006 represents one of the largest hazardous waste streams amenable to recycling. EPA is considering changes to the existing RCRA regulations to encourage safe recycling and management practices of wastewater treatment sludge from electroplating operations, and to reduce regulations applicable to electroplating sludge that is sufficiently high in metals and sufficiently low in other toxic constituents.

Under RCRA, a hazardous waste is defined as 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 is managed. EPA is planning to revise the definition of solid waste, removing the necessity of RCRA control where it is unnecessary and thereby increasing reuse and recycling of hazardous waste, improving resource conservation, and improving materials management.

To reduce regulatory burdens, EPA is considering adding four solvents to the hazardous-waste exemptions for mixtures of spent solvents (used solvents that are not fit for further use without being processed) in wastewater treatment plants; revising provisions, such as de minimis quantities and the definition of point of application of exemption; and clarifying the applicability of exemptions to incinerator scrubber water. This effort, if finalized, would allow more facilities to be eligible for regulatory exemptions and more wastes to be exempted from hazardous-waste regulation.

To further reduce administrative burdens, efforts are underway to eliminate duplicative and nonessential paperwork imposed by RCRA reporting and recordkeeping requirements. This rule would have minimal impact on the protectiveness of RCRA regulations. It would eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of RCRA regulations.

EPA also plans to streamline the permit process by creating a standardized permit for facilities that generate waste and routinely manage the waste on-site in tanks, containers, and containment buildings. This standardized permit process would allow facilities to obtain and modify permits more easily, while maintaining the protectiveness currently existing in the individual RCRA permit process.

Of these actions, two support nominations of reform candidates in public comments responding to OMB's 2001 Report to Congress on the Costs and Benefits of Regulations. The Revision of Wastewater Treatment Exemptions for Hazardous Waste Mixtures proposed rule supports the nomination to revise the Mixture and Derived-From final rule to exempt waste streams resulting from the treatment of hazardous wastes from RCRA subtitle C, unless those waste streams themselves exhibit a characteristic of hazardous wastes. This nomination received an OMB priority level of 1 (high priority). This proposal is expected to be published in January 2003.

Likewise, the Revisions to the Definition of Solid Waste proposed rule supports the nomination to revise the definition of solid waste to grant an exemption from RCRA for materials destined for recycling or reuse. This nomination received an OMB priority level of 2 (medium priority). This proposal is expected to be published in April 2003.

Furthermore, one of OSWER's proposed actions, Modifications to RCRA Rules Associated with Solvent-Contaminated Shop Towels and Wipes proposed rule, may have small-business impacts. Initial analysis of options has found that some approaches may impose some costs on small business. The economic impacts are expected to be minor, since the estimated incremental costs are small relative to sales.

Office of Environmental Information

The top regulatory priority of EPA's Office of Environmental Information (OEI) will be the finalization of the Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR). This rule will address electronic reporting by companies regulated under all of EPA's programs — air, water, pesticides, toxic substances, wastes, and emergency response. CROMERRR would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, this rule would set the conditions for allowing electronic reporting under State, tribal, or local environmental programs that operate under EPA authorization.

CROMERRR is intended to make electronic reporting as simple, efficient, and cost effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no

obstacles to adopting new technologies as they emerge.

To ensure that authorized programs at the State, tribal, and local levels meet CROMERRR's goals, the rule would specify a set of criteria that these programs must satisfy as they initiate electronic reporting or recordkeeping. The final rule would specify a process for certifying that these programs meet the criteria. EPA is on schedule to finalize CROMERRR by the third quarter of FY 2003. In response to public comment, a decision was made to focus the final rule on electronic reporting only, and to defer coverage of electronic recordkeeping until a later time. Also in response to comments, EPA currently is exploring a streamlined process to review State programs for electronic reporting.

Finally, in response to OMB's prompt letter pertaining to EPA's progress in implementing an integrated system of reporting, EPA has made further progress in implementing the Central Data Exchange (CDX). CDX is on track to provide electronic reporting services for all significant environmental data collections. All but one of the major environmental data exchanges with states will be operational through CDX by the end of 2004. Also, for the first time next year, Toxics Release Inventory (TRI) reporters will be able to send and view paperless reports using a form of electronic authentication that will substitute for a paper signature.

EPA ACTIONS OF SPECIAL INTEREST TO SMALL BUSINESSES

Many EPA regulations, and several actions included in this Regulatory Plan, are of substantial interest to small businesses. Because small businesses face special challenges in their efforts to understand and comply with environmental regulations, EPA is taking a number of actions across the Agency to help small businesses fulfill their environmental responsibilities. The Agency's Small Business Ombudsman provides one-stop assistance to small businesses looking for answers to environmental questions. The Agency is involving small businesses earlier in the regulatory development process, and developing alternative approaches — like self-certification — that work better for small businesses. EPA is providing a number of services, like compliance assistance centers, disclosure incentives, and a National Compliance Assistance Clearinghouse, that help small businesses better manage their compliance efforts. Small businesses are being rewarded for voluntary innovative efforts and environmental leadership, and EPA is investing in new technologies and management tools that small businesses can use in the future.

Because EPA's regulations affect many small businesses in many different ways, the Agency is committed to integrating and simplifying its activities in ways that help small businesses comply. In particular, EPA is preparing a revised small business strategy entitled Integrating EPA's Small Business Activities: A Strategy to Meet the Needs of Small Businesses. The revised strategy reflects input received over the past two years from a series of interviews within EPA and with focus groups, States, industry representatives, and other interested stakeholders to better understand the environmental regulatory issues and obstacles facing small businesses. In FY 2003, EPA will implement the strategy's recommendations to better integrate its activities that support small businesses, including how the Agency provides technical assistance and outreach, develops regulations that minimize burden, and simplifies participation in EPA's voluntary programs.

EPA

PRERULE STAGE

115. PESTICIDES; EMERGENCY EXEMPTION PROCESS REVISIONS

Priority:

Other Significant

Legal Authority:

7 USC 136(p)

CFR Citation:

40 CFR 166

Legal Deadline:

None

Abstract:

EPA will publish a Federal Register notice to revise the pesticide emergency exemption process under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, based on recent recommendations from the States. Rulemaking will not be undertaken at this time because the revisions are to operational practices used to implement the program and are consistent with current regulations. Emergency exemptions allow temporary use of a pesticide not in accordance with registration requirements when emergency conditions exist. EPA identified a number of issues, which have been refined through informal discussions with States, user groups, and other stakeholders.

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, expedite decisions on applications (which is critical in emergency situations) and potentially reduce risk to human health and the environment.

Summary of Legal Basis:

FIFRA section 18 authorizes EPA to temporarily exempt States from the requirements of registration to alleviate an emergency condition.

Alternatives:

Several measures for streamlining or improving the emergency exemption process are being considered by the Agency. EPA has analyzed these measures 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 economic impact, options with varying cost do not apply.

Anticipated Cost and Benefits:

Because this action would provide regulatory relief, no costs are anticipated. Potential benefits include the reduced burden and cost to States and Federal agencies that apply for emergency exemptions, reduced burden to EPA, and, some cases, reduced risk to human health and the environment. Indirect benefits may accrue to users of pesticides under emergency exemptions if changes result in faster review and approval, or greater availability of pesticides. No economic assessment of costs and benefits has yet been conducted.

Risks:

In general, the measures being considered are primarily intended to

reduce burdens for States and EPA and achieve efficiencies in the program. There is potential risk reduction in reduced use of pesticides.

Timetable:

Action	Date	FR Cite
Notice	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4216

Sectors Affected:

9241 Administration of Environmental Quality Programs

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RIN: 2070–AD36

EPA

116. ● ENDOCRINE DISRUPTOR SCREENING PROGRAM; PRIORITY SETTING CRITERIA

Priority:

Other Significant

Legal Authority:

15 USC 2603 TSCA; 21 USC 346(a) FFDCA; 42 USC 300(a)(17) SDWA; 7 USC 136 FIFRA

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

EPA published a proposed policy statement in the Federal Register setting forth the Endocrine Disruptor Screening Program on December 28, 1998. In that FR Notice, the Agency described the major elements that the Program had developed to comply with the requirements of FFDCA section 408(p) as amended by FQPA. One of those elements is Priority Setting which was defined as the collection, evaluation, and analysis of relevant information to determine the general order in which chemical substances and mixtures will be subjected to screening and testing. Under this current action, EPA is developing priority setting criteria to be used by the Agency to identify the initial list of chemicals for which Tier 1 testing will be required.

Statement of Need:

The Endocrine Disruptor Screening Program fulfills the statutory direction and authority to screen pesticide chemicals and drinking water contaminants for their potential to disrupt the endocrine system and adversely affect human health.

Summary of Legal Basis:

The mandate to screen pesticide chemicals for estrogenic effects that may affect human health is the Federal Food, Drug and Cosmetic Act (FFDCA) as amended in the Food Quality Protection Act (21 U.S.C. 346a(p)). FFDCA also provides EPA authority to require testing of substances that may have an effect that is cumulative to that of a pesticide chemical. Discretionary authority to test contaminants in sources of drinking water is in the Safe Drinking Water Act as amended in 1996 (42 U.S.C. 300j-17). General authority to test chemicals and pesticides is in TSCA (15 U.S.C. 2603) and FIFRA (7 U.S.C. 136), respectively.

Alternatives:

A Federal role is mandated under cited authority. There is no alternative to role of the Federal Government on this issue to ensure that pesticides, commercial chemicals and contaminants are screened and tested for endocrine disruption potential. A limited amount of testing may be conducted voluntarily but this will fall far short of the systematic screening which is necessary to protect public health and the environment and ensure the public that all important substances have been adequately evaluated.

Anticipated Cost and Benefits:

None.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk from exposure to chemicals operating through an endocrine mediated pathway. Preliminary studies show possible adverse effects on humans. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish and shellfish have been documented in the U.S., Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the U.S. to proceed on a two track strategy: research on the basic science regarding endocrine disruption and screening to identify which chemicals are capable of interacting with the endocrine system. The combination of research and test data developed by this program will enable EPA to take action to reduce chemical risks.

Timetable:

Action	Date	FR Cite
Notice Proposed Priority Setting Criteria & Request for Comment	12/00/02	
Notice Final Priority Setting Criteria	06/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN No. 4727

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RIN: 2070–AD59

EPA

117. ● SUSTAINABLE FUTURES; VOLUNTARY PILOT PROJECT UNDER THE TSCA NEW CHEMICAL PROGRAM

Priority:

Other Significant

Legal Authority:

Not Yet Determined

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

Sustainable Futures is a voluntary pilot project initiated by EPA to encourage the application of pollution prevention principles during the development of new chemicals submitted as premanufacture notices (PMNs) under section 5 of the Toxic Substances Control Act (TSCA). The goal of this pilot project is to encourage pollution prevention and the development of inherently low-hazard chemicals. Also, the Agency seeks to gain additional data and experience regarding the pollution prevention, risk reduction, and source reduction benefits of use of hazard, exposure, and risk-screening methodologies such as EPA's Pollution Prevention Framework in new product development efforts.

Statement of Need:

Chemical manufacturers need quick, inexpensive, reliable methods for screening chemicals for risk early-on in the chemical development process. Manufacturers of new chemical substances often have product or process alternatives available and/or under consideration at R&D. Unfortunately, little or no data are available about the potential hazards or risks of alternatives under consideration. As a result, stakeholders often make commercialization decisions without an understanding of the risk trade-offs of product or process alternatives under consideration. Commercialization decisions are often made ''blind'' to risk considerations. Sustainable Futures is a technology-transfer approach to risk reduction and pollution prevention. Under Sustainable Futures, the Agency will give sophisticated computerized risk-screening methodologies, called the P2 Framework, to chemical companies, together with training and detailed technical assistance. The P2 Framework allows companies to evaluate chemical alternatives based on a computerized analysis of chemical structure. The P2 Framework can be used early-on in R&D, even before a chemical is synthesized, to render screening-level assessments of chemicals under study and alternatives available. R&D is the optimal point to initiative risk screening because alternatives are more plentiful at R&D and the cost of change is lowest. Risk screening at R&R is the purest form of pollution prevention.

Summary of Legal Basis:

Section 5 of TSCA gives EPA authority to review and, where necessary, control unreasonable risks associated with new chemicals. An important approach to risk control is to give chemical manufacturers sophisticated, cost-effective screening methodologies that allow stakeholders to self-identify problematic chemicals, resulting in submission of inherently low-risk new chemicals. The Pollution Prevention Act encourages approaches that prevent the introduction of hazardous materials. The P2 Framework is one approach toward this objective.

Alternatives:

One alternative would be to ask the industry to test new chemical substances to determine the level of risk, if any. Such an approach would increase costs and delay introduction of materials into the market place. There is no statutory authority to require testing prior to submission of a premanufacture notice. A second alternative is the status quo, where chemical commercialization decisions are made without an understanding of risk trade-offs of product and process alternatives.

Anticipated Cost and Benefits:

Cost to participating stakeholders will be low. Almost all stakeholders currently have computer equipment sufficiently powerful to run assessment methodologies offered through Sustainable Futures. Training, offered by EPA at no cost, will be needed, however. Eastman Kodak conducted an independent study of the benefits of conducting risk screening at R&D using the P2 Framework - the central concept of the Sustainable Futures Initiative. Kodak found they saved between 13.5 percent and 100 percent of product development costs for each chemical evaluated at R&D. Other benefits seen in the Kodak case study include reduction in generation of chemical wastes, reduced time to market, reduced regulatory liability and better utilization of health, safety and environmental staff.

Risks:

The methodologies included in the P2 Framework, i.e., the foundation of the Sustainable Futures Initiative, are screening-level methodologies with an inherent degree of uncertainty. As a result, it is possible that a low risk chemical might be mistakenly identified as posing human or environment concerns. The opposite is also possible, i.e., a hazardous chemical might be mistakenly viewed as posing low hazard as a result of application of the P2 Framework methodologies.

Timetable:

Action	Date	FR Cite
Notice Announcing Voluntary Pilot Project	11/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN No. 4734

Sectors Affected:

325 Chemical Manufacturing; 32411 Petroleum Refineries

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RIN: 2070–AD60

EPA

118. CLEAN WATER ACT DEFINITION OF WATERS OF THE UNITED STATES

Priority:

Other Significant

Legal Authority:

33 USC 1361 CWA sec 501; 33 USC 1362 CWA sec 502

CFR Citation:

33 CFR 328.3(a); 40 CFR 110.1; 40 CFR 112.2; 40 CFR 116.3; 40 CFR 117.1; 40 CFR 122.2; 40 CFR 230.3(s); 40 CFR 232.2; 40 CFR 257.3-1(d); 40 CFR Part 300, Appendix E; 40 CFR 401.11(I)

Legal Deadline:

None

Abstract:

This action involves joint rulemaking by EPA and the Department of the Army to amend the regulatory definition of waters of the United States. The action would clarify the jurisdictional status under the Clean Water Act (CWA) of ''isolated intrastate non-navigable waters and wetlands.'' The existing regulations contain language asserting jurisdiction over isolated intrastate waters, but that regulatory provision has been the subject of a January 9, 2001, U.S. Supreme Court opinion, Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers (SWANCC). In SWANCC, the Court held that the scope of ''waters of the United States'' protected under the Clean Water Act did not extend to isolated intrastate non-navigable waters based solely on presence of migratory birds. While SWANCC did not actually invalidate regulations under the CWA, the decision does establish limitations on their use. Revision of the regulatory language is necessary to address the Court's decision, improve regulatory clarity, and provide more specificity regarding CWA jurisdiction. Among others things, the rulemaking would clarify CWA jurisdiction for entities (e.g., industrial, commercial, governmental) that discharge pollutants, including dredged or fill material, to isolated intrastate surface waters or wetlands. Small entities or State/local/tribal governments might be affected by a change in regulatory definition of ''waters of the United States'' if they either are regulated under or help administer CWA programs affecting such waters, e.g. sections 402, 404, 311.

Significant impacts on such entities or governments are not anticipated, as the proposed regulatory revisions would be consistent with the Supreme Court ruling.

Statement of Need:

The need for this rule stems from the Supreme Court's 2001 decision in Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers (SWANCC), which has raised substantive questions regarding the extent to which isolated intrastate non-navigable waters are included within the geographic scope of jurisdiction under the Clean Water Act. Rulemaking will help clarify issues to ensure that Clean Water Act protections are in place for the appropriate set of wetlands and other waters of the United States.

Summary of Legal Basis:

Although the Supreme Court's decision in SWANCC did not invalidate regulations under the CWA, it raised questions that can be most effectively answered via rulemaking on the various regulations concerning CWA jurisdiction.

Alternatives:

The Agency will seek public input on alternatives via an advance notice of proposed rulemaking prior to proposing a rulemaking.

Anticipated Cost and Benefits:

Cost/benefit information will be developed/solicited as part of the ANPRM and proposal process. However, significant changes in the magnitude or distribution of costs and benefits are not anticipated, as the rule is primarily focused on how Clean Water Act jurisdiction for relevant programs is interpreted in light of the SWANCC Supreme Court decision.

Risks:

Risk information will be solicited as part of the ANPRM and proposal process. However, significant changes in the magnitude or distribution of risk are not anticipated as the rule is primarily focused on how Clean Water Act jurisdiction for relevant programs is interpreted in light of the SWANCC Supreme Court decision.

Timetable:

Action	Date	FR Cite
ANPRM	11/00/02	
NPRM	06/00/03	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 2804

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RIN: 2040–AB74

EPA

PROPOSED RULE STAGE

119. NESHAP: PLYWOOD AND COMPOSITE WOOD PRODUCTS

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 7412(d)

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

This project is to develop national emission standards for hazardous air pollutants (NESHAP) by establishing maximum achievable control technology (MACT) for facilities manufacturing wood panels and engineered wood products. MACT standards are under development to reduce the release of hazardous air pollutants (HAP) from all industries to protect the public health and environment. Emissions of HAP from this industry have been associated with, but are not limited to, the drying of wood and binders. This rule is anticipated to apply to the manufacture of products involving wood and some

kind of binder or bonding agent. This project may include, but is not limited to, facilities that manufacture waferboard, hardboard fiber board (MDF), oriented strandboard (OSB), medium density fiberboard, particleboard, strawboard, hardwood and softwood plywood, glue-laminated lumber, laminated veneer lumber, and engineered wood products. The source category may also include lumber drying kilns at sawmills which are located on the same site as a facility that manufactures any of the wood products mentioned above. The project may also include some coatings operations. The name of the source category was formerly Plywood and Particleboard MACT.

Statement of Need:

Plywood and Composite Wood Products is a source category listed to be regulated under section 112 of the Clean Air Act.

Summary of Legal Basis:

Clean Air Act Section 112

Alternatives:

The principal alternatives are to set standards at or beyond the ''floor'' level of stringency. The ''floor is the minimum stringency implied by the congressionally given formula in section 112 of the Clean Air Act.

Anticipated Cost and Benefits:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. In addition, an Economic Impact Analysis and Regulatory Impact Analysis have been prepared.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 3820

Sectors Affected:

32121 Veneer, Plywood, and Engineered Wood Product Manufacturing

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RIN: 2060–AG52

EPA

120. NESHAP: RECIPROCATING INTERNAL COMBUSTION ENGINE

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 7412 CAA sec 112; PL 101-549

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

The stationary reciprocating internal combustion engine source category is listed as a major source of hazardous air pollutants (HAPs) under section 112 of the Clean Air Act (CAA). A major source is one which emits more than 10 tons/yr of one HAP or more than 25 tons/yr of a combination of 189 HAPs. The EPA will gather information on HAP emissions from internal combustion engines and determine the appropriate maximum achievable control technology (MACT) to reduce HAP emissions. The EPA will use information that has already been developed, if possible, by gathering information by working with State/local agencies, vendors, manufacturers of internal combustion engines, owners and operators of internal combustion engines, and environmentalists.

Statement of Need:

Reciprocating Internal Combustion Engines is a source category listed to be regulated under Section 112 of the Clean Air Act.

Summary of Legal Basis:

Section 112 of the Clean Air Act.

Alternatives:

The principal alternatives are to set standards at or beyond the ''floor'' level of stringency. The ''floor is the minimum stringency implied by the Congressionally-given formula in Section 112 of the Clean Air Act.

Anticipated Cost and Benefits:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. Therefore, separate cost/benefit analyses are not conducted for individual rulemakings within the MACT program. Total annualized cost for rule is $248 million, average cost/facility $62,000 for 4600 existing sources and 20,000 new sources.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State, Local

Additional Information:

SAN No. 3656

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RIN: 2060–AG63

EPA

121. NESHAP: INDUSTRIAL, COMMERCIAL, AND INSTITUTIONAL BOILERS AND PROCESS HEATERS

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 7412

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

The Clean Air Act, as amended in 1990, requires EPA to develop emission standards for sources of hazardous air pollutants (HAPs). Industrial boilers, institutional/commercial boilers and process heaters are among the potential source categories to be regulated under section 112 of the CAA. Emissions of HAPs will be addressed by this rulemaking for both new and existing sources. EPA promulgated an NSPS for these source categories in 1987 and 1990. The standards for the NESHAP are to be technology-based and are to require the maximum achievable control technology (MACT) as described in section 112 of the CAA.

Statement of Need:

Industrial boilers, institutional/commercial boilers, and process heaters are source categories listed to be regulated under Section 112 of the Clean Air Act.

Summary of Legal Basis:

Section 112 of the Clean Air Act.

Alternatives:

Alternatives will be presented as part of the proposed rule.

Anticipated Cost and Benefits:

Implementation of the rulemaking would reduce nationwide emissions of air toxics by 58,000 tons per year in the 5th year. Mercury emissions would be reduced by almost 2 tons per year. Those reductions would lower ambient air concentrations and levels of exposure. In addition to HAP emissions reductions, reductions in criteria pollutant emissions (i.e., particulate matter, sulfur dioxide) would also be realized. The total nationwide capital costs for the rulemaking as proposed is about $1.7 billion, with an annualized cost of $840 million.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. The risks from this industry are those normally associated with combustion, such as exposure to particulate matter and sulfur oxides.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 3837

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RIN: 2060–AG69

EPA

122. NESHAP: SURFACE COATING OF AUTOMOBILES AND LIGHT-DUTY TRUCKS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 63

Legal Deadline:

None

Abstract:

The Clean Air Act, as amended in 1990, requires EPA to develop emission standards for sources of hazardous air pollutants (HAPs). The surface coating of new automobiles and light-duty trucks is among the source categories to be regulated under section 112 of the CAA. Emissions of HAPs will be addressed by this rulemaking for both new and existing sources. EPA promulgated an NSPS for this source category in 1980. The standards for the NESHAP are to be technology-based and are to require the maximum achievable control technology as described in section 112 of the CAA.

Statement of Need:

Surface coating of automobiles and light-duty trucks is a source category listed to be regulated under section 112 of the CAA.

Summary of Legal Basis:

Section 112 of the Clean Air Act.

Alternatives:

Alternatives have been explored as the proposal has been developed. The alternatives include the minimum required ''floor'' level of control and other more stringent options.

Anticipated Cost and Benefits:

The estimated total annual costs, including costs for recordkeeping and reporting, to the affected industry of the rule is $150 million. The rule is projected to reduce emissions of hazardous air pollutants by 6,000 tons per year. A regulatory impact analysis will accompany the proposed rule.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. The risks from this industry are those normally associated with surface coating operations, such as exposure to coating solvents which are hazardous air pollutants.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local

Additional Information:

SAN No. 3907

Sectors Affected:

33611 Automobile and Light Duty Motor Vehicle Manufacturing; 336112 Light Truck and Utility Vehicle Manufacturing; 336211 Motor Vehicle Body Manufacturing

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RIN: 2060–AG99

EPA

123. TRANSPORTATION CONFORMITY AMENDMENTS: RESPONSE TO MARCH 2, 1999, COURT DECISION

Priority:

Other Significant

Legal Authority:

42 USC 7401 to 7671q

CFR Citation:

40 CFR 93

Legal Deadline:

None

Abstract:

The Clean Air Act requires EPA to promulgate rules that establish the criteria and procedures for determining whether highway and transit plans, programs, and projects conform to state air-quality plans. Conformity means that the transportation actions will not cause or worsen violations of air quality standards or delay timely attainment of the standards. The original conformity rule was finalized on November 24, 1993, and most recently amended on August 15, 1997. On March 2, 1999, the U.S. Court of Appeals overturned certain provisions of the 1997 conformity amendments. This rulemaking will amend the conformity rule in compliance with the court decision. The rulemaking will formalize the May 14, 1999, EPA guidance and the June 18, 1999, DOT guidance that was issued to guide action on this issue until a rulemaking could be issued. Specifically, the rulemaking will clarify the types of projects that can be implemented in the absence of a conforming transportation plan. It will also explain EPA's process for reviewing newly submitted air quality plans and when those submissions can be used for conformity purposes.

Statement of Need:

The U.S. Court of Appeals remanded some provisions of EPA's conformity rule. The conformity rule must be amended in compliance with the court decision.

Summary of Legal Basis:

The Clean Air Act requires transportation plans, programs, and projects to conform to State air-quality plans. The Clean Air Act also requires EPA to establish rules for how to determine the conformity of transportation actions.

Alternatives:

EPA's alternatives are constrained by the court decision.

Anticipated Cost and Benefits:

This amendment will not change the results of the economic analysis performed for the original transportation conformity rule, which was summarized in the preamble to that rule on 11/24/93 at 58 FR 62214.

Risks:

Transportation conformity is a process designed to help achieve attainment with the National Ambient Air Quality Standards. The risks addressed by the rule are therefore those risks associated with non-achievment of such standards.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4340

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RIN: 2060–AI56

EPA

124. CONTROL OF EMISSIONS FROM SPARK IGNITION MARINE VESSELS AND HIGHWAY MOTORCYCLES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7401 to 7671(q)

CFR Citation:

40 CFR 94

Legal Deadline:

None

Abstract:

EPA is proposing to take actions to reduce emissions from two categories of engines. The first category, highway motorcycles, have existing emission standards that were put in place over twenty years ago. Emissions control technologies have advanced significantly since that time, and EPA believes it is appropriate to put in place more stringent standards for HC and NOx that reflect this progress. The proposed standards are consistent with standards California has recently promulgated, thereby creating the opportunity to industry to produce and market products nationwide. The second categoy of emissions sources addressed in this proposal is gasoline-powered marine vessels. Specifically, EPA is proposing to control evaporative emissions from these sources through the application of fuel tank and hose controls that can significantly reduce HC emissions from these sources. This proposal is the first set of emissions standards for this category.

Statement of Need:

Ozone pollution poses a serious threat to the health and well-being of millions of Americans. This rulemaking addresses control measures to reduce emissions from highway motorcycles and gasoline fuel systems for marine vessels.

Summary of Legal Basis:

42 USC 7521 and 7547.

Alternatives:

The proposal describes alternatives that could be adopted as part of the final rule. Small business compliance flexibilities are included for both categories of standards. For the motorcycle portion of the proposal, alternative emission standards are less attractive given the benefits associated with harmonizing the Federal program with existing California requirements.

Anticipated Cost and Benefits:

Costs and benefits will be analyzed as part of the final rule review process. The standards included in the proposal are cost-effective, with significant reductions estimated for HC and NOx emissions from motorcycles and HC for the evaporative emissions controls. In addition, the evaporative emissions controls are expected to lead to significant fuel savings for the owners and operators of these sources.

Risks:

The risks addressed by this program are primarily those associated with nonattainment of the National Ambient Air Quality Standards for ozone. There are also serious public health and welfare benefits from controlling emissions from these sources, such as reductions in regional haze and acid deposition.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	08/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4626

Sectors Affected:

333924 Industrial Truck, Tractor, Trailer and Stacker Machinery Manufacturing; 335312 Motor and Generator Manufacturing; 42183 Industrial Machinery and Equipment Wholesalers

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RIN: 2060–AJ90

EPA

125. IMPLEMENTATION RULE FOR 8-HOUR OZONE NAAQS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 7408; 42 USC 7410; 42 USC 7501-7511f; 42 USC 7601(a)(1)

CFR Citation:

40 CFR 51 (revision)

Legal Deadline:

None

Abstract:

This rule would provide specific requirements for State and local air pollution control agencies to prepare State implementation plans (SIPs) under the 8-hour national ambient air quality standard (NAAQS) for ozone, published by EPA on July 18, 1997. The Clean Air Act 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 Clean Air Act 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 Clean Air Act and the Supreme Court's ruling. This rule would provide detailed provisions to address the Clean Air Act's requirements for State Implementation Plans (SIPs) and would thus affect State and local air agencies. 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 Clean Air Act. Tribal lands that are not attaining the 8-hour ozone standard may be affected and could voluntarily submit a Tribal Implementation Plan (TIP), but would not be required to submit a TIP. In cases where a TIP is not submitted, EPA would have the responsibility for planning in those areas.

Statement of Need:

This action is needed in response to the U.S. Supreme Court's ruling in February 2001 (Whitman v. American Trucking Assoc.,, 121 S.Ct.903) that stated that EPA has the authority to implement a revised ozone NAAQS but that EPA could not ignore the provisions of subpart 2 when implementing the 8-hour NAAQS. The Supreme Court identified several portions of subpart 2 that are ill-fitted to the revised NAAQS but left it to EPA to develop a reasonable implementation approach. Consequently, EPA is developing a rule to implement the 8-hour ozone NAAQS under the provisions of subpart 2 of the CAA.

Summary of Legal Basis:

Title I of the Clean Air Act.

Alternatives:

This entry comprises the action the Agency plans to take to implement the 8-hour ozone NAAQS. The major alternative facing the Agency was whether to implement the standard strictly on a State-by-State basis, as has been the norm in the past, or to take Federal action to address the fact that emissions from one State affect the ability of other States to achieve the ozone NAAQS. The other major set of alternatives involved various possible strategies for infrastructure design, such as the designations of nonattainment areas and the requirements that apply to them.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis for the final ozone NAAQS, and is preparing a cost analysis for this 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	12/00/02	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Tribal

Additional Information:

SAN No. 4625

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RIN: 2060–AJ99

EPA

126. CONTROL OF EMISSIONS OF AIR POLLUTION FROM NONROAD DIESEL ENGINES AND FUEL

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

15 USC 2002

CFR Citation:

40 CFR 89

Legal Deadline:

None

Abstract:

On October 23, 1998, EPA finalized emission standards for nonroad compression ignition (i.e., diesel) engines for engines over 37 kW(50hp). The regulation reduced the NOx + HC emissions standard by 30 percent to 37 percent (based on the power class) from the previous 6.9 g/hp-hr NOx and 1.0 g/hp-hr HC standard beginning in 1999. As a follow-up to that 1998 rulemaking, the Agency is now undertaking a technology review, pursuant to the Clean Air Act, to assess whether more stringent standards are now feasible, and to promulgate such standards if the findings are positive. The technology review will reassess the NOx + HC standards and will set the next phase of particulate matter standards for over 37 kW and up to 560 kW. The emission limits will also be reexamined for the under 37 kW scheduled for implementation in 2004. The issue of the sulfur content of nonroad diesel

fuel will be raised and consideration given to lowering the fuel sulfur level with an ultimate 15 ppm cap. The certification duty cycle for this class of engines will also be revisited to implement a transient duty cycle that gives some assurance of better in-use control of particulate matter.

Statement of Need:

Ozone and particulate pollution pose a serious threat to the health and well-being of millions of Americans and a large burden to the U.S. economy. This rulemaking will address additional national control measures to reduce emissions, including emissions of nitrogen oxides, hydrocarbons and particulate matter, from nonroad heavy-duty diesel engines, and will also require reduced sulfur levels in nonroad diesel fuel, in order to protect the public health and welfare.

Summary of Legal Basis:

CAA title II part A section 213, 217.

Alternatives:

Alternatives will be considered as the rulemaking proposal is developed.

Anticipated Cost and Benefits:

Costs and benefits will be assessed as the rulemaking proposal is developed.

Risks:

The risks addressed by this program are primarily those associated with nonattainment of the National Ambient Air Quality Standards for ozone and particulate matter. There are also serious public health and environmental problems associated with toxic air pollution, acid rain, reduced visibility and nitrogen loading of estuaries.

Timetable:

Action	Date	FR Cite
NPRM	04/00/03	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local

Additional Information:

SAN No. 4675

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RIN: 2060–AK27

EPA

127. PREVENTION OF SIGNIFICANT DETERIORATION (PSD) AND NONATTAINMENT NEW SOURCE REVIEW (NSR): ROUTINE MAINTENANCE, REPAIR, AND REPLACEMENT

Priority:

Economically Significant

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 51.165; 40 CFR 51.166; 40 CFR 52.21; 40 CFR 52.24

Legal Deadline:

None

Abstract:

The EPA is proposing revisions to the regulations governing the NSR programs mandated by parts C and D of title I of the Clean Air Act (Act). These proposed changes reflect the EPA's consideration of the discussions and recommendations of the President's National Energy Policy Report and from various stakeholders including representatives from industry, State and local governments, and environmental groups. The proposed changes provide a future category of activities that would be considered to be routine maintenance, repair, and replacement (RMR&R) under the NSR program. The changes are intended to provide greater regulatory certainty without sacrificing the current level of environmental protection and benefit derived from the program. We believe that these changes will facilitate the safe, efficient, and reliable operation of affected facilities.

Statement of Need:

The current New Source Review regulations provide for an exclusion from the definition of major modifications for ''routine maintenance, repair, and replacement'' activities; however, they do not provide a definition of this term. Specific questions regarding the application of this term have been addressed on a case-by-case basis. By providing a future category of activities that would be considered to be routine maintenance, repair, and replacement (RMR&R) under the NSR program, these changes will provide greater regulatory certainty without sacrificing the current level of environmental protection and benefit derived from the program.

Summary of Legal Basis:

42 USC 7411(a)(4)

Alternatives:

Alternative considerations that will affect what activities would be considered to be RMR&R will be included in the proposal.

Anticipated Cost and Benefits:

The Agency will conduct analyses to the extent appropriate to inform decisions on the rule. Such analyses will be introduced as part of the proposed rule and developed further for the final rule.

Risks:

Risk information will be developed as appropriate as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Rule	10/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4676

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RIN: 2060–AK28

EPA

128. • ENDOCRINE DISRUPTER SCREENING PROGRAM; IMPLEMENTING THE SCREENING AND TESTING PHASE

Priority:

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

Legal Authority:

15 USC 2603 TSCA; 21 USC 346(a) FFDCA; 42 USC 300(a)(17) SDWA; 7 USC 136 FIFRA

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The screening and testing phase of the Endocrine Disruptor Screening Program (EDSP) potentially will encompass a broad range of types of chemicals, including pesticide chemicals, TSCA chemicals, chemicals that may be found in sources of drinking water, chemicals that may have an effect that is cumulative to the effect of a pesticide chemical, chemicals that are both pesticide chemicals and TSCA chemicals, and other chemicals that are combinations of these types of chemicals. This proposed rule will describe EPA's proposed procedures and processes that EPA will use when implementing the screening and testing phase of the EDSP. Specifically, depending on decisions that the Agency makes regarding implementation of the testing phase of the EDSP, the proposed rule will describe the authorities that it may invoke to require testing and, if necessary, establish the process that the Agency will use to require the testing.

Statement of Need:

The Endocrine Disruptor Screening Program Implementation of the Screening and Testing Phase fulfills the statutory direction and authority to screen pesticide chemicals and drinking water contaminants for their potential to disrupt the endocrine system and adversely affect human health.

Summary of Legal Basis:

The screening and testing phase of the Endocrine Disruptor Screening Program (EDSP) potentially will encompass a broad range of types of chemicals, including pesticide chemicals, TSCA chemicals, chemicals that may be found in sources of drinking water, chemicals that may have an effect that is cumulative to the effect of a pesticide chemical, chemicals that are both pesticide chemicals and TSCA chemicals, and other chemicals that are combinations of these types of chemicals. As discussed in the Proposed Statement of Policy, EPA has a number of authorities at its disposal to require testing of these types of chemicals. The Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(p) provides EPA authority to require testing of all pesticide chemicals and any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if EPA determines that a substantial population may be exposed to the substance (21 U.S.C. 346a)(p)). Likewise, the Safe Drinking Water Act (SDWA) provides EPA with authority to require testing of any substance that may be found in sources of drinking water if EPA determines that a substantial population may be exposed to the substance (42 U.S.C. section 300j-17). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides EPA with authority to require testing of pesticides if EPA determines that additional data are required to maintain in effect an existing registration (7 U.S.C. section 136a(c)(2)(B)). The Toxic Substances Control Act (TSCA) provides authority for EPA to require testing of TSCA chemicals, provided that it makes certain hazard and/or exposure findings (15 U.S.C. section 2603). In addition, EPA has authority to issue consent orders to require testing when interested parties agree on an acceptable testing program (51 FR 23706 (June 30, 1986)).

Alternatives:

A Federal role is mandated under cited authority. There is no alternative to role of the Federal Government on this issue to ensure that pesticides, commercial chemicals and contaminants are screened and tested for endocrine disruption potential. A limited amount of testing may be conducted voluntarily but this will fall far short of the systematic screening which is necessary to protect public health and the environment and ensure the public that all important substances have been adequately evaluated.

Anticipated Cost and Benefits:

It is too early to project the costs and benefits of this program accurately. However, the Agency recognizes that the rule could potentially have significant cost implications, depending on the screening criteria and testing requirements. For example, as a rough estimate, the screening battery currently under consideration is estimated to cost $200,000 per chemical. It is also too early to quantify the benefits of this program mathematically. The goal of the program is to reduce the risks identified below.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk from exposure to chemicals operating through an endocrine mediated pathway. Preliminary studies show possible adverse effects on humans. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish and shellfish have been documented in the U.S., Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the U.S. to proceed on a two track strategy: research on the basic science regarding endocrine disruption and screening to identify which chemicals are capable of interacting with the endocrine system. The combination of research and test data developed by this program will enable EPA to take action to reduce chemical risks.

Timetable:

Action	Date	FR Cite
NPRM Proposed Procedural Rule	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN No. 4728

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RIN: 2070–AD61

EPA

129. MODIFICATIONS TO RCRA RULES ASSOCIATED WITH SOLVENT-CONTAMINATED SHOP TOWELS AND WIPES

Priority:

Other Significant

Legal Authority:

42 USC 6921

CFR Citation:

40 CFR 261

Legal Deadline:

None

Abstract:

This action would modify RCRA rules that impact the management of solvent-contaminated shop towels and wipes. Solvent-contaminated shop towels and wipes are used throughout industry for equipment cleaning and other related facility operations. The spent shop towels and wipes can be hazardous wastes when the solvent used is either a characteristic or listed solvent. An examination of industry use and management practices reveals that many facilities may use only small amounts of solvent on their disposable wipes, and use small numbers of wipes daily, suggesting that these materials may sometimes pose little or no risk to human health and the environment if disposed in municipal landfills. Similarly, situations exist where both disposable wipes and reusable shop towels are not being managed according to prescribed Federal and States' rules and policies. Problems with this issue have persisted since the late 1980s.

Statement of Need:

After being asked by multiple stakeholders to examine this waste stream, EPA is considering changing the requirements for management of both reusable and disposable solvent-contaminated industrial wipes. This will encourage pollution prevention and recycling of hazardous solvents, make the management standards more consistent with the risks these materials pose, and clarify existing Federal policies regarding these materials.

Summary of Legal Basis:

No aspect of this action is required by statute or court order.

Alternatives:

EPA is considering options that would either exempt solvent-contaminated industrial wipes from the definition of hazardous waste or exclude them from the definition of solid waste when certain conditions are met. These conditions would address the amount of solvent present in the wipes during transportation, as well as container requirements for accumulation and transportation.

Anticipated Cost and Benefits:

The anticipated benefits of this rule include annual cost savings for generators of disposable and reusable industrial wipes. Other benefits include the potential for pollution prevention and for increased recycling of hazardous solvents used in conjunction with industrial wipes.

Risks:

The analyses associated with this action find that the options being considered would not cause risks from disposal or re-use of solvent-contaminated wipes to increase from current regulations.

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4091

Sectors Affected:

323 Printing and Related Support Activities; 325 Chemical Manufacturing; 332 Fabricated Metal Product Manufacturing; 333 Machinery Manufacturing; 334 Computer and Electronic Product Manufacturing; 336 Transportation Equipment Manufacturing; 337 Furniture and Related Product Manufacturing; 441 Motor Vehicle and Parts Dealers; 811 Repair and Maintenance; 812 Personal and Laundry Services

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RIN: 2050–AE51

EPA

130. REVISION OF WASTEWATER TREATMENT EXEMPTIONS FOR HAZARDOUS WASTE MIXTURES

Priority:

Other Significant

Legal Authority:

42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6924; 42 USC 6926

CFR Citation:

40 CFR 261.3(a)(2)(iv)(A)-(E)(Revision)

Legal Deadline:

None

Abstract:

EPA is looking into proposing to add up to four solvents (benzene, 2-ethoxyethanol, 1,1,2-trichloroethane, and 2-nitropropane) to the hazardous waste exemptions for mixtures of spent solvents in wastewater treatment plants (headworks rule) at 40 CFR 261.3(a)(2)(iv)(A)-(B). Spent solvents are solvents that have been used and are no longer fit for use without being regenerated, reclaimed, or otherwise processed. In addition, EPA is considering proposing: (1) changes to implementation of rule from using mass balance only, to choice of using direct monitoring; (2) adding certain leachates to allowed categories of wastestreams; (3) revising other provisions of rule, such as de minimis quantities and the

definition of point of application of exemption; and (4) clarifying applicability of exemption to incinerator scrubber waters.

Statement of Need:

This action is deregulatory. Federal action in this case will give States more flexibility in implementing the regulations. In addition, the Agency has been asked to look into this issue in Congressional Committee Appropriations Report Language.

Summary of Legal Basis:

This action is not required by statutory or court order.

Alternatives:

The Agency is considering this rule without any alternatives. Some aspects of the proposal provide alternatives for the regulated community in complying with the regulations (e.g., direct monitoring of solvents vs. mass balance). Future rulemaking may expand on some of the regulatory options contained in the proposal.

Anticipated Cost and Benefits:

This proposal, if finalized, is expected to provide cost savings to the regulatory community because more facilities will be eligible for regulatory exemptions and more wastes may be exempt from hazardous waste regulation.

Risks:

Since this is deregulatory, there is no risk reduction. However, the Agency performed a conservative risk analysis and found that risk is not increased above any level of concern by this action.

Timetable:

Action	Date	FR Cite
NPRM Revisions for wastewater treatment exemptions	01/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4501

Sectors Affected:

31-33 Manufacturing; 562 Waste Management and Remediation Services

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RIN: 2050–AE84

EPA

131. INCREASE METALS RECLAMATION FROM F006 WASTE STREAMS

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

Not Yet Determined

CFR Citation:

40 CFR 261

Legal Deadline:

None

Abstract:

Currently wastewater treatment (WWT) sludges from electroplating operations (waste code F006) are identified as listed hazardous wastes. EPA is considering proposing changes to existing regulations intended to encourage safe recycling and management practices of this waste stream. We are considering reducing regulations for electroplating sludges that are sufficiently high in metal(s) and sufficiently low in other toxic constituents to be recovered.

Statement of Need:

F006 represents one of the largest hazardous waste streams amenable to recycling. Eliminating impediments to the safe recycling of F006 through regulatory changes would potentially facilitate this outcome - thereby decreasing the amount of hazardous waste disposed.

Summary of Legal Basis:

No aspect of this action is required by statutory or court order.

Alternatives:

EPA is evaluating alternatives that would either exempt from the definition of hazardous waste or exclude from the definition of solid waste F006 destined for recycling provided specified conditions were met. Specific conditions would address proper handling, possibly notification, certification, etc.

Anticipated Cost and Benefits:

Costs to generating facilities would be reduced relative to current compliance costs. Benefits include the potential for increased recycling of F006, thereby reducing the amount of virgin materials that must be extracted from the land. Safe handling of this material also would be maintained.

Risks:

Any options evaluated and proposed would ensure that the risks from recycling F006 would not increase over current regulations. In particular, the risks from managing the material on the land would be addressed.

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN No. 4651

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RIN: 2050–AE97

EPA

132. REVISIONS TO THE DEFINITION OF SOLID WASTE

Priority:

Other Significant

Legal Authority:

RCRA Section 1004(27); 42 USC 6903(27)

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 is 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 (AMC I, API I, AMC II, ABR, API II, etc.). 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 decided to initiate development of a proposed rule to revise the definition of solid waste. We expect that the proposed rule will be broad in scope and will specifically address materials undergoing reclamation. In the context of reclamation, we plan to discuss options for how to distinguish materials that are discarded from materials that remain in use in a continuous industrial process and we anticipate proposing a definition of ''continuous industrial process.'' Generally, we believe that removing the specter of RCRA control where it is not necessary can spur increased reuse and recycling of hazardous waste, and will lead to better resource conservation and improved materials management overall.

Statement of Need:

This proposal responds to court decisions about EPA's definition of solid waste under RCRA. See Association of Battery Recyclers v. EPA, 208 F.3d 1047 (2000).

Summary of Legal Basis:

See above.

Alternatives:

No alternatives are being considered.

Anticipated Cost and Benefits:

EPA currently anticipates that this rule, when finalized, will result in a net savings to the part of the regulated community affected by the rule (those facilities involved in recycling that is part of a continuous process within the generating industry). These facilities will no longer have to comply with the RCRA hazardous waste management requirements.

Timetable:

Action	Date	FR Cite
NPRM	04/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN No. 4670

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RIN: 2050–AE98

EPA

133. NPDES PERMIT REQUIREMENTS FOR MUNICIPAL SANITARY AND COMBINED SEWER COLLECTION SYSTEMS, MUNICIPAL SATELLITE COLLECTION SYSTEMS, SANITARY SEWER OVERFLOWS, AND PEAK EXCESS FLOW TREATMENT FACILITIES

Priority:

Other Significant

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1314 CWA sec 304; 33 USC 1318 CWA sec 308; 33 USC 1342 CWA sec 402; 33 USC 1361 CWA sec 501(a)

CFR Citation:

40 CFR 122.38; 40 CFR 122.41; 40 CFR 122.42

Legal Deadline:

None

Abstract:

EPA is developing a notice of proposed rulemaking that would propose a broad-based regulatory framework for sanitary sewer collection systems under the NPDES program. The Agency is proposing standard permit conditions for inclusion in permits for publicly owned treatment works (POTWs) and municipal sanitary sewer collection systems. The standard requirements address reporting, public notification, and recordkeeping requirements for sanitary sewer overflows (SSOs), capacity assurance, management, operation and maintenance requirements for municipal sanitary sewer collection systems; and a prohibition on SSOs. The Agency is also proposing a regulatory framework for applying NPDES permit conditions, including applicable standard permit conditions, to municipal satellite collection systems. Municipal satellite collection systems are sanitary sewers owned or operated by a municipality that conveys wastewater to a POTW operated by a different municipality. EPA is also proposing to clarify NPDES requirements, including secondary treatment requirements, for discharges from peak excess flow treatment facilities.

Statement of Need:

The proposed regulation is intended to address three interrelated issues: (1) the risks to health and the environment caused by SSOs; (2) the need to protect and enhance local, State and Federal investments in sewer system infrastructure; and (3) the need to provide a clear and consistent regulatory program for collection systems. Risks to health/environment: EPA estimates that about 55,000 SSO events occur each year, and perhaps ten times this many instances occur where sewage backs up into basements. These events lead to a variety of damages, including exposure of people to health risks; lowered water quality; and property damage and clean-up costs. Protection of Investments in Sewer System Infrastructure: Sanitary sewer collection systems represent a major national investment in community infrastructure. EPA estimates that these systems have a replacement value of $1 to $2 trillion. Another source estimates that wastewater collection and

treatment systems represent about 10 to 15 percent of the value of all publicly owned infrastructure in the United States. The substantial frequency of SSOs and other collection system failures indicates that operation, maintenance, repair and rehabilitation of sewer systems needs to improve.

Providing Clear and Consistent Regulatory Program for Collection Systems — States are implementing the existing NPDES regulations relevant to sanitary sewer collection systems in widely differing ways.

Summary of Legal Basis:

EPA is considering whether to publish a proposed rule that would require NPDES permits for municipal sanitary sewer collection systems to contain a standard provision for better operation and management of systems to avoid SSOs, increased attention to system planning, and better notification to the public in the event of an overflow. These proposed standard permit conditions would derive from Clean Water Act (CWA) sections 304(i), 308, and 402(a). Section 402(a) of the CWA authorizes EPA to prescribe permit conditions as necessary to carry out the provisions of the CWA, including permit conditions on data and information collection and reporting. Section 308 of the CWA authorizes EPA to require NPDES permittees to establish, maintain, and report records for determining whether there has been a violation of the CWA. The prohibition of SSO discharges is a technology-based limitation that is based, in part, on CWA section 301(a) which prohibits a discharge to waters of the United States except in compliance with an NPDES permit. The prohibition is also based on EPA's interpretation of the Act that discharges from a separate sanitary sewer system need to meet effluent limitations based on secondary treatment as defined by EPA and any more stringent limitation necessary to meet water quality standards.

Legal authority for the requirements for municipal satellite collection systems derives from the definition of ''publicly owned treatment works.'' CWA section 212(2)(A) defines ''treatment works'' to include ''any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature . . . including . . . intercepting sewers, outfall sewers, sewage collection systems . . . .'' EPA regulations define the term ''publicly owned treatment works similarly at 40 CFR 122.2 and 403.1.

Alternatives:

NPDES requirements for municipal sanitary sewer collection systems currently under consideration include the five major alternatives discussed below. The first alternative would require NPDES permits for municipal sanitary sewer collection systems to contain a standard provision for better operation and management of systems to avoid SSOs, increased attention to system planning, and better notification to the public in the event of an overflow. The second alternative would involve extending the requirements of the proposed rule to privately owned satellite collection systems. The third alternative would be to change the technology-based standard for discharges from sanitary sewers from secondary treatment to best available technology economically achievable (BAT)/ best practicable control technology currently available (BCT). The fourth alternative would be a no-action alternative. The fifth alternative would be a prescriptive capacity, management, operation, and maintenance provision. In addition to these alternatives, a number of municipalities have suggested additional alternatives which are being considered.

Anticipated Cost and Benefits:

EPA is considering a proposed rule that would require NPDES permits for municipal sanitary sewer collection systems contain standard provisions for better operation and management of systems, increase attention to system planning, and better public notification in the event of an overflow. EPA is in the process of estimating the annual costs and benefits associated with this proposal.

Risks:

EPA estimates that there are at least 55,000 SSO events per year and an additional 400,000 occurrences of sewage backing up into basements. The health and environmental risks attributed to SSOs vary depending on a number of factors including location and season (potential for public exposure), frequency, volume, the amount and type of pollutants present in the discharge, and the uses, conditions, and characteristics of the receiving waters. SSOs can release raw sewage to areas where they present high risks of human exposure, such as streets, private property, basements, and receiving waters used for drinking water, fishing and shellfishing, or contact recreation. The most immediate health risks associated with SSOs are potential exposure to bacteria, viruses, and other pathogens. Major groups of disease-causing organisms or agents associated with untreated SSOs include: bacteria, viruses, protozoa, and helminths (intestinal worms). These pathogens can cause diseases range in severity from mild gastroenteritis (causing stomach cramps and diarrhea) to diseases that can be life-threatening, such as cholera, infectious hepatitis, dysentery, and severe gastroenteritis. Adverse health consequences can be more severe for children, the elderly, and those with weakened immune systems. In addition to pathogens, raw sewage may contain metals, synthetic chemicals (including endocrine system disruptors), nutrients, pesticides, and oils, which also can be detrimental to the health of humans and wildlife. SSOs may affect the quality and uses of waters of the United States. Adverse water quality impacts from SSOs may include changes to the physical characteristics and viability of aquatic habitats, causing fish kills. In 2001, sewer line blockages and breaks were cited in 4 percent and SSOs were cited in 2 percent of beach closures and swimming advisories in the United States.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

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

Additional Information:

SAN No. 3999

Sectors Affected:

22132 Sewage Treatment Facilities

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RIN: 2040–AD02

EPA

134. 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 goverments and the private sector.

Legal Authority:

40 USC 300g-1(b); SDWA 1412(b); 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 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 will analyze 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, will provide a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was available previously. EPA will also use 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 pathogens, 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 and 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 healthly individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of Cryptosporidium in drinking water sources through the Information Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems have an unacceptably high risk for Cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for Cryptosporidium through monitoring and prescribe an appropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

Summary of Legal Basis:

Section 1412(b)(7)(A) of SDWA allows 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 along 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 will have an annual economic impact of $100 million or more. The majority of people (approximately 67 percent) are served by public water systems that use a surface water or ground water under

the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. 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	06/00/03	
Final Action	07/00/04	

Regulatory Flexibility Analysis Required:

Yes

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

135. 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 goverments and the private sector.

Legal Authority:

40 USC 300g-1(b); SDWA 1412(b); 42 USC 300f; 42 USC 300g-2; 42 USC 300g-3; 42 USC 300g-4; 42 USC 300g-5; 42 USC 300g-6; 42 USC 300j-4; 42 USC 300j-9; 42 USC 300j-11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

Final, Statutory, July 14, 2003.

Abstract:

This Regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that will be promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process although the impacts may be limited to community water systems (CWSs) and nontransient noncommunity 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 will analyze 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, will provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was available previously. EPA will also use 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 and 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 along 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 $100 million or more. 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	06/00/03	
Final Action	07/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

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

EPA

136. MINIMIZING ADVERSE ENVIRONMENTAL IMPACT FROM COOLING WATER INTAKE STRUCTURES AT EXISTING FACILITIES UNDER SECTION 316(B) OF THE CLEAN WATER ACT, PHASE 3

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1316 CWA sec 306; 33 USC 1326 CWA sec 316; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 125

Legal Deadline:

NPRM, Judicial, June 15, 2003.

Final, Judicial, December 15, 2004.

Abstract:

This rulemaking affects, at a minimum, existing facilities that use cooling water intake structures, and whose intake flow levels exceed a minimum threshold EPA will determine during this rulemaking. The affected facilities include: (1) electricity generating facilities not covered by Phase 2 regulations; (2) pulp and paper manufacturing facilities; (3) chemicals and allied products manufacturing facilities; (4) petroleum and coal products manufacturing facilities; and (5) primary metals manufacturing facilities. Section 316(b) of the Clean Water Act provides that any standard established pursuant to sections 301 or 306 of the Clean Water Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. A primary purpose of this action is to minimize the impingement and entrainment of fish and other aquatic organisms by cooling water intake structures. Impingement refers to trapping fish and other aquatic life against cooling water intake structures. Entrainment occurs when aquatic organisms, eggs and larvae are drawn into the cooling system, through the heat exchanger, and then pumped back out with significant injury or mortality to the entrained organisms.

Statement of Need:

In the absence of national regulations, Permit Directors have regulated cooling water intake structures incompletely and inconsistently, especially with respect to the manufacturing sector. In some instances, permit issuance or reissuance has been significantly delayed or permit decisions from 20 years ago have not been reevaluated. Tons of fish and other aquatic organisms may be cropped annually as a result of cooling water intake structures at a single large intake or cumulative impact at multiple small intakes on the same waterbody. By court order, EPA must propose and take final action on this regulation. This regulation may have substantial ecological benefits.

Summary of Legal Basis:

This action is required under an Amended Consent Decree in Riverkeeper Inc. et al. v. Whitman, 93 Civ. 0314 (AGS)(U.S. District Court, Southern District of New York, November 21, 2000).

Alternatives:

This analysis will cover various sizes and types of potentially regulated facilities. EPA is considering whether to regulate on a site-specific, waterbody category, or national basis. EPA is also

considering several flow thresholds, below which the regulation would not apply.

Anticipated Cost and Benefits:

Costs are not yet determined, but are expected to exceed $100 million. A qualitative assessment of benefits at several large and small facilities indicates the potential for significant benefits when intakes are controlled. Costs and benefits are generally expected to be smaller at facilities that use smaller amounts of cooling water.

Risks:

Cooling water intake structures may pose significant risks for aquatic ecosystems.

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4543

Sectors Affected:

21 Mining; 211111 Crude Petroleum and Natural Gas Extraction; 211112 Natural Gas Liquid Extraction; 22111 Electric Power Generation; 22133 Steam and Air-Conditioning Supply; 311 Food Manufacturing; 3122 Tobacco Manufacturing; 313 Textile Mills; 321 Wood Product Manufacturing; 322 Paper Manufacturing; 324 Petroleum and Coal Products Manufacturing; 325 Chemical Manufacturing; 326 Plastics and Rubber Products Manufacturing; 327 Nonmetallic Mineral Product Manufacturing; 331 Primary Metal Manufacturing; 332 Fabricated Metal Product Manufacturing; 333 Machinery Manufacturing; 334 Computer and Electronic Product Manufacturing; 335 Electrical Equipment, Appliance and Component Manufacturing; 336 Transportation Equipment Manufacturing; 61131 Colleges, Universities and Professional Schools

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RIN: 2040–AD70

EPA

137. WATERSHED RULE: TOTAL MAXIMUM DAILY LOAD (TMDL) PROGRAM REVISIONS

Priority:

Other Significant

Legal Authority:

33 USC 1313; 33 USC 1329; 33 USC 1342

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 130; 40 CFR 131

Legal Deadline:

None

Abstract:

Amend regulations governing the TMDL program to ensure that it is effective and allows for active participation by all stakeholders including local governments and communities. The amendments will address: the scope and content of the list of impaired waters required by section 303(d) of the Clean Water Act, the scope and content of TMDLs, EPA's role in helping States establish 303(d) lists and TMDLs so that impaired waters are restored, and the framework for implementing TMDLs provided by State CPPs and watershed plans. EPA is also proposing revision to the NPDES permitting regulations.

Statement of Need:

This action will propose a new framework for accomplishing the water quality planning and management provisions of the Clean Water Act (CWA). EPA believes that this framework based on the watershed approach will allow jurisdictions (i.e., State, territories and authorized tribes) to use the Total Maximum Daily Load (TMDL) program to more effectively contribute to improving the Nation's water quality. The proposal recognizes that the major responsibility for water quality management resides with these jurisdictions. The goal of the proposal is to provide jurisdictions with a tailored yet flexible approach to water quality management that meets the unique needs and situation of each jurisdiction and of local communities while at the same time ensuring that progress is made towards restoring the Nation's waters so that they attain and maintain water quality standards. The proposal revitalizes and strengthens the Continuing Planning Process (CPP) as a focus for a variety of jurisdictions' water quality planning and implementation activities. The proposal seeks to increase TMDL program flexibility and enhance stakeholder participation, promote opportunities for trading, and increase efficiencies in establishing, approving and implementing TMDLs. EPA is also proposing revisions to the NPDES permit regulations.

Summary of Legal Basis:

These revisions to EPA's TMDL rules are authorized by, among others, sections 303(d) and (e) of the CWA that: (1) require States to identify impaired waters within their boundaries and establish TMDLs for those waters at levels necessary to implement water quality standards, and (2) require States to have a continuing planning process resulting in a plan for all navigable waters that EPA reviews from time to time.

Anticipated Cost and Benefits:

Estimates under development.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN No. 4623

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RIN: 2040–AD82

EPA

138. • WITHDRAWAL OF TOTAL MAXIMUM DAILY LOAD (TMDL) PROGRAM REVISIONS

Priority:

Other Significant

Legal Authority:

33 USC 1313

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 130

Legal Deadline:

None

Abstract:

EPA is proposing to withdraw the July 2000 rule, rather than allow it to go into effect. EPA believes that significant changes would need to be made to the July 2000 rule before it could serve as the blueprint for an efficient and effective TMDL program. Furthermore, EPA needs additional time beyond April 2003 to promulgate new revisions to the TMDL program that will enable EPA and jurisdictions to best achieve the goals of the Clean Water Act. Regulations that EPA promulgated in 1985 and amended in 1992 would remain the regulations in effect for implementing the TMDL Program until EPA finalizes any future TMDL rules.

Statement of Need:

Due to the significant controversy, pending litigation and lack of stakeholder consensus on key aspects of the July 2000 rule, it has become apparent to EPA that, as promulgated, the July 2000 rule cannot function as the blueprint for an efficient and effective TMDL program without significant revisions. Moreover, the existence of the approaching April 30, 2003, effective date for the July 2000 rule - a mere eight months away - is beginning to act as an unnecessary and artificial distraction from an orderly completion of the Agency's efforts now underway to chart the future direction and scope of the TMDL program. Consequently, EPA is proposing to withdraw the July 2000 TMDL rule so that the Agency can proceed in an orderly process to revise the TMDL rules without concern that those efforts will be adversely affected by the July 2000 rule's effective date.

Summary of Legal Basis:

These revisions to EPA's TMDL rules are authorized by, among others, sections 303(d) and (e) of the CWA that: (1) require States to identify impaired waters within their boundaries and establish TMDLs for those waters at levels necessary to implement water quality standards, and (2) require States to have a continuing planning process resulting in a plan for all navigable waters that EPA reviews from time to time. If the July 2000 TMDL regulations are not withdrawn, they will become effective on April 30, 2003.

Alternatives:

Whether the July 2000 rule should be withdrawn or not.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
Final Action	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN No. 4729

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RIN: 2040–AD84

EPA

FINAL RULE STAGE

139. OVERVIEW OF RULEMAKINGS FOR THE PURPOSE OF REDUCING INTERSTATE OZONE TRANSPORT

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7410

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

The Clean Air Act (CAA) requires that a State implementation plan (SIP) contain provisions to prevent a State's facilities or sources from contributing significantly to air pollution that is transported downwind to other States, exacerbating their inability to meet the national ambient air quality standards for ozone. Through a two-year effort known as the Ozone Transport Assessment Group (OTAG) , EPA worked in partnership with the 37 easternmost States and the District of Columbia, industry representatives, and environmental groups to address ozone precursor and ozone transport. This multiyear collaboration resulted in the most comprehensive analysis of ozone transport ever conducted. The OTAG States voted in favor of a range of strategies to reduce nitrogen oxide emissions from utilities and other major sources. Building on the

recommendations of OTAG, EPA issued a rule known as the NOx SIP Call (10/27/98, 63 FR 57355) requiring 22 States and the District of Columbia to submit revisions to their SIPs to address the regional transport of nitrogen oxides (a precursor to ozone formation known as NOx). By reducing emissions of NOx, the actions directed by these plans will decrease the formation and transport of ozone across State boundaries in the eastern half of the United States. This rule was challenged in court, and on March 3, 2000, the U.S. Court of Appeals for the District of Columbia issued a decision largely upholding the NOx SIP Call, but remanded four narrow issues to EPA for further rulemaking action. In an August 30, 2000, Court Order, emission reduction measures are required to be in place by May 31, 2004. On June 8, 2001, the Court made a related decision concerning the NOx SIP Call Technical Amendment rulemakings which largely upheld Phase I of the NOx SIP Call, but remanded one issue to EPA. EPA is now addressing the remanded issues in separate rulemakings (see SAN 4433 and SAN 4679 in today's Regulatory Agenda). A notice of data availability was published on 8/3/01 which made new data publicly available for notice-and-comment. A second notice of data availability was published in on March 11, 2002, listing additional items which were made publicly available. Final action was published on 5/1/02 (67 FR 21868). In addition to the SIP Call provisions, Federal Implementation Plans (FIPs) may also be needed to reduce regional transport if any affected State fails to adequately revise its SIP to comply with the NOx SIP call (see SAN 4096 in today's Regulatory Agenda). In addition to the SIP Call remedy, the Clean Air Act also gave States the right to petition EPA to take other Federal action to prevent ozone transport that affects downwind States. Accordingly, under section 126 of the CAA, eight Northeastern States filed petitions requesting EPA to make findings and require decreases in NOx emissions from

Statement of Need:

It has long been recognized that ozone transport is a major factor in the difficulty many States are having in attaining the clean-air standards for ozone. This was made more clear by the OTAG analysis outlined above.

Summary of Legal Basis:

Clean Air Act Section 110 provides the legal basis for addressing transport of air pollution.

Alternatives:

The Clean Air Act specifies the SIP Call process, the FIP process, and the Section 126 petition process as alternate approaches to remedying the problem of ozone transport. EPA intends to use these alternatives as appropriate in an integrated program.

Anticipated Cost and Benefits:

As outlined in the Regulatory Impact Analysis for the NOx SIP Call, the rule will result in 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, increases in yields of commercial forests currently exposed to elevated ozone levels, and reductions in loadings of nitrogen to sensitivity estuaries, helping State and local government reach target reduction goals for estuaries such as Chesapeake Bay, Albermarle-Pamlico Sound and Long Island Sound. Due to practical analytical limitations, we cannot quantify and/or monetize all potential benefits of this action. Within these limitations, the quantified and monetized benefits were estimated in the Regulatory Impact Analysis to range from $1.1 billion to $4.2 billion annually. Annual costs were estimated at $1.7 billion. All figures are in 1990 dollars.

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 are outlined in detail in the Regulatory Impact Analysis for the NOx SIP Call.

Timetable:

Action	Date	FR Cite
NPRM NOx FIPs (SAN 4096)	10/21/98	63 FR 56393
Final Action NOx SIP Call	10/27/98	63 FR 57355
Final Action Section 126 Findings	05/25/99	64 FR 28250
Final Action Section 126 Approvals and Remedy	01/18/00	65 FR 2674
NODA Notice of Data Availability for NOx SIP Call/Section 126 rule	08/03/01	66 FR 40609
NPRM Phase II NOx SIP Call Proposal (SAN 4433)	02/22/02	67 FR 8395
NODA Notice of Data Availability for NOx SIP Call/Section126 Rule	03/11/02	67 FR 10844
Final Action Data Harmonization (Section 126/NOx SIP Call)	04/30/02	67 FR 21522
Final Action Response to Remands Concerning Growth Factors	05/01/02	67 FR 21868
Final Action Final Phase II NOx SIP Call (SAN 4433)	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

Additional Information:

SAN No. 4466

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RIN: 2060–AJ20

EPA

140. CONTROL OF EMISSIONS OF AIR POLLUTION FROM NEW MARINE COMPRESSION-IGNITION ENGINES AT OR ABOVE 30 LITERS PER CYLINDER

Priority:

Other Significant

Legal Authority:

42 USC 7621 et seq; 42 USC 7542 et seq

CFR Citation:

40 CFR 94

Legal Deadline:

Final, Judicial, January 31, 2003, Finalize emission standards for new compression-ignition marine engines at or above 30 liters per cylinder.

Abstract:

This rule will set exhaust emission standards for new marine compression-ignition engines at or above 30 liters per cylinder installed on vessels flagged by the United States and will determine whether it is appropriate to apply these standards to foreign flag vessels that use U.S. ports. The proposed rule set out a primary control option of aligning emission standards with standards included in a pending international agreement beginning in 2004. The status of the international agreement is an issue to consider as we determine appropriate final standards. We also asked for comment on a second tier of more stringent NOx standards starting in 2007 as well as potential controls on sulfur levels in diesel fuel used in these vessels. Emissions control from marine vessels is important to various port cities as the contribution from marine vessels to their emissions inventories is projected to grow as steps are taken to reduce Nox and PM emissions from other sources.

Statement of Need:

Ozone and particulate pollution pose a serious threat to the health and well-being of millions of Americans. This rulemaking addresses control measures to reduce emissions from large diesel-powered marine engines, with a focus on engine controls that can reduce NOx emissions. The proposal also asked for comments on controlling sulfur levels in diesel fuel used in such vessels, which can lead to particulate matter reductions.

Summary of Legal Basis:

42 USC 7522-7525, 7541-7545, 7547, 7549, 7550, and 7601(a)

Alternatives:

The proposed rule included extensive cost and emissions reductions estimates for one primary option and two different control scenarios for NOx emissions - 30 percent, 50 percent, and 80 percent reductions from the assumed baseline levels associated with compliance with international standards. This rule also includes information regarding costs and benefits associated with fuel control options.

Anticipated Cost and Benefits:

There are negligible costs and marginal unanticipated benefits associated with compliance with the baseline control scenario included in the proposal as engine manufacturers are already meeting the specified emission levels through application of a pending international agreement. The costs and benefits of the primary option for a second tier of standards are estimated to be less than $200/ton for NOx control. Cost and benefit information is also provided for the alternative options as well.

Risks:

The risks addressed by this program are primarliy those associated with nonattainment of the National Ambient Air Quality Standards for ozone and particulate matter. There are also serious public health and welfare benefits from controlling emissions from these sources, such as reductions in regional haze and acid deposition.

Timetable:

Action	Date	FR Cite
NPRM	05/29/02	67 FR 37548
Final Action	01/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4622

Sectors Affected:

333618 Other Engine Equipment Manufacturing; 3366 Ship and Boat Building

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RIN: 2060–AJ98

EPA

141. MANAGEMENT OF CEMENT KILN DUST (CKD)

Priority:

Other Significant

Legal Authority:

42 USC 6912(a) RCRA sec 2002(a); 42 USC 6921(a) RCRA sec 3001(a)

CFR Citation:

40 CFR 256; 40 CFR 259; 40 CFR 261; 40 CFR 264

Legal Deadline:

None

Abstract:

In December 1993, EPA submitted a Report to Congress with its findings on the nature and management practices associated with cement kiln dust (CKD). In 1995, EPA determined that some additional control of CKD was needed and published a regulatory determination (60 FR 7366, 2/7/95). On August 20, 1999, EPA issued a proposed rule (64 FR 45632) outlining the Agency's preferred regulatory approach (i.e., an exemption from hazardous waste listing for properly managed CKD) and several optional approaches including requirements solely under RCRA Subtitle D. On July 25, 2002, the Agency published a Notice of Data Availability to announce the availability for public inspection and comment of recently acquired data on CKD. The Agency is considering an approach whereby it would finalize protective CKD management standards.

Statement of Need:

EPA issued a regulatory determination finding that additional control of CKD was warranted. The Agency stated that its concerns about the potential harm to human health and the environment posed by some CKD suggest the need for some level of regulation under RCRA Subtitle C authority. The Agency is now considering an approach whereby it would finalize protective CKD management standards. Active consideration of the proposed mismanagement-based listing would be temporarily suspended for a period of three to five years. During this time EPA would collect data to evaluate the effectiveness of CKD management practices and States' regulatory programs. If after its evaluation the Agency deems CKD management practices and States' regulatory programs to be effective in protecting human health and the environment, the Agency would formally withdraw the

Subtitle C portion of the 1999 proposal and would revisit the 1995 CKD regulatory determination. Otherwise, if the Agency deems CKD management practices and State regulatory programs to be ineffective after this period, the Agency would pursue regulation of mismanaged CKD under RCRA Subtitle C.

Summary of Legal Basis:

There are no applicable statutory or judicial deadlines for the CKD rulemaking effort. However, section 3001(b)(3)(C) of RCRA contemplates a rule in light of the Administrator's 1995 determination that further regulation of CKD was warranted.

Alternatives:

In the 1995 Regulatory Determination, the Agency stated its concerns about the potential harm to human health and the environment posed by some CKD suggest the need for some level of regulation under RCRA subtitle authority. Although the Agency is considering issuing the protective CKD management standards as a RCRA subtitle D rule, if after a three- to five-year evaluation period the Agency deems CKD management practices and State regulatory programs to be ineffective, the Agency would pursue regulation of mismanagement CKD under RCRA subtitle C.

Anticipated Cost and Benefits:

The Agency estimated the proposed rule would affect the economy by less than $100 million per year. EPA also estimated that the proposed rule may result in a reduced risk of 0.0004 to 0.003 cancer cases per year (best estimate - 0.0006) and 29 to 315 fewer persons (best estimate - 43) exposed to potential noncancer health effects due to food chain exposures (i.e., vegetables, beef, and/or milk) to ''backyard'' gardeners and subsistence farmers. In addition, the population analysis indicated that between 669 and 5,895 recreational fishers (best estimate - 999) would avoid exposure to contaminant levels that may result in noncancer health effects. The population analysis indicated that 18 to 4,118 individuals (best estimate - 2,378) would avoid exposure to particulate matter in excess of the National Ambient Air Quality Standards (NAAQS). The rule should also help prevent contaminated CKD leachate from impacting groundwater resources.

Risks:

For the 1993 Report to Congress and 1995 Regulatory Determination, the Agency modeled individual risks from direct and indirect pathways for 83 plants. The Agency concluded that the risks from direct pathways (i.e., drinking water ingestion, incidental ingestion, and chemical inhalation) were low or negligible. The Agency caveated these conclusions by noting that (1) about half of the plants are underlain by limestone formations in areas of karst landscape and may be susceptible to fissures and hydraulic characteristics that allow leachate to directly enter groundwater without dilution or attenuation and cannot be modeled with current techniques; (2) empirical evidence indicated groundwater contamination in areas of both karst and non-karst terrain; and (3) modeling results for fine particulate emissions for 28 cement plants out of 52 modeled may have exceedances of NAAQS at plant boundaries and may result in risks from fine particulate inhalation at nearby residences.

For the indirect pathways, the Agency concluded that releases from about 12 percent of the 83 plants studied may result in cancer risks greater than 1x10-5 for highly exposed individuals (i.e., subsistence fishers and subsistence farmers). Similarly, the Agency concluded that releases from about 12 percent of the 83 plants may result in noncancer hazard ratios greater than 1.0 for highly exposed individuals.

Timetable:

Action	Date	FR Cite
Notice Regulatory Determination	02/07/95	60 FR 7366
NPRM	08/20/99	64 FR 45632
Notice of Data Availability	07/25/02	67 FR 48648
Final Action	06/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 3856

Sectors Affected:

32731 Cement Manufacturing

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RIN: 2050–AE34

EPA

142. STANDARDIZED PERMIT FOR RCRA HAZARDOUS WASTE MANAGEMENT FACILITIES

Priority:

Other Significant

Legal Authority:

42 USC 6905; 42 USC 6912; 42 USC 6924; 42 USC 6925; 42 USC 6927; 42 USC 6974

CFR Citation:

40 CFR 124; 40 CFR 267; 40 CFR 270

Legal Deadline:

None

Abstract:

EPA has proposed creating a new type of general permit, called a standardized permit, for facilities that generate waste and routinely manage the waste on-site in tanks, containers, and containment buildings. Under the standardized permit, facility owners and operators would certify compliance with generic design and operating conditions set on a national basis. The permitting agency would review the certifications submitted by the facility owners and operators. The permitting agency would also be able to impose additional site-specific terms and conditions for corrective action or other purposes, as called for by RCRA. Ensuring compliance with the standardized permit's terms and conditions would occur during inspection of the facility after the permit has been issued. The standardized permit should streamline the permit process by allowing facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the

individual RCRA permit process. The proposal raised issues for public comment on how all facilities receiving RCRA permits can satisfy RCRA corrective action requirements under appropriate alternative state cleanup programs and on financial assurance issues. The Agency is developing a final rule addressing this topic.

Statement of Need:

The Agency convened a special task force in 1994 to look at permitting activities throughout its different programs and to make specific recommendations to improve these permitting programs. This task force, known as the Permits Improvement Team (PIT), spent two years working with stakeholders from the Agency, State permitting agencies, industry, and the environmental community. The PIT stakeholders mentioned, among other things, that permitting activities should be commensurate with the complexity of the activity. The stakeholders felt that current Agency permitting programs were not flexible enough to allow streamlined procedures for routine permitting activities. Currently, facilities that store, treat, or dispose of hazardous waste must obtain site-specific ''individual'' permits prescribing conditions for each ''unit'' (e.g., tank, container area, etc.) in which hazardous waste is managed. Experience gained by the Agency and States over the past 165 years has shown that not all the waste management activities are at the same level of complexity. Some activities, such as thermal treatment or land disposal of hazardous wastes, are more complex than storage of hazardous waste. The Agency believes that thermal treatment and land disposal activities continue to warrant ''individual'' permits, prescribing unit-specific conditions. However, the Agency believes that some accommodation can be made for hazardous waste management practices in standardized units such as tanks, container storage areas, and containment buildings. In April 1996, the PIT tentatively recommended, among other things, that regulations be developed to allow ''standardized permits'' for on-site storage and nonthermal treatment of hazardous waste in tanks, containers, and containment buildings. On October 12, 2001, the Agency proposed revising the RCRA regulations to allow for this type of permit, and is preparing to finalize the rule.

Summary of Legal Basis:

Facilities that manage hazardous waste are required under RCRA to obtain a permit and carry out corrective action as necessary (see: RCRA Section 3004, 3005, 3008, and 3010). EPA has discretion under these statutory provisions to apply different permitting procedures to different types of facilities. No aspect of this streamlining action is required by court order.

Alternatives:

EPA considered several options regarding RCRA permits and corrective action alternatives. The Agency proposed to limit the scope of the rule to facilities that generate waste and manage it on-site, but asked for comment on whether to expand that scope to facilities that manage wastes generated off-site. The Agency also asked for comment on the option of allowing a facility's RCRA corrective action activities to be postponed if corrective action is being carried out under an approved state remedial program.

Anticipated Cost and Benefits:

The RCRA standardized permit is an optional rule designed to streamline the regulatory burden to EPA/States, as well as to private sector facilities covered by the rule, by reducing the amount of information collected, submitted, and reviewed for RCRA hazardous waste permit actions (i.e., new permit applications, permit modifications, and permit renewals). Because the rule proposed to streamline existing RCRA regulation, rather than add new RCRA regulation, implementation of the rule by the EPA and by States with EPA-authorized permitting programs is expected to result in economic benefits in the form of national cost savings from reducing both government and private sector resources required for the RCRA permit process. The national workload level of RCRA permit actions involving on-site hazardous waste storage and nonthermal treatment units has averaged 92 permit determinations per year over the 10-year period 1990-1999. Relative to this average annual workload, EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately $100 to $5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. On a national basis, the rule is expected to generate a minimum of $0.36 to $0.53 million in average annual paperwork cost savings, based on the scope of the proposed rule, which was limited to on-site waste management facilities. However, the final rule may expand the initial scope of eligible facilities, which could easily double or triple the national cost savings benefits (i.e., $1.1 to $1.6 million per year in cost savings).

Risks:

The purpose of this rule is to streamline existing RCRA permit application and issuance procedures to achieve national paperwork burden reduction. Because of the facts that facilities covered by this rule: (a) are currently already required to obtain RCRA permits, and (b) are relatively simple to design, install/construct, operate, and clean-close, this rule is expected to have minimal incremental effects on existing levels of human health and environmental risk for these types of hazardous waste management facilities.

Timetable:

Action	Date	FR Cite
NPRM	10/12/01	66 FR 52191
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4028

Sectors Affected:

32411 Petroleum Refineries; 3251 Basic Chemical Manufacturing; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing; 325211 Plastics Material and Resin Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32551 Paint and Coating Manufacturing; 332813 Electroplating, Plating, Polishing, Anodizing and Coloring

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RIN: 2050–AE44

EPA

143. OFFICE OF SOLID WASTE BURDEN REDUCTION PROJECT

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; ...

CFR Citation:

40 CFR 260; 40 CFR 261; 40 CFR 264; 40 CFR 265; 40 CFR 266; 40 CFR 268; 40 CFR 270

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. After reviewing the comments received on the NODA, EPA proposed (67 FR 2518, 1/17/02) to implement many of these ideas. The proposal was designed to eliminate duplicative and nonessential paperwork.

The main ideas for the final rulemaking are: (1) eliminating or modifying one-third of the 334 RCRA-required notices and reports that are sent by the regulated community to states and EPA; (2) eliminating the RCRA emergency response training requirements that overlap with the Occupational Safety and Health Administration requirements; (3) eliminating the need for facilities to record personnel descriptions; (4) decreasing the owner/operator self-inspection frequency of hazardous waste tanks to weekly; (5) providing states and EPA with the opportunity to lengthen owner/operator self-inspection frequencies on a case-by-case basis for containers, containment buildings, and tanks; (6) eliminating the Land Disposal Restrictions generator waste determinations, recycler notifications and certifications, hazardous debris notifications and characteristic waste determinations, and streamlining the characteristic waste notification procedures; and (7) modifying the groundwater monitoring requirements for hazardous waste facilities.

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 cost-benefit analysis showed a savings of $120 million and 929,000 hours. The rule will have minimal impact on the protectiveness of the RCRA regulations. It will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations.

Risks:

The rule will have no risk impacts.

Timetable:

Action	Date	FR Cite
Notice of Data Availability	06/18/99	64 FR 32859
NPRM	01/17/02	67 FR 2518
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4084

Sectors Affected:

323 Printing and Related Support Activities; 324 Petroleum and Coal Products Manufacturing; 325 Chemical Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 332 Fabricated Metal Product Manufacturing; 334 Computer and Electronic Product Manufacturing; 562 Waste Management and Remediation Services

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RIN: 2050–AE50

EPA

144. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUNDWATER RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300f; SDWA 1412

CFR Citation:

40 CFR 141 400 to 406; 40 CFR 142 14 to 16 (revision)

Legal Deadline:

Final, Statutory, October 30, 2004, Before Stage 2 Disinfection Byproducts Rule.

Abstract:

EPA has proposed a targeted risk-based regulatory strategy for all public water systems served by ground water. The proposed requirements provide a meaningful opportunity to reduce public health risk associated with the consumption of waterborne pathogens from fecal contamination for a substantial number of people served by ground water sources. 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.

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 primacy agency to perform surveys every three to five years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring option adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multi-barrier option, which was proposed by EPA, adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive, results in a routine source water fecal indicator monitoring requirement. The multi-barrier option and the sanitary survey and triggered monitoring options are targeted regulatory approaches designed to identify wells that are fecally contaminated or are at a high risk for contamination. These across-the-board disinfection option would require all systems to install treatment instead of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

Anticipated Cost and Benefits:

EPA estimates the cost of the proposed GWR will be $183 million dollars per year (using a 3 percent discount rate). More than half of the estimated costs are for corrective actions which systems will be required to take to fix or prevent fecal contamination. The remainder of the costs are due to increased scope and frequency of sanitary surveys, hydrogeologic sensitivity assessments and source water monitoring. System costs are expected to be $162 million per year for implementation of the GWR. States are expected to incur costs of $21 million per year. Cost estimates do not include land acquisition, public notification or the potential cost of illness due to exposure to disinfection byproducts. 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), 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	08/00/03	

Regulatory Flexibility Analysis Required:

Yes

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. 2340

Statutory deadline for final rule: After August 6, 1999, but before the Administrator promulgates a Stage II rulemaking for disinfection byproducts (currently scheduled for October 2004).

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AA97

EPA

145. EFFLUENT GUIDELINES AND STANDARDS FOR THE METAL PRODUCTS AND MACHINERY CATEGORY, PHASES 1 AND 2

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

33 USC 1311CWA sec 301; 33 USC 1314 CWA sec 304; 33 USC 1316 CWA sec 306; 33 USC 1317 CWA sec 307; 33 USC 1318 CWA sec 308; 33 USC 1342 CWA sec 402; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 413; 40 CFR 433; 40 CFR 438; 40 CFR 463; 40 CFR 464; 40 CFR 467; 40 CFR 471

Legal Deadline:

NPRM, Judicial, October 31, 2000.

Final, Judicial, December 31, 2002.

Abstract:

EPA is developing effluent limitations guidelines for facilities that generate wastewater while processing metal parts; metal products; and machinery, including manufacture, assembly, rebuilding, repair, and maintenance. In 1995 EPA proposed regulations for seven industrial groups: aircraft, aerospace, hardware, ordnance, stationary industrial equipment, mobile industrial equipment, and electronic equipment. EPA has consolidated this rulemaking with a second phase, whose scope would include additional industrial groups such as: bus and truck, household equipment, instruments, motor vehicles, office machines, precious metals and jewelry, railroads, job shops, printed circuit boards, and ships and boats. The rule will cover sites not currently covered by previous metals effluent limitations guidelines and will update 20 year old regulations to reflect changes in process control and pollution prevention practices. The deadlines and timetable apply to the consolidated Phase 1 and 2 rulemaking.

Statement of Need:

Roughly a quarter of the facilities in this industry are currently regulated by national effluent limitations guidelines. Many facilities have inadequate wastewater treatment, in terms of best available technology. Current effluent limitations guidelines for parts of this industry were developed 20 years ago and do not always reflect current practices of pollution prevention and wastewater treatment. The MP&M rule enhances protection of public health and the environment by reducing the discharge of toxic metals and organics into the environment.

Summary of Legal Basis:

The Clean Water Act requires EPA to establish effluent limitations guidelines and pretreatment standards to limit the pollutants discharged from point sources. In addition, EPA is bound by a provision in a Consent Decree entered in settlement of Natural Resources Defense Council et al. v. Whitman (D.D.C. No. 89-2980) to propose regulations for this industry by October 2000.

Alternatives:

The Agency is deliberating on final regulatory options. Estimates of costs and benefits are not available at the time EPA prepared this entry for the Regulatory Plan.

Anticipated Cost and Benefits:

The Agency is deliberating on final regulatory options. Estimates of risk and risk reduction are not available at the time EPA prepared this entry for the Regulatory Plan.

Risks:

EPA estimates that compliance with this regulation will reduce the annual discharge of conventional pollutants by at least 115 million pounds, priority pollutants by 12 million pounds, and non-conventional metal and organic pollutants by 43 million pounds. These reductions represent significant improvements in water quality. The amounts are substantial in terms of point source controls.

Timetable:

Action	Date	FR Cite
NPRM (Phase 1)	05/30/95	60 FR 28210
NPRM (Consolidated Phase 1 and 2)	01/03/01	66 FR 424
NODA	06/05/02	67 FR 38752
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local

Additional Information:

SAN No. 2806

Sectors Affected:

332 Fabricated Metal Product Manufacturing; 333 Machinery Manufacturing; 334 Computer and Electronic Product Manufacturing; 335 Electrical Equipment, Appliance and Component Manufacturing; 336 Transportation Equipment Manufacturing; 337 Furniture and Related Product Manufacturing; 339 Miscellaneous Manufacturing

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RIN: 2040–AB79

EPA

146. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM PERMIT REGULATION AND EFFLUENT GUIDELINES AND STANDARDS FOR CONCENTRATED ANIMAL FEEDING OPERATIONS (CAFOS)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1314 CWA sec 304; 33 USC 1316 CWA sec 306; 33 USC 1317 CWA sec 307; 33 USC 1318 CWA sec 308; 33 USC 1342 CWA sec 402; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 122.23; 40 CFR 412

Legal Deadline:

NPRM, Judicial, December 15, 2000, Effluent guidelines and standards only.

Final, Judicial, December 15, 2002, Effluent guidelines and standards only.

Abstract:

Concentrated animal feeding operations (CAFOs) are covered by existing effluent guidelines at 40 CFR 412 and by permitting regulations at 40 CFR 122.23. This action will revise the existing effluent guidelines primarily to address swine, poultry, beef, and dairy cattle operations and will revise the NPDES regulation for CAFOs. Feedlot operations are substantial contributors of nutrients in surface waters that have

severe anoxia (low levels of dissolved oxygen) and problem algae blooms.

Statement of Need:

The existing CAFO regulations were promulgated in the 1970's. Since that time, the animal production industry has changed significantly, and revisions to those regulations are appropriate. Contamination of surface water results from breaches of lagoons, runoff from feedlots, direct contact of animals with surface water, and manure applied to land in excess of crop nutrient needs. Nutrients, most notably nitrogen and phosphorus, are essential for profitable crop and animal agriculture. However, nitrogen and phosphorus export in watershed runoff can accelerate the eutrophication of surface waters. Rapid growth and intensification of animal production in many areas has created regional imbalances in nutrient inputs and nutrient output. In many of these areas nutrients produced in animal manure exceed crop needs and pose risks to the environment.

Summary of Legal Basis:

The Clean Water Act (CWA) authorizes EPA to establish and to revise if appropriate effluent limitations guidelines and standards to regulate the quality of point source discharges. The Act also authorizes EPA to promulgate implementating regulations for NPDES permitting program.EPA is also required to revisit these effluent guidelines to satisfy a provision in a Consent Decree entered in settlement of Natural Resources Defense Council et al v. Whitman, (D.D.C No. 89-2980).

Alternatives:

The CWA requires effluent guidelines to be established on a technology basis. EPA generally bases limitations on the performance of specific technology levels, such as the best available technology economically achievable. For animal feeding operations, EPA is considering a range of regulatory alternatives that includes management practices, traditional pollution control technologies, and alternative technologies/practices that recover the energy value or alter the handling /marketability characteristics of animal wastes. EPA is also considering whether alternative pollution control requirements should be established for smaller animal feeding operations. The NPDES regulation for CAFOs defines which facilities are covered by the permit regulation, and will specify the permit requirements necessary to protect water quality. EPA is considering adding additional animal types to its definition, and is considering amending the size facility or conditions that define which facilities are CAFOs subject to permitting. Requirements that specifically address land application of manure are also being considered.

Anticipated Cost and Benefits:

The Agency is deliberating on final regulatory options. Estimates of costs and benefits are not available at the time this Regulatory Plan was prepared.

Risks:

The regulatory changes under consideration will reduce adverse water quality impacts caused by runoff from animal feeding operations, thereby reducing risks to aquatic habitat and public health.

Timetable:

Action	Date	FR Cite
NPRM	01/12/01	66 FR 2959
NODA	11/21/01	66 FR 58556
NODA	07/23/02	67 FR 48107
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4153

Sectors Affected:

11221 Hog and Pig Farming; 11232 Broilers and Other Meat Type Chicken Production; 11231 Chicken Egg Production; 112112 Cattle Feedlots; 11212 Dairy Cattle and Milk Production; 11241 Sheep Farming; 11233 Turkey Production; 11292 Horse and Other Equine Production; 11239 Other Poultry Production

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RIN: 2040–AD19

EPA

147. MINIMIZING ADVERSE ENVIRONMENTAL IMPACT FROM COOLING WATER INTAKE STRUCTURES AT EXISTING FACILITIES UNDER SECTION 316(B) OF THE CLEAN WATER ACT, PHASE 2

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1316 CWA sec 306; 33 USC 1326 CWA sec 316; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 125

Legal Deadline:

NPRM, Judicial, February 28, 2002.

Final, Judicial, August 28, 2003.

Abstract:

This rulemaking affects, at a minimum, existing electricity generating facilities that employ cooling water intake structures and whose intake flow levels exceed a minimum threshold to be determined by EPA during the rulemaking. Section 316(b) of the Clean Water Act provides that any standard established pursuant to sections 301 or 306 of the Clean Water Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. A

primary purpose of the rulemaking is to minimize any adverse environmental impact that may be associated with the impingement and entrainment of fish and other aquatic organisms by cooling water intake structures. Impingement refers to trapping fish and other aquatic life on intake screens or similar devices where they may be injured or killed. Entrainment occurs when smaller aquatic organisms, eggs, and larvae are drawn into a cooling system, and then pumped back out, often with significant injury or mortality due to heat, physical stress or exposure to chemicals.

Statement of Need:

In the absence of national regulations, Permit Directors have implemented cooling water intake limitations incompletely and inconsistently and, in some cases, permit issuance or reissuance has been significantly delayed. Tons of fish and other aquatic organisms may be cropped annually as a result of cooling water intake structures at a single large facility. By court order, EPA must propose and take final action on this regulation. This regulation may have substantial ecological benefits.

Summary of Legal Basis:

This action is required under an Amended Consent Decree in Riverkeeper Inc. et al. v. Whitman, 93 Civ. 0314 (AGS) (U.S. District Court, Southern District of New York, November 21, 2000).

Alternatives:

The analysis will cover various sizes, types of potentially regulated facilities, and control technologies. EPA is considering whether to regulate site-by-site, nationally, or on the basis of broad categories of water body types.

Anticipated Cost and Benefits:

Costs are estimated in the proposal to be $182 million annually (capital and compliance). The benefits of the proposed rule are approximately $700 million. Costs and benefits are generally, as expected, smaller at facilities that use smaller amounts of cooling water.

Risks:

Cooling water intake structures may pose significant risks for aquatic ecosystems.

Timetable:

Action	Date	FR Cite
NPRM	04/09/02	67 FR 17122
Final Action	08/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4474

Sectors Affected:

22111 Electric Power Generation

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RIN: 2040–AD62

EPA

148. CROSS-MEDIA ELECTRONIC REPORTING (ER) AND RECORDKEEPING RULE

Priority:

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

Legal Authority:

PL 104-13; PL 105-277

CFR Citation:

40 CFR 3 (New); 40 CFR 9 (Revision)

Legal Deadline:

None

Abstract:

As proposed, the Cross-Media Electronic Reporting (ER) and Recordkeeping Rule (CROMERRR) was intended to provide a uniform legal framework for paperless electronic reporting and recordkeeping, including electronic signature/certification, across EPA's environmental compliance programs. Based on public comment, however, EPA now plans to focus on finalizing the electronic reporting components of proposed CROMERRR, and to defer further action on the electronic recordkeeping components until a later time. Under current plans, the final electronic reporting (ER) rule will address electronic reporting by companies regulated under all of EPA's programs: air, water, pesticides, toxic substances, wastes, and emergency response. The final rule would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, the rule would set the conditions for allowing electronic reporting under State, tribal or local environmental programs that operate under EPA authorization.

The final ER rule is intended to make electronic reporting as simple, efficient, and cost-effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no obstacles to adopting new technologies as they emerge.

To ensure that authorized programs at the State, tribal, and local levels meet EPA's electronic reporting goals, the final ER rule would specify a set of criteria that these program s must satisfy as they initiate electronic reporting. In response to public comments, EPA is also planning to include provisions for a streamlined process for EPA to review and approve authorized program revisions or modifications to allow electronic reporting.

Statement of Need:

EPA is required by the Government Paperwork Elimination Act (GPEA) of 1998 to make the option of electronic reporting and recordkeeping available, where practicable, to its regulated community by 2003. To meet this deadline and comply with GPEA, EPA believes that it needs to put a new legal framework in place by that time at least for electronic reporting. A final ER rule would provide for this legal framework by: (1) removing legal obstacles to electronic reporting posed by explicit references to paper and paper-based processes in EPA regulations; and (2) assuring that electronically submitted documents will have the same legal and evidentiary force as their paper counterparts, whether the submission is

directly to EPA or under an EPA-authorized program.

Summary of Legal Basis:

Government Paperwork Elimination Act (GPEA) of 1998. GPEA requires Federal agencies to provide, where practicable, the option of electronic reporting and recordkeeping to their regulated communities by 2003.

Alternatives:

One alternative to an EPA cross-media ER rule that applies to most compliance reports under 40 CFR would be individual rulemakings by each of the program offices. EPA's past experience with program-by-program ER rulemakings has demonstrated that such an approach would not bring EPA into compliance with GPEA by the 2003 deadline. EPA also considered the use of guidance instead of rulemaking, but rejected this alternative based principally on a concern that program enforceability depends greatly on the ability to mandate a certain level of functionality for systems that will be used to receive electronic reports and other electronic documents.

Anticipated Cost and Benefits:

EPA received a number of comments on the assumptions used to generate the cost and benefit estimates for the electronic reporting components of proposed CROMERRR; based on this feedback, EPA decided to develop a new analysis of the costs and benefits for the final ER rule. As a part of this effort, EPA has conducted extensive follow-up interviews with commenters, reevaluated existing sources of information, and conducted new market research on ER technologies. The results have led to revisions in certain of the assumptions associated with the CROMERRR proposal that bear on the ER rule=s costs and benefits to State and local governments, to regulated entities, and to the federal government. For example, with respect to State and local governments, proposed CROMERRR had assumed that the costs and benefits of electronic reporting under authorized programs could be attributed entirely to the rule. EPA has since learned that a significant number of electronic reporting systems already operate under such programs; correspondingly, the ER rule cannot take credit for the costs and benefits of electronic reporting in such cases, but only for the costs or benefits that result from changes that occur as a result of the rule. With respect to regulated entities, EPA had had to adjust a number of assumptions associated with electronic signature requirements, including those related to the number of registered signature-holders at each facility, and the availability of acceptable alternatives to Public Key Infrastructure- based electronic signature approaches in many instances. EPA is also refining its estimate of the number of potentially affected regulated entities. With respect to the federal government, EPA has reconsidered the general costs and benefits of electronic reporting based on experience operating EPA's Central Data Exchange and other EPA systems, and based also on an in-depth analyses of business processes and associated costs for several major EPA programs implementing electronic reporting.

Based on these and other revisions to our assumptions, EPA has developed preliminary new cost/benefit results. They indicate that regulated entities will accrue modest net benefits from the ER rule; state and local government agencies will break even or experience modest benefits; and EPA will experience modest benefits. Concerning regulated entities in particular, the costs of the ER rule for those that use web forms would be negligible, insofar as EPA intends to provide the web forms and signature capabilities needed. For entities that use some form of file exchange B in XML, flat file, or other format B EPA anticipates that entities would incur additional up-front costs, but the savings would be larger over time, given the greater opportunities to fully automate the reporting functions. Qualitative benefits of electronic reporting were also identified, including: enhanced data quality, faster public access to submitted data, better tracking of compliance submissions, and opportunities for reengineering current paper processes.

Finally, comments on the CROMERRR also indicated the need for substantial reworking of the cost and benefit analyses with respect to the electronic record-keeping components of the proposal. Given EPA's current focus on electronic reporting, EPA will defer additional economic analysis in this area until we resume work on electronic recordkeeping.

Risks:

The risks are undetermined.

Timetable:

Action	Date	FR Cite
NPRM Resubmittal	08/31/01	66 FR 46161
Final Action	05/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 4270

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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 (ADA), 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.

Under the Chair's Five-Point Plan, the EEOC is focusing on emerging workplace trends and using proactive prevention, proficient resolution, strategic enforcement, alternative dispute resolution, and our own model workplace to enhance enforcement efforts. The significant regulatory action now under consideration by the EEOC resolves an important and timely question under the ADEA and serves the goals of proactive prevention and proficient resolution.

The significant action of a regulatory nature now under consideration is amending regulations governing age discrimination in employment to exempt from the prohibitions of the ADEA the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits. This rule will ensure that the application of the ADEA does not discourage employers from providing health benefits to their retirees.

(Consistent with section 4(c) of Executive Order 12866, this statement was reviewed and approved by the Chair of the Agency. The statement has not been reviewed or approved by the other members of the Commission).

EEOC

PROPOSED RULE STAGE

149. 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 USC 621 et seq. (ADEA or Act), the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits.

Statement of Need:

In August 2001, the Commission announced that it would consider the relationship between the ADEA and employer-sponsored retiree health benefit plans that alter, reduce, or eliminate benefits upon eligibility for Medicare or a comparable State-sponsored retiree health benefits program. There has been a decline in the number of employers providing retiree health benefits over the last 10 years. Various factors have contributed to this erosion, including the increased cost of health care coverage, an increased demand for such coverage as large numbers of workers near retirement age, and changes in the way accounting rules treat the long-term costs of providing retiree health benefits. Another factor has been employer concern about the potential application of the ADEA to employer-sponsored retiree health benefits. The Commission is proposing a narrowly drawn ADEA exemption that permits the practice of coordinating employer-provided retiree health coverage with eligibility for Medicare or a State-sponsored retiree health benefits program, so that the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees.

Summary of Legal Basis:

Pursuant to section 9 of the ADEA, the Commission is authorized to establish reasonable exemptions to and from any or all provisions of the Act as it may find necessary and proper in the public interest.

Alternatives:

The Commission considered various alternatives in developing this proposal. The Commission will consider all alternatives offered by the public commenters.

Anticipated Cost and Benefits:

The Commission recognizes that while employers are under no legal obligation to offer retiree health benefits, some employers choose to do so in order to maintain a competitive advantage in the marketplace, using these and other benefits to attract and retain the best talent available to work for their organizations. The proposed rule will ensure that the application of the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees who otherwise would have to obtain such coverage in the private individual marketplace at significant personal expense. The Commission believes that it is in the best interest of both employers and employees for the Commission to pursue a policy that permits employers to offer these benefits to the greatest extent possible. It is not anticipated that the proposal will result in increased costs.

Risks:

The proposed regulatory action will reduce the risks of liability for noncompliance with the statute by exempting certain employer practices from regulation. This proposal does not address risks to public safety or the environment.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local

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 2003 regulatory priorities are to complete conversion of the Federal Property Management Regulations to the Federal Management Regulation (FMR) and to complete the rewrite of the Federal Travel Regulation (FTR).

GSA is writing the FMR and FTR so that its regulations are consistent and sensible, and limit the regulatory burden placed on Government officials and the public. GSA has adopted a question and answer format to make them easier to read and understand, and non-regulatory guidance is being moved into other, less formal publications such as customer service guides.

As necessary, GSA will prepare its regulations so that they address national health and security concerns, particularly those created as a result of the events of September 11, 2001.

BILLING CODE 6840–34–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Statement of Regulatory Priorities

The National Aeronautics and Space Administration (NASA) was established by the National Aeronautics and Space Act of 1958 (the Act), 42 United States Code (U.S.C.) 2451 *et seq.*, which laid the foundation for NASA's mission. The Act authorizes NASA, among other things, to conduct space activities devoted to peaceful purposes for the benefit of humankind; to preserve the leadership of the United States in aeronautics and space science and technology; and to expand knowledge of the Earth and space. To carry out this mission, NASA is authorized to conduct research for the solution of problems of flight within and outside the Earth's atmosphere; to develop, construct, test, and operate aeronautical and space vehicles for research purposes; to operate space transportation systems, including the Space Shuttle and the International Space Station; and to perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with human-tended, robotic, and expendable vehicles and arranges for the most effective utilization of the scientific and engineering resources of the United States with other nations engaged in aeronautical and space activities for peaceful purposes.

NASA's mission, as documented in its 2000 Strategic Plan, is to advance and communicate scientific knowledge and understanding of the Earth, the solar system, and the universe; to advance human exploration, use, and development of space; and to research, develop, verify, and transfer advanced aeronautics and space technologies.

The following are narrative descriptions of the most important regulations being planned for publication in the **Federal Register** during fiscal year (FY) 2003.

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 2003, except to conform to FAR changes that are currently being promulgated in part 27, Patents, Data, and Copyrights, and part 47, Transportation.

In a continuing effort to keep the NFS current with NASA initiatives and Federal procurement policy, minor revisions to the NFS will be published. For instance, NFS regulations addressing Acquisition of Investigations, part 1872, will be amended to incorporate NASA's risk-centered approach to acquisition including safety and security, and to update guidance. Current policy and procedures for NASA's midrange acquisitions, part 1871, are being reviewed for incorporation into NFS part 1815. Changes to internal administrative procedures, such as internal notification of awards, are being considered in response to the Freedom to Manage initiative, as well as use of electronic reporting mechanisms.

Additionally, changes to policy and guidance in the NFS and Grant and Cooperative Agreement Handbook (14 CFR 1260 and 14 CFR 1274) are being considered with the aim of introducing further competition in support of competitive sourcing activities at NASA.

To reduce the time and cost spent by the Agency and our industry partners in the procurement of basic and applied research under cooperative agreements, NASA is focusing on streamlining our processes. To go forward in this effort, policy and guidance associated with the generation and review of Cooperative Agreements Notices (CAN) is being considered. Additionally, changes necessary for implementing a common format for grant announcements and addressing other internal management practices will be made.

NASA is continuing consideration of revisions to the cross-waiver of liability regulation at 14 CFR part 1266. Specifically, NASA is considering implementation of the cross-waiver of liability provision of the intergovernmental agreement of the International Space Station and refinement and clarification of contractual cross-waivers in NASA agreements involving launch services.

BILLING CODE 7510–01–S

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)

Statement of Regulatory Priorities

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 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 2003. The first, included in the regulatory plan, is to review and revise, where necessary, 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.

The second, completing rulemaking actions relating to electronic records management and transfer of electronic records to NARA, is part of our Electronic Records Management (ERM) Initiative, one of the Administration's 24 E-Government Initiatives. This initiative will provide guidance on electronic records management applicable Governmentwide and will enable agencies to transfer electronic records to NARA in a variety of data types and formats so that they may be preserved for future use by the Government and citizens.

Our third priority regulatory action is updating and rewriting in plain language our research room regulations and restrictions on access regulations in 36 CFR parts 1254 and 1256. NARA's mission is to ensure ready access to the essential evidence that documents the rights of American citizens, the actions of Federal officials, and the national experience. NARA research rooms receive more than 270,000 research visits per year from individuals using our archival holdings. We also respond to nearly 477,000 inquiries about our archival holdings annually. The regulations in 36 parts 1254 and 1256 address how we serve these researchers.

NARA does not have any planned regulatory actions that relate to the events of September 11, 2001 or that are of particular concern to small businesses.

NARA

PRERULE STAGE

150. ● 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 1201

Legal Deadline:

None

Abstract:

As part of its initiative to redesign Federal records management, NARA is reviewing its records management regulations in 36 CFR ch. XII, subchapter B to ensure that the regulations are appropriate, effective, and clear. Where needed, we intend to develop updated regulations.

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 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	11/00/02	
End Review	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

http://www.archives.gov/records__management/initiatives/rm__redesign__project.html

URL For Public Comments:

http://www.archives.gov/about__us/opportunities__for__comment/opportunities__for__comment.html

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BILLING CODE 7515–01–S

OFFICE OF PERSONNEL MANAGEMENT (OPM)

Statement of Regulatory Priorities

The Office of Personnel Management (OPM) is the Federal Government's human resources and personnel manager. In the coming year, the priority for OPM's regulatory efforts will continue to be the modernization and improvement of human resources management to support the Administration's initiatives. In particular, it has been and continues to be OPM's primary regulatory objective to institute human resources management reforms and flexibilities that will enable the Federal Government to recruit, manage, and retain the high-quality, diverse workforce that departments and agencies require to carry out their respective missions for the American people.

OPM's focus on reforming human resources management also supports the Administration's objectives and priorities expressed in the *President's Management Agenda,* which 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. On February 28, 2002, the Director of OPM, Kay Coles James, appointed Marta Brito Perez as the agency's Project Director for Human Capital Performance to implement this critical element of the *President's Management Agenda.* This project will advance the agenda by way of regulation as necessary and appropriate during the coming year.

Other than any regulations that may be required to implement legislation creating the Department of Homeland Security, none of the regulations are related to the events of September 11, 2001. Similarly, none of the regulations addressed in OPM's regulatory plan are of particular concern to small businesses, were among the 71 regulations nominated as reform candidates in public comments responding to OMB's 2001 Report to Congress on the Costs and Benefits of Regulations, or have been the subject of an OIRA ''prompt letter.''

Department of Homeland Security

On June 6, 2002, President Bush proposed the creation of a new Department of Homeland Security. As proposed, this new Department would be formed by consolidating approximately 170,000 Federal employees, who are currently employed in numerous agencies and under a multitude of employment and pay titles and systems, into one organization. In addition, the President's proposal specifically requested flexibility in the management of any of the Department's human resources that may be directly engaged in critical security functions. Once the President's proposed legislation is passed, it is anticipated that the massive reorganization will require regulatory action by OPM to implement the specific legislation and develop a human resources management system. Given the urgent mission of the Department of Homeland Security, it is certain that this regulatory activity will be a priority for OPM in the coming year. However, until the actual legislation creating the Department is passed and signed, no specific necessary regulatory action can be identified.

Compensation Reform

On May 1, 2002, OPM Director, Kay Coles James, initiated a discussion of Federal compensation reform by releasing an agency White Paper: *A Fresh Start for Federal Pay: The Case for Modernization.* The purpose of the paper was to stimulate debate toward developing concrete proposals for improving the current Federal pay system. Proposals discussed may require statutory and regulatory action to implement. All stakeholders will be consulted before any modifications to the system are initiated. Compensation reform is a central element to a modern Federal workforce and is necessary for improving the management of human capital, a central element of the *President's Management Agenda.*

Managerial Flexibilities Act

The President's Managerial Flexibilities Act of 2001 is still pending in Congress. When it is passed, OPM will promulgate new, or modify existing regulations to implement employment restructuring assistance, voluntary early retirement, recruitment and retention incentives, results-oriented performance evaluation and compensation for senior executives, human resources management innovations, and hiring flexibilities.

Outsourcing

OPM continues to examine new ways to allow the private sector to contribute to mission delivery. OPM continues to work on converting positions in the Employment Service Technology Support Center to the private sector over a five-year period. OPM is also examining all Federal Retirement Program functions that are comparable to functions performed by commercial entities. The most sweeping long-term change under study is a comprehensive review of OPM's reimbursable services to determine if a different structure, based on increased reliance on private sector providers, would be more cost efficient.

Delayering and Restructuring

OPM is finalizing a sweeping restructuring plan that will dramatically redesign the agency to improve OPM's organization to better deliver services to the Federal workforce, our agency customers, and the American people. The new structure will result in a significantly flatter, more streamlined agency that is much better positioned to focus on customer service, and strategically aligned to help the President carry out his agenda. Supervisory ratios will be increased and employees redeployed to service delivery by centralizing internal functions and terminating programs when their missions have been completed. Most of this can be done administratively, without the need for further regulatory action. However, to the extent program functions are defined by regulation, they will have to be promulgated, modified, or eliminated.

e-Government

A second initiative in the *President's Management Agenda* is Expanded Electronic Government. The Office of Management and Budget has broken this item down into 24 e-Government initiatives and OPM has been designated as the managing partner on 5 of these initiatives: e-Recruitment (Recruitment One Stop), e-Clearance, e-Training, e-Payroll, and e-Enterprise HR Integration (e-EHRI). OPM currently is examining the necessary regulatory efforts needed to implement these programs.

The Office of Personnel Management will continue to accept the challenge of improving our human resources management systems in order to attract and keep the best possible talent, to promote fairness and diversity, to preserve the merit-based civil service system that serves as the cornerstone of our Democracy, to effectively protect the homeland, and to create a Government that truly serves and produces results for our citizens.

BILLING CODE 6325–44–S

PENSION BENEFIT GUARANTY CORPORATION (PBGC)

Statement of Regulatory and Deregulatory Priorities

PBGC Insurance Programs

The Pension Benefit Guaranty Corporation (PBGC) administers two insurance programs for private defined benefit plans under title IV of the Employee Retirement Income Security Act of 1974 (ERISA): A single-employer plan termination insurance program and a multiemployer plan insolvency insurance program. The PBGC protects the pensions of nearly 44 million working men and women in about 35,000 private defined benefit plans, including about 1,700 multiemployer plans.

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 2001, the PBGC was trustee of almost 3,000 plans and paid $1,044 million in benefits to about 269,000 people during 2001. Another 355,000 people will receive benefits when they retire in the future.

Most terminating single-employer plans terminate with sufficient assets to pay all benefits. The PBGC has administrative responsibility for these terminations (standard terminations), but its role is limited to seeing that proper procedures are followed and participants and beneficiaries receive their plan benefits.

The multiemployer program (which covers about 9.4 million workers and retirees in about 1,700 insured plans) is funded and administered separately from the single-employer program and differs in several significant ways. The multiemployer program covers only collectively bargained plans involving more than one unrelated employer. The PBGC provides financial assistance (in the form of a repayable loan) to the plan if the plan is unable to pay benefits at the guaranteed level. Guaranteed benefits are generally less than a participant's full benefit under the plan (and less than the single-employer guaranteed benefit). PBGC financial assistance occurs infrequently.

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.

Objectives and Priorities

PBGC regulatory objectives and priorities are developed in the context of the statutory purposes of title IV: (1) to encourage voluntary private pension plans, (2) to provide for the timely and uninterrupted payment of pension benefits to participants and beneficiaries, and (3) to maintain the premiums that support the insurance programs at the lowest possible levels consistent with carrying out the PBGC's statutory obligations (ERISA section 4002(a)).

The PBGC implements its statutory purposes by developing regulations designed: (1) to assure the security of the pension benefits of workers, retirees, and beneficiaries; (2) to improve services to participants; (3) to ensure that the statutory provisions designed to minimize losses for participants and PBGC in the event of plan termination are effectively implemented; (4) to encourage the establishment and maintenance of voluntary private pension plans; (5) to facilitate the collection of monies owed to plans and to the PBGC, while keeping the related costs and burdens as low as possible; and (6) to simplify the termination process.

Regulatory Priorities

The PBGC has focused on changes that would simplify the rules and reduce regulatory burden.

Relief for Plans and Sponsors Affected by the September 11, 2001, Terrorist Attacks

In response to the needs of covered plans and sponsors affected by the September 11, 2001, terrorist attacks, PBGC provided the following relief for plans in designated federal disaster areas and others affected by the disaster:

- Waived penalties for late payment of PBGC premiums.
- Extended the deadlines for fully funded terminating plans to give notices to participants and the PBGC and to transfer to the PBGC payments for missing participants.
- Extended the deadline for issuing the notice to participants that certain underfunded plans are required to provide to inform participants of plan funding levels and limitations on PBGC guarantees.
- Extended the deadlines for reporting certain Reportable Events.
- Extended the deadline for requesting reconsideration or appealing PBGC determinations under the PBGC's administrative review regulation.
- Provided case-by-case relief in other cases.

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, in recent years, the PBGC made the following changes, which are very helpful to small plans and their sponsors:

- Extended the time limits for various actions required to terminate a fully funded single-employer plan in a standard termination.
- Simplified its premium forms by introducing a new ''Form 1-EZ'' for use by single-employer plans that are exempt from the PBGC's variable-rate premium.
- Extended the filing date for PBGC premiums to match the latest Form 5500 filing date.
- Reduced penalties for late premiums that are paid before the PBGC notifies the plan of the delinquency.

Other Regulatory Simplifications and Relief

PBGC has provided additional regulatory simplifications and relief. Specifically, the PBGC:

- Stopped the reduction of monthly benefits under its actuarial recoupment method once the nominal amount of the benefit overpayment is repaid.
- Provided participants with benefits valued up to $5,000 in PBGC-trusteed plans with the choice of receiving their benefit in the form of an annuity or a lump sum.
- Encouraged self-correction of premium underpayments by making it easier to qualify for safe-harbor penalty relief.
- Published a proposed penalty policy to provide guidance on assessment and review of penalties and on what constitutes ''reasonable cause'' for a penalty waiver.

- Simplified its valuation assumptions by adopting a single set of assumptions for allocation purposes.
- Decided to continue to calculate and publish its lump sum interest rates indefinitely and amended its regulations to make it easier for practitioners to refer to those rates.
- Solicited public comment on benefit valuation and payment issues relating to terminated cash balance plans that use variable indices to determine future retirement benefits.
- Amended its premium regulation to allow plan administrators to pay a prorated premium for a short plan year rather than paying a full year's premium and requesting a refund.
- Amended its premium regulation to simplify and narrow the definition of ''participant'' for PBGC premium purposes.

In FY 2002, the PBGC:

- Amended its benefit payments regulations to give participants more choices of annuity benefit forms, to clarify what it means to be able to ''retire'' under plan provisions for certain purposes under title IV of ERISA, and to add rules on who will get certain payments the PBGC owes to a participant at the time of death.
- Amended its administrative review regulation to expedite the appeals process by authorizing a single member of the PBGC's Appeals Board to decide routine appeals.

The PBGC is continuing to review its regulations to look for further simplification opportunities. The PBGC's regulatory plan for October 1, 2002, to September 30, 2003, consists of one significant regulatory action.

PBGC

PROPOSED RULE STAGE

151. 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 Pension Benefit Guaranty Corporation is considering amending its benefit valuation and asset allocation regulations by adopting more current mortality tables and otherwise simplifying and improving its valuation assumptions and methods.

Statement of Need:

The PBGC's regulations prescribe rules for valuing a terminating plan's benefits for several purposes, including (1) determining employer liability and (2) allocating assets to determine benefit entitlements. The PBGC's interest assumption for valuing benefits, when combined with the PBGC's mortality assumption, is intended to reflect the market price of single-premium, nonparticipating group annuity contracts for terminating plans. In developing its interest assumptions, the PBGC uses data from surveys conducted by the American Council of Life Insurers. The PBGC currently uses a mortality assumption based on the 1983 Group Annuity Mortality Table in its benefit valuation and asset allocation regulations (29 CFR parts 4044 and 4281).

In May 1995, the Society of Actuaries Group Annuity Valuation Table Task Force issued a report that recommends new mortality tables for a new Group Annuity Reserve Valuation Standard and a new Group Annuity Mortality Valuation Standard. In December 1996, the National Association of Insurance Commissioners adopted the new tables as models for determining reserve liabilities for group annuities. The PBGC is considering incorporating these tables into its regulations and making other modifications.

Summary of Legal Basis:

The PBGC has the authority to issue rules and regulations necessary to carry out the purposes of title IV of ERISA.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Cost estimates are not yet available. However, the PBGC expects that this regulation will not have a material effect on costs.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/97	62 FR 12982
ANPRM Comment Period End	05/19/97	
NPRM	03/00/03	
NPRM Comment Period End	05/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1212–AA55

BILLING CODE 7708–01–S

RAILROAD RETIREMENT BOARD (RRB)

Statement of Regulatory and Deregulatory Priorities

The Railroad Retirement Board (Board) administers a retirement program for railroad workers and their families under the Railroad Retirement Act of 1974, and an unemployment insurance and sickness benefit program for railroad workers under the Railroad Unemployment Insurance Act. Regulations by the Board under these two statutes and certain Governmentwide statutes are contained in chapter II of title 20 of the Code of Federal Regulations.

The Board has been involved in a multiyear project to review, revise, and update its regulations. During this project the Board has published final rules amending all of its regulations. In addition, there are several regulations actively under consideration by the Board at this time. The Board's short-term plan is to publish final regulations to complete the total review and revision project undertaken previously. The agency has also initiated a review of its regulations to assess the need for changes that may be required by the Railroad Retirement and Survivors Improvement Act of 2001.

The regulations issued by the Board are designated to be informative and to assist the agency's constituents in the railroad industry with an understanding of the benefit systems administered by the Board. In promulgating regulations, the agency is mindful of the burdens that may be imposed on the public and crafts its regulations in such a way as to impose the least possible burden on the public. In addition, through regulation, the Board makes every effort to simplify and streamline administration of the programs it administers. We believe the Board's regulatory review program is consistent with the priorities of the Administration.

The Board has not implemented regulations related to the events of September 11, 2001, and is unlikely to do so. The agency does, however, follow the guidelines and regulations instituted by other Government agencies that have Homeland Security authority for establishing such regulations. Examples of those areas would be: Federal agency facility management and security and computer security awareness.

It is highly unlikely that any regulations in the regulatory plan of this agency would be of particular concern to small business.

RRB

PROPOSED RULE STAGE

152. ● APPLICATION FOR ANNUITY OR LUMP SUM

Priority:

Other Significant

Legal Authority:

45 USC 231d; 45 USC 231f

CFR Citation:

20 CFR 217.5; 20 CFR 217.6; 20 CFR 217.15 to 217.18

Legal Deadline:

None

Abstract:

The Railroad Retirement Board amends its regulations to permit the filing of applications for annuity or lump sum electronically via the Internet in accordance with the provisions of the Government Paperwork Elimination Act.

Statement of Need:

Sections 1701-1710 of the Government Paperwork Elimination Act, Public Law 205-277 (codified as 44 U.S.C. sec. 3504n), require Federal agencies to provide for the option of electronic maintenance, submission, or disclosure of information, when practicable, as a substitute for paper. The proposed changes to part 217 of the Board's regulations will permit the filing of applications under the Railroad Retirement Act electronically via the Internet.

Summary of Legal Basis:

The general authority for the issuance of regulations under the Railroad Retirement Act (RRA) is provided for in section 7(b)(5) of the RRA (45 U.S.C. 231f(b)(5)).

Alternatives:

None.

Anticipated Cost and Benefits:

While this amendment should result in modest savings in administrative costs due to the streamlining of procedures, the benefits are those extended to the agency's constituents who may file applications for benefits electronically via the Internet.

Risks:

None anticipated.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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RIN: 3220–AB55

RRB

153. ● ACCOUNT BENEFITS RATIO

Priority:

Other Significant

Legal Authority:

45 USC 231f(b)(5); 45 USC 231u(a)

CFR Citation:

20 CFR 206

Legal Deadline:

None

Abstract:

The Railroad Retirement Board adds a new part 206 to its regulations as information, and to advise that the Board will annually compute the account benefits ratio for the railroad retirement system, and will make a projection of the account benefits ratio and the average account benefits ratio for future years.

Statement of Need:

Sections 108 and 204 of the Railroad Retirement and Survivors' Improvement Act of 2001 (Pub.L. 107-90) amended the Railroad Retirement Act to require the Board to annually compute the account benefits ratios for the railroad retirement system and make a projection of the account benefits ratio and the average account benefits ratio for future years. Effective for calendar years after 2003, the tier II tax rate will be determined in accord with a formula that relies on the average account benefits ratio. See section 3241 of the Internal Revenue Code as amended by section 204 of Public Law 107-90. The Railroad Retirement Board has decided

to set forth in a new part 206 of the Board's regulations (20 CFR 206) how it will compute the ''account benefits ratio'' in accordance with sections 108 and 204 of the Railroad Retirement and Survivors' Improvement Act of 2001 so that all parties, rail labor, rail management, and the public, will be aware of how the Board intends to compute the account benefits ratio.

Summary of Legal Basis:

The general authority for the issuance of regulations under the Railroad Retirement Act (RRA) is provided for in section 7(b)(5) of the RRA (45 U.S.C. 231f(b)(5)); see also 45 U.S.C. 231u(a)(l).

Alternatives:

None.

Anticipated Cost and Benefits:

The costs associated with the addition of a new part to the Board's regulations are administrative in nature, and include the costs associated with drafting and publishing the regulation as a proposed and then a final rule. The benefits are those extended to the agency's constituents who will be aware of how the account benefits ratio is computed.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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RIN: 3220–AB56

RRB

FINAL RULE STAGE

154. REQUESTS FOR RECONSIDERATION AND APPEALS WITHIN THE BOARD

Priority:

Other Significant

Legal Authority:

45 USC 231f(b)(5); 45 USC 231g; 45 USC 355

CFR Citation:

20 CFR 260; 20 CFR 320

Legal Deadline:

None

Abstract:

The Railroad Retirement Board is amending 20 CFR sections 260 and 320 to provide for its field offices to make timeliness determinations on requests for reconsideration of decisions of the RRB's various adjudicating units.

Statement of Need:

The amendments to parts 260 and 320 deal with administrative reviews of denials of claims for benefits or requests for waiver of recovery of overpayments under the Railroad Retirement and Railroad Unemployment Insurance Acts. The amendments streamline the admininstrative review process, and generally provide certain protections for a claimant that have not previously been available, without diminishing his or her rights in other areas.

Summary of Legal Basis:

The general authority for the issuance of regulations under the Railroad Retirement Act (RRA) is provided for in section 7(b)(5) of the RRA (45 U.S.C. 231f(b)(5)); under the Railroad Unemployment Insurance Act (RUIA), the general authority for the issuance of regulations is found in section 5(a) (45 U.S.C. 355(a)) of the RUIA.

Alternatives:

None.

Anticipated Cost and Benefits:

While this regulation should result in modest savings in administrative costs due to the streamlining of procedures, the benefits are those extended to the agency's constituents as a result of the overall additional protections provided.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/29/02	67 FR 15127
NPRM Comment Period End	05/28/02	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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BILLING CODE 7905–01–S

SMALL BUSINESS ADMINISTRATION (SBA)

Statement of Regulatory Priorities

Overview

The Small Business Administration (SBA) is America's small business resource. SBA's mission is to promote and deliver financial and business development programs to America's entrepreneurs in the most efficient and effective manner possible.

With a portfolio of guaranteed business and disaster loans, SBA is the Nation's largest single financial backer of small businesses. Through our financial assistance programs, each year, SBA seeks to serve small companies by facilitating access to capital and credit. The SBA also helps entrepreneurs to start and grow their businesses through its resource-partner programs.

SBA is committed to:

- Listening to small businesses to make sure SBA is meeting the needs of the small business community;
- Working with its financial partners to improve small business access to capital through SBA's loan and venture capital programs;
- Providing technical assistance and guidance through its entrepreneurial development partners 24 hours a day;
- Establishing new and strengthening existing public and private partnerships to encourage greater contracting and business opportunities for small businesses.
- Measuring outcomes, such as revenue growth, job creation, and business longevity, to ensure SBA operates its programs in an efficient and effective manner.

SBA's regulatory priorities for the coming year will focus on strengthening SBA's management of programs, streamlining its HUBZone Program, and increasing opportunities for women-owned businesses.

SBA's Regulatory Plan

Small Business Lending Company Regulations

SBA is currently drafting proposed regulations that will strengthen the Agency's management and oversight of the Small Business Lending Company (SBLC) Program. SBA guarantees loans through approximately 7,000 lenders, of which 14 are SBLCs that are not otherwise regulated by Federal or State authorities. Further, consistent with congressional and Administration policy, certain SBA lenders are delegated authority to make credit decisions on loans guaranteed by SBA. At the present time, all of the SBLCs are preferred lenders with authority to make such credit decisions. The SBLCs hold approximately 20 percent of the outstanding loans guaranteed by SBA and are subject to safety and soundness examinations by SBA on a 12- to 24-month cycle. This rulemaking will clarify and strengthen the existing rules governing SBLCs in the areas of monitoring, oversight and enforcement, safe and sound operations, and compliance with SBA regulations.

HUBZone Empowerment Contracting Program

SBA is proposing regulations that will incorporate changes enacted by Public Law 106-554. The amended regulations will address eligibility requirements for small business concerns owned by Native American Tribal Governments and Community Development Corporations and the addition of new HUBZone areas called redesignated areas. The proposed amendments will streamline the program to make it more efficient.

Regulation as a Result of September 11, 2001, Events

Small Business Size Standards; Travel Agencies Affected by September 11, 2001

The events of September 11, 2001, directly impacted travel agencies. The traveling public cancelled and rescheduled existing travel arrangements and many postponed further travel. Many small travel agencies saw their business decline by 20 to 50 percent. To address this situation, after consultation with the industry and other interested parties, SBA issued an interim final rule on March 15, 2002, that increased the size standard for travel agencies, North American Industry Classification System (NAICS) code 561510, from $1 million to $3 million for economic injury disaster loan (EIDL) assistance. SBA believes that this action better defines the size of businesses in this industry that should be eligible for EIDL loans as a result of the September 11, 2001, terrorist attacks and for EIDL assistance to businesses in the declared disaster areas. On May 31, 2002, SBA issued a final rule, after taking into consideration comments received on the interim final rule.

SBA

PROPOSED RULE STAGE

155. SMALL BUSINESS LENDING COMPANIES REGULATIONS

Priority:

Other Significant

Legal Authority:

15 USC 634(b)(6); 15 USC 636(a); 15 USC 636(b)

CFR Citation:

13 CFR 120.470

Legal Deadline:

None

Abstract:

This rulemaking would amend 13 CFR 120.470 to clarify and strengthen the rules regarding Small Business Lending Companies (SBLCs) monitoring and oversight for safety and soundness, compliance, and related areas.

Statement of Need:

Section 7(a) of the Small Business Act states that the Small Business Administration (SBA) may provide financing to small businesses ''directly or in cooperation with banks or other financial institutions.'' Presently, SBA guarantees loans through approximately 7,000 lenders. Of these lenders, about 14 are Small Business Lending Companies (SBLCs) that are not otherwise regulated by Federal or State chartering, licensing, or similar regulatory control. SBA examines or audits these SBLCs periodically. Congressional and Administration policy to privatize SBA lending and levels in loan volume require that SBA increase its SBLC oversight. To that end, SBA will draft regulations that strengthen the Agency's management of the SBLC Program.

Summary of Legal Basis:

Not required by statute or court order.

Alternatives:

This rulemaking amends and expands SBA's existing regulations on the SBLC Program.

Anticipated Cost and Benefits:

This rulemaking is designed to strengthen SBA's regulations regarding the SBLC Program. Some additional costs associated with additional reporting by the SBLCs to the SBA is anticipated.

Risks:

This regulation poses no risks to the public health and safety or to the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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SBA

FINAL RULE STAGE

156. HUBZONE EMPOWERMENT CONTRACTING PROGRAM

Priority:

Other Significant

Legal Authority:

15 USC 632(a); 15 USC 634(b)(6); 15 USC 637(a); 15 USC 644(c); 15 USC 662(5); PL 105-135, sec 601 et seq, 111 Stat 2592; sec 304, PL 103-403, 108 Stat 4175, 4188

CFR Citation:

13 CFR 121; 13 CFR 125; 13 CFR 126

Legal Deadline:

None

Abstract:

SBA proposes to amend its regulations for the HUBZone Empowerment Contracting Program to incorporate changes enacted by Public Law 106-554. The amended regulation addresses eligibility requirements for small business concerns owned by Native American Tribal Governments and Community Development Corporations and the addition of new HUBZone areas called redesignated areas. This rule proposes: (1) consolidating all subcontracting requirements into one regulation, (2) language on how to petition for changes in subcontracting requirements, (3) to apply nonmanufacturer rules consistently for all programs, (4) how small nonmanufacturers should submit products of any manufacturer for contracts below the simplified acquisition threshold, (5) addressing statutory amendments, and (6) making technical changes.

Statement of Need:

SBA must amend its HUBZone regulations in order to implement changes in the Small Business Act mandated by Public Law 106-554, to correct typographical errors, and to streamline the program.

Summary of Legal Basis:

According to 15 U.S.C. section 657a, SBA's Administrator is charged with carrying out the HUBZone Program. On December 21, 2000, the President signed into law Public Law 106-554, which amends the HUBZone Program. To carry out the program, SBA must implement these statutory changes by amending its regulations.

Alternatives:

The Agency considered issuing policy notices explaining the changes to the statute. However, this is not sufficient because the current regulations do not address the statutory changes to the program and therefore, if the regulations are not amended, the public would be confused.

Anticipated Cost and Benefits:

The proposed amendments to the HUBZone regulation would simplify the program to make it more efficient. Therefore, the benefits would be quicker processing time of HUBZone applications.

Risks:

There is no risk to the Agency.

Timetable:

Action	Date	FR Cite
NPRM	01/28/02	67 FR 3826
NPRM Comment Period Extended	02/26/02	67 FR 8739
NPRM Comment Period End	02/27/02	
NPRM Comment Period End	03/29/02	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

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BILLING CODE 8025–01–S

SOCIAL SECURITY ADMINISTRATION (SSA)

Statement of Regulatory Priorities

The Social Security Administration (SSA) administers the retirement, survivors', and disability insurance programs under title II of the Social Security Act (the Act) and the Supplemental Security Income (SSI) program under title XVI of the Act. 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 ten entries for the Regulatory Plan represent areas of major importance to the administration of the retirement, survivors', disability, and SSI benefit programs. Each individual initiative is described more fully after this Statement of Regulatory Priorities.

Serve the Public

Providing the best service possible to the public remains a principal objective of SSA. To that end, we have included in the Plan a final rule on Expansion of the Use of Video Teleconference Technology in Hearings Before Administrative Law Judges of the Social Security Administration. We expect that expanding the availability of this technology will improve service by providing faster access to a hearing.

Improve the Disability Process

As the continued improvement of the disability program is an area of vital interest to SSA, we have included on the Plan two final rules that address disability. One final rule will update the medical listings used to evaluate digestive impairments. The revisions will ensure that the listings reflect advances in medical knowledge, treatment, and methods of evaluating these impairments. The other final rule implements elements of the redesigned disability claims process that have been tested and found to use our resources more effectively to award benefits at the earliest point possible.

Reduce Fraud

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.

To further enhance the integrity of SSA's enumeration process for assigning Social Security Numbers (SSNs), we plan to publish a proposed rule that would change evidence requirements for assigning SSNs. This proposed rule would clarify what ''valid nonwork reasons'' are in order to reduce the opportunity for fraud through misusing and/or improperly attaining SSNs.

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 proposing rules that reflect provisions of various laws intended to strengthen our oversight of the representative payee program.

We have also included final rules that provide us with additional tools to strengthen the integrity of the Social Security and SSI programs. One final rule implements a provision of the Foster Care Independence Act of 1999, authorizing SSA to obtain information from financial institutions in order to determine initial or continuing eligibility for SSI benefits.

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 final rule that will enable us to collect qualifying, delinquent title II and XVI debts owed by former beneficiaries who are currently employed in other-than-Federal employment. We are also developing a proposed rule on Federal salary offset to provide the same authority for similar debts owed by former beneficiaries who are currently employed by the Federal government.

Another proposal would enable us to conduct six-month pilot projects in order to test and gather information on the use of photographic identification to address the issue of impersonation in the disability claims process.

Simplify the SSI Program

SSA is proposing a rule that would simplify our SSI regulations. This proposed change would modify three rules concerning what we consider as income or resources available to an applicant or recipient. We propose to no longer consider gifts of clothing as income when we decide whether a person can receive SSI benefits or when we compute the amount of benefits. We also propose to exclude, from our determination of resources, one automobile if it is used for transportation, without consideration of its value. Finally, we propose to no longer count household goods and personal effects as resources when we decide whether a person can receive SSI benefits.

SSA

PROPOSED RULE STAGE

157. 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. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

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) in order for SSA to participate in the Federal Salary Offset program. Treasury's regulation 31 CFR section 3714 (administrative offset) and 5 U.S.C. 5514 (salary offset).

Summary of Legal Basis:

SSA's use of the Federal Salary Offset program is authorized by 42 U.S.C. 404(f), as amended by section 31001(z)(2) of Public Law 104-134, the Debt Collection Improvement Act of 1996, 42 U.S.C. 1383(b), as amended by section 203 of Public Law 106-169, the Foster Care Independence Act of 1999 and 5 U.S.C. 5514.

Alternatives:

None. SSA must have regulations, approved by the Office of Personnel Management, in order to use Federal salary offset to collect debts owed by Federal employees. See 5 U.S.C. 5514(b) and 5 CFR 550.1104.

Anticipated Cost and Benefits:

Undetermined at this time.

Risks:

At this time we have not identified any risks associated with the proposal.

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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SSA

158. ADMINISTRATIVE WAGE GARNISHMENT (TO REPAY A DEBT OWED TO THE SOCIAL SECURITY ADMINISTRATION) (724P)

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

31 USC 3720D; 42 USC 405; 42 USC 902; 42 USC 1383

CFR Citation:

20 CFR 404.527; 20 CFR 404.903; 20 CFR 4416.590; 20 CFR 416.1403; 20 CFR 422.401 to 422.403; 20 CFR 422.405; 20 CFR 422.410; 20 CFR 422.415; 20 CFR 422.420; 20 CFR 422.425; 20 CFR 422.430; 20 CFR 422.435; 20 CFR 422.440; 20 CFR 422.445

Legal Deadline:

None

Abstract:

This initiative will enable the Social Security Administration (SSA) to use administrative wage garnishment to collect administrative debts and to collect qualifying, delinquent titles II and XVI overpayment debts owed by individuals who are now employed in other than Federal employment. Administrative wage garnishment allows SSA to order an employer to deduct a percentage of the disposable pay earned by the worker/debtor and to send that amount to SSA as payment toward satisfying the delinquent debt. Administrative wage garnishment does not require a court judgment to impose the withholding order.

Statement of Need:

This regulation is necessary in order for SSA to use administrative wage garnishment as a tool in its debt collection process.

Summary of Legal Basis:

SSA is authorized to use administrative wage garnishment by 31 U.S.C. 3720D, added by section 31001(o) of Public Law 104-134, the Debt Collection Improvement Act of 1996.

Alternatives:

None—without regulatory authority SSA would be unable to proceed with administrative wage garnishment in a manner that addresses SSA's particular needs and processes. SSA must either adopt by reference the Treasury Department's regulations on wage garnishment hearings or prescribe SSA regulations regarding such hearings consistent with those Treasury Department regulations. See 31 CFR 285.11(f)(1).

Anticipated Cost and Benefits:

The administrative costs for the first year of implementation, including systems start-up costs, will be about 25 work years (WY) and $2 million in fiscal year (FY) 2003. Ongoing costs, once the regulation is fully implemented, are estimated to be about 65 WYs and $5 million per year, with higher costs of 80 WYs and $6 million for FY 2005 as older cases are cleared.

The estimated overpayment collections that we could receive for the title II program will be nothing in FY 2003, $25 million in FYs 2004 and 2005, and $15 million in FYs 2006 and 2007. The estimated collections for the title XVI program will be less than $2.5 million in FYs 2003 and 2004, and $10 million in FYs 2005, 2006, and 2007.

Risks:

At this time we have not identified any risks associated with the proposal.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	09/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

State, Local, Tribal, Federal

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SSA

159. EVIDENCE REQUIREMENT FOR ASSIGNMENT OF SOCIAL SECURITY ADMINISTRATION NUMBERS (SSNS) AND ASSIGNMENT OF SSNS FOR NONWORK PURPOSES (751P)

Priority:

Other Significant

Legal Authority:

42 USC 405; 42 USC 432; 42 USC 902(a)(5); 42 USC 1320b-1; 42 USC 1320b-13

CFR Citation:

20 CFR 422.104; 20 CFR 422.107

Legal Deadline:

None

Abstract:

We propose to change our rules regarding the age at which a mandatory

in-person interview is required for original applications for an SSN. In addition, we propose eliminating the waiver of evidence of identity for children under age 7 who are applying for an original SSN card. Under these proposals, SSA will require an in-person interview with all individuals age 12 or older who are applying for an original SSN, and SSA will no longer waive the requirement to provide evidence of identity in original applications for a child under age 7. SSA will clarify that evidence of identity must contain sufficient biographical information to identify the individual. Additionally, we propose to eliminate reference to a pilot no longer under consideration by SSA pertaining to the processing of replacement SSN cards for United States (U.S.) citizens.

We also propose to clarify our rules regarding when we will assign an SSN to an alien who is legally in the U.S. but not under authority of law permitting him or her to work in the U.S. We are proposing to define a ''valid nonwork purpose'' as those instances when a Federal statute or regulation requires an alien to have an SSN in order to receive a federally-funded benefit to which the alien has established entitlement, or when a State or local law requires an alien to have an SSN in order to receive general public assistance benefits (i.e., a public benefit that is means-tested) to which the alien has established entitlement.

Statement of Need:

These revised regulations are necessary to further enhance the integrity of SSA's enumeration processes for assigning Social Security Numbers (SSNs). By changing evidence requirements for assignment of SSNs and by defining ''valid nonwork reasons,'' we intend to reduce the opportunity for fraud through misuse and/or improper attainment of SSNs.

Summary of Legal Basis:

None.

Alternatives:

In developing the policies for the age at which a mandatory in-person interview is required and the reasons for which a nonwork SSN is assigned, we considered but rejected the following options.

Age for Mandatory In-Person Interview -

When considering the age at which to set the in-person interview, we felt that it was rare for individuals to obtain an SSN for the first time as late as 12 years of age. However, we rejected a younger age because we felt that such interviews with younger children would be overly burdensome on the child and unproductive for SSA, even with the parent in attendance. We believe that the proposed age 12 threshold for in-person interviews provides the best balance between allowing us to screen effectively for a prior SSN without being overly burdensome on the child.

Reasons for Nonwork SSN -

We considered limiting the assignment of nonwork SSNs to where there is a Federal statute or regulation that requires the alien to furnish an SSN to receive a federally-funded benefit or service and the alien is legally in the U.S. but not under authority of law permitting him or her to work in the U.S. However, we have not observed significant fraud in the area of nonwork SSNs assigned for general public assistance benefits and we do not want to unnecessarily impact access to general public assistance programs.

Anticipated Cost and Benefits:

This regulation may result in a negligible increase in administrative costs. Enhancing the integrity of SSA's enumeration processes should result in fewer opportunities for SSN fraud, including the fraud associated with identity theft.

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	10/12/99	64 FR 55217
ANPRM Comment Period End	12/13/99	
NPRM	12/00/02	
Final Action	11/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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SSA

160. ● CLAIMANT IDENTIFICATION PILOT PROJECTS (937P)

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 405

CFR Citation:

20 CFR 404.617 (New); 20 CFR 416.217 (New)

Legal Deadline:

None

Abstract:

This initiative will enable the Social Security Administration (SSA) to conduct six-month pilot projects in order to test and gather information on the use of photographic identification to address the issue of complicit impersonation in the disability claims process. All field offices in South Carolina and Kansas, nine field offices in New York City, and the Augusta, Georgia field office will require that applicants filing for title II and title XVI disability benefits allow SSA to take their photographs and make them part of the SSA disability claims file. Failure to cooperate will result in denial of benefits. We will permit an exception to the photograph requirement when an individual has a valid religious objection.

Statement of Need:

The rule would provide regulatory authority to conduct the pilot projects.

Summary of Legal Basis:

Section 205(a) of the Social Security Act, as amended (42 U.S.C. 405) provides SSA with broad authority to set reasonable rules to ensure the integrity of Social Security programs. The proposed Claimant ID regulation is not specifically required by any statute or court order.

Alternatives:

None.

Anticipated Cost and Benefits:

Costs are undetermined at this time. Benefits would include the collection of data that will be used to analyze the feasibility and effectiveness of rolling out such a regulation on a national basis. This process will strengthen the integrity of the disability claims process by helping to ensure that the individual filing the application is the same individual examined by the consultative examination physician. These procedures would help to identify and/or deter individuals who are attempting to defraud the disability programs.

Risks:

At this time we have not identified any risks associated with the proposal.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	
Final Action	02/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Federal

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SSA

161. ● REPRESENTATIVE PAYMENT UNDER TITLES II, VIII, AND XVI OF THE SOCIAL SECURITY ACT (949P)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 401(j); 42 USC 902(a)(5); 42 USC 405 note; 42 USC 421 note; 42 USC 1383(a)(2); 42 USC 1383(d)(1); 42 USC 404(f); 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 405(j); 42 USC 405(k); 42 USC 421; 42 USC 425; 42 USC 1007

CFR Citation:

20 CFR 404.902; 20 CFR 404.2011; 20 CFR 404.2021; 20 CFR 404.2022; 20 CFR 404.2024; 20 CFR 404.2025; 20 CFR 404.2030; 20 CFR 404.2035; 20 CFR 404.2040(a); 20 CFR 404.2041; 20 CFR 404.2045; 20 CFR 404.2050; 20 CFR 404.2065; 20 CFR 416.611; 20 CFR 416.621; 20 CFR 416.622; 20 CFR 416.624; 20 CFR 416.625; 20 CFR 416.630; 20 CFR 416.635; 20 CFR 416.640(a); 20 CFR 416.641; 20 CFR 416.645; 20 CFR 416.650; 20 CFR 416.665; 20 CFR 416.1402

Legal Deadline:

None

Abstract:

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries determined 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 regulations are required to reflect these legislative improvements and to further our program integrity efforts.

Statement of Need:

These regulations, which reflect certain provisions of Public Law 101-508, 103-296, 104-121, 105-33, 106-169 and 106-170, modify existing representative payee procedures by: (1) requiring the Social Security Administration to do a more extensive investigation of representative payee applicants, generally limiting to one month the deferral or suspension of direct payment of benefits pending selection of a payee; (2) providing stricter standards in determining the fitness of representative payee applicants to manage benefit payments on behalf of beneficiaries; (3) requiring SSA to repay the beneficiary or an alternate payee, an amount equal to any misused funds resulting from SSA's negligent failure to investigate or monitor a representative payee; (4) granting certain payees the authority to collect a fee from beneficiaries and defining the amount of bonding necessary to provide adequate protection for our beneficiaries and the nature of licenses that are pertinent for a fee for service organization; (5) changing how SSA treats persons whose drug addition or an alcohol condition is material to his/her disability; and (6) requiring SSA to compile and maintain a centralized file of certain beneficiary and payee information.

Summary of Legal Basis:

These regulations implement section 5105 of Public Law 101-508, section 210 of Public Law 103-296, section 105 of Public Law 104-121, section 5525 of Public Law 105-33, section 251 and 1136 of Public Law 106-169 and section 401 of Public Law 106-70.

Alternatives:

None.

Anticipated Cost and Benefits:

Any costs associated with these regulations are reflected in the President's budget as part of legislative implementation. They are required to further our program integrity efforts.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

State, Local

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SSA

162. • REMOVAL OF CLOTHING FROM THE DEFINITIONS OF INCOME AND IN-KIND SUPPORT AND MAINTENANCE, EXCLUSIONS OF ONE AUTOMOBILE AND HOUSEHOLD GOODS AND PERSONAL EFFECTS UNDER SSI FROM RESOURCES (950P)

Priority:

Other Significant

Legal Authority:

Sec 1612 of the Social Security Act; Sec 1613(a)(2)(A) of the Social Security Act

CFR Citation:

20 CFR 416.1102 to 416.1104; 20 CFR 416.1121; 20 CFR 416.1124; 20 CFR 416.1130; 20 CFR 416.1133; 20 CFR 416.1140; 20 CFR 416.1142; 20 CFR 416.1144 to 416.1145; 20 CFR 416.1147 to 416.1149; 20 CFR 416.1157; 20 CFR 416.1210; 20 CFR 416.1216; 20 CFR 416.1218

Legal Deadline:

None

Abstract:

We propose to make the following changes to our rules on determining income and resources under the Supplemental Security Income (SSI) program.

1. We propose to remove clothing from the definition of income and from the definition of in-kind support and maintenance. As a result, we generally will not count gifts of clothing as income when we decide whether a person can receive SSI benefits or when we compute the amount of benefits.

2. We propose to simplify our rules on how we exclude an automobile in determining the resources of a SSI applicant or recipient. Specifically, we propose to exclude one automobile from resources if it is used for transportation, without consideration of its value.

3. We propose to change our resources counting rules in the SSI program by eliminating the dollar value limit for the exclusion of household goods and personal effects. As a result, we would not count household goods and personal effects as resources when we decide whether a person can receive SSI benefits.

Statement of Need:

These changes will simplify our rules, making them less cumbersome to administer and easier for the public to understand and follow, and thereby reducing the potential for payment errors. These changes also will make SSI financial eligibility rules more consistent with those of other means-tested Federal programs. The changes also will eliminate the need to ask claimants, beneficiaries, and other members of their household certain questions that have been viewed as intrusive. By no longer counting gifts of clothing as income, we will remove a disincentive for family members to help needy relatives.

Summary of Legal Basis:

None.

Alternatives:

Clothing

None.

Automobile -

We considered revising the regulations to provide that SSA will assume that the recipient's automobile meets the use requirements for total exclusion of one automobile, absent evidence to the contrary. We did not select this option because it would not change the rule but only how we apply it. It does not go far enough in simplifying the SSI program. By revising the use requirements to exclude a car if it is used for transportation, thus replacing the four present specific transportation exclusion criteria, we will simplify the process.

We considered excluding the value of one automobile, regardless of use. We did not select this option because it would allow for the routine exclusion of an automobile even if it were not used for transportation. Such an approach would exclude an inoperable vehicle, a vehicle not being used at all, or a vehicle only used for recreation (such as a dune buggy). We maintain that it is unreasonable to exclude from resources the value of a vehicle that is not used for transportation.

We also considered increasing the excludable value of an automobile not meeting the use test to $11,000. We did not select this option because it would not simplify the SSI program.

Household Goods and Personal Effects -

Instead of excluding the entire value of household goods and personal effects, we considered raising the excludable limit to $10,000 from the current level of $2,000. We decided not to pursue this option because it would not provide any policy simplification. It would increase the amount excluded but it would not eliminate the need for the current time-consuming and complex procedures for determining the market value of an individual's household goods and personal effects.

Anticipated Cost and Benefits:

We estimate that the program costs and administrative costs for these regulatory changes would be negligible.

The proposed rules will simplify the administrative process of valuing noncash items. The change to the household goods and personal effects exclusion would simplify our rules and improve work efficiency by eliminating the need to inventory an individual's household goods and personal effects and determine their current market value. The proposed changes would also serve to make our rules less intrusive and more protective of the dignity of individuals seeking SSI benefits.

Risks:

These proposed changes would simplify complex SSI rules without disadvantaging SSI applicants or recipients or significantly increasing program or administrative costs.

Clothing -

There are no significant concerns.

Automobile -

Our experience shows that most SSI beneficiaries do not own expensive cars. Still, it is possible that a beneficiary may, under our proposal, own an automobile that is used for transportation (and therefore excluded) and that is worth a considerable amount of money.

Household Goods and Personal Effects -

Under the proposed change to the household goods and personal effects exclusion, we would continue to

recognize that individuals applying for SSI may own items that have investment value and which may be quite valuable. Such items as gems, jewelry, and collectibles would still be considered countable resources and subject to the SSI resource limit. Thus, the proposed exclusion for household goods and personal effects would not create an unintended exclusion for items that have investment value.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	
Final Action	09/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AF84

SSA

FINAL RULE STAGE

163. OASDI AND SSI; ADMINISTRATIVE REVIEW PROCESS; VIDEO TELECONFERENCING APPEARANCES BEFORE ADMINISTRATIVE LAW JUDGES OF THE SOCIAL SECURITY ADMINISTRATION (737F)

Priority:

Other Significant

Legal Authority:

42 USC 205(a); 42 USC 205(b); 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.929; 20 CFR 404.936; 20 CFR 404.938; 20 CFR 404.950; 20 CFR 416.1429; 20 CFR 416.1436; 20 CFR 416.1438; 20 CFR 416.1450

Legal Deadline:

None

Abstract:

This final rule revises our rules to permit us to conduct hearings before an administrative law judge (ALJ) at which a party or parties to the hearing and/or witness or witnesses may appear before the ALJ by video teleconference (VTC). The revised rules provide that if we schedule a hearing as one at which a party would appear by VTC, rather than in person, and the party objects to use of that procedure, we will reschedule the hearing as one at which the party may appear in person. We will be requesting public comments on this final rule.

Statement of Need:

Our regulations provide for a hearing in person before an ALJ. Traditionally, this has meant that the individual requesting a hearing makes his or her appearance in the same room as the ALJ. These changes will allow us to schedule a party to appear by VTC without requiring prior written consent, and set out the right of the party to decline such an appearance. We believe that conducting hearings by VTC will improve our efficiency and allow us to improve the service we can provide to individuals requesting a hearing.

The VTC provision will aid in reducing the average processing time for hearings by eliminating much of the time some ALJ's must spend to travel to remote sites to conduct hearings face-to-face.

Summary of Legal Basis:

None.

Alternatives:

Require participation in a scheduled VTC appearance with no right to decline a VTC appearance.

Anticipated Cost and Benefits:

Improved public service by providing faster access to a hearing.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/05/01	66 FR 1059
NPRM Comment Period End	03/06/01	
Final Action	11/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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Related RIN: Previously reported as 0960-AA05

RIN: 0960–AE97

SSA

164. 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, subpart P, app 1

Legal Deadline:

None

Abstract:

Listings 5.00 and 105.00 of appendix 1 to the disability regulation at 20 CFR part 404, subpart P describe those digestive impairments that are considered severe enough to prevent a person from doing any gainful activity or, for a child claiming SSI payments under title XVI, that are considered severe enough to result in marked and severe functional limitations. Comprehensive revisions to these listings are being made to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medicine. 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.

Since there would be no changes or only minor technical changes in using this alternative, the program and administrative costs would be the same as under the current rules. However, the program savings associated with the proposed rules would not be achieved.

Anticipated Cost and Benefits:

We are projecting savings in program expenditures as a result of these actions, described in more detail below.

Program Savings -

1. Title II

We estimate that, if finalized, these proposed rules would result in reduced program outlays resulting in the following savings (in millions of dollars) to the title II program ($295 million total in a 5-year period beginning in FY 2003).

2. Title XVI

We estimate that, if finalized, these proposed rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the SSI program ($85 million in a 5-year period beginning in FY 2003).

(Note: Federal SSI payments due on October 1st in fiscal years 2006 and 2007 are included with payments for the prior fiscal year.)

Program Costs -

We do not expect any program costs to result from these proposed regulations.

Administrative Savings -

We do not expect any administrative savings to result from these proposed regulations.

Administrative Costs -

We expect that, if finalized, there will be some administrative costs associated with these proposed rules. If finalized, the proposed rules are expected to result in administrative costs less than 25 work years and less than $2 million per year.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/14/01	66 FR 57009
NPRM Comment Period End	01/14/02	
Final Action	03/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 0960–AF28

SSA

165. ACCESS TO INFORMATION HELD BY FINANCIAL INSTITUTIONS (815F)

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1383(e); PL 106-169, sec 213

CFR Citation:

20 CFR 416.200; 20 CFR 416.207; 20 CFR 416.421; 20 CFR 416.640; 20 CFR 416.1231; 20 CFR 416.1242; 20 CFR 416.1245; 20 CFR 416.1247; 20 CFR 416.1320; 20 CFR 416.1321; 20 CFR 416.1335; 20 CFR 416.1337; 20 CFR 416.1618

Legal Deadline:

None

Abstract:

These final rules implement law that will enhance our access to bank account information of Supplemental Security Income (SSI) applicants and recipients and other individuals whose income and resources we consider as being available to the applicant or recipient.

Statement of Need:

This final rule is required to implement section 213 of Public Law 106-169, the Foster Care Independence Act of 1999.

Summary of Legal Basis:

Required by section 213 of Public Law 106-169.

Alternatives:

None.

Anticipated Cost and Benefits:

First year administrative costs are projected not to exceed $1.5 million. Subsequent year costs are projected not to exceed $6 million annually. It is estimated that this project will produce first-year program savings of $22 million. When fully implemented, it is estimated that program savings will be $85 million annually.

Risks:

Undetermined at this time.

Timetable:

Action	Date	FR Cite
NPRM	05/02/02	67 FR 22021
NPRM Comment Period End	07/01/02	
Final Action	11/00/02	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 0960–AF43

SSA

166. NEW DISABILITY CLAIMS PROCESS—ROLES OF STATE AGENCY (816F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 405(a); 42 USC 902(a)(5)

CFR Citation:

20 CFR 404.1512; 20 CFR 404.1513; 20 CFR 404.1526; 20 CFR 404.1527; 20 CFR 404.1529; 20 CFR 404.1546; 20 CFR 404.1615; 20 CFR 404.1616; 20 CFR 416.912; 20 CFR 416.913; 20 CFR 416.926; 20 CFR 416.927; 20 CFR 416.929; 20 CFR 416.946; 20 CFR 416.1015; 20 CFR 416.1016

Legal Deadline:

None

Abstract:

We plan to revise our regulations that pertain to the processing of initial claims for disability benefits under title II and title XVI of the Social Security Act at the initial and reconsideration steps of the administrative review process. Under these final rules, certain State agency disability examiners, familiarly called ''single decisionmakers,'' will be responsible for the disability determinations in many initial claims for disability benefits. However, they will be able to ask for advice from State agency medical or psychological consultants when they decide they need it. We also plan to review other rules to reflect these changes, including our rules about how we decide whether a person's impairment(s) medically equals a listing.

Statement of Need:

This regulation will permit us to use resources more effectively to ensure that disabled claimants are awarded benefits at the earliest point in the claims process.

Summary of Legal Basis:

None.

Alternatives:

The agency continues to consider various options for further redesign of the disability claims process.

Anticipated Cost and Benefits:

The 5-year estimates for implementation indicates an incremental benefit cost of $2.4 billion for OASDI and SSI combined, and $1.3 billion for Medicare and Medicaid combined.

Risks:

Not yet established.

Timetable:

Action	Date	FR Cite
NPRM	01/19/01	66 FR 5494
NPRM Comment Period End	03/20/01	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Federal

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Related RIN: Merged With 0960-AE73

RIN: 0960–AF44

BILLING CODE 4191–02–S

FEDERAL HOUSING FINANCE BOARD (FHFB)

Statement of Regulatory and Deregulatory Priorities

The Federal Housing Finance Board (Finance Board) is an independent agency that is charged under the Federal Home Loan Bank Act (Bank Act) with supervising and regulating the Nation's Federal Home Loan Bank (Bank) System. The Bank System comprises 12 regional cooperative Banks that are owned by their respective member financial institutions. The Banks provide wholesale credit to members and certain nonmembers to be used for mortgage lending and related community lending activities. The 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 2003 that would be required to be included in a regulatory plan.

The Finance Board's highest regulatory priorities during 2003 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 develop, based on its analysis of recently-solicited comments, an appropriate regulatory response to requests that a single financial institution be permitted to become a member of more than one Bank.

The Finance Board also intends to consider regulations that will:

- Review the structure of authorized acquired member asset products to determine if Banks have sufficient flexibility in creating new products that will be responsive to member needs;
- 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; and
- Improve public disclosure by the Banks including addressing the requirements of the Securities Act of 1933 and Securities Exchange Act of 1934, as these Acts are interpreted and applied by the SEC.

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 mission. The Commission's mission is to administer the shipping statutes as effectively as possible to provide an efficient, competitive, market-driven, and nondiscriminatory ocean transportation system in an environment free of unfair foreign maritime trade practices. The Commission's regulations are designed to implement each of the statutes the Agency administers in a manner consistent with this mission and in a way that minimizes regulatory costs, fosters economic efficiencies, relies on the marketplace to determine industry growth, and promotes international harmony.

Recent legislation continues to impact the Federal regulatory scheme regarding international ocean shipping. The legislation required new regulations, as well as the revision of many of the Commission's substantive regulations. One of the principal changes was the elimination of the requirement that carriers file tariffs with the Commission listing their rates and charges. Carriers are now required to publish their rates in private automated systems. The Commission continues to assess its regulations implementing this requirement, as well as other requirements of the new legislation.

Common carriers remain concerned as to the content requirements of agreements filed with the Commission. Carriers have expressed a desire for better delineation as to what matters do or do not have to be filed and have suggested that the Commission's rules should provide protections for confidential business information, provide maximum flexibility for carriers to modify cooperative arrangements, and include guidance tailored for different types of agreements. The Commission previously initiated an inquiry to solicit comments from the ocean transportation industry and the general public to assist the Commission in formulating new rules governing content requirements. This matter continues to be assessed and will be considered during calendar year 2002. 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 been updating its nonperformance coverage requirements to correspond more closely with current industry conditions and contemplates proposing additional changes in calendar year 2002.

The principal objective or priority of the Agency's current regulatory plan will be to continue to assess major existing regulations for continuing need, effectiveness, burden on the regulated industry, fairness, and clarity. The Commission issued its 2-year study of the Ocean Shipping Reform Act of 1998 in September 2001. Findings and conclusions from that report could result in consideration of specific issues for rulemaking proposals.

The Commission continues to have under review, *inter alia*, regulations regarding certain requirements applicable to vessel-operating common carrier agreements and co-loading arrangements between non-vessel-operating common carriers. 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)

I. REGULATORY PRIORITIES

Background

The Federal Trade Commission (FTC or Commission) is an independent agency charged with protecting American consumers from ''unfair methods of competition'' and ''unfair or deceptive acts or practices'' in the marketplace. The Commission strives to ensure that consumers benefit from a vigorously competitive marketplace. The Commission's work is rooted in a belief that free markets work — that competition among producers and information in the hands of consumers bring the best products at the lowest prices for consumers, spur efficiency and innovation, and strengthen the economy.

The Commission pursues its goal of promoting competition in the marketplace through two different, but complementary, approaches. First, for competition to thrive, curbing deception and fraud is critical. Through its consumer protection activities, the Commission seeks to ensure that consumers receive accurate, not false or 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.

Regulatory Actions Related to Events of September 11, 2001

On October 25, 2001, President Bush signed the USA PATRIOT Act of 2001, Pub. L. 107-56, 115 Stat. 272, which contains provisions that have a significant impact on the Telemarketing Sales Rule (TSR). The TSR, 16 CFR part 310, which was adopted pursuant to the Telemarketing and Consumer Fraud and Abuse Prevention Act of 1994 (Telemarketing Act), 15 USC 6101-6108, requires telemarketers to disclose certain material information; prohibits misrepresentations; limits the times of day telemarketers may call consumers; prohibits calls to a consumer who has asked not to be called again; and sets payment restrictions for the sale of certain goods and services. Sec. 1011 of the USA PATRIOT Act, also referred to as the Crimes Against Charitable Americans Act of 2001, 15 U.S.C. 6101 note, amends the Telemarketing Act to extend the coverage of the TSR to charitable fund raising conducted by for-profit telemarketers for, or on behalf of, charitable organizations.

On January 30, 2002, the Commission announced its proposal to amend the TSR and published a Notice of Proposed Rulemaking (NPRM). Among other things, the proposed Rule would establish a centralized national ''do not call'' registry, would prohibit telemarketers from receiving or sharing a consumer's billing information with anyone else, and would prohibit telemarketers from blocking ''Caller ID'' information. In addition, as mandated by the USA PATRIOT Act, the Commission's proposal adds certain disclosures and other requirements applicable to for-profit telemarketers who solicit charitable donations. Staff held a three-day public workshop from June 5-7, 2002, to discuss these and other proposed changes to the Rule. On May 24, 2002, the Commission also issued a related NPRM proposing that user fees be imposed on telemarketers and their seller or telemarketer clients for access to the national ''do not call'' registry in order to establish and maintain the registry. *See* 67 FR 37362 (May 29, 2002). Staff plans to forward its recommendations to the Commission by fall 2002.

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 *et seq*. Under the Commission's program, however, rules have been reviewed on a ten-year schedule as resources permit, not just once as usually 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.'' The program's goal is to ensure that all of the Commission's rules and guides remain beneficial and in the public interest.

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 or in the public interest. As a result of the review program, the Commission has repealed 48 percent of its trade regulation rules and 55 percent of its guides since 1992.

Calendar Year 2002 Reviews and Reviews in Process

As part of the Commission's ten-year review program, in 2002 the Commission continued reviews of seven rules. The Commission also commenced the review of one rule regarding Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles, 16 CFR part 309 and one industry guide regarding Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 CFR part 255.[1]

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. For example, as discussed in greater detail in the September 11, 2001

[1] In publishing the regulatory review schedule each year, the Commission indicates that the tentative timetable may be modified in the future to incorporate new legislative rules, or to respond to external factors (such as changes in the law) or other considerations *See, e.g.,* 67 FR 9630 (Mar. 4, 2002).

section above, the Commission announced on January 22, 2002, its proposal to amend the Telemarketing Sales Rule (TSR), 16 CFR part 310, and published a notice of proposed rulemaking (NPRM). Among other things, the proposed Rule would establish a centralized national ''do not call'' registry, would prohibit telemarketers from receiving or sharing a consumer's billing information with anyone else, and would prohibit telemarketers from blocking ''Caller ID'' information. In addition, as mandated by Sec. 1011 of the USA PATRIOT Act, also referred to as the Crimes Against Charitable Americans Act of 2001, 15 U.S.C. 6101 note, the Commission's proposal adds certain disclosures and other requirements applicable to for-profit telemarketers who solicit charitable donations. Staff held a three-day public workshop from June 5-7, 2002, to discuss these and other proposed changes to the Rule. On May 24, 2002, the Commission also issued a related NPRM proposing that user fees be imposed on telemarketers and their seller or telemarketer clients for access to the national ''do not call'' registry in order to establish and maintain the registry. *See* 67 Fed. Reg. 37362 (May 29, 2002). Staff plans to forward its recommendations to the Commission by fall 2002.

In addition, the Commission's review of the Pay-Per-Call Rule, 16 CFR part 308, is proceeding. The Commission has held workshops to discuss proposed amendments to its Pay-Per-Call 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 base information and entertainment services. The most recent workshop, held May 20 and 21, 1999, focused on discussions of the use of 800 and other toll-free numbers to offer pay-per-call services, the scope of the Rule, the dispute resolution process, the requirements for a presubscription agreement, and the need for obtaining express authorization from consumers before placing charges on their telephone bills. Staff anticipates forwarding its recommendation to the Commission by early 2003.

The Commission's review of the Franchise Rule, 16 CFR part 436, is also continuing. The Commission accepted comments on an NPRM with the text of a revised rule until December 21, 1999, and rebuttal comments until January 31, 2000. The proposal addresses issues including: (1) changing the timing for making disclosures; (2) clarifying the application of the Rule to international franchise sales; (3) expanding the Rule to require additional disclosures, including pending franchiser-initiated lawsuits involving the franchise relationship, franchiser use of gag clauses and, in some instances, trademark specific franchisee associations; (4) permitting disclosures through electronic media, including the Internet; and (5) expanding the Rule's exemptions to address sophisticated investors. In June 2001, Bureau of Consumer Protection Staff issued *Franchise and Business Opportunity Program Review 1993-2000: A Review of the Complaint Data, Law Enforcement and Consumer Education.* Staff expects to forward its report on the rulemaking to the Commission by the end of 2002.

In addition, the Commission's review of the Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Regulations), 16 CFR part 307, is proceeding. Issued to implement the requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986, 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 early next year.

The review of the R-Value Rule, 16 CFR part 460, is also proceeding. As part of the Commission's regulatory review program, the Commission published an advance notice of proposed rulemaking (ANPRM) on the R-Value Rule for home insulation. *See* 64 FR 48023 (Sept. 1, 1999). Staff is currently reviewing the comments and expects to forward its recommendation to the Commission regarding proposed substantive amendments to the Rule, and anticipates publication of the NPRM late this fall.

In 1999, the Commission began its regulatory review of certain aspects of the Funeral Industry Practices Rule (Funeral Rule or Rule), 16 CFR part 453. 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 not only state prices and descriptions, but also contain specific disclosures. The Rule enables consumers to select and purchase only the goods and services they want, except for those which 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 Commission's 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 24249 (May 5, 1999). In response to requests of industry members, the Commission determined to extend the comment period. A public workshop conference was held on November 18, 1999, to explore issues raised in the comments submitted. Staff expects to forward its recommendation to the Commission by early 2003.

Final Actions

Since publication of the 2001 Regulatory Plan, the Commission has taken final actions on three rulemakings. First, on May 17, 2002, the Commission issued a final Financial Information Safeguards Rule, 16 CFR, part 314, governing the safeguarding of customer records and information for the financial institutions that are subject to its jurisdiction. Section 501(b) of the Gramm-Leach-Bliley Act, Pub. L. No. 106-102,[2] required the Federal Trade Commission to implement and enforce appropriate standards for financial institutions subject to the agency's jurisdiction to safeguard customers' records and information (safeguards standards) by rule. After publishing both a request for comments and a notice of proposed rulemaking. *See* 66 FR 41162 (Aug. 7, 2001), the Commission considered about forty-five public comments before issuing the final Financial Information Safeguards Rule, 16 CFR part 314, on May 17, 2002. *See* 67 FR 36483 (May 23, 2002). As required by section 501(b) of Gramm-Leach-Bliley, the standards are intended to ensure the security and

[2]The Commission previously published its final rule implementing other Gramm-Leach-Bliley requirements in its Rule on Privacy of Consumer Financial Information, 16 CFR part 313. *See* 65 FR 33646 (May 24, 2000).

confidentiality of customer records and information; protect against any anticipated threats or hazards to the security or integrity of such records; and protect against unauthorized access to or use of such records or information that could result in substantial harm or inconvenience to any customer.

Second, on April 17, 2002, the Commission amended the Children's Online Privacy Protection (COPPA) Rule, 16 CFR part 312, extending by three years (until April 21, 2005) the sliding scale mechanism of verifying parental consent by Web sites or online services. *See* 67 FR 18818 (Apr. 17, 2002). During October 2001, the Commission had proposed a two-year extension of the sliding scale mechanism from April 21, 2002, until April 21, 2004 because the anticipated progress in available technology of verifying such consent had not occurred since the initial COPPA Rule became effective April 21, 2000. 66 FR 54963 (Oct. 31, 2001). The public comments received in response to the Commission's October 2001 NPRM indicated that secure electronic technology and infomediary services are not yet widely available at a reasonable cost and that the sliding scale mechanism to date has been an effective method for obtaining parental consent.

Third, the Commission has also withdrawn its review of a portion of the Amplifier Rule, 16 CFR part 432, from the Unified Agenda because the Commission does not anticipate any further action in this supplemental rulemaking proceeding in the near future. On December 22, 2000, the Commission issued a final rule clarifying the testing procedure for self-powered speakers, and eliminating or modifying certain testing and disclosure requirements that had outlived their usefulness to consumers. *See* 65 FR 81232 (Dec. 22, 2000). At the same time, the Commission also issued a supplemental notice of proposed rulemaking (SNPRM) to seek comment on proposed testing procedures for ''home theater'' receivers with five or more channels. *See* 65 FR 80798 (Dec. 22, 2000). The comment period for the SNPRM ended on March 30, 2001. On January 15, 2002, the Commission announced that it would keep the rulemaking record open but defer action on the proposed supplemental rule to allow an industry working group time to establish a voluntary consensus standard of measuring the power output of multichannel receivers and amplifiers. *See* 67 FR 1915 (Jan. 15, 2002).

With respect to Industry Guides, the Commission finished its review and rescinded the Guides for the Household Furniture Industry (Furniture Guides), 16 CFR part 250. On April 11, 2000, the Commission had initiated its regulatory review of the Furniture Guides, which were issued on December 21, 1973, and had requested comments about the overall costs and benefits and the continuing need for them. *See* 65 FR 18933 (Apr. 11, 2000). The Commission received one comment from the American Furniture Manufacturers Association (AFMA), which expressed concern that the Furniture Guides have little practical use to members of the furniture industry due to significant changes in technology and terminology since they were first promulgated. In the almost thirty years since the Furniture Guides were issued, the Commission has not received any complaints relating to practices covered by the Guides. Further, within the last ten years, the Commission has not had to initiate any enforcement action relating to these Guides. For these reasons, the Commission has determined that the Guides are no longer necessary. If deceptive practices prove to be a problem in this industry in the future, the Commission can deter manufacturers and sellers from misleading consumers in the labeling, advertising or sale of household furniture products by pursuing enforcement actions under the FTC Act on a case-by-case basis.

The Commission completed its review and retained Guides for the Rebuilt, Reconditioned, and Other Used Automobile Parts Industry (Used Auto Parts Guides or Guides), 16 CFR part 20, with updated language and minor revisions. *See* 67 FR 9919 (Mar. 5, 2002). The Used Auto Parts Guides, effective since 1962, advise industry members not to misrepresent the age of the product, the condition of the product, the extent of the rebuilding of the product, or that the rebuilder was the original manufacturer. Industry members must also conspicuously disclose in advertising and packaging that the products include used parts, if that is the case. During April 1998, the Commission published a Federal Register notice seeking comment on the overall costs and benefits of the Used Auto Parts Guides and whether there was a continuing need for them. *See* 63 FR 17132 (Apr. 8, 1998). Seven of the eight written comments received favored keeping these Guides. In retaining the Used Auto Parts Guides, the Commission also updated the list of commonly rebuilt used automobile parts contained in section 20.0 of these Guides and clarified that these Guides apply to advertising in electronic format, such as on the Internet. Finally, the Commission updated and streamlined certain language in the Used Auto Parts Guides to conform to current FTC practice.

The Commission has also completed its review and retained the Guide Concerning Fuel Advertising for New Automobiles (Fuel Economy Guide or Guide), concluding that consumers will continue to benefit from accurate information in the advertising of fuel economy figures for new vehicles. *See* 67 FR 9924 (March 4, 2002). Adopted in 1975 and subsequently revised twice, the Fuel Economy Guide is designed to prevent deceptive fuel economy advertising and to facilitate the use of fuel economy claims in advertising. Since its issuance, this Guide has advised marketers to disclose the established fuel economy of the vehicle as determined by the Environmental Protection Agency (EPA) under the Automobile Information Disclosure Act, 15 USC 2206, in advertisements that make representations regarding the fuel economy of a new vehicle. These EPA fuel economy numbers also appear on window labels attached to new automobiles. After considering a variety of factors during its review, including eight public comments, the Commission has concluded that the Fuel Economy Guide's benefits to consumers far outweigh the minimal cost to vehicle manufacturers of complying with its provisions.

Calendar Year 2003 Reviews

On March 4, 2002, the Commission issued a Federal Register notice announcing that the agency will commence the review of one rule and two guides during calendar year 2003. *See* 67 FR 9630 (Mar. 4, 2002). The review will include the Rules and Regulations Under the Hobby Protection Act, 16 CFR part 304; Tire Advertising and Labeling Guides, 16 CFR part 228; and Statements of General Policy or Interpretations Under the Fair Credit Reporting Act, 16 CFR part 600.

Summary

With regard to both content and process, the FTC's ongoing and proposed regulatory actions are compatible 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 Financial Information Safeguards Rule, 16 CFR, part 314 (2002) is consistent with the President's Statement of Regulatory Philosophy and Principles, Executive Order. 12866 section l(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 55 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, sec. 1.

II. REGULATORY ACTIONS

The Commission has no rules that constitute ''significant regulatory actions'' under the definition in Executive Order 12866.

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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 NIGC's regulatory priorities for the next fiscal year are to:

1. Amend regulations implementing the Freedom of Information Act (FOIA); and
2. Finalize rules that set forth procedures for collecting debts owed to the agency.

NIGC

PROPOSED RULE STAGE

167. FREEDOM OF INFORMATION ACT PROCEDURES (AMENDMENTS)

Priority:

Other Significant

Legal Authority:

5 USC 552

CFR Citation:

25 CFR 517.3; 25 CFR 517.6; 25 CFR 517.8

Legal Deadline:

None

Abstract:

These rules will revise the current regulations to make them consistent with the amended Freedom of Information Act (FOIA). The rules will also update information such as addresses and copying fees.

Statement of Need:

Amendments to the Freedom of Information Act (FOIA) Procedures are necessary to better implement the amended Act.

Summary of Legal Basis:

The Freedom of Information Act (FOIA) requires that each Federal agency shall publish procedures by which the public may obtain information. (5 U.S.C. 552(a)(1)). The Commission relies on this section of FOIA to authorize promulgation of this regulation.

Alternatives:

At this time, the only alternative is to continue using the current FOIA Procedures.

Anticipated Cost and Benefits:

The potential benefit of this regulatory action is improved compliance with FOIA. The anticipated costs of the regulation are unknown at this time.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 3141–AA21

NIGC

FINAL RULE STAGE

168. DEBT COLLECTION

Priority:

Other Significant

Legal Authority:

31 USC 3716; 25 USC 2713(a)(1)

CFR Citation:

25 CFR 580

Legal Deadline:

None

Abstract:

This regulation will establish a process for the assessment, notification, and collection of debts owed the National Indian Gaming Commission.

Statement of Need:

The Commission has determined that regulations are necessary for the assessment, notification, and collection of debts owed the NIGC.

Summary of Legal Basis:

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 this section of the statute to authorize the promulgation of standards for collecting debts owed the Commission.

Alternatives:

The Commission has no alternative but to promulgate this debt collection procedure for gaming facilities operated on Indian lands.

Anticipated Cost and Benefits:

The potential benefits to this regulatory action are to establish and define for the regulated community the procedure by which the Commission will enforce the collection debts owed the Commission. This regulatory action will provide the Commission with a process for the efficient and effective collection of debts.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/20/01	66 FR 58056
Interim Final Rule Comment Period End	01/04/02	
Interim Final Rule Comment Period Reopened	01/09/02	67 FR 1273
Interim Final Rule Comment Period End	01/14/02	
Final Rule	01/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

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