Federal Register
Vol. 68, No. 245
Monday, December 22, 2003

The Regulatory Plan

INTRODUCTION TO THE FALL 2003 REGULATORY PLAN

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

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

Federal Regulatory Policy

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

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

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

In pursuing this goal of establishing an effective, results-oriented regulatory system, the Bush Administration has increased the level of public involvement and transparency in its review and clearance of new and existing regulations. First, in 2002 OMB sought public comment on a major regulatory reform initiative. In response to this public solicitation, OMB received recommendations on 316 distinct rules, guidance documents, and paperwork requirements from over 1,700 commenters. In its review of the 316 nominations, OMB found that 109 of the reform ideas were already being addressed by agencies, and another 51 ideas were referred to independent agencies for their consideration. Of the 156 reform nominations that OMB determined were ripe for consideration by Cabinet-level agencies and the Environmental Protection Agency, agencies have decided to pursue 34 rules and 11 guidance documents for reform, are undecided about 26 rules and 4 guidance documents, and have decided not to pursue reform of 62 rules and 19 guidance documents at this time.

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

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 issued guidelines on October 1, 2002 under the Information Quality Law to ensure the ''quality, objectivity, utility, and integrity'' of all information disseminated by Federal agencies. Under these guidelines, Federal agencies are taking appropriate steps to incorporate the information quality performance standards into agency information dissemination practices, and developing pre-dissemination review procedures to substantiate the quality of information before it is disseminated. Under the agency information quality guidelines, ''affected persons'' can request that the agencies correct information if they believe that scientific, technical, economic, statistical or other information disseminated does not meet the agency and OMB standards. If the requestor is dissatisfied with the initial agency response to a correction request, an appeal opportunity is provided by the agencies. To date, agencies have received and responded to approximately 30 complaints that appear to be stimulated by the Information Quality Law. Although we are still in the early phases of implementation, agencies are aware that ensuring the high quality of government information disseminations is a high priority of the Administration.

As part of its efforts to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal agencies, OMB recently issued a proposed bulletin to realize the benefits of meaningful peer review of the most important science disseminated by the Federal government regarding regulatory topics. 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 can become even more effective and reliable.

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

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

The Administration's 2003 Regulatory Priorities

With regard to Federal regulation, the Bush Administration's objective is quality, not quantity. Those rules that are adopted promise to be more effective, less intrusive, and more cost-effective in achieving national objectives while demonstrating greater durability in the face of political and legal attack. The Regulatory Plan is integral to enhancing the quality of Federal regulations, and OMB seeks to ensure that the public is provided with the information needed to understand and comment on the Federal regulatory agenda. Accordingly, the 2003 Regulatory Plan highlights the following themes:

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 those nominated by the public as reform candidates last year (see OMB's 2003 Report to Congress on the Costs and Benefits of Federal Regulations); and

4. issues that have been the subject of an OIRA ''prompt letter.''

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

Specifically, 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 is undertaking 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 conclude 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 were designed to prevent the systems from unreasonably prejudicing the competitive position of other airlines and to ensure that travel agencies would 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.'' To assist small businesses, the Small Business Administration (SBA) will work to decrease the complexity of small business size standards, thereby encouraging small businesses to participate in the Federal Government's small business programs. The SBA intends to reduce the number of different size standards levels. This restructuring will simplify the identification of small businesses and the use of size standards in Federal small business programs.

Improving Public Health and Safety

The Federal Government's role in improving public health and safety is broad in scope. The Administration's 2003 regulatory priorities include a Department of Labor rulemaking on child labor. 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 Health and Human Services' Food and Drug Administration (FDA) will issue a rule on Reducing Medical Errors and Enhancing

Patient Safety. An upcoming final rule will require human drug products to have a scannable bar code that will reduce medication errors.

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) has proposed a rule 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 final rule in spring 2004.

EPA has promulgated 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

In its continued efforts to prevent future security threats and provide relief for individuals affected by the tragedies of the September 11, 2001 terrorist attacks, the Federal Government is revisiting and establishing practices and procedures to strengthen homeland security. 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. Furthermore, these agencies are working to coordinate their rulemaking activities with those from the Department of Homeland Security.

The Administration will continue to pursue regulatory actions necessary to ensure homeland security. The Department of Homeland Security will conclude work on a Trade Act regulation that will require the submission of arrival and departure manifests electronically in advance of an aircraft or vessel's arrival in or departure from the United States. The Department will also work on a regulation for the critical infrastructure program, which will determine the receipt, care, and storage procedures of critical infrastructure information voluntarily submitted by the public. The protection of critical infrastructure reduces the vulnerability of the United States to acts of terrorism. Furthermore, the Department will propose a rule which will provide critical incentives for the development and deployment of antiterrorism technologies.

Conclusion

Smarter regulatory policies, created through public participation, transparency, and cooperation across Federal agencies, seek to accomplish these five national objectives. Some of the following department or agency plans provide information on regulatory priorities in the context of these specific programs and initiatives. All agencies' plans are a reflection of the Administration's Federal Regulatory Policy objectives, which aim at implementing an effective and results-oriented regulatory system.

DEPARTMENT OF AGRICULTURE

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
1	National Organic Program: Add Standards for the Organic Certification of Wild Captured Aquatic Animals (TM–01–08)	0581–AB97	Prerule Stage
2	National Dairy Promotion and Research Program (DA–02–03)	0581–AC16	Proposed Rule Stage
3	Livestock Mandatory Reporting Program-Lamb Amendment (LS–01–08)	0581–AB98	Final Rule Stage
4	Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Fish, Perishable Agricultural Commodities, and Peanuts (LS–03–04)	0581–AC26	Final Rule Stage
5	Chronic Wasting Disease in Elk and Deer; Interstate Movement Restrictions and Payment of Indemnity	0579–AB35	Proposed Rule Stage
6	Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities	0579–AB73	Proposed Rule Stage
7	Foot-and-Mouth Disease; Payment of Indemnity	0579–AB34	Final Rule Stage
8	Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins	0579–AB47	Final Rule Stage
9	Multi-Family Housing (MFH) Reinvention	0575–AC13	Final Rule Stage
10	Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions to WIC Food Packages	0584–AD39	Prerule Stage
11	Commodity Supplemental Food Program (CSFP): Plain Language, Program Accountability, and Program Flexibility	0584–AC84	Proposed Rule Stage
12	Food Stamp Program: Simplification and State Flexibility	0584–AD22	Proposed Rule Stage
13	FSP: High Performance Bonuses	0584–AD29	Proposed Rule Stage
14	FSP: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD30	Proposed Rule Stage
15	FSP: Employment and Training Program Provisions of the Farm Security and Rural Investment Act of 2002	0584–AD32	Proposed Rule Stage
16	Senior Farmers' Market Nutrition Program (SFMNP)	0584–AD35	Proposed Rule Stage
17	FSP: Discretionary Quality Control Provisions of Title IV of Public Law 107–171	0584–AD37	Proposed Rule Stage
18	Child and Adult Care Food Program: Improving Management and Program Integrity	0584–AC24	Final Rule Stage
19	Food Stamp Program: Vehicle and Maximum Excess Shelter Expense Deduction Provisions of Public Law 106–387	0584–AD13	Final Rule Stage
20	FSP: Non-Discretionary Quality Control Provisions of Title IV of Public Law 107–171	0584–AD31	Final Rule Stage
21	Performance Standards for Bacon	0583–AC49	Proposed Rule Stage
22	Egg and Egg Products Inspection Regulations	0583–AC58	Proposed Rule Stage
23	Elimination of Chilling Time and Temperature Requirements for Ready-To-Cook Poultry	0583–AC87	Proposed Rule Stage
24	Emergency Regulations To Prevent Meat Food and Meat Products That May Contain the BSE Agent From Entering Commerce	0583–AC88	Proposed Rule Stage
25	Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems	0583–AD00	Proposed Rule Stage
26	Performance Standards for Ready-To-Eat Meat and Poultry Products	0583–AC46	Final Rule Stage
27	Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products	0583–AC60	Final Rule Stage
28	National Forest System Land Management Planning	0596–AB86	Final Rule Stage
29	National Security Emergency	0570–AA48	Proposed Rule Stage
30	Renewable Energy Systems and Energy Efficiency Improvements	0570–AA50	Proposed Rule Stage
31	Conservation Security Program	0578–AA36	Proposed Rule Stage

DEPARTMENT OF COMMERCE

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
32	Amendment 13 to the Northeast Multispecies Fishery Management Plan (FMP)	0648–AN17	Proposed Rule Stage

DEPARTMENT OF DEFENSE

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

DEPARTMENT OF EDUCATION

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

DEPARTMENT OF ENERGY

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
35	Energy Efficiency Standards for Residential Furnaces, Boilers, and Mobile Home Furnaces	1904–AA78	Prerule Stage
36	Energy Efficiency Standards for Electric Distribution Transformers	1904–AB08	Prerule Stage
37	Energy Efficiency Standards for Commercial Central Air Conditioning Units and Heat Pumps Rated 65–240 kBtus/Hr	1904–AB09	Prerule Stage
38	Worker Safety and Health	1901–AA99	Proposed Rule Stage
39	Radiation Protection of the Public and the Environment	1901–AA38	Final Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
40	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29	Proposed Rule Stage
41	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10	Proposed Rule Stage
42	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14	Proposed Rule Stage
43	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25	Proposed Rule Stage
44	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35	Proposed Rule Stage
45	Definition of ''Serious Adverse Health Consequences'' Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AF06	Proposed Rule Stage
46	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol	0910–AF18	Proposed Rule Stage
47	Labeling for Human Prescription Drugs; Revised Format	0910–AA94	Final Rule Stage
48	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97	Final Rule Stage
49	CGMP for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)	0910–AB76	Final Rule Stage

DEPARTMENT OF HEALTH AND HUMAN SERVICES (Continued)

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
50	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88	Final Rule Stage
51	Bar Code Label Requirements for Human Drug Products and Blood	0910–AC26	Final Rule Stage
52	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC38	Final Rule Stage
53	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC39	Final Rule Stage
54	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61	Final Rule Stage
55	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P)	0938–AG82	Proposed Rule Stage
56	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS–3835–P)	0938–AH17	Proposed Rule Stage
57	Organ Procurement Organization Conditions for Coverage (CMS–3064–P)	0938–AK81	Proposed Rule Stage
58	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS–2130–P)	0938–AL26	Proposed Rule Stage
59	Prospective Payment System for Inpatient Psychiatric Facilities FY 2004 (CMS–1213–F)	0938–AL50	Proposed Rule Stage
60	Hospital Patients' Rights CoP-Standard Safety Compliance Committees (CMS–3120–P)	0938–AM39	Proposed Rule Stage
61	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS–2065–F)	0938–AJ96	Final Rule Stage
62	Revisions to the Medicare Appeals Process (CMS–4004–FC)	0938–AL67	Final Rule Stage
63	Revisions to the Appeals Process for Initial Claim Determinations (CMS–4064–F)	0938–AM73	Final Rule Stage

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
64	Treble Damages for Failure To Engage in Loss Mitigation (FR–4553)	2501–AC66	Proposed Rule Stage
65	The Secretary of HUD's Regulation of Fannie Mae and Freddie Mac (FR–4790)	2501–AC92	Proposed Rule Stage
66	American Dream Downpayment Initiative (FR–4832)	2501–AC93	Final Rule Stage
67	Disposition of HUD-Owned Single Family Assets in Asset Control Areas (FR–4471)	2502–AH40	Proposed Rule Stage
68	Revisions to FHA Credit Watch Termination Initiative (FR–4625)	2502–AH60	Final Rule Stage
69	Lender Accountability for Appraisals (FR–4722)	2502–AH78	Final Rule Stage
70	Community Development Block Grant Program Revision of CDBG Eligibility and National Objective Regulations (FR–4699)	2506–AC12	Proposed Rule Stage
71	Capital Fund Program (FR–4880)	2577–AC50	Proposed Rule Stage

DEPARTMENT OF THE INTERIOR

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
72	Endangered Species and Pesticide Regulation	1018–AI95	Proposed Rule Stage
73	Snowmobile Regulations for Yellowstone and Grand Teton National Parks and JDR Parkway	1024–AD11	Final Rule Stage
74	Relief or Reduction in Royalty Rates—Deep Gas Provisions	1010–AD01	Final Rule Stage

DEPARTMENT OF JUSTICE

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
75	Nondiscrimination on the Basis of Disability in Public Accommodations and Commercial Facilities	1190–AA44	Proposed Rule Stage
76	Nondiscrimination on the Basis of Disability in State and Local Government Services	1190–AA46	Proposed Rule Stage

DEPARTMENT OF LABOR

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
77	Family and Medical Leave Act of 1993	1215–AB35	Proposed Rule Stage
78	Child Labor Regulations, Orders, and Statements of Interpretation (ESA/W–H)	1215–AA09	Final Rule Stage
79	Defining and Delimiting the Term ''Any Employee Employed in a Bona Fide Executive, Administrative, or Professional Capacity'' (ESA/W–H)	1215–AA14	Final Rule Stage
80	Trade Adjustment Assistance for Workers	1205–AB32	Proposed Rule Stage
81	Labor Certification Process for the Permanent Employment of Aliens in the United States	1205–AA66	Final Rule Stage
82	Senior Community Service Employment Program	1205–AB28	Final Rule Stage
83	Rulemaking Relating to Termination of Abandoned Individual Account Plans	1210–AA97	Proposed Rule Stage
84	Regulations Implementing the Health Care Access, Portability, and Renewability Provisions of the Health Insurance Portability and Accountability Act of 1996	1210–AA54	Final Rule Stage
85	Rulemaking Relating to Notice Requirements for Continuation of Health Care Coverage	1210–AA60	Final Rule Stage
86	Prohibiting Discrimination Against Participants and Beneficiaries Based on Health Status	1210–AA77	Final Rule Stage
87	Asbestos Exposure Limit	1219–AB24	Proposed Rule Stage
88	Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners	1219–AB29	Final Rule Stage
89	Occupational Exposure to Hexavalent Chromium (Preventing Occupational Illness: Chromium)	1218–AB45	Prerule Stage
90	Occupational Exposure to Crystalline Silica	1218–AB70	Prerule Stage
91	Assigned Protection Factors: Amendments to the Final Rule on Respiratory Protection	1218–AA05	Final Rule Stage
92	Fire Protection in Shipyard Employment (Part 1915, Subpart P) (Shipyards: Fire Safety)	1218–AB51	Final Rule Stage
93	Standards Improvement (Miscellaneous Changes) for General Industry, Marine Terminals, and Construction Standards (Phase II)	1218–AB81	Final Rule Stage
94	Uniformed Services Employment and Reemployment Rights Act Regulations	1293–AA09	Proposed Rule Stage

DEPARTMENT OF TRANSPORTATION

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
95	Computer Reservations System Regulations Comprehensive Review	2105–AC65	Final Rule Stage
96	Flight Simulation Device Qualification	2120–AH07	Final Rule Stage
97	Reforming the Automobile Fuel Economy Standards Program	2127–AJ17	Prerule Stage
98	Side Impact Protection Upgrade—Standard 214	2127–AJ10	Proposed Rule Stage

DEPARTMENT OF THE TREASURY

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
99	Revision of Brewery Regulations and Issuance of Regulations for Taverns on Brewery Premises (Brewpubs)	1513–AA02	Proposed Rule Stage

DEPARTMENT OF VETERANS AFFAIRS

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

ENVIRONMENTAL PROTECTION AGENCY

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
101	Endocrine Disruptor Screening Program; Priority Setting Criteria	2070–AD59	Prerule Stage
102	Electric Utility Steam Generating Unit MACT Regulation	2060–AJ65	Proposed Rule Stage
103	Implementation Rule for PM–2.5 NAAQS	2060–AK74	Proposed Rule Stage
104	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Allowables Plantwide Applicability Limit (PAL), Aggregation, and Debottlenecking	2060–AL75	Proposed Rule Stage
105	Lead-Based Paint Activities; Training and Certification for Renovation and Remodeling	2070–AC83	Proposed Rule Stage
106	Pesticides; Emergency Exemption Process Revisions	2070–AD36	Proposed Rule Stage
107	Acceptability of Research Using Human Subjects	2070–AD57	Proposed Rule Stage
108	Endocrine Disrupter Screening Program; Implementing the Screening and Testing Phase	2070–AD61	Proposed Rule Stage
109	NESHAPS: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors	2050–AE01	Proposed Rule Stage
110	Standards for the Management of Coal Combustion Wastes Generated by Commercial Electric Power Producers	2050–AE81	Proposed Rule Stage
111	Increase Metals Reclamation From F006 Waste Streams	2050–AE97	Proposed Rule Stage
112	Standards and Practices for Conducting ''All Appropriate Inquiry''	2050–AF04	Proposed Rule Stage
113	Regulatory Amendments to the F019 Hazardous Waste Listing To Exclude the Wastewater Treatment Sludges From the Chemical Conversion Coating Process (Zinc Phosphating) of Automobile Bodies of Aluminum	2050–AG15	Proposed Rule Stage
114	Watershed Rule: Total Maximum Daily Load (TMDL) Program Revisions	2040–AD82	Proposed Rule Stage
115	NESHAP: Plywood and Composite Wood Products	2060–AG52	Final Rule Stage
116	NESHAP: Reciprocating Internal Combustion Engine	2060–AG63	Final Rule Stage
117	NESHAP: Industrial, Commercial, and Institutional Boilers and Process Heaters	2060–AG69	Final Rule Stage
118	NESHAP: Surface Coating of Automobiles and Light-Duty Trucks	2060–AG99	Final Rule Stage
119	Implementation Rule for 8-hour Ozone NAAQS	2060–AJ99	Final Rule Stage
120	Control of Emissions of Air Pollution From Nonroad Diesel Engines and Fuel	2060–AK27	Final Rule Stage
121	Hazardous Waste Manifest Regulation	2050–AE21	Final Rule Stage
122	Management of Cement Kiln Dust (CKD)	2050–AE34	Final Rule Stage
123	Standardized Permit for RCRA Hazardous Waste Management Facilities	2050–AE44	Final Rule Stage
124	Office of Solid Waste Burden Reduction Initiative	2050–AE50	Final Rule Stage
125	Recycling of Cathode Ray Tubes (CRTs) and Mercury-Containing Equipment: Changes to Hazardous Waste Regulations	2050–AE52	Final Rule Stage
126	National Primary Drinking Water Regulations: Groundwater Rule	2040–AA97	Final Rule Stage
127	National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule	2040–AD37	Final Rule Stage
128	National Primary Drinking Water Regulations: Stage 2 Disinfection Byproducts Rule	2040–AD38	Final Rule Stage
129	Effluent Guidelines and Standards for the Construction and Development Industry	2040–AD42	Final Rule Stage
130	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 Stage

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

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

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
132	Federal Records Management	3095–AB16	Prerule Stage

PENSION BENEFIT GUARANTY CORPORATION

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

RAILROAD RETIREMENT BOARD

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
134	Electronic Filing of Applications and Claims for Benefits Under the Railroad Unemployment Insurance Act	3220–AB57	Proposed Rule Stage
135	Application for Annuity or Lump Sum	3220–AB55	Final Rule Stage

SMALL BUSINESS ADMINISTRATION

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
136	Small Business Lending Companies Regulations	3245–AE14	Proposed Rule Stage
137	Small Business Size Standards; Restructuring of Size Standards	3245–AF11	Proposed Rule Stage

SOCIAL SECURITY ADMINISTRATION

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
138	Privacy and Disclosure of Official Records and Information (711P)	0960–AE88	Proposed Rule Stage
139	Federal Salary Offset (Withholding a Portion of a Federal Employee's Salary To Collect a Delinquent Debt Owed to the Social Security Administration) (721P)	0960–AE89	Proposed Rule Stage
140	Representative Payment Under Titles II, VIII, and XVI of the Social Security Act (949F)	0960–AF83	Proposed Rule Stage
141	Elimination of Clothing From the Definitions of Income and In-Kind Support and Maintenance, Exclusions of One Automobile, and Household Goods and Personal Effects Under SSI From Resources (950P)	0960–AF84	Proposed Rule Stage
142	Evidence Requirement for Assignment of Social Security Numbers (SSNs); Assignment of SSNs to Foreign Students (960P)	0960–AF87	Proposed Rule Stage

SOCIAL SECURITY ADMINISTRATION (Continued)

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
143	Amendments to the Ticket to Work and Self-Sufficiency Program (967P)	0960–AF89	Proposed Rule Stage
144	Elimination of Parent-to-Child Deeming for Individuals Who No Longer Meet the Definition of Spouse of the Natural or Adoptive Parent (793P)	0960–AF96	Proposed Rule Stage
145	Administrative Wage Garnishment (To Repay a Debt Owed to the Social Security Administration) (724F)	0960–AE92	Final Rule Stage
146	OASDI and SSI; Administrative Review Process; Video Teleconferencing Appearances Before Administrative Law Judges of the Social Security Administration (737F)	0960–AE97	Final Rule Stage
147	Revised Medical Criteria for Evaluating Impairments of the Digestive System (800F)	0960–AF28	Final Rule Stage
148	Continuation of Benefit Payment to Certain Individuals Who Are Participating in a Program of Vocational Rehabilitation Services, Employment Services, or Other Support Services (925F)	0960–AF86	Final Rule Stage
149	Administrative Review Process; Incorporation by Reference of Oral Findings of Fact and Rationale in Wholly Favorable Written Decisions (964I)	0960–AF92	Final Rule Stage

NATIONAL INDIAN GAMING COMMISSION

Sequence Number	Title	Regulation Identification Number	Rulemaking Stage
150	Technical Standards for Game Classifications, Gaming Machines, and Gaming Systems	3141–AA29	Proposed Rule Stage

DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

In 2004, USDA plans to issue a variety of regulations that address a wide range of agricultural issues. Our principle focus will be the continued implementation of the Farm Security and Rural Investment Act of 2002 (Farm Bill) as farmers, ranchers, and other USDA customers participate in new and existing Federal farm programs. While the Farm Bill and other future legislative initiatives are implemented, the Department is working to reduce the regulatory burden on program participants by focusing as much as possible on outcome-based regulation through implementing more efficient and simplified information collections and continuing to migrate to efficient electronic services and capabilities. Important areas of activity include the following:

- 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.
- The Department will continue to develop regulations that support alternative markets for agricultural products and activities, such as biobased products and bioenergy processes.

Reducing Paperwork Burden on Customers

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. To meet the requirements of the Government Paperwork Elimination Act (GPEA), agencies across the Department are providing electronic alternatives to their traditionally paper-based customer transactions. The Farm Service Agency, Natural Resources Conservation Service, Rural Development, and Risk Management Agency continue supporting the objectives of the Freedom to E-File Act through their efforts to comply with GPEA. [Freedom to E-File directed the agencies, to the maximum extent practicable, to modify forms into user-friendly formats with user instructions and to permit those forms to be downloaded and submitted via facsimile, mail, or similar means.] As a result, producers should have the option to electronically file forms and all other documentation. Complimentary to the activities to comply with GPEA, the Department is implementing an electronic authentication capability that allows customers to ''sign-on'' once and conduct business with all USDA agencies. Underlying these efforts will be analyses to identify and eliminate redundant data collections and streamline collection instructions. The end result of implementing these initiatives 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. The 2002 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

Nine agencies are represented in this regulatory plan. 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 Forest Service, the Natural Resources Conservation Service, the Rural Housing Service, and the Rural Business-Cooperative Service. This document represents summary information on prospective significant regulations as called for in Executive Order 12866. A brief comment on each of the eight agencies 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, assist owners and operators of farms and ranches to conserve and enhance soil, water, and related natural resources, provide credit to new or disadvantaged farmers and ranchers, and help farm operations recover from the effects of disaster, as prescribed by various statutes.

Priorities: FSA's priority for 2004 will be to continue implementing the 2002 Farm Bill, the Farm Security and Rural Investment Act of 2002. The 2002 Farm Bill governs Federal farm programs for 2003 through 2007. Among its major provisions, it provides 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 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 new programs required complete revision of the existing program regulations. 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, 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 associations.

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 the majority of the forms used by farm program and farm loan program customer groups. Most 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 in 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' 2004 regulatory plan supports the broad goals and objectives in the Agency's strategic plan that include:

Improved nutrition of children and low-income people. This goal represents FNS' efforts to improve nutrition by providing access to program benefits (Food Stamps, WIC food packages, commodities, and State administrative funds), nutrition education, and quality meals and other benefits. It includes three major objectives: 1) improved food security, which reflects nutrition assistance benefits issued to program participants; 2) healthy food choices among FNS program participants, which represents our efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion, and to support healthy eating and physical activity to address the epidemic of overweight and obesity; and 3) improved nutritional quality of meals, food packages, commodities, and other program benefits, which represents our efforts to ensure that program benefits meet the appropriate nutrition standards to effectively improve nutrition for program participants.

In support of this goal, FNS plans to publish proposed rules and develop final rules implementing provisions of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171), as well as under other authorities, that will give States additional new flexibility to streamline complex rules, simplify program administration, support work, and improve access to benefits. This includes provisions to restore food stamp eligibility to legal immigrants who have lived in this country for at least 5 years, as well as immigrant children and disabled, without a waiting period, and other changes that will reduce reporting burden on working families. The Agency also plans to issue an advance notice of proposed rulemaking addressing possible changes to the food packages provided in WIC.

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 trafficking and Food Stamp and WIC participant, vendor, and administrative fraud; and 2) improved efficiency of program administration, which represents our efforts to streamline program operations and improve program structures as necessary to maximize their effectiveness.

In support of this goal, FNS plans to publish proposed rules and develop final rules implementing provisions of Public Law 107–171 that give States substantial new flexibility to streamline some of the Food Stamp Program's complex rules, making it easier to administer, less error-prone, and more accessible to those eligible for its benefits. Another pair of rules implementing this law will offer most States relief from costly sanctions 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 an implementing rule, making changes in Child and Adult Care Food Program (CACFP) rules 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 wholesome, not adulterated, and properly marked, labeled, and packaged.

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

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

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

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

FSIS intends to propose regulations to prohibit for use as human food certain materials from cattle. Scientific studies have demonstrated that such materials from cattle presenting clinical signs of bovine spongiform encephalopathy (BSE) contain the agent that causes the disease. To date, no cases of BSE have been found in the United States cattle herd. However, the USDA response to BSE has been proactive and preventive. In this proposed rule, FSIS seeks to mitigate a foreseeable risk.

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

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

In addition, FSIS is planning to propose requirements for federally inspected egg product plants to develop and implement HACCP systems and sanitation standard operating procedures. The Agency will be proposing pathogen reduction performance standards for egg products. Further, the Agency will be proposing to remove requirements for approval by FSIS of egg-product plant drawings, specifications, and equipment prior to use, and to end the system for pre-marketing approval of labeling for egg products.

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

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

Post-September 11, 2001, initiatives: FSIS has not proposed new regulations in response to the September 11, 2001, events. In 2001, however, FSIS issued non-regulatory security guidelines for food plants within the Agency's jurisdiction, and in August this year, the Agency issued similar guidelines for the transportation and distribution of meat, poultry, and egg products.

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

Animal and Plant Health Inspection Service

Mission: The 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 strengthen the protection provided to plant resources. Planned initiatives include revisions to the regulations for the introduction of organisms and products altered or produced through genetic engineering to

reflect new consolidated authorities under the Plant Protection Act and revisions to the regulations for the importation of nursery stock (plants, roots, seeds, bulbs, and other propagative materials) to reduce the pest risk posed by imported propagative material.

The Agency is proceeding with plans to amend the regulations for the importation of unmanufactured wood by adopting an international standard for treatment of solid wood packing material.

In recognizing the need to minimize impediments to trade while providing necessary protection to plant resources, APHIS is developing a proposal to streamline the process for approving new fruits and vegetables for importation.

APHIS has regulatory initiatives to ensure that a comprehensive framework is in place to address the threats posed to animal resources. These include initiatives to ensure the adequate 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, as well as several initiatives related to the group of neurological diseases known as transmissible spongiform encephalopathies, including scrapie (a disease of sheep and goats), bovine spongiform encephalopathy (BSE, which affects cattle), and chronic wasting disease (a disease of deer and elk). BSE-related projects include rulemaking to address the relatively low risks posed by certain imports from countries such as Canada, where BSE has been detected but where effective measures have been in place to prevent its spread through the animal and human food chain. Also, following receipt of comments on an advance notice of proposed rulemaking published earlier this year, APHIS, in coordination with the Department's Food Safety and Inspection Service, is considering various options for addressing the disease risks that may be presented by the disposal of nonambulatory animals and dead stock should BSE be introduced into the United States.

APHIS is also continuing to work with the Centers for Disease Control and Prevention to implement and amend, as necessary, regulations for the possession, use, and transfer of biological agents and toxins that could pose a severe disease or pest risk to animals and plants or their products.

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

Agricultural Marketing Service

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

Priorities: (1) On October 27, 2003, AMS published a proposed rule in the Federal Register to amend the Livestock Mandatory Reporting regulations to modify the requirements for the submission of information on domestic and imported boxed lamb cuts sales. This action would amend the definition of ''carlot-based'' by adding language to limit carlot-based sales of boxed lamb cuts to transactions between a buyer and a seller consisting of 1,000 pounds or more of one or more individually boxed lamb items and amend the definition of ''importer'' by reducing the volume level of annual lamb imports establishing a person as an importer from 5,000 metric tons of lamb meat products per year to 2,500 metric tons. These amendments would improve AMS' ability to publish meaningful market information on sales of imported and domestic lamb cuts.

(2) As mandated by the 2002 Farm Bill, AMS is establishing a mandatory country of origin program for beef, lamb, pork, fish, perishable agricultural commodities, and peanuts. Under current Federal laws and regulations, country of origin labeling is not universally required for these commodities. In particular, labeling of U.S. origin is not mandatory, and labeling of imported products at the consumer level is required only in certain circumstances. Thus, consumers desiring to purchase products based on country of origin are not fully able to do so. A proposed rule was developed based on interim voluntary guidelines also required by the 2002 Farm Bill that were issued on October 8, 2002, and related input from listening sessions held throughout the country during 2003. The proposed rule was published in the Federal Register on October 30, 2003.

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

(4) Under the 2002 Farm Bill, the Federal Agriculture Improvement and Reform Act (1996 Farm Bill) was amended to exempt any person that produces and markets solely 100 percent organic products from paying assessments under a commodity promotion law. The 1996 Farm Bill governs all research and promotion programs and certain marketing order programs. AMS plans to issue two proposed rules to implement this requirement. Currently, there are 16 existing national research and promotion programs and 28 marketing order programs that contain market promotion provisions.

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

Forest Service

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

Priorities:The Forest Service's priority for fall 2003 is to publish final regulations at 36 CFR part 219, subpart A, to establish a framework for National

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

Natural Resources Conservation Service

Mission: As a part of USDA Natural Resources Conservation Service (NRCS) works to improve natural resources conditions on working lands. NRCS helps farmers, ranchers, and operators by providing technical and financial assistance for adopting conservation practices on their lands.

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

Rural Housing Service

Mission: As a 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.

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.

The new regulation was published in the **Federal Register** as a proposed rule on June 2, 2003. We received 2,965 comments from 136 respondents. The Agency is now reviewing those comments and preparing the Final Rule Document for an estimated publication date of June 30, 2004.

Rural Business-Cooperative Service

Mission: The mission of the Rural Business-Cooperative Service is to enhance the quality of life for rural Americans by providing leadership in building competitive businesses including sustainable cooperatives that can prosper in the global marketplace.

We meet these goals by:

Investing financial resources and providing technical assistance to businesses and cooperatives located in rural communities; and

Establishing strategic alliances and partnerships that leverage public, private, and cooperative resources to create jobs and stimulate rural economic activity.

Priorities: The key regulatory priority for the fall 2003 regulatory plan is the RBS Renewable Energy Systems and Energy Efficiency Improvements Proposed Rule.

Renewable Energy Systems and Energy Efficiency Improvements.

This proposed rule resulted from section 9006 of the Farm Security and Rural Investment Act of 2002 (Act), which requires that the Secretary establish a program to ''make loans, loan guarantees, and grants to farmers, ranchers, and rural small businesses to purchase renewable energy systems and make energy efficiency improvements.'' The Act directs that, in funding such projects, USDA direct and guaranteed loans and grant financing is not to exceed 50 percent of the cost of the activity and grant-only funding is not to exceed 25 percent of the cost of the activity.

Since this is a new program, guidelines need to be established concerning the nature of the program and the delivery model to be used, so that a full set of implementation policies can be developed. The Office of General Counsel has mandated that regulations must be in place to operate the program. The proposed rule will establish regulations to implement the direct and guaranteed loan and grant program. These regulations will allow for the integration of all program authorities and permit full attention to all of the potential contingencies and issues.

USDA—Agricultural Marketing Service (AMS)

PRERULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 6501 through 6522

CFR Citation:

7 CFR 205

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

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

Anticipated Cost and Benefits:

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

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

Risks:

None.

Timetable:

Action	Date	FR Cite
ANPRM	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State, Tribal

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USDA—AMS

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 4501 et seq

CFR Citation:

7 CFR 1150

Legal Deadline:

Final, Statutory, August 2002, Final.

Abstract:

The 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 Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), which amended the Dairy Promotion and Research Program. 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 program assessments collected. It is estimated that the fees will be approximately $60,000 monthly after start-up. The annual assessment collected will be approximately $9.5 million.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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USDA—AMS

FINAL RULE STAGE

3. 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 to 1636(h)) as an amendment to the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.). The Act gives USDA 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	10/27/03	68 FR 61141
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

State

Federalism:

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

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USDA—AMS

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

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

7 USC 1621 through 1627, Agricultural Marketing Act of 1946

CFR Citation:

7 CFR 60

Legal Deadline:

Final, Statutory, September 30, 2004, Final.

Abstract:

The Agricultural Marketing Services (AMS) issued a proposed rule on October 30, 2003, to implement a mandatory country of origin labeling program for covered commodities as mandated by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171). The Farm Security and Rural Investment Act amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin labeling program not later than September 30, 2004. Covered commodities include muscle cuts of beef (including veal), lamb, and pork; ground beef, ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities (fresh and frozen fruits and vegetables); and peanuts.

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

Various methods are being considered by which the objectives of this law could be accomplished. The proposed rule specifically invites comment on several alternatives including alternative definitions for ''processed food item,'' alternative labeling of mixed origin, and alternatives to using ''slaughtered'' on the label. The proposed rule provides for a 60–day comment period which closes on December 29, 2003. In formulating the final mandatory regulations, the Agency will analyze all of the public comments that were received and will give due consideration to any alternatives brought forth by the commenters.

Anticipated Cost and Benefits:

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

Risks:

AMS has not identified any risks at this time.

Timetable:

Action	Date	FR Cite
NPRM	10/30/03	68 FR 61944
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

State

Federalism:

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

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USDA—Animal and Plant Health Inspection Service (APHIS)

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8316

CFR Citation:

9 CFR 55; 9 CFR 81

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

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

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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USDA—APHIS

6. ● BOVINE SPONGIFORM ENCEPHALOPATHY: MINIMAL RISK REGIONS AND IMPORTATION OF COMMODITIES

Priority:

Other Significant

Legal Authority:

7 USC 450; 7 USC 1622; 7 USC 7701 to 7772; 7 USC 8301 to 8317; 21 USC 136 to 136a; 31 USC 9701; 42 USC 4331 to 4332

CFR Citation:

9 CFR 93 to 95

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine encephalopathy (BSE) into the United States via live ruminants and ruminant products and would add Canada to this category.

Statement of Need:

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent and is not known to exist in the United States. It appears that BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. The regulations in 9 CFR parts 93, 94, 95, and 96 have prohibited the importation of live ruminants and certain ruminant products and byproducts from two categories of regions: Those regions in which BSE is known to exist, and those regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Based on a review of the risk presented by regions in which a BSE-affected animal has been diagnosed, but in which precautionary measures have been taken that reduce the risk of BSE being introduced into the United States by imports from such regions, we are developing a rule that would recognize an additional category of regions—the BSE minimal—risk region. The rule would allow the importation of certain live ruminants and ruminant products and byproducts from minimal risk regions under certain conditions and would designate Canada as a minimal-risk region. This action is based on our assessment that the rule would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

Summary of Legal Basis:

The Animal Health Protection Act (7 U.S.C. 8301 to 8317) provides that regulation of animals and other articles

by the Secretary of Agriculture is necessary to prevent and eliminate burdens on interstate and foreign commerce; to effectively regulate interstate commerce and foreign commerce; and to protect the agriculture, environment, economy, and health and welfare of the people of the United States.

Alternatives:

Alternatives to this rulemaking would be to continue to prohibit certain ruminants and ruminant products from entering from Canada or to allow these commodities to enter under less restrictive conditions than are being considered. To continue to prohibit these imports from Canada, when feasible precautionary measures are available, would be contrary to trade policies called for in the World Trade Organization's ''Agreement on Sanitary and Phytosanitary Measures.'' On the other hand, importations without appropriate mitigation measures would subject the United States to an unacceptable risk of BSE introduction. APHIS is committed to ensuring that the ruminant populations of the United States are fully protected from the introduction of BSE and believes that this rule is a balanced, science-based response to the detection of BSE in Canada, given Canada's actions since detection of the disease and the rule's inclusion of appropriate risk mitigation requirements.

Anticipated Cost and Benefits:

On August 8, 2003, the Secretary announced that certain ruminant-derived products would be allowed to enter the United States from Canada under permit. Several of the items included in the announcement are also covered by this rulemaking. The most important one is boneless beef from cattle less than 30 months of age. APHIS has analyzed the potential effects of the importation of commodities covered by the rule, including ones, such as boneless beef, that could be imported under permit on or after August 8, 2003, by comparing U.S. markets with and without these imports from Canada. Slaughter cattle, feeder cattle, and beef would be the main commodities affected by reinstatement of the importation of ruminant and ruminant products from Canada. In the near term, the additional supplies would cause prices to fall. Percentage price declines indicated by the results of the analyses for slaughter, cattle, feeder cattle, and beef suggest that near-term effects on affected entities would not be significant. The price declines would be accompanied by an increase in the number of cattle slaughtered and a decrease in the number of slaughtered cattle supplied by U.S. entities. These changes translate into a positive net benefit in the near term. It is emphasized that the estimated effects would be near term, occurring during the first year or so following the reestablishment of imports. In the longer term, production and marketing adjustments by U.S. and Canadian firms, and those in other countries in response to changed market conditions, would create new price-quantity equilibriums. Also, if other countries do not accept the age restrictions and other precautionary measures as adequate safeguards, U.S. exports of those commodities could be affected.

Risks:

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of BSE into the United States, APHIS published an interim rule on May 29, 2003 (68 FR 31939–31940, Docket No. 03–058–1), effective retroactively to May 20, 2003, to add Canada to the list of regions where BSE exists. As a result of that action, the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada are prohibited or restricted. This rulemaking would relieve restrictions on the importation of ruminants and ruminant products and byproducts from Canada by establishing Canada as a BSE minimal-risk region based on an analysis of the conditions considered for such a designation and the information available regarding how Canada meets those conditions. The risk document, ''Risk Analysis: BSE Risk From Importation of Designated Ruminants and Ruminant Products From Canada Into the United States, September 5, 2003,'' also identifies the measures that APHIS believes are necessary to mitigate any BSE risk that specific commodities imported from Canada might present to the United States.

Timetable:

Action	Date	FR Cite
NPRM	11/04/03	68 FR 62386
NPRM Comment Period End	01/05/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal

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USDA—APHIS

FINAL RULE STAGE

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

Priority:

Other Significant

Legal Authority:

7 USC 8301 to 8317

CFR Citation:

9 CFR 53

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

as well as the payment of an indemnity to those persons who suffer loss of property as a result of foot-and-mouth disease.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

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

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, State

Additional Information:

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

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RIN: 0579–AB34

USDA–APHIS

8. AGRICULTURAL BIOTERRORISM PROTECTION ACT OF 2002; POSSESSION, USE, AND TRANSFER OF 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, a 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, as well as regulations concerning the possession, use, and transfer of listed biological agents and toxins.

Statement of Need:

Section 212 of the Public Health Security and Bioterrorism Response Act of 2002 (Pub. L. 107–188) requires the Secretary of Agriculture to establish regulations for the possession, use, and transfer of biological agents and toxins that she determines have the potential to pose a severe threat to animal or plant health or to animal or plant products. Among other things, the Act requires the regulations to require registration with the Secretary and include appropriate safeguard and security measures, including database checks by the Attorney General of individuals and facilities seeking to register with the Secretary.

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 to 204) and the Department of Agriculture (subtitle B, sections 211 to 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.

Anticipated Cost and Benefits:

While the costs associated with this rule could be considerable, some of those impacts are somewhat offset by previous requirements, funding from other sources for upgrades that would otherwise be mandated by this rule, and flexibility in the rules that allow for site-specific needs to be met in the most cost-effective manner possible. In addition, these costs are greatly outweighed by the benefits of preventing a deliberate introduction of a listed agent or toxin into the United States. Should any listed agent or toxin be intentionally introduced, the consequences would be significant as is demonstrated by natural outbreaks that have occurred. Consequences could include costs of eradiation efforts, disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. Deliberate introduction greatly increases the probability of an agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life.

Risks:

The regulations include 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	12/13/02	67 FR 76908
Second Interim Final Rule Comment Period End	02/11/03	
Second Interim Final Rule Effective	02/11/03	
Third Interim Final Rule; Provisional Registration	11/03/03	68 FR 62218
Third Interim Final Rule Effective	11/03/03	
Third Interim Final Rule Comment Period End	01/02/04	
Fourth Interim Final Rule; Amending Overlap Toxin Exclusion	12/00/03	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, State

Additional Information:

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

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USDA—Rural Housing Service (RHS)

FINAL RULE STAGE

9. MULTI–FAMILY HOUSING (MFH) REINVENTION

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. Funding for rehabilitation, preservation, and future new construction is being addressed through the budget process. To not publish the rule would substantially restrict RHS' ability to effectively administer the programs and cost the Agency significant credibility with the public and oversight organizations.

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.

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.

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.

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	06/02/03	68 FR 32872
NPRM Comment Period End	08/01/03	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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USDA—Food and Nutrition Service (FNS)

PRERULE STAGE

10. ● SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC): REVISIONS TO WIC FOOD PACKAGES

Priority:

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

Legal Authority:

42 USC 1786

CFR Citation:

7 CFR 246

Legal Deadline:

None

Abstract:

Through this Advance Notice of Proposed Rulemaking (ANPRM), the Department is seeking public comment on the nutritional needs of the diverse WIC population and how health and development outcomes could best be improved via revision of regulations governing the WIC food packages. The Department will use comments received through this ANPRM and science from the Institute of Medicine, Food and Nutrition Board to develop a Notice of Proposed Rulemaking. (03–002)

Statement of Need:

The WIC Program provides supplemental foods designed to provide specific nutrients shown by research to be lacking in the WIC population's diet. WIC food packages and nutrition education are the chief means by which WIC affects the dietary quality and habits of participants. WIC food packages were designed to supplement participants' diets with nutritionally dense foods that prevent iron-deficiency anemia; complement the eating patterns of pre-school children; and address the special nutrition requirements of pregnant and breastfeeding women. The WIC food packages were last revised in 1980. 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. In light of emerging nutrition-related health issues and the new research-based Dietary Reference Intakes through this Notice, the Department is soliciting public comments to determine if the food packages can and should be revised to meet the nutritional needs of participants more effectively. And if so, what specific changes should be made to the food packages and why. Public comment will inform decisions and bolster the scientific and programmatic integrity of any rule that is proposed as a result of this process.

Summary of Legal Basis:

Public Law 95–627, enacted in November 1976, defined supplemental foods as those foods containing nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding, and postpartum women, infants, and children, as prescribed by the Secretary of Agriculture. The program direction stipulated by that law remains in effect today (42 U.S.C. 1786(b)(14)). The law also directs the Secretary in section 17(f)(11) of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1786(f)(11)), to assure that, to the degree possible, the fat, sugar, and salt contents of WIC foods are appropriate. The law provides substantial latitude to the Department to prescribe by regulation the most appropriate supplemental foods. Historically, the Department has based its prescriptions of WIC foods on sound nutritional research and input from State and local agencies, the health and scientific communities, industry, and the general public. Current WIC food package regulations were published in 1980 (45 FR 74854, November 12, 1980) that are consistent with the direction provided in Public Law 95–627.

In recent years, the Department has received numerous requests from WIC State agencies and participants to modify the current food packages to permit greater substitution of foods or introduction of new foods. Requests for revisions to the WIC food packages have also been received from Congress and other organizations with interests in the welfare of WIC participants.

Specifically, Congress requested through appropriations report language for fiscal years 2001–2002 (H.R. 106–619, S.R. 106–288, H.R. 107–116, and S.R. 107–41) that the Department develop a WIC food package rule that includes fruits and vegetables and that allows for cultural accommodations.

Alternatives:

The September 15, 2003, ANPRM includes 11 questions seeking alternatives, information, and supporting rationale. In the rulemaking process, the Department wishes to respond to the congressional request, as well as requests from other interested entities within the WIC community (including the National Advisory Council on Maternal, Infant, and Fetal Nutrition; the National WIC Association; and the American Dietetic Association) by soliciting recommendations from the public for scientifically based revisions to the WIC food packages that do not significantly increase the cost to the program or change the supplemental nature of the program. The Department is dedicated to addressing the many implications of a comprehensive revision of WIC food packages, specifically: Cultural and ethnic food preferences; commercial availability, variety, and appeal of foods; versatility in food preparation; feasibility of apportionment into daily servings for an individual over a month's time; State and local agency flexibility to design the food prescription; administrative feasibility and manageability by the State and local agencies and vendors; and burden and incentive for participants, potential participants, and their families.

The Department has enlisted the Food and Nutrition Board to provide independent technical experts to review comments submitted in response to this Notice, as well as available science, and to develop recommendations on revising the WIC food packages for the Department's consideration. The Department will then use the results of this independent review to shape a proposed rulemaking containing specific modifications to the WIC food packages.

Anticipated Cost and Benefits:

No cost/benefit information is necessary for this ANPRM. A detailed regulatory impact analysis outlining the specific costs and benefits of each proposed change to the WIC food packages will be developed and issued along with the proposed rulemaking, including response to the comments on the ANPRM.

Risks:

By issuing the ANPRM, the Department is minimizing the risk of inadvertently omitting or misrepresenting issues that may be critical to the best possible revision of the WIC food packages. The ANPRM offers the public an opportunity to participate in the Department's promulgation of a proposed rulemaking to revise the WIC food packages. The public will have a subsequent opportunity to submit comments on such revisions when the proposed rule is published.

Timetable:

Action	Date	FR Cite
ANPRM	09/15/03	68 FR 53903
ANPRM Comment Period End	12/15/03	
NPRM	06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

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

URL For More Information:

www.fns.usda.gov/wic/whatsnew.htm

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USDA—FNS

PROPOSED RULE STAGE

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

Priority:

Other Significant

Legal Authority:

PL 101–624; PL 104–127

CFR Citation:

7 CFR 247

Legal Deadline:

None

Abstract:

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

Statement of Need:

This rule is necessary to amend regulatory provisions in 7 CFR part 247 to increase program accountability and flexibility for program operators and incorporate legislative provisions that have been implemented through program policy.

Summary of Legal Basis:

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

Alternatives:

No alternatives available.

Anticipated Cost and Benefits:

Changes in the proposed rule reduce the burden imposed on State and local

agencies while ensuring program accountability, and are generally insignificant to the costs or overall operations of the program.

Risks:

There are no risks involved with this proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	10/31/03	68 FR 62164
NPRM Comment Period End	12/30/03	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State, Tribal

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USDA—FNS

12. 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	01/00/04	
NPRM Comment Period End	03/00/04	
Final Action	05/00/05	
Final Action Effective	07/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

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USDA—FNS

13. FSP: HIGH PERFORMANCE BONUSES

Priority:

Other Significant

Legal Authority:

PL 107–171

CFR Citation:

7 CFR 272; 7 CFR 275

Legal Deadline:

None

Abstract:

This action will 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 implement the performance measures used to award high performance bonuses for fiscal years 2005 and beyond.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

Undetermined

Risks:

The law mandates that we publish the performance measures for the high

performance bonuses for FY 2005 and beyond. 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	12/00/03	
NPRM Comment Period End	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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USDA—FNS

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

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

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

CFR Citation:

7 CFR 273

Legal Deadline:

None

Abstract:

This 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 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 August 22, 1996)—effective October 1, 2002, (2) are under 18 regardless of date of entry (current law limits eligibility to children who were in the country on August 22, 1996)—effective October 1, 2003, and beyond, or (3) have lived in the U.S. for 5 years as a qualified alien beginning on date of entry—effective April 1, 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	11/00/03	
NPRM Comment Period End	12/00/03	

Action	Date	FR Cite
Final Action	12/00/04	
Final Action Effective	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

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USDA—FNS

15. 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	11/00/03	
NPRM Comment Period End	01/00/04	
Final Action	12/00/04	
Final Action Effective	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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USDA—FNS

16. SENIOR FARMERS' MARKET NUTRITION PROGRAM (SFMNP)

Priority:

Other Significant

Legal Authority:

PL 107–171, sec 4306

CFR Citation:

7 CFR 249

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

USDA considered a variety of alternatives when constructing the regulation for the SFMNP. Primarily, the proposed regulation is modeled after the WIC Farmers' Market Nutrition Program and the Senior Farmers' Market Nutrition Pilot Programs. Consistency lends to administrative ease among the State agencies, localities, and USDA, as well as provides continuity to beneficiaries and

farmers who have been operating the pilot programs since 2001. Nevertheless, USDA addressed seven specific alternatives: Type of grant structure, eligible grantees and recipients, the use of community-supported agriculture programs, provision of administrative funding, eligibility requirements, verification procedures, and benefit levels. Each of these alternatives is explored in detail in the preamble to the proposed rulemaking.

Anticipated Cost and Benefits:

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

Risks:

The proposed rule carries a 90-day comment period, during which interested parties may submit comments on any and all provisions contained in the rulemaking. Once the comment period has expired, all comments received will be carefully considered in the development of the final rule. Opportunities for training on and discussion of the SFMNP regulations (in both their proposed and final forms) will be offered to State agencies and other entities with a vested interest in the operation and administration of the SFMNP.

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	
NPRM Comment Period End	05/00/04	
Final Action	09/00/04	
Final Action Effective	10/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

URL For More Information:

www.fns.usda.gov

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USDA—FNS

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

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

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

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	
NPRM Comment Period Ends	05/00/04	
Final Action	12/00/04	
Final Action Effective	01/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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USDA—FNS

FINAL RULE STAGE

18. 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 miscategorized or incomplete income eligibility statements. In addition, audits and investigations conducted by the Office of Inspector General (OIG) have raised serious concerns regarding the adequacy of financial and administrative controls in CACFP. Based on its findings, OIG recommended changes to CACFP review requirements and management controls.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

Risks:

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

Timetable:

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

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Federalism:

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

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RIN: 0584–AC24

USDA—FNS

19. FOOD STAMP PROGRAM: VEHICLE AND MAXIMUM EXCESS SHELTER EXPENSE DEDUCTION PROVISIONS OF PUBLIC LAW 106–387

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 106–387

CFR Citation:

7 CFR 273.8; 7 CFR 273.9

Legal Deadline:

None

Abstract:

This proposed rule will (1) implement a revision of the Food Stamp Program's resource eligibility standards regarding vehicle ownership and (2) set the maximum excess shelter expense deduction for fiscal year 2001 and, for future years, index it to the Consumer Price Index. (01–006)

Statement of Need:

This rule is necessary to implement revisions to the Food Stamp Program's resource eligibility standards regarding vehicle ownership and maximum excess shelter expense deduction.

Summary of Legal Basis:

All provisions of this proposed rule are mandated by Public Law 106–387.

Alternatives:

The alternative would be not to revise current rules, which have been superseded by changes brought about by Public Law 106–387.

Anticipated Cost and Benefits:

Low-income households will benefit by claiming larger income deductions for shelter expenses, thereby obtaining higher food stamp benefits. The new vehicle ownership provisions will make more low-income households eligible for food stamps and make it easier for them to own a reliable vehicle. States will benefit by having more flexibility and simpler administrative options for determining the effect of vehicle ownership upon food stamp eligibility.

Risks:

Not implementing this proposed rule would ignore the mandates contained in Public Law 106–387.

Timetable:

Action	Date	FR Cite
NPRM	08/29/03	68 FR 51932
NPRM Comment Period End	10/28/03	
Final Action	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

URL For Public Comments:

www.fns.usda.gov/fsp/rules/regulations/default.htm

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USDA—FNS

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

Priority:

Other Significant

Legal Authority:

7 USC 2011 to 2032; PL 107–171

CFR Citation:

7 CFR 273; 7 CFR 275

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

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

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State

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RIN: 0584–AD31

USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

21. PERFORMANCE STANDARDS FOR BACON

Priority:

Other Significant

Legal Authority:

21 USC 601 et seq

CFR Citation:

9 CFR 424.22(b)

Legal Deadline:

None

Abstract:

FSIS is proposing to revise the regulatory provisions concerning the production and testing of pumped 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 to produce pumped bacon would be required to limit the presence of nitrosamines when the product is cooked.

Statement of Need:

FSIS is proposing to replace restrictive provisions concerning the processing of pumped 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 to 695), a meat or meat food product is adulterated ''if it bears or contains any poisonous or deleterious substance that may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health'' (21 U.S.C. 601(m)(1)). Volatile nitrosamines are deleterious because they are carcinogenic, and though not added directly to pumped 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 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 currently address nitrosamines as hazards reasonably likely to occur may incur some costs. Also, establishments that choose to test their products for nitrosamines after this rule becomes effective may incur some costs. Because this rule provides establishments the flexibility to develop new procedures for producing bacon, this rule may result in profits to processors who develop cheaper means of producing product or who develop a pumped bacon product with wide consumer appeal.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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USDA—FSIS

22. 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 to 1056). It is not the result of any specific mandate by the Congress or a Federal court.

Alternatives:

A team of FSIS economists and food technologists is conducting a cost-benefit analysis to evaluate the potential economic impacts of several alternatives on the public, 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 enteritis 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	06/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, State

Federalism:

Undetermined

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USDA—FSIS

23. ELIMINATION OF CHILLING TIME AND TEMPERATURE REQUIREMENTS FOR READY-TO-COOK POULTRY

Priority:

Other Significant

Legal Authority:

21 USC 451 to 470

CFR Citation:

9 CFR 381.66

Legal Deadline:

None

Abstract:

FSIS is proposing 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 to 470).

Alternatives:

FSIS evaluated five regulatory alternatives: (1) Taking no regulatory action; (2) replacing the command-and-control requirements with a performance standard; (3) requiring meatpackers, as well as poultry processors, to comply with such a performance standard; (4) requiring all establishments that prepare raw meat or poultry products or handle, transport, or receive the products in transportation to comply with a performance standard; or (5) removing the command-and-control requirements from the poultry products inspection regulations. The Agency chose the 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	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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USDA—FSIS

24. 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, neurological 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 to 695), FSIS issues regulations governing the production of meat and meat food products. The regulations, along with FSIS inspection programs, are designed to ensure that meat food products are safe, not adulterated, and properly marked, labeled, and packaged.

Alternatives:

As an alternative to the 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	09/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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RIN: 0583–AC88

USDA—FSIS

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

Priority:

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

Legal Authority:

21 USC 601 to 695

CFR Citation:

9 CFR 301.2; 9 CFR 318.24 (Revision); 9 CFR 3

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 1994. 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 to 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

databases 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	12/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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RIN: 0583–AD00

USDA–FSIS

FINAL RULE STAGE

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

Statement of Need:

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

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

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

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

with lower levels of contamination resulting from improved in-plant process verification and sanitation.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	02/27/01	66 FR 12590
NPRM Comment Period End	05/29/01	
NPRM Comment Period Extended	07/03/01	66 FR 35112
NPRM Comment Period End	09/10/01	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

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USDA—FSIS

27. 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 will require nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase. FSIS will also require nutrition information on the label of ground or chopped meat and poultry products. The requirements for ground or chopped products will be consistent with those for multi-ingredient products.

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

Statement of Need:

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

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

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

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

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

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/18/01	66 FR 4970
NPRM Comment Period End	04/18/01	
Extension of Comment Period	04/20/01	66 FR 20213
NPRM Comment Period End	07/17/01	
Interim Final Rule	12/00/03	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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USDA—Forest Service (FS)

FINAL RULE STAGE

28. NATIONAL FOREST SYSTEM LAND MANAGEMENT PLANNING

Priority:

Other Significant

Legal Authority:

16 USC et seq; 5 USC 301

CFR Citation:

36 CFR 219, subpart A

Legal Deadline:

None

Abstract:

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

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits focused on key activities in land and resource management planning for which costs could be estimated under the 1982, 2000, and final planning rules. Based on costs that can be quantified, this final rule is estimated to save an average of $9.8 million annually, compared to the expected costs under the 1982 rule, and about $36 million per year compared to the 2000 rule. The discounted value of the cost savings over the 15-year planning horizon is estimated to be $92 million for the final rule when compared to the 1982 rule and approximately $324 million when compared to the 2000 rule.

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	12/06/02	67 FR 72770
NPRM Comment Period End	03/24/03	
Final Action	11/00/03	
Final Action Effective	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—Rural Business-Cooperative Service (RBS)

PROPOSED RULE STAGE

29. ● NATIONAL SECURITY EMERGENCY

Priority:

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

Legal Authority:

7 USC 1963

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The Rural Business-Cooperative Service (RBS) proposes to streamline procedures for loans and grants for existing business and industry direct and guarantee loan programs. This rulemaking will also establish emergency regulations for the community facilities program currently administered within the Rural Housing Service (RHS).

We are concurrently undertaking to prepare draft emergency legislation to expand both the nature of authorized financial assistance and the eligible applicant pool to assure maximum flexibility on the part of the Secretary in helping to alleviate the economic distress in rural areas when a national security emergency is declared. In the event this standby legislation is enacted, the scope of this rulemaking will be modified accordingly.

The proposed rule will include the following changes to current procedures for existing programs:

—The proposed rule will provide that the Agency may waive credit requirements that would otherwise apply to processing direct loans and guarantees.

—The proposed rule will provide that the Agency may substitute a ''best efforts'' test in allowing substitutions for application requirements. For example, if credit history documentation has been destroyed or is not available, an affidavit from a creditor familiar with the borrower's payment history prior to the emergency might suffice.

—We anticipate that environmental review requirements will be streamlined—most notably in the areas of public notice and comment periods.

—We will substitute ''to the best of my knowledge'' certifications for firm documentation requirements where reasonable and appropriate.

—We will provide exceptions to the requirements of the Paperwork Reduction Act that allow flexibility to USDA in the form and nature of information collections allowed under emergency conditions.

Statement of Need:

Executive Order 12656 directs the Secretary of Agriculture to develop plans to provide for the continuation of agricultural production, food processing, storage, and distribution through the wholesale level in national security emergencies and to provide for the domestic distribution of seed, feed, fertilizer, and farm equipment to agricultural producers.

In section 14(a) of USDA Departmental Regulation 1800–1 (Departmental Emergency Programs Responsibilities), the Secretary provides that RBS will, in cooperation with other government agencies at all levels: Promote economic development in affected rural areas by developing strategies that respond to the conditions created by an emergency; provide financial aid for needed community facilities; and provide business development assistance.

Absent supplemental legislation, if an emergency occurs, the financial resources that RBS will be able to deploy (expedited or not) will be a function of remaining appropriation levels across a spectrum of stove-piped program authorizations—where the types of assistance, eligible borrowers and eligible purposes must all be administered in accordance with different requirements. The best an emergency regulation can do under those circumstances is provide for expedited deployment of these remaining financial resources.

The intent and expectation is that the rulemaking will ultimately reflect supplemental legislation that accords maximum discretion to the Secretary in alleviating the capital needs of businesses in rural areas created by the emergency.

Summary of Legal Basis:

Section 323 of the Consolidated Farm and Rural Development Act [9 U.S.C. 1963] (Con Act) provides for direct or insured emergency loans for any purpose already authorized under subtitles A or B of the Con Act.

Alternatives:

In the case of a national security emergency, without this rulemaking, RBS would strive to execute the current programs within the then remaining appropriation levels as expeditiously as possible.

As discussed above, we expect to pursue standby legislation that will provide authorization for both grant and loan authority, a broad spectrum of eligible purposes and applicants, and include appropriations as well. This standby legislation would be effective as and when a national security emergency were declared and pertain only to the geographic areas affected.

Anticipated Cost and Benefits:

Absent standby emergency legislation that augments existing program budget authority, there is no incremental budget impact presented by this rulemaking. This regulation will only be effective upon the declaration of a National Security Emergency as contemplated by Executive Order 12656.

The streamlining of some processing requirements will facilitate faster deployment of RBS program funds, and in the case of RHS, the remaining available appropriations for essential community facilities.

Risks:

The greatest risk associated with streamlined processing and waivers of credit evaluation criteria is that of nonperforming loans resulting from this

emergency regulation that otherwise would not have been made in the first place. The historic experience of RBS in the case of several natural disasters, however, is that the loan portfolios made under challenging conditions have actually out-performed the rest of the portfolio. It is not possible to know how future emergency loan performance will compare with the rest of the loan portfolio exposure.

Timetable:

Action	Date	FR Cite
NPRM	11/00/03	
NPRM Comment Period End	01/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—RBS

30. ● RENEWABLE ENERGY SYSTEMS AND ENERGY EFFICIENCY IMPROVEMENTS

Priority:

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

Legal Authority:

7 USC 8106

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

Section 9006 of the Farm Bill directs the implementation of a direct and guaranteed loan and grant program for renewable energy systems and energy efficiency improvements for farmers, ranchers, and rural small businesses. For fiscal year (FY) 2003, a Notice of Funds Availability was published on April 8 for the grant program.

The proposed rule will establish regulations to implement the direct and guaranteed loan and grant program. These regulations will allow for the integration of all program authorities and permit full attention to all of the potential contingencies and issues.

Statement of Need:

Section 9006 of the Farm Security and Rural Investment Act of 2002 (Act) requires that the Secretary establish a program to ''make loans, loan guarantees, and grants to farmers, ranchers, and rural small businesses to purchase renewable energy systems and make energy efficiency improvements. The Act directs that in funding such projects, USDA direct and guaranteed loans and grant financing is not to exceed 50 percent of the cost of the activity, and grant-only funding is not to exceed 25 percent of the cost of the activity. For 5 years, beginning in FY 2003, the Commodity Credit Corporation is to provide $23 million in budget authority annually for these purposes. Since this is a new program, guidelines need to be established concerning the nature of the program and the delivery model to be used, so that a full set of implementation policies can be developed. The Office of General Counsel has mandated that regulations must be in place to operate the program.

Summary of Legal Basis:

The Act mandates that assistance under section 9006 of the Act begin in FY 2003, with funds from the Commodity Credit Corporation, and continue for 5 fiscal years.

Alternatives:

None.

Anticipated Cost and Benefits:

The proposed action will have no financial impact on the public or the Government. However, it will have a positive impact for farmers, ranchers, and rural small businesses; improve the delivery of USDA's energy-oriented assistance; and be in the best interest of the Government and public.

Risks:

The only risk is, if the regulation is not done, fiscal year 2004 funding would be lost.

Timetable:

Action	Date	FR Cite
NPRM	11/00/03	
NPRM Comment Period End	01/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

None

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USDA—Natural Resources Conservation Service (NRCS)

PROPOSED RULE STAGE

31. CONSERVATION SECURITY PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

16 USC 3838

CFR Citation:

7 CFR 1470

Legal Deadline:

None

Abstract:

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

Statement of Need:

USDA intends that CSP will recognize those farmers and ranchers, the land stewards, who meet the highest

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

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

Summary of Legal Basis:

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

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

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

Alternatives:

NRCS Preferred Approach:

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

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

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

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

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

Alternative Approaches:

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

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

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

4. Limit the number of tiers of participation offered.

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

Anticipated Cost and Benefits:

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

The model calculates the overall CSP payment by calculating several payment components individually, and then by summing the results of: The base payment, cost-sharing for installation of new structural practices and adoption of new land management practices, cost-sharing for maintenance of existing structural and land management practices, and enhancement payments. The Net Present Value (NPV) of each payment is determined by a payment rate per acre, the number of acres to which the payment applies, contract years in which the payment is made (i.e., whether the payment is made on a one-time or annual basis), discounted to the present using a 7 percent annual discount rate. Payments for structural and land management practices were calculated using a methodology similar to that used for the Environmental Quality Incentives Program (EQIP) Benefit/Cost Analysis, Final Report, May 29, 2003.

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Federalism:

Undetermined

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BILLING CODE 3410–90–S

DEPARTMENT OF COMMERCE (DOC)

Statement of Regulatory and Deregulatory Priorities

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

Build for the future and promote U.S. economic competitiveness in the global marketplace by strengthening and safeguarding the Nation's economic infrastructure;

Keep America competitive with cutting-edge science and technology and an unrivaled information base; and

Provide effective management and stewardship of our Nation's resources and assets to ensure sustainable economic opportunities.

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

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

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

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

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

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

The Department has taken steps to ensure that all of the President's priorities, particularly those that concern small business, are implemented. On August 13, 2002, the President issued Executive Order 13272, which directs the Department to take appropriate account of the potential impact on small businesses, small governmental jurisdictions, and small organizations during the rulemaking process. In accordance with the Executive order, the Department published guidelines that establish procedures and policies to promote compliance with the Executive order and the Regulatory Flexibility Act. This guidance ensures that the Department properly considers the impact of its rules on small entities prior to implementation.

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

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

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

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

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

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

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

Responding to the Administration's Regulatory Philosophy and Principles

The vast majority of the Department's programs and activities do not involve regulation. Of the Department's 12

primary operating units, only two—the Bureau of Industry and Security (BIS) and the National Oceanic and Atmospheric Administration (NOAA)—plan significant preregulatory or regulatory actions for this Regulatory Plan year. Of all the significant actions planned by the Department, NOAA plans to complete an action, entitled Amendment 13 to the Northeast Multispecies Fishery Management Plan (FMP), which rises to the level of ''most important'' of the Department's ''significant regulatory actions''. Further information on this action is provided below.

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

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

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

National Oceanic and Atmospheric Administration

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

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

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

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

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

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

Magnuson-Stevens Act Rulemakings

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

rulemaking is triggered by an FMC, the Magnuson-Stevens Act places stringent deadlines upon NMFS by which it must exercise its rulemaking responsibilities.

While most of these rulemakings will be minor, involving only the opening or closing of a fishery under an existing FMP, one action concerning the Northeastern Multispecies Fishery Management Plan is of particular significance and we designate it as one of the ''most important'' of the Department's ''significant regulatory actions''. In this action NMFS plans to amend its regulations to implement provisions of Amendment 13 to the Northeast (NE) Multispecies Fishery Management Plan (FMP). The principal objectives of Amendment 13 include measures to implement a formal rebuilding program for overfished stocks and to end overfishing on those stocks where it is occurring and to bring the FMP into full compliance with the Magnuson-Stevens Act. In addition, this rule would implement provisions that respond to the requirements of the Court Orders in the lawsuits of *Conservation Law Foundation, et al. v. Donald Evans, et al. (CLF v. Evans)*and *American Oceans Campaign, et al. v. William M. Daley, et al. (AOC v. Daley).* Additional information concerning this rule is found below.

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

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

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

Bureau of Industry and Security

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

Major Programs and Activities

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

BIS is also responsible for:

Enforcing the export control and antiboycott provisions of the Export Administration Act (EAA), as well as other statutes such as the Fastener Quality Act. The EAA is enforced through a variety of administrative, civil, and criminal sanctions.

Analyzing and protecting the defense industrial and technology base, pursuant to the Defense Production Act and other laws. As the Defense Department increases its reliance on dual-use high technology goods as part of its cost-cutting efforts, ensuring that we remain competitive in those sectors and subsectors is critical to our national security.

Helping Ukraine, Kazakstan, Belarus, Russia, and other newly emerging countries develop effective export control systems. The effectiveness of U.S. export controls can be severely undercut if ''rogue states'' or terrorists gain access to sensitive goods and technology from other supplier countries.

Working with former defense plants in the Newly Independent States to help make a successful transition to profitable and peaceful civilian endeavors. This involves helping remove unnecessary obstacles to trade and investment and identifying opportunities for joint ventures with U.S. companies.

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

DOC—National Oceanic and Atmospheric Administration (NOAA)

PROPOSED RULE STAGE

32. AMENDMENT 13 TO THE NORTHEAST MULTISPECIES FISHERY MANAGEMENT PLAN (FMP)

Priority:

Economically Significant

Legal Authority:

16 USC 1801 et seq

CFR Citation:

50 CFR 648

Legal Deadline:

Final, Judicial, May 1, 2004, Final.

Final, Statutory, Final.

Abstract:

This action would amend the FMP to address the Magnuson-Stevens Act requirement to implement a stock rebuilding program for all of the regulated multispecies. Management measures may include a days-at-sea reduction, gear reductions, and area management.

Statement of Need:

On December 28, 2001, a decision was rendered by the U.S. District Court for the District of Columbia on a lawsuit brought by the Conservation Law Foundation (CLF), Center for Marine Conservation, National Audubon Society and Natural Resources Defense Council against NMFS (CLF v. Evans, Case No. 00CVO1134, (D.D.C., December 28, 2001)). The lawsuit alleged that Framework Adjustment 33 to the FMP violated the overfishing, rebuilding, and bycatch provisions of the Magnuson-Stevens Act (16 U.S.C 1801, et seq.) as amended by the Sustainable Fisheries Act (SFA). The court granted plaintiffs' motion for summary judgment on all counts, but did not impose a remedy. Instead, the court asked the parties to the lawsuit to propose remedies consistent with the court's findings. Shortly thereafter, several additional parties were allowed to intervene in the lawsuit for purposes of proposing the appropriate remedy. These parties (intervenors) included the States of Maine, New Hampshire, Massachusetts, and Rhode Island, and three industry groups. Additional background on the lawsuit is contained in the preambles to the interim rules published by NMFS on April 29, 2002 (67 FR 21140), May 6, 2002 (67 FR 30331), and June 5, 2002 (67 FR 38608), and in the proposed interim rule published July 1, 2002 (67 FR 44139).

From April 5–9, 2002, plaintiffs, defendants and intervenors engaged in court-sponsored mediation to try to agree upon mutually acceptable short-term and long-term solutions to present to the court as an appropriate remedy. Although these discussions ended with no agreement, several of the parties continued mediation and filed a settlement agreement with the court on April 16, 2002. In addition to NMFS, the parties signing the agreement include CLF, which is one of the plaintiff conservation groups, all four state intervenors, and two of three industry intervenors.

In order to ensure the implementation of protective management measures by May 1, 2002, NMFS, notwithstanding that the court had then not yet issued its remedial order, filed an interim final rule with the Office of the Federal Register on April 25, 2002, for publication on April 29, 2002. The interim final rule that was published on April 29, 2002, implemented measures identical to the short-term measures contained in the settlement agreement filed with the court.

On April 26, 2002, the court issued a remedial order that ordered the promulgation of two specific sets of management measures—one to be effective from May 1, 2002, to July 31, 2002, and the other from August 1, 2002, until promulgation of Amendment 13 to the FMP. The court-ordered measures for the first set of measures were, in the majority, identical with those contained in the settlement agreement and the measures contained in NMFS' April 29, 2002, interim final rule. However, the court-ordered measures included additional provisions and an accelerated schedule of effectiveness for all measures, which were not contained in either the settlement agreement or the April 29, 2002, interim final rule. According to the court, these additional provisions were included to strengthen the settlement agreement provisions ''in terms of reducing overfishing and minimizing bycatch without risking the lives of fishers or endangering the future of their communities and their way of life.'' Remedial order, p. 13. Further, the court ordered that NMFS publish in the Federal Register, as quickly as possible, an ''amended interim rule and an amended second interim rule'' that would ''include the departures from the Settlement Agreement incorporated in the Remedial Order.'' To comply with the court order, NMFS published a second interim final rule (amended interim rule) to modify the measures implemented through the April 29, 2002, interim final rule and to accelerate the effectiveness of the gear restrictions, as required by the remedial order. Because the court's remedial order was not entirely consistent with the terms of the settlement agreement, NMFS, CLF, and the intervenors filed motions for reconsideration with the court requesting that the court implement the terms of the settlement agreement without change.

On May 23, 2002, the court issued an order, in the case of CLF v. Evans, granting the motions for reconsideration on the basis that ''the important changes made by the Court in the complex and carefully crafted Settlement Agreement Among Certain Parties . . . would produce unintended consequences.'' The court ordered that the settlement agreement be implemented according to its terms; that the Secretary of Commerce (Secretary) publish an interim rule, effective no later than June 1, 2002, to reduce overfishing in the first quarter of the 2002–2003 fishing year; that the Secretary publish another interim rule to be effective no later than August 1, 2002, to reduce overfishing beginning with the second quarter of the 2002–2003 fishing year, and continuing until implementation of Amendment 13 to the FMP, which complies with the overfishing, rebuilding, and bycatch provisions of the SFA; and that, no later than August 22, 2003, the Secretary promulgate such an amendment to the FMP. The court further ordered that the Secretary shall make public the most current scientific information to enable completion of the FMP Amendment no later than December 1, 2002, provide at least 5 percent observer coverage, and inform the court of the steps taken to comply with the order no later than September 5, 2002. The order relating to observer coverage differs from the settlement agreement in that it requires a minimal level of 5 percent at first and 10 percent by May 1, 2003, unless it can be established by scientific information that an increase is not necessary. NMFS implemented a program to provide at least 5 percent observer coverage in the multispecies fishery for the period August 1, 2002, to April 30, 2003, and thereafter, at a level of at least 5 percent depending on statistical need.

In response to the May 23, 2002, court order, on May 31, 2002, NMFS filed

an interim final rule with the Federal Register on June 5, 2002 (67 FR 38608) that implemented regulations for the June 1 through July 31, 2002, period, consistent with the settlement agreement. On July 1, 2002, NMFS published a proposed interim rule (67 FR 44139) for measures ordered by the court to be effective August 1, 2002; public comments were accepted through July 16, 2002. The interim final rule published August 1, 2002 (67 FR 50292) implemented management measures for the period August 1, 2002, through the implementation of Amendment 13, in accordance with the settlement agreement and the remedial order. Amendment 13, which will bring the FMP into full compliance with the SFA, is under development by NMFS and the New England Fishery Management Council (Council) and was intended to be implemented by August 22, 2003. The interim final rule is an interim action necessary to reduce overfishing consistent with and pursuant to section 305(c) of the Magnuson-Stevens Act while Amendment 13 is being developed. Under the provisions of section 305(c)(3) of the Magnuson-Stevens Act, interim measures shall remain in effect for not more than 180 days after the date of publication, and may be extended by publication in the Federal Register for one additional period of not more than 180 days, provided that the public has had an opportunity to comment on the interim measures. On January 22, 2003, NMFS published a notice of continuation of these regulations (68 FR 2919) announcing the continuation of the management measures to reduce overfishing through July 27, 2003. NMFS and two of the plaintiffs filed a motion with the court requesting an extension of the August 22, 2003, implementation schedule until May 1, 2004. The court granted an extension of the court—ordered timeline for Amendment implementation until May 1, 2004. On April 24, 2003, NMFS published a proposed emergency action (68 FR 20097) requesting comments on measures to ensure that the regulations governing the Northeast Multispecies Fishery continued to be in compliance with the court's order. On June 27, 2003, NMFS published a final emergency rule (68 FR 38234) continuing most of the measures contained in the settlement agreement ordered by the court. This emergency action is necessary to ensure that there exist measures to reduce overfishing until implementation of Amendment 13.

Summary of Legal Basis:

The regulations implementing measures contained in the Northeast Multispecies FMP are governed by the Magnuson-Stevens Act. The Magnuson-Stevens Act mandates that action be taken if the size of a fish stock declines below a specified level or if the annual harvest rate is too high. Although the numbers of fish of many of the 15 groundfish species (20 stocks) have increased substantially in recent years and harvest rates have gradually declined, for many stocks the rate of increase must be accelerated to comply with the law, and for other stocks the harvest rate must be reduced. As a result of the CLF v. Evans, a Federal judge ruled that the Northeast Multispecies FMP does not comply with the Magnuson-Stevens Act and ordered that Amendment 13 measures must bring the FMP into compliance with the Magnuson-Stevens Act. In addition to this lawsuit, Amendment 13 includes alternatives to address the court—ordered remedy in the case of AOC v. Daley. In this case the Court ruled that elements of the amendment adopted to comply with the essential fish habitat provisions of the Magnuson-Stevens Act were not in compliance with the National Environmental Policy Act. Therefore, Amendment 13 will bring the Northeast Multispecies FMP into compliance with the Magnuson-Stevens Act and respond to the requirements of the court orders in the lawsuits of CLF v. Evans and AOC v. Daley.

Alternatives:

The principal objectives of Amendment 13 include rebuilding overfished stocks, ending overfishing, reducing unused effort in the fishery, addressing administrative issues, maintaining flexibility in the fishery, reducing bycatch, and minimizing the impact of the fishery on fish habitat and protected species such as whales and turtles. There are three major categories of impacts considered for each measure—biological, economic, and social impacts. The impacts on bycatch, habitat, and enforcement are also considered. The public has opportunities to provide comments on the proposed alternatives under consideration. On August 29, 2003, the Notice of Availability (NOA) for the draft supplemental environmental impact statement was published in the Federal Register. This document provides an analysis of alternatives under consideration in Amendment 13. This document also contains a preliminary regulatory economic evaluation of the alternatives. The comment period on this document closes on October 15, 2003. The public will also be provided with an opportunity to provide comments during formal Secretarial review of Amendment 13. An NOA for the Amendment and the proposed rule will be published in the Federal Register with comment periods specific to each. The Secretary will approve, disapprove, or partially approve the Amendment within 30 days of the close of the comment period on the NOA. A final rule implementing any approved portions of the Amendment will be published in the Federal Register.

Anticipated Cost and Benefits:

The Magnuson-Stevens Act is designed to realize the full potential of the fishery resources over the long term for the benefit of the Nation and the fishing industry. The process of achieving this goal can, and does, have serious impacts on fishermen and dependent communities. NMFS and the Council are fully aware of potential impacts from proposed management measures and work to ensure not only the long-term sustainability of groundfish resources, but also the economic vitality of New England fishing communities. There are likely short-term costs to the New England fishing industry in order to obtain long-term benefits to all users of the groundfish resource.

Timetable:

Action	Date	FR Cite
NPRM	01/00/04	
NPRM Comment Period End	02/00/04	
Final Action	04/00/04	
Final Action Effective	05/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, State

Additional Information:

The National Marine Fisheries Service (NMFS) amends its regulations to implement provisions of Amendment 13 to the Northeast (NE) Multispecies Fishery Management Plan (FMP). The principal objectives of Amendment 13 include measures to implement a formal rebuilding program for overfished stocks and to end overfishing on those stocks where it is occurring and to bring the FMP into full compliance with the Magnuson-Stevens Fishery Conservation and

Management Act (Magnuson-Stevens Act). In addition, this rule implements provisions that respond to the requirements of the Court Orders in the lawsuits of Conservation Law Foundation et al. v. Donald Evans et al. (CLF v. Evans) and American Oceans Campaign, et al. v. William M. Daley, et al. (AOC v. Daley).

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RIN: 0648–AN17
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, 2003, 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 worldwide communications capabilities that are available on the Internet. Realizing that increased public participation in the rulemaking process improves the quality and acceptability of regulations, DoD is committed to exploring the use of information technology (IT) in rule development and implementation. IT provides the public with easier and more meaningful access to the processing of regulations. Furthermore, the Department endeavors to increase the use of automation in the Notice and Comment rulemaking process in an effort to reduce time pressures and increase public access in the regulatory process. Notable progress has been made in the Defense acquisition regulations area toward achieving the Administration's E-government initiative of making it simpler for citizens to receive high-quality service from the Federal Government, inform citizens, and allow access to the development of rules.

Performance-Based Regulations

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

Outreach Initiatives

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

The Department is actively engaged in addressing the requirements of the Government Paperwork Elimination Act (GPEA) in implementing electronic government and in achieving IT accessibility for individuals with disabilities. This is consistent with the Administration's strategy of advancing E-government as expressed in ''The President's Management Agenda.''

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 2002-D026, Procurements for Defense Against or Recovery From Terrorism or Nuclear, Biological, Chemical, or Radiological Attack, implements sections 852 through 856 of the Homeland Security Act of 2002. Sections 852 through 856 provide new authorities for acquisitions by or for an executive agency of property or services that are to be used to facilitate defense against or recovery from terrorism or nuclear, biological, chemical, or radiological attack. An interim rule was published in the **Federal Register** on January 27, 2003, as part of Federal Acquisition Circular (FAC 2001-012) (68 FR 4048).

DFARS Case 2002-D042, Contractor Performance of Security-Guard Functions, implements section 332 of the National Defense Authorization Act of Fiscal Year 2003. Section 332 provides temporary authority for contractor performance of security-guard functions to meet increased requirement since September 11, 2001.

An interim rule was published in the **Federal Register** on February 14, 2003 (68 FR 7443).

Suggestions From the Public for Reform'Status of DoD Items

In the report entitled ''Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities,'' there were two regulations and two guidance documents from the Army Corps of Engineers (Corps) that were nominated for reform.

Two commenters suggested that the Corps' nationwide permit program should be modified. One of these commenters stated that the nationwide permits make it easier to dredge and fill wetlands. This commenter also expressed concern that recently issued guidance on mitigation places too much discretion in the hands of local Corps personnel to determine mitigation requirements for activities authorized by Corps permits. This commenter said that the nationwide permits should be made more restrictive to ensure that they authorize only activities with minimal impacts. In contrast, the other commenter stated that the acreage limits for nationwide permits are too low, and require more project proponents to obtain individual permits, which results in construction delays. This commenter indicated that the acreage limits for the nationwide permits should be reevaluated and the nationwide permit program should be modified to minimize paperwork and prevent unnecessary delays at all levels of government.

The latest issuance of the nationwide permits was published in the January 15, 2002, issue of the **Federal Register** (67 FR 2020), and those nationwide permits expire on March 18, 2007. The nationwide permits are not classified as regulations. They are permits that authorize certain minor activities in waters of the United States that result in minimal adverse effects on the aquatic environment, individually and cumulatively. Although the nationwide permits are not regulations, the Corps coordinated the issuance 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 nationwide permits that were published on January 15, 2002, reflect the result of this interagency coordination.

The acreage limits for nationwide permits are established so that those permits can be used to authorize most activities that have minimal adverse effects on the environment. Every 5 years, the terms and conditions of the nationwide permits are subject to a public notice and comment process, to ensure that the nationwide permits authorize only those activities with minimal individual and cumulative adverse environmental effects. Mitigation may be required to ensure that authorized activities result in minimal adverse environmental effects. Mitigation requirements are determined by local Corps personnel to account for regional differences in aquatic resources.

One commenter recommended that the Corps and Environmental Protection Agency (EPA) revisit the revisions to the Clean Water Act regulatory definitions of ''fill material'' and ''discharge of fill material'' that were published on May 9, 2002 (67 FR 31129). This commenter said that an Environmental Impact Statement should be prepared to fully examine the implications of changing these regulatory definitions. This commenter also stated that a more thorough regulatory impact analysis should be conducted under E.O. 12866. The changes to the regulatory definitions of ''fill material'' and ''discharge of fill material'' that were published in the May 9, 2002, **Federal Register** resulted from the public notice and comment process required by the Administrative Procedures Act. The Corp does not agree that these changes require an Environmental Impact Statement, because the revised definitions will not significantly affect the quality of the human environment. The revised definitions provide consistency between the Corps' and EPA's regulations governing discharges of fill material into waters of the United States.

One of the guidance documents recommended for reform is the joint guidance issued by the Corps and EPA on January 19, 2001, concerning the U.S. Supreme Court decision in the Solid Waste Agency of Northern Cook County vs. U.S. Army Corps of Engineers, 531 U.S. 159 (2001) (SWANCC). The commenter stated this joint guidance inappropriately limits the U.S. Supreme Court's ruling in that case. In the January 15, 2003, issue of the **Federal Register**, the Corps and EPA issued an Advance Notice of Proposed Rulemaking (ANPRM) to obtain early comment on issues related to the scope of waters subject to Clean Water Act jurisdiction in light of the SWANCC decision by the U.S. Supreme Court. In appendix A of this ANPRM, there is a joint memorandum issued by the Corps and EPA that provides clarifying guidance regarding the U.S. Supreme Count's decision in SWANCC. This joint memorandum supercedes the January 19, 2001, guidance document cited by the commenter. The comments received in response to the ANPRM will be used to develop a proposed rule that addresses Clean Water Act jurisdiction in light of the SWANCC decision.

Other guidance documents recommended for reform relate to wetland delineation, especially the 1987 ''Corps of Engineers Wetlands Delineation Manual'' (1987 Manual). The 1987 Manual contains the procedures the Corps uses for identifying the boundaries of wetlands. One commenter stated that rulemaking procedures should be applied to the 1987 Manual, as well as the criteria used to identify jurisdictional wetlands and other waters of the United States. Another commenter indicated that wetland regulation has impeded real estate development. The Corps has begun an effort to update and clarify the 1987 Manual. This effort may also include the development of regional wetland delineation manuals. Any proposed changes to the 1987 Manual, or the issuance of regional wetland delineation manuals, will be subject to the public notice and comment procedures required by the Administrative Procedures Act.

Specific Priorities

For this regulatory plan, there are 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,'' addresses one significant regulatory action as defined by Executive Order 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) 2004, the U.S. Army Corps of Engineers is proposing to complete 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, in conjunction with the Environmental Protection Agency (EPA), may propose a new regulation to provide additional clarification to the regulatory definition of ''waters of the United States'' for the purposes of the Clean Water Act.

The U.S. Army Corps of Engineers was directed by Congress in section 601 of the Water Resources Development Act of 2000 (Pub. L. 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. On July 10, 2003, the Acting Secretary of the Army submitted the final programmatic regulations to OMB for final Administration review. OMB will vet the final programmatic regulations with appropriate Federal agencies and hold several interagency meetings before clearing the final regulations for publication in **Federal Register**. The final programmatic regulations require the concurrence of the Governor of Florida and the Secretary of the Interior and 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.

The Department of the Army and the Environmental Protection Agency completed one Advance Notice of Proposed Rulemaking (ANPRM) in 2003. In a notice published in the January 15, 2003, issue of the **Federal Register** (68 FR 1991) the Army and EPA requested early comment on issues associated with the scope of waters that are subject to the Clean Water Act, in light of the U.S. Supreme Court decision in Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers, 531 U.S. 159 (2001) (SWANCC). The ANPRM solicited information or data from the public, scientific community, and Federal and State resource agencies on the implications of the SWANCC decision on issues of regulatory jurisdiction under the Clean Water Act. In response to the ANPRM, approximately 150,000 comments were received. The Army and EPA are in the process of reviewing those comments to develop a Notice of Proposed Rulemaking that may be issued later this year.

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 (NHPA) 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. Forty-one comments were received in response to this notice. After completing its review of those comments, the Corps may propose, in fiscal year 2004, changes to 33 CFR part 325, appendix C, to bring the regulation into conformance with the new ACHP at 36 CFR part 800, or work with the ACHP to develop other Federal agency program alternatives, to comply with the requirements of the NHPA and other historic preservation laws.

Defense Procurement and Acquisition Policy

Defense Procurement and Acquisition Policy launched a major transformation initiative to identify dramatic improvements and reductions to procurement policies, procedures, and processes in the Defense Federal Acquisition Regulation Supplement (DFARS). The focus of the DFARS will be clear requirements/procedures of law, mandatory DoD-wide policy, deviations from the FAR, and delegations of authority. Procedures and guidance internal to DoD will be contained in a non-regulatory second book that is electronically linked to the DFARS. This approach can foster an environment of flexibility and innovation, supporting a more rapid and responsive change process. The DFARS Transformation Task Force recommended more than 700 noncomplex changes and approximately 83 significant proposals, including proposed changes to the Federal Acquisition Regulation (FAR) and legislative changes. We have opened more than 75 new DFARS cases to implement the noncomplex proposals and the ''first wave'' of DFARS proposals. Some of these proposals include:

- Implement a proposal to mark all Government property in the hands of a contractor with a unique item identifier and to establish a value for such property.
- Eliminate application of the Balance of Payments Program to DoD acquisition except as a reporting requirement.
- Standardize payment and billing instructions in the DFARS.
- Delete the requirement to conduct periodic risk assessments and production surveillance of contractors that do not have Government contracts with criticality designators A or B, unless specifically requested by the Contracting Officer.

In addition, the Department of Defense continuously reviews the FAR and continues to lead Government efforts to simplify the following acquisition processes:

- Consider FAR and DFARS changes to facilitate timely contract closeout.

- Require contractors to submit electronic representations and certifications via the Business Partner Network.
- Clarify labor standards for contracts involving construction.
- 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.
- 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 policy on the applicability of cost accounting standards. The goal of this initiative is to modify and streamline the applicability of Federal cost accounting standards.
- Revise the FAR part 45, Government Property, to organize and streamline the property disposal procedures and 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 in 2004.

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 be used to 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 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 was 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. The Department met with State and tribal representatives during preparation of the proposed rule published in August 2003. DoD plans to evaluate comments and publish a final rule in 2004.

DOD—U.S. Army Corps of Engineers (COE)

FINAL RULE STAGE

33. 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, Final.

Abstract:

The U.S. Army Corps of Engineers was directed by Congress in section 601 of the Water Resources Development Act of 2000 (Pub. L. 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	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

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BILLING CODE 5001–08–S

DEPARTMENT OF EDUCATION (ED)

Statement of Regulatory and Deregulatory Priorities

General

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

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 757,500 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 invite comments on all proposed regulations through the Internet.

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 will revise regulations to eliminate barriers that inhibit coordination across programs (such as by creating common definitions). This should help reduce the frequency of reports and eliminate unnecessary data requirements.

We have piloted two Internet-based software applications, e-Application and e-Reports. These enable applicants, grantees, and grant teams to file and process applications and 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 excellence. One-ED is 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, and will provide 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. Implementing 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.

No Child Left Behind

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

Each State, Puerto Rico, and the District of Columbia has submitted an accountability plan, and each plan was approved by the Department'a major milestone achieved in record time. Educators and parents across the country have embraced the principles of this law and are working hard to implement it in their communities.

The Department will now focus on helping States place a highly qualified teacher in every classroom; expanding the opportunities for qualified students to receive tutoring and other supplemental services; and identifying schools in need of improvement and making sure they are getting the assistance they need to get back on track.

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

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

PRERULE STAGE

34. REAUTHORIZATION OF THE INDIVIDUALS WITH DISABILITIES EDUCATION ACT

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

20 USC 1400 to 1487

CFR Citation:

34 CFR ch III

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

New legislation.

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
Notice	01/10/02	67 FR 1411
ANPRM	08/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

URL For Public Comments:

www.regulations.gov

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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

The Department's ongoing rulemaking activities related to energy efficiency standards and determinations have been categorized as high, medium, or low priority. 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**.

During the coming year, the Department expects to revise the energy efficiency standards for residential furnaces, boilers, and mobile home furnaces; electric distribution transformers; commercial unitary air conditioners and heat pumps rated 65-240 kBtu/hr; and for small duct high velocity residential air conditioning. Additional information and timetables for these high priority actions can be found below. In addition, the Department will continue working on the analyses required to revise the standards for packaged terminal air conditioners and heat pumps, oil- and gas-fired commercial packaged boilers, 3-phased air conditioners and heat pumps rated less than 65 kBtu/hr, single package vertical air conditioners and heat pumps, and tankless gas-fired instantaneous water heaters.

The Department plans to publish final rules concerning test procedures for clothes washers, 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 2003. In addition, the Department will be proposing in December 2003, to add a new part, 10 CFR 851, Worker Safety and Health, that would establish basic requirements to ensure workers are protected from safety and health hazards at DOE facilities.

DOE—Energy Efficiency and Renewable Energy (EE)

PRERULE STAGE

35. 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, Final.

Abstract:

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

This is the initial review of the statutory standards for 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:

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

Alternatives:

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

Anticipated Cost and Benefits:

The specific costs and benefits of 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 Btus of energy from 1993 to 2015, resulting in estimated consumer savings of $1.7 billion per year in 2000 and estimated annual emission reductions of 107 million tons of carbon dioxide and 280 thousand tons of nitrogen oxides in that year. Under the existing standards, the discounted energy savings for consumers are 2.5 times greater than the upfront price premium paid for the appliance.

Risks:

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

Timetable:

Action	Date	FR Cite
ANPRM	09/08/93	58 FR 47326
Framework Workshop	07/17/01	
Venting Workshop	05/08/02	
ANPRM	02/00/04	
NPRM	01/00/05	
Final Action	09/00/05	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local, State

Additional Information:

The Department published a notice in the Federal Register on July 8, 2003, to announce that its statement in the semiannual regulatory agenda, 68 FR 30192, 30195 (May 27, 2003), to reclassify the activity on Energy Efficiency Standards for Residential Furnaces, Boilers, and Mobile Home Furnaces to a low priority was inadvertent and that the Department remains committed to involving stakeholders per the Process Rule. The Department is currently completing its economic analyses for potential new standards and expects to publish an ANPRM for public review and comment by February 2004. This action is a high priority, and the Department is working actively on this action.

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DOE—EE

36. ENERGY EFFICIENCY STANDARDS FOR ELECTRIC DISTRIBUTION TRANSFORMERS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 6317

CFR Citation:

10 CFR 430

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Alternatives:

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

Anticipated Cost and Benefits:

The specific costs and benefits for 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 Btus

of energy from 1993 to 2015, resulting in estimated consumer savings of $1.7 billion per year in the year 2000 and estimated annual emission reductions of 107 million tons of carbon dioxide and 280 thousand tons of nitrogen oxides in the year 2000. Under the existing standards, the discounted energy savings for consumers are 2.5 times greater than the up-front price premium paid for the appliance.

Risks:

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

Timetable:

Action	Date	FR Cite
Determination Notice	10/22/97	62 FR 54809
ANPRM	11/00/03	
NPRM	11/00/04	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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DOE—EE

37. 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 certain types of major residential appliances and certain types of commercial equipment. EPCA requires DOE to amend the standards for products whenever ASHRAE amends its standards.

Statement of Need:

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 certain types of major residential appliances and certain types of commercial equipment and requires DOE to amend the standard for this product when ASHRAE amends its standards, as recently occurred.

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	11/00/03	
NPRM	11/00/04	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

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DOE—Departmental and Others (ENDEP)

PROPOSED RULE STAGE

38. WORKER SAFETY AND HEALTH

Priority:

Other Significant

Legal Authority:

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

CFR Citation:

10 CFR 851

Legal Deadline:

Final, Statutory, December 2, 2003, Final.

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

None

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	12/08/03	68 FR 68276
NPRM Comment Period End	02/06/04	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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DOE—ENDEP

FINAL RULE STAGE

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39. RADIATION PROTECTION OF THE PUBLIC AND THE ENVIRONMENT

Priority:

Other Significant

Legal Authority:

42 USC 2201; 42 USC 7191

CFR Citation:

10 CFR 834

Legal Deadline:

None

Abstract:

This action would add a new 10 CFR 834 to DOE's regulations establishing a body of rules setting forth the basic requirements for ensuring radiation protection of the public and environment in connection with DOE nuclear activities. These requirements stem from the Department's ongoing effort to strengthen the protection of health, safety, and the environment from the nuclear and chemical hazards posed by these DOE activities. Major elements of the proposal 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	09/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

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BILLING CODE 6450–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

The Department of Health and Human Services (HHS) 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 especially affect some of the Nation's most vulnerable populations, including children, the elderly, and persons with disabilities. And, in one way or another, HHS activities touch the lives of virtually every person in our country, citizens and noncitizens alike.

HHS's programs and activities include: Medicare, Medicaid, support for public health preparedness, 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 of every age, in every location, and in every walk of life.

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

Since the attacks of 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. In addition, consistent with the Secretary's priorities, the Department has taken important actions to enhance coordination of regulations across all its components.

FY 2004 Regulatory Themes

The Secretary has adopted four overarching regulatory themes for FY 2004:

- Improving the Nation's ability to prepare for and/or respond to public health emergencies and disasters;
- Reducing medical errors and enhancing patient safety;
- Modernizing Medicare, especially through issuing regulations emanating from Medicare-reform legislation, and
- Protecting America's consumers

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 Disasters

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

- Two final rules to improve readiness to respond to threats of food-safety bioterrorism, by ordering the detention of perishable food items, and by requiring the maintenance of certain food-handling records;
- A proposed rule to define a key term in the food-safety regulations so that FDA may move quickly and consistently in responding to a threatened or actual attack on the U.S. food supply;
- A proposed rule providing for an exception from the general requirement for informed consent in the use of investigational devices to identify chemical, biological, radiological or nuclear agents in a potential terrorist threat or other public health emergency; and
- A final rule for implementing a compensation program for individuals adversely affected by smallpox immunizations.

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 final rule requiring human drug products to have a scanable bar code that will reduce medication errors;
- 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; and
- A final rule to enhance and make more timely the safety reporting on drugs and biologics.

Modernizing Medicare

Medicare provides health care coverage for 41 million Americans. The Secretary is working with the Congress on legislation that will provide new options for America's seniors under Medicare. The provisions of the Medicare-reform legislation were still under discussion at the deadline for submissions to The Regulatory Plan, but issuing the regulations required under the legislation will be among the Secretary's top priorities.

The following regulatory actions, supported by already existing statutory authority, will also effect important improvements in Medicare:

- A final rule to expedite the Medicare coverage appeals;
- Two regulatory proposals to establish clearer performance standards under Medicare for organ procurement organizations, and a new mechanism for reapproval of organ transplant centers; and
- A proposed rule under which current requirements for Medicare reimbursement for services to persons with End Stage Renal Disease would be completely overhauled and simplified.

Protecting America's Consumers

Consumer health and safety is a major concern for the public and the Secretary. Consumers are inundated

each year with an availability of new products and ingredients. 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 final rule to standardize the manufacturing and packaging of dietary supplements; and
- A proposed rule to strengthen safety requirements for the storage and distribution of eggs.

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. Humphry Building, 200 Independence Avenue SW., Washington, DC 20201.

REGULATIONS BY THEME

1. Improving the Department's Ability to Respond to Emergencies and Disasters:

- Smallpox Injury Compensation Program
- Definition of ''Serious Adverse Health Consequences'' under the Public Health Security and Bioterroism Preparedness and Response Act of 2002
- Establishment and Maintenance of Food Product Records
- Administrative Detention of Food for Human or Animal Consumption
- Exception from General Requirements for Informed Consent

2. Reducing Medical Errors and Enhancing Patient Safety:

- Bar Code Label Requirements for Human Drug Products
- 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
- Safety Reporting on Drugs and Biologics

3. Modernizing Medicare

- Revisions to the Medicare Appeals Process
- End Stage Renal Disease Conditions for Coverage
- Prospective Payment System for Psychiatric Hospitals

4. Protecting America's Consumers:

- Manufacturing and Packaging of Dietary Supplements;
- Review of National Medicare Coverage Determinations
- Control of Salmonella Enteriditis in Shell Eggs

HHS—Office of the Secretary (OS)

PROPOSED RULE STAGE

40. ● HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

Priority:

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

Legal Authority:

Subtitle F of title II of PL 104–191; 42 USC 1320d–5

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This rulemaking would seek to establish a framework for enforcing compliance with the ''administrative simplification'' provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996—subtitle F of title II of Public Law 104–191 (42 U.S.C. 1320d–5).

Statement of Need:

The civil money penalty provisions of the above-cited statute provide, together with the criminal penalties authorized by 42 U.S.C. 1320d–6, the means by which the Federal Government may ensure compliance with the national standards adopted by the HHS Secretary under this statute. Regulation is needed to enable the Department to: 1) determine a basis for and amounts of civil money penalties that may be levied pursuant to the above-cited statute; and 2) establish procedures for the conduct of investigations and hearings with respect to the imposition of such penalties.

Summary of Legal Basis:

This regulation will implement provisions of 42 U.S.C. 1320d–5 and 42 U.S.C. 1320a–7a relating to the imposition of civil money penalties by the Secretary for violations of the rules adopted by the Secretary pursuant to subtitle F.

Alternatives:

The proposed procedural provisions of the rule would generally follow the civil money penalty procedures adopted by the Department's Office of the Inspector General (OIG) with respect to the conduct of investigation and hearings regarding the imposition of civil money penalties in cases of fraud and abuse. These procedures are codified at 45 C.F.R. parts 1003, 1005, and 1006. While the Department considered adopting different procedures, it decided not to do this for several reasons: the statutory language in section 1320d–5 specifically referring to the procedures adopted under section 1320a–7a (i.e., the OIG rules); the extensive experience of industry with the OIG rules; and the general agreement within the Department that the OIG rules provide workable procedures.

Anticipated Cost and Benefits:

The costs of this rule will consist primarily of the costs incurred by both the Department and any covered entities that are attributable to the investigation and hearing processes. These costs are expected to be minimal. Costs associated with compliance by entities subject to the HIPAA Administrative Simplification standards are not attributable to this rule.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—Substance Abuse and Mental Health Services Administration (SAMHSA)

PROPOSED RULE STAGE

41. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH

Priority:

Other Significant

Legal Authority:

PL 106–310

CFR Citation:

Not Yet Determined

Legal Deadline:

NPRM, Statutory, April 2001, NPRM.

Abstract:

The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Statement of Need:

In recent years, media, Government, and consumer reports of deaths and injuries occurring due to the use of seclusion and restraints have heightened concern about these mechanisms as interventions. The appropriate use of seclusion and restraint has been debated and regulated in various health care settings for many years. Researchers have examined the use of seclusion and restraint related injuries and deaths, and potential alternatives to address safety and care concerns while posing less inherent risk to the individual. Patient advocates, States and others have lobbied for reduced and more highly regulated use. States, health care facilities and professionals have examined mechanisms for reduction, and some have implemented training programs addressing alternatives as well as to promote applications that will minimize patient risk.

Summary of Legal Basis:

Sections 595 through 595B of the Public Health Service (PHS) Act (42 U.S.C. 290jj–290jj–2) as amended by the Children's Health (CHA) Act of 2000 (Pub. L. 106–310), section 3207, part I.

Alternatives:

No other regulatory alternatives were considered. The CHA requires the Secretary to promulgate regulations after consultation with appropriate State, local, public and private protection and advocacy organizations, health care professionals, social workers, facilities, and patients. Current regulations do exist, in some form, for hospitals and residential treatment facilities, while nursing homes and ICFs/MR use survey guidelines. The statutory language required that regulations be promulgated within one year of its enactment. This proposed rule is currently two years behind its mandated time of publication.

Anticipated Cost and Benefits:

The anticipated benefits include enhanced patient safety and better consumer protections. Increases in staff education and training are expected to lead to treatment alternatives and decreases in the use of seclusion and restraint as a means of intervention, which then leads to less traumatic experiences for both consumers and staff. The regulation creates a change in facility practices and policies on the use of seclusion and restraint. The regulation will create standard criteria for nonmedical community-based facilities for children and youth who receive PHS Act funds that will establish an industrywide effect on consumers who are receiving services within these facilities. The regulation creates consistent criteria for staff training and certification, facility staffing, and defining and reporting on seclusion and restraint.

The anticipated cost is based on regulations that will place requirements on all States as well as a projected estimate of 500 facilities. At this time, the extent of potential facilities is unattainable until the notice of proposed rulemaking is issued. It is estimated that the cost will be $7 million a year. The proposed rule will specifically solicit comments on actual staff training and reporting costs, and it is assumed this cost will decrease since a number of States and/or facilities have existing training and reporting requirements.

Risks:

The risk in implementing the regulation—

1. Increase in cost for States and facilities in staff training, however, most facilities that currently use seclusion and restraint have some general staff training requirements. The CHA will only expand the content of this training.

2. Increase possibility of States having their PHS funding status in jeopardy due to noncompliance with regulations. States and industry may raise concern that the CHA's enforcement aspect is too harsh.

3. Confusion regarding what facilities are covered or not by the regulations as well as different standards for similar facilities based if they are or are not recipients of PHS Act funding.

The risk in not implementing the regulation—

1. Continued unregulated seclusion and restraint in certain Federally funded facilities.

2. Continued incidence as well as under reporting of deaths as a result of seclusion and restraint, or deaths that occur within 24 hours after an individual has been secluded or restrained, or where it is reasonable to assume that the individual's death was caused by being placed in seclusion or restraints.

3. Barrage of continued concerns from advocacy groups, the media and the Congress to publish this regulation, as well as requests from facilities for guidance.

4. Lack of protection for special needs populations, such as children, adolescents, persons with mental illness, developmental disabilities, or co-occurring mental retardation who are disproportionately affected by the

usage of seclusion or restraints as a common form of intervention.

5. Lack of direction to organizations, advocacy groups, and more than 500 facilities for common definitions, industry language, and minimum criteria on staff training.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

State

Federalism:

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

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HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

42. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

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

CFR Citation:

21 CFR 16; 21 CFR 116; 21 CFR 118

Legal Deadline:

None

Abstract:

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

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

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

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

Statement of Need:

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

Summary of Legal Basis:

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

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

Any potential for contamination of eggs with SE and its subsequent survival or growth must be considered a very serious risk because of the possibility that such contamination, survival, and

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

43. 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 an amendment to the exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

Statement of Need:

The agency is proposing this action because it is concerned that, during a potential terrorism event or other public health emergency, delaying testing of specimens to obtain informed consent may threaten the life of the subjects or others who have been exposed to or who may be at risk of exposure to a chemical, biological, radiological, or nuclear agent.

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 the requirement of obtaining informed consent in life-threatening situations such as those considered here. Section 520(g)(3)(D) of the Act provides specifically for an exception from informed consent for investigational devices, subject to such conditions as the agency may prescribe. That section 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 the investigational 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 in writing with this three-part determination before the product is used 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. The investigator must submit the required documentation to the IRB within 5 days after the use of the device.

Alternatives:

The other option available to the agency is to work within the existing regulatory scheme. FDA believes that this option may result in delayed, improper or no diagnosis, and delayed, improper or no treatment for persons exposed to these agents because health professionals may not use these investigational products in a timely way or may not use them at all because of their inability to obtain informed consent.

Anticipated Cost and Benefits:

The minimal burdens imposed by this rule are offset by the fact that, in the absence of this rule, the investigator 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 or other public health emergency. 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 including receiving delayed treatment, 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	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HHS—FDA

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

Priority:

Other Significant

Legal Authority:

21 USC 355b

CFR Citation:

21 CFR 201; 21 CFR 208; 21 CFR 209

Legal Deadline:

Final, Statutory, January 4, 2003, Final.

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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HHS—FDA

45. • DEFINITION OF ''SERIOUS ADVERSE HEALTH CONSEQUENCES'' UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority:

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

Legal Authority:

21 USC 334(h)(1)(A); 21 USC 335a(b)(3); 21 USC 343(v); 21 USC 350c(a) and (b); 21 USC 371; 21 USC 374(a)(1); 21 USC 381(j)(1) and (m)(2)(B)(ii); 21 USC 398(a)

CFR Citation:

21 CFR 1.3(c)

Legal Deadline:

None

Abstract:

The proposed rule would define the term ''serious adverse health consequences'' for purposes of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and any implementing regulations and guidance. The term is used to describe the standard that is the basis for FDA to exercise certain authorities provided in sections 303, 304, 306, 307, 308, and 310 of title III (Protecting Safety and Security of the Food and Drug Supply), subtitle A (Protection of Food Supply), of the Bioterrorism Act.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law on June 12, 2002. The Bioterrorism Act contains the term ''serious adverse health consequences'' to describe the standard relating to exercising many of the new authorities provided therein. Together with the final rules implementing sections 303, 306, and 307 of the Bioterrorism Act, and the other sections of the Bioterrorism Act incorporating the ''serious adverse health consequences'' term, a definition of the term will further enable FDA to act quickly and consistently in responding to a threatened or actual terrorist attack on the U.S. food supply or to other food-related, public health emergencies. A definition of the ''serious adverse health consequences'' term will promote uniformity and consistency across FDA in understanding of the term and determining an appropriate response. In addition, a definition of the term will inform the public and stakeholders about what FDA considers to be a serious adverse health consequence under the Bioterrorism Act.

Summary of Legal Basis:

FDA is relying on section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) in issuing this proposed rule. FDA is also relying on the following sections of the Bioterrorism Act which the term ''serious adverse health consequences'' appears: Section 303(a) (21 U.S.C. 334(h)(1)(A)), Section 303(c) (21 U.S.C. 381(j)(1)), Section 304(a)(2)(C) (21 U.S.C. 335a(b)(3)), Section 306(a) (21 U.S.C. 350c(a) and (b)), Section 306(b) (21 U.S.C. 374(a)(1)), Section 307(a) (21 U.S.C. 381(m)(2)(B)(ii)), Section 308(b) (21 U.S.C. 343(v)), and Section 310 (21 U.S.C. 398(a)).

Alternatives:

In the interests of quickly providing the agency's interpretation of ''serious adverse health consequences'' to the public, FDA considered explaining the term in guidance. The agency concluded, however, that this option is neither effective nor efficient because guidance does not have the force and effect of law. If the definition or its application is ever challenged, guidance will receive less deference

than if the definition were in a regulation.

FDA also considered explaining the term in guidance followed by a regulation at a later date. This option was considered because it offers the advantage of rapidly informing the public about the agency's position while the agency gathers more information and experience in applying the definition. The agency concluded that guidance followed by a regulation was undesirable. First, as to the initial guidance, FDA would meet the same problems described above for the ''guidance only'' option. Second, this option creates a burdensome process for FDA by doubling the agency's responsibilities—first, to publish guidance, and second, to engage in notice and comment rulemaking. FDA resources will be conserved by avoiding this two-step process. Further, there is the possibility that once guidance publishes, a regulation might not follow. As a result, the definition might never have the force and effect of law.

FDA also considered defining or explaining ''serious adverse health consequences'' in preambles to rules promulgated under the Bioterrorism Act. However, implementing regulations are not required for all sections of the Bioterrorism Act that incorporate the term. Thus, the term would not be publicly addressed in the context of all of the applicable sections of the Bioterrorism Act. Second, because preambles are not codified and incorporated into the Code of Federal Regulations, the context and interpretation of the term eventually may become disassociated from the codified regulations. Finally, the rule ing of the Bioterrorism Act had already been published or were going to be published soon when this option was considered. Thus, there was insufficient time to include this discussion in the preambles to the current proposed rules for these sections.

FDA also considered adopting one of the two similar definitions for ''serious adverse health consequences'' or the definition for ''serious injury'' in the medical devices regulations to promote consistency within the agency and avoid confusion. (In the medical devices reporting regulations, the preamble to the final rule states that ''the agency intends for 'serious adverse health consequences' to have the same meaning as 'serious injury' under the [Medical Device Reporting] rule.'') This option could promote greater consistency within the agency, avoid confusion, and also save time. However, the agency believes that a broader definition must be used for foods and feeds in order to satisfy Congressional intent. Specifically, it must be clear that the definition of ''serious adverse health consequences,'' for purposes of the Bioterrorism Act, (1) expressly includes vulnerable populations, and (2) expressly apply to food for humans and animals. In addition, there are terms incorporating the concept of ''serious'' in CDER and CDRH regulations. The definitions of these terms are not entirely consistent because they are tailored to the needs of each Center and apply only to specific portions of the applicable regulations, i.e., they have specific uses and contexts. Thus, a specific definition for ''serious adverse health consequences'' under the Bioterrorism Act is necessary in order to avoid confusion among differing definitions of ''serious,'' ''serious injury,'' or ''serious adverse health consequences'' in other regulations, and the context in which these terms are defined and applied. The proposed definition would apply to: (1) all foods and feeds in bioterrorist events and other public health emergencies; and (2) all populations, vulnerable or healthy, effectively having very wide applicability in a wide variety of emergency situations. Finally, FDA considered leaving the term undefined, thereby providing maximum flexibility for determining what constitutes ''serious adverse health consequences'' on a case-by-case basis. By not defining, the agency could avoid the potential consequences of a definition that is either too broad or too narrow. However, leaving the term undefined could cause confusion and inconsistency in implementation. Moreover, if an agency action under the Act is challenged, an undefined term will be left to a court's interpretation. A court, however, is not the most appropriate or expert body to decide the meaning of ''serious adverse health consequences.''

Anticipated Cost and Benefits:

The impact of this proposed rule will depend on how FDA decides to define the term ''serious adverse health consequences,'' which is used as a standard for taking action under the administrative detention, record keeping, and prior notice provisions of the Bioterrorism Act. The broader the definition, the greater the cost and benefits associated with it. For example, if ''serious adverse health consequences'' were defined to include any case of foodborne illness, then foods would be administratively detained more often than if the definition were limited to cases resulting in death. A broader definition will mean the term is used more frequently in conjunction with the provisions of the Bioterrorism Act; and therefore, there will be more costs, but there will also be more benefits.

Risks:

Regulations implementing legislation to protect the health of citizens against bioterrorism and other public health emergencies 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. This proposed rule would support those regulations by defining a key term contained therein, thereby improving FDA's ability to act quickly and consistently in responding to a threatened or actual terrorist attack on the U.S. food supply or to other food-related, public health emergencies.

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AF06

HHS—FDA

46. • USE OF OZONE-DEPLETING SUBSTANCES: REMOVAL OF ESSENTIAL USE DESIGNATION; ALBUTEROL

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 402; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 343; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 42 USC 7671 et seq

CFR Citation:

21 CFR 2.125

Legal Deadline:

None

Abstract:

Under the Clean Air Act, the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services, in consultation with the Environmental Protection Agency, is required to determine whether an FDA-regulated product that releases an ozone-depleting substance (ODS) is essential. The two agencies have tentatively determined that the two currently marketed non-ODS metered-dose inhalers (MDIs) will be satisfactory alternatives to albuterol MDIs that contain ODS, and are proposing to remove the essential use designations for albuterol MDIs. If the essential use designation is removed, albuterol MDIs that contain an ODS could not be marketed after a suitable transition period. The proposed rule will specifically ask for comments on which phase-out period length will best ensure a smooth transition and minimize any adverse affects on the public health.

Statement of Need:

Chlorofluorocarbons (CFCs) are organic compounds that contain carbon, chlorine, and fluorine atoms. CFCs were first used commercially in the early 1930's and were later found to be useful as propellants in self-pressurized aerosol products, such as MDIs. CFCs are very stable in the troposphere—the lowest part of the atmosphere. They move to the stratosphere, a region that begins about 10–16 kilometers (km) (6–10 miles) above Earth's surface and extends up to about 50 km (31 miles) altitude. Within the stratosphere there is a zone about 15 to 40 km (10–25 miles) above the Earth's surfaces in which ozone is relatively highly concentrated. The zone in the stratosphere is generally called the ozone layer. Once in the stratosphere, CFCs are broken down by strong ultraviolet light, where they release chlorine atoms that then deplete stratospheric ozone. Depletion of stratospheric ozone by CFCs and other ODS will lead to higher UVB levels, which in turn will cause increased skin cancers and cataracts and potential damage to some marine organisms, plants, and plastics.

The link between CFCs and the depletion of stratospheric ozone was discovered in the mid-1970's. Since 1978, the U.S. government has pursued a consistent policy of limiting the production and use of ODS, including CFCs.

Summary of Legal Basis:

The Clean Air Act and EPA's implementing regulations contain general prohibitions on the use and manufacture of ODS, such as CFCs. Exceptions to these bans are provided for specific medical products that FDA, in consultation with EPA, has found to be essential. FDA's essential use determinations have been contained in 21 C.F.R. section 2.125.

FDA published a new 21 C.F.R. section 2.125 in the Federal Register on July 24, 2002 (67 FR 48370), (corrected in the Federal Registers of July 30, 2002 (67 FR 49396) and September 17, 2002 (67 FR 58678)). Section 2.125 provides criteria for determining when a use is essential and when a use is no longer essential. The procedures to determine when a use is no longer essential were implemented to better carry out responsibilities under both the Clean Air Act and the Montreal Protocol on Substances that Deplete the Ozone Layer, (September 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st sess., 26 I. L. M. 1541 (1987)).

Fran Du Melle, Executive Vice President of the American Lung Association, submitted a citizen petition on behalf of the U.S. Stakeholders Group on MDI Transition on January 29, 2003 (Docket No. 03P-0029/CP1). The petition requested that FDA initiate rulemaking to remove the essential use of albuterol MDIs. After evaluating the petition, comments submitted in response to the petition, and other information, FDA has tentatively determined that albuterol MDIs meet the criteria in section 2.125 for removal of an essential use.

Alternatives:

In the proposed rule, FDA will specifically request comments on the best effective date for any final rule to remove the essential use status of albuterol. FDA will consider which dates will allow manufacturers to obtain the capacity to produce adequate numbers of non-ODS albuterol MDIs. FDA will also consider which dates might minimize any financial burden on patients who would have to switch to non-ODS albuterol MDIs.

Anticipated Cost and Benefits:

The expected benefit from this rulemaking, as part of an overall policy to eliminate production and use of ODSs, is the preservation of the Earth's stratospheric ozone.

Currently there are generic versions of ODS albuterol MDIs, while there are no generic non-ODS albuterol MDIs. This rulemaking could force patients to switch from lower-priced generic versions of ODS albuterol MDIs to higher-priced non-ODS albuterol MDIs.

Risks:

FDA is concerned about the possibility that some patients might stop using needed drugs because the prices of non-ODS albuterol MDIs might be higher than those of ODS albuterol MDIs.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	
NPRM Comment Period End	06/00/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

FINAL RULE STAGE

47. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

Priority:

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

Legal Authority:

21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 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 C.F.R. 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.

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 C.F.R. 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	
NPRM Comment Period Reopening End	06/22/01	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

48. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a–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 C.F.R. 312.32 for sponsors of investigational drugs for human use. FDA also has safety reporting requirements in sections 21 C.F.R. 310.305, 314.80, 314.98 and 600.80 and 600.81 for applicants, manufacturers, packers, and distributors of approved human drug and biological products. FDA has undertaken a major effort to clarify and revise these regulations to improve the management of risks associated with the use of these products. For this purpose, the agency is proposing to implement certain definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to provide more effective and efficient safety reporting to regulatory authorities worldwide. Currently, the United States, European Union, and Japan require submission of safety information for marketed drug and biological products using different reporting formats and different reporting intervals.

Summary of Legal Basis:

The agency has broad authority under sections 505 and 701 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355 and 371) and section 351 of the Public Health Service Act

(42 U.S.C. 262) to monitor the safety of drug and biological products for human use.

Alternatives:

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

Anticipated Cost and Benefits:

Manufacturers of human drug and biological products currently have limited incentives to invest capital and resources in standardized global safety reporting systems because individual firms acting alone cannot attain the economic gains of harmonization. This 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	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Comment Review End	09/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

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HHS—FDA

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

Priority:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

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

Timetable:

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

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

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

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

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

CFR Citation:

21 CFR 111

Legal Deadline:

None

Abstract:

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

Statement of Need:

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

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

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

Risks:

Any potential for consumers to be provided adulterated (e.g., contaminated with industrial chemicals, pesticides, microbial pathogens, or dangerous misidentified ingredients or toxic components of ingredients) products must be considered a very serious risk because of the possibility that such contamination could be widespread,

affecting whole segments of the population, causing some severe long-term effects and even loss of life. Dietary supplements are used by a large segment of the American public. Moreover, they are often used by segments of the population that are particularly vulnerable to adulterated products, such as the elderly, young children, pregnant and nursing women, and persons who may have serious illnesses or are taking medications that may adversely interact with dietary supplements. FDA has adopted or proposed manufacturing controls for a number of foods and commodities that present potential health hazards to consumers if not processed properly, including seafood, juice products, and fruits and vegetables, and it is appropriate that FDA consider whether manufacturing controls are necessary to assure consumers that dietary supplements are not adulterated during the manufacturing, packing, or holding process.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Comment Review End	01/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—FDA

51. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD

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 final rule would require human drug products and biological 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. The final rule would also require the use of machine-readable information on blood and blood component container labels.

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 many 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.

FDA proposed to require certain drug products to be bar coded. The bar code would contain certain information about the product, such as its National Drug Code number. The bar code, when used in conjunction with bar code scanners and computer equipment, will enable health professionals to decrease the medication error rate.

For blood and blood components intended for transfusion, FDA proposed to require the use of machine-readable informatin in a format approved by the Director of the Center for Biologics Evaluation and Research.

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). 502(a) of the Act prohibits the false or misleading labeling of drugs. 502(f) of the Act requires drug labeling to have adequate directions for use, adequate warnings against use by patients where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of

administering in such a manner and form as necessary to protect uses.

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 C.F.R. 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 allowing the use of automatic identification technologies either in place or in addition to the bar code. However, use of incompatible or expensive technologies could deter hospitals and health care professionals from buying scanning or reading equipment.

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 approximately $78 million over a 20-year period.

The rule's principal benefit would be a reduction in the number of medication errors, including reduced mortality and morbidity. FDA's preliminary estimate is that the reduced mortality and morbidity will yield a benefit of $44.8 billion over a 20-year period.

Risks:

The proposed rule invited comment on whether the final rule should contain a general exemption provision. There is a risk that an exemption provision could result in many exemption requests which, if granted, could reduce the rule's effectiveness.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12500
Final Rule	01/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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HHS—FDA

52. ADMINISTRATIVE DETENTION OF FOOD FOR HUMAN OR ANIMAL CONSUMPTION UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 334; 21 USC 331; 21 USC 381; 21 USC 371

CFR Citation:

21 CFR 1; 21 CFR 10.45(d); 21 CFR 16.1(b)(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 of FDA has 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 certain enforcement actions (i.e., seizures and injunctions) against perishable foods.

FDA intends to implement section 303 of the Act by issuing a regulation to provide for: 1) a detention procedure; 2) expedited procedures for enforcement actions with respect to perishable foods; 3) security procedures for detained foods including moving them to a secure facility, as appropriate; and 4) 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 (Pub. L. 107–188), 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) (21 U.S.C. 334(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 (21 U.S.C. 331) 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.

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 opportunity for an informal hearing, to confirm or terminate a detention order within five days of an appeal. Section 201(x) of the FFDCA (21 U.S.C. 321(x), defines ''informal hearing'' and describes the requirements necessary for informal hearings. 21 C.F.R. part 16 outlines FDA's informal hearing procedures in greater detail. Part 16 allows minimum timeframes to request and hold an informal hearing, but provides no requirements or limitations on the length of the informal hearing. FDA is finalizing a rule tailored to the administrative detention provisions in the Bioterrorism Act which necessitates some modifications to the provisions in part 16. If FDA were to include the minor modifications in a guidance document, FDA would not be able to enforce the new provisions because guidance documents are not binding (21 C.F.R. 10.115(d)). If FDA chose simply to follow part 16, the agency 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 required by the Bioterrorism Act.

Anticipated Cost and Benefits:

In the analysis of the proposed rule, we estimated that this rule would result in social costs of $0 to $38 million per year due to product transportation, storage, loss of product value during storage, marking or labeling, and the cost of appeals. We may need to revise these estimates after reviewing the comments we received on the proposed rule. Administrative detention would generate benefits because it improves our ability to respond to outbreaks from accidental and deliberate contamination of food, and to deter deliberate contamination. We have insufficient information to estimate benefits.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	05/09/03	68 FR 25242
NPRM Comment Period End	07/08/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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RIN: 0910–AC38

HHS—FDA

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

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

PL 107–188, sec 306

CFR Citation:

21 CFR 1

Legal Deadline:

None

Abstract:

This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. The Act authorizes regulations that require the establishment and maintenance of records, for not longer than two years, that would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. Section 306 of the Act also added section 414(a) and amended section 704(a) of FFDCA to permit FDA to inspect these records and other information if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Statement of Need:

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law on June 12, 2002. The regulations will implement section 306 of the Bioterrorism Act.

Summary of Legal Basis:

Section 306 of the Bioterrorism Act amended the FFDCA by adding section 414(b), which authorizes the Secretary to establish by regulation requirements for the creation and maintenance of records. That section of the Bioterrorism Act also added section 414(a) and amended section 704(a) of the FFDCA to permit FDA to inspect records and other information under

certain circumstances. In addition, section 306 of the Bioterrorism Act also amends section 301 of the Federal Food, Drug, and Cosmetic Act by making the failure to establish or maintain any record required by the new regulations, or refusal to permit access to those records or other information as required by the new regulations, a prohibited act.

Alternatives:

None.

Anticipated Cost and Benefits:

The records provisions will be classified as significant under Executive Order 12866 (having an annual effect on the economy of over $100 million). The recordkeeping provisions would impose a substantial cost on industry. A first estimate is that the proposed provisions will cost the food industry approximately $235 million in the first year, approximately $510 million in the second year, and approximately $220 million every year there after.

The provisions will improve substantially FDA's ability to respond to outbreaks from deliberate and accidental contamination of food. FDA will use data collected by the Center for Disease Control (CDC) and FDA on past outbreaks to estimate the benefit of improved documentation in standard tracing investigations. Of the 1,344 food-borne illness outbreaks CDC identified in 1999, only 368 (27 percent) had a confirmed etiology. A host of factors contribute to the inability to identify the cause of an outbreak, but many investigations are hampered by the lack of adequate records identifying the chain of custody of foods. While, it is not possible to directly estimate the benefits of averting a terrorist attack, as we do not know what form an attack might take or the probability of an attack occurring, FDA uses data collected by the agency on past outbreaks to estimate the benefit of the recordkeeping provisions on standard traceback investigations. Specifically we estimate the extent to which improved recordkeeping practices will facilitate faster traceback investigations.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	05/09/03	68 FR 25188
NPRM Comment Period End	07/08/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

URL For More Information:

www.fda.gov/oc/bioterrorism/bioact.html

URL For Public Comments:

www.fda.gov/ohrms/dockets/02n0277/02n0277.htm

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HHS—Health Resources and Services Administration (HRSA)

FINAL RULE STAGE

54. • SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

Priority:

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

Legal Authority:

PL 108–20, 117 Stat 638

CFR Citation:

42 CFR 102

Legal Deadline:

None

Abstract:

To provide benefits to certain persons harmed as a result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a result of contracting vaccinia through accidental exposure to certain persons. The Secretary may also provide death benefits to certain survivors of people who died as a direct result of these injuries.

Statement of Need:

This interim final rule will meet the need to set out the administrative policies, procedures, and requirements governing the Smallpox Vaccine Injury Compensation Program (the SVIC Program). Thus, the rule will describe the categories of eligible requesters under the SVIC Program (smallpox vaccine recipients, vaccinia contacts, survivors of deceased smallpox vaccine recipients or vaccinia contacts, and representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), as well as the types of benefits available (medical benefits, benefits for lost employment income, and death benefits). It will also detail how requesters can submit medical documentation concerning eligibility, concerning whether their injuries are included among those listed in the Table of Injuries published in the Federal Register on August 27, 2003, and the time frames for the onset of those injuries, nontable injuries, and injuries from other covered countermeasures (e.g., cidofovir and vaccinia immune globulin). The rule will describe the filing deadlines and the documentation needed for the Secretary to make both eligibility and benefits determinations. In addition, the regulation will provide a detailed explanation as to how each type of benefit will be calculated, the limitations imposed on such benefits, and the method of payment.

Summary of Legal Basis:

The SVIC Program was authorized by the Smallpox Emergency Personnel Protection Act of 2003, Public Law 108–20, 117 Stat. 638.

Alternatives:

In order to implement the statute, the Department is clearly obligated to take the kinds of steps described above.

Anticipated Cost and Benefits:

The SVIC Program is designed to provide benefits to certain persons harmed as a direct result of receiving smallpox-covered countermeasures, including the smallpox vaccine, or as

a direct result of contracting vaccinia through certain accidental exposures. Minimal administrative costs are associated with this rulemaking.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HHS—Centers for Medicare & Medicaid Services (CMS)

PROPOSED RULE STAGE

55. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P)

Priority:

Other Significant

Legal Authority:

42 USC 1395rr

CFR Citation:

42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412; 42 CFR 488; 42 CFR 489; 42 CFR 494; 42 CFR 413; 42 CFR 414

Legal Deadline:

None

Abstract:

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

Statement of Need:

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 226 of the Act. 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 that do not reflect current medical practices or scientific advances in the field.

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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HHS—CMS

56. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–P)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh

CFR Citation:

42 CFR 482

Legal Deadline:

None

Abstract:

This proposed rule would establish conditions of participation for Medicare-covered transplants.

Statement of Need:

CMS' present criteria for heart, liver, and lung transplantation centers were developed at a time when the Department's policies were intended to promote long-term survival of transplanted organs through use of patient selection policies that avoided selection of high risk patients and use of unadjusted actuarial survival as a measure of outcome and experience. More than 64,000 Americans are waiting for organ transplants, yet only about 20,000 receive organs annually.

About 4,000 persons die each year waiting for an organ to become available. We consider of paramount importance our role in promoting awareness of the organ transplant situation, encouraging increased organ donation, fostering proper stewardship of this scarce national resource, and ensuring that Federal policies result in equitable distribution of organs. While the goal of promoting long-term survival is laudable, we have subsequently concluded that such criteria deter transplantation of high-risk patients, may not promote equitable distribution of organs, and may potentially increase deaths awaiting transplant.

The existing transplant notices address patient selection, patient management, commitment, facility plans, experience and survival rates, maintenance of data, organ procurement, laboratory services, and billing. All policies require facilities to have a minimum of 2 years transplantation experience before applying for Medicare approval. The issue of setting the standards for Medicare-approved transplant facilities is complex and difficult. On one hand, CMS wants to ensure that Medicare beneficiaries are treated only in facilities that provide quality care. As CMS limits the number of centers CMS approve, however we could create limited access to this lifesaving technology. CMS strives to strike a balance between organ allocation and quality of care. While CMS expects facilities to continue to be responsible for appropriate organ transplant policies and protocols for these components, CMS does not believe it is essential for facilities to report the details of these polices. CMS strongly believes that successful organ transplantation requires the skills and experience of an interdisciplinary team. Therefore, CMS intends to focus regulations on the actual care being furnished and outcomes of that care. Consequently, CMS is proposing to evaluate facility survival rates and experience. CMS proposes to retain only requirements that are directly related to patient outcomes or that are necessary for data purposes. These requirements are: (1) volume—have performed 20 transplants minimum during the past 4 complete calendar years; (2) data submission—data on numbers of transplants date of transplant, patient diagnosis, patient status, donor types, date of most recent ascertained survival, and length of survival over the past 4 years; (3) outcomes—unadjusted actuarial 1-year patient survival is equal to or greater than the mean risk adjusted for 1-year patient survival for all transplant centers in the Nation less 10 percent points calculated during the last reapproved period. CMS believes these standards requirements are in concert with the Department's commitment to the equitable organ allocation initiative.

In developing the proposed rule, CMS has given serious consideration to the recommendations from the Institute of Medicine as well as from the panel of the CMS Town Hall Meeting held in December 1999. These recommendations have captured the latest thinking in outcome measures of transplant centers and they entail aspects of facilities linked to coverage, methodologies for measuring outcomes at transplant centers, data used for approving centers, and thresholds for approving centers.

Summary of Legal Basis:

Section 1102 of the Social Security Act (the Act) authorizes the Secretary to make and publish rules and regulations, as may be necessary to the efficient administration of Section 1871 of the Act states, ''The Secretary shall prescribe such regulations as may be necessary to carry out the administration of insurance programs under this title.'' Given the concern that the Department has in ensuring proper stewardship of the Nation's limited organ supply and the concern that CMS has in ensuring the Medicare beneficiaries are afforded high quality health care, CMS believes it is appropriate for the Secretary to use this broad authority to regulate Medicare payment for organ transplantation.

Alternatives:

For the most part, Medicare transplant center criteria have been implemented through a series of notices in the Federal Register. The exception is the kidney transplant criteria that have been implemented at 42 C.F.R. part 405, subpart U. The use of Federal Register notices to announce the criteria has proven difficult for hospitals desiring to become Medicare approved transplant centers. Hospitals have difficulty in researching the approved criteria and, once it is located, do not know if it is current. CMS believes it is important to codify the requirements for Medicare approval of transplant centers in regulations. Therefore, CMS is proposing to include the transplant center criteria as a component of the hospital conditions of participation. Thus, the criteria for all five transplant types (heart, liver, lung, kidney, and pancreas) would be located in the same area, for ease of reference and understanding. Another option is to update the current scattered transplant policies and maintain the process-oriented standards without focusing on patient outcomes. However, based on the rationale discussed, CMS believes it is important to promulgate this rule to fulfill our commitment to equitable organ allocation and optimal patient outcomes.

Anticipated Cost and Benefits:

The expected benefits from the proposed rule include easy references and a better understanding of the criteria used by facilities, improved patient outcomes, and facilitation of the most equitable and medically effective use of organs that are donated in trust for transplantation.

CMS has not yet quantified the costs. Response to the proposed rule should help to determine the cost of there requirements.

Risks:

If the CoP Criteria for Approval of Facilities to Perform Medicare-Covered Transplants are not promulgated, the current transplant policies will not allow CMS to take advantage of continuing advances in the health care delivery field or to keep current with growing demands for services, and the distribution of organs will remain inequitable.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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HHS—CMS

57. 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, Final.

Abstract:

This rule would establish conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from 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 recertification 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
NPRM	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

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

Priority:

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

Legal Authority:

PL 105–554, Children's Health Act of 2000

CFR Citation:

42 CFR 101; 42 CFR 418; 42 CFR 482; 42 CFR 483; 42 CFR 485; . . .

Legal Deadline:

None

Abstract:

This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Statement of Need:

In recent years, media, Government, and consumer reports of deaths and injuries occurring due to the use of restraint or seclusion have heightened concern about these mechanisms as interventions. Concern about use is nothing new, however; the appropriate use of restraint and seclusion has been debated and regulated in various health care settings for many years. Researchers have examined the use of restraint and seclusion, related injuries

and deaths, and potential alternatives to address safety and care concerns while posing less inherent risk to the individual. Patient advocates have lobbied for reduced and more highly regulated use. Health care facilities and professionals have examined mechanisms for reduction, and some have implemented training programs to promote safe application and use. Reports of injuries and deaths, however, have brought concerns about care and safety to the forefront. The issue has gained national attention, with a call for regulation across health care settings.

Several highly publicized newspaper articles and Federal reports are the impetus for this regulation. The CHA established a significant collaboration of several important children's health bills. CMS has responsibility for part H, which established certain requirements related to the rights of residents of certain facilities receiving Federal funds. SAMHSA intends to publish a notice of proposed rulemaking to implement part I, which sets forth requirements related to the rights of residents of certain nonmedical, community-based facilities for children and youth. The CHA establishes for certain facilities common definitions, staff training standards, reporting requirements, and strict enforcement criteria.

Summary of Legal Basis:

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

Alternatives:

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

Anticipated Cost and Benefits:

The anticipated benefits include enhanced patient safety and better consumer protections. Increases in staff education and training are expected to lead to treatment alternatives and decreases in the use of restraint and seclusion as a means of intervention, which then leads to less traumatic experiences for both beneficiaries and staff. The regulation creates a change in facility practices and policies on the use of restraint or seclusion as a treatment mechanism. The regulation will create standard criteria for patient or residential care facilities that receive Federal funds, which will establish an 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 32,350 Medicare and Medicaid funded facilities. At this time, however, the extent of potential facilities affected is unattainable until comments are received from other HHS agencies. It is estimated that the cost will be roughly $0.5 billion a year for Federal Medicaid, and $2.5 to $3 billion for all payers. The proposed rule will specifically solicit comments on actual staff training and reporting costs, and it is assumed this cost will decrease since the majority of facilities currently have training and reporting requirements.

Risks:

The risk in implementing the regulation—

1. Increase in cost for facilities in staff training, however, facilities that currently use restraint or seclusion as a form of intervention have some general staff training requirements. The CHA will only expand the content of this training.

2. Increase possibility of facilities having their Federal funding status placed in jeopardy due to noncompliance with regulations. Industry may raise concern that the CHA's enforcement aspect is too harsh. For nursing homes, argument may occur that the CHA's enforcement goes against the intent of the Congress and its OBRA '87 language to devise other alternative sanctions besides termination from the Medicare or Medicaid programs.

3. Concern from facilities that currently do not have any regulations governing the use of restraints or seclusion (e.g., nursing homes, hospice inpatient facilities, critical access hospitals, however nursing homes have requirements in their survey guidance materials).

The risk in not implementing the regulation—

1. Continued unregulated use of restraint and seclusion in certain Federally funded facilities.

2. Continued under reporting of deaths as a result of restraint or seclusion, or deaths that occur within 24 hours after an individual has been restrained or in seclusion, or where it is reasonable to assume that the individual's death was caused by being placed in restraints or in seclusion.

3. Barrage of continued concerns from advocacy groups and the Congress to publish this regulation, as well as requests from facilities for guidance.

4. Lack of protection for special needs populations, such as children, adolescents, persons with mental illness, developmental disabilities, or co-occurring mental retardation who are disproportionately affected by the usage of restraint or seclusion as a common form of intervention.

5. Lack of direction to organizations, advocacy groups and more than 32,350 facilities for developing common definition.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—CMS

59. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FY 2004 (CMS–1213–F)

Priority:

Other Significant

Legal Authority:

PL 106–113; Sec 124 of the Social Security Act ; Sec 1886 of the Social Security Act

CFR Citation:

42 CFR 412, subpart N

Legal Deadline:

NPRM, Statutory, October 1, 2002, NPRM.

Abstract:

This rule sets forth a prospective payment system (PPS) for inpatient psychiatric facilities and psychiatric units.

Statement of Need:

This rule sets forth a PPS for psychiatric hospitals and psychiatric part units. It would replace the current TEFRA payment mechanism for inpatient psychiatric facilities (IPF).

Summary of Legal Basis:

Section 124 of Balanced Budget Refinement Act of 1999 mandated implementation of an 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 budget-neutral payment system may adversely affect certain classes of facilities.

Timetable:

Action	Date	FR Cite
NPRM	11/28/03	68 FR 66919
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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HHS—CMS

60. HOSPITAL PATIENTS' RIGHTS COP-STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1395bb; 42 USC 1395x; 42 USC 1396d

CFR Citation:

42 CFR 482

Legal Deadline:

None

Abstract:

This proposed rule would allow hospitals to waive the current requirement that a physician or licensed independent practitioner perform a one-hour face-to-face evaluation of a patient in restraint or seclusion for the purpose of behavior management. Under this proposed rule, a hospital could choose to have the one-hour assessment performed by another practitioner, such as a registered nurse, if that hospital established a Protections Compliance Committee to oversee the use of restraint or seclusion

Statement of Need:

The hospital patients' rights regulation was published in the Federal Register as an interim final rule on July 2, 1999 and became effective on August 2, 1999 (see 42 C.F.R. 482.13). Since then, the hospital industry and physicians have asserted that the requirement that a physician or licensed independent practitioner (LIP) evaluate a patient within one hour of the initiation of an intervention, contained at section 482.13(f)(3)(ii)(C), is too burdensome. In the interim final rule, we stated ''in situations where a restraint must be used for behavior management, increased vigilance is required because of the heightened potential for harm or injury as the patient struggles or resists. Furthermore, there is an immediate need for assessment of what has triggered this behavior and for continuous monitoring of the patient's condition.'' Therefore, we specified that a physician or LIP evaluate the patient face-to-face within one hour of the application of restraint or the use of seclusion.

This proposed rule would allow a hospital to waive the current requirement that a physician or LIP perform a face-to-face evaluation of a patient in restraint or seclusion for behavior management within one hour of the initiation of restraint or seclusion. In lieu of the one hour face-to-face evaluation by a physician or LIP, the hospital would be able to designate a registered nurse (RN) to perform the evaluation if the hospital also creates a Protections Compliance Committee (PCC) to oversee the hospital's use of restraint or seclusion.

Summary of Legal Basis:

Hospitals must meet certain conditions 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. The statute (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 modifying the current CoP that requires a physician to perform the one-hour evaluation to allow an appropriately trained RN to perform the evaluation without the added PCC. However, in response to advocacy group concerns that this would lessen the protections already afforded patients in hospitals, we opted not to use this approach.

Anticipated Cost and Benefits:

Because the provisions of this rule would be voluntary and we have no data to indicate how many hospitals would participate, it is difficult to determine the amount of any economic impact on an individual hospital. We would expect that a hospital, in choosing this option, would weigh costs and benefits of requiring a physician or LIP to perform the one

hour evaluation versus the costs and benefits of forming a Protections Compliance Committee.

Risks:

This proposed rule is intended to encourage the emphasis of patient safety in hospitals, while offering some relief from perceived burden.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

Federalism:

Undetermined

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HHS—CMS

FINAL RULE STAGE

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61. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1396d

CFR Citation:

42 CFR 441; 42 CFR 483

Legal Deadline:

None

Abstract:

This final rule addresses standards of practices that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints and seclusion.

Statement of Need:

The standards were developed to eliminate the risk to children and adolescents from inappropriate restraint and seclusion that were substantiated by reports of deaths and injuries that occurred in these facilities. This final rule will clarify and revise the regulations in response to public comments that were received on the previous interim final rules.

Summary of Legal Basis:

Section 1902(a)(9)(A) of the Social Security Act (the Act) requires the State health agency or other State medical agency to establish and maintain health standards for private and public institutions in which recipients of medical assistance, under the State plan, may receive care or services. Section 1905(h) of the Act defines the term ''impatient psychiatric hospital services for individuals under age 21'' as inpatient services that are provided in an institution (or distinct part hereof) that is a psychiatric hospital or in another in patient setting that the Secretary has specified in regulations. In this final rule, we are defining ''psychiatric residential treatment facilities'' as an inpatient setting in conformity with the definition of an institution as set forth in section 1905(h)of the Act.

The Children's Health Act (CHA) of 2000 (Pub. L. 106–310), which amended the Public Health Section of the Act to require the health care facilities receiving support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from any restraints or involuntary seclusion imposed for purposes of discipline or convenience. The Children's Health Act permits the Secretary to issue regulations that afford residents greater protections regarding restraint and seclusion than the standards published in the new law. Our final rule provides greater protections than those required in section 3207 of the Children's Health Act.

Alternatives:

None.

Anticipated Cost and Benefits:

The average costs for psychiatric residential treatment facilities to implement this rule are estimated to be around $65 million per year for the first 5 years.

We believe that requirements of this rule will have a direct impact on the use of restraint and seclusion in residential treatment facilities. Specifically, we are limiting the use of restraint and seclusion to emergency safety situations only and have specifically defined an emergency safety situation for purposes of this rule. By limiting the use of restraint and seclusion we expect to better protect residents from the use of restraint and seclusion as a means of coercion, discipline, staff convenience, or retaliation.

Risks:

There is the potential for great risks to facility residents if the current regulations are not revised and reports of inappropriate restraint and seclusion practices continue.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/22/01	66 FR 7148
60-Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—CMS

62. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

Priority:

Other Significant

Legal Authority:

Sec 521 of BIPA

CFR Citation:

42 CFR 405

Legal Deadline:

NPRM, Statutory, October 1, 2002, NPRM.

Abstract:

This final regulation with comment incorporates recommendations from a Social Security Administration (SSA)/Health and Human Services (HHS) workgroup to improve the Administrative Law Judge (ALJ) hearing process. ALJ-conducted hearings for Medicare fee-for-service and managed care cases are governed by SSA disability regulations which apply to SSA disability cases, not to Medicare. Regulations improve the integrity of the appeals process, because they are specific to the adjudication of Medicare cases. They also incorporate the revisions to appeals policy required by section 521 of Benefits Improvement and Protection Act of 2000 (BIPA).

Statement of Need:

This regulation is necessary to implement section 1869(b)(1)(f) of the Social Security Act (the Act), which requires the establishment of an expedited appeals process enabling beneficiaries to appeal discharges from provider settings. This process will apply to provider discharges and service terminations by skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. The process will be similar to the expedited review process that will be available to Medicare+Choice enrollees beginning in January under our April 4, 2003 final rule. Quality improvement organizations will likely conduct these reviews.

Summary of Legal Basis:

Section 1869(b)(1)(F) of the Act, as amended by section 521 of the Benefits Improvement & Protection Act of 2000, requires the Secretary to implement appeal procedures by October 1, 2002.

Alternatives:

None, the changes are required by the statute.

Anticipated Cost and Benefits:

The cost of implementing this rule will be $34.2 million to the Federal Government. The benefit will result in new and expanded appeal rights for beneficiaries.

Risks:

The failure to publish this regulation will result in further delay of a new expedited appeals process for beneficiaries.

Timetable:

Action	Date	FR Cite
NPRM	11/15/02	67 FR 69312
Final Rule	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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HHS—CMS

63. ● REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

Sec 521 of BIPA

CFR Citation:

42 CFR 40S

Legal Deadline:

None

Abstract:

This final rule will revise the Medicare appeals process by adding five-tiered (five levels) of review. It will remove the distinction between the processing of initial determination and appeals under part A and part B required by section 521 of Benefits Improvement and Protection Act of 2000 (BIPA).

Statement of Need:

This regulation is necessary to implement section 1869 of the Social Security Act (the Act). Major provisions include the following:

1. The implementation of identical rules for Medicare part A and B claims appeals.

2. The establishment of qualified independent contractors (QICs), with panels of physicians making medical necessity determinations.

3. Shorter time frames at all appeal levels.

4. Other improvements to the Medicare claims appeals process.

Key components of the final rule include new notice and evidence submission standards, the procedures for adjudicating escalated cases, the promulgation of Medicare-specific regulations for administrative law judge hearings, the feasibility of telephone and in-person appeals under the new BIPA timeframes, reopening rules, and transition policies for the move from the existing appeals procedures.

Summary of Legal Basis:

Section 1869(b) of the Act, as amended by section 521 of Benefits Improvement & Protection Act of 2000, requires the Secretary to implement claims appeal procedures by October 1, 2002.

Alternatives:

None, the changes are required by the statute.

Anticipated Cost and Benefits:

None, the changes are required by the statute.

Risks:

None, the changes are required by the statute.

Timetable:

Action	Date	FR Cite
Final Action	07/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Undetermined

Government Levels Affected:

Federal

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DEPARTMENT OF HOMELAND SECURITY (DHS)

Statement of Regulatory Priorities

The President signed the Homeland Security Act on November 25, 2002. DHS officially ''stood up'' as an agency on January 24, 2003, and most of its component agencies transferred in on March 1, 2003. The final components and agencies were in place within DHS by July 1, 2003. The Homeland Security Act created a new executive department of the United States with the following missions:

- Prevent terrorist attacks within the United States;
- Reduce America's vulnerability to terrorism;
- Minimize the damage and assist in the recovery from terrorist attacks that do occur within the United States;
- Carry out all functions of entities transferred to the Department, including by acting as a focal point regarding natural and manmade crises and emergency planning;
- Ensure that the functions of entities transferred to the Department that are not related directly to securing the homeland are not diminished or neglected except by a specific explicit Act of Congress;
- Ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland; and
- Monitor connections between illegal drug trafficking and terrorism, coordinate efforts to sever such connections, and otherwise contribute to efforts to interdict illegal drug trafficking.

The first and overriding priority of the Department 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. Accordingly, the Department has issued a comprehensive suite of maritime security regulations that strengthen and add additional protective layers of defense to the Nation's port security. The regulations specify requirements for security assessments, development of security plans, mandate access control, security monitoring, and implement physical, passenger, persons, baggage and cargo security measures. Our skies are safer by requiring security programs for aircraft weighing 12,500 pounds or more. Additionally, the Department is requiring private charter security rules. These rules will require that individuals and their accessible property are screened before boarding and that flight crews have criminal history background checks. Our borders are safer through the implementation of many security-based measures including the Student and Exchange Visitor Information System that provides for tracking and monitoring functionality and for maintaining current information on nonimmigrant students and exchange visitors; and through the proposed implementation of a new entry-exit system, the U.S. Visitor and Immigrant Status Indication Technology System, designed to make entering the United States easier for legitimate tourist, student, and business travelers while making it more difficult to enter the United States illegally through the implementation of biometrically authorized documents. The Department, also, is promulgating advanced cargo reporting regulations to facilitate timely targeting of shipments of goods for heightened scrutiny. These rules are intended to facilitate both commerce and security by speeding decision-making and enhancing certainty for the trade community. The Department is also facilitating antiterrorism initiatives through various rulemaking projects, including the implementing regulations under the Support Antiterrorism by Fostering Effective Technologies Act of 2002. This rule provides incentives to persons to develop antiterrorism technologies. The Department is encouraging the public, through rulemaking, to voluntarily submit information regarding security vulnerabilities that will assist the Department in developing strategies for protecting critical infrastructure.

DHS continues to fulfill its charge to carry out functions within the Department that are not directly related to securing the homeland. Most notably, the proposed rulemakings for disaster relief that will provide Federal assistance to individuals and households affected by natural and manmade disasters, and the issuing of proposed standards for living organisms in Ship's ballast water discharged in the United States. In the trade arena, DHS issued regulations that facilitated free trade in implementing various Andean, Caribbean, and African preference programs enacted last year by Congress. These rules provide the framework in which traders make investment-backed decisions to avail free trade.

BILLING CODE 4410–10–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The regulatory plan for the Department of Housing and Urban Development for fiscal year (FY) 2004 highlights the Department's most significant regulations and policy initiatives, as established by Secretary Martinez, for the upcoming fiscal year. This regulatory plan reflects HUD's role as the primary Federal agency responsible for expanding homeownership, increasing access to affordable housing free from discrimination, improving and developing the Nation's communities, and addressing the housing needs of our Nation's most vulnerable. 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 is also committed to breaking down the barriers that keep too many families—especially minorities—from owning their own home. Toward this goal, HUD has taken significant steps to make the homebuying process less confusing and less expensive, and has and will continue to reduce predatory lending practices while enhancing accountability in the home purchase process.

While HUD is passionate about its mission to increase the ranks of America's homeowners, its agenda is broad and covers every aspect of single-family and multifamily housing, the special needs of vulnerable citizens and urban and economic development. Touching America's communities, HUD is committed to providing the capital and resources to improve economic conditions in distressed communities and helping local organizations access the resources they need to make their communities more livable. Touching the lives of individuals and families with special needs, HUD is committed to ending chronic homelessness, and ensuring adequate housing for the elderly, persons with disabilities, and people living with HIV/AIDS. HUD's mission is also to promote affordable housing and improve the physical quality and management accountability of public and assisted housing.

Under the leadership of Secretary Martinez, HUD's regulatory plan for FY 2004 builds upon the successes of the previous fiscal year through regulations that are designed to expand homeownership opportunities, promote decent affordable housing for all, particularly the most vulnerable Americans, and strengthen America's communities.

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, as well as 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 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 a 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 continues its commitment to reduce predatory lending practices and enhance accountability in the home purchase process. Predatory lending may be undertaken by creditors, brokers, or home improvement contractors. It involves deception or fraud, manipulating the borrower through aggressive sales tactics, or taking unfair advantage of a borrower's lack of understanding about loan terms. 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. Predatory lending poses a barrier to expanding homeownership, barring significant numbers of Americans from owning a piece of the American Dream. Predatory lending also threatens homeownership by placing on borrowers loans that are so expensive or have such high rates that borrowers are unable to pay and therefore risk default on their loans.

To combat predatory lending, HUD will continue to pursue regulations that enhance lender accountability for appraisals, establish criteria by which home inspectors are placed on and removed from the Federal Housing Administration (FHA) Inspector Roster, and strengthen FHA's Credit Watch Initiative. Other rules will enhance accountability of nonprofits participating in the Section 203(k) Rehabilitation Program and enhance lender compliance and accountability.

Regulatory Action: Revisions to FHA Credit Watch

Under the FHA Credit Watch Termination Initiative, FHA systematically reviews mortgagees' early default and claim rates, that is, defaults and claims on mortgagees' loans during the initial 24 months following endorsement. Mortgagees with excessive default and claim rates are considered to be on Credit Watch status and, in cases of more severe performance deficiencies, HUD may terminate the mortgagee's loan origination approval authority. This final rule will amend HUD's regulations for the FHA Credit Watch Termination Initiative and provide greater safeguards for the FHA mortgage insurance fund. Among the

revisions to be made, this rule will provide for a fully computerized Credit Watch notification process through use of the FHA Neighborhood Watch Early Warning System. As a result, a mortgagee will be considered to be on Credit Watch status if, at any time, it has a default and claim rate of higher than 150 percent of the normal rate, and its origination approval agreement has not been terminated. The rule will also prohibit a mortgagee that has received a notice of proposed termination of its origination approval agreement from establishing a new branch for the origination of FHA-insured mortgages in the lending area covered by the proposed termination.

Regulatory Action: Single-Family Mortgage Insurance; Lender Accountability for Appraisals

The success of the FHA single-family mortgage insurance program, and HUD's ability to protect the FHA Insurance Fund, begins with the quality of appraisals on properties that secure FHA mortgages. Most appraisers perform appraisals in accordance with FHA standards. There are some instances, however, in which some lenders tacitly require appraisers to make the appraisal computations match the sales price to ensure that a home sale and mortgage loan closes for the appraiser to obtain additional business. Other instances have occurred, including recent episodes of predatory lending activity in several areas of the country, whereby lenders, realtors, investors, and others have participated in so-called property ''flipping'' schemes to inflate home prices and perpetuate sales that generate fees and charges to participants in the transaction. There are additional examples of fraudulent activity that could have been prevented if the underwriters had properly reviewed the appraisal reports. This rule will clarify and strengthen HUD's regulations concerning the responsibilities of lenders approved by the FHA in the selection of appraisers to perform appraisals on properties that will be the security for FHA-insured mortgages. Among other things, the rule will provide that lenders are responsible for the quality of appraisals on properties securing FHA-insured mortgages. Lenders that knowingly submit appraisals to HUD that do not meet FHA requirements will be subject to the imposition of sanctions by the HUD Mortgagee Review Board. HUD believes these changes will help protect the FHA Insurance Fund, ensure better compliance with appraisal standards, and help to ensure that homebuyers receive an accurate statement of appraised value.

Priority: Expanding Homeownership—Helping Existing Homeowners Keep Their Homes

It is not enough to help more families become homeowners. HUD is also increasing the focus on assisting new homeowners to maintain their homeownership status. Among the ways HUD is advancing this goal is through homeownership counseling, foreclosure prevention activities, and better monitoring of appraisals. In particular, the requirement imposed on FHA lenders to engage in loss mitigation has proven a successful strategy for assisting homeowners to keep their homes and will be strengthened.

Regulatory Action: Treble Damages for Failure To Engage in Loss Mitigation

The HUD Appropriations Act for fiscal year1999 amended the National Housing Act (NHA) to add a triple penalty for failure to engage in appropriate loss mitigation to the existing civil money penalty system. Section 230(a) of title II of the NHA, as amended, makes it mandatory for the mortgagee, upon the default of a single-family mortgage, to engage in loss mitigation actions, including, but not limited to, special forbearance, loan modification, and deeds in lieu of foreclosure, for the purpose of providing alternatives to foreclosure. This proposed rule would amend HUD's civil money penalty regulations to reflect HUD's authorization to impose treble damages on a mortgagee for any mortgage for which the mortgagee had a duty but failed to engage in appropriate loss mitigation actions. The proposed rule follows publication of an advanced notice of proposed rulemaking (ANPRM) and takes into consideration public comments received on the ANPRM.

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 provide a positive, stable environment for children. Indeed, in areas where homeownership flourishes, neighborhoods are more stable, residents are more civic-minded, schools are better, and crime rates decline. Homeownership has a positive and pronounced effect on the nation's economy. Under the leadership of Secretary Martinez, HUD is determined to simplify the home buying process and, in doing so, expand homeownership to thousands of first-time American 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.

HUD's rulemaking on RESPA (RESPA: Simplifying and Improving the Process of Obtaining Mortgages To Reduce Settlement Costs to Consumers) was commenced to achieve these objectives. HUD's rule on RESPA has proposed 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 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—The American Dream Downpayment Initiative

HUD is committed to helping greater numbers of lower-income and minority families realize the American dream. Census figures indicate that while nearly 70 percent of all American households are homeowners, less than half of all African-American and Hispanic families own their own homes. To remove the barriers that cause this discrepancy, HUD intends to provide downpayment assistance through its American Dream Downpayment Initiative. The initiative will provide grants to States and local governments

under HUD's HOME Investment Partnership program. Enacted into law in 1992, the HOME program has successfully helped to expand the supply of decent, affordable housing for deserving families by providing funds to communities to address housing shortages and needs. HUD believes that reducing homebuying costs will help people achieve the American dream of homeownership and help to sustain the momentum in our nation's housing boom.

Regulatory Action: The HOME Investment Partnerships Program; American Dream Downpayment Initiative

This rule establishes regulations for a new homebuyer assistance initiative under the HOME Program, which is known as the American Dream Downpayment Initiative (ADDI). The purpose of the ADDI is to assist participating jurisdictions to address one of the most formidable barriers to homeownership by low-income families—the cost of the downpayment necessary for purchase of a home. Through the ADDI, HUD will make formula grants to HOME participating jurisdictions for the purpose of providing downpayment assistance to low-income families. HUD must make the ADDI funds available in accordance with a formula. This rule will codify the formula for allocation of ADDI funds to HOME participating jurisdictions, identify eligible activities and costs under the ADDI, and establish other applicable requirements.

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 Enterprises)

Through this rule, HUD will issue new housing goal levels for the purchase of mortgages by Fannie Mae and Freddie Mac for future years. 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: Supporting Community and Economic Development

Under Secretary Martinez's leadership, HUD has refocused its energy toward its core missions. One core mission is community and economic development. Community development activities include many different programs that provide assistance to a variety of grantees. One program, the Community Development Block Grant (CDBG) program, provides annual grants on a formula basis to entitled cities, urban counties, and States for the purpose of developing viable urban communities providing decent housing and a suitable living environment. The CDBG program is also designed to expand economic opportunities, principally for low- and moderate-income persons. Another program, the Community Renewal Initiative for Renewal Communities/ Empowerment Zones/ Enterprise Communities (RC/EZ/EC), offers an innovative approach to revitalization. Underlying each of these programs is the strong belief that economic development improves communities and the citizens of those communities.

Regulatory Action: CDBG Funding for Brownfields Activities

This proposed rule would revise the CDBG program regulations to clarify the eligibility of brownfields cleanup, development or redevelopment within existing program eligibility categories. As a result, the rule will improve the ability of entitlement communities and States' grant recipients to use CDBG funds for brownfields activities. By making the cleanup and development of environmentally contaminated properties eligible for funding, the Department will move toward achieving one of the objectives under the CDBG Program, which is eliminating slums or blighting conditions.

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 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: Capital Fund Program

Section 519 of QHWRA amended section 9 of the United States Housing Act of 1937 (1937 Act) to provide a Capital Fund, to be established by HUD for the purpose of making assistance available to public housing authorities (PHAs) to carry out capital and management improvement activities. This proposed rule would establish the full regulatory framework for the Capital Fund Program. The Capital Fund Program addresses the capital and management improvement needs of PHAs and replaces the Comprehensive Grant Program and the Comprehensive Improvement Assistance Program. This proposed rule would complement the final rule that ensures the effective and timely obligation and expenditure of funds under the Public Housing Capital Fund Program.

The Priority Regulations that Comprise HUD's FY 2004 Regulatory Plan

A more detailed description of the priority regulations that comprise HUD's FY 2004 regulatory plan follows.

HUD—Office of the Secretary (HUDSEC)

PROPOSED RULE STAGE

64. TREBLE DAMAGES FOR FAILURE TO ENGAGE IN LOSS MITIGATION (FR–4553)

Priority:

Other Significant

Legal Authority:

12 USC 1715u; 12 USC 1735f–14; 12 USC 1701q–1; 12 USC 1703; 1735f–15; 15 USC 1717a; 28 USC 2641 note; 12 USC 1709; 12 USC 1710; 12 USC 1715b; 42 USC 3535(d)

CFR Citation:

24 CFR 30; 24 CFR 203

Legal Deadline:

None

Abstract:

This rule would implement sections 601(f), (g), and (h) of the fiscal year 1999 HUD Appropriations Act (Pub. L. 105–276, approved October 21, 1998). These sections amend the National Housing Act, which establishes the basic framework for HUD's single family mortgage insurance programs. Specifically, section 601(f) amends section 230 of the National Housing Act (42 U.S.C. 1715u) (entitled Authority to Assist Mortgagors in Default) to provide that, upon default of an insured single family mortgage, lenders must engage in loss mitigation activities for the purpose of providing an alternative to foreclosure. Further, sections 601(g) and (h) amend section 536 of the National Housing Act (12 U.S.C. 1735f–14) (entitled Civil Money Penalties Against Mortgagees, Lenders, and Other Participants in FHA Programs) to provide for the imposition of treble civil money penalties on lenders that fail to engage in loss mitigation activities, as required under amended section 230.

Statement of Need:

This rule implements a law that allows HUD to assess civil money penalties for specific types of mortgage lender violations, including failure to engage in loss mitigation. The law also directs HUD to implement regulations as it determines necessary to implement the civil money penalty provisions. This rule is necessary to encourage certain lenders that rarely engage in loss mitigation activities to do so. Failure to engage in loss mitigation leads to additional claims on FHA's insurance funds. Greater emphasis by certain lenders on loss mitigation will act to reduce those claims and enhance the health of the funds.

Summary of Legal Basis:

Section 230 of the National Housing Act (NHA), (12 U.S.C. 1715u), requires mortgage lenders utilizing FHA-insured financing to engage in loss mitigation actions upon the default of any insured mortgage. Section 536(b)(1)(I) of the NHA (12 U.S.C. 1735f–14(b)(1)(I)) includes failure to engage in loss mitigation among the activities for which HUD may assess civil penalties. Section 536(a) of the NHA (12 U.S.C. 1735f–14(a)) provides that in the case of failure to engage in loss mitigation, the penalty may be tripled. Section 536(h) of the NHA (12 U.S.C. 1735f–14(h)) provides that HUD shall issue regulations to implement these provisions as it determines is appropriate.

Alternatives:

This action is a rule of general applicability and future effect that does not fall into any of the rulemaking exceptions.

Anticipated Cost and Benefits:

This rule will penalize lenders that have particularly poor records in the area of loss mitigation. By encouraging these lenders to engage in loss mitigation activities upon default, this rule will provide benefits to the insurance fund in the form of reduced claims on the insurance fund and hence reduced payouts.

Risks:

This rule imposes no risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
ANPRM	12/06/00	65 FR 76520
ANPRM Comment Period End	02/05/01	
NPRM	01/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HUD—HUDSEC

65. 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 1723i; 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 going forward 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 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	To Be	Determined

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HUD—HUDSEC

FINAL RULE STAGE

66. AMERICAN DREAM DOWNPAYMENT INITIATIVE (FR–4832)

Priority:

Other Significant

Legal Authority:

42 USC 3535(d); 42 USC 12701 to 12839

CFR Citation:

24 CFR 92

Legal Deadline:

None

Abstract:

This rule establishes regulations for the American Dream Downpayment Initiative (ADDI). Through the ADDI, HUD will make formula grants to participating jurisdictions under the HOME Investment Partnerships program for the purpose of assisting low-income families achieve homeownership. HUD must make the ADDI funds available in accordance with a formula. This rule codifies the formula for allocation of ADDI funds to HOME participating jurisdictions, identifies eligible activities and costs under the ADDI, and establishes other applicable requirements. This rule specifies that ADDI funds may be used for downpayment assistance towards the purchase of single family housing by low-income families.

Statement of Need:

Increasing homeownership opportunities is an important national goal. As noted in the National Affordable Housing Act, there is a critical need to increase the supply of decent, safe, and sanitary housing for all Americans, particularly among low-income families. ADDI will play an important role in providing increased homeownership opportunities and in meeting Secretary Martinez's commitment of adding 5.5 million new minority homeowners by 2010. This rule will codify the formula for the allocation of ADDI funds to HOME participating jurisdictions.

Summary of Legal Basis:

Title II of the National Affordable Housing Act authorizes, through the HOME program, funding to participating jurisdictions for various housing purposes, including strengthening public-private partnerships to increase the supply of affordable housing, including homeownership opportunities. The ADDI is a statutorily created homebuyer assistance initiative under the HOME program. The purpose of the initiative is to assist participating jurisdictions to address one of the most formidable barriers to homeownership by low-income families — the cost associated with the purchase of a home.

Alternatives:

The ADDI will be incorporated as part of the HOME program regulations, which require rulemaking.

Anticipated Cost and Benefits:

Additional administrative costs of this rule should be minimal since the formula allocation of this program is similar to the existing HOME formula allocation. The benefits of increased homeownership opportunities to the economy, the stability of communities, and to families who are currently under—housed, on the other hand, are high.

Risks:

This rule imposes no risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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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:

None

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	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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HUD—OH

FINAL RULE STAGE

68. REVISIONS TO FHA CREDIT WATCH TERMINATION INITIATIVE (FR–4625)

Priority:

Other Significant

Legal Authority:

12 USC 1703; 12 USC 1709; 12 USC 1715b; 42 USC 3535(d)

CFR Citation:

24 CFR 202

Legal Deadline:

None

Abstract:

This rule would make several amendments to HUD's regulations for the Federal Housing Administration (FHA) Credit Watch Termination Initiative. Under the Credit Watch Termination Initiative, HUD identifies mortgagees with unsatisfactory performance levels and takes ameliorative action at an early stage. The rule states that mortgagees will be responsible for using HUD's Electronic Neighborhood Watch Early Warning System to monitor their performance. Among other changes, the rule also prohibits a mortgagee that has received a notice of proposed termination of its origination approval agreement from establishing a new branch for the origination of FHA-insured mortgages in the lending area covered by the proposed termination. The rule also establishes that the default and claim thresholds underlying the Credit Watch Termination Initiative apply to both underwriting and originating mortgagees.

Statement of Need:

Credit Watch is intended to increase lender accountability. Under Credit Watch, HUD reviews the number of defaults and claims on mortgages originated by each mortgagee in the geographic area served by a HUD field office. Mortgages with excessive default and claim rates are placed on Credit Watch Status and, in cases of more severe performance deficiencies, HUD may terminate the mortgagee's loan origination approval authority. This rule will strengthen HUD's oversight of mortgages, providing for electronic notification of Credit Watch Status and ensuring that mortgages whose loan origination authority has been revoked do not evade this action by establishing a new branch for the origination of FHA-insured mortgages in the lending area covered by the termination notice.

Summary of Legal Basis:

HUD has authority to address deficiencies in the performance of lenders' loans as provided in the HUD mortgagee approval regulations at 24 CFR 203.3.

Alternatives:

The changes made by this final rule would modify regulatory requirements and, therefore, must also be promulgated through regulation.

Anticipated Cost and Benefits:

This rule should have minimal impact for mortgagees that have in place, and are effectively using, an adequate

quality control plan for loan origination. Credit watch will eliminate, from the FHA program, mortgagees that have default and claims rates that significantly exceed the national rate. As a result, the rule will help protect the FHA Insurance Fund, and benefit the public and most FHA mortgagees.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	04/01/03	68 FR 15906
NPRM Comment Period End	06/02/03	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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HUD—OH

69. LENDER ACCOUNTABILITY FOR APPRAISALS (FR–4722)

Priority:

Other Significant

Legal Authority:

12 USC 1708 to 1710; 12 USC 1715b; 12 USC 1715u; 12 USC 1735f–14; 42 USC 3535(d)

CFR Citation:

24 CFR 25; 24 CFR 203

Legal Deadline:

None

Abstract:

This rule clarifies and strengthens HUD's regulations concerning the responsibilities of lenders approved by the Federal Housing Administration (FHA) in the selection of appraisers to perform appraisals on properties that will be the security for FHA-insured mortgages. First, the rule provides that lenders are responsible for the quality of appraisals on properties securing FHA-insured mortgages. Further, the rule specifically provides that lenders that knowingly submit appraisals to HUD that do not meet FHA requirements are subject to the imposition of sanctions by the HUD Mortgagee Review Board. The rule applies to both sponsor lenders, who underwrite loans, and loan correspondent lenders, who originate loans on behalf of their sponsors. HUD believes these changes will help protect the FHA Insurance Fund, ensure better compliance with appraisal standards, and help to ensure that homebuyers receive an accurate statement of appraised value. This final rule follows publication of a January 13, 2003, proposed rule and takes into consideration the public comments on the proposed rule.

Statement of Need:

The success of the FHA single family mortgage insurance program, and HUD's ability to protect the FHA Insurance Fund, begins with the quality of appraisals on properties that secure FHA mortgages. HUD believes that it is in the public interest to adopt rules that require lenders to be held responsible for the accuracy and quality of appraisals. Adopting such rules would also help to protect first-time and low- and moderate-income homebuyers from acquiring over valued property and/or property in poor condition.

Summary of Legal Basis:

The National Housing Act provides the method for calculating the maximum mortgage amount that FHA can insure. The calculations required by the statute are based on the appraised value of the property that is security for the mortgage. This authority includes establishing appraisal standards as the Secretary may prescribe.

Alternatives:

Nonregulatory initiatives to date have not proven to be sufficiently successful in addressing the issue of ensuring consistently accurate, high-quality appraisals.

Anticipated Cost and Benefits:

This rulemaking will provide that lenders are responsible for the quality of appraisals on properties securing FHA insured mortgages. HUD believes these changes will protect the FHA Insurance Fund, ensure better compliance with appraisal standards, and help to ensure that homebuyers receive an accurate statement of appraised value.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	01/13/03	68 FR 1766
NPRM Comment Period End	03/14/03	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HUD—Office of Community Planning and Development (CPD)

PROPOSED RULE STAGE

70. COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM REVISION OF CDBG ELIGIBILITY AND NATIONAL OBJECTIVE REGULATIONS (FR–4699)

Priority:

Other Significant

Legal Authority:

42 USC 3535(d); 42 USC 5301 et seq

CFR Citation:

24 CFR 570

Legal Deadline:

None

Abstract:

This rule will improve the ability of entitlement communities and States' grant recipients to use Community

Development Block Grant (CDBG) funds for brownfields activities. The rule will clarify the eligibility of activities involving the cleanup and development of environmentally contaminated properties under section 105(a) of the Housing and Community Development Act of 1974. The rule also will increase CDBG recipients' flexibility to undertake activities meeting the national objective of preventing or eliminating slums or blighting conditions. The criteria for meeting the slum/blight national objective will be revised to specifically recognize economic obsolescence of buildings and the presence of environmental contaminants as blighting influences on an area or property. This rule will further clarify the list of activities that may be undertaken to address the slum/blight national objective criteria on a spot basis. Finally, this rule makes corresponding changes in the eligibility regulations governing the Section 108 Loan Guarantee component of the CDBG program.

Statement of Need:

The purpose of the CDBG Program is to provide decent housing, a suitable living environment and expanded economic opportunities, primarily for persons of low and moderate income. This rule does not add any new eligibility categories to section 105 of the Housing and Development Act of 1974, but rather would expand the scope of the current listing of eligible activities to include environmental remediation and development of contaminated sites. HUD believes that these changes will facilitate the use of CDBG funds for economic development objectives, reduce the administrative burden on grantees and focus efforts on assisting the residents of low- and moderate-income neighborhoods.

Summary of Legal Basis:

Section 104 of the Housing and Community Development Act of 1974 establishes certain national objectives for CDBG-assisted activities. Among other goals, section 104 makes the prevention or elimination of slums or blight a national objective for the CDBG program.

Alternatives:

The changes made by this rule would modify regulatory requirements and, therefore, must also be promulgated through regulation.

Anticipated Cost and Benefits:

Grantees will gain the flexibility to use CDBG funds to assist in redeveloping a larger universe of properties whose conditions negatively influence the condition of the surrounding area. This change will stimulate economic development through the redevelopment of contaminated industrial properties furthering activities that meet the objective of preventing or eliminating slums or blighting conditions.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Agency Contact:

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HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

71. ● CAPITAL FUND PROGRAM (FR–4880)

Priority:

Other Significant

Legal Authority:

42 USC 1437g; 42 USC 1437z–7; 42 USC 3535(d)

CFR Citation:

24 CFR 905

Legal Deadline:

None

Abstract:

This rule will implement the new Capital Fund Program for the capital and management improvement needs of public housing agencies. This rule will implement the regulatory framework for the Capital Fund Program that will govern the use of the assistance made available from the Capital Fund formula. The new rule at part 905 will replace and remove several other rules that currently govern a PHA's use of HUD assistance including part 941—Public Housing Development, and part 968—Public Housing Modernization. This rule will continue and expand the streamlining of procedures and requirements initiated under the Comprehensive Grant and Comprehensive Improvement programs at part 968.

Statement of Need:

Assistance under the Capital Fund Program is the primary, regular source of funding made available by HUD to a PHA for its capital activities, including modernization and development of public housing. This rule will implement the requirements for the use of assistance made available under the Capital Fund program. The regulations will provide the appropriate notice of the legal framework for the program, and clear and uniform guidance for program operation.

Summary of Legal Basis:

Sections 518, 519, and 539 of the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105–276, approved October 21, 1998) (referred to as QHWRA), amending sections 9 and 5, and adding section 35(g) of the U.S. Housing Act of 1937.

Alternatives:

The changes made by this rule would modify existing regulatory requirements and, therefore, must also be promulgated through regulations.

Anticipated Cost and Benefits:

The costs of the program as administered with one fund from which a PHA will fund all of its capital needs is the same as under existing provisions. The benefits of having one funding mechanism for all such needs, and the provision of additional flexibility to PHAs to manage their physical assets provides increased benefits to the PHAs. Likewise, uniform program administration of these funds will provide increased benefits to the PHAs.

Risks:

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

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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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 388 park units, 540 wildlife refuges, 24,000 miles of trails, and approximately 1.7'billion acres submerged in offshore waters. The Department protects natural, historic, and cultural resources; recovers endangered species; manages water projects; manages forests and fights wildland fires; leases public lands for coal, oil and gas production to meet the Nation's energy needs; educates children in Indian schools; and provides recreational opportunities for almost 300 million visitors annually in our national parks. To fulfill these responsibilities, the Department generates scientific information relating to land and resource management.

The Department is committed to achieving its stewardship objectives in partnership with States, communities, landowners, and others through consultation, cooperation, and communication.

We will review and update the Department's regulations and policies to ensure that they are effective and efficient and promote accountability. Special emphasis will be given to regulations and policies that:

- Adopt performance-based approaches focusing on achieving results in the most cost-effective and timely manner;
- Incorporate the best available science and utilize peer review where appropriate;
- Promote partnerships with States, other groups, and individuals;
- Provide incentives for private landowners to achieve conservation goals; and
- Minimize regulatory and procedural burdens, promoting fairness, transparency, and accountability by agency regulators while maintaining performance goals.

Major Regulatory Areas

Among the Department's bureaus and offices, the Office of Surface Mining Reclamation and Enforcement (OSM) has a significant concentration of regulatory responsibilities. OSM, in partnership with the States and Indian tribes, establishes and enforces environmental standards for coal mining and reclamation operations. In addition, OSM administers the abandoned mine land reclamation program, which is funded by a fee assessed on each ton of coal produced. Money from these fees is placed in a fund that, subject to appropriation, is used to reclaim lands and waters impacted by historic mining activities conducted before the enactment of the Surface Mining Control and Reclamation Act of 1977. Authority to collect the fee is scheduled to expire in September 2004 unless reauthorized by Congress. Other DOI bureaus rely on regulations to implement legislatively mandated programs that focus on the management of natural resources and public or trust lands. Some of these regulatory activities include:

- Management of migratory birds and preservation of certain marine mammals and endangered species;
- Management of dedicated lands, such as national parks, wildlife refuges, and American Indian trust lands;
- Management of public lands open to multiple use;
- Leasing and oversight of development of Federal energy, minerals, and renewable resources;
- Management of revenues from American Indian and Federal minerals;
- Fulfillment of trust and other responsibilities pertaining to American Indian tribes;
- Natural resource damage assessments; and
- Management of financial and nonfinancial assistance programs.

Regulatory Policy

How DOI Regulatory Procedures Relate to the Administration's Regulatory Policies

Within the requirements and guidance in Executive Orders 12866, 12630, and 13132, DOI's'regulatory programs seek to:

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

DOI bureaus have taken the initiative in working with other Federal agencies, non-Federal government agencies, and public entities to make our regulations easier to comply with and understand. Regulatory improvement is a continuing process that requires the participation of all affected parties. We strive to include all affected entities in the decisionmaking process and to issue rules efficiently. To better manage and review the regulatory process, we have revised our internal rulemaking and information quality guidance. Our regulatory process ensures that bureaus share ideas on how to reduce regulatory burdens while meeting the requirements of the laws they enforce and improving their stewardship of the environment and resources under their purview. Results have included:

- Increased bureau awareness of and responsiveness to the needs of small businesses and better compliance with the Small Business Regulatory Enforcement Fairness Act (SBREFA);
- A Departmentwide effort to evaluate the economic effects of planned rules and regulations;
- Issuance of guidance in the Departmental Manual to ensure the use of plain language;
- Issuance of new guidance in the Departmental Manual to ensure that Departmental National Environmental Policy Act reforms 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.

Implementing the President's National Energy Policy

The President's National Energy Policy promotes ''dependable, affordable, and environmentally sound production and distribution of energy for the future.'' The Department of the Interior plays a vital role in implementing the President's energy policy goals. The lands and facilities managed by the Department account for nearly 30 percent of all the energy produced in the United States.

The Department is taking over 100 actions to implement the President's

energy policy, including several regulatory actions. The 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 B Alaska. The Minerals Management Service proposed a rule in March 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 final rule is expected in the fall. 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. OSM anticipates that Congress will reauthorize the Abandoned Mine Land Fee, which is scheduled to expire in September 2004. However, OSM is making contingency rulemaking plans should Congress decide otherwise. These and other regulatory actions within the Department are designed to streamline permitting processes and encourage environmentally sound energy production.

Encouraging Responsible Management of the Nation's Resources

The Department's mission includes protecting and providing access to our Nation's natural and cultural heritage and honoring our trust responsibilities to tribes. We are committed to this mission and to applying laws and regulations fairly and effectively. The Department's priorities include protecting public health and safety, restoring and maintaining public lands, ameliorating land and resource-management problems on public lands, and ensuring accountability and compliance with Federal laws and regulations.

The Department is continuing to work together with State and local governments, landowners, conservation groups, and the business community to conserve species and habitat. Building on successful approaches such as habitat conservation plans, safe harbor agreements, and candidate conservation agreements, the Department is reviewing its policies and regulations to identify opportunities to streamline the regulatory process where possible, consistent with protection of wildlife, and to enhance incentive-based programs to encourage landowners and others to implement voluntary conservation measures. For example, the Fish and Wildlife Service has issued guidance to promote the establishment of conservation banks as a tool to offset adverse impacts to species listed under the Endangered Species Act and restore habitat.

The Department is improving incentives through administrative flexibility under the Endangered Species Act. Released for public comment in September are proposed rule changes intended to provide greater clarity of what is allowable under incidental take permits and provide greater private landowner protections under safe harbor agreements. The first improvements of procedures relate to enhancement of survival permits (actions intended to improve survival or habitat of a species) and will refine and clarify the application requirements. The second, which relates to the issuing of safe harbor permits, will make the process easier to understand and will provide participating landowners greater certainty. Comments are expected in October. A final rule will follow several weeks later.

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

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

On August 22, 2002, the President announced a new initiative that will significantly reduce the damage caused by catastrophic wildfires, by removing unnecessary regulatory obstacles that hinder active forest management to improve forest health. He also called upon Congress to work with his Administration to pass legislation that addresses the unhealthy forest crisis by expediting procedures for forest thinning and restoration projects. In May 2003, the Administration completed implementation of the administrative improvements President Bush called for as part of his Healthy Forests Initiative. These improvements will reduce complex procedures, provide more timely decisions and provide great flexibility in emergency situations. These include the use of a ''categorical exclusion''—established by rule—of administrative means to focus necessary but administrative requirements for addressing fires; streamlined and focused ''model EA'' template to ensure concise environmental assessments for fuels treatment projects; and proposed changes, via rule, to ESA regulations designed to allow agencies that regularly and routinely achieve ''findings of no adverse impacts'' the ability to make a determination that the fuels treatment project will not adversely impact species.

The National Park Service has completed a Supplemental Environmental Impact Statement regarding snowmobile management in Yellowstone and Grand Teton National Parks and John D. Rockefeller, Jr. Memorial Parkway. The Record of Decision was signed in March 2003. The ROD requires the use of new snowmobile engine technology, otherwise known as Best Available Technology, in machines entering the parks. The new technology will likely improve air quality problems associated with high numbers of users and the use of older machines. The proposed regulations will likely reduce adverse economic impact projected to result if snowmobiles were to be completely prohibited 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, comply 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 past year, the Department has worked extensively with the Federal Energy Regulatory Commission (FERC), along with the Departments of Commerce and Agriculture, to establish a new integrated licensing process that will reduce both the time and cost of obtaining a FERC hydropower license. In July 2003 FERC issued its new rules.

Encouraging Public Participation and Involvement in the Regulatory Process

The Department is encouraging increased public participation in the regulatory process to improve results by ensuring that regulatory policies take into account the knowledge and ideas of our customers, regulated community, and other interested participants. The Department is reaching out to communities to seek public input on a variety of regulatory issues. For example, every year FWS establishes migratory bird hunting seasons in partnership with ''flyway councils,'' which are made up of State fish and wildlife agencies. As the process evolves each year, FWS holds a series of public meetings to give other interested parties, including hunters and other groups, opportunities to participate in establishing the upcoming season's regulations.

Similarly, the Bureau of Land Management (BLM) uses Resource Advisory Councils (RACs) made up of affected parties to help prepare land management plans and regulations that it issues under the Rangeland Reform Act.

In addition, the Department has recently completed a review of its NEPA compliance program and proposed new procedures aimed at improving public participation and reducing excess paperwork and redundancy of effort in the field. This has led to concrete reform measures. On August 29, 2003, a draft of the new NEPA reforms was sent to the **Federal Register** for notice and public comment. Once the public comments are complete, the changes will be codified in the Department and bureau handbooks. The reforms cover a number of areas. They include: consensus based management, public participation, community based training, use of integrated analysis, adaptive management, and tiered and transferred analysis. Each of these concepts is aimed at ensuring the field staff have the tools to tailor their approach to the NEPA process to local needs and interests. Along with the departmental manual changes, policy guidance was distributed to bureaus earlier this year on how to implement the major reforms.

We encourage public consultation during the regulatory process. For example:

- OSM is continuing its outreach to interested groups to improve the substance and quality of rules and, to the greatest extent possible, achieve consensus on regulatory issues;
- The Bureau of Indian Affairs is finalizing its roads program rule that was developed using the negotiated rulemaking process, which has resulted in a rule that better serves the diverse needs of the Native American community, reflecting the importance of the roads program to the individual tribes and the varying needs of the tribal governments;
- The 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 has included two phases of snowmobile regulations, the last of which will be concluded this winter.

Regulatory Actions Related to the Events of September 11, 2001

The Bureau of Reclamation is responsible for protecting 348 reservoirs and more than 500 Federal dams, 58 hydroelectric plants, and over 8 million acres of Federal property. Public Law 107-69 granted Reclamation law enforcement authority for its lands. Reclamation finalized an interim rule published in April 2002 for one year that implements this authority. It has since been extended through 2005.

Rules of Particular Interest to Small Businesses

The National Park Service snowmobiling rule for Yellowstone and Grand Teton National Parks and the John D. Rockefeller Memorial Parkway is of great interest to small business in the area of the parks, in particular those who rent snowmobiles. A draft economic analysis and a visitor survey each point towards economic benefit to businesses in gateway communities, with some costs incurred by non-snowmobile users of the parks.

The Future of DOI

Interior has developed a new Departmentwide strategic plan in response to congressional, OMB and other appraisals indicating that Interior's ten separate strategic planning documents are too long and lack the appropriate agency-level focus. The process of developing the new strategic plan provides the Secretary with an opportunity to:

- Incorporate key Administration and Secretarial priorities into Interior's goals and performance measures,
- Consult with key interested constituents on the future direction of the Department, and
- Make Interior programs more ''results-oriented'' and accountable to citizens.

Interior also 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, we plan to submit only Departmentwide strategic and annual plans to the Congress.

Bureaus and Offices Within DOI

The following brief descriptions summarize the regulatory functions of DOI's major regulatory bureaus and offices.

Bureau of Indian Affairs

The Bureau of Indian Affairs (BIA) is responsible for managing trust responsibilities to the Indian tribes and encouraging tribal governments to assume responsibility for BIA programs.

The Bureau's rulemaking and policy development processes are designed to foster public and tribal awareness of the standards and procedures that directly affect them. The processes also encourage the public and the tribes to participate in developing these standards and procedures. The goals of BIA regulatory policies are to: (a)'Ensure consistent policies within BIA that result in uniform interactions with the tribal governments; (b) facilitate tribal involvement in managing, planning, and evaluating BIA programs and services; and (c) ensure continued protection of tribal treaties and statutory rights.

Bureau of Land Management

The Bureau of Land Management manages approximately 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; 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, which 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 resource values;
- 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 objectives 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 the regulations on grazing administration exclusive of Alaska to remove provisions found unlawful in Federal court. This revision will: Make our procedures more responsive to the needs of livestock operators; protect the public interest in sustained yield use of these lands; and protect the environment.
- Completing the revision of the regulations on administration of rights-of-way on the public lands to increase cost recovery to levels that properly compensate BLM for our administrative and monitoring costs and to raise the cap on strict liability for right-of-way holders to a reasonable level in light of costs for environmental cleanup.

All BLM regulations affect small businesses because many, if not most, business entities that operate on public lands meet the definition of a small business established by the Small Business Administration (SBA). No BLM regulation is specifically targeted at small business. All BLM regulations apply equally to entities not qualified as small businesses.

Of the high priority regulations listed above, the mining and grazing regulation projects are probably of particular concern to small businesses. Most livestock operators and mining companies are small businesses, as classified by SBA.

The grazing rule will amend in several respects the grazing regulations that BLM promulgated on February 22, 1995 (59 FR 29206). It will not fundamentally change them. When published, the proposed rule will rely on a regulatory flexibility analysis prepared by BLM for the 1995 final rule. At that time, we determined that the 1995 rule would not have a significant impact on a substantial number of small entities. That analysis still applies.

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, we are finalizing a rule to revise current regulations at 30 CFR part 203. The rule will 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 to review 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 two are the result of legislation.

OSM has sought to develop an economical, safe, and environmentally sound program for the surface mining of coal by providing a stable, consistent regulatory, results-focused framework. At the same time, however, OSM has recognized the need: (a) To respond to local conditions; (b) to provide flexibility to react to technological change; (c) to be sensitive to geographic diversity; and (d) to eliminate burdensome recordkeeping and reporting requirements that over time have proved unnecessary to ensure an effective regulatory program.

Major regulatory objectives regarding the mining of surface coal include:

- Regulatory certainty so that coal companies know what is expected of them and citizens know what is intended and how they can participate;
- Continuing consultation, cooperation, and communication with interest groups during the rulemaking process in order to increase the quality of the rulemaking, and, to the greatest extent possible, reflect consensus on regulatory issues.

U.S. Fish and Wildlife Service

The mission of the U.S. Fish and Wildlife Service is working with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people. Four principal mission goals include:

- The sustainability of fish and wildlife populations. We conserve, protect, restore, and enhance fish, wildlife, and plant populations entrusted to our care. We carry out this mission goal through migratory bird conservation at home and abroad; native fisheries restoration; recovery and protection of threatened and endangered species; prevention and control of invasive species; and work with our international partners.
- Habitat conservation'a network of lands and waters. Cooperating with others, we strive to conserve an ecologically diverse network of lands and waters of various ownership that provide habitat for fish, wildlife, and plant resources. This mission goal emphasizes two kinds of strategic actions: (1) the development of formal agreements and plans with partners who provide habitat for multiple species, and (2) the actual conservation work necessary to protect, restore, and enhance those habitats vital to fish and wildlife populations. Our 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. We provide opportunities to the public to enjoy, understand, and participate in the use and conservation of fish and wildlife resources. The Service directs activities on national wildlife refuges and national fish hatcheries that increase opportunities for public involvement with fish and wildlife resources. Such opportunities include hunting, fishing, wildlife observation and photography, and environmental education and interpretation, as well as hands-on experiences through volunteer conservation activities on Service lands.
- Partnerships in natural resources. We support and strengthen partnerships with tribal, State, and local governments and others in their efforts to conserve and enjoy fish, wildlife, and plants and habitats. We administer Federal grants to States and territories for restoration of fish and wildlife resources and have a continuing commitment to work with tribal governments. We also promote partnerships with other Federal agencies where common goals can be developed.

The Service carries out these mission goals through several types of regulations. 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 while carrying out our responsibility to protect the natural resources entrusted to our care. In carrying out our assistance programs, we administer regulations to help interested parties obtain Federal assistance and then comply with applicable laws and Federal requirements. Some Service regulations permit activities otherwise prohibited by law. These regulations allow possession, sale, or trade, scientific research, and educational activities involving fish and wildlife and their parts or products. In general, these regulations supplement State regulations and cover activities that involve interstate or foreign commerce.

We enforce regulations that govern public access, use, and recreation on 540 national wildlife refuges and in national fish hatcheries. We authorize

only uses that are compatible with the purpose for which each area was established, are consistent with State and local laws where practical, and afford the public appropriate economic and recreational opportunity.

We administer 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.

We also implement regulations to fulfill our statutory obligation to identify and conserve species faced with extinction under the Endangered Species Act (ESA), and to conserve certain mammals under the Marine Mammal Protection Act. The basis for determining endangered and threatened species under the ESA is limited to biological considerations. Regulations enhance the conservation of ESA-listed species and help other Federal agencies comply with the ESA. Under section 7 of the ESA, all Federal agencies must consult with the Service on actions that may jeopardize their continued existence or result in the destruction or adverse modification of their critical habitats. In designating critical habitat for listed species, the Service considers biological information and economic and other impacts of the designation. Areas may be excluded if the benefits of exclusion outweigh the benefits of inclusion, provided that such exclusion will not result in the extinction of the species. The Department is currently reviewing guidance for designation of critical habitat. The guidance will provide policy direction and a process for developing critical habitat designations. The intent is that this guidance be used in the field for 6 months to ensure that it provides the outcome intended. If the field testing is successful, we anticipate developing a rule to put the guidelines in place permanently.

In support of the President's Healthy Forests Initiative, the Service and the National Marine Fisheries Service are proposing counterpart regulations that will provide for an alternative consultation process under section 7 of the ESA for those projects that support the National Fire Plan (NFP). These proposed counterpart regulations should significantly accelerate planning, review, and implementation of NFP actions, and by doing so, should contribute to achieving the habitat management and ecosystem restoration activities contemplated in the NFP. These proposed regulations will be equally protective of listed species as the current process because the standards for determining adverse effects remain unchanged.

We are also working with the Environmental Protection Agency and the National Oceanic and Atmospheric Administration on counterpart consultation regulations for ESA Section 7 consultations on pesticide registrations. Currently, EPA registers pesticides through a lengthy process that considers a number of environmental factors. The volume of registrations and reregistrations and the fact that the EPA registration process differs significantly from most of the Service's usual consultations require that we develop a particular process that addresses the special circumstance of these agency actions. An advance notice of proposed rulemaking was published in the **Federal Register** on January 24, 2003 (68 FR 3785) on this issue.

National Park Service

The National Park Service is dedicated to conserving the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations. The Service also manages a great variety of national and international programs designed to help extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.

There are 388 units in the National Park System, including national parks and monuments; scenic parkways, preserves, trails, riverways, seashores, lakeshores, and recreation areas; and historic sites associated with important movements, events, and personalities of the American past. The NPS develops and implements park management plans and staffs the areas under its administration. It relates the natural values and historical significance of these areas to the public through talks, tours, films, exhibits, and other interpretive media. It operates campgrounds and other visitor facilities and provides, usually through concessions, lodging, food, and transportation services in many areas.

The NPS also administers the following programs: the State portion of the Land and Water Conservation Fund; Federal Lands to Parks; nationwide outdoor recreation coordination and information, and State Comprehensive Outdoor Recreation Planning; Rivers, Trails and Conservation Assistance; National Trails System; Hydropower Recreation Assistance; National Register of Historic Places; National Historic Landmarks; National Natural Landmarks; American Battlefield Protection; National Maritime Heritage Grants; Native American Graves Protection and Repatriation; Tribal Heritage Preservation Grants; Technical Preservation Services; Historic American Buildings Survey; Historic American Engineering Record; Historic American Landscapes Survey; and Interagency Archeological Services.

The NPS's regulatory activities focus on management of the National Park System and management of the programs assigned to it by Congress (and listed in the previous paragraph). Park-related regulations are designed to protect park resources while encouraging appropriate uses of the parks, consistent with each park's mission. Those regulations help ensure safe and sustainable public use, access, and recreation in the parks. Program-related regulations establish the procedures and standards by which the NPS will implement its legislated program responsibilities regarding, for example, the National Register Program and the Native American Graves Protection and Repatriation Act. The NPS regulatory program develops and reviews regulations for consistency with statutory law, current Administration priorities, and Service-wide policies.

Bureau of Reclamation

The Bureau of Reclamation's mission is to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. To accomplish this mission, Reclamation applies management, engineering, and scientific skills that result in effective and environmentally sensitive solutions.

Reclamation projects provide for some or all of the following concurrent purposes: Irrigation water service, municipal and industrial water supply, hydroelectric power generation, water quality improvement, groundwater management, fish and wildlife enhancement, outdoor recreation, flood control, navigation, river regulation and control, system optimization, and related uses. Reclamation has increased security at its facilities and is implementing its law enforcement authorization received in November 2001.

Reclamation's regulatory program is designed to ensure that its mission is carried out expeditiously, efficiently, and with an emphasis on cooperative problemsolving.

Office of the Secretary, Natural Resource Damage Assessment and Restoration Program

The regulatory functions of the Natural Resource Damage Assessment and Restoration Program (Restoration Program) stem from requirements under section 301(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). Section 301(c) requires the development of natural resource damage assessment rules and the biennial review and revisions, as appropriate, of these rules. Rules have been promulgated for the optional use of natural resource trustees to assess compensation for damages to natural resources caused by hazardous substances. The Restoration Program is overseeing the study and possible promulgation of additional rules pursuant to section 301(c)(2) and the review and possible revision of the existing rule in compliance with section 301(c)(3).

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.

DOI—United States Fish and Wildlife Service (FWS)

PROPOSED RULE STAGE

72. ENDANGERED SPECIES AND PESTICIDE REGULATION

Priority:

Other Significant

Legal Authority:

16 USC 1531 et seq

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This proposed rulemaking announces the intention of the U.S. Fish and Wildlife Service, National Marine Fisheries Service, and the U.S. Environmental Protection Agency to conduct rulemaking to promulgate ''counterpart regulations'' under the Endangered Species Act (ESA) for completing ESA section 7 consultation on EPA pesticide registration actions.

Statement of Need:

We are working with the Environmental Protection Agency and the National Oceanic and Atmospheric Administration on counterpart consultation regulations for ESA section 7 consultations on pesticide registrations. Currently, EPA registers pesticides through a lengthy process that considers a number of environmental factors. The volume of registrations and reregistrations and the fact that the EPA registration process differs significantly from most of the Service's usual consultations requires that we develop a particular process that addresses the special circumstance of these agency actions. An advance notice of rulemaking was published in the Federal Register on January 24, 2003 (68 FR 3785) on this issue.

Timetable:

Action	Date	FR Cite
ANPRM	01/24/03	68 FR 3786
NPRM	11/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal

Federalism:

Undetermined

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DOI—National Park Service (NPS)

FINAL RULE STAGE

73. SNOWMOBILE REGULATIONS FOR YELLOWSTONE AND GRAND TETON NATIONAL PARKS AND JDR PARKWAY

Priority:

Other Significant

Legal Authority:

16 USC 1; 16 USC 3; 16 USC 462k; 16 USC 9a; 16 USC 460(q); . . .

CFR Citation:

36 CFR 7.13; 36 CFR 7.21; 36 CFR 7.22

Legal Deadline:

Final, Judicial, December 15, 2003, Final.

The NPS entered into a Settlement Agreement with the International Snowmobile Manufacturers Association and others in June 2001. The agreement was a result of a lawsuit initiated by ISMA disputing provisions of snowmobile regulations issued at the end of the Clinton Administration. The agreement has been amended and final regulations are required by December 15, 2003.

Abstract:

This is the final phase of a series of regulations modifying the use restrictions for snowmobiles and snowcoaches in Yellowstone and Grand Teton National Parks. This regulation, when published as a final rule, will implement new provisions for snowmobile and snowcoach management that arose from the Record of Decision signed March 25, 2003. The NPS will be working to have the final rule in effect before the start of the 2003–2004 winter use season.

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 analyze 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. That settlement agreement was amended and final regulations are now required by December 15, 2003.

Alternatives:

The only alternative to these regulations would be to allow provisions of the existing regulations for the parks go into effect for the winter use season 2003–2004. 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. Those snowmobiles would not be required to be cleaner or quieter.

Anticipated Cost and Benefits:

For the purposes of the benefit-cost analysis, the 2002 ''delay rule'' (alternative 1b in the SEIS) represents the baseline against which other alternatives were compared. Under this baseline, most snowmobile use would be prohibited in the parks as of the winter of 2004–2005, with restrictions on snowmobile use phased in during the winter of 2003–2004. Alternatives 2–4 should provide greater economic benefits to snowmobile riders and businesses that support them since they are less restrictive relative to the baseline. The primary group that would incur costs under alternatives 2–4 would be the park visitors who do not ride snowmobiles and the businesses that provide services to these visitors as well as members of the general public who place a value on protecting park resources from the negative externalities associated with snowmobile use. Of the alternatives that allow for snowmobile use, alternative 3 is expected to impose the lowest cost on non-snowmobile users. Alternative 4 is expected to impose only slightly higher costs on non-snowmobile users than alternative 3.

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 by 50 percent beginning during the winter use season 2003–2004. Allowing the existing regulations to become effective would cause adverse economic impacts to the local communities and surrounding three-State area.

Timetable:

Action	Date	FR Cite
NPRM	08/27/03	68 FR 51526
NPRM Comment Period End	10/14/03	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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DOI—Minerals Management Service (MMS)

FINAL RULE STAGE

74. 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 ''nonproducing'' leases in the Gulf of Mexico west of 87 degrees, 30 minutes West longitude. It gives the Secretary of the Interior the authority to (1) promote development or increased production on producing and nonproducing leases, or (2) encourage production of marginal resources on producing and nonproducing 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.

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	03/26/03	68 FR 14867
NPRM Comment Period End	05/27/03	
Final Action	11/00/03	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

Agency Contact:

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BILLING CODE 4310–RK–S

DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The first and overriding priority of the Department of Justice is to prevent, detect, disrupt and dismantle terrorism while preserving constitutional liberties. To fulfill this mission, the Department is devoting all the resources necessary and utilizing all legal authorities to eliminate terrorist networks, to prevent terrorist attacks, and to bring to justice those who kill Americans in the name of murderous ideologies. It is engaged in an aggressive arrest and detention campaign of lawbreakers with a single objective: To get terrorists off the street before they can harm more Americans. In addition to using investigative, prosecutorial, and other law enforcement activities, the Department is also using the regulatory process to enhance its ability to prevent future terrorist acts and safeguard our borders while ensuring that America remains a place of welcome to foreigners who come here to visit, work, or live peacefully.

On March 1, 2003, pursuant to the Homeland Security Act of 2002 (HSA), the responsibility for providing immigration-related services and benefits such as naturalization and work authorization was transferred from the Justice Department's Immigration and Naturalization Service (INS) to the Bureau of Citizenship and Immigration Services (BCIS) in the Department of Homeland Security (DHS). The Attorney General has a continuing role in supervising removal and bond cases (conducted by the immigration judges and the Board of Immigration Appeals in the Executive Office for Immigration Review (EOIR)), as well as civil litigation and criminal prosecutions relating to the immigration laws.

The Department of Justice's regulatory priorities focus in particular on two regulatory initiatives in the areas of civil rights. However, in addition to these 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 anti-terrorism and law enforcement priorities.

Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of firearms and explosives. ATF's mission and regulations are designed to:

- Curb illegal traffic in, and criminal use of, firearms, and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence;
- Facilitate investigations of violations of Federal explosives laws and arson-for-profit schemes;
- Regulate the firearms and explosives industries, including systems for licenses and permits;
- Assure the collection of all National Firearms Act (NFA) firearms taxes and obtain a high level of voluntary compliance with all laws governing the firearms industry; and
- Assist the States in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes and alcohol in avoidance of Federal and State taxes.

ATF will continue, as a priority during fiscal year 2004, modifications to its regulations governing commerce in explosives. ATF continues analysis of its regulations governing storage requirements for explosives, including fireworks explosive materials. ATF plans to issue final regulations implementing the provisions of the Safe Explosives Act, title XI, subtitle C, of Public Law 107-296, the Homeland Security Act of 2002 (enacted November 25, 2002).

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. 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 and the Methamphetamine Anti-Proliferation Act of 2000, which regulate certain drug products that are being diverted for the production of methamphetamine.

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 revise its regulations implementing titles II and III of the ADA to amend the ADA Standards for Accessible Design (28 CFR part 36, appendix A) to be consistent with the revised ADA accessibility guidelines 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 revised ADA Accessibility Guidelines as the ADA Standards for Accessible Design when the revised guidelines have been published in final form.

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 discrete 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.

Office of Justice Programs

The Office of Justice Programs is developing International Terrorism Victim Compensation Program regulations (RIN 1121-AA63 to implement the International Terrorism Victim Compensation Program. This program is contained in the Victims of Trafficking and Violence Protection Act of 2000 (Pub. L. 104-208), which directs the Office of Victims of Crime Director to compensate victims of acts of international terrorism that occur outside the United States for expenses associated with that victimization.

Regulations Published or Being Developed Because of September 11, 2001

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.

Executive Office for Immigration Review

- RIN 1125-AA47 (formerly, 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.

DOJ—Civil Rights Division (CRT)

PROPOSED RULE STAGE

75. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN PUBLIC ACCOMMODATIONS AND COMMERCIAL FACILITIES

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, and an Availability of Draft Final Guidelines on April 2, 2002. In order to maintain consistency between ADAAG and the ADA Standards, the Department is reviewing its title III regulations and expects to propose, in one or more stages, to adopt 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. The second stage will initiate the review of the regulation in accordance with the requirements of section 610 of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including title III. Section 306(c) of the ADA requires the Attorney General to promulgate regulations implementing title III that are consistent with the Access Board's ADA guidelines. Because this rule will adopt standards that are consistent with the minimum guidelines issued by the Access Board, this rule is required by statute. Similarly, the Department's review of its title III regulation is being undertaken to comply with the requirements of the Regulatory Flexibility Act, as amended by SBREFA.

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above under Legal Authority and Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation. Pursuant to SBREFA, the Department's title III regulation will consider whether alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Access Board has analyzed the effect of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they constitute a significant regulatory action for purposes of Executive Order 12866. The Access Board's determination will apply as well to the revised ADA standards published by the Department. The Department's proposed procedural amendments will not have a significant impact on small entities.

As part of its November 1999 NPRM, the Access Board published a summary of the regulatory assessment that it had prepared, including a cost impact analysis and a discussion of regulatory alternatives considered. The Access Board will prepare and publish in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Access Board's regulatory assessment will also apply to the Department's proposed adoption of revised ADAAG as ADA standards insofar as the standards apply to new construction and alteration. The Department will also prepare an additional regulatory assessment of the estimated annual cost of compliance with the revised standards with regard to existing facilities.

Risks:

Without the proposed changes to the Department's title III regulation, the ADA Standards will fail to be consistent with the ADAAG.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	
NPRM Comment Period End	08/00/04	

Regulatory Flexibility Analysis Required:

Yes

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

76. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN STATE AND LOCAL GOVERNMENT SERVICES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509 to 510; 42 USC 12134; PL 101–336

CFR Citation:

28 CFR 35

Legal Deadline:

None

Abstract:

On July 26, 1991, the Department published its final rule implementing title II of the Americans with Disabilities Act (ADA). On November 16, 1999, the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) issued its first comprehensive review of the ADA Accessibility Guidelines, which form the basis of the Department's ADA Standards for Accessible Design. The Access Board published an Availability of Draft Final Guidelines on April 2, 2002. 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.

As part of its November 1999 NPRM, the Access Board published a summary of the regulatory assessment that it had prepared, including a cost impact analysis and a discussion of regulatory alternatives considered. The Access Board will prepare and publish in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Access Board's regulatory assessment will also apply to the Department's proposed adoption of revised ADAAG as ADA standards insofar as the standards apply to new construction and alteration. The Department will also prepare an additional regulatory assessment of the estimated annual cost of compliance with the revised standards with regard to existing facilities.

The Access Board has made every effort to lessen the impact of its proposed guidelines on State and local governments but recognizes that the guidelines will have some federalism effects. These affects are discussed in the Access Board's regulatory assessment, which also applies to the Department's proposed rule.

Risks:

Without this amendment to the Department's ADA regulations, regulated entities will be subject to confusion and delay as they attempt to sort out the requirements of conflicting design standards. This amendment should eliminate the costs and risks associated with that process.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	
NPRM Comment Period End	08/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Federalism:

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

Additional Information:

RIN 1190–AA46, which will effect changes to 28 CFR 35 (the Department's regulation implementing title II of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190–AA44, which will effect changes to 28 CFR 36 (the Department's regulation implementing title III of the ADA). By adopting revised ADAAG, this rulemaking will, among other things, address changes to the ADA Standards previously proposed in RINs 1190–AA26, 1190–AA36, and 1190–AA38, which have been withdrawn and merged into this rulemaking. These changes include accessibility standards for State and local government facilities that had been previously published by the Access Board (RIN 1190–AA26) and the timing for the compliance of State and local governments with the curb-cut requirements of the title II regulation (RIN 1190–AA36). In order to consolidate regulatory actions implementing title II of the ADA, on February 15, 2000, RINs 1190–AA26 and 1190–AA38 were merged into this rulemaking and on March 5, 2002, RIN 1190–AA36 was merged into this rulemaking.

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BILLING CODE 4410–BP–S

DEPARTMENT OF LABOR (DOL)

2003 Regulatory Plan

Executive Summary: Protecting America's Workers

Since its creation in 1913, the Department of Labor has been guided by the idea that workers deserve safe and healthy workspaces, as well as protection of their wages and pensions. Protecting America's workers is a top priority of the Secretary of Labor. The Department works to enforce laws and regulations to ensure the health and safety of the American workforce. The vast majority of employers work hard to keep their employees and workplaces safe and secure. The Department is committed to aggressively enforcing the laws which protect employees. DOL also strives to provide employers with the knowledge and tools they need to carry out their legal obligations. The Secretary has made protecting workers through the coupling of compliance assistance and tough enforcement one of her top priorities. Her compliance assistance initiative is based on the proven success that comes when government, employers, unions and employees work together.

Compliance assistance works to prevent injuries before they occur. Educating and encouraging employers helps workers far more than enforcement alone, since no enforcement process can possibly identify every violation of the law, and fines and penalties can never fully redress losses of life, health, and economic well being.

DOL has responsibilities beyond worker protection. It recognizes that workers need constant updating of skills to compete in a changing marketplace. DOL helps employers and workers bridge the gap between the requirements of new high-technology jobs and the skills of the workers who are needed to fill them. Workers also need information about protection of their health insurance and pension benefits. The rights of workers returning to their jobs after military service must also be protected.

The Secretary of Labor's Regulatory Plan for Accomplishing These Objectives

In general, DOL tries to help employees and employers meet their needs in a cooperative fashion. DOL will maintain health and safety standards and protect employees working with the regulated community. DOL considers the following proposals to be proactive, common sense approaches to the issues most clearly needing regulatory attention.

The Department's Regulatory Priorities

DOL has identified 19 high priority items for regulatory action. Seven 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 is committed to ensuring safer and healthier workplaces for the nation's miners in a number of ways, and will continue to concentrate on improving existing health standards and addressing emerging health hazards in mining.

MSHA is considering lowering the 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 early in 2002 to allow early participation by interested parties in the rulemaking. MSHA will continue to evaluate those comments as it prepares a notice of proposed rulemaking.

MSHA also continues its rulemaking on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (RIN 1219-AB29). A proposed rule was published in August 2003. MSHA will address several provisions of the final standard, including changing the diesel particulate matter surrogate from total carbon to elemental carbon establishing the hierarchy of controls that MSHA applies to metal and nonmetal mines pursuant to its enforcement policy for exposure-based health standards, and addressing the diesel particulate matter control plan.

The comment period for MSHA's two coal mine dust rules (AB14 and AB18) has been extended in order to obtain information and data on personal dust monitors, a potentially promising technology currently being tested by NIOSH. These proposed rules will remain on the regulatory agenda. MSHA will be collaborating with NIOSH, miners' representatives, industry, and manufacturers in the in-mine testing of personal dust monitors. The results of this collaborative effort will guide MSHA in determining how to use these devices and the need for revisions to the coal mine dust sampling requirements.

The Occupational Safety and Health Administration oversees a wide range of measures in the public and private sectors. OSHA is committed to establishing clear and sensible priorities, and to continuing to reduce occupational deaths, injuries, and illnesses.

Four of OSHA's high-priority initiatives address health standards. The first, a revision to the Respiratory Protection Standard, will address Assigned Protection Factors for different types of respirators (RIN 1218-AA05). This action will improve respiratory protection for employees required to wear respirators and will make it easier for employers to choose the appropriate respirator for a given task. OSHA published an NPRM on June 6, 2003, and has scheduled an informal public hearing to begin on January 28, 2004.

OSHA's second initiative in the area of health standards addresses worker exposures to crystalline silica (RIN 1218-AB70). This substance is one of the most widely found in workplaces, and data indicate that exposure to it may cause silicosis, a debilitating respiratory disease, and perhaps cancer as well. OSHA is currently obtaining input from small businesses about regulatory approaches through a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel. This rule was discussed in the 2002 OMB Report to Congress on the Costs and Benefits of Regulations.

OSHA's third health initiative addresses worker exposure to hexavalent chromium (RIN 1218-AB45). Approximately one million workers are exposed to this substance in general industry, maritime, construction and agriculture. Exposure to hexavalent chromium is associated with lung cancer and dermatoses. OSHA intends to initiate the SBREFA panel process in January 2004. This standard was discussed in OMB's 2002 Report to Congress on the Costs and Benefits of Regulation.

The fourth health initiative, OSHA's Standards Improvement Project, will streamline a number of health standards by removing language that is outdated, duplicative, unnecessary or inconsistent (RIN 1218-AB81). These changes will reduce the time and effort needed to understand and comply with these standards. An NPRM was published October 31, 2002. A hearing was held in July 2003, and OSHA is currently preparing its final rule.

OSHA also has an initiative in the area of safety standards, Fire Protection in Shipyard Employment (RIN 1218-AB51). An NPRM was published on December 12, 2002, and a final rule is currently being prepared. This rule will provide a comprehensive approach to dealing with fires in shipyard environments to help prevent deaths and injuries.

Protection of pension and health benefits continues to be a priority of the Secretary. She has played a role in strengthening the retirement security of workers by supporting enhanced disclosure of their pension rights, increased freedom for workers to diversify their retirement savings, expanded access to investment advice, advance notice of 401(k) plan blackout periods, and restrictions on insider trading of employer stock during blackout periods. The last two proposals were enacted as part of the Sarbanes-Oxley Act of 2002. DOL adopted regulations implementing the blackout notice changes to the Employee Retirement Income Security Act (ERISA) in January 2003.

Consistent with the Secretary's priorities for FY 2004, the Employee Benefits Security Administration (EBSA) will focus on compliance assistance for pension and group health plans. Specific initiatives for group health plans include regulations concerning the application of the COBRA continuation of coverage notice provisions (RIN 1210-AA60); HIPAA access, portability and renewability provisions (RIN 1210-AA54); and HIPAA nondiscrimination provisions of ERISA (RIN 1210-AA77). With respect to pension plans, the Department will focus on the development of standards to facilitate the payment of benefits from 401(k) and other defined contribution plans that have been abandoned by their sponsors (RIN 1210-AA97).

ERISA's requirements affect an estimated 730,000 private sector employee pension benefit plans (covering approximately 99 million participants); an estimated 2.5 million group health benefit plans (covering 131 million participants and dependents); and 3.4 million other welfare benefits plans (covering approximately 190 million participants).

The Secretary's emphasis on meeting the needs of the 21st century workforce is reflected in the plan of the Employment and Training Administration (ETA) to issue regulations reflecting recent changes to the Trade Adjustment Assistance (TAA) program, as enacted in the Trade Act of 2002 (RIN 1205-AB32). The proposed rule would address the many new features of the TAA program: consolidation of the TAA and NAFTA-TAA programs; more rapid 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 the community service employment program 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 re-engineer the permanent labor certification process (RIN 1205-AA66). ETA's goals are to make fundamental changes that will streamline the process; save resources; improve the effectiveness of the program; and better serve the Department of Labor's customers. This rule was discussed in the 2002 OMB Report to Congress on the Costs and Benefits of Regulations.

The Employment Standards Administration (ESA) has set forth four priority regulatory initiatives. ESA's first initiative updates the child labor rules issued under the Fair Labor Standards Act (FLSA) to address changes in the nature of the workplace and situations in which minors may operate certain kinds of machinery (RIN 1215-AA09). While young workers need employment experiences that will help them gain the skills needed to find and hold good jobs later in life, they also need to focus on obtaining a high-quality education, and the assurance that their work hours are reasonable will help them in doing so.

ESA's second initiative 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 discussed in OMB's 2001 and 2002 Reports to Congress on the Costs and Benefits of Regulations. An NPRM was published on March 31, 2003. In developing proposed changes, ESA is carefully examining the issues raised by various interested parties. Changes to these rules will help employers meet their obligations and will enhance workers' understanding of their rights and benefits.

ESA's third initiative pertains to regulations issued under the Family and Medical Leave Act (FMLA) that were also discussed in OMB's 2001 and 2002 Reports to Congress on the Costs and Benefits of Regulations. Revisions will be proposed to the FMLA's implementing regulations to address issues raised by the decision of the U.S. Supreme Court in *Ragsdale v. Wolverine World Wide, Inc.,* 122 S. Ct. 1155 (2002), and the decisions of other courts.

ESA's fourth initiative involves programs administered by its Office of Labor-Management Standards (OLMS). The statutes administered by OLMS require labor organizations in the private sector and the Federal sector to file annual financial reports with the Department.' OLMS' initiative proposes revising the reporting forms (Forms LM-2, LM-3, and LM-4) and the creation of a new Form T-1 for trusts involving labor organizations in order to improve the transparency and accountability of labor organizations to their members, the public, and the government.' An NPRM was published on December 27, 2002 (RIN 1215-AB34).

Finally, the Secretary's commitment to protecting the employment rights of servicemembers as they return to the civilian workforce is reflected by the Veterans' Employment and Training Service's initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA). USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA. Authoritative written guidance interpreting USERRA will ensure that our servicemembers serve secure in the knowledge that they will be able to return to their jobs with the same pay, benefits, and status they would have attained had they not been away on military duty.

DOL—Employment Standards Administration (ESA)

PROPOSED RULE STAGE

77. 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	06/00/04	
NPRM Comment Period End	08/00/04	

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

78. CHILD LABOR REGULATIONS, ORDERS, AND STATEMENTS OF INTERPRETATION (ESA/W–H)

Priority:

Other Significant

Legal Authority:

29 USC 203(l)

CFR Citation:

29 CFR 570

Legal Deadline:

None

Abstract:

Section 3(l) of the Fair Labor Standards Act requires the Secretary of Labor to issue regulations with respect to minors between 14 and 16 years of age ensuring that the periods and conditions of their employment do not interfere with their schooling, health, or well-being. The Secretary is also directed to designate occupations that are particularly hazardous for minors 16 and 17 years of age. Child Labor Regulation No. 3 sets forth the permissible industries and occupations in which 14- and 15-year-olds may be employed, and specifies the number of hours in a day and in a week, and time periods within a day, that such minors may be employed. The Department has invited public comment in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders, and whether changes are needed in some of the applicable hazardous occupation orders. Comment has also been solicited on whether revisions should be considered in the permissible hours and time-of-day standards for 14- and 15-year-olds. Comment has been sought on appropriate changes required to implement school-to-work transition

programs. Additionally, Congress enacted Public Law 104–174 (August 6, 1996), which amended FLSA section 13(c) and requires changes in the regulations under Hazardous Occupation Order No. 12 regarding power-driven paper balers and compactors, to allow 16- and 17-year-olds to load, but not operate or unload, machines meeting applicable American National Standards Institute (ANSI) safety standards and certain other conditions. Congress also passed the Drive for Teen Employment Act, Public Law 105–334 (October 31, 1998), which prohibits minors under age 17 from driving automobiles and trucks on public roads on the job and sets criteria for 17-year-olds to drive such vehicles on public roads on the job.

Statement of Need:

Because of changes in the workplace and the introduction of new processes and technologies, the Department is undertaking a comprehensive review of the regulatory criteria applicable to child labor. Other factors necessitating a review of the child labor regulations are changes in places where young workers find employment opportunities, the existence of differing Federal and State standards, and the divergent views on how best to correlate school and work experiences.

Under the Fair Labor Standards Act, the Secretary of Labor is directed to provide by regulation or by order for the employment of youth between 14 and 16 years of age under periods and conditions which will not interfere with their schooling, health and well-being. The Secretary is also directed to designate occupations that are particularly hazardous for youth between the ages of 16 and 18 years or detrimental to their health or well-being. The Secretary has done so by specifying, in regulations, the permissible industries and occupations in which 14- and 15-year-olds may be employed, and the number of hours per day and week and the time periods within a day in which they may be employed. In addition, these regulations designate the occupations declared particularly hazardous for minors between 16 and 18 years of age or detrimental to their health or well-being.

Public comment has been invited in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders or necessitate revision to some of the existing hazardous orders. Comment has also been invited on whether revisions should be considered in the permissible hours and time-of-day standards for the employment of 14- and 15-year-olds, and whether revisions should be considered to facilitate school-to-work transition programs. When issuing the regulatory proposals (after review of public comments on the advance notice of proposed rulemaking), the Department's focus was on assuring healthy, safe and fair workplaces for young workers, and at the same time promoting job opportunities for young people and making regulatory standards less burdensome to the regulated community.

The Department will also be considering what additional revisions to the hazardous occupation orders will be undertaken to address recommendations of the National Institute for Occupational Safety and Health in its May 2002 report to the Department.

Summary of Legal Basis:

These regulations are issued under sections 3(l), 11, 12, and 13 of the Fair Labor Standards Act, 29 U.S.C. sections 203(l), 211, 212, and 213 which require the Secretary of Labor to issue regulations prescribing permissible time periods and conditions of employment for minors between 14 and 16 years old so as not to interfere with their schooling, health, or well-being, and to designate occupations that are particularly hazardous or detrimental to the health or well-being of minors under 18 years old.

Alternatives:

Regulatory alternatives developed based on recent legislation and the public comments responding to the advance notice of proposed rulemaking included specific proposed additions or modifications to the paper baler, teen driving, explosive materials, and roofing hazardous occupation orders, and proposed changes to the permissible cooking activities that 14- and 15-year-olds may perform in retail establishments.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of this regulatory action indicated that the rule was not economically significant. Benefits will include safer working environments and the avoidance of injuries with respect to young workers.

Risks:

The child labor regulations, by ensuring that permissible job opportunities for working youth are safe and healthy and not detrimental to their education as required by the statute, produce positive benefits by reducing health and productivity costs employers may otherwise incur from higher accident and injury rates to young and inexperienced workers. Given the limited nature of the changes in the proposed rule, a detailed assessment of the magnitude of risk was not prepared.

Timetable:

Action	Date	FR Cite
Final 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	02/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1215–AA09

DOL—ESA

79. 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 ''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 6.5 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	03/31/03	68 FR 15560
NPRM Comment Period End	06/30/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State

Federalism:

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

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RIN: 1215–AA14

DOL—Employment and Training Administration (ETA)

PROPOSED RULE STAGE

80. TRADE ADJUSTMENT ASSISTANCE FOR WORKERS

Priority:

Other Significant

Legal Authority:

19 USC 2320; Secretary's Order No. 3–81, 46 FR 31117

CFR Citation:

29 CFR 90; 20 CFR 617; 20 CFR 618; 20 CFR 666; 20 CFR 672; . . .

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.

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 create a new 20 CFR part 618 to incorporate the amendments and be written in plain English, while amending WIA regs at 20 CFR parts 666 and 672 regarding Rapid Response and National Emergency Grants as they relate to the TAA program.

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, 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	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

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RIN: 1205–AB32

DOL—ETA

FINAL RULE STAGE

81. LABOR CERTIFICATION PROCESS FOR THE PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES

Priority:

Other Significant

Legal Authority:

29 USC 49 et seq; 8 USC 1182(a)(5)(A), 1189(p)(1)

CFR Citation:

20 CFR 656

Legal Deadline:

None

Abstract:

The Employment and Training Administration (ETA) is in the process of reengineering the permanent labor certification process. ETA's goals are to make fundamental changes and refinements that will streamline the process, save resources, improve the effectiveness of the program and better serve the Department of Labor's (DOL) customer.

Statement of Need:

The labor certification process has been described as being complicated, costly and time consuming. Due to the increases in the volume of applications received and a lack of adequate resources, it can take up to 2 years or more to complete processing an application. The process also requires substantial State and Federal resources to administer and is reportedly costly and burdensome to employers as well. Cuts in Federal funding for both the permanent labor certification program and the U.S. Employment Service have made it difficult for State and Federal administrators to keep up with the process. ETA, therefore, is taking steps to improve effectiveness of the various regulatory requirements and the application processing procedures, with a view to achieving savings in resources both for the Government and employers, without diminishing protections now afforded U.S. workers by the current regulatory and administrative requirements.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 212(a)(5)(A) of the Immigration and Nationality Act.

Alternatives:

Regulatory alternatives are now being developed by the Department. The public was afforded an opportunity to comment on the Department's plans for streamlining the permanent labor certification process in a notice of proposed rulemaking which was published in the Federal Register on May 6, 2002.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits have not been determined at this time. Preliminary estimates will be developed after a decision is made as to what regulatory amendments are necessary and after the implementing forms and automated systems to support a streamlined permanent labor certification process have been developed.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	05/06/02	67 FR 30465
NPRM Comment Period End	07/05/02	67 FR 30466
Final Action	11/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, State

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DOL–ETA

82. 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	04/28/03	68 FR 22520
NPRM Comment Period End	06/12/03	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

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DOL—Employee Benefits Security Administration (EBSA)

PROPOSED RULE STAGE

83. • RULEMAKING RELATING TO TERMINATION OF ABANDONED INDIVIDUAL ACCOUNT PLANS

Priority:

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

Legal Authority:

29 USC 1135

CFR Citation:

29 CFR 2591

Legal Deadline:

None

Abstract:

This rulemaking will establish a procedure and standards for distributing the benefits of individual account plans that have been abandoned by their sponsoring employers or plan administrators.

Statement of Need:

Thousands of individual account plans have, for a variety of reasons, been abandond by their sponsors, creating problems for plan participants, administrators, financial institutions (e.g., banks, insurance companies, mutual funds), the courts and the Federal government. At present, the potential liability and costs attendant to terminating such plans and distributing the assets inhibits financial institutions and others from taking on this responsibility. Due to on-going administrative costs and other factors, the continued maintenance of such plans is often not in the interest of the participants and beneficiaries. This rulemaking will establish a procedure for a financial institution that holds the assets of such a plan to terminate the plan and distribute its assets to the participants and beneficiaries. The rulemaking will also include standards for determining when plans may be terminated pursuant to this procedure and for carrying out the functions necessay to distribute benefits and shut down plan operation.

Summary of Legal Basis:

Section 505 of ERISA provides that the Secretary may prescribe such regulations as the Secretary finds necessary and appropriate to carryout the provisions of Title I of the Act. Section 403(d)(1) provides that, upon termination of such a plan, the assets shall be distributed generally in accordance with the provisions that apply to defined benefit plans, ''except as otherwise provided in regulations of the Secretary.'' ERISA section 3(16)(A) permits the Secretary to issue regulations designating an administrator for a plan where the plan document makes no designation and the plan sponsor cannot be identified. ERISA section 110 to establish an alternate means of compliance with ERISA's reporting and disclosure provisions.

Alternatives:

Alternatives will be considered following a determination of the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed, as appropriate, following a determination regarding the alternatives to be considered.

Risks:

Failure to provide guidance in this area will leave the retirement benefits of participants and beneficiaries in abandoned plans at risk of being significantly diminished by ongoing plan administrative expenses, rather than distributed to participants and beneficiaries in connection with a timely and orderly termination of the plan.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

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RIN: 1210–AA97

DOL—EBSA

FINAL RULE STAGE

84. 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, Other.

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended title I of ERISA by adding a new part 7, designed to improve health care access, portability and renewability. This rulemaking will provide regulatory guidance to implement these provisions.

Statement of Need:

In general, the health care portability provisions in part 7 of ERISA provide for increased portability and availability of group health coverage through limitations on the imposition of any preexisting condition exclusion and special enrollment rights in group health plans after loss of other health

coverage or a life event. Plan sponsors, administrators and participants need guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Part 7 of ERISA specifies the portability and other requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 of ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning Part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Request for Information	10/25/99	64 FR 57520
Comment Period End	01/25/00	
Final Rule	02/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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RIN: 1210–AA54

DOL—EBSA

85. 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	05/28/03	68 FR 31832
NPRM Comment Period End	07/28/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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RIN: 1210–AA60

DOL—EBSA

86. PROHIBITING DISCRIMINATION AGAINST PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS

Priority:

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

Legal Authority:

29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1182; 29 USC 1191c; 29 USC 1194

CFR Citation:

29 CFR 2590.702

Legal Deadline:

None

Abstract:

Section 702 of the Employee Retirement Income Security Act of

1974, amended by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), establishes that a group health plan or a health insurance issuer may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. These provisions are also contained in the Internal Revenue Code under the jurisdiction of the Department of the Treasury, and the Public Health Service Act under the jurisdiction of the Department of Health and Human Services.

On April 8, 1997, the Department, in conjunction with the Departments of the Treasury and Health and Human Services (collectively, the Departments) published interim final regulations implementing the nondiscrimination provisions of HIPAA. These regulations can be found at 26 CFR 54.9802–1 (Treasury), 29 CFR 2590.702 (Labor), and 45 CFR 146.121 (HHS). That notice of rulemaking also solicited comments on the nondiscrimination provisions and indicated that the Departments intend to issue further regulations on the nondiscrimination rules. This rulemaking contains additional regulatory interim guidance under HIPAA's nondiscrimination provisions. In addition, the rulemaking contains proposed guidance on bona fide wellness programs.

Statement of Need:

Part 7 of ERISA provides that group health plans and health insurance issuers may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any health status-related factor. Plan sponsors, administrators, and participants need additional guidance from the Department with regard to how they can fulfill their respective obligations under these statutory provisions.

Summary of Legal Basis:

Section 702 of ERISA specifies the respective nondiscrimination requirements for group health plans and health insurance issuers. Section 734 of ERISA provides that the Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of part 7 ERISA. In addition, section 505 of ERISA authorizes the Secretary to issue regulations clarifying the provisions of title I of ERISA.

Risks:

Failure to provide guidance concerning part 7 of ERISA may impede compliance with the law.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period	07/07/97	
NPRM	01/08/01	66 FR 1421
NPRM Comment Period End	04/09/01	
Second Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Comment Period	04/09/01	
Final Rule	03/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

This item has been split off from RIN 1210–AA54.

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RIN: 1210–AA77

DOL—Mine Safety and Health Administration (MSHA)

PROPOSED RULE STAGE

87. ASBESTOS EXPOSURE LIMIT

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 56; 30 CFR 57; 30 CFR 71

Legal Deadline:

None

Abstract:

MSHA's permissible exposure limit (PEL) for asbestos applies to surface (30 CFR part 56) and underground (30 CFR part 57) metal and nonmetal mines and to surface coal mines and surface areas of underground coal mines (30 CFR part 71) and is over 20 years old. MSHA is considering rulemaking to lower the PEL in order to reduce the risk of miners developing asbestos-induced occupational disease. A 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 in 1976 for coal mining (41 FR 10223) and 1978 for metal and nonmetal mining (43 FR 54064). During inspections, MSHA routinely takes samples, which are analyzed for compliance with its standard.

Other Federal agencies have addressed this issue by lowering their PEL for asbestos. For example, the Occupational Safety and Health Administration, working in conjunction with the Environmental Protection Agency, enacted a revised asbestos standard in 1994 that lowered the permissible exposure limit to an 8-hour time-weighted average limit of 0.1 fiber per cubic centimeter of air and the excursion limit to 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes. These lowered limits reflected increased asbestos-related disease risk to asbestos-exposed workers.

Summary of Legal Basis:

Promulgation of this regulation is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

The Agency has increased sampling efforts in an attempt to determine

current miners' exposure levels to asbestos, including taking samples at all existing vermiculite, taconite, talc, and other mines to determine whether asbestos is present and at what levels. In early 2000, MSHA began an intensive sampling effort at operations with potential asbestos exposure. These efforts continue. While sampling, MSHA staff discussed with miners and mine operators the potential hazards of asbestos and the types of preventive measures that could be implemented to reduce exposures. The course of action MSHA takes in addressing asbestos hazards to miners will, in part, be based on these sampling results.

Anticipated Cost and Benefits:

MSHA will develop a preliminary regulatory economic analysis to accompany any proposed rule that may be developed.

Risks:

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 asbestosis, mesothelioma, and other forms of cancers.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/02	67 FR 15134
Notice of Public Meetings	03/29/02	
Notice of Change to Public Meetings	04/18/02	67 FR 19140
ANPRM Comment Period End	06/27/02	
NPRM	05/00/04	

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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DOL—MSHA

FINAL RULE STAGE

88. 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 (66 FR 5706). The final rule established new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines. The rule establishes an interim concentration limit of 400 micrograms of total carbon per cubic meter of air that became applicable July 20, 2002, and a final concentration limit of 160 micrograms to become applicable after January 19, 2006. Industry challenged the rule and organized labor intervened in the litigation. Settlement negotiations with the litigants have resulted in further regulatory actions on several requirements of the rule. One final rule has been published (67 FR 9180). This new rulemaking will address the remaining issues. MSHA issued an ANPRM on September 25, 2002 to obtain additional information and to develop a proposed rule in 2003.

Statement of Need:

As a result of the first partial settlement with the litigants, MSHA published two documents in the Federal Register on July 5, 2001. One document delayed the effective date of 57.5066(b) regarding the tagging provisions of the maintenance standard; clarified the effective dates of certain provisions of the final rule; and gave correction amendments.

The second document was a proposed rule to clarify 57.5066(b)(1) and (b)(2) of the maintenance standards and to add a new paragraph (b)(3) to 57.5067 regarding the transfer of existing diesel equipment from one underground mine to another underground mine. The final rule on these issues was published February 27, 2002, and became effective March 29, 2002.

As a request of the second partial settlement agreement, MSHA also agreed to proposed specific changes to the 2001 DPM final rule. On September 25, 2002, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) (67 FR 60199). In response to commenters, MSHA intends at this time to propose changes only to the interim DPM standard of 400 micrograms per cubic meter of air. In a separate rulemaking, the Agency will propose a rule to revise the final concentration limit of 160 micrograms per cubic meter of air pursuant to the DPM settlement agreement. The scope of both rulemakings is limited to the settlement agreement. The current rulemaking addresses the following provisions:

57.5060(a)—Propose to change the existing DPM surrogate from total carbon to elemental carbon; propose that a single personal sample of miner's exposure would be an adequate basis for MSHA compliance determinations; and propose the current hierarchy of controls that MSHA applies in its existing metal and nonmetal exposure based health standards for abating violations.

57.5060(c)—Propose to adapt to the interim limit the existing provision that allows mine operators to apply to the Secretary for additional time to come into compliance with the final concentration limit. MSHA also agreed to propose to include consideration of economic feasibility, and to allow for annual renewals of such special extensions.

57.5060(d)—This existing provision permits miners to engage in certain activities in concentrations exceeding the interim and final limits upon

application and approval from the Secretary. MSHA asked commenters if this provision should be removed since the Agency agreed to propose the existing hierarchy of controls.

57.5060(e)—MSHA agreed to propose to remove the existing prohibition on the use of personal protective equipment.

57.5060(f)—MSHA agreed to propose to remove the prohibition on the use of administrative controls.

57.5061(b)—MSHA is proposing to change the reference from ''total carbon'' to ''elemental carbon.''

57.5061(c)—MSHA is proposing to delete the references to ''area'' and ''occupational'' sampling for compliance.

57.5062—MSHA agreed to propose revisions to the existing diesel control plan.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 101 and 103 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

This rulemaking action is a result of the parties' settlement agreement. This action will not decrease protection for miners.

Anticipated Cost and Benefits:

MSHA's preliminary economic analysis indicates minimum costs to the mining industry.

Risks:

Several epidemiological studies have found that exposure to diesel exhaust presents potential health risk to the miners. These potential adverse health effects range from headaches and nausea to respiratory disease and cancer. In the confined space of the underground mining environment, occupational exposure to diesel exhaust may present a greater hazard due to ventilation limitations and the presence of other airborne contaminants, such as toxic mine dusts or mine gases. We believe that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate matter. Proceeding with rulemaking on the provisions discussed above will more effectively reduce miners exposure to DPM.

Timetable:

Action	Date	FR Cite
ANPRM	09/25/02	67 FR 60199
ANPRM Comment Period End	11/25/02	
NPRM	08/14/03	68 FR 48668
NPRM Comment Period End	10/14/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

None

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DOL—Occupational Safety and Health Administration (OSHA)

PRERULE STAGE

89. OCCUPATIONAL EXPOSURE TO HEXAVALENT CHROMIUM (PREVENTING OCCUPATIONAL ILLNESS: CHROMIUM)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910

Legal Deadline:

NPRM, Judicial, October 4, 2004, NPRM.

Abstract:

In July 1993, the Occupational Safety and Health Administration (OSHA) was petitioned for an emergency temporary standard (ETS) to reduce the permissible exposure limit (PEL) for occupational exposures to hexavalent chromium (CrVI). The Oil, Chemical, and Atomic Workers International Unions (OCAW) and Public Citizen's Health research Group (HRG) petitioned OSHA to promulgate an ETS to lower the PEL for CrVI compounds to 0.5 micrograms per cubic meter of air (ug/mg3) as an eight-hour, time-weighted average (TWA). The current PEL in general industry is a ceiling value of 100 ug/m3, measured as CrVI and reported as chromic anhydride (CrO3). The amount of CrVI in the anhydride compound equates to a PEL of 52 ug/m3. The ceiling limit applies to all forms of CrVI, including chromic acid and chromates, lead chromate, and zinc chromate. The current PEL of CrVI in the construction industry is 100 ug/m3 as a TWA PEL, which also equates to a 52 ug/m3. After reviewing the petition, OSHA denied the request for an ETS and initiated a section 6(b)(5) rulemaking.

OSHA began collecting data and performing preliminary analyses relevant to occupational exposure to CrVI. However, in 1997, OSHA was sued by HRG for unreasonable delay in issuing a final CrVI standard. The 3rd Circuit, U.S. Court of Appeals ruled in OSHA's favor and the Agency continued its data collection and analytic efforts on CrVI. In 2002, OSHA was sued again by HRG for continued unreasonable delay in issuing a final CrVI standard. In August, 2002 OSHA published a Request for Information on CrVI to solicit additional information on key issues related to controlling exposures to CrVI and on December 4, 2002 OSHA announced its intent to proceed with developing a proposed standard. On December 24, 2002, the 3rd Circuit, U.S. Court of Appeal ruled in favor of HRG and ordered the Agency to proceed expeditiously with a CrVI standard. A subsequent order from the court on April 2, 2003 established an October 4, 2004 deadline for publication of a proposed standard and a January 18, 2006 deadline for publication of the final standard.

The major illnesses associated with occupational exposure to CrVI are lung cancer and dermatoses. OSHA estimates that approximately one million workers are exposed to CrVI on a regular basis in all industries. The major uses of CrVI are: as a structural and anticorrosive element in the production of stainless steel, ferrochromium, iron and steel, and in electroplating, welding and painting.

Statement of Need:

Approximately one million workers are exposed to CrVI in general industry, maritime, construction, and agriculture. Industries or work processes that could be particularly affected by a standard for CrVI include: Electroplating, welding, painting, chromate production, chromate pigment production, ferrochromium production,

iron and steel production, chromium catalyst production, and chromium dioxide and sulfate production. Exposure to CrVI has been shown to produce lung cancer, an often fatal disease, among workers exposed to CrVI compounds. The International Agency for Research on Cancer (IARC) classifies CrVI compounds as a Group 1 Carcinogen: Agents considered to be carcinogenic in humans. The Environmental Protection Agency (EPA) and the American Conference of Governmental Hygienists (ACGIH) have also designated CrVI compounds as known and confirmed human carcinogens, respectively. Similarly, the National Institute for Occupational Safety and Health (NIOSH) considers CrVI compounds to be potential occupational carcinogens. OSHA's current standards for CrVI compounds, adopted in 1971, were established to protect against nasal irritation. Therefore, there is a need to revise the current standard to protect workers from lung cancer.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of lung cancer and dermatoses and that rulemaking is needed to substantially reduce the risk.

Alternatives:

OSHA had considered non-regulatory approaches, including the dissemination of guidance on its web site. However, OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of CrVI and the Agency has been ordered by the U.S. Court of Appeals to move forward with a final rule. 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 been developed.

Risks:

A detailed risk analysis has not yet been completed for this rule.

Timetable:

Action	Date	FR Cite
Request for Information	08/22/02	67 FR 54389
Comment Period End	11/20/02	
Initiate SBREFA Process	12/00/03	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

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DOL—OSHA

90. OCCUPATIONAL EXPOSURE TO CRYSTALLINE SILICA

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910; 29 CFR 1915; 29 CFR 1917; 29 CFR 1918; 29 CFR 1926

Legal Deadline:

None

Abstract:

Crystalline silica is a significant component of the earth's crust, and many workers in a wide range of industries are exposed to it, usually in the form of respirable quartz or, less frequently, cristobalite. Chronic silicosis is a uniquely occupational disease resulting from exposure of employees over long periods of time (10 years or more). Exposure to high levels of respirable crystalline silica causes acute or accelerated forms of silicosis that are ultimately fatal. The current OSHA permissible exposure limit (PEL) for general industry is based on a formula recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1971 (PEL=10mg/cubic meter/(% silica + 2), as respirable dust). The current PEL for construction and maritime (derived from ACGIH's 1962 Threshold Limit Value) is based on particle counting technology, which is considered obsolete. NIOSH and ACGIH recommend a 50ug/m3 exposure limit for respirable crystalline silica.

Both industry and worker groups have recognized that a comprehensive standard for crystalline silica is needed to provide for exposure monitoring, medical surveillance, and worker training. The American Society for Testing and Materials (ASTM) has published a recommended standard for addressing the hazards of crystalline silica. The Building Construction Trades Department of the AFL–CIO has also developed a recommended comprehensive program standard. These standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance.

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 analytical methods to ensure that employers and employees are receiving reliable data on 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. The Advisory Committee for Construction Safety and Health has also formed a silica working group to assist the Agency in addressing construction-related issues during the development of the proposed rule.

Statement of Need:

Over two million workers are exposed to crystalline silica dust in general industry, construction and maritime industries. Industries that could be particularly affected by a standard for crystalline silica include: foundries, industries that have abrasive blasting operations, paint manufacture, glass and concrete product manufacture, brick making, china and pottery manufacture, manufacture of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing. The seriousness of the health hazards associated with silica exposure is demonstrated by the fatalities and disabling illnesses that

continue to occur; between 1990 and 1996, 200 to 300 deaths per year are known to have occurred where silicosis was identified on death certificates as an underlying or contributing cause of death. It is likely that many more cases have occurred where silicosis went undetected. In addition, the International Agency for Research on Cancer (IARC) has designated crystalline silica as a known human carcinogen. Exposure to crystalline silica has also been associated with an increased risk of developing tuberculosis and other nonmalignant respiratory diseases, as well as, renal and autoimmune respiratory diseases. Exposure studies and OSHA enforcement data indicate that some workers continue to be exposed to levels of crystalline silica far in excess of current exposure limits. Congress has included compensation of silicosis victims on Federal nuclear testing sites in the Energy Employees' Occupational Illness Compensation Program Act of 2000. There is a particular need for the Agency to modernize its exposure limits for construction and maritime, and to address some specific issues that will need to be resolved to propose a comprehensive standard.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of silicosis and other serious disease and that rulemaking is needed to substantially reduce the risk. In addition, the proposed rule will recognize that the PELs for construction and maritime are outdated and need to be revised to reflect current sampling and analytical technologies.

Alternatives:

Over the past several years, the Agency has attempted to address this problem through a variety of non-regulatory approaches, including initiation of a Special Emphasis Program on silica in October 1997, sponsorship with NIOSH and MSHA of the National Conference to Eliminate Silicosis, and dissemination of guidance information on its Web site. OSHA has determined that rulemaking is a necessary step to ensure that workers are protected from the hazards of crystalline silica. The Agency is currently evaluating several options for the scope of the rulemaking.

Anticipated Cost and Benefits:

The scope of the proposed rulemaking and estimates of the costs and benefits are still under development.

Risks:

A detailed risk analysis has not yet been completed for this rule.

Timetable:

Action	Date	FR Cite
Complete SBREFA Report	01/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Undetermined

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DOL—OSHA

FINAL RULE STAGE

91. ASSIGNED PROTECTION FACTORS: AMENDMENTS TO THE FINAL RULE ON RESPIRATORY PROTECTION

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910.134

Legal Deadline:

None

Abstract:

In January 1998, OSHA published the final Respiratory Protection standard (29 CFR 1910.134), except for reserved provisions on assigned protection factors (APFs) and maximum use concentrations (MUCs). APFs are numbers that describe the effectiveness of the various classes of respirators in reducing employee exposure to airborne contaminants (including particulates, gases, vapors, biological agents, etc.). Employers, employees, and safety and health professionals use APFs to determine the type of respirator to protect the health of employees in various hazardous environments. Maximum use concentrations establish the maximum airborne concentration of a contaminant in which a respirator with a given APF may be used.

Currently, OSHA relies on the APFs developed by NIOSH in the 1980s unless OSHA has assigned a different APF in a substance-specific health standard. However, many employers follow the more recent APFs published in the industry consensus standard, ANSI Z88.2–1992. For some classes of respirators, the NIOSH and ANSI APFs vary greatly.

This rulemaking action will complete the 1998 standard, reduce compliance confusion among employers, and provide employees with consistent and appropriate respiratory protection. On June 6, 2003, OSHA published an NPRM on Assigned Protection Factors in the Federal Register at 68 FR 34036 containing a proposed APF table, and requesting public comment. The extended comment period ended October 2, 2003.

Statement of Need:

About five million employees wear respirators as part of their regular job duties. Due to inconsistencies between the APFs found in the current industry consensus standard (ANSI Z88.2–1992) and in the NIOSH Respirator Decision Logic, employers, employees, and safety and health professionals are often uncertain about what respirator to select to provide protection against hazardous air contaminants. 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 estimated compliance costs for OSHA's proposed APF rule are $4.6 million. The APFs proposed in this rulemaking help to ensure that the benefits attributed to proper respiratory protection under 29 CFR 1910.134 are achieved, as well as provide an additional degree of protection.

Risks:

The preamble to the final Respiratory Protection rule (63 FR 1270, Jan. 8, 1998) discusses the significance of the risks potentially associated with the use of respiratory protection. No independent finding of significant risk has been made for the APF rulemaking, since it only addresses a single provision of the larger rule.

Timetable:

Action	Date	FR Cite
ANPRM	05/14/82	47 FR 20803
ANPRM Comment Period End	09/13/82	
NPRM	11/15/94	59 FR 58884
Final Rule	01/08/98	63 FR 1152
Final Rule Effective	04/08/98	
NPRM	06/06/03	68 FR 34036
NPRM Comment Period End	09/04/03	
Other/NPRM Comment Period Extended	10/02/03	68 FR 53311
Public Hearing on 01/28/2004	11/12/03	68 FR 64036
Final Rule: Revocation of Respiratory Protection M. TB	12/00/03	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

At the time of the revision of the 1972 standard, OSHA decided that because its proposed standard for occupational exposure to tuberculosis (TB), published three months earlier, included a comprehensive respiratory protection provision, the agency would allow compliance with the previous respirator standard for TB protection until completion of the TB rulemaking. Thus, pending conclusion of the TB rulemaking, OSHA redesignated the old respiratory protection standard in a new section entitled ''Respiratory Protection for M. Tuberculosis.'' Because OSHA has decided to withdraw its proposed TB standard, the agency is revoking the designated respiratory protection standard, and will begin applying the general industry respiratory protection standard (29 CFR 1910.134) to respiratory protection against TB.

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DOL—OSHA

92. 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 published 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 work force. 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:

The Agency has estimated annual costs of the NPRM to be $4.3 million, and that there will be cost savings of $6.2 million, in addition to avoiding fatalities and injuries.

Risks:

The Agency has estimated that compliance with the NPRM would prevent one fatality and 102 lost workday injuries annually.

Timetable:

Action	Date	FR Cite
NPRM	12/11/02	67 FR 76213
Comment Period End	03/11/03	
Final Rule	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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DOL—OSHA

93. 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 and health standards.

Statement of Need:

Some parts of OSHA's standards are out of date, duplicative, unnecessary, or inconsistent. The Agency needs to periodically review its standards and make needed corrections. This effort results in standards that are easier for employers and employees to follow and comply with, and thus enhances compliance and worker protection.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary finding that the OSHA standards need to be updated to bring them up to date, reduce inconsistency, and remove unneeded provisions.

Alternatives:

OSHA has considered updating each standard as problems are discovered, but has determined that it is better to make such changes to groups of standards so it is easier for the public to comment on like standards. OSHA has also considered the inclusion of safety standards that need to be updated. However, the Agency has decided to pursue a separate rulemaking for safety issues because the standards to be updated are of interest to different stakeholders.

Anticipated Cost and Benefits:

This revision of OSHA's standards is a deregulatory action. It will reduce employers' compliance obligations.

Risks:

The project does not address specific risks, but is intended to improve OSHA's standards by bringing them up 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	
NPRM Comment Period Extended	01/08/03	68 FR 1023
Second NPRM Comment Period End	01/30/03	
Public Hearing	07/08/03	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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DOL—Office of the Assistant Secretary for Veterans' Employment & Training (ASVET)

PROPOSED RULE STAGE

94. UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT REGULATIONS

Priority:

Other Significant

Legal Authority:

38 USC 4331(a)

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The Secretary's commitment to protecting the employment rights of servicemembers as they return to the civilian work force is reflected by the initiative to promulgate regulations implementing the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA). USERRA provides employment and reemployment protections for members of the uniformed services, including veterans and members of the Reserve and National Guard. The Department has not previously issued implementing regulations under USERRA, albeit the law dates back to 1994. Authoritative written guidance interpreting USERRA will ensure that our servicemembers serve secure in the knowledge that they will be able to return to their jobs with the same pay, benefits, and status they would have attained had they not been away on military duty.

Statement of Need:

The Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA), 38 U.S.C. 4301–4333, provides employment and reemployment rights for members of the uniformed services, including veterans and members of the Reserve and National Guard. Under USERRA, service members who leave their civilian jobs for military service can perform their duties with the knowledge that they will be able to return to their jobs with the same pay, benefits, and status they would have attained had they not been away on duty. USERRA also assures that they will not suffer discrimination in

employment because of their military service.

The Department has not issued implementing regulations under USERRA. In the absence of regulations, VETS has engaged in significant compliance assistance efforts, including a Non-Technical Resource Guide to USERRA, briefings for service members and employers, a web-based elaws Advisor and other web-based aids such as FAQs, a toll-free help line for basic USERRA questions, and informal email responses to electronic inquiries. VETS has also issued about 40 memoranda interpreting issues that have arisen under USERRA. In addition, VETS has prepared a draft USERRA Handbook as part of its compliance assistance efforts. A copy of the draft Handbook is attached.

Approximately 300,000 members of the National Guard and Reserve have been called up since the President's declaration of a national emergency following the attacks of September 11, 2001. As service members conclude their tours of duty and return to civilian employment, it is important for employers to recognize that USERRA requires that returning veterans receive many important benefits of employment that they would have attained had they been continuously employed. It is also important for service members to know what their rights and responsibilities are under the law, and how the Department can assist them in enforcing these rights.

In the past year, the Department has experienced a tremendous increase in the number of inquiries from employers and members of the Reserves. The Department has responded to over 9,500 requests for technical assistance, and has provided USERRA briefings to nearly 50,000 persons, including members of the National Guard, Reserve and employer groups. These numbers are conservative, as not all instances of technical assistance have been documented. The volume of technical assistance requests indicates a strong public interest in authoritative written guidance from the Department. The complexity of the issues raised demonstrates the value of such guidance.

Another consideration is the possibility of the call to active duty of a large number of additional National Guard and Reserve members. The ongoing war on terrorism is widely expected to last for a significant period of time. Persons currently mobilized are serving for much longer periods of time than those who served in Desert Storm, thereby causing greater concerns among the Reserve and employer communities. Any escalation of the use of National Guard and Reserve personnel will cause a corresponding increase in the need for USERRA information among Reservists, employers and the public. Authoritative written USERRA guidance will ensure that the capability of VETS' staff to respond promptly is not exceeded and that the information provided is uniform and correct.

The high volume of requests for technical assistance received by the Department since September 2001 indicates that there is a significant need for authoritative USERRA guidance. USERRA regulations would provide authoritative guidance by codifying the Department's interpretations of the law and the Department's procedures for enforcing the law.

Summary of Legal Basis:

USERRA authorizes the Secretary of Labor, in consultation with the Secretary of Defense, to issue regulations implementing USERRA with regard to States, local governments and private employers. 38 U.S.C. 4331(a).

Alternatives:

In lieu of regulations, the Department could choose to continue its compliance assistance efforts, and could issue interpretations of USERRA in the form of the USERRA Handbook, policy memoranda or other less formal means. These would not benefit from broad-based public input, nor would they receive the same level of deference as regulations. See United States v. Mead Corp., 533 U.S. 218, 230 (2001).

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Local, State

Agency Contact:

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BILLING CODE 4510–23–S

DEPARTMENT OF TRANSPORTATION (DOT)

Statement of Regulatory Priorities

The Department of Transportation (DOT) consists of nine operating administrations, the Bureau of Transportation Statistics and the Office of the Secretary, each of which has statutory responsibility for a wide range of regulations. For example, DOT regulates safety in the aviation, motor carrier, railroad, mass transit, motor vehicle, commercial space, and pipeline transportation areas. DOT regulates aviation consumer and economic issues and provides financial assistance and writes the necessary implementing rules for programs involving highways, airports, mass transit, the maritime industry, railroads, and motor vehicle safety. It writes regulations carrying out such disparate statutes as the Americans with Disabilities Act and the Uniform Time Act. Finally, DOT has responsibility for developing policies that implement a wide range of regulations that govern internal programs such as acquisition and grants, access for the disabled, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, and the use of aircraft and vehicles.

The Department has adopted a regulatory philosophy that applies to all its rulemaking activities. This philosophy is articulated as follows: DOT regulations must be clear, simple, timely, fair, reasonable, and necessary. They will be issued only after an appropriate opportunity for public comment, which must provide an equal chance for all affected interests to participate, and after appropriate consultation with other governmental entities. The Department will fully consider the comments received. It will assess the risks addressed by the rules and their costs and benefits, including the cumulative effects. The Department will consider appropriate alternatives, including nonregulatory approaches. It will also make every effort to ensure that legislation does not impose unreasonable mandates.

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 email notification when the Department issues a rulemaking document; creation of an electronic rulemaking tracking and coordination system; the use of direct final rulemaking; and the use of regulatory negotiation are a few examples of this.

In addition, the Department continues to engage in a wide variety of activities to help cement the partnerships between its agencies and its customers that will produce good results for transportation programs and safety. The Department's agencies also have established a number of continuing partnership mechanisms in the form of rulemaking advisory committees.

The Department 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.

One of the Department's primary efforts during the past year was to overhaul and expedite the rulemaking process and to move long-pending rulemaking projects to completion. To achieve these goals, the Department took a number of steps. For example, the Department created an effective tracking system for significant rulemakings to ensure that rules are either completed in a timely manner or that delays are identified and fixed. Through this tracking system, a monthly report is generated. To make its efforts more transparent, the Department has made this report internet-accessible. By doing this, the Department is providing valuable information concerning our rulemaking activity and is providing information necessary for the public to evaluate the Department's progress in meeting its commitment to completing rulemakings in a timely manner.

The Department also conducted a review of the current status of all rulemakings pending within the Department. This review helped to identify and resolve problems with delay of older rulemakings, and has resulted in a significant increase in our rulemaking productivity. Furthermore, in a concerted effort to ''clean up'' the Department's Regulatory Agenda, we also identified a number of proceedings for which no action had been taken in a number of years. Those proceedings for which no further action was contemplated were withdrawn or terminated in a July 2003 notice published in the Federal Register.

The Department will continue to place great emphasis on the need to complete high quality rulemakings by involving senior Departmental officials in regular meetings to resolve issues expeditiously.

Office of the Secretary of Transportation (OST)

The Office of the Secretary (OST) oversees the regulatory process for the Department. OST implements the Department's regulatory policies and procedures and is responsible for ensuring the involvement of top management in regulatory decisionmaking. Through the General Counsel's office, OST is also responsible for ensuring that the Department complies with Executive Order 12866 and other legal and policy requirements affecting rulemaking, including new statutes and Executive Orders. Although OST's principal role concerns the review of the Department's significant rulemakings, this office has the lead role in the substance of projects concerning aviation economic rules and those affecting the various elements of the Department.

OST provides guidance and training regarding compliance with regulatory requirements and process for use by personnel throughout the Department. OST also plays an instrumental part in the Department's efforts to improve our economic analyses, risk assessments, and regulatory flexibility analyses.

OST also leads and coordinates the Department's response to Administration and congressional proposals that concern the regulatory process. The General Counsel's Office works closely with representatives of other agencies, the Office of Management and Budget, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

During fiscal year 2004, OST expects to complete work on a final rule on

Computer Reservation Systems. 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 these reporting requirements during FY 2004.

Federal Aviation Administration (FAA)

The FAA issues regulations to provide a safe, secure, and efficient global aviation system for civil aircraft. In an effort to make sure their rules are concise and easy to understand, the FAA reexamined the use of plain language in its regulations. The initial result of this review was revisions to 14 CFR part 11, which delineates the process for rulemaking changes. We have extended this initiative to include plain language revisions to our regulatory documents, advisory material, handbook guidance, and all reports and correspondence we prepare. Other actions include:

Supporting the FAA's Safety Agenda on Safer Skies. This agenda is based on a comprehensive review of the causes of aviation accidents and is designed to bring about a five-fold(80 percent) reduction in fatal accidents. Projects related to controlled flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decisionmaking, and cabin safety are some of the focus areas identified that may result in rulemaking advisory and guidance materials.

Continuing to involve the aviation community early in the regulatory process. The Aviation Rulemaking Advisory Committee completed numerous reports and recommendations, leading to the publication of seven regulatory actions and issuance of several advisory circulars and other guidance materials. The FAA Aging Transport Nonstructural Systems Plan addresses concerns with potential safety issues associated with problems that may develop in transport category airplanes systems as a result of wear and degradation in service. One important component of the plan is use of the Aging Transport Nonstructural Systems Rulemaking Advisory Committee to provide a mechanism for public input to FAA activities. The FAA will continue to receive recommendations from the Committee in the form of regulations, guidance materials, and training requirements supporting enhanced airworthiness for airplane systems.

Continuing to harmonize the U.S. aviation regulations with those of other countries. The harmonization of the U.S. regulations with the European Joint Aviation Regulations (JAR) is the FAA's most comprehensive long-term rulemaking effort. The differences worldwide in certification standards, practice and procedures, and operating rules must be identified and minimized to reduce the regulatory burden on the international aviation system. The differences between the FAA regulations and the requirements of other nations impose a heavy burden on U.S. aircraft manufacturers and operations. Harmonization and standardization should help the U.S. aerospace industry remain internationally competitive. While the overall effort to achieve this is global, it will be accomplished by many small, individual, nonsignificant rulemaking projects. The FAA has published 41 regulations based on recommendations of ARAC that will lead to harmonizing FAA regulations and Joint Aviation Requirements.

Continuing to recognize the needs of small entities by complying with the Small Business Regulatory Enforcement Fairness Act and addressing small entity concerns whenever appropriate in rulemaking documents. In response the Act, the FAA has established a Small Entity Contact, a Web site on FAA's home page, a toll-free number, and an email 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 2003-2004 include final rules concerning certification of airports and flight simulation device requirements.

Federal Highway Administration (FHWA)

The FHWA anticipates that its priority for fiscal year 2004 will be the ongoing regulatory implementation of the Transportation Equity Act for the 21st Century, 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)

FMCSA commenced operations on January 2, 2000, pursuant to the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Public Law 106 173;159), as codified at 49 U.S.C. 167; 113, to improve the administration of the Federal motor carrier safety program. The agency's primary mission is to reduce crashes, injuries, and fatalities involving large trucks and buses. Since its inception, FMCSA has developed a strong Safety Action Plan to guide it toward reducing the number of large truck- and bus-involved fatalities. DOT's safety goal for all its surface transportation agencies is to reduce the fatality rate by 41% during a period from 1996 to 2008. Although any life lost in a traffic crash is too many, FMCSA will strive to meet and exceed this safety goal. For example, regulations relating to performance standards for vehicles, drivers and motor carriers will help achieve this goal. In MCSIA, Congress put special emphasis on the importance of timely rulemaking as a way to achieve reductions in the number and severity of large truck-involved crashes. FMCSA is committed to developing an effective and efficient regulatory program that meets the expectations of Congress, its stakeholders and partners, and the general public. To improve both the quality and timeliness of the agency's rulemakings, FMCSA established a rulemaking process for the development of its motor carrier safety regulations.

In fiscal year 2004, FMCSA must issue the following final rules pursuant to the settlement agreement entered into by the parties and the court's order in In re Citizens for Reliable and Safe Highways, et al., No. 02-1363 (D.C. Cir.) (February 21, 2003): Safety Performance History of New Drivers (03/2004); Minimum Training Requirements for Longer Combination Vehicle (LCV) Operators and LCV Driver-Instructor

Requirements (03/2004); Minimum Training Requirements for Entry-Level Commercial Motor Vehicle Operators 05/2004); and Hazardous Materials Safety Permits (06/2004). It also continues to expedite a number of other important rulemakings.

National Highway Traffic Safety Administration (NHTSA)

The statutory responsibilities of the National Highway Traffic Safety Administration (NHTSA) relating to motor vehicles include reducing the number of, and mitigating the effects of, motor vehicle crashes and related fatalities and injuries; providing safety performance information to aid prospective purchasers of vehicles, child restraints, and tires; and improving automotive fuel efficiency. NHTSA pursues policies that encourage the development of nonregulatory approaches when feasible in meeting its statutory mandates. It issues new standards and regulations or amendments to existing standards and regulations when appropriate. It ensures that regulatory alternatives reflect a careful assessment of the problem and a comprehensive analysis of the benefits, costs, and other impacts associated with the proposed regulatory action. Finally, it considers alternatives consistent with the Administration's regulatory principles.

NHTSA has identified two high priority vehicle safety areas, vehicle compatibility and rollover mitigation, and released reports in 2003 analyzing problems in each of those areas and describing actions to address them. An important regulatory priority, upgrading side impact protection, will aid efforts in both of these areas. Another regulatory priority for NHTSA is reforming the automobile fuel economy standards program (CAFE). In addition, NHTSA has published its plan for vehicle safety rulemaking priorities, NHTSA Vehicle Safety Rulemaking Priorities and Supporting Research: 2003-2006. The plan highlights the agency's priority rulemaking actions to help address the most significant vehicle safety needs.

In addition to numerous programs that focus on the safe performance of motor vehicles, the Agency is engaged in a variety of programs to improve driver and occupant behavior. These programs emphasize the human aspects of motor vehicle safety and recognize the important role of the States in this common pursuit. NHTSA has identified two high priority areas, safety belt use and impaired driving. It released a report in 2003 analyzing safety belt use problems and describing actions to address them. A report addressing impaired driving is expected later this year. Other behavioral efforts include encouraging initiatives in such areas as child safety-seat use, activities aimed at combating aggressive driving, and consumer information activities.

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 the consensus recommendations serve the public interest, the resulting rule is very likely to be better understood, more widely accepted, more cost-beneficial, and more correctly applied. Where consensus cannot be achieved, however, FRA will fulfill its regulatory role without the benefit of RSAC's recommendations.

The RSAC has met on a quarterly basis so far and currently has working groups addressing the following tasks: 1) the review of FRA regulations for their applicability to historic railroads; 2) the development of safety standards for locomotive crashworthiness; 3) the development of safety standards for locomotive working conditions; 4) the development of locomotive event recorder accident survivability standards; 5) the development of regulations governing the use of processor-based signal and train control systems; 6) the revision of FRA's blue signal protection requirements for workers performing certain duties on, under or between rolling equipment; and 7) the revision of FRA's standards for the safety of cars used by railroad carriers to transport passengers.

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 2003-2004 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 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.

In conjunction with the Office of the Secretary, 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)

FINAL RULE STAGE

95. +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 has regulated 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 disclosing fares and travel agency service fees by travel agencies. The Department has issued a notice of proposed rulemaking that tentatively concluded that most of the rules should be readopted, possibly with changes, for comment on other options, including terminating most or all of the rules. As part of this action, we are 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 no system operating in the United States is controlled by any U.S. 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 a notice of proposed rulemaking asking for comment on whether the Department should readopt most of the existing rules, except the rules prohibiting systems from charging airlines discriminatory fees and the rule requiring airlines with a system ownership interest to sell their services through competing systems. The Department also asked for comment on whether the rules should be phased out or eliminated, and on whether the rules should be strengthened in several respects.

Anticipated Cost and Benefits:

The Department included 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 had also been able to 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 could also impose excessive costs on the systems and airlines. The Department asked for comment on whether the risks still exist in light of on-going industry developments 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	11/15/02	67 FR 69366
NPRM Extension of Comment Period	12/09/02	67 FR 72869
NPRM Notice of Petition Response Date	01/09/03	
NPRM Comment Period End	01/14/03	
NPRM Reply Comment Period End	02/13/03	
Extended Comment Period End	03/16/03	
NPRM Comment Period Extended	05/09/03	68 FR 24896
Extended Reply Comment Period End	05/15/03	
Comment Period End	06/09/03	
Final Action	01/00/04	

Regulatory Flexibility Analysis Required:

Yes

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—Federal Aviation Administration (FAA)

FINAL RULE STAGE

96. +FLIGHT SIMULATION DEVICE QUALIFICATION

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 44701 to 44703; 49 USC 44707; 49 USC 44709; 49 USC 44711; 49 USC 45102 to 45103; 49 USC 45301 to 45302

CFR Citation:

14 CFR 1; 14 CFR 11; 14 CFR 60; 14 CFR 61; 14 CFR 63; 14 CFR 141; 14 CFR 142

Legal Deadline:

None

Abstract:

This action will amend the regulations establishing flight simulation device qualification requirements for all certificate holders in a new part. The basis of these requirements currently exists in different parts of the FAA's regulations and in advisory circulars. The proposed changes would consolidate and update flight simulation device requirements. This action is significant because of substantial public interest.

Statement of Need:

It is important to consolidate and update flight simulation device requirements to ensure that users of flight simulation devices receive the best possible training in devices that closely match the performance and handling characteristics of the aircraft being simulated.

Summary of Legal Basis:

Section 44701, title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

The FAA chartered an Aviation Rulemaking Committee to develop alternative rule language to Notice No. 02–11.

Anticipated Cost and Benefits:

The FAA has placed a Draft Regulatory Evaluation of the NPRM in the docket.

Risks:

The purpose of this rulemaking is to ensure that users of flight simulation devices receive the best possible training in devices that closely match the performance and handling characteristics of the aircraft being simulated.

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 20284
NPRM Comment Period Extended	11/15/02	67 FR 69149
Notice of On-Line Public Forum	11/21/02	67 FR 70184
NPRM Comment Period End	12/24/02	
NPRM Extended Comment Period End	02/24/03	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 2120–AH07

DOT—National Highway Traffic Safety Administration (NHTSA)

PRERULE STAGE

97. ● +REFORMING THE AUTOMOBILE FUEL ECONOMY STANDARDS PROGRAM

Priority:

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

Legal Authority:

49 USC 32910

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

Through this action, the agency intends to begin a public discussion on potential ways, within current statutory authority, to update the Corporate Average Fuel Economy (CAFE) Program and to make it more consistent with our public policy objectives. The agency will seek comments on a number of possible concepts and measures, and invite the public to present additional concepts not presented here. The discussion is not intended to address the stringency of proposed CAFE standards in the future, but rather the basic structure of the CAFE program. The agency is interested in any suggestions towards revamping the CAFE program in such a way as to enhance overall fuel economy while protecting occupant safety and American jobs.

The potential changes range from modest changes to existing definitions separating passenger cars from light trucks (i.e., vans, pickup trucks and SUVs) to more significant structural changes to light truck fuel economy standards. The definitional changes could potentially expand the definition of light truck to include larger SUV's that are not currently subject to fuel economy standards, add criteria to existing definitions of light trucks and ensure that vehicles subject to the lower fuel economy standards applicable to trucks have sufficient functionality to be properly classified as trucks. The advance notice also requests comment on changing the existing approach to setting light truck fuel economy standards from one of setting a fixed standard applicable to all sizes of trucks in the light truck fleet to one of setting a standard that changes in relationship to a selected attribute of trucks in the fleet. Under such an attribute-based standard, the required fuel economy would change in relationship to either the weight of the vehicle, the size of the vehicle, or both.

Statement of Need:

There are four prominent criticisms of the light truck CAFE program. They relate to energy security, traffic safety, employment of American workers, and modernization of the definition and classification of light trucks. First, concern has been raised that the energy-saving potential of the CAFE program is hampered by the current regulatory structure. Second, concern has been raised that the current light truck CAFE standards could create safety risks by encouraging vehicle manufacturers to achieve greater fuel economy by downweighting their light truck offerings. A third reason for considering CAFE reform relates to the adverse economic impacts that may result from such future increases in the stringency of CAFE standards. A fourth reason for considering CAFE reform is to modernize the definitions and classifications of light trucks within the program. The markets for, and designs of, cars and light trucks have changed substantially since the inception of the CAFE program in the late 1970's.

Summary of Legal Basis:

Section 32910(d) of Title 49 of the United States Code provides that the Administrator may prescribe regulations necessary to carry out his duties under Chapter 329, Automobile fuel economy.

Alternatives:

The advanced notice of proposed rulemaking sets forth a number of alternative courses of action that could be pursued singly or in combination. In addition to these, the agency could simply choose not to pursue any changes to the CAFE program.

Anticipated Cost and Benefits:

The costs and benefits of the potential changes addressed in this action have not yet been assessed. Given the wide variety of actions that could be taken, calculating, estimating or predicting the costs and benefits for the potential changes would be extremely speculative.

Risks:

Changes to the structure of the CAFE standards or changes to the definitions of light trucks may have positive or negative safety impacts. Given the wide variety of actions that could be taken, calculating, estimating or predicting safety impacts for the potential changes would be extremely speculative.

Timetable:

Action	Date	FR Cite
ANPRM	11/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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DOT—NHTSA

PROPOSED RULE STAGE

98. ● +SIDE IMPACT PROTECTION UPGRADE–STANDARD 214

Priority:

Other Significant

Legal Authority:

49 USC 322; 49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166

CFR Citation:

49 CFR 571.214

Legal Deadline:

None

Abstract:

Two Federal motor vehicle safety standards (FMVSS) No. 201, ''Occupant Protection in Interior Impact'' and No. 214, ''Side Impact Protection,'' specify requirements for side impact protection. At present, FMVSS No. 214 specifies a moving deformable barrier (MDB) test addressing mainly the chest injury problem. The head injury reduction is partially addressed in FMVSS No. 201. The agency is considering amending FMVSS No. 214 to add a vehicle-to-pole impact test to reduce the number of fatal and serious head injuries not addressed in FMVSS No. 201.

Statement of Need:

While the side impact protection standard currently specifies a MDB test for the purpose of reducing chest injuries, the head injury problem in side crashes is not addressed by the standard. In 1990, when the standard was published, no safety countermeasures were available to address this problem effectively. In 1995, the agency amended the occupant protection in the interior impact standard (FMVSS No. 201) to add an in-vehicle component test for enhanced upper interior head impact protection. However, head impacts with exterior objects, such as trees, poles, and narrow rigid structures, are not addressed in the requirements of FMVSS No. 201. These head impacts constitute a serious safety problem today. On the other hand, there are readily available countermeasures now, such as advanced inflatable head protection systems, which would provide occupant protection in these crashes. The agency plans to address this safety problem by amending the side impact protection standard (FMVSS No. 214) to add a vehicle-to-pole test.

Summary of Legal Basis:

Section 30111, title 49 of the USC, states that Secretary shall prescribe motor vehicle safety standards. 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 to improve the side impact standard.

Alternatives:

The agency will examine existing test procedures developed by various organizations, conduct research on the development of a new MDB and advanced dummy test devices, and keep abreast of the development of new head protection systems.

Anticipated Cost and Benefits:

The agency is evaluating the benefits and costs associated with requiring a vehicle-to-pole test in FMVSS No. 214.

Risks:

Current motor vehicles provide numerous occupant protection systems, such as air bags, safety seat belts, and strategically placed energy absorption padding. Nevertheless, approximately 1,440 fatal and 2,400 serious head injuries involving nearside occupants occur annually in non-rollover side crashes without full occupant ejections. ''Nearside occupants'' are those sitting on the struck side of the vehicle in which they are riding.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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BILLING CODE 4910–62–S

DEPARTMENT OF THE TREASURY (TREAS)

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are:

- To promote prosperous and stable American and world economies, including promoting domestic economic growth and maintaining our Nation's leadership in global economic issues, supervising national banks and thrift institutions, and helping to bring residents of distressed communities into the economic mainstream.
- To manage the Government's finances by protecting the revenue and collecting the correct amount of revenue under the Internal Revenue Code, overseeing customs revenue functions, financing the Federal Government and managing its fiscal operations, and producing our Nation's coins and currency.
- To safeguard our financial systems by enforcing laws relating to Federal Government securities and developing regulations to combat money laundering.

Consistent with these missions, most regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President. Unless circumstances require otherwise, it is the policy of the Department to issue a notice of proposed rulemaking and carefully consider public comments before adopting a final rule. Also, in particular cases, the Department invites interested parties to submit views on rulemaking projects while a proposed rule is being developed, and holds public hearings to discuss proposed rules.

In response to the events of September 11, 2001, the President signed the USA PATRIOT Act of 2001 into law on October 26, 2001. Over the past two years, the Department of the Treasury has accorded the highest priority to developing and issuing regulations to implement the provisions in this historic legislation that target money laundering and terrorist financing. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Financial Crimes Enforcement Network (FinCEN).

On November 26, 2002, the President signed into law the Terrorism Risk Insurance Act of 2002. The purpose of this legislation is to address disruptions in the market for terrorism risk insurance. The new law established a temporary Federal reinsurance program under which the Federal Government will share the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers. Over the past year, the Department of the Treasury has accorded the highest priority to developing and issuing regulations to implement the provisions of this Act. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Terrorism Risk Insurance Program Office.

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Order 12866, and to develop regulations that maximize aggregate net benefits to society while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Terrorism Risk Insurance Program Office

The Office of the Assistant Secretary for Financial Institutions is responsible for developing promulgating regulations implementing the Terrorism Risk Insurance Act of 2002 (TRIA). The Terrorism Risk Insurance Program Office, which is part of the Office of the Assistant Secretary for Financial Institutions, is responsible for operational implementation of the Act. The purposes of this legislation, which was enacted as a consequence of the events of September 11, 2001, are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections. TRIA established a temporary Federal reinsurance program under which the Federal Government will share the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers.

Over the past year, the Office of the Assistant Secretary has worked quickly to implement TRIA by issuing both informal guidance and formal regulations. The regulations issued to date set forth key definitions that Treasury will use in implementing the Program as well as procedures insurers must follow to comply with the requirements of TRIA. During fiscal year 2004, the Office will focus on developing regulations to implement the procedures and policies associated with filing claims under TRIA.

Customs Revenue Functions

On November 25, 2002, the President signed the Homeland Security Act of 2002 (the Act), establishing the Department of Homeland Security (DHS). The Act transferred the United States Customs Service from the Department of the Treasury to the DHS, where it is now known as the Bureau of Customs and Border Protection (BCBP). Notwithstanding the transfer of the Customs Service to DHS, the Act provides that the Secretary of the Treasury retains sole legal authority over the customs revenue functions. The Act also authorizes the Secretary of the Treasury to delegate any of the retained authority over customs revenue functions to the Secretary of Homeland Security. By Treasury Department Order No. 100-16, the Secretary of the Treasury delegated to the Secretary of Homeland Security authority to prescribe regulations pertaining to the customs revenue functions. This Order further provided that the Secretary of the Treasury retained the sole authority to approve any such regulations concerning import quotas or trade bans, user fees, marking, labeling, copyright and trademark enforcement, and the completion of entry or substance of entry summary including duty assessment and collection, classification, valuation, application of the U.S. Harmonized Schedules, eligibility or requirements for preferential trade programs and the establishment of recordkeeping requirements relating thereto.

During fiscal year 2003, Treasury and CBP issued several regulations involving the customs revenue functions not delegated to DHS. Among these were the following interim regulations that implement the trade benefit provisions of the Trade Act of 2002:

- The Andean Trade Promotion and Drug Eradication Act
- The Caribbean Basin Economic Recovery Act
- The African Growth and Opportunity Act

During fiscal year 2004, Treasury and BCBP plan to finalize these interim regulations. In addition, Treasury and BCBP plan to finalize regulations that will implement a provision of the Tariff and Suspension Act of 2000 by

establishing procedures for allowing the duty-free entry of prototypes that are to be used exclusively in product development, testing, evaluation or quality control.

Treasury and BCBP also plan to continue moving forward with amendments to improve its regulatory procedures began under the authority granted by the Customs Modernization provisions of the North American Free Trade Implementation Act (Customs Mod Act). These efforts, in accordance with the principles of Executive Order 12866, have involved and will continue to involve significant input from the importing public. BCBP will also continue to test new programs to see if they work before proceeding with proposed rulemaking to permanently establish the programs.

Community Development Financial Institutions Fund

The Community Development Financial Institutions Fund (Fund) was established by the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4701 *et seq.*). The primary purpose of the Fund is to promote economic revitalization and community development through investments in, and assistance to, community development financial institutions (CDFIs), principally through the CDFI Program. In fiscal year 2004, the CDFI Program will comprise two components: the Financial Assistance Component and the Technical Assistance Component. In addition, the Fund administers the Native American CDFI Development (NACD) 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 fiscal year 2004, the Fund also plans to administer the Native American CDFI Assistance (NACA) Program, which will provide financial assistance awards and technical assistance grants (including operating grants and grants to purchase goods and services) to CDFIs that serve Native American, Alaska Native, and Native Hawaiian communities, or ''sponsor organizations'' (i.e., nonprofits or tribes or tribal entities that will form CDFIs that serve Native American, Alaska Native, and/or Native Hawaiian communities).

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 2004 regulatory priority will focus on the NMTC Program, by developing guidance and/or regulations regarding aspects of the administration and operation of the program.

Financial Crimes Enforcement Network

The regulations of the Financial Crimes Enforcement Network (FinCEN) constitute the core of Treasury's anti-money laundering initiatives and are an essential component of Treasury's anti-narcotics effort. FinCEN's regulations implement the Bank Secrecy Act (BSA), as amended in October 2001 by the USA PATRIOT Act. The BSA authorizes the Secretary of the Treasury to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, or regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures. FinCEN is working closely with the Treasury Offices of the General Counsel, Terrorism/Violent Crimes, and Financial Institutions to develop regulations to implement the amendments to the BSA made by the USA PATRIOT Act that target money laundering and terrorist financing.

FinCEN's regulatory priorities for fiscal year 2004 include the following projects, all of which are related to the events of September 11, 2001:

- *Due Diligence for Correspondent Accounts and Private Banking Accounts.* This final rule implements section 312 of the USA PATRIOT Act, which requires certain financial institutions to establish due diligence policies, procedures, and controls reasonably designed to detect and report money laundering through correspondent accounts and private baking accounts established or maintained for non-U.S. persons.
- *Anti-Money Laundering Programs.* These final and proposed rules implement section 352 of the USA PATRIOT Act, under which financial institutions must adopt anti-money laundering programs. FinCEN expects to finalize interim final rules issued in April 2002 for banks and other depository institutions, casinos, securities broker-dealers, futures commissionmerchants, mutual funds, operators of credit card systems, and money services businesses. FinCEN also expects to finalize rules proposed in September 2002 for insurance companies and unregistered investment companies, rules proposed in February 2003 for dealers in precious metals, stones, or jewels, and rules proposed in May 2003 for investment advisers and commodity trading advisers. FinCEN will issue a proposed rule for loan or finance companies (including pawnbrokers). Finally, FinCEN expects to determine whether to issue a series of proposed rules for other financial institutions'vehicles sellers; persons involved in real estate closings and settlements; and travel agencies'after reviewing comments received in response to a series of advance notices of proposed rulemaking.
- *Suspicious Activity Reporting.* FinCEN expects to finalize rules proposed under section 356(b) of the USA PATRIOT Act, which requires futures commission merchants to report suspicious transactions. FinCEN also expects to finalize several rules proposed under 31 U.S.C. 5318(g) equiring insurance companies, mutual funds, and futures commission merchants to report suspicious transactions.

Internal Revenue Service

The Internal Revenue Service, working with the Office of the Assistant Secretary (Tax Policy), promulgates regulations that interpret and implement the Internal Revenue Code and related tax statutes. The purpose of these regulations is to carry out the tax policy determined by Congress in a fair, impartial and reasonable manner, taking into account the intent of Congress, the realities of relevant transactions, the need for the Government to administer the rules and monitor compliance, and the overall integrity of the Federal tax system. The goal is to make the regulations practical and as clear and simple as possible.

Most Internal Revenue Service regulations interpret tax statutes to resolve ambiguities or fill gaps in the tax statutes. This includes interpreting particular words, applying rules to broad classes of circumstances, and resolving apparent and potential conflicts between various statutory provisions.

During fiscal year 2004 the Internal Revenue Service will accord priority to the following regulatory projects:

- *Application of the Repeal of the General Utilities Doctrine in the Context of Consolidated Returns.* The IRS and Treasury intend to issue additional regulatory guidance on the application of the repeal of the *General Utilities* doctrine in the context of consolidated returns. The repeal of *General Utilities* is intended to preserve the integrity of the corporate tax base by ensuring that corporate level tax is ultimately paid on the net income of taxable corporations and the net appreciation in their assets. This project involves ensuring that this result occurs in the context of consolidated returns. Consolidated returns have a system in which the tax basis in the stock of subsidiary members is adjusted to reflect income earned by the subsidiary. Under this system, when the group starts out with more basis in the stock of a subsidiary than the subsidiary has in its assets—for example, when the group buys the stock of a corporation at a price that reflects the unrealized appreciation in the corporation's assets—it may be possible to structure transactions that undermine the intended effect of *General Utilities* repeal.

The IRS and Treasury issued temporary regulations (26 CFR 1.337(d)-2T) that disallow certain losses that have the effect of offsetting the taxable income or gain that should exist under *General Utilities* repeal. During the coming fiscal year, the IRS and Treasury plan to reexamine these regulations and issue new regulatory guidance (of a type to be determined once the project is well under way).

- *Safe Harbor Methodology for Determining the Fair Market Value of Financial Instruments that are Marked to Market.* Section 475 of the Internal Revenue Code requires dealers in stocks, evidences of indebtedness, derivative financial instruments, and other securities to mark those securities to market at the end of each tax year. That is, those dealers must compute their taxable income by either including those securities in inventory, or treating them as having been sold, for their fair market value at the end of the tax year. Certain dealers in commodities and traders in securities or commodities may elect to mark those securities or commodities to market under section 475. There have been disagreements between the IRS and some taxpayers about how to determine the fair market value of some securities, including certain derivative financial instruments. The IRS and Treasury are considering whether to publish proposed regulations that would allow dealers in securities (and perhaps dealers in commodities and traders in securities or commodities) to use a safe harbor method to satisfy the statutory requirement to determine the fair market value of items marked to market. As a first step in this process, the IRS and Treasury issued an advance notice of proposed rulemaking (ANPRM) on May 5, 2003, describing and explaining a possible framework for a safe harbor that might allow taxpayers to use as fair market value for section 475 purposes the value used on certain financial statements. That ANPRM stated certain broad principles that any safe harbor finally adopted would have to meet (including the importance of maintaining and furnishing to the IRS appropriate records) and requested both general and specific comments concerning the adoption of a financial statement conformity (or other) safe harbor. It also requested comments on the scope of any safe harbor, concerning which taxpayers could use it, what financial statements would qualify, and what securities (or commodities) would be covered.

Whether this regulation is of particular concern to small business depends on decisions to be made in the future about whether to limit the scope of the project to dealers in securities or to extend it to traders. Few if any dealers in securities are small businesses, but many traders in securities or commodities may be small businesses.

- *Capitalization of Interest and Carrying Charges Properly Allocable to Straddles.* Sections 1092 and 263(g) were enacted in 1981 to address tax abuses caused by straddles in commodity futures contracts but are broadly worded to deal with other abusive straddles. Section 1092 limits loss recognition on a position in a straddle where there are two or more offsetting positions in the same personal property. Section 263(g) disallows a deduction for interest and carrying charges properly allocable to personal property that is part of a straddle. In general, a straddle arises when a taxpayer holds offsetting positions with respect to personal property. The positions are described as offsetting because the taxpayer's risk of loss in one position is substantially diminished due to the second position.

The IRS and Treasury will issue final regulations clarifying the circumstances in which a taxpayer must capitalize interest and carrying charges incurred to purchase or carry personal property that is part of a straddle. The regulations will address the definition of personal property for purposes of section 263(g), the types of expenses to be subject to capitalization, and the operation of the capitalization rules. In addition, the regulations will indicate when a debt obligation will be treated as a position in personal property that is part of a straddle. The regulations will also clarify the application of the straddle anti-abuse rules to various financial instruments and straddle transactions that have been developed since 1981.

- *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 section 263(a), however, no immediate deduction is allowed for expenditures to acquire, create, or enhance property with a useful life that extends substantially beyond the taxable year. Such expenditures are capital expenditures that generally may be recovered only in future taxable years, as the property is used in the taxpayer's trade or business. In recent years, there has been much uncertainty and controversy regarding whether expenditures to acquire, create, or enhance intangible assets or benefits are currently deductible under section 162, or are capital expenditures under section 263(a). The IRS and Treasury issued proposed regulations on December 19, 2002, that provide rules to clarify the circumstances in which taxpayers must capitalize expenditures to acquire, create, or enhance intangible assets or benefits. During fiscal year 2004, the IRS and Treasury intend to finalize these regulations.
- *Credit for Household and Dependent Care Services.* Section 21 of the Internal Revenue Code allows a credit for an amount equal to a percentage of employment-

related expenses paid by an individual who maintains a household that includes a qualifying individual (usually a child under age 13). Section 21, originally enacted in 1976, has been amended repeatedly. The 2001 amendments increased the credit significantly. The regulations, currently found under section 1.44A of the Income Tax Regulations, have not been amended or updated since 1984. This regulation project will update the regulations to reflect the statutory changes and will clarify issues relating to payments for certain services.

- *International Restructurings.* Multinational businesses operating in a global economy undergo acquisitions, mergers, consolidations, and other reorganizations involving entities in different countries. A number of technical issues have arisen concerning the Federal income tax treatment of these international restructurings. These issues include, for example, the treatment under section 368(a)(1)(A) of statutory mergers and consolidations that involve one or more foreign corporations, including transactions involving a disregarded entity; the application of the international provisions to section 304 transactions and other guidance in light of the 1997 amendments to section 304; the interaction of cross border restructurings and the dual consolidated loss rules under section 1503(d); and the effect of international reorganizations on earnings and profits, including previously taxed earnings and profits. The IRS and Treasury expect to issue regulations that will address these issues during fiscal year 2004.
- *Dividends from Qualified Foreign Corporations Eligible for 15 Percent Rate.* The Jobs and Growth Tax Relief Reconciliation Act of 2003 affords the 15 percent rate to certain dividends received by individuals from ''qualified foreign corporations.'' A number of technical issues have arisen concerning the application of this provision. These issues include, for example, which treaties qualify as comprehensive income tax treaties that have been determined satisfactory for purposes of this provision, including an exchange of information program; what is the test of whether stock is readily tradable on an established securities market in the United States; and the interaction of this provision and various anti-deferral regimes. The IRS and Treasury expect to issue regulations that will interpret and address issues arising under this provision during fiscal year 2004.
- *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 2004.
- *Partnership Equity for Services.* Like other businesses, partnerships frequently issue interests in partnership equity to service providers. Although there currently is some guidance on a partnership's issuance of a profits interest to a service provider, there is little guidance on the Federal income tax consequences (to the service provider and the partnership) on the issuance, in connection with the performance of services, of an interest in partnership capital or an option to acquire such an interest. More specifically, uncertainty exists as to whether the principles of section 83 apply to the issuance of such interests and whether the partnership recognizes gain on the issuance of a capital interest to, or the exercise of an option by, a service provider. In this project, the IRS and Treasury will provide guidance on these and related issues.
- *Corporate Estimated Tax.* Section 6655 of the Internal Revenue Code sets forth the requirements for the payment of estimated income taxes by corporations. The existing regulations under section 6655 do not reflect significant changes to the tax law since 1984. The IRS and Treasury expect to issue proposed regulations that will reflect changes to the tax law since 1984 and that will provide clear rules for taxpayers to follow and the Internal Revenue Service to administer. Among other issues, the proposed regulations will address the alternative methods for computing quarterly installments of estimated tax and the treatment of certain items when computing quarterly installments of estimated tax.
- *Minimum Required Distributions.* Section 401(a)(9) of the Internal Revenue Code requires tax-qualified retirement plans to begin distributions to participants and beneficiaries upon the occurrence of certain events, such as attainment of age 70½ and termination of employment. Final regulations providing guidance on these requirements as they apply to defined contribution plans were published in the Federal Register on April 17, 2002. The IRS and Treasury will issue regulations providing guidance on the requirements of section 401(a)(9) as they apply to defined benefit plans.
- *Incentive Stock Options.* Employers provide various types of stock options to their employees. Certain stock options, known as incentive stock options, are eligible for special tax benefits that are not available for other stock options. Specifically, if certain requirements are satisfied, the employee is not taxed on the grant or the exercise of the option, but only when the stock subject to the option is sold. Moreover, if these requirements are satisfied, the employee is taxed at capital gains rates, rather than ordinary income rates. The IRS and Treasury will issue final regulations providing comprehensive guidance on the requirements applicable to incentive stock options. Proposed regulations providing guidance on these requirements were published in the Federal Register on June 9, 2003.

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 2003 include:

- *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.
- *Customer Identification Programs for Banks, Savings Associations, and Credit Unions (31 CFR 103 and 12 CFR 21).* The Department of the Treasury, through the Financial Crimes Enforcement Network, the OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision, and National Credit Union Administration published a final rule implementing section 326 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001. Section 326 requires a regulation that contains minimum standards that financial institutions must implement: 1) to verify the identity of any person seeking to open an account; 2) to maintain records of the information used to verify the person's identity; and 3) to determine whether the person appears on any lists of known or suspected terrorists or terrorist organizations provided to the financial institution by any Government agency.
- *Rules, Policies, and Procedures for Corporate Activities (Electronic Filings) (12 CFR Part 5).* The OCC published an interim rule with request for comment that would make revisions to part 5 filing requirements to facilitate electronic filings for certain applications. The purpose of these changes is to permit national banks to file certain classes of applications electronically and to inform national banks where they may find detailed procedural information on electronic filings. The rule clarifies circumstances under which the OCC may adopt filing procedures different from those otherwise required by part 5.
- *Removal, Suspension, and Debarment of Accountants From Performing Audit Services (12 CFR Part 19).* The OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision, published a final rule 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). The final rule establishes rules of practice and procedure to implement this authority and reflect the agencies' increasing concern with the quality of audits and internal controls for financial reporting at insured depository institutions. The final rule enhances the agencies' ability to address misconduct by accountants who perform annual audit and attestation services.
- *Community and Economic Development Entities, Community Development Projects and Other Public Welfare Investments (12 CFR Part 24).* The OCC published a final rule amending part 24, the regulation governing national bank investments that are designed primarily to promote the public welfare. The final rule updates the regulation to reflect the additional types of public welfare investment structures that have become more common in recent years and that are permissible under the governing statute. It also clarifies the statutory standard that applies to the activities of those entities; simplifies the standards for making public welfare investments; clarifies how a national bank calculates the value of its public welfare investments for purposes of complying with the rule's investment limits; simplifies the regulation's investment self-certification and prior approval processes; and expands the list of examples of qualifying public welfare investments that satisfy the rule's requirements.

The OCC's regulatory priorities for fiscal year 2004 include projects in the following areas:

- *Risk-Based Capital Guidelines; Capital Adequacy Guidelines; Capital Maintenance: Interim Capital Treatment of Consolidated Asset-Backed Commercial Paper Program Assets (12 CFR Part 3).* The Office of the Comptroller of the Currency, together with the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision, are planning to amend their risk-based capital standards by providing an interim treatment for assets in asset-backed commercial paper (ABCP) programs that are consolidated onto the balance sheets of sponsoring banks, bank holding companies, and thrifts (collectively, sponsoring banking organizations) as a result of a recently issued accounting interpretation, Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46). Specifically, the interim capital treatment allows sponsoring banking organizations to remove consolidated ABCP program assets from their risk-weighted asset base for the purpose of calculating their risk-based capital ratios. This interim capital treatment will be in effect only for the regulatory reporting periods ending September 30 and December 31, 2003, and March 31, 2004. This interim rule is planned to be issued in conjunction with a joint agency notice of proposed rulemaking that would also require banking organizations to hold risk-based capital against liquidity facilities provided to ABCP programs with an original maturity of one year or less, and a risk-based capital charge for early amortization risk associated with certain types of revolving securitizations.
- *Risk-Based Capital Guidelines; Implementation of New Basel Capital Accord (12 CFR Part 3).* The OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision published an advance notice of proposed rulemaking

(ANPRM) soliciting industry comments on a proposed framework for implementing the New Basel Capital Accord in the United States. In particular, this ANPRM describes significant elements of the Advanced Internal Ratings-Based approach for credit risk and the Advanced Measurement Approaches for operational risk (together, the advanced approaches). The ANPRM specifies criteria that would be used to determine banking organizations that would be required to use the advanced approaches, subject to meeting certain qualifying criteria, supervisory standards, and disclosure requirements. Other banking organizations that meet the criteria, standards, and requirements also would be eligible to use the advanced approaches. Under the advanced approaches, banking organization would use internal estimates of certain risk components as key inputs in the determination of their regulatory capital requirements.

- *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.
- *Recordkeeping Requirements for Bank Exceptions from Securities Broker or Dealer Registration (12 CFR To Be Determined).* The OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision are planning to issue a joint notice of proposed rulemaking that contains recordkeeping requirements that implement section 204 of the Gramm-Leach-Bliley Act. Section 204 directs the Federal banking agencies to establish recordkeeping requirements for banks relying on exceptions to the definitions of ''broker'' and ''dealer'' contained in paragraphs (4) and (5) of section 3(a) of the Securities Exchange Act of 1934.
- *Fair Credit Reporting Act (12 CFR Part 41).* The OCC, along with the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision, are planning to publish a revised notice of proposed rulemaking concerning a rule that would 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.
- *Rules, Policies, and Procedures for Corporate Activities; Bank Activities and Operations; Real Estate Lending and Appraisals (12 CFR Parts 3, 5, 6, 7, 9, 28, and 34).* The OCC published a notice of proposed rulemaking that proposed to amend several of its regulations to update and clarify them in various respects. Proposed revisions to parts 5 and 7 would implement new authority provided to national banks by sections 1204, 1205, and 1206 of the American Homeownership and Economic Opportunity Act of 2000. Section 1204 permits national banks to reorganize directly to be controlled by a holding company. Section 1205 increases the maximum term of service for national bank directors, permits the OCC to adopt regulations allowing for staggered terms for directors, and permits national banks to apply for permission to have more than 25 directors. Section 1206 permits national banks to merge with one or more of their nonbank affiliates, subject to OCC approval. In order to clarify issues that have arisen in connection with the scope of OCC's visitorial powers, the proposal would revise part 7. The proposal also contains other amendments to parts 5, 7, 9, and 34, as well as several technical corrections.
- *Community Reinvestment Act (CRA) Regulations (12 CFR Part 25).* The OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision, 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.
- *Maintenance of Records (12 CFR Part 7).* The OCC plans to issue a notice of proposed rulemaking that would invite comment on a revision to part 7 that would require entities subject to the jurisdiction of the OCC to establish and maintain accurate and complete documentation and records, and allow the OCC timely access to such records. The proposed revision would also provide that when a bank discloses documents and records to the OCC during the supervisory process, such a disclosure is not voluntary and is not made to an adversary.
- *Rules, Policies, and Procedures for Corporate Activities; International Banking Activities (12 CFR Parts 5 and 28).* The OCC issued a notice of proposed rulemaking proposing to amend its regulations pertaining to the foreign operations of national banks, and of Federal branches and agencies of foreign banks operating in the United States. The OCC is clarifying or revising a number of application procedures, including the standards for approval that would apply. It permits Federal branches and agencies to operate with one license in the United States, with a license issued only for the initial Federal branch or agency, rather than requiring each office of a foreign bank to have a separate license. It also permits a Federal branch to operate a loan production office as part of its branch license. In addition, the OCC proposes to implement through its regulation a number of OCC interpretations regarding the capital equivalency deposit required of Federal branches and agencies. The OCC also proposes to revise several definitions.
- *Interagency Guidelines Establishing Standards for Safety and Soundness (12 CFR Part 30).* The OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision, plan to issue a notice of proposed rulemaking to amend their Interagency Guidelines to add a new subsection, pursuant to which a depository institution should establish and maintain new policies and standards designed to ensure an effective system of corporate governance. This amendment is intended to address potential weaknesses in management and corporate governance practices.
- *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.

- *Reporting and Disclosure Requirements for National Banks With Securities Registered Under the Securities Exchange Act of 1934; Securities Offering Disclosure Rules (12 CFR Parts 11 and 16).* The OCC published a notice of proposed rulemaking to revise its regulations to reflect amendments to the Securities Exchange Act of 1934 (Exchange Act) made by the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act). These amendments to the Exchange Act give the OCC the authority to administer and enforce a number of the Sarbanes-Oxley Act's new reporting, disclosure, and corporate governance requirements with respect to national banks that have a class of securities registered under the Exchange Act. The OCC is also proposing to make conforming revisions to its rules that prescribe securities offering disclosure rules for national banks that issue securities that are not subject to the registration requirements of the Securities Act of 1933.
- *Bank Activities and Operations; Real Estate Lending and Appraisals (12 CFR Parts 7 and 34).* The OCC issued a notice of proposed rulemaking to amend parts 7 and 34 of its regulations to add provisions clarifying the applicability of state law to national banks. These provisions would identify types of State laws that are preempted, as well as types of State laws that generally are not preempted, in the context of national bank lending, deposit-taking, and other authorized activities.
- *Rules, Policies, and Procedures for Corporate Activities (12 CFR Part 5).* The OCC plans to issue a notice of proposed rulemaking that will require national banks to receive OCC approval before selling or otherwise disposing of all or substantially all of its assets. This proposed rule also provides that the OCC will apply the same standards as it applies to the establishment of a de novo bank to notices to acquire control of such bank.
- *Electronic Filing and Disclosure of Beneficial Ownership Reports (12 CFR Part 11).* The OCC plans to issue an interim rule with request for comments that implements provisions enacted in the Sarbanes-Oxley Act of 2002 requiring the electronic filing of certain beneficial ownership reports by officers, directors, and major shareholders (insiders) that have equity securities registered under the Securities Exchange Act of 1934. Insiders of registered national banks must file these reports with the OCC. This interim rule requires that, in addition to the statutory requirements, all beneficial ownership reports required to be filed with the OCC must be filed electronically and posted on a registered national bank's Web site, if it has one. The Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation are imposing similar requirements.

Office of Thrift Supervision

As the primary Federal regulator of the thrift industry, the Office of Thrift Supervision (OTS) has established regulatory objectives and priorities to supervise thrift institutions effectively and efficiently. These objectives include maintaining and enhancing the safety and soundness of the thrift industry; a flexible, responsive regulatory structure that enables savings associations to provide credit and other financial services to their communities, particularly housing mortgage credit; and a risk-focused, timely approach to supervision.

OTS 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.* This initiative was published, along with draft supervisory guidance, as an advance notice of proposed rulemaking, introducing the domestic implementation of the New Basel Capital Accord (Basel II). It included an introduction to the advanced internal ratings-based (IRB) approach to credit risk, and included modifications to the current U.S. domestic capital framework.
- *Capital Adequacy.* The four Federal banking agencies plan to issue a joint notice of proposed rulemaking seeking comment on ways to modify the capital adequacy framework for all banking organizations. Among the elements of the proposal will be consideration of a uniform regulatory structure, elimination of outdated requirements, reallocation of certain assets to more appropriate risk weights, and general streamlining and burden reduction.

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.

OTS plans to issue a final rule conforming its regulations on transactions with affiliates to Regulation W and implementing additional restrictions imposed on savings associations under section 11(a) of the Home Owners' Loan Act. Also, OTS plans to adopt as final an interim rule that amended its annual independent audit requirements for small, nonpublic, highly rated savings associations that voluntarily obtain independent audits. Additionally, OTS is issuing a final rule amending its regulation governing agency offices of Federal savings associations to conform that regulation to recent changes to OTS' fiduciary activities regulations.

Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB) issues regulations to enforce the Federal laws relating to the manufacture and commerce of alcohol products, tobacco products, and the Federal excise tax on firearms and ammunition. TTB's mission and regulations are designed to:

- Regulate the alcohol and tobacco industries, including systems for licenses and permits;
- Assure the collection of all alcohol, tobacco, and firearms and ammunition taxes, and obtain a high level of voluntary compliance with all laws governing those industries;
- Suppress commercial bribery, consumer deception, and other prohibited practices in the alcoholic beverage industry; and
- Assist the States and other Federal agencies in their efforts to eliminate

interstate trafficking in, and the sale and distribution of, cigarettes in avoidance of State taxes.

In 2004, TTB will continue its multi-year plan to revise its regulations in plain language. TTB will update and revise regulations to be more clear and concise, using the principles of plain language. TTB began the groundwork for this priority in 2002 by starting recodifications in title 27 of the Code of Federal Regulations. These changes reorganize TTB regulations into a more logical sequence. The plain language revisions will make TTB rules more accessible to small businesses and to the public.

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), as amended.
- Implementing Treasury's borrowing authority, including rules governing the sale and issue of savings bonds, marketable Treasury securities, and State and local Government securities.
- Setting out the terms and conditions by which Treasury may redeem (buy back) outstanding, unmatured marketable Treasury securities through debt buyback operations.
- Governing the acceptability and valuation of all collateral pledged to secure deposits of public monies and other financial interests of the Federal Government.

Treasury's GSA rules govern financial responsibility, the protection of customer funds and securities, recordkeeping, reporting, audit, and large position reporting for all government securities brokers and dealers, including financial institutions. During fiscal year 2004, BPD will give priority to developing technical conforming amendments to the customer protection requirements in the GSA regulations based on the recent changes made by the Securities and Exchange Commission to its customer protection rules for brokers and dealers. The modifications will allow for the expansion of the categories of collateral registered Government securities brokers and dealers may pledge when borrowing securities from customers. BPD also plans to give priority to expanding an exemption in the GSA regulations to include savings associations regulated by the Office of Thrift Supervision that hold Government securities in a fiduciary and custodial capacity.

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 2004, BPD will accord priority to issuing the Uniform Offering Circular in plain language. This will communicate the auction rules in a more direct and effective manner.

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 2004, 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 will 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 that establishes standards for Federal Government payments and collections via the ACH system. FMS will revise this rule in order to stay current with private industry rules and to facilitate the continued expansion of electronic commerce.
- *Checks Drawn on the United States Treasury (31 CFR Part 240)*: FMS will issue a final rule governing the indorsement and payment of checks drawn on the United States Treasury. Last fiscal year, FMS proposed revisions that 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 will issue a final rule governing the offset of Federal Government payments to collect delinquent nontax debt owed to Federal agencies. Last fiscal year, FMS issued an interim rule (with request for comments) clarifying the policies and procedures applicable to the collection of such debt through the Treasury Offset Program.

TREAS—Alcohol and Tobacco Tax and Trade Bureau (TTB)

PROPOSED RULE STAGE

99. 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:

TTB intends to streamline regulations applying to breweries. TTB 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:

TTB 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:

TTB 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. TTB 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 TTB.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Transferred from RIN 1512–AB37

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RIN: 1513–AA02

BILLING CODE 4810–25–S

DEPARTMENT OF VETERANS AFFAIRS (VA)

Statement of Regulatory Priorities

The Department of Veterans Affairs (VA) administers benefit programs that recognize the important public obligations to those who served this Nation. VA's regulatory responsibility is almost solely confined to carrying out mandates of the laws enacted by Congress relating to programs for veterans and their beneficiaries. VA's major regulatory objective is to implement these laws with fairness, justice, and efficiency.

Most of the regulations issued by VA involve at least one of three VA components: The Veterans Benefits Administration, the Veterans Health Administration, and the National Cemetery Administration. The primary mission of the Veterans Benefits Administration is to provide high-quality and timely nonmedical benefits to eligible veterans and their beneficiaries. The primary mission of the Veterans Health Administration is to provide high-quality health care on a timely basis to eligible veterans through its system of medical centers, nursing homes, domiciliaries, and outpatient medical and dental facilities. The primary mission of the National Cemetery Administration is to bury eligible veterans, members of the Reserve components, and their dependents in VA National Cemeteries and to maintain those cemeteries as national shrines in perpetuity as a final tribute of a grateful Nation to honor the memory and service of those who served in the Armed Forces.

VA's regulatory priorities include a special project to undertake a comprehensive review and improvement of its existing regulations. The first portion of this project is devoted to reviewing, reorganizing, and rewriting the VA's compensation and pension regulations found in part 3 of 38 CFR. The goal of the Regulation Rewrite Project is to improve the clarity and logical consistency of these regulations in order to better inform veterans and their family members of their entitlements.

The Department of Veterans Affairs' 2003 regulatory plan contains one rulemaking action from the Veterans Health Administration. The Veterans Health Administration rulemaking is RIN 2900-AL51 ''Enrollment'Provision of Hospital and Outpatient Care to Veterans Subpriorities of Priority Categories 7 and 8 and Annual Enrollment Level Decision,'' which amends the Department's medical regulations to protect the quality and improve the timeliness of care provided to veterans in higher enrollment-priority categories.

VA

FINAL RULE STAGE

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100. ENROLLMENT—PROVISION OF HOSPITAL AND OUTPATIENT CARE TO VETERANS—SUBPRIORITIES OF PRIORITY CATEGORIES 7 AND 8 AND ENROLLMENT LEVEL DECISION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 104–262

CFR Citation:

38 CFR 17.36

Legal Deadline:

None

Abstract:

As required by Public Law 104–262, the Veterans' Health Care Eligibility Reform Act of 1996, the Secretary of the Department of Veterans Affairs must make an annual decision concerning enrollment in VA's health care system in order to ensure that medical services provided are both timely and acceptable in quality. This document amends existing regulations to establish subpriorities within priority categories 7 and 8 and to publish FY 2003 enrollment decision as determined by the Secretary.

Statement of Need:

Public Law 104–262, the Veterans' Health Care Eligibility Reform Act of 1996, requires the Secretary of Veterans Affairs to make annual decisions concerning enrollment in VA's health care system in order to ensure that resources are available to provide medical services that are both timely and acceptable in quality. This document announces the enrollment decision to suspend the enrollment of additional veterans who are in the lowest statutory enrollment category (priority category 8). This also amends existing regulations to establish additional subpriorities within priority categories 7 and 8.

Summary of Legal Basis:

38 CFR 17.36(c) requires that the Secretary determine which categories of veterans are eligible to be enrolled and that the Secretary notify eligible enrollees of the determination by announcing it in the Federal Register.

Alternatives:

The Department had to consider placing additional enrollees on waiting lists and extending the waiting period for eligible enrollees seeking appointments for care as alternatives.

Anticipated Cost and Benefits:

By suspending enrollment of additional priority category 8 veterans, VA would avoid significant additional medical benefits costs and begin to bring demand in line with capacity, which will reduce the number of veterans on waiting lists. Without action to suspend new enrollment, the cost projection for FY 2003 is $23.455 billion. This is based on the projected average enrollment for FY 2003 of 6,991,405, together with the projected expenditures that would be needed to provide the medical benefits package to all enrollees. Suspending new enrollment would reduce enrollment in priority category 8 by 164,367 in FY 2003, which is expected to grow to over 520,000 by FY 2005.

Risks:

Without action to suspend new enrollment, patient safety and quality and access to care would be adversely affected.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/17/03	68 FR 2670
Interim Final Rule Effective	01/17/03	
Interim Final Rule Comment Period End	03/18/03	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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RIN: 2900–AL51

BILLING CODE 8320–01–S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Priorities

OVERVIEW

The U.S. Environmental Protection Agency (EPA) is the leading Federal agency responsible for protecting environmental quality and controlling the effects of pollution on human health. Since its creation in 1970, EPA has taken actions that have led to measurable improvements in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful pesticides.

EPA fulfills its mission using a variety of tools, such as technical assistance, funding, voluntary partnerships, research, and education. And in carrying out its statutory responsibilities, EPA also develops regulations that provide protection against a variety of environmental risks. In the coming year, EPA's top regulatory priority is supporting passage and implementation of the Clear Skies Initiative, a legislative proposal of the Bush Administration that would reduce emissions of the three most harmful air pollutants, nitrogen oxides, sulfur dioxides, and mercury, at levels 70 percent below year 2000 levels. Other regulatory priorities include completing rules that will reduce emissions from off-road diesel engines and reduce the risks from microbial pathogens, especially cryptosporidium, in drinking water.

Sound Science and Economic Analysis

These and other regulatory activities are supported by a strong commitment to sound science and economic analysis. EPA conducts scientific and economic research on an ongoing basis, independently and in collaboration with others, to obtain the base of knowledge that is needed to understand and solve complex ecological and human health problems.

EPA's priorities for scientific research align with the Agency's five strategic goals. For Clean Air, science priorities focus on emissions, fate and transport, exposures, mechanisms of injury, and health effects of criteria air pollutants. Science priorities for Clean and Safe Water address water quality and drinking water. The science priorities for Land Preservation and Restoration focus on improving characterization, measuring, and monitoring methods; enhancing methods and models for estimating ecological effects; reducing uncertainty in human health and ecological risks; and developing more cost-effective and reliable remediation and treatment technologies. The science priorities for Healthy Communities and Ecosystems are wide ranging and comprise a variety of priorities among multiple program offices, as well as basic research. The science priorities for Compliance and Environmental Stewardship are pollution prevention practices; new technology development; socioeconomics; and decisionmaking related to compliance, enforcement, incentives, monitoring, and innovative approaches to environmental stewardship. In addition, EPA has identified cross-cutting science priorities that span several programs and help the Agency accomplish multiple science objectives. These are aggregate and cumulative risk assessment, genomics, computational toxicology, environmental indicators and susceptible subpopulations as high-priority cross-cutting activities. Advances in these areas will improve EPA's capability to predict and reduce potential human health and ecological risks under all five of the Agency's goals.

EPA's emphasis on economic and policy analysis supports the Agency's continuing dedication to quantifying the costs and benefits of its air, land and water regulations, policies and programs. In the coming year, EPA will expand its economic research programs to improve the measurement of environmental benefits, focusing on efforts to value the benefits of preserving goods and services provided by ecological systems. EPA will continue to undertake studies to quantify the social benefits and costs of established and new economically significant rules, including preparation of a revised comprehensive evaluation of the economic benefits and costs of programs established under the Clean Air Act.

Innovative Approaches

Increasingly, EPA's regulations reflect innovative approaches that go beyond traditional technology-based standards and aim to improve performance and cut costs. Some of the innovations likely to influence EPA's regulations in fiscal year (FY) 2004 include market-based incentives that harness the power of economics to drive decisionmaking, flexible implementation options that provide regulated entities with more choices in deciding how to achieve an environmental goal, and information provisions that highlight environmental performance and provide an impetus for improvement. EPA will also support environmental technology innovation by allowing use of innovative technologies in its regulations. For example, through a national environmental technology competition, EPA is conducting demonstrations of innovative technologies for removing arsenic from drinking water to enable small drinking water systems to cost-effectively comply with EPA's new standards. The first twelve of over twenty planned demonstrations will begin by December 2003.

Another innovative approach for achieving environmental results is fostering voluntary action. Today EPA manages a suite of voluntary programs, such as WasteWise and Energy Star, that help organizations achieve measurable environmental improvements. While these programs are designed to support efforts to reduce pollution in ways that are not required by regulation, they often have the secondary effect of improving the quality of regulations. For example, by working closely with trade associations and other organizations, EPA has been able to develop regulations that meet environmental goals while also being responsive to special needs, interests, and circumstances surrounding a particular issue. Given the potential to improve the quality of regulations and, in some cases, to eliminate the need for regulation altogether, EPA will continue to promote and support development of voluntary programs.

Regulatory flexibility, cost reduction, information transfer, and technology development are all objectives fueling EPA's innovation investments. However, before any innovation is adopted, EPA conducts pilot tests to ensure feasibility and evaluate the results. In the coming year, EPA will explore innovative approaches in cooperation with many partners. In particular, EPA will work with States through the Joint Agreement on Regulatory Innovation, the newly established State Innovation Grant program, and other mechanisms. To realize the greatest value from each innovation, EPA will also work to expand use of proven innovations on the broadest possible scale. This includes working with States to apply Massachusetts's highly successful Environmental Results Program to improve environmental compliance and accountability among priority small business sectors.

Attention to Small Businesses

Helping small businesses improve environmental performance is a top priority for EPA. EPA offers a variety of services for small businesses, including a toll-free hotline, a semiannual newsletter, online expert systems, and for some sectors, compliance assistance centers that focus on the unique environmental management issues facing specific industries. EPA also maintains a Small Business Ombudsman which provides a point of contact for small businesses and ensures compliance with the Small Business Paperwork Relief Act of 2002.

In FY 2003, EPA updated its Small Business Strategy to unify its many small business services and help small businesses fulfill their environmental responsibilities. The strategy focuses on improving EPA's understanding of small business issues, and improving small businesses' understanding of EPA. The strategy also aims to involve small businesses earlier in the regulatory development process and to develop alternative regulatory approaches - such as self-certification procedures - that work better for small businesses. Other objectives include developing compliance tools to make it easier for small businesses to comply as well as rewards that recognize small businesses for their environmental stewardship.

In FY 2004, EPA will focus on implementing the Small Business Strategy. By better coordinating small business activities, EPA aims to improve its technical assistance and outreach efforts, minimize burden to small businesses in its regulations, and simplify small businesses' participation in its voluntary programs.

A number of rules included in this plan may be of particular interest to small businesses. The following are intended to provide regulatory relief:

Office of Solid Waste Burden Reduction Project Final Rule

Increase Metals Reclamation from F006 Waste Streams Proposed Rule

Standardized Permit for RCRA Hazardous Waste Management Facilities Final Rule

Recycling of Cathode Ray Tubes and Mercury-Containing Equipment: Changes to Hazardous Waste Regulations Final Rule

Other rules in this plan may potentially have significant impacts on small businesses. They include:

Standards and Practices for Conducting ''All Appropriate Inquiry'' Proposed Rule

Groundwater Rule

Lead-Based Paint Activities: Training and Certification for Renovation and Remodeling

Effluent Guidelines and Standards for the Construction and Development Industry

Long-Term 2 Enhanced Surface Water Treatment Rule

Stage 2 Disinfection Byproducts Rule

Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel

National Security

EPA is one of many Federal agencies with responsibilities related to national security. This new priority is affecting the structure of EPA's programs, the Agency's budget, and its regulatory agenda. Virtually every office within EPA has had to extend its reach above EPA's core environmental mission to encompass this new priority. Some offices are working to prevent future terrorist attacks and enhance preparedness through the research of water and building security, and through teams devoted to counterterrorism law enforcement support, water and wastewater infrastructure protection, building air protection, food security, and information infrastructure security. Other programs have focused on improving various ways to respond in the event of an incident, including EPA's extensive emergency response network (including chemical, biological, and radiological emergency response), the EPA Emergency Operations Center, and National Decontamination Teams. These many activities highlight EPA's new priority and help to ensure that the nation is better protected and prepared for a terrorist event.

As this new priority has such broad implications for the Agency, a need was seen by the Administrator for a central office to ensure that EPA's policies regarding terrorism incident preparedness and response promote efficiency, collaboration, and reduction of gaps. This new office formed in February 2003 as the Administrator's Office of Homeland Security (OHS), which has the major responsibilities of leading and coordinating homeland security activities and policy development across the Agency. The office is working to ensure that, while EPA continues to meet its core environmental protection mission, the Agency is also evolving to meet its homeland security responsibilities, assuring that EPA's new priority receives the necessary attention.

HIGHLIGHTS OF EPA'S REGULATORY PLAN

Office of Air and Radiation

The principal regulatory priority of EPA's Office of Air and Radiation (OAR) for FY 2004 is to protect public health and the environment from the harmful effects of fine particulate matter and ozone, the two air pollutants that persist widely in the Nation's air in amounts that exceed Clean Air Act health standards. Exposure to these pollutants is associated with numerous harmful effects on human health, including respiratory problems, heart and lung disease, and premature death. OAR is also continuing with priority efforts to address cancer-causing air toxics pollution by implementing a toxics-control program under the Clean Air Act. OAR is also working to increase the effectiveness and efficiency of its permitting programs, which are the main mechanisms through which these protections are implemented. These efforts are described briefly below.

OAR's principal vehicle to address the continuing problem of particulate and ozone pollution is the Clear Skies legislative proposal, which would achieve large reductions in the emissions that cause particulate and ozone pollution through use of a ''cap-and-trade'' system similar to the one that has proved so successful in EPA's Acid Rain program. This pollution, largely from electric powerplants and large industrial boilers, is transported on the wind over long distances from the Midwest to the east coast, and is a major factor in the pollution problems of eastern cities. The plan also describes a rulemaking to address emissions of off-road vehicles, which are significant sources of ozone and particulate pollution. Nonroad engines are used in construction equipment and other vehicles that do not normally travel on roads and highways. The nonroad rule will set new emission standards for these engines, and will also greatly lower the amount of sulfur in diesel fuel, which will reduce sulfur pollution in the air and also ensure that the engines' pollution controls are not prevented from working properly by being ''fouled'' with high-sulfur fuel.

EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990 by implementing the Maximum Achievable Control Technology (MACT) program, which has the goal of controlling toxic air pollution from major emitters nationwide. Toxic air pollution is a term that covers a large number of industrial chemicals and other substances that

have been shown to cause cancer, birth defects, and developmental problems in children. To date, EPA's air toxics program has focused primarily on reducing emissions from large industrial sources, such as petroleum refineries and chemical manufacturing plants, through technology-based standards. When fully implemented, the overall MACT program will reduce more than one million tons of toxic air emissions per year. The rules listed in this year's Regulatory Plan-covering electric utilities, industrial boilers, institutional/commercial boilers, wood manufacturing, reciprocating engines, 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.

Since many air quality programs are administered through permitting programs, OAR continues to work toward improving these programs to increase efficiency and reduce regulatory burden. Currently, OAR is developing several rulemakings to streamline and improve its two principal permitting programs. The first effort, to revise the New Source Review program, will clarify the circumstances under which companies must obtain construction permits before building new facilities or significantly modifying existing facilities. These revisions will provide more regulatory certainty by clarifying compliance requirements, and will also make the program easier to administer while maintaining its environmental benefits. The second effort will streamline and simplify the Operating Permits program, which requires that all operating facilities have a valid permit assuring that they meet all applicable air-pollution regulations. In both cases, OAR is drawing upon many years of intense involvement with major stakeholders, who have helped shape a suite of reforms that are expected to both improve the environmental effectiveness of these programs and make them easier to comply with.

The annual report on the costs and benefits of regulations, entitled Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities, that is prepared by the Office of Management and Budget (OMB) and submitted to Congress each year, included several nominations for reform from the public. In FY 2004, OAR expects to address through regulatory action one of the areas raised: New Source Review (Comments #16, 30, 77, 187, 188, 189, and 196). (For a copy of these comments, go to OMB's compilation of the comments at http://www.whitehouse.gov/omb/inforeg/key__comments.html.)

Office of Water

EPA's Office of Water has established five regulatory priorities for the coming year. They include rules affecting cooling water intakes, industrial and municipal wastewater pollution, the Total Maximum Daily Load (TMDL) Program, and drinking water.

EPA intends to issue a final rule to control the adverse environmental impacts associated with cooling water intakes. Many power plants and factories withdraw large volumes of water from rivers, lakes, or other water bodies to cool their production equipment. As required by the CWA, EPA must ensure that the location, design, construction, and capacity of these cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. EPA intends to issue a final rule addressing cooling water intake structures at large steam electric power plants. These facilities (and to a small degree, household ratepayers) will bear the costs of this rule. 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 regulations to help control industrial and municipal wastewater pollution. EPA expects to issue final effluent guidelines that would reduce the discharge of pollutants contained in storm water runoff from construction sites. These requirements are expected to result in significant improvements in water quality as a result of construction site owners and operators using best management practices.

EPA plans to propose a rule establishing a new framework for accomplishing the water quality planning and management provisions of the 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 proposed new framework seeks to increase TMDL program flexibility, enhance stakeholder participation, promote opportunities for trading, and increase efficiencies in establishing, approving, and implementing TMDLs.

Finally, EPA is developing three rules to protect the safety of drinking water. First, EPA is developing a final Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). This rule would reduce risks from microbial pathogens, especially Cryptosporidium, in public water systems that use surface water sources. LT2ESWTR provisions would target systems where current standards do not provide sufficient protection, including both filtered systems with elevated source water pathogen levels and unfiltered systems. Second, EPA plans to finalize the Groundwater Rule, a rule that addresses fecal contamination in public water systems served by groundwater sources. Finally, EPA is developing a final Stage 2 Disinfectants and Disinfection Byproducts Rule to control exposure to disinfection byproducts beyond the requirements of the Stage 1 Disinfectants and Disinfection Byproducts Rule. This rule will respond to new data the Agency has received on: disinfection byproduct occurrence; bladder, colon, and rectal cancer; and possible reproductive and developmental health effects.

Office of Prevention, Pesticides, and Toxic Substances

Evidence suggests that environmental exposure to man-made chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in human and wildlife populations. The Food Quality Protection Act directed EPA to develop a chemical screening program (the Endocrine Disruptor Screening Program, EDSP), using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. EPA is implementing recommendations from a scientific advisory committee, which was established to advise EPA on the EDSP, by developing and validating test systems for determining whether a chemical may have effects similar to those produced by naturally occurring hormones. As part of this program EPA is also designing a framework for procedures and processes to use when implementing the EDSP, and is

developing an initial list of chemicals for which testing will be required. A proposed chemical selection approach for this initial list of chemicals was published in the **Federal Register** in December 2002 for public comment, and the comment period ended April 1, 2003. A notice on the final approach is expected to be published in early 2004.

To address high production volume (HPV) chemicals, the Agency launched the HPV Initiativein April 1998, which is a data collection and development program established by OPPTS for existing U.S. HPV chemicals. Under this initiative, HPV chemicals are defined as organic chemicals manufactured (including imported) at or above 1 million pounds per year based on information submitted under the 1990 Inventory Update Rule established pursuant to the Toxic Substances Control Act (TSCA). Through the HPV Initiative, which includes a voluntary component (the HPV Challenge Program) for certain international efforts and rulemaking under TSCA, basic screening level hazard datanecessary to provide critical information about the environmental fate and potential hazards associated with HPV chemicals will be collected or, where necessary, developed. Data collected and/or developed under the HPV Initiative will provide critical basic information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action. Of the estimated 2,800 HPV chemicals included in the HPV Initiative, under the voluntary HPV Challenge Program component, EPA received commitments from 338 companies individually or through consortia and the International Council of Chemical Associations (ICCA) to sponsor 2,165. As of August 2003, EPA has received 225 test plans covering 1,055 chemicals either individually or as part of a chemical category. EPA plans to issue a final rule to require testing for a number (30 or so) of the HPV chemicals that were not sponsored as part of the voluntary HPV Challenge Program.

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline and various food sources, remaining lead-based paint in older houses continues to be a significant source of childhood lead poisoning. Section 402(c) of the Toxic Substances Control Act (TSCA) directs EPA to address renovation and remodeling activities in these older houses by first conducting a study of the extent to which persons engaged in various types of renovation and remodeling activities are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities, the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others. Given the significant number of older houses affected, such a rule is likely to have a potentially significant economic impact. In an effort to minimize that impact, the Agency is working with stakeholders to explore the development of non-rulemaking approaches for reducing the potential creation of lead-based paint hazards from renovation or remodeling activities. The lead-based paint program activities are intended to insure that the individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under six years old.

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 has already reduced the review time for emergency exemptions significantly. Other changes that EPA is considering have the potential for further streamlining the exemption program and allowing more flexibility in its applicability.

EPA anticipates it will develop a policy or regulation setting forth criteria and standards the Agency would use in deciding the extent to which it will rely on certain kinds of human research to support its actions to protect public health and the environment. In developing a future policy or rule, EPA will consider the public comments received in response to the advance notice of proposed rulemaking published in the **Federal Register** on May 7, 2003 (68 FR 24410), and will also carefully consider advice from the National Academy of Sciences expected in December 2003. The policy or rule would establish rigorous scientific and ethical standards that EPA would apply in its analysis of various types of research involving people exposed to toxicants to identify or quantify their effects. The Agency will particularly focus on ''third-party intentional dosing human studies,'' but recognizes that standards applicable to these studies may also be applicable to other types of studies. ''Third party studies'' refers to research not conducted or supported by EPA or other federal agencies, and therefore not governed by the regulation for Protection of Human Subjects, widely referred to as the Common Rule (40 CFR part 26).

Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) has a number of regulatory priorities aimed at improving environmental quality. Protection of public health and the environment and environmental stewardship are two key themes, as is reducing burden on the regulated community where environmental protections are maintained.

During the 1990s, EPA determined that additional control is needed for cement kiln dust, a high-volume byproduct material of the cement manufacturing process that potentially contains hazardous constituents, such as lead, cadmium and chromium. EPA also committed to develop regulations that would be tailored to protect human health and the environment while limiting burden on the regulated community. EPA proposed a comprehensive set of standards for the management of cement kiln dust in 1999, and plans to finalize standards soon.

Likewise, in response to an earlier determination that coal combustion wastes could pose significant risks to human health and the environment if they are not properly managed, EPA is developing standards for the management of coal combustion wastes generated by commercial electric power producers. When implemented, the standards will prevent contamination or damage to groundwaters and surface waters.

EPA will further promote and protect air quality by reducing emissions of arsenic, beryllium, cadmium, chromium, dioxins and furans, hydrogen chloride, lead, manganese, and mercury, all of which cause adverse health effects. EPA plans to propose national emission standards for these hazardous air pollutants for hazardous waste combustors. This proposal will also contain a response to the Cement Kiln Recycling Coalition petition of the Administrator to withdraw Agency policy and technical guidance concerning site-specific risk assessments for hazardous waste combustors and re-issue them as regulations, if EPA continues to believe that they are necessary. This proposal also supports a reform nomination for site-specific risk assessments in the Resource Conservation and Recovery Act (RCRA) that was mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations.

EPA is determining whether wastes from the manufacturing of dyes and pigments present a hazard to human health and the environment. If so, EPA will propose their listing under RCRA subtitle C.

OSWER's Environmental Stewardship priority promotes revitalizing the land, including cleaning up and redeveloping Brownfields. The Small Business Liability Relief and Brownfields Revitalization Act addresses the need for bona fide prospective purchasers, contiguous property owners, and innocent landowners to conduct ''all appropriate inquiry'' into prior ownership and use of the property at the time the party acquires the property. EPA is seeking to provide purchasers of contaminated property with clarity regarding the procedures and standards for conducting an ''all appropriate inquiry'' so as to limit CERCLA liability.

To further promote environmental stewardship, EPA is encouraging recycling. One of the largest hazardous waste streams amenable to recycling is the wastewater treatment sludges from electroplating operations (waste code F006). EPA is considering changes to the existing RCRA regulations to encourage safe recycling and waste management practices of wastewater treatment sludges from electroplating operations. These electroplating sludges are sufficiently high in metal(s) and sufficiently low in other toxic constituents.

EPA also seeks to remove unnecessary regulatory barriers to recycling of Cathode Ray Tubes. These tubes, which are found in televisions and computer monitors, contain lead to protect users from X-rays.

To reduce burden on the regulated community, Agency efforts are underway to eliminate duplicative and non-essential paperwork burden imposed by RCRA reporting and recordkeeping requirements. This rule will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations.

EPA also intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum. The current Federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a RCRA hazardous waste. Yet, such sludges do not contain the constituents for which the F019 hazardous waste was originally listed (cyanide and chromium).

EPA also plans to streamline both the RCRA permit and hazardous waste manifest processes. The Agency is creating a standardized permit for RCRA facilities that generate hazardous waste and routinely manage the waste on-site in tanks, containers, and containment buildings. This standardized permit process would allow facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process.

Likewise, the Agency plans to reduce paperwork burden by standardizing the Uniform Hazardous Waste Manifest, which is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of RCRA hazardous waste during its transportation. EPA plans to specify one format for the manifests that may be used in all States. EPA is working toward standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes.

Office of Environmental Information

The top regulatory priority of EPA's Office of Environmental Information (OEI) will be to finalize the Cross-Media Electronic Reporting and Recordkeeping 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 will remove existing regulatory obstacles to electronic reporting, and it will set requirements for companies choosing to report electronically. In addition, this rule will 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 2004. 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, EPA has implemented an integrated system to support the electronic reporting needs of EPA media programs, known as Central Data Exchange (CDX). CDX currently provides electronic reporting services to more than 14,000 users in six major media programs and is on track to provide electronic reporting services for all significant environmental data collections over the next two years. All but one of the major environmental data exchanges with States will be operational through CDX by the end of 2004, and the outstanding data exchange will be operational by the end of FY 2005. In addition, beginning in the spring of 2002, Toxics Release Inventory (TRI) reporters were able to useTRI - Made Easy (TRI-ME) software to submit their forms electronically over the Internet through CDX. However, reporters still had to submit a paper certification letter. Beginning in the spring of 2003, TRI reporters no longer need to submit paper certification letters; instead, they are now able to use the TRI-ME software to submit data over

the Internet using CDX with electronic signature.

EPA

PRERULE STAGE

101. 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 of the Program EPA had developed to comply with the requirements of FFDCA section 408(p) as amended by FQPA. One of those elements is priority setting which was defined as the collection, evaluation, and analysis of relevant information to determine the general order in which chemical substances and mixtures will be subjected to screening and testing. Under this current action, EPA is developing a priority setting approach to be used by the Agency to identify the initial list of chemicals for which tier 1 testing will be required. On December 30, 2002, EPA published in the Federal Register for public comment a proposed chemical selection approach for this initial list of chemicals. The public comment period on this proposed approach was extended to April 1, 2003 in a Federal Register notice dated February 26, 2003. Following consideration of comments on this proposed approach, EPA will issue a Federal Register notice setting forth its final approach. Although this action is not a rulemaking, the Agency has included it in the Regulatory Agenda to help inform the public.

Statement of Need:

The Endocrine Disruptor Screening Program fulfills the statutory 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 require testing of chemicals and pesticides is in TSCA (15 U.S.C. 2603) and FIFRA (7 U.S.C. 136) respectively.

Alternatives:

A federal role is mandated under cited authority. There is no alternative to 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 a endocrine mediated pathway. Preliminary studies show decreases on IQ tests and increases in aggression in children. Severe malformations of the genitals of boys has increased steadily over the last two decades. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish and shellfish have been documented in the United States, Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the United States 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 RfC	12/30/02	67 FR 79611
Notice ECP	02/26/03	68 FR 8901
Notice Final	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN 4727.

Split from RIN 2070–AD26.

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RIN: 2070–AD59

EPA

PROPOSED RULE STAGE

102. ELECTRIC UTILITY STEAM GENERATING UNIT MACT REGULATION

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 7412

CFR Citation:

40 CFR 63

Legal Deadline:

NPRM, Judicial, December 15, 2003, NPRM.

Final, Judicial, December 15, 2004, Final.

Abstract:

In December 2000, the EPA determined that regulation of hazardous air pollutant emissions (HAP) from oil- and coal-fired electric utility steam generating units was necessary and appropriate. This finding was based on the results of the study mandated by section 112(n)(1)(A) of the Clean Air Act, as amended. The regulation(s) will be developed under section 112 and will result in standards based on the use of maximum achievable control technology (MACT). The primary benefit will be the reduction of mercury emissions to the atmosphere from coal-fired units but other HAP will also be reduced. Small businesses and State/local/tribal governments could be impacted (particularly those governments owning or operating oil- or coal-fired electric generation facilities).

Statement of Need:

Oil and coal-fired electric utility steam generating units were added (December 20, 2000) to the list of source categories to be regulated under section 112 of the Clean Air Act, as amended.

Summary of Legal Basis:

Section 112 of the Clean Air Act, as amended.

Alternatives:

Alternatives will be identified as the proposal is developed.

Anticipated Cost and Benefits:

It is anticipated that this rule will result in significant costs to the affected industry, including Federal, State, and local entities that own/operate electric utility steam generating units. These costs will be identified as the proposal is developed.

Risks:

Risk information will become available as the proposal is developed.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN 4571.

Sectors Affected:

221112 Fossil Fuel Electric Power Generation

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RIN: 2060–AJ65

EPA

103. IMPLEMENTATION RULE FOR PM–2.5 NAAQS

Priority:

Other Significant

Unfunded Mandates:

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

Legal Authority:

42 USC 7410; 42 USC 7501 et seq

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

In 1997, EPA promulgated revised National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM–2.5). The rule described in this paragraph—the Implementation Rule for PM–2.5 NAAQS—will include requirements and guidance for State and local air pollution agencies to develop and submit State implementation plans (SIPs) designed to bring the areas into attainment with the 1997 standards. These SIP-development activities include conducting technical analyses to identify effective strategies for reducing emissions contributing to PM–2.5 levels, and adopting regulations as needed in order to attain the standards. Ambient air quality monitoring for 1999–2001 shows that areas exceeding the standards are located throughout the eastern half of the United States and in California. Estimates show that compliance with the standards will prevent thousands of premature deaths from heart and lung disease, tens of thousands of hospital admissions and emergency room visits, and millions of absences from school and work every year.

Statement of Need:

This rule is needed in order to provide guidance to State and local agencies in preparing State implementation plans (SIPs) designed to bring areas into attainment with the 1997 PM–2.5 standards. The implementation requirements for nonattainment areas are generally described in subpart 1 of section 172 of the Clean Air Act. This rule provides further interpretation of those requirements for the PM–2.5 standards.

Summary of Legal Basis:

42 USC 7410 and 42 USC 7501 et seq.

Alternatives:

Alternatives will be explored as the proposal is developed.

Anticipated Cost and Benefits:

This information will be provided as the proposal is developed.

Risks:

The risks addressed by this rule are those addressed by the 1997 NAAQS rule—i.e., the health and environmental risks associated with nonattainment of the NAAQS. These risks were summarized in detail in the analyses accompanying the 1997 NAAQS rule.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4752.

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RIN: 2060–AK74

EPA

104. ● PREVENTION OF SIGNIFICANT DETERIORATION (PSD) AND NONATTAINMENT NEW SOURCE REVIEW (NSR): ALLOWABLES PLANTWIDE APPLICABILITY LIMIT (PAL), AGGREGATION, AND DEBOTTLENECKING

Priority:

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

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 51.165; 40 CFR 51.166; 40 CFR 52.21

Legal Deadline:

None

Abstract:

EPA recently promulgated NSR rules for a Plantwide Applicability Limit (PAL) based on actual emissions that applies to existing major stationary sources. This year, EPA will propose an allowables PAL provision based on a facility's allowable emissions. If a company commits to keep its facility emissions below Allowables PAL level, then these regulations will allow the plant owners to avoid the NSR permitting process when they make changes at individual units at the plant, as long as the total emissions from the facility will not increase. This package will also include an aggregation provision which will propose that, for the purposes of NSR applicability, a project is considered separate and independent from any other project unless the project is dependent upon another project to be economically or technically viable, or if the project is intentionally split from other projects to avoid NSR. The package will also include a debottlenecking provision which addresses emissions from units that change as a result of a physical or operational change to another unit at the facility. EPA will propose that, when calculating actual emissions associated with a physical change or change in the method of operation, sources generally should look only at the unit undergoing the change. Emissions from units ''upstream'' or ''downstream'' of the unit being changed should be considered only when the permitted emissions limit of the upstream or downstream unit would be exceeded or increased as a result of the change.

Statement of Need:

The current New Source Review program provides for emissions from multiple projects to be aggregated (aggregation) as one single project under certain circumstances. Similarly, when making a PSD applicability calculation, emissions from units whose effective capacity and potential to emit have been increased as a result of a modification to another unit (debottlenecked units), must be included in the initial PSD applicability calculations. Specific questions regarding the application of these two terms have been addressed on a case-by-case basis. By completing this rulemaking, regulated entities and regulatory agencies will be provided an additional level of certainty in addressing applicability issues. We recently promulgated NSR rules for a Plantwide Applicability Limit (PAL) based on actual emissions that applies to existing major stationary sources. In 2003, we will propose an allowables PAL based on a facility's allowable emissions mainly for greenfield sources. If a company commits to keep its facility emissions below Allowables PAL level, then these regulations will allow the plant owners to avoid the NSR permitting process when they make changes at individual units at the plant, as long as the total emissions from the facility will not increase. This would provide flexibility for sources to respond rapidly to market changes without compromising environmental protection.

Summary of Legal Basis:

42 USC 7411(a)(4)

Alternatives:

Alternatives will be developed as the rulemaking proceeds.

Anticipated Cost and Benefits:

Cost and benefit information will be developed as appropriate as the rulemaking proceeds.

Risks:

Risk information will be developed as appropriate as the rulemaking proceeds.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
Final Action	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4793.

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RIN: 2060–AL75

EPA

105. LEAD–BASED PAINT ACTIVITIES; TRAINING AND CERTIFICATION FOR RENOVATION AND REMODELING

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 2682 TSCA 402

CFR Citation:

40 CFR 745

Legal Deadline:

Final, Statutory, October 28, 1996.

Abstract:

Under section 402(c)(2) of the Toxic Substances Control Act (TSCA) title IV, EPA conducted a study of the extent to which persons engaged in renovation and remodeling activities in target housing are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard. EPA must use the results of this study and consult with interested parties to determine which categories of renovation and remodeling activities require training and certification. EPA must then revise the training and certification regulations originally developed for individuals performing lead-based paint abatement under section 402(a) of TSCA title IV to apply them to the renovation and remodeling categories. If EPA determines that any category does not require certification, EPA must publish an explanation of the basis for that determination.

Statement of Need:

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood, (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline, and food sources, remaining paint in older houses continues to be a significant source of childhood lead poisoning. These rules will help insure that individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under 6 years old.

Summary of Legal Basis:

This regulation is mandated by TSCA section 402(c). TSCA section 402(c) directs EPA to address renovation and remodeling activities by first conducting a study of the extent to which persons engaged in various typed of renovation and remodeling activities are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others.

Alternatives:

TSCA section 402(c) states that should the Administrator determine that any category of contractors engaged in renovation or remodeling does not require certification; the Administrator may publish an explanation of the basis for that determination.

Anticipated Cost and Benefits:

EPA's quantitative cost estimates fall into four categories: Training Costs, Work Practice Costs, Clearance Testing Costs, and Administrative Costs. The estimates vary depending upon the option selected. In most cases we expect that requirements related to Clearance Testing and Work Practices will contribute the most to overall rule cost. The benefits analysis will not provide direct quantitative measures of each (or any) option. EPA does not have a complete risk assessment (with dose-response functions) that would permit direct quantitative estimates. We do have other data, such as estimated loadings of Pb generated by renovation work, number and type of renovation events, demographics of the exposed population, and the costs of various health effects previously linked to Pb exposure. With the available information we are able to utilize several qualitative approaches to frame the benefits associated with an effective renovation rule.

Risks:

These rules are aimed at reducing the prevalence and severity of lead poisoning, particularly in children. The Agency has concluded that many R&R work activities can produce or release large quantities of lead and may be associated with elevated blood lead levels. These activities include, but are not limited to: sanding, cutting, window replacement, and demolition. Lead exposure to R&R workers appears to be less of a problem than to building occupants (especially young children). Some workers (and homeowners) are occasionally exposed to high levels of lead. Any work activity that produces dust and debris may create a lead exposure problem.

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	
Final Action	10/00/06	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN 3557.

Sectors Affected:

23599 All Other Special Trade Contractors; 23551 Carpentry Contractors; 53111 Lessors of Residential Buildings and Dwellings; 23322 Multifamily Housing Construction; 23521 Painting and Wall Covering Contractors; 531311 Residential Property Managers; 23321 Single Family Housing Construction; 54138 Testing Laboratories

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RIN: 2070–AC83

EPA

106. PESTICIDES; EMERGENCY EXEMPTION PROCESS REVISIONS

Priority:

Other Significant

Legal Authority:

7 USC 136p; 7 USC 136w

CFR Citation:

40 CFR 166

Legal Deadline:

None

Abstract:

EPA will publish a Notice of Proposed Rulemaking in the Federal Register proposing several improvements to the pesticide emergency exemption process under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Two of these potential improvements are currently being tested through a limited pilot, and are based on recommendations from the States which are the primary applicants for emergency exemptions. EPA has established regulations under section 18 of FIFRA which allow a Federal or State agency to apply for an emergency exemption to allow an unregistered use of a pesticide for a limited time when such use is necessary to alleviate an emergency condition.

Statement of Need:

In 1996, stakeholders, including States and Federal agencies, identified a number of issues related to improving the emergency exemption process. States and Federal agencies are the only applicants for emergency exemptions. Representatives of States have recommended modifications to the current process for application, review and approval of emergency exemptions. If adopted, the changes would reduce unnecessary burden to both applicants and EPA, and expedite decisions on applications (which is critical in emergency situations).

Summary of Legal Basis:

FIFRA section 18 authorizes EPA to temporarily exempt States from the requirements of registration to alleviate an emergency condition.

Alternatives:

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:

These procedural improvements are not expected to increase existing costs related to this program. In fact, this action is likely to provide reduced burden and cost to states and federal agencies that apply for emergency exemptions and reduced burden to EPA. Indirect benefits may accrue to users of pesticides under emergency exemptions if changes result in faster review and approval, or greater availability of pesticides. Although not required, EPA expects to assess the potential economic impacts of this action.

Risks:

In general, the measures being considered are primarily intended to reduce burdens for States and EPA and achieve efficiencies in the program. No impact on risk is anticipated.

Timetable:

Action	Date	FR Cite
Notice	04/24/03	68 FR 20145
NPRM	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN 4216.

Sectors Affected:

9241 Administration of Environmental Quality Programs

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RIN: 2070–AD36

EPA

107. ACCEPTABILITY OF RESEARCH USING HUMAN SUBJECTS

Priority:

Other Significant

Legal Authority:

5 USC 301; 7 USC 136a; 7 USC 136w; 15 USC 2603; 21 USC 346a; 42 USC 300v–1(b); 42 USC 7601; 33 USC 1361; 42 USC 9615; 42 USC 11048; 42 USC 6912; 42 USC 300j–9

CFR Citation:

40 CFR 26 (Revision)

Legal Deadline:

None

Abstract:

EPA is evaluating its current policy with respect to the protection of human research subjects in testing not conducted or supported by the Federal government. Current EPA regulations in 40 CFR part 26 apply to research conducted or supported by the Agency or ''otherwise subject to regulation.'' No action has been taken yet to give effect to the ''otherwise subject to regulation'' phrase. In addition, EPA has asked the advice of the National Academy of Sciences (NAS) on several issues surrounding the acceptability and interpretation of third party studies involving deliberate dosing of human subjects for the purpose of defining or quantifying toxic endpoints. EPA will seek public comment on issues related to Agency use of human research data in its regulatory decisionmaking. EPA believes the process being initiated will serve two important Agency goals: ensuring the availability of sound and appropriate scientific data in its decisions, and protection of the interests, rights and safety of human research subjects. EPA may issue one or more documents, which may include policy statements, rulemaking or requests for public comment.

Statement of Need:

In July 1998, the Agency committed that EPA would not consider human research in its regulatory decisions unless a policy were in place that could assure any such studies met the highest scientific and ethical standards. The Agency convened a special joint subcommittee of the FIFRA Scientific Advisory Panel and the EPA Science Advisory Board to advise on this policy. The subcommittee completed its report in September 2000. In December 2001 the Agency sought the advice of the National Academy of Sciences on several difficult issues. A report from the NAS is expected in December 2003. In December 2001 the Agency clarified its interim policy, committing, subject to certain exceptions, not to consider or rely on any third party studies involving intentional dosing of human

subjects with toxicants for the purpose of defining or quantifying their effects until a final policy is in place, and clarifying that this interim policy applies across all Agency programs. In June 2003, in response to a challenge of the interim policy, the U.S. Court of Appeals vacated the interim policy and stated that as a consequence of the Agency's ''previous practice of considering third party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide,'' was reinstated ''until it is replaced by a lawfully promulgated regulation.'' If ultimately deemed acceptable for consideration, some human research could significantly affect the Agency's risk assessments of some pesticides and other toxicants.

Summary of Legal Basis:

Several statutes contain provisions that involve Agency regulatory decisions that are or may be based on testing not conducted or supported by the Agency. For example, FIFRA section 3 directs EPA to define data requirements supporting pesticide decisions and to establish guidelines for conducting research to support pesticide decisions; and FFDCA section 408 directs EPA to, among other things, consider available and reliable data in support of pesticide tolerance decisions. FIFRA sec. 4(g)(1) directs the Administrator to ''conduct a thorough examination'' of ''all data submitted under this section (section 4)'' and of ''all other available data found by the Administrator to be relevant.''

Alternatives:

Still to be identified.

Anticipated Cost and Benefits:

No analysis has been performed yet.

Risks:

No analysis has been performed yet.

Timetable:

Action	Date	FR Cite
ANPRM	05/07/03	68 FR 24410
NPRM	10/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN 4610.

Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

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RIN: 2070–AD57

EPA

108. 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. EPA may publish in the Federal Register the procedures and processes that the Agency 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 action will describe the authorities that EPA 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. section 346(a)(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, as a rough estimate, the screening battery 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 in paragraph 22 below.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk from exposure to chemicals operating through a endocrine mediated pathway. Preliminary studies show decreases on IQ tests and increases in aggression in children. Severe malformations of the genitals of boys has increased steadily over the last two decades. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish and shellfish have been documented in the United States, Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the United States 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	07/00/04	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN 4728. Split from RIN 2070–AD26. In August 2000, the Agency submited the required Status Report to Congress. In March 2002, the Agency submitted the requested status report to Congress on the Endocrine Disruptor Methods Validation subcommittee under the National Advisory Council on Environmental Policy and Technology.

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RIN: 2070–AD61

EPA

109. NESHAPS: STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR HAZARDOUS WASTE COMBUSTORS

Priority:

Other Significant

Legal Authority:

42 USC 6924 ''RCRA 3004''; 42 USC 6925 ''RCRA 3005''; 42 USC 7412 ''CAA 112''; 42 USC 7414 ''CAA 114''

CFR Citation:

40 CFR 60; 40 CFR 63; 40 CFR 260; 40 CFR 264; 40 CFR 265; 40 CFR 266; 40 CFR 270

Legal Deadline:

NPRM, Judicial, March 31, 2004.

Final, Judicial, June 15, 2005.

Abstract:

On September 30, 1999, EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn hazardous waste (referred to as the phase I rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the phase I rule. On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow them time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 15, 2005. This rulemaking will propose and finalize the Phase I replacement standards. Also, in this rulemaking effort, we are developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as phase II sources because the standards were originally scheduled to be promulgated after phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the phase II sources by the same date as those for phase I (June 15, 2005). EPA is developing options for calculating the emission standards that are considered to be consistent with both the statutory requirements and the opinion of the Court. Potential costs and benefits are not yet available, because emission standards must be selected before the cost/benefit analyses begin.pI and phase II sources in December of 2003.

Statement of Need:

Section 112 of the Clean Air Act requires that the EPA promulgate regulations requiring the control of hazardous air pollutants from major and certain area sources. The control of hazardous air pollutants is achieved through promulgation of emission standards under sections 112(d) and (f) and, in appropriate circumstances, work practice standards under section 112(h).

On September 30, 1999 EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn

hazardous waste (referred to as the phase I rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the phase I rule.

Summary of Legal Basis:

On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 14, 2005. EPA is working towards promulgation by this date. EPA is also developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as phase II sources because the standards were originally scheduled to be promulgated after phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the phase II sources by the same date as those for phase I (June 14, 2005).

Alternatives:

EPA is developing options for calculating the emission standards that are considered to be consistent with both the statutory requirements and the opinion of the Court.

Anticipated Cost and Benefits:

Potential costs and benefits are not yet available, because emission standards must be selected before the cost/benefit analyses can be completed. EPA plans to propose emission standards and compliance provisions for both the phase I and phase II sources in March 2004.

Risks:

For the 1999 rule, we estimated the avoided incidence of mortality and morbidity associated with reductions in particulate matter (PM) emissions. Estimates of cases of mortality and morbidity avoided were made for children and the elderly, as well as the general population, using concentration-response functions derived from human epidemiological studies. Morbidity effects included respiratory and cardiovascular illnesses requiring hospitalization, as well as other illnesses not requiring hospitalization, such as acute and chronic bronchitis and acute upper and lower respiratory symptoms. For this rule, we are comparing characteristics of the sources covered by the 1999 rule to the sources covered by the replacement rule that are related to risk. These characteristics include emissions, stack characteristics, meteorology, and population. Based on the results of the statistical comparisons, we will infer whether the risks will be about the same, less than, or greater than the 1999 rule. Risk inferences for boilers and HCl production furnaces will be based on comparisons with incinerators for the 1999 rule.

Timetable:

Action	Date	FR Cite
NPRM–CK	04/19/96	61 FR 17358
Final—Fasttrack	06/19/98	63 FR 33782
Final—CK	09/30/99	64 FR 52828
NODA	07/27/00	65 FR 39581
DF 1	07/03/01	66 FR 35087
NPRM—Phase1	07/03/01	66 FR 35126
Parallel Proposal	07/03/01	66 FR 35124
Direct Final Action	10/15/01	66 FR 52361
Final Compliance Extension	12/06/01	66 FR 63313
Interim Final Action	02/13/02	67 FR 6792
Final HAP	02/14/02	67 FR 6968
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN 3333. For information on the Phase I portion of this effort, see SAN 4418, RIN 2050–AE79.

Sectors Affected:

3335 -; 3343 Audio and Video Equipment Manufacturing; 3251 Basic Chemical Manufacturing; 3273 Cement and Concrete Product Manufacturing; 3271 Clay Product and Refractory Manufacturing; 3328 Coating, Engraving, Heat Treating and Allied Activities; 3342 Communications Equipment Manufacturing; 3341 Computer and Peripheral Equipment Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 45431 Fuel Dealers; 3332 Industrial Machinery Manufacturing; 3274 Lime, Gypsum and Gypsum Product Manufacturing; 3327 Machine Shops, Turned Product, and Screw, Nut and Bolt Manufacturing; 3362 Motor Vehicle Body and Trailer Manufacturing; 3361 Motor Vehicle Manufacturing; 3363 Motor Vehicle Parts Manufacturing; 2123 Non-Metallic Mineral Mining and Quarrying; 3259 Other Chemical Product Manufacturing; 3329 Other Fabricated Metal Product Manufacturing; 3339 Other General Purpose Machinery Manufacturing; 3279 Other Nonmetallic Mineral Product Manufacturing; 3255 Paint, Coating, Adhesive, and Sealant Manufacturing; 3253 Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing; 3241 Petroleum and Coal Products Manufacturing; 4227 Petroleum and Petroleum Products Wholesalers; 3254 Pharmaceutical and Medicine Manufacturing; 3231 Printing and Related Support Activities; 5629 Remediation and Other Waste Management Services; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing; 3344 Semiconductor and Other Electronic Component Manufacturing; 22132 Sewage Treatment Facilities; 5622 Waste Treatment and Disposal

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RIN: 2050–AE01

EPA

110. STANDARDS FOR THE MANAGEMENT OF COAL COMBUSTION WASTES GENERATED BY COMMERCIAL ELECTRIC POWER PRODUCERS

Priority:

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

Unfunded Mandates:

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

Legal Authority:

42 USC 6907(a)(3); 42 USC 6944(a)

CFR Citation:

40 CFR 257

Legal Deadline:

None

Abstract:

This action is for the development of nonhazardous waste regulations under subtitle D of the RCRA statute. The regulations will apply to landfill and surface impoundment facilities that manage coal combustion wastes generated by steam electric power generators, i.e., electric utilities and independent power producers. This action results from EPA's regulatory determination for fossil fuel combustion wastes (see 65 FR 32214, May 22, 2000), which concluded that waste management regulations under RCRA are appropriate for certain coal combustion wastes. The utility industry has made significant improvement in its waste management practices over recent years, and most state regulatory programs are similarly improving. However, public comment and other analyses have convinced the Agency that coal combustion wastes could pose significant risks to human health and the environment if they are not properly managed. There is sufficient evidence that adequate controls may not be in place. For example, 62 percent of existing utility impoundments do not have groundwater monitoring; thus, their impact on ground and surface waters cannot be evaluated in light of numerous damage cases identified by the Agency that involve management of these wastes. The intended benefits of this action will be to prevent contamination or damage to ground waters and surface waters, thereby avoiding risk to human health and the environment, including ecological risks. The Agency is currently analyzing the human health and ecological risks, costs, and economic impact of this action as it develops the proposed regulation. The Agency has considered alternatives to this action, including regulating these wastes as hazardous wastes under subtitle C of RCRA, but has rejected this approach as discussed in the regulatory determination (see 65 FR 32214, May 22, 2000). EPA has also considered issuing guidance instead of regulations to industry and state and local governments to focus on these remaining waste management issues but concluded that there will probably continue to be some gaps in practices and controls and is concerned at the possibility that these will go undressed. The Agency also believes the timeframe for improvement of current practices is likely to be longer in the absence of federal regulation.

Statement of Need:

Public comment and other analyses have convinced the Agency that coal combustion wastes could pose significant risks to human health and the environment if they are not properly managed. There is sufficient evidence that adequate controls may not be in place, including for ground water monitoring, lining of waste management units, and mismanagement of the wastes in sand and gravel pits and similar geologies. A significant number of environmental damage cases indicate that past management practices were insufficient. The intended benefits of this regulatory action will be to prevent contamination or damage to ground waters and surface waters, and to prevent ecological risks.

Summary of Legal Basis:

The rules that are being developed pursuant to RCRA subtitle D are not mandated by statute or court order. Rather, the Agency concluded from its finding in the required RCRA section 3001 (b) determination that, while RCRA subtitle C regulations for hazardous wastes are not warranted, RCRA nonhazardous waste regulations are necessary. The nonhazardous waste regulations will address gaps in existing Federal and State requirements for the management of these wastes in order to protect human health and the environment.

Alternatives:

The Agency has considered regulating these wastes as hazardous wastes under subtitle C of RCRA or a nonhazardous wastes under subtitle D of RCRA. The Agency also has considered issuing guidance instead of regulations to industry and state and local government to focus on the key waste management issues. However, the Agency concluded that some gaps in waste management practices would likely continue and is concerned that these gaps would continue to go unaddressed. The Agency concluded that non-hazardous waste regulations under subtitle D of RCRA are most appropriate.

Anticipated Cost and Benefits:

The costing, economics, and benefits analyses are under study pending results of the risk assessment. Costs will include direct costs to the generators of coal combustion wastes for management according to the regulation. Benefits will include damage avoidance to ground water and surface water resources, including sources of drinking water that could affect human health. No additional information is available at this time.

Risks:

The Agency has a comprehensive risk analysis underway to determine the cross-media impacts of managing these wastes, with a focus on impacts to ground waters and surface waters and their human health implications. The risk analysis will also identify ecological impacts of waste management. While the risk analysis is nearing completion, no quantitative measures of risk are available yet, and, thus, no information of risk magnitude or risk reduction efforts is available at this time.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

Undetermined

Additional Information:

SAN 4470. This rule may also impact Federal, State, local or tribal governments that own coal-burning commercial electric power generating facilities.

Sectors Affected:

221112 Fossil Fuel Electric Power Generation

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RIN: 2050–AE81

EPA

111. INCREASE METALS RECLAMATION FROM F006 WASTE STREAMS

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

Not Yet Determined

CFR Citation:

40 CFR 261

Legal Deadline:

None

Abstract:

Many metal finishers and other industrial sectors generate an electroplating sludge as part of their production process that is amenable to recycling, i.e., the sludge contains economically recoverable amounts of metals such as copper, nickel, zinc, etc. Currently, these sludges (F006) are listed hazardous wastes subject to RCRA regulations. Many generators continue to send these sludges for treatment and disposal when they could be recycled. Similarly, generators currently sending their sludges for recycling receive no economic benefit for this practice. Since the mid-1990's, EPA has been working with industry and the States to create incentives for safe recycling and has promulgated rules to foster this practice. However, EPA is interested in exploring whether further regulatory changes are warranted.

EPA is currently evaluating several options that would provide regulatory relief to generators and handlers of F006. All options would reduce regulatory costs to generators and handlers relative to the current RCRA subtitle C regulatory program.

Statement of Need:

F006 represents one of the largest hazardous waste streams amenable to recycling. Currently, there is no differentiation in regulatory requirements the land disposal and recycling of F006 electroplating sludges. This effort seeks to evaluate different regulatory options that would eliminate existing disincentives to the safe recycling of F006 with the ultimate objective of possibly proposing changes to the existing regulatory framework. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006, increased natural resource conservation by reducing emissions from landfills and surface waters.

Summary of Legal Basis:

RCRA sections 2002, 3001–3004, 42 U.S.C. 6912, 6921 to 6924. No aspect of this action is required by statutory or court order.

Alternatives:

Regulatory options being examined would affect generators and possibly other handlers of F006, i.e., consolidators, commercial hazardous waste recyclers and mineral processing facilities. EPA is also considering various options for the minimum amount of recoverable metals contained in F006 electroplating sludges.

Anticipated Cost and Benefits:

This rule is designed to provide regulatory relief to generators and possibly other handlers of F006. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006 and increasing natural resource conservation by reducing emissions from landfills and surface waters.

Risks:

Options being evaluated would ensure that the risks posed from recycling F006 would not increase. These risks include storage and management of the materials throughout the recycling process, as well as any nonrecyclable constituents included in the F006.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

SAN 4651.

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RIN: 2050–AE97

EPA

112. STANDARDS AND PRACTICES FOR CONDUCTING ''ALL APPROPRIATE INQUIRY''

Priority:

Other Significant

Legal Authority:

42 USC 9601 et seq

CFR Citation:

40 CFR 312

Legal Deadline:

Final, Statutory, January 11, 2004, Final.

Abstract:

The Small Business Liability Relief and Brownfields Revitalization Act (the Brownfields Law) amended a number of provisions in CERCLA including section 101(35)(B) and includes, among other things, new provisions regarding limitations on CERCLA liability for certain landowners. As part of these provisions, the Brownfields Law addresses the need for bona fide prospective purchasers, contiguous property owners, and innocent landowners to conduct ''all appropriate inquiry'' into prior ownership and use of the property at the time the party acquires the property.

In the Brownfields Law, Congress directed EPA to promulgate regulations establishing standards and practices for conducting ''all appropriate inquiry.'' Section 101 (35)(B)(iii) of the law includes criteria that EPA is required to address in setting these standards and practices. This regulation will establish the Federal standards for conducting ''all appropriate inquiry,'' pursuant to the Act. Recipients of

Brownfields Assessment Grants will be regulated by the final action. Purchasers of contaminated properties who wish to assert certain limitations on CERCLA liability may choose to follow the promulgated procedures and standards.

EPA is developing the Federal standard for all appropriate inquiry under a negotiated rulemaking process. EPA established a FACA committee charged with negotiating a Federal standard in accordance with the statutory criteria.

Statement of Need:

The need for this action is the congressional mandate in the Small Business Liability Relief and Brownfields Revitalization Act. Section 101(35)(B)(ii) of the law, Congress directs the EPA Administrator to establish (by regulation) standards and practices for the purpose of satisfying the requirement to carry out all appropriate inquiries. Congressional intent or ''need'' is that purchasers of potentially contaminated property must conduct an inquiry or investigation into the environmental conditions of a property prior to purchasing the property to ensure an understanding of the extent of prior and ongoing environment conditions to establish liability.

Summary of Legal Basis:

In Section 101(35)(B)(ii) of the Small Business Liability Relief and Brownfields Revitalization Act Congress directs the EPA Administrator to establish (by regulation) standards and practices for the purpose of satisfying the requirement to carry out all appropriate inquiries.

Alternatives:

EPA may consider alternative standards for specific portions of the regulatory requirements, if viable and suitable alternatives are identified by the FACA committee chartered to negotiate the rulemakings. No such alternatives have been identified to date.

Anticipated Cost and Benefits:

Costs associated with the new Federal standard may include incremental costs, associated with using the new Federal standard, that are over and above the costs associated with the privately developed standards currently employed in conducting all appropriate inquiry for the purposes of real estate transaction. This rulemaking will not impose new mandatory requirements on any entities, other than recipients of Federal brownfields grants provided for the purpose of assessing or characterizing brownfields sites. Other than these grant recipients, the standards will be applicable to purchasers of contaminated properties who wish to assert certain limitations on CERCLA liability. The benefits of the regulation may include providing purchasers of contaminated property with clarity regarding the procedures and standards for the conduct of ''all appropriate inquiry'' required to assert certain limitations on CERCLA liability.

Risks:

This regulatory action will not directly address risks to human health or the environment.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4739. State, local and Tribal governments affected if they are grant recipients.

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RIN: 2050–AF04

EPA

113. ● REGULATORY AMENDMENTS TO THE F019 HAZARDOUS WASTE LISTING TO EXCLUDE THE WASTEWATER TREATMENT SLUDGES FROM THE CHEMICAL CONVERSION COATING PROCESS (ZINC PHOSPHATING) OF AUTOMOBILE BODIES OF ALUMINUM

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1006 et seq

CFR Citation:

40 CFR 261.31; 40 CFR 302.4

Legal Deadline:

None

Abstract:

Automobile manufacturers are adding aluminum or aluminized components to automobiles to reduce the weight of vehicles to increase fuel economy. When aluminum components are added to the automobile assembly process, the current federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a hazardous waste under the Resource Conservation and Recovery Act. EPA intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum.

Statement of Need:

This action when finalized will reduce the burden on the automobile industry from treating sludges from the process of zinc phosphating of aluminum as hazardous wastes. The applicable listed hazardous waste (F019) was listed as such because it contains cyanide and chromium. The sludges from the zinc phosphating of aluminum do not contain any of these constituents.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Additional Information:

SAN 4834.

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RIN: 2050–AG15

EPA

114. WATERSHED RULE: TOTAL MAXIMUM DAILY LOAD (TMDL) PROGRAM REVISIONS

Priority:

Other Significant

Legal Authority:

33 USC 1313; 33 USC 1329; 33 USC 1342; 33 USC 1256

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 124; 40 CFR 130

Legal Deadline:

None

Abstract:

Amend regulations governing the TMDL program to ensure that it is effective, 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., States, 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 jurisdiction's 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, section 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	12/00/03	
Final Action	10/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN 4623.

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RIN: 2040–AD82

EPA

FINAL RULE STAGE

115. 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.

Final, Judicial, February 27, 2004.

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 hardboard, oriented strandboard (OSB), medium density fiberboard (MDF), particleboard, 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. 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	01/09/03	68 FR 1276
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

SAN 3820.

Sectors Affected:

32121 Veneer, Plywood, and Engineered Wood Product Manufacturing

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RIN: 2060–AG52

EPA

116. 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 112; PL 101–549

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Final, Judicial, February 27, 2004.

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 reciprocating internal combustion engine (RICE) MACT was published in the Federal Register on December 19, 2002. A public hearing was held on January 21, 2003 and the public comment period closed on February 18, 2003. Comments and data received during the comment period are being evaluated. The anticipated date of the final RICE rule being signed by the Administrator is February 27, 2004.

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	12/19/02	67 FR 77830
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Local, State

Additional Information:

SAN 3656.

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RIN: 2060–AG63

EPA

117. 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.

Final, Judicial, February 27, 2004.

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:

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:

Implementation of the rulemaking would reduce nationwide emissions of air toxics by 58,000 tons per year in the fifth 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	01/13/03	68 FR 1660
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Local

Additional Information:

SAN 3837.

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RIN: 2060–AG69

EPA

118. NESHAP: SURFACE COATING OF AUTOMOBILES AND LIGHT–DUTY TRUCKS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7412

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Judicial, February 27, 2004.

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 categorie in 1980. The standards for the NESHAP are to be technology-based are 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:

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:

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	12/24/02	67 FR 78612
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Additional Information:

SAN 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

119. IMPLEMENTATION RULE FOR 8–HOUR OZONE NAAQS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 7408; 42 USC 7410; 42 USC 7501 to 7511f; 42 USC 7601(a)(1)

CFR Citation:

40 CFR 51; 40 CFR 50; 40 CFR 81

Legal Deadline:

None

Abstract:

This rule would provide specific requirements for State and local air pollution control agencies and tribes to prepare State implementation plans (SIPs) and Tribal Implementation Plans (TIPs) under the 8-hour national ambient air quality standard (NAAQS) for ozone, published by EPA on July 18, 1997. The Clean Air Act (CAA) requires EPA to set ambient air quality standards and requires States to submit SIPs to implement those standards. The 1997 standards were challenged in court, but in February 2001, the Supreme Court determined that EPA has authority to implement a revised ozone standard, but ruled that EPA must reconsider its implementation plan for moving from the 1-hour standard to the revised standard. The Supreme Court identified conflicts between different parts of the CAA related to implementation of a revised NAAQS, provided some direction to EPA for resolving the conflicts, and left it to EPA to develop a reasonable approach for implementation. Thus, this rulemaking must address the requirements of the CAA and the Supreme Court's ruling. This rule would provide detailed provisions to address the CAA requirements for SIPs and TIPs and would thus affect States and Tribes. States with areas that are not attaining the 8-hour ozone NAAQS will have to develop—as part of their SIPs—emission limits and other requirements to attain the NAAQS within the timeframes set forth in the CAA. Tribal lands that are not attaining the 8-hour ozone standard may be affected, and could voluntarily submit a TIP, but would not be required to submit a TIP. In cases where a TIP is not submitted, EPA would have the responsibility for planning in those areas.

Statement of Need:

This action is needed in response to the U.S. Supreme Court's ruling in February 2001 (Whitman v. American Trucking Assoc., 121 S.Ct.903) that stated that EPA has the authority to implement a revised ozone NAAQS but that EPA could not ignore the provisions of subpart 2 when implementing the 8-hour NAAQS. The Supreme Court identified several portions of subpart 2 that are ill-fitted to the revised NAAQS but left it to EPA to develop a reasonable implementation approach. Consequently, EPA is developing a rule to implement the 8-hour ozone NAAQS under the provisions of subpart 2 of the CAA.

Summary of Legal Basis:

Title I of the Clean Air Act.

Alternatives:

This entry comprises the action the Agency plans to take to implement the 8-hour ozone NAAQS. The major alternatives facing the Agency is whether the 8-hour O3 NAAQS should be implemented under the less prescriptive part of the Clean Air Act (title I, part D, subpart 1) or the more prescriptive part of the Act (subpart 2). Another major set of alternatives concern the kind of transition EPA should make from implementation of the current 1-hour ozone standard to the new 8-hour ozone standard.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis for the final ozone NAAQS, and has prepared a cost analysis for the proposed implementation rule. The

benefits of the rule are those associated with attainment of the ozone NAAQS including significant improvements in premature mortality, chronic asthma, chronic and acute bronchitis, upper and lower respiratory symptoms, work days lost, decreased worker productivity, visibility in urban and suburban areas, and increases in yields of commercial forests currently exposed to elevated ozone levels.

Risks:

The risks addressed by this action are the likelihood of experiencing increased health and environmental effects associated with nonattainment of the National Ambient Air Quality Standard for ozone. These effects are briefly described above in the ''costs and benefits'' section, and they were outlined in detail in the Regulatory Impact Analysis for the ozone NAAQS rulemaking. The results are summarized in the Federal Register notice for that rulemaking (62 FR 38856, July 18, 1997).

Timetable:

Action	Date	FR Cite
NPRM	06/02/03	68 FR 32802
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State, Tribal

Additional Information:

SAN 4625.

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RIN: 2060–AJ99

EPA

120. 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 May 23, 2003, EPA proposed new emission controls for nonroad diesel engines, which are generally used in industrial, mining, and agricultural applications. The control strategies proposed focused around the use of advanced exhaust aftertreatment technologies for the first time in these applications. This technology reduces emissions of NOx, NMHC, and PM of over 90 percent. The standards would phase-in between 2008 and 2014, with different implementation schedules applicable to each of the five engine horsepower categories. Less stringent standards would apply to the smallest horsepower category. Coupled with these proposed engine standards is a two-step reduction in fuel sulfur levels, going from uncontrolled levels to 500 ppm in 2007 and then to 15 ppm in 2010. All nonroad diesel fuel, including that used in locomotive and marine applications, is covered in the first step while locomotive and marine fuel is not involved in the second step. This overall program builds on the successful 2007 highway diesel program the Agency completed in 2000.

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 sections 213 and 217.

Alternatives:

Eleven separate alternatives were analyzed as part of the proposal. Estimated cost impacts and benefits were estimated where possible. The alternatives looked at varying implementation dates or control strategies of both the fuel and engine standards. In addition, controlling sulfur levels to 15 ppm in 2010 for locomotive and marine diesel fuel was also analyzed.

Anticipated Cost and Benefits:

The total cost (engine and fuel standards) estimate of the proposed requirements was approximately $1.5 billion per year. In 2030, when the full effects of the rule would be in place, the quantifiable benefits would be approximately $81 billion per year. This estimate includes the impacts of reducing 9,600 cases of premature mortality, almost a million work lost days, and improvements to recreational visibility.

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	05/23/03	68 FR 28327
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State

Additional Information:

SAN 4675.

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RIN: 2060–AK27

EPA

121. HAZARDOUS WASTE MANIFEST REGULATION

Priority:

Other Significant

Legal Authority:

42 USC 6922 RCRA 3002; 42 USC 6923 RCRA 3003; 42 USC 6924 RCRA 3004; 42 USC 6926 RCRA 3006; PL 105–277; Government Paperwork Elimination Act 17

CFR Citation:

40 CFR 260; 40 CFR 262; 40 CFR 263; 40 CFR 264; 40 CFR 265; 40 CFR 271

Legal Deadline:

None

Abstract:

The Uniform Hazardous Waste Manifest (Form 8700–22) is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of hazardous waste during its transportation. Waste handlers (e.g., generators and transporters) are required to use the manifest, and States may not require a different manifest in its place. However, the manifest has State blocks which allow States, at their option, to require the entry of additional specific information to serve their State's regulatory needs. Under the current regulations more than 20 States print the manifest form in accordance with the format specified in federal regulations. However, the variability among State manifest programs associated with state optional blocks, different copy distribution schemes, and the manifest hierarchical acquisition scheme has drawn complaints from the regulated community. Variability among States' Manifest programs and the manifest system's current reliance on paper result in significant paperwork and cost burden to waste handlers and States who choose to collect manifest information. The Agency intends to standardize further the manifest form elements, and to specify one format for the manifests that may be used in all states. In addition, the Agency intends to announce standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes. Finally, the Agency intends to pursue an optional approach that would use information technologies to conduct the manifest process electronically, thereby reducing paperwork burden, and improving the speed and accuracy of preparing, transmitting, and recordkeeping the manifest form. However, the Agency will bifurcate the manifest rule so that the form revisions may be expedited, while additional analysis on the e-manifest continues.

Statement of Need:

Since the adoption of the Uniform Manifest by EPA and the Department of Transportation (DOT) in 1984, the regulated community and authorized states have pressed EPA to adopt changes that would simplify and further reduce the variability among the hazardous waste manifest forms required and distributed by the states. In addition, the recent focus on electronic government has highlighted the potential advantages of an electronic manifest system in terms of reduced paperwork burdens and more timely waste tracking. This action responds to these needs with a truly universal set of manifest data elements and a manifest format that will be identical in all states, as well as standards that will allow the manifest data to be completed, signed, transmitted, and recorded electronically.

Summary of Legal Basis:

EPA's regulations implementing the manifest are based on section 3002(a)(5) of the RCRA statute, which requires that EPA include in its hazardous waste generator regulations requirements addressing the ''use of a manifest system and ony other reasonable means necessary'' to assure that all such hazardous waste is designated for and designated for and arrives at treatment, storage, or disposal facilities that have been permitted under RCRA subtitle C requirements. Secion 3003(a)(3) of the Act requires transporters of hazardous waste to comply with the manifest system, while section 3004(a)(2) requires compliance with the manifest system by treatment, storage, and disposal facilities. Moreover, according to section 1004(12) of the Act, the manifest is defined as the ''form used for identifying the quantity, composition, and the origin, routing, and destination of hazardous waste during its transportation from the point of generation to the point of disposal, treatment, or storage.'' The manifest also serves as teh ''shipping paper'' meeting DOT requirements for the transportation of hazardous materials under the Federal Hazardous Materials laws and regulations.

EPA's current manifest regulations require generators to obtain manifest froms from the authorized States. The generator must complete the paper form by identifying the type and quantity of hazardous waste in off-site shipments, as well as the identities of the transporters and waste receiving facilities that will manage the waste. The regulations require waste handlers to sign the manifest form by hand when they receive a waste shipment, and to retain copies of the signed manifests that document the chain of custody of a shipment, and any discrepancies.

EPA and DOT have authority to eliminate variability among state manifests, since DOT's hazardous materials laws generally call for uniformity in the use of hazardous materials shipping papers such as the manifest, and EPA must regulate transportation consistently with DOT. EPA and DOT consented in 1984 to the inclusion of several ''optional'' data fields, but our experience with the manifest system has demonstrated that the inclusion of optional fields introduces excessive variability and burden for waste handlers. EPA also has authority to automate the waste tracking functions of the manifest, since the Act states that EPA can employ any reasonable means necessary to track waste shipments under a manifest system. There is nothing in the statute that precludes EPA from establishing standards allowing electronic manifesting of shipments, as well as use of the traditional paper forms.

Alternatives:

The form revisions part of the rulemaking examines alternatives to the current system that allows authorized states to print and distribute slightly varying manifest forms (typically for a fee) to waste handlers generating or shipping waste in a particular state.

This rule would establish a precise Federal specification for the manifest that would preclude variability in manifest forms, wherever they are used. This option was proposed in May 2001, and was supported by the great preponderance of commenters who submitted written comments to the docket.

The rule also examines alternative electronic formats for completing electronic manifests, and alternative methods for signing manifests electronically. Moreover, EPA has been examining in response to comments whether electronic manifest systems should be developed in a decentralized fashion by private companies in adherence with standards announced by EPA (the proposed approach), or, developed and hosted centrally in a national system. We expect that additional stakeholder outreach will be necessary to determine the appropriate design and functionality of the e-manifest approach for the final rule. Therefore, the e-manifest part of the rulemaking has been separated from the form revisions part of the rule, so that final action on the form revisions will not be delayed by future outreach and analysis conducted in connection with the e-manifest.

Anticipated Cost and Benefits:

The baseline manifest system results in annual paperwork burdens of 4.6 million hours and annual costs of about $193 million. In developing the May 2001, proposed rule, EPA estimated that the proposed revisions to the hazardous waste manifest system (form changes and electronic manifest) would reduce the paperwork burdens impoosed by the manifest by 765,000 to 1.24 million hours annually, and would reduce annual costs by $24–$37 million. The rule should also eliminate much of the complexity that arises from having to obtain and comply with states' slightly varying manifest forms, and the burden and complexity of having to supply information to satisfy the current so-called ''optional'' state fields. The ability to complete and transmit manifest data electronically should improve the accuracy of manifest data, and the timeliness and effectiveness of waste shipment tracking.

Risks:

This rule addresses only administrative requirements for tracking waste shipments. The rule does not address risks posed by particular substances or waste management activities, and no risk assessments have been prepared to support this action.

Timetable:

Action	Date	FR Cite
NPRM	05/22/01	66 FR 28240
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN 3147. Because of significant issues identified during the public comment period on the electronic manifest part of the rule, this part of the rule has been separated from the form revisions part of the rule for purposes of publishing a final action. The form revisions part of the rule will be finalized first, while final action on the electronic manifest must await further stakeholder outreach and analysis.

Sectors Affected:

325 Chemical Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 332 Fabricated Metal Product Manufacturing; 2122 Metal Ore Mining; 2111 Oil and Gas Extraction; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 3221 Pulp, Paper, and Paperboard Mills; 482 Rail Transportation; 484 Truck Transportation; 5621 Waste Collection; 5622 Waste Treatment and Disposal; 483 Water Transportation

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RIN: 2050–AE21

EPA

122. MANAGEMENT OF CEMENT KILN DUST (CKD)

Priority:

Other Significant

Legal Authority:

42 USC 6912(a) RCRA 2002(a); 42 USC 6921(a) RCRA 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 (67 FR 48648) to announce the availability for public inspection and comment of recently acquired data on CKD.

The Agency is now considering an approach whereby it would finalize the proposed option of issuing the protective CKD management standards as described in the August 20, 1999 proposal as a RCRA subtitle D rule. The Agency would temporarily suspend its active consideration of the proposed listing of mismanaged CKD as a hazardous waste, and assess how CKD management practices and state regulatory programs evolve over the next three to five years. Based on this assessment, EPA will then proceed to either formally withdraw or promulgate the portion of the 1999 proposal that classifies as a RCRA hazardous waste CKD that has been egregiously mismanaged.

EPA will be promoting pollution prevention, recycling, and safer disposal of CKD by considering finalization of protective management standards for this waste. The Agency believes that these management standards are a creative, affordable, and common sense approach that can

protect human health and the environment without imposing unnecessary regulatory burdens on the cement kiln industry. These standards provide a new, tailored framework that safeguards ground water and limits risk from releases of dust to air.

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 effect the economy by less than $100 million per year. EPA also estimated that the proposed rule may result in a reduced risk of).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—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 1	02/07/95	60 FR 7366
NPRM	08/20/99	64 FR 45632
Notice 2	07/25/02	67 FR 48648
Notice 3	11/08/02	67 FR 68130
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN 3856.

Sectors Affected:

32731 Cement Manufacturing

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RIN: 2050–AE34

EPA

123. 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 onsite in tanks, containers, and containment buildings. Under the standardized permit, facility owners and operators would certify compliance with generic design and operating conditions set on a national basis. The permitting agency would review the certifications submitted by the facility owners and operators. The permitting agency would also be able to impose additional site-specific terms and conditions for corrective action or other purposes, as called for by RCRA. Ensuring compliance with the standardized permit's terms and conditions would occur during inspection of the facility after the permit has been issued. The standardized permit should streamline the permit process by allowing facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process. EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately $100 to $5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. The proposal raised issues for public comment on how all facilities receiving RCRA permits can satisfy RCRA corrective action requirements under appropriate alternative state cleanup programs and on financial assurance issues. The Agency is developing a final rule addressing this topic.

Statement of Need:

The Agency convened a special task force in 1994 to look at permitting activities throughout its different programs and to make specific recommendations to improve these permitting programs. This task force, known as the Permits Improvement Team (PIT), spent two years working with stakeholders from the Agency, State permitting agencies, industry, and the environmental community. The PIT stakeholders mentioned, among other things, that permitting activities should be commensurate with the complexity of the activity. The stakeholders felt that current Agency permitting programs were not flexible enough to allow streamlined procedures for routine permitting activities. Currently, facilities that store, treat, or dispose of hazardous waste must obtain site-specific ''individual'' permits prescribing conditions for each ''unit'' (e.g., tank, container area, etc.) in which hazardous waste is managed. Experience gained by the Agency and states over the past 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 onsite 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 onsite, but asked for comment on whether to expand that scope to facilities that manage wastes generated offsite. 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 onsite 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	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN 4028.

Sectors Affected:

3251 Basic Chemical Manufacturing; 332813 Electroplating, Plating, Polishing, Anodizing and Coloring; 32551 Paint and Coating Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32411 Petroleum Refineries; 325211 Plastics Material and Resin Manufacturing; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing

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RIN: 2050–AE44

EPA

124. OFFICE OF SOLID WASTE BURDEN REDUCTION INITIATIVE

Priority:

Other Significant

Legal Authority:

42 USC 6907; 42 USC 6912(a); 42 USC 6921 to 6927; 42 USC 6930; 42 USC 6934; 42 USC 6935; 42 USC 6937 to 6939; 42 USC 6944; 42 USC 6949(a); 42 USC 6974; PL 104–13

CFR Citation:

40 CFR 261.38; 40 CFR 264.16; 40 CFR 264.52; 40 CFR 264.56; 40 CFR 264.73; 40 CFR 264.98 et seq; 40 CFR 265.16; 40 CFR 265.52; 40 CFR 265.56; 40 CFR 265.73; 40 CFR 265.98 et seq; 40 CFR 266.103; 40 CFR 261.4; 40 CFR 268.7; 40 CFR 268.9

Legal Deadline:

None

Abstract:

EPA plans to reduce the burden imposed by the RCRA reporting and recordkeeping requirements to help meet the Federal Governmentwide goal established by the Paperwork Reduction Act (PRA).

In June 1999, EPA published a Notice of Data Availability (NODA) in the Federal Register (64 FR 32859) to seek comment on a number of burden reduction ideas. 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. EPA is planning to issue a notice to seek further input on a number of changes we proposed. EPA will then finalize this burden reduction effort.

Statement of Need:

The Paperwork Reduction Act of 1995 establishes a Federal Governmentwide goal to reduce the paperwork and reporting burden it imposes. The RCRA Burden Reduction Initiative Proposed rulemaking makes the regulatory changes necessary to meet this goal.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

Reducing recordkeeping and reporting will require changes in our regulations. There was no alternative to doing a rulemaking. The Agency sought opinions from the regulated community on various burden reduction possibilities.

Anticipated Cost and Benefits:

Our cost-benefit analysis showed a savings of $120 million and 929,000 hours for the final rule. The rule will have minimal impact on the protectiveness of the RCRA regulations. It will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations.

Risks:

The rule will have no risk impacts.

Timetable:

Action	Date	FR Cite
Notice of Data Availability	06/18/99	64 FR 32859
NPRM	01/17/02	67 FR 2518
NODA	10/29/03	68 FR 61662
Final Action	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4084. Applicable SIC codes: Chemicals and Allied Products (28), Primary Metal Industries (33), Fabricated Metals (34), Industrial Machinery and Equipment (35), Electrical Equipment (36), Transportation Equipment (37), Other Manufacturing, Transportation and Utilities (40–49), Wholesale Trade (50–51), Services (70–89) and Other SIC Groups

Sectors Affected:

325 Chemical Manufacturing; 334 Computer and Electronic Product Manufacturing; 332 Fabricated Metal Product Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 562 Waste Management and Remediation Services

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RIN: 2050–AE50

EPA

125. RECYCLING OF CATHODE RAY TUBES (CRTS) AND MERCURY–CONTAINING EQUIPMENT: CHANGES TO HAZARDOUS WASTE REGULATIONS

Priority:

Other Significant

Legal Authority:

42 USC 6912(a); 42 USC 6921 to 6925

CFR Citation:

40 CFR 261; 40 CFR 273

Legal Deadline:

None

Abstract:

This action will ultimately revise the existing Federal hazardous waste regulations to encourage recycling and better management of Cathode Ray

Tubes (CRTs) by providing a conditional exclusion from the definition of solid waste for CRTs being recycled. A CRT is the display component of a television or computer monitor. A CRT is made largely of specialized glasses, some of which contain lead to protect the user from X-rays inside the CRT. Due to the lead, when they are disposed of or reclaimed, some CRTs are hazardous wastes under the Federal Resource Conservation and Recovery Act (RCRA) regulations. This rule will also streamline RCRA requirements for managing mercury-containing equipment by adding such equipment to the universal waste rule. This rule is planned in response to a June 9, 1998 recommendation on CRT recycling from the Common Sense Initiative (CSI) Council to the Environmental Protection Agency (EPA), and in response to a petition from the Utilities Solid Waste Activities Group regarding mercury-containing equipment. The goal of this action is to improve management and encourage recycling, thereby minimizing disposal of mercury, increasing resource recovery, and enhancing protection of human health and the environment. The mercury-containing equipment rule will be published at a later date.

Statement of Need:

This rule is needed to respond to recommendations of the Electronics Subcommittee of the CSI Council regarding CRT recycling, and also to respond to a petition from the Utilities Solid Waste Activities Group regarding management of mercury-containing equipment. It is also needed to streamline RCRA requirements for these materials to encourage better management and recycling.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

EPA solicited comments on alternative management requirements, including notification and tracking, accumulation requirements, requirements for CRT glass processors, export requirements, and disposal requirements.

Anticipated Cost and Benefits:

EPA estimates that, if finalized, this action would result in annual savings of up to $3 million to reduce administrative, transportation, and management costs compared to current regulations.

Risks:

The risks are undetermined.

Timetable:

Action	Date	FR Cite
NPRM	06/12/02	67 FR 40507
Final Action	05/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4092.

Sectors Affected:

334411 Electron Tube Manufacturing

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RIN: 2050–AE52

EPA

126. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUNDWATER RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300 g–1''SDWA 1412 (b)(8)''

CFR Citation:

40 CFR 141; 40 CFR 142

Legal Deadline:

Other, Statutory, Other.

Abstract:

EPA has proposed a targeted risk-based regulatory strategy for all public water systems served by groundwater. The proposed requirements provide a meaningful opportunity to reduce public health risk 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 groundwater 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 groundwater.''

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 by-products. The total estimated value of these benefits is $205 million per year, $139 million from avoided illness and $66 million from avoided deaths. These benefits are monetized based on a cost of illness and a value of statistical life. These estimates do not include pain and suffering associated with viral and bacterial illness avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality.

Risks:

EPA estimates that currently over 200,000 illnesses and 18 deaths occur each year due to viral and bacterial contamination of public groundwater systems. Children, the elderly, and the immunocompromised are particularly sensitive to the waterborne pathogens and account for between 20 and 30 percent of the illnesses and deaths. As proposed, the GWR is expected to reduce the total number of 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	04/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

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

Additional Information:

SAN 2340. Statutory deadline for final rule: After August 6, 1999, but not later than the Administrator promulgates a Stage II rulemaking for disinfection byproducts (currently scheduled for October 2004).

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

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RIN: 2040–AA97

EPA

127. NATIONAL PRIMARY DRINKING WATER REGULATIONS: LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300f; 42 USC 300g–1; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

None

Abstract:

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will control risk from microbial pathogens in drinking water. It is being developed simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) which will address risk caused by the use of disinfectants in drinking water. This rule could affect all public water systems that use surface water as a source. Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the LT2ESWTR, EPA has analyzed a significant body of new survey data on microbial pathogens in source and finished waters, as well as data on parameters which could serve as indicators of microbial risk. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, has provided a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was available previously. EPA has also used significant new data on the efficiency of treatment processes for the removal and inactivation of microorganisms, as well as new information on the pathogenicity of certain 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; an agreement in principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is to reduce health risks posed by cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoa which causes cryptosporidiosis, a severe gastrointestinal disease. While cryptosporidiosis is generally self limiting in healthy individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of cryptosporidium in drinking water sources through the Information Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems have an unacceptably high risk for cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for cryptosporidium through monitoring and prescribe an appropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

Summary of Legal Basis:

Section 1412(b)(7)(A) of SDWA 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, as proposed will have an annual cost of $73 to $111 million per year. The majority of people (approximately 67 percent) are served by public water systems that use a surface water or ground water under the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. EPA estimates that the proposed LT2ESWTR would prevent up to 1,020,000 cases of cryptosporidiosis annually with an economic benefit of up to $1.4 billion. In addition, EPA has recently identified UV light as a technology that can achieve high levels of cryptosporidium inactivation at relatively low cost.

Risks:

Approximately 67 percent of consumers are served by drinking water systems that use surface water sources or ground water under the direct influence of surface water. Survey data indicate that cryptosporidium is prevalent in drinking water sources and current levels of treatment may not be adequate to control highly resistant pathogens like cryptosporidium. Cryptosporidiosis is a potentially fatal disease in people with weak immune systems, such as infants, the elderly, people with AIDS, and people taking immune suppressing drugs like cancer and transplant patients. By requiring additional treatment for those systems with the highest concentrations of cryptosporidium in their source waters, EPA expects to significantly reduce current risk.

Timetable:

Action	Date	FR Cite
NPRM	08/11/03	68 FR 47639
Final Action	07/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

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

Additional Information:

SAN 4341.

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD37

EPA

128. NATIONAL PRIMARY DRINKING WATER REGULATIONS: STAGE 2 DISINFECTION BYPRODUCTS RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

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

Legal Authority:

42 USC 300f; 42 USC 300g–2; 42 USC 300g–3; 42 USC 300g–4; 42 USC 300g–5; 42 USC 300g–6; 42 USC 300j–4; 42 USC 300j–9; 42 USC 300j–11

CFR Citation:

40 CFR 141 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 analyzed a significant body of new survey data on source water quality parameters, treatment data and disinfection byproduct occurrence. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was available previously. EPA also used new information on the health effects of exposure to DBPs to determine effective regulatory requirements for controlling risk. On March 30, 1999, EPA reconvened a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an Agreement in Principle was signed in September 2000 outlining the proposed rule options.

Statement of Need:

The purpose of the Stage 2 Disinfectants/Disinfection Byproducts Rule (DBPR) is to reduce potential health risks posed by disinfection byproducts (DBPs). Certain DBPs have been shown in laboratory tests to be carcinogens or to cause adverse reproductive and developmental health effects. In addition, epidemiology studies have indicated that exposure to chlorinated water may increase the risk of bladder cancer, miscarriage, and certain developmental defects. The Stage 2 DBPR is designed to reduce peak events in DBP exposure in order to mitigate these potential health risks.

Summary of Legal Basis:

Section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than July 14, 2003. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule 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 $59–65 million. Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants and potentially exposed to DBPs. Thus, a large number of people will benefit from the Stage 2 DBPR.

Risks:

Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Due to the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health. EPA estimates that the Stage 2 DBPR will decrease exposure to DBPs on average but more importantly, the rule will significantly reduce exposure to peak occurrences of DBPs.

Timetable:

Action	Date	FR Cite
NPRM	08/18/03	68 FR 49548
Final Action	07/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

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

Additional Information:

SAN 4342.

Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040–AD38

EPA

129. EFFLUENT GUIDELINES AND STANDARDS FOR THE CONSTRUCTION AND DEVELOPMENT INDUSTRY

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 301; 33 USC 1314 CWA 304; 33 USC 1316 CWA 306; 33 USC 1318 CWA 308; 33 USC 1342 CWA 402; 33 USC 1361 CWA 501

CFR Citation:

40 CFR 450; 40 CFR 122

Legal Deadline:

NPRM, Judicial, May 15, 2002.

Final, Judicial, March 31, 2004.

Abstract:

The effluent guidelines would apply to some construction activities associated with new development, as well as to those associated with redevelopment activities. The regulations would address storm water runoff from construction sites during the active phase of construction. Construction activity is a major source of sediment and other pollutants discharged to the nation's waters. Industries potentially affected by this rulemaking include land developers, home builders, builders of commercial and industrial property, and other private and public sector construction site owners and operators. EPA proposed design criteria for erosion and sediment controls. These requirements would be implemented in NPDES storm water permits issued to construction site owners and operators.

Statement of Need:

The 2000 National Water Quality Inventory Report to Congress indicates that 39 percent of assessed rivers and streams are impaired for one or more uses. Siltation is the leading pollutant causing water quality problems in 31 percent of these impaired rivers and streams. Storm water discharges from construction and development projects contain sediment that contribute to water quality impairment. There is currently wide variation in existing requirements across the nation designed to control construction site storm water discharges. The effluent guidelines would provide a national set of criteria for the selection, design, installation, and maintenance of erosion and sediment controls to control storm water discharges from construction sites. These requirements are expected to significantly reduce the discharge of sediment from construction sites and improve water quality.

Summary of Legal Basis:

The Clean Water Act authorizes EPA to establish effluent limitations guidelines and 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. Reilly (D.D.C. No.89–2980) to propose regulations for this industry by May 15, 2002, and to take final action by March 31, 2004.

Alternatives:

The Clean Water Act directs EPA to establish a technology basis for the effluent guidelines. Limitations are based on the performance of specific technology levels, such as the best available technology economically achievable. EPA is considering a range of pollution control technologies and is also considering construction site size exemptions to reduce the impact on small dischargers.

Anticipated Cost and Benefits:

The annualized costs of the proposed effluent guidelines are estimated to range from $130 million to $505 million and the annualized monetized benefits are expected to range from $10 million to $22 million. The costs include capital costs to install erosion and sediment controls as well as operation and maintenance costs. The benefits from the effluent guidelines are expected to occur by reducing discharges of sediment to water bodies. In addition to the monetized benefits, EPA expects there to be significant nonquantified and nonmonetized benefits to aquatic habitat and aquatic resources.

Risks:

The effluent guidelines are expected to result in a reduction of the discharge of pollutants to surface waters, primarily sediment. Sediment discharges to surface waters present a significant risk to aquatic resources.

Timetable:

Action	Date	FR Cite
NPRM	06/24/02	67 FR 42644
Final Action	03/00/04	

Regulatory Flexibility Analysis Required:

Yes

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4280.

For more information on the construction and development rule visit Web site.

Sectors Affected:

233 Building, Developing and General Contracting; 234 Heavy Construction

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RIN: 2040–AD42

EPA

130. 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 301; 33 USC 1316 CWA 306; 33 USC 1326 CWA 316; 33 USC 1361 CWA 501

CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 125

Legal Deadline:

NPRM, Judicial, February 28, 2002.

Final, Judicial, February 16, 2004.

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. This regulation may have substantial ecological benefits. By court order, EPA must propose and take final action on this regulation.

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:

Based on a notice of data availability, costs are estimated to be $265 million annually. The benefits of the proposed rule include quantifiable increases in commercial and recreational fisheries and difficult-to-quantify nonuse benefits. Costs and benefits are 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	04/09/02	67 FR 17122
NODA	03/19/03	68 FR 13522
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

SAN 4474. Split from RIN 2040–AC34.

Sectors Affected:

2211 Electric Power Generation, Transmission and Distribution

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RIN: 2040–AD62

BILLING CODE 6560–50–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

Statement of Regulatory and Deregulatory Priorities

The mission of the Equal Employment Opportunity Commission (EEOC, Commission, or Agency) is to ensure equality of opportunity in employment by vigorously enforcing six Federal statutes. These statutes are: Title VII of the Civil Rights Act of 1964, as amended (prohibits employment discrimination on the basis of race, color, sex, religion, or national origin); the Equal Pay Act of 1963, as amended; the Age Discrimination in Employment Act of 1967 (ADEA), as amended; title I of the Americans with Disabilities Act of 1990, as amended, and sections 501 and 505 of the Rehabilitation Act of 1973, as amended (disability); and the Government Employee Rights Act of 1991, which extends protections against employment discrimination to certain employees who were not previously covered.

The significant action of a regulatory nature now under consideration is amending regulations governing age discrimination in employment to exempt from the prohibitions of the Age Discrimination in Employment Act (ADEA) the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits. This rule will ensure that the application of the ADEA does not discourage employers from providing health benefits to their retirees. The Commission does not believe that the proposed exemption will have a significant impact on small business entities under the Regulatory Flexibility Act because it imposes no economic or reporting burdens on such firms.

Consistent with section 4(c) of Executive Order 12866, this statement was reviewed and approved by the Chair of the Agency. The statement has not been reviewed or approved by the other members of the Commission.

EEOC

FINAL RULE STAGE

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131. COORDINATION OF RETIREE HEALTH BENEFITS WITH MEDICARE AND STATE HEALTH BENEFITS

Priority:

Other Significant

Legal Authority:

29 USC 628

CFR Citation:

29 CFR 1625

Legal Deadline:

None

Abstract:

The Commission proposes to exempt from the prohibitions of the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 et seq. (ADEA or Act), the practice of altering, reducing, or eliminating employer-sponsored retiree health benefits when retirees become eligible for Medicare or comparable State retiree health benefits.

Statement of Need:

In August 2001, the Commission announced that it would consider the relationship between the ADEA and employer-sponsored retiree health benefit plans that alter, reduce, or eliminate benefits upon eligibility for Medicare or a comparable State-sponsored retiree health benefits program. There has been a decline in the number of employers providing retiree health benefits over the last 10 years. Various factors have contributed to this erosion, including the increased cost of health care coverage, an increased demand for such coverage as large numbers of workers near retirement age, and changes in the way accounting rules treat the long-term costs of providing retiree health benefits. Another factor has been employer concern about the potential application of the ADEA to employer-sponsored retiree health benefits. The Commission is proposing a narrowly drawn ADEA exemption that permits the practice of coordinating employer-provided retiree health coverage with eligibility for Medicare or a State-sponsored retiree health benefits program, so that the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees.

Summary of Legal Basis:

Pursuant to section 9 of the ADEA, the Commission is authorized to establish reasonable exemptions to and from any or all provisions of the Act as it may find necessary and proper in the public interest.

Alternatives:

The Commission considered various alternatives in developing this proposal. The Commission will consider all alternatives offered by the public commenters.

Anticipated Cost and Benefits:

The Commission recognizes that while employers are under no legal obligation to offer retiree health benefits, some employers choose to do so in order to maintain a competitive advantage in the marketplace, using these and other benefits to attract and retain the best talent available to work for their organizations. The proposed rule will ensure that the application of the ADEA does not discourage employers from providing, or continuing to provide, health benefits to their retirees who otherwise would have to obtain such coverage in the private individual marketplace at significant personal expense. The Commission believes that it is in the best interest of both employers and employees for the Commission to pursue a policy that permits employers to offer these benefits to the greatest extent possible. It is not anticipated that the proposal will result in increased costs.

Risks:

The proposed regulatory action will reduce the risks of liability for noncompliance with the statute by exempting certain employer practices from regulation. This proposal does not address risks to public safety or the environment.

Timetable:

Action	Date	FR Cite
NPRM	07/14/03	68 FR 41542
NPRM Comment Period End	09/12/03	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State

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RIN: 3046–AA72
BILLING CODE 6570–01–S

GENERAL SERVICES ADMINISTRATION (GSA)

Statement of Regulatory and Deregulatory Priorities

The General Services Administration (GSA) establishes Governmentwide policy for construction and operation of buildings, procurement and distribution of supplies, travel and transportation, acquisition, electronic commerce, management of advisory committees, and utilization and disposal of real and personal property.

GSA's fiscal year 2004 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 6820–34–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Statement of Regulatory Priorities

The National Aeronautics and Space Administration (NASA) was established by the National Aeronautics and Space Act of 1958 (the Act), 42 United States Code (U.S.C.) 2451 et seq., which laid the foundation for NASA's mission. The Act authorizes NASA, among other things, to conduct space activities devoted to peaceful purposes for the benefit of humankind; to preserve the leadership of the United States in aeronautics and space science and technology; and to expand knowledge of the Earth and space. To carry out this mission, NASA is authorized to conduct research for the solution of problems of flight within and outside the Earth's atmosphere; to develop, construct, test, and operate aeronautical and space vehicles for research purposes; to operate space transportation systems, including the Space Shuttle and the International Space Station; and to perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with human-tended, robotic, and expendable vehicles and arranges for the most effective utilization of the scientific and engineering resources of the United States with other nations engaged in aeronautical and space activities for peaceful purposes.

NASA's mission, as documented in its 2003 Strategic Plan, is to understand and protect our home planet, to explore the universe and search for life, and to inspire the generation of explorers as only NASA can.

Our mission is driven by science, exploration, and discovery, and it will be carried out with a firm commitment to fiscal responsibility. We will study climate change and the natural and human-induced hazards to Earth's ecosystem. We will help to counter the threat of international terrorism by developing technologies that can improve the security and safety of our air transportation system. We will lead the world into a new understanding of our planet, our solar system, and the universe around us, and in so doing, we will begin to understand whether life may have developed elsewhere in the cosmos.

The following are narrative descriptions of the most important regulations being planned for publication in the **Federal Register** during fiscal year (FY) 2004.

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 2004, 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.

Re-issuance of the NFS is planned for FY 2004. As part of this re-issuance, the NFS is being reviewed to identify and remove from the Code of Federal Regulations (CFR) those portions of the NFS containing information that consists of internal Agency administrative procedures and guidance. The NFS document will continue to contain both information requiring codification in the CFR and internal Agency guidance in a single document that is available on the Internet.

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

Overview

The National Archives and Records Administration (NARA) issues regulations directed to other Federal agencies and to the public. Records management regulations directed to Federal agencies concern the proper management and disposition of Federal records. Through the Information Security Oversight Office (ISOO), NARA also issues Governmentwide regulations concerning information security classification and declassification programs. NARA regulations directed to the public address access to and use of our historically valuable holdings, including archives, donated historical materials, Nixon Presidential materials, and Presidential records. NARA also issues regulations relating to the National Historical Publications and Records Commission (NHPRC) grant programs.

NARA has three regulatory priorities for fiscal year 2004. The first, included in The Regulatory Plan, is to complete the review of our records management regulations in 36 CFR ch. XII, subchapter B, and begin revising and updating the regulations. We anticipate that we will be proposing a new organizational framework for the records management regulations to make them easier to use. This regulatory activity is part of a major NARA initiative to review and redesign our records management program that started in 2000.

The second priority is to complete the necessary actions relating to the review of our records center facility standards regulation in 36 CFR part 1228, subpart K. This regulation affects small businesses and is discussed in greater detail in the following section.

Our third priority regulatory action is completing the revision of our research room regulations and restrictions on access regulations in 36 CFR parts 1254 and 1256, including writing them in plain language. 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.

Regulations of Particular Concern to Small Businesses

NARA's regulation specifying facility standards for records storage facilities that house Federal records (RIN 3095-AA81) has been identified as being of particular concern to small businesses. The regulation went into effect in 2000 and was among the public reform nominations in the Office of Management and Budget's (OMB) 2002 Report to Congress on the Costs and Benefits of Regulations. OMB referred this regulation to NARA for evaluation. Because of the stated concerns that the regulation places a burden on small businesses, we are reviewing the regulation to identify possible modifications to the regulation that will still ensure protection of Federal records while reducing the burden on records centers that are small businesses. This review may result in further rulemaking activity.

NARA

PRERULE STAGE

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132. FEDERAL RECORDS MANAGEMENT

Priority:

Other Significant

Legal Authority:

44 USC 2104(a); 44 USC ch 21; 44 USC ch 29; 44 USC ch 33

CFR Citation:

36 CFR 1220 to 1238

Legal Deadline:

None

Abstract:

As part of its initiative to redesign Federal records management, NARA is 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 are developing 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	09/17/02	
ANPRM	02/00/04	
ANPRM Comment Period End	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

URL For More Information:

www.archives.gov/records__management/initiatives/strategic__directions.html

URL For Public Comments:

www.regulations.gov

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BILLING CODE 7515–01–S

OFFICE OF PERSONNEL MANAGEMENT (OPM)

Statement of Regulatory Priorities

The Office of Personnel Management (OPM) is the human resources (HR) and personnel manager for the President and the Federal Government. The primary focus of OPM's regulatory efforts in the coming year will continue to be the modernization and improvement of HR management to support the President's goal of creating a Government that is citizen-centered, results-oriented and market-based. To this end, OPM's primary regulatory objective is to implement improvements to HR management 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.

The President's Management Agenda recognizes the critical role that human resources management must play in reforming Government by identifying the Strategic Management of Human Capital as the first of its five core Governmentwide initiatives. OPM is the managing partner on this Presidential Initiative and has aggressively implemented a program to assist other agencies in achieving success in this area through aligning human resources management practices with agency missions and objectives. OPM will implement this initiative by way of regulation as necessary and appropriate during the coming year.

Department of Homeland Security

The Homeland Security Act (HSA) authorized the creation of the Department of Homeland Security (DHS) through the combination of components of 22 other departments and agencies. In addition, the HSA granted the President flexibility in the management of the Department's human resources that are directly engaged in critical security functions. OPM has been working with DHS to design a personnel system that incorporates the HR flexibilities required to protect national security and to identify and address regulatory changes that will create an HR system that is responsive to the critical needs of the Department. Given the urgent mission of DHS, it is certain that this regulatory activity will continue to be a priority for OPM in the coming year.

Compensation Reform

OPM continues to study compensation reform and to gather information from stakeholders following the publication of OPM Director Kay Coles James' white paper on Federal compensation reform: A Fresh Start for Federal Pay: The Case for Modernization. In addition, a proposal to establish a $500 million Human Capital Performance Fund (HCPF) was included in the President's budget for fiscal year 2004. Pending final legislative action, OPM will be prepared to promulgate regulations to implement its provisions. In addition, because compensation reform is a necessary element of improving the management of human capital—a central goal of the President's Management Agenda—OPM anticipates making promulgation of compensation reform regulations a priority in 2004.

e-Government

OPM has been designated as the managing partner on 5 of the 24 e-Government initiatives in the President's Management Agenda. Specifically, OPM is the managing partner for Recruitment One Stop, e-Clearance, e-Training, e-Payroll, and e-Enterprise HR Integration (e-EHRI). In addition, the Office of Management and Budget (OMB) have asked OPM to submit a business case for a sixth e-Government initiative, electronic Human Resource Information Systems (e-HRIS). OMB has indicated that OPM would be the managing partner of this initiative if OMB decides to go forward with the project. These initiatives will require promulgation of new or modified regulations.

No FEAR Regulations

In July, the President delegated responsibility for promulgating regulations pursuant to title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 to OPM. The provisions of title II relate to reimbursement of the judgment fund, notice and training for applicants and employees, and reporting requirements by agencies. Additionally, OPM will promulgate regulations for completing a comprehensive study on disciplinary actions and issuing guidance on best practices that agencies can adopt.

OPM will continue to improve the Federal Government's human resources management systems in order to preserve the merit-based civil service system, promote fairness and diversity, and provide a workforce that allows the Government to achieve results for the American taxpayer.

Human Resources Flexibilities

OPM implemented five new HR authorities enacted in the HSA through interim regulations. In February 2003, OPM published Voluntary Separation Incentive Program regulations that provided agencies with Governmentwide buyout authority. Upon OPM approval, agencies may use this authority as an important workforce reshaping tool in support of their human capital needs.

In June 2003, OPM provided agencies with four additional flexibilities. These new authorities provide agencies with: increased flexibility in assessing applicants using alternative (category-based) rating and selection procedures; the ability to select qualified candidates for competitive service positions using direct-hire procedures; authority to pay or reimburse academic degree training costs from appropriated or other available funds and increased flexibility in academic degree training to address agency-specific human capital objectives; and revised voluntary early retirement authority criteria to address reshaping and restructuring issues. The authorities provide agencies with additional tools to recruit, retain, and reshape their workforce to meet critical mission goals and objectives. These five interim regulations allowed agencies immediate access to these new tools while simultaneously soliciting comments on potential program improvements. OPM is currently reviewing the comments received and will publish final regulations during the coming year.

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 32,000 private defined benefit plans, including about 1,700 multiemployer plans.

The PBGC receives no funds from general tax revenues. Operations are financed by insurance premiums, investment income, assets from pension plans trusteed by the PBGC, and recoveries from the companies formerly responsible for the trusteed plans.

To carry out these functions, the PBGC must issue regulations interpreting such matters as the termination process, establishment of procedures for the payment of premiums, and assessment and collection of employer liability.

Single-employer Program

Under the single-employer program, the PBGC pays guaranteed and certain other pension benefits to participants and beneficiaries if their plan terminates with insufficient assets (distress and involuntary terminations). At the end of fiscal year 2002, the PBGC was trustee of about 3,100 plans and paid $1,537 million in benefits to about 362,000 people during 2002. Another 326,000 people will receive benefits when they retire in the future.

Most terminating single-employer plans terminate with sufficient assets to pay all benefits. The PBGC has administrative responsibility for these terminations (standard terminations), but its role is limited to seeing that proper procedures are followed and participants and beneficiaries receive their plan benefits.

The private defined benefit pension system has been under pressure for some time and has become a matter of public concern. In July 2003, the Administration proposed legislative changes to: (1) improve the accuracy of pension liability measurements by modifying the discount interest rate; (2) increase the transparency of pension plan information and make public pension underfunding information provided to PBGC for companies with over $50 million in underfunding; and (3) require immediate funding of accruals, benefit increases, and lump sum payments in certain situations involving a financially distressed company. The PBGC's guarantee limit would be fixed as of the date a plan sponsor files for bankruptcy. The Administration is exploring additional funding reforms to protect workers' retirement security.

Other Administration proposals before the Congress are: (1) reduced premiums for new plans and plans of small employers; (2) expansion of the Missing Participants program to terminated multiemployer plans and terminated defined contribution plans; (3) acceleration of benefit determinations in terminated underfunded single-employer plans by streamlining the valuation of recoveries on due and unpaid contributions and employer liability claims and simplifying benefit determinations for substantial owners; and (4) payment of interest on premium refunds.

Multiemployer Program

The multiemployer program (which covers about 9.5 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 less than single-employer guaranteed benefits.

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.
- 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.
- 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.

In FY 2003, the PBGC issued a proposed rule that would: (1) remove requirements that might limit electronic filing with PBGC or electronic issuances to others; (2) simplify and consolidate PBGC's rules on filing and issuance methods, determining filing and issuance dates, and computing various periods of time for filings and issuances; and (3) provide rules for maintaining records by electronic means. (The PBGC implemented these changes in a final rule issued in early FY 2004.)

The PBGC is continuing to review its regulations to look for further simplification opportunities. The PBGC's regulatory plan for October 1, 2003, to September 30, 2004, consists of one significant regulatory action.

PBGC

PROPOSED RULE STAGE

133. 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	02/00/04	
NPRM Comment Period End	04/00/04	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

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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 and sickness benefit program for railroad workers under the Railroad Unemployment Insurance Act. Regulations issued 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 nearly 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 systematic 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 Railroad Retirement Board are designed 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 and objectives 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 businesses.

RRB

PROPOSED RULE STAGE

134. ELECTRONIC FILING OF APPLICATIONS AND CLAIMS FOR BENEFITS UNDER THE RAILROAD UNEMPLOYMENT INSURANCE ACT

Priority:

Other Significant

Legal Authority:

45 USC 355; 45 USC 362(l)

CFR Citation:

20 CFR 321

Legal Deadline:

None

Abstract:

The Railroad Retirement Board amends its regulations to add a new part 321 to permit the electronic filing of applications and claims under the Railroad Unemployment Insurance Act 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 as a substitute for paper, when practicable. The addition of part 321 to the Board's regulations will provide our constituents with an option to electronically file applications and claims under the Railroad Unemployment Insurance Act via the Internet in accordance with the provisions of the Government Paperwork Elimination Act.

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 may result in modest savings in administrative costs due to the streamlining of procedures, the benefits are those extended to the agency's constituents by offering an alternative means to file for benefits.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/07/03	68 FR 63041
NPRM Comment Period End	01/06/04	
Final Rule	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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RRB

FINAL RULE STAGE

135. 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 payment 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	12/18/02	67 FR 77448
NPRM Comment Period End	02/18/03	
Final Rule	02/00/04	

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 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 ensure 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; and
- 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 its programs, and improving conditions for small business. All of SBA's rule concern small businesses and programs promoting small 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.

Prime Contracting Assistance; Contract Bundling

SBA's regulations revise the definition of contract bundling to expressly include contracting bundling multiple award contract vehicles and task and delivery orders under such vehicles that were not currently addressed in existing regulations. The regulation requires procuring activities, well in advance of public notice, to coordinate their proposed acquisition strategies or plans contemplating award of a contract or order above specified dollar thresholds ($7 million for DOD, $5 million for NASA, DOE, and GSA, and $2 million for other civilian agencies) with agency Small Business Specialists (SBS). The SBS in turn, is required to notify the Office of Small and Disadvantaged Business Utilization (OSDBU) when those strategies include contract bundling that is unnecessary, unjustified, or not identified as such by the procuring activity. Activities are now required to provide bundling justification documentation to the agency OSDBU when the threshold for ''substantial bundling''' is met. In addition, the agencies' OSDBUs will perform certain oversight functions regarding bundled contracts. This regulation implements the recommendations of the Office of Management and Budget (OMB) in its report entitled ''Contract Bundling, A strategy for Increasing Federal Contracting Opportunities for Small Businesses.'' It has the potential of supplying millions of dollars of additional contracting opportunities to small businesses.

Small Business Size Standard; Restructuring of Size Standards

SBA is drafting a proposed regulation to restructure small business size standards by reducing the number of different size standards levels. SBA has established size standards for each private sector by industry. Under the current structure, one of 37 different size standard levels has been established for 1,151 industries. Some users find the SBA's small business size standards complex and therefore difficult to understand and use for their purposes. Small businesses will benefit from a simpler set of size standards because they will find it easier to determine if they are a small business and they will be subject to fewer different size standards. Federal Government contracting officers and commercial lenders will benefit because a reduced number of size standard levels will be easier to administer in their contracting and loan activities.

SBA

PROPOSED RULE STAGE

136. 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	12/00/03	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

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SBA

137. ● SMALL BUSINESS SIZE STANDARDS; RESTRUCTURING OF SIZE STANDARDS

Priority:

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

Legal Authority:

15 USC 632

CFR Citation:

13 CFR 121

Legal Deadline:

None

Abstract:

The SBA proposes to restructure its small business size standards by reducing the number of different size standards levels. This restructuring will simplify the identification of which businesses are small and the use of size standards in Federal small business programs.

Statement of Need:

Some users find the SBA's small business size standards complex and therefore difficult to understand and use for their purposes. This apparent complexity may also discourage some small businesses from participating in Federal Government small business programs. To address this concern, the SBA intends to restructure and simplify its size standards by reducing the overall number of different size standards levels.

Summary of Legal Basis:

The Small Business Act (15 U.S.C. 632(a)) delegates to the SBA Administrator the responsibility for establishing small business definitions. The Act also requires that small business definitions vary to reflect industry differences.

Alternatives:

The SBA considered establishing a single size standard for a broad grouping of industries, such as entire industry sectors or subsector. The SBA does not believe this is a practical alternative, because the characteristics of industries within a sector or subsector vary too widely to support one size standard.

Anticipated Cost and Benefits:

Costs to the Federal Government will be negligible. There will be savings to the Federal Government because of reduced administrative costs. Neither the costs nor the savings are quantifiable. Small businesses will benefit because they will find it easier to determine if they are a small business and they will be subject to fewer different size standards. Federal Government contracting officers and commercial lenders will benefit because size standards will be easier to administer in their contracting and loan activities.

Risks:

Simplification may affect some businesses' eligibility for Federal Government small business programs. The SBA believes that they will be few in number. Also, new, simplified size standards are at risk of being considered inappropriate. The SBA is addressing these issues in the development of its proposal.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

Regulatory Flexibility Analysis Required:

Yes

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 12 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 three initiatives to improve public service.

One is 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. On February 03, 2003 (68 FR 5210), we published a final rule to do so, and also requested further comments from the public. We are preparing another final rule responding to the public comments we received.

Furthermore, we plan to revise our regulations to permit an Administrative Law Judge to incorporate into the written decision, when wholly favorable, the findings and reasons stated orally at a hearing, if they remain applicable. We believe this revision may reduce the time needed to issue wholly favorable decisions after a hearing.

In addition, we are including a proposed rule that would describe additional safeguards against inappropriate disclosure of personal information and set out special procedures concerning access to medical records.

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 three 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.

Another final rule will provide for continued benefit payments to certain individuals who recover medically while participating in certain vocational rehabilitation programs.

A proposed rule would revise several areas of our regulations on the Ticket to Work program to improve the support of disabled individuals who want and need assistance to return to the workforce.

Improve Stewardship

SSA bears a responsibility to ensure we are effective stewards of the public trust placed in us. We are including in the Plan several regulatory initiatives designed to strengthen our stewardship and program integrity activities; some also reflect the goal to improve financial performance contained in the President's Management Agenda.

We plan to clarify our rules for assigning Social Security Numbers to add evidentiary requirements for foreign academic students classified ''F-1'' by the Bureau of Citizenship and Immigration Services.

For beneficiaries who are not able to manage their own benefits due to legal incompetence or medical infirmity, we must assure that benefits paid to representatives on their behalf are used properly. We are developing final rules that reflect provisions of various laws intended to strengthen our oversight of the representative payee program. We have also included rules that provide us with additional tools to strengthen the integrity of the Social Security and SSI programs.

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.

Simplify the SSI Program

SSA is proposing two rules that would simplify our SSI regulations.

One proposal 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.

Another proposed rule would change our rules for deeming of income and resources from a stepparent to an eligible child when the child resides with a stepparent but not the natural or adoptive parent. We believe this change will simplify the rules concerning deeming under these circumstances.

SSA

PROPOSED RULE STAGE

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138. PRIVACY AND DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION (711P)

Priority:

Other Significant

Legal Authority:

5 USC 552; 5 USC 552a; 42 USC 1306(a); 42 USC 902(a)(5)

CFR Citation:

20 CFR 401.30; 20 CFR 401.45; 20 CFR 401.55; 20 CFR 401.150; 20 CFR 401.180

Legal Deadline:

None

Abstract:

We propose to revise our privacy and disclosure rules to:

1. More fully describe the role and function of the Privacy Officer;

2. Describe safeguards against inappropriate disclosure of personal information when individuals request information about themselves by

electronic means (e.g., through the Internet);

3. Conform to special procedures on an individual's access to medical records; and

4. Add a new section to grant direct access to a minor's medical records by the minor's parent or legal guardian acting on the minor's behalf.

Statement of Need:

These revised regulations are necessary to:

1. Provide the expanded regulatory support for the existing responsibilities and functions of the Privacy Officer as required by the Privacy Act and related Office of Management and Budget (OMB) guidelines;

2. Articulate the safeguards that ensure the appropriate procedures for access to and disclosure of personally identifiable information in the electronic environment;

3. Conform the regulations to our practice and systems of records, which set out special procedures under which individuals whose medical records may potentially present an adverse effect may have access to this information; and

4. Conform to the special procedures in our systems of records for access to medical records.

Summary of Legal Basis:

Revisions are needed to incorporate into the regulations special procedures for providing individuals access to their medical records to ensure the ultimate disclosure of the records to the requesting individual, as set out in our systems of records.

Alternatives:

None.

Anticipated Cost and Benefits:

1. Revised role of Privacy Officer:

Cost—None.

Benefit—Increased public awareness of the privacy officer's role and responsibility in protecting the privacy and disclosure of the information SSA collects and maintains; general oversight to the Agency on privacy and disclosure activities.

2. Description of safeguards against inappropriate disclosure of personal information by electronic means:

Cost—None.

Benefit—Increase public awareness of the safeguards employed by SSA to maintain the security, confidentiality, and integrity of the information we collect and maintain.

3. Conform to special procedures on an individual's access to medical records; and

4. Add a new section to grant direct access to a minor's medical records by the minor's parent or legal guardian acting on the minor's behalf:

Cost—None.

Benefit—Regulatory guidelines will facilitate access for individuals whose medical records may have adverse effects.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

139. FEDERAL SALARY OFFSET (WITHHOLDING A PORTION OF A FEDERAL EMPLOYEE'S SALARY TO COLLECT A DELINQUENT DEBT OWED TO THE SOCIAL SECURITY ADMINISTRATION) (721P)

Priority:

Other Significant

Legal Authority:

42 USC 404; 42 USC 405; 42 USC 902; 42 USC 1383; 5 USC 5514

CFR Citation:

20 CFR 422

Legal Deadline:

None

Abstract:

This initiative would enable the Social Security Administration (SSA) to collect from Federal salaries qualifying, delinquent title II and title XVI overpayments debts and administrative debts owed by individuals who are currently Federal employees. The debt collection would be accomplished by the partial reduction of the employee's disposable salary.

Statement of Need:

This regulation is required by 5 U.S.C. 5514(b) and by regulations of the Department of the Treasury (Treasury) and the Office of Personnel Management (OPM) in order for SSA to participate in the Federal Salary Offset program. Treasury's regulation is 31 CFR 285.7; OPM's regulation is 5 CFR 550.1104.

Summary of Legal Basis:

SSA's use of the Federal Salary Offset program is authorized by 42 U.S.C. 404(f), 42 U.S.C. and 5 U.S.C. 5514.

Alternatives:

None. SSA must have regulations, approved by OPM, in order to use Federal salary offset to collect debts owed by Federal employees. See 5 U.S.C. 5514(b) and 5 C.F.R. 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	03/00/04	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

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SSA

140. REPRESENTATIVE PAYMENT UNDER TITLES II, VIII, AND XVI OF THE SOCIAL SECURITY ACT (949F)

Priority:

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

Legal Authority:

42 USC 401(j); 42 USC 902(a)(5); 43 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 421; 42 USC 425; 42 USC 1007; 42 USC 1010

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 404.2040(a); 20 CFR 404.2041; 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 416.650; 20 CFR 416.665; 20 CFR 416.1402; 20 CFR 408.601; 20 CFR 408.610; 20 CFR 408.611; 20 CFR 408.615; 20 CFR 408.620; 20 CFR 408.621; 20 CFR 408.622; 20 CFR 408.624; 20 CFR 408.625; 20 CFR 408.630; 20 CFR 408.635; 20 CFR 408.640; 20 CFR 408.641; 20 CFR 408.645; 20 CFR 408.650; 20 CFR 408.655; 20 CFR 408.660; 20 CFR 408.665

Legal Deadline:

None

Abstract:

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries judged incapable of managing or directing someone else to manage their benefits. Congress determined that improvements to the representative payment procedures were needed to assure program integrity. These regulations are required 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 1 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; (5) changing how SSA treats persons with a drug addiction or an alcohol condition; 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 201 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	09/25/03	68 FR 55323
NPRM Comment Period End	11/24/03	
Final Action	06/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

Local, State

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SSA

141. ELIMINATION OF CLOTHING FROM THE DEFINITIONS OF INCOME AND IN–KIND SUPPORT AND MAINTENANCE, EXCLUSIONS OF ONE AUTOMOBILE, AND HOUSEHOLD GOODS AND PERSONAL EFFECTS UNDER SSI FROM RESOURCES (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 households certain questions that have been viewed as intrusive. By no longer counting gifts of clothing as income, we will remove a disincentive for family members to help needy relatives.

Summary of Legal Basis:

None.

Alternatives:

Clothing—

None.

Automobile—

We considered revising the regulations to provide that SSA will assume that the recipient's automobile meets the use requirements for total exclusion of one automobile, absent evidence to the contrary. We did not select this option because it would not change the rule but only how we apply it. It does not go far enough in simplifying the SSI program. By revising the use requirements to exclude a car if it is used for transportation, thus replacing the four present specific transportation exclusion criteria, we will simplify the process.

We considered excluding the value of one automobile, regardless of use. We did not select this option because it would allow for the routine exclusion of an automobile even if it were not used for transportation. Such an approach would exclude an inoperable vehicle, a vehicle not being used at all, or a vehicle only used for recreation (such as a dune buggy). We maintain that it is unreasonable to exclude from resources the value of a vehicle that is not used for transportation.

We also considered increasing the excludable value of an automobile not meeting the use test to $11,000. We did not select this option because it would not simplify the SSI program.

Household Goods and Personal Effects—

Instead of excluding the entire value of household goods and personal effects, we considered raising the excludable limit to $10,000 from the current level of $2,000. We decided not to pursue this option because it would not provide any policy simplification. It would increase the amount excluded but it would not eliminate the need for the current time-consuming and complex procedures for determining the market value of an individual's household goods and personal effects.

Anticipated Cost and Benefits:

We estimate that the program costs and administrative costs for these regulatory changes would be negligible.

The proposed rules will simplify the administrative process of valuing noncash items. The change to the household goods and personal effects exclusion would simplify our rules and improve work efficiency by eliminating the need to inventory an individual's household goods and personal effects and determine their current market value. The 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	01/00/04	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

142. EVIDENCE REQUIREMENT FOR ASSIGNMENT OF SOCIAL SECURITY NUMBERS (SSNS); ASSIGNMENT OF SSNS TO FOREIGN STUDENTS (960P)

Priority:

Other Significant

Legal Authority:

42 USC 405

CFR Citation:

20 CFR 422.105; 20 CFR 422.107

Legal Deadline:

None

Abstract:

We propose to clarify our rules for assigning Social Security Numbers (SSNs) to foreign academic students in the Bureau of Citizenship and Immigration Services (BCIS, formerly the Immigration and Naturalization Service or INS) classification status F–1. Specifically, we propose to add additional evidentiary requirements for F–1 students who apply for SSNs. In addition to meeting SSA's requirement to provide evidence of age, identity, legal alien status, and work authorization, an F–1 student who does not have a valid BCIS-issued Employment Authorization Document (EAD) will be required to present evidence that on-campus employment has been secured before we will assign an SSN.

Statement of Need:

These revised regulations are necessary to further enhance the integrity of SSA's enumeration processes for assigning SSNs. By clarifying the evidence requirements for assignment of SSNs, we intend to reduce the opportunity for fraud through misuse and/or improper attainment of SSNs.

Summary of Legal Basis:

None.

Alternatives:

We considered just requiring schools to certify the number of on-campus jobs available (including as a subset those being held for F–1 students) and the number of F–1 students who want to work. However, we do not believe it adequately addresses our need to ensure that the individual student applicant for an SSN is working or has obtained a job before we will assign him or her an SSN. As such, this alternative would do little to achieve our objective in making the regulations changes, which is to reduce the opportunity for fraud through misuse and/or improper attainment of SSNs.

Anticipated Cost and Benefits:

The program costs associated with these revised regulations are negligible. Also, there are negligible administrative costs (i.e., less than 25 work years and less than $2 million). Benefits to SSA include enhancing the integrity of SSA's enumeration processes and helping to alleviate the proliferation of SSNs thereby resulting in fewer opportunities for SSN fraud, including the fraud associated with identity theft.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
Final Action	08/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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RIN: 0960–AF87

SSA

143. AMENDMENTS TO THE TICKET TO WORK AND SELF–SUFFICIENCY PROGRAM (967P)

Priority:

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

Legal Authority:

42 USC 902(a)(5)

CFR Citation:

20 CFR 411.115; 20 CFR 411.125 to 411.140; 20 CFR 411.150 to 411.155; 20 CFR 411.171; 20 CFR 411.350 to 411.375; 20 CFR 411.385 to 411.395; 20 CFR 411.500 to 411.510; 20 CFR 411.525 to 411.565; 20 CFR 411.575 to 411.585

Legal Deadline:

None

Abstract:

These proposed rules are intended to amend the final rules implementing the Ticket to Work and Self-Sufficiency Program under section 1148 of the Social Security Act: to expand beneficiary eligibility to receive tickets under this program; to clarify the rules for assignment of a beneficiary ticket to a State vocational rehabilitation (VR) agency; to revise the rules for payment when a beneficiary receives services from both a State VR agency and an employment network (EN); and, consistent with the Commissioner's authority in section 1148(h) of the Act, to revise the rules for milestone and outcome payments to ENs, in order to increase the incentives for providers of employment and other support services to participate in this program.

Statement of Need:

This proposed regulatory action is necessary to respond to our experience and recommendations we have received since we began implementation of the Ticket to Work and Self-Sufficiency Program in February 2002, in order to increase the incentives for providers of employment services, vocational rehabilitation services, and other support services to participate in this program, and to expand the options available to beneficiaries with disabilities to obtain services to assist them to go to work and attain self-sufficiency.

Summary of Legal Basis:

None.

Alternatives:

We considered not revising the current regulations implementing the Ticket to Work program. However, we believe that these revisions to eligibility to receive a ticket, to clarify the rules for assignment of a ticket to a State VR agency, and to amend the rules for paying ENs are necessary to increase participation in the Ticket to Work program by providers of services and by beneficiaries with disabilities, in order to ensure that these beneficiaries can seek the services necessary to obtain and retain employment and reduce their dependency on cash benefit programs.

Anticipated Cost and Benefits:

We anticipated initial costs to increase due to up-front payments to ENs, and potential savings in later years as ENs are encouraged to serve additional beneficiaries and assist them to achieve self-sufficiency and reduce their dependency on cash benefit programs, including the Supplemental Security Income and Social Security Disability Insurance programs.

Risks:

At this time, we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	
Final Action	10/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

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RIN: 0960–AF89

SSA

144. ● ELIMINATION OF PARENT–TO–CHILD DEEMING FOR INDIVIDUALS WHO NO LONGER MEET THE DEFINITION OF SPOUSE OF THE NATURAL OR ADOPTIVE PARENT (793P)

Priority:

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

Legal Authority:

Sec 1614(f)(2) of the Social Security Act

CFR Citation:

20 CFR 416.1101; 20 CFR 416.1160; 20 CFR 416.1202; 20 CFR 416.1851; 20 CFR 416.1856

Legal Deadline:

None

Abstract:

We propose to change the Supplemental Security Income (SSI) parent-to-child deeming rules to no longer consider the income and resources of a stepparent when an eligible child resides in the household with a stepparent, but not his or her natural or adoptive parent. We will clarify that a stepparent no longer meets the definition of a ''parent'' when his or her spouse dies or leaves the household. Thus, an eligible child is not subject to deeming from a stepparent unless the child lives with both his or her natural or adoptive parent and the stepparent. We also propose changing the age at which an individual is no longer considered an ineligible child for purposes of deeming from 21 to 22. We believe this change will simplify our rules for both the public and our public contact employees.

Statement of Need:

The U.S. Court of Appeals, Second Circuit, ruled on a case involving a natural parent who abandoned the family home leaving her spouse with sole physical custody of an eligible child. Social Security Acquiescence Ruling 99–1(2) currently applies the Court's decision to the States of Connecticut, Vermont, and New York. The proposed rules will set uniform national policy with respect to this issue. Further, changing the definition of ''ineligible child'' for purposes of deeming will make uniform all regulatory definitions of ''child'' for SSI purposes. This will simplify our rules, making them less cumbersome to administer and easier for the public to understand and follow.

Summary of Legal Basis:

None.

Alternatives:

None.

Anticipated Cost and Benefits:

We estimate that the program costs and administrative costs for these regulatory changes would be negligible.

Risks:

These proposed rules will ensure our parent-to-child deeming rules are consistent with respect to our current regulatory definition of ''parent'' and ''child.'' Policy will uniformly be set nationwide and will make our rules less difficult for the public to understand.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	
Final Action	02/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

FINAL RULE STAGE

145. ADMINISTRATIVE WAGE GARNISHMENT (TO REPAY A DEBT OWED TO THE SOCIAL SECURITY ADMINISTRATION) (724F)

Priority:

Other Significant

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 416.590; 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.

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	11/15/02	67 FR 69164
NPRM Comment Period End	01/14/03	
Final Action	02/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Federal, Local, State, Tribal

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SSA

146. 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:

These final rules consider and respond to public comments received on final rules with request for comment that we published on February 3, 2003, to authorize us to conduct hearings before an Administrative Law Judge (ALJ) at which a party or parties to the hearing and/or a witness or witnesses may appear before the ALJ by video teleconference (VTC). The final rules with request for comment 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 requested public comment on the final rules of February 3, 2003, because they made a significant change in a provision included in our notice of proposed rulemaking for these rules. Unlike the proposed rules, which would have given claimants the right to veto the use of VTC to take their own testimony and the testimony of expert witnesses, the final rules with request for comment give claimants the right to veto the use of VTC only for the purpose of taking their own testimony.

Statement of Need:

We received public comments on the final rules with request for comment. We must publish final rules to state our responses to the comments and our decision regarding whether to make changes in the final rules of February 3, 2003, which authorized our use of VTC to conduct appearances at ALJ hearings effective March 5, 2003.

Summary of Legal Basis:

None.

Alternatives:

None.

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 Rule with Request for Comment	02/03/03	68 FR 5210
Final Rule Effective	03/05/03	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

147. REVISED MEDICAL CRITERIA FOR EVALUATING IMPAIRMENTS OF THE DIGESTIVE SYSTEM (800F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

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:

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: 5-year total may not be equal to the sum of the annual totals due to rounding-out.)

(Note: Federal SSI payments due on October 1st in fiscal years 2006 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	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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SSA

148. CONTINUATION OF BENEFIT PAYMENT TO CERTAIN INDIVIDUALS WHO ARE PARTICIPATING IN A PROGRAM OF VOCATIONAL REHABILITATION SERVICES, EMPLOYMENT SERVICES, OR OTHER SUPPORT SERVICES (925F)

Priority:

Other Significant

Legal Authority:

42 USC 902(a)(5)

CFR Citation:

20 CFR 404.316; 20 CFR 404.327 (New); 20 CFR 404.328 (New); 20 CFR 404.337; 20 CFR 404.352; 20 CFR 404.902; 20 CFR 404.1586; 20 CFR 404.1596; 20 CFR 404.1597; 20 CFR 416.1321; 20 CFR 416.1331; 20 CFR 416.1338; 20 CFR 416.1402

Legal Deadline:

None

Abstract:

These final rules revise the regulations that provide for the continuation of benefit payments to certain individuals who recover medically while participating in a vocational rehabilitation program with a State vocational rehabilitation agency. We are revising these regulations because of statutory amendments, which extend eligibility for these continued benefit payments to certain individuals who recover medically while participating in another appropriate program of vocational rehabilitation services. These include individuals participating in the Ticket to Work and Self-Sufficiency Program or another program of vocational rehabilitation services, employment services, or other services approved by the Commissioner of Social Security.

Prior to November 1991, the Social Security Act provided for the continuation of payment of Social Security Disability Insurance and Supplemental Security Income disability and blindness benefits to individuals whose disability or blindness ended for medical reasons while they were participating in an approved State vocational rehabilitation program under title I of the Rehabilitation Act of 1973, if the Commissioner of Social Security determined that completion or continuation of the program would increase the likelihood of the individual's permanent removal from the disability benefits rolls. The Omnibus Budget Reconciliation Act of 1987 extended eligibility for continued benefits to individuals who receive Supplemental Security Income benefits based on blindness. (We implemented this change by issuing operating instructions effective April 1, 1988, the effective date of the amendment.) The Omnibus Budget Reconciliation Act of 1990 extended eligibility for continued benefits to individuals participating in an approved non-State vocational rehabilitation program at the time their disability ended. (We implemented this change by issuing operating instructions effective November 1991, the effective date of the amendments.) The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 requires the redetermination of eligibility based on disability of individuals who attain age 18, based on the rules for determining initial eligibility for adults. These redeterminations are not continuing disability reviews, however, we are revising our regulations to provide that an individual whose disability has ended as a result of an age—18 redetermination may qualify for continued benefits based on participation in an approved program and increased likelihood of permanent removal from the disability rolls, if the individual meets all other requirements for continued benefits. The Ticket to Work and Work Incentives Improvement Act of 1999 authorizes continued benefits for a person who medically recovers while participating in a program consisting of the Ticket to Work program or another program of vocational rehabilitation services, employment services, or other support services approved by the Commissioner of Social Security, provided that the other requirements for benefit continuation are met.

These rules will explain what we mean by ''an appropriate program of vocational rehabilitation services, employment services, or other support services.'' They will explain when an individual will be considered to be ''participating'' in the program. They will explain how we will determine whether an individual's completion of or continuation in an appropriate program of vocational rehabilitation services, employment services, or other support services will increase the likelihood that the individual will not have to return to the disability rolls. They will also explain that, for students age 18 through 21, ''an appropriate program of vocational rehabilitation services, employment services, or other support services'' includes an individualized education plan developed under polices and procedures approved by the Secretary of Education for assistance to States for the education of child under the Individuals with Disabilities Act, as amended.

Statement of Need:

These final regulations are necessary to conform our regulations to amendments enacted in the Ticket to Work and Work Incentives Improvement Act of 1999, as well as the amendments enacted in the Omnibus Budget Reconciliation Act of 1990 and the Omnibus Budget Reconciliation Act of 1987; and as the result of a provision enacted in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Summary of Legal Basis:

None.

Alternatives:

None.

Anticipated Cost and Benefits:

For the 5-year period from fiscal year 2004 through 2008, the estimated effects on Federal Supplemental Security Income payments for increased payments for children range from $4 million in fiscal year 2004 to $46 million in fiscal year 2008. The estimated impact on the Federal share of Medicaid payments during this 5-year period range from $3 million in fiscal year 2004 to $41 million in fiscal year 2008.

Risks:

At this time, we have not identified any risks associated with this proposal.

Timetable:

Action	Date	FR Cite
NPRM	08/01/03	68 FR 45180
NPRM Comment Period End	09/30/03	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

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SSA

149. ADMINISTRATIVE REVIEW PROCESS; INCORPORATION BY REFERENCE OF ORAL FINDINGS OF FACT AND RATIONALE IN WHOLLY FAVORABLE WRITTEN DECISIONS (964I)

Priority:

Other Significant

Legal Authority:

42 USC 405(a); 42 USC 405(b); 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.953; 20 CFR 416.1453

Legal Deadline:

None

Abstract:

These interim final rules revise our regulations to provide that if an Administrative Law Judge (ALJ) enters a wholly favorable, oral decision into the record of a hearing, the ALJ may subsequently issue a written decision that gives the findings and reasons for the decision by incorporating by reference the findings and reasons stated orally at the hearing, provided that the ALJ does not determine subsequent to the hearing that the oral findings and reasons should be changed.

Statement of Need:

In fiscal year 2002, we announced a number of short-term actions to reduce delays in processing requests for ALJ hearings. One of these actions was to allow ALJs to issue oral decisions from the bench at the close of the hearing. We have found that ALJs are not frequently issuing oral decisions from the bench because of the duplication of work involved in issuing the oral decision and then subsequently issuing a written decision that fulfills existing provisions of our regulations requiring ALJs to issue written decisions that give the findings of fact and the reasons for the decision. We believe we can make it easier to use the bench decision procedure to reduce the time required to issue wholly favorable decisions by amending our regulations to explicitly authorize ALJs to issue wholly favorable written decisions that incorporate by reference the findings and rational stated orally in a bench decision.

Summary of Legal Basis:

None.

Alternatives:

Interpret our existing regulations to allow ALJs to issue written, wholly favorable decisions that give the findings of fact and rationale for the decision by incorporating by reference the findings and rationale stated in an oral decision that the ALJ entered into the record at the hearing.

Anticipated Cost and Benefits:

Improved public service by facilitating use of the oral decision procedure to reduce the time required to issue wholly favorable decisions.

Risks:

None.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/00/04	
Final Action	09/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

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FEDERAL HOUSING FINANCE BOARD (FHFB)

Statement of Regulatory and Deregulatory Priorities

The Federal Housing Finance Board (Finance Board) is an independent agency that is charged under the Federal Home Loan Bank Act (Bank Act) with supervising and regulating the Nation's Federal Home Loan Bank (Bank) System. The Bank System comprises 12 regional cooperative Banks that are owned by their respective member financial institutions. The Banks provide wholesale credit to members and certain nonmembers to be used for mortgage lending and related community lending activities. The Banks also acquire mortgage assets from members as a means of advancing their housing finance mission. The Bank System also includes the Office of Finance, which issues Bank System consolidated obligations. The Finance Board is required to prepare a regulatory plan pursuant to section 4 of Executive Order 12866. At this time, the Finance Board does not anticipate taking any significant regulatory or deregulatory actions during 2004 that would be required to be included in a regulatory plan.

The Finance Board's highest regulatory priorities during 2004 continue to be to ensure the safety and soundness of the Bank System and to ensure that the Banks fulfill their housing finance and community investment mission. In furtherance of these statutory mandates, the Finance Board expects to consider regulations that will:

- Revise the acquired member asset (AMA) regulation to place greater responsibility with each Bank to design and manage its AMA program, subject to ongoing supervisory review by the Finance Board;
- More clearly delineate the responsibilities and the accountability of the board of directors for governance of a Bank, thereby strengthening the role of the boards in the Banks' operations;
- Streamline the Finance Board's review of new business activities proposed by a Bank to more clearly focus the regulatory review process on ensuring that a new product, service, or activity will not endanger the continued safe and sound operation of the Bank;
- Streamline the community support requirements to eliminate unnecessary regulatory burden, while preserving the statutory intent of ensuring that members' access to long-term advances reflects such factors as their record of performance under the Community Reinvestment Act and their record of lending to first-time homebuyers;
- Improve the operations and efficiency of the Affordable Housing Program by more clearly delineating the Banks' responsibilities for program administration and for satisfying the statutory directive that the subsidy benefit very low-income, low-income, and moderate-income households;
- Improve public disclosure by the Banks including addressing the requirements of the Securities Exchange Act of 1934, as that Act is interpreted and applied by the SEC; and
- Develop, based on its analysis of recently solicited comments and other research, an appropriate regulatory response to possible renewed requests that a single financial institution be permitted to become a member of more than one Bank.

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, secure, market-driven, and nondiscriminatory ocean transportation system in an environment free of unfair foreign maritime trade practices and market-distorting activities. 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.

The Ocean Shipping Reform Act of 1998 (OSRA) continues to impact the Federal regulatory scheme regarding international ocean shipping. The legislation required new regulations, as well as the revision of many of the Commission's substantive regulations. One of the principal changes was the elimination of the requirement that carriers file tariffs with the Commission listing their rates and charges. Carriers are now required to publish their rates in private automated systems. The Commission continues to assess its regulations implementing this requirement, as well as other requirements of the new legislation.

Common carriers remain concerned as to the content requirements of agreements filed with the Commission. Carriers have expressed a desire for better delineation as to what matters do or do not have to be filed and have suggested that the Commission's rules should provide protections for confidential business information, provide maximum flexibility for carriers to modify cooperative arrangements, and include guidance tailored for different types of agreements. The Commission 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 2003, along with current requirements applicable to agreement carriers' filing of operating data and minutes of meetings. 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, in calendar year 2003, will be assessing public comments on changes it previously proposed.

The principal objective or priority of the Agency's current regulatory plan will be to continue to assess major existing regulations for continuing need, burden on the regulated industry, and clarity. The Commission issued its 2-year study of OSRA in September 2001. It still is possible that findings and conclusions from that report could result in consideration of specific issues for rulemaking proposals.

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.

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FEDERAL TRADE COMMISSION (FTC)

Statement of Regulatory Priorities

I. REGULATORY PRIORITIES

Background

The Federal Trade Commission (FTC or Commission) is an independent agency charged with protecting American consumers from ''unfair methods of competition'' and ''unfair or deceptive acts or practices'' in the marketplace. The Commission strives to ensure that consumers benefit from a vigorously competitive marketplace. The Commission's work is rooted in a belief that free markets work—that competition among producers and information in the hands of consumers bring the best products at the lowest prices for consumers, spur efficiency and innovation, and strengthen the economy.

The Commission pursues its goal of promoting competition in the marketplace through two different, but complementary, approaches. First, for competition to thrive, curbing deception and fraud is critical. Through its consumer protection activities, the Commission seeks to ensure that consumers receive accurate, 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.

After amending the Telemarketing Sales Rule (TSR), 16 CFR part 310, 68 Fed. Reg. 4580 (Jan. 29, 2003), to establish a national ''do not call'' registry, the Commission opened the registry on June 26, 2003. Consumers can register for free in two ways: online at DONOTCALL.GOV or by telephone at 1(888) 382-1222. As of October 1, 2003, it became illegal for most telemarketers to call a number listed on the registry. Also, the Commission issued additional amendments on July 31, 2003, imposing fees on entities accessing the ''do not call'' registry. *See* 68 FR 45134 (July 31, 2003). The rule changes require sellers to pay the annual fee for access to the national registry; impose an annual fee of $25 per area code, with the maximum annual fee of $7,375; allow access to up to five area codes for free; and set October 1, 2003, as the effective date for the ''do-not-call'' provisions of the amended TSR. To comply with the amended TSR's ''do not call'' provisions by this effective date, all covered sellers are required to access the registry for the first time between September 1 and September 30, 2003.

Industry Self-Regulation, Textile Leniency Policy and Compliance Partnerships With Industry

The Commission continues to be committed to protecting consumers by means that burden businesses the least. To that end, it has encouraged industry self-regulation, developed a corporate leniency policy for certain rule violations, and established compliance partnerships where appropriate.

The Commission has issued reports that encourage industry self-regulation in several areas. In the entertainment industry, the Commission has urged self-regulation for violent media products marketed to children. *See, e.g.,*Federal Trade Commission, Marketing Violent Entertainment to Children: A Twenty-One Month Follow-Up Review of Industry Practices in the Motion Picture, Music Recording & Electronic Game Industries (June 2002), http://www.ftc.gov/reports/violence/mvecrpt0206.pdf. The Commission also continues to encourage companies in the alcohol industry to engage in self-regulation to ensure that advertising for products containing alcohol is not directed at underage youths.

In addition, in the weight-loss product advertising area, the Commission has proposed a strengthened self-regulatory response from the industry and more media responsibility to address the widespread problem of blatantly false efficacy claims. Also, with respect to the Children's Online Privacy Protection Act (COPPA), the Commission has approved the safe harbor programs of three organizations whose self-regulatory guidelines and programs protect children's privacy to the same or greater extent as COPPA.

Recently, the Commission announced the Textile Corporate Leniency Policy Statement for minor and inadvertent violations of the Textile or Wool Rules that are self-reported by the company. 67 FR 71566 (Dec. 2, 2002). Generally, the purpose of the Textile Corporate Leniency Policy is to help increase overall compliance with the rules while also minimizing the burden on business of inadvertent labeling errors that are not likely to cause injury to consumers. Under this policy, the Commission announced the factors that staff will consider in allowing the mislabeled goods to be sold without relabeling. The policy follows the Commission's Civil Penalty Leniency Program for small businesses, but is not limited to small businesses or situations involving civil penalties.

The Commission has also engaged industry in compliance partnerships in at least two areas involving the funeral and franchise industries. Specifically, the Commission's Funeral Rule Offender Program (FROP), conducted in

partnership with the National Association of Funeral Directors (NAFD), is designed to educate funeral home operators found in violation of the requirements of the Funeral Rule, 16 CFR part 453, so that they can meet the rule's disclosure requirements. Approximately 200 funeral homes have participated in the program since its inception in 1996. In addition, the Commission established the Franchise Rule Alternative Law Enforcement Program in partnership with the International Franchise Association (IFA), a nonprofit organization that represents both franchisors and franchisees. This program is designed to assist franchisors found to have a minor or technical violation of the Franchise Rule, 16 CFR part 436, in complying with the rule. (Violations involving fraud or other Section 5 violations are not candidates for referral to the program.) The IFA trains the franchisor how to comply with the rule and monitors its business for a period of years. Where appropriate, the program will offer franchisees the opportunity to mediate claims arising from the law violations. Since December 1998, eleven companies have agreed to participate in the program.

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. For many rules this has resulted in more frequent reviews than is generally required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, in that it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a ''significant economic impact upon a substantial number of small entities.'' 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 nor 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 2003 Reviews

In early 2004, the Commission plans to publish a Federal Register notice announcing which rules and guides it will begin to review that year. 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.,*68 FR 2465 (Jan. 17, 2003).

All of the new matters currently under review pertain to consumer protection and are intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions. During 2003, the Commission announced its intention to begin the review of one rule regarding Rules and Regulations Under the Hobby Protection Act, 16 CFR part 304, two industry guides regarding Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 CFR part 255, and Tire Advertising and Labeling Guides, 16 CFR part 228, and the Statement of General Policy or Interpretations Under the Fair Credit Reporting Act, 16 CFR part 600.

We discuss below some of the highlights of the actions already taken or that we propose to take.

Rules and Regulations Under the Hobby Protection Act: The Commission requested public comments on March 3, 2003, about the economic impact and benefits of the Rules and Regulations Under the Hobby Protection Act and whether changes in the relevant technologies—such as e-mail and the Internet—affect the Rule since it was issued. *See*68 FR 9856 (Mar. 3, 2003). After assessing public comments, staff expects to forward its recommendation to the Commission by the end of 2003.

Guides Concerning Use of Endorsements and Testimonials in Advertising: The staff expects to forward to the Commission its recommendation that the Commission issue a notice during late 2003 or early 2004, seeking public comment about, among other things, whether there is a continuing need for the Guides Concerning Use of Endorsements and Testimonials in Advertising and what changes, if any, should be made to the Guides to increase the benefits of the Guides.

Tire Advertising and Labeling Guides: The Commission issued a notice seeking public comment about, among other things, whether there is a continuing need for the Tire Advertising and Labeling Guides and what changes, if any, should be made to the Guides to increase the benefits of the Guides to purchasers. 68 FR 50984 (Aug. 25, 2003).

Statement of General Policy or Interpretations Under the Fair Credit Reporting Act: Staff plans to recommend that the Commission issue a notice requesting comments on the Statement of General Policy or Interpretations Under the Fair Credit Reporting Act in Spring 2004, or after the Congress amends the Fair Credit Reporting Act because part of the Act expires on December 31, 2003.

Ongoing Reviews

As part of the Commission's ten-year review program, in 2003 the Commission continued reviews of six rules. First, in the review of the R-Value Rule for home insulation, 16 CFR part 460, the Commission reviewed the comments received on the Advance Notice of Proposed Rulemaking (ANPRM) and issued a notice of Proposed Rulemaking (NPRM) which announced a number of proposed amendments to the rule. *See* 68 FR 41872 (July 15, 2003). After assessing the public comments, staff expects to forward its recommendation to the Commission regarding substantive amendments to the Rule by early 2004.

Second, with respect to the Premerger Notification and Report Form, in addition to the final rules issued by the Commission and described under Final Actions below, in late 2003, the staff anticipates forwarding its recommendation to the Commission to allow parties to file the premerger notification and report form electronically via the Internet. Staff also plans to forward its recommendation to the Commission in spring or summer 2004 concerning issuance of an NPRM to revise its treatment of non-corporate entities.

Third, in the review of the Franchise Rule, 16 CFR part 436, 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 that include: (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 early 2004.

Fourth, 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 this rule including provisions to combat telephone bill ''cramming''—inserting unauthorized charges on consumers' phone bills—and other abuses in the sale of products and services that are billed to the telephone including voicemail, 900-number services, and other telephone based information and entertainment services. The most recent workshop focused on discussions of the use of 800 and other toll-free numbers to offer pay-per-call services, the scope of the Rule, the dispute resolution process, the requirements for a presubscription agreement, and the need for obtaining express authorization from consumers before placing charges on their telephone bills. Staff anticipates forwarding its recommendation to the Commission during the spring of 2004.

Fifth, the Commission's review of the Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Regulations), 16 CFR part 307, is 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 during the winter of 2004.

Finally, the Commission began its regulatory review of certain aspects of the Funeral Industry Practices Rule (Funeral Rule or Rule), 16 CFR part 453, in 1999. The Funeral Rule, which became effective in 1984, and was amended in 1994, requires providers of funeral goods and services to give consumers itemized lists of funeral goods and services that 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 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 subsequently held to explore issues raised in the comments submitted. Staff expects to forward its recommendation to the Commission early in 2005.

Final Actions

Since publication of the 2002 Regulatory Plan, the Commission has taken final actions on three rulemakings. After amending the Telemarketing Sales Rule (TSR), 16 CFR part 310 (68 FR 4580, Jan. 29, 2003), to establish a national ''do not call'' registry, the Commission opened the registry on June 26, 2003. Consumers can register for free in two ways: online at DONOTCALL.GOV or by telephone at 1(888) 382-1222. As of October 1, 2003, it became illegal for most telemarketers to call a number listed on the registry. Also, the Commission issued additional amendments on July 31, 2003, that imposed fees on entities accessing the ''do not call'' registry. *See*68 FR 45134 (July 31, 2003). The rule changes required sellers to pay the annual fee for access to the national registry; imposed an annual fee of $25 per area code, with the maximum annual fee of $7,375; allowed access to up to five area codes for free; and set October 1, 2003, as the effective date for the ''do not call'' provisions of the amended TSR. To comply with the amended TSR's ''do not call'' provisions by this effective date, all covered sellers were required to access the registry for the first time between September 1 and September 30, 2003.

For the Premerger Notification Rules and Report Form, the Commission announced final amendments to parts 801 and 803 of the interim rules on January 17, 2003. On February 1, 2001, the Commission published interim and proposed rules amending the Hart-Scott-Rodino Rules (HSR Rules) contained in 16 CFR parts 801, 802, and 803. The interim rules took effect upon publication and implemented amendments to section 7A of the Clayton Act, 66 FR 8679 (Feb. 1, 2001). The proposed rules set forth other changes improving and updating the HSR Rules. 66 FR 8723 (Feb. 1, 2001). This current action was in response to comments that had been received during the comment period for the interim final rules. The Commission also received other comments in response to the February 1, 2001, Federal Register notices that were not relevant to the changes promulgated by either the interim or proposed rules issued during 2001. These additional comments remain under consideration and may be addressed by future rulemaking.

For the Appliance Labeling Rule, the Commission granted a conditional exemption from certain EnergyGuide testing and labeling requirements on certain home appliances for the remainder of the calendar year of 2003 to allow manufacturers to use the new (J1) test procedure immediately instead of waiting until the beginning of 2004. *See*68 FR 36458 (June 18, 2003). The Commission also amended the Rule to require explanatory language on EnergyGuide labels for all models beginning January 1, 2004.

Summary

In both content and process, the FTC's ongoing and proposed regulatory actions are consistent with the President's priorities. The actions under consideration inform and protect consumers and reduce the regulatory burdens on businesses. The Commission will continue working toward these goals. The Commission's ten-year review program is patterned after provisions in the Regulatory Flexibility

Act and complies with the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission's ten-year program also is consistent with section 5(a) of Executive Order 12866, 58 FR 51735 (Sept. 30, 1993), which directs executive branch agencies to develop a plan to reevaluate periodically all of their significant existing regulations. In addition, the Telemarketing Sales Rule, 16 CFR part 310 (2003), is consistent with the President's Statement of Regulatory Philosophy and Principles, Executive Order 12866, section 1(a), which directs agencies to promulgate only such regulations as are, *inter alia,* required by law or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public.

As set forth in Executive Order 12866, the Commission continues to identify and weigh the costs and benefits of proposed actions and possible alternative actions, and to receive the broadest practicable array of comment from affected consumers, businesses, and the public at large. As stated above, since 1992 the Commission has repealed 48 percent of its trade regulation rules and 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, section 1.

II. REGULATORY ACTIONS

The Commission does not plan to propose any rules that would be a ''significant regulatory action'' under the definition in Executive Order 12866.

BILLING CODE 6750–01–S

NATIONAL INDIAN GAMING COMMISSION (NIGC)

Statement of Regulatory Priorities

The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (NIGC or the Commission). The stated purpose of the Commission is to regulate the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments. It is the Commission's intention to provide regulation of Indian gaming to adequately shield it from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players.

The regulatory priorities for the next fiscal year reflect the Commission's commitment to upholding the principles of IGRA. The gaming industry changes rapidly with advancements in machine technology. It is crucial for the vitality of Indian gaming that regulators have the ability to respond quickly to these changes. To that end, the Commission has decided that the development of technical standards for game classifications, gaming machines, and related gaming systems is an important initiative for the promotion and protection of tribal gaming.

Additionally, the Commission will be making technical amendments to the minimal internal control standards. These amendments will correct isolated problems that have been brought to the Commission's attention by tribal gaming operators and regulators.

The Commission has been innovative in using active outreach efforts to inform its generic policy development and its rulemaking efforts. For example, the Commission has had great success in using regional meetings, both formal and informal, with tribal governments to gather views on current and proposed Commission initiatives. The Commission anticipates that these consultations with regulated tribes will play an important role in the development of technical standards.

NIGC

PROPOSED RULE STAGE

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150. ● TECHNICAL STANDARDS FOR GAME CLASSIFICATIONS, GAMING MACHINES, AND GAMING SYSTEMS

Priority:

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

Unfunded Mandates:

Undetermined

Legal Authority:

25 USC 2706

CFR Citation:

25 CFR 501

Legal Deadline:

None

Abstract:

It is necessary for the National Indian Gaming Commission (NIGC) to promulgate regulations establishing technical standards for game classifications because of the distinction between class II and class III gaming set forth in IGRA. Technical changes make it difficult for regulators to keep up with the gaming industry. By establishing technical standards, tribal gaming commissions, the primary regulators of tribal gaming, will more easily be able to distinguish between class II and class III machines. Further, it is necessary for the Commission to establish technical standards for the actual operation of gaming machines and systems and the equipment related to their operation.

Statement of Need:

Technical standards are needed to assure that regulators can determine game classifications and so that machine games are operated in a manner that ensures uniformity and integrity in tribal gaming.

Summary of Legal Basis:

It is the goal of the NIGC to provide regulation of Indian gaming to shield it from organized crime and other corrupting influences as well as assuring that gaming is conducted fairly and honestly. (25 U.S.C. 2702). The Commission is charged with the responsibility of monitoring gaming conducted on Indian lands. (25 U.S.C. 2706(b)(1)). IGRA expressly authorizes the Commission to ''promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the (Act).'' (25 U.S.C. 2706(b)(10)). The Commission relies on these sections of the statute to authorize the promulgation of technical standards for game classifications and for gaming machines to ensure uniformity and integrity in tribal gaming.

Alternatives:

The Commission can either: (1) issue a rule establishing technical standards for game classifications and gaming machines, or (2) continue evaluating classifications on a case-by-case basis.

Anticipated Cost and Benefits:

The development of technical standards will reduce the cost of regulation to the Federal Government. Additionally, technical standards will aid tribal governments in the regulations of their gaming activities as well as prevent loss associated with defective or substandard gaming devices. The only anticipated cost will be to gaming machine manufacturers.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Federalism:

Undetermined

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