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Office of
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Analysis

DR 1512-1

REGULATORY DECISIONMAKING REQUIREMENTS

2312

REGULATORY DECISIONMAKING REQUIREMENTS

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FOREWORD

Every regulatory action published by USDA must comply with applicable Executive Orders, statutes, and regulations, be legally sufficient, and be consistent with USDA policy and budget objectives. The requirements and procedures specified in this Departmental Regulation are intended to help ensure that USDA regulatory actions meet a high standard for clarity, conciseness, and effectiveness; comply with all applicable Executive Orders, laws, and regulations; and, are consistent with USDA policy and budget objectives.

This USDA Departmental Regulation on Regulatory Decisionmaking Requirements was last revised on December 21, 1995, in order to incorporate significant changes in Government-wide and USDA policy and practice regarding the development and review of regulatory actions since the previous Departmental Regulation dated September 7, 1990. Most notably, these changes are reflected in Executive Order 12866, "Regulatory Planning and Review," dated September 30, 1993, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Public Law. 103-354), and the Unfunded Mandates Reform Act of 1995 (Public Law. 104-4). The December 21, 1995, version of this Departmental Regulation also incorporated all applicable Executive Orders, directives, and related material affecting regulations that had been issued since September 7, 1990.

Executive Order 12866: (1) directs regulatory agencies to periodically submit to the Office of Management and Budget (OMB) a summary of planned regulatory actions, indicating the level of significance; (2) provides a classification system for planned regulatory actions so that greater focus can be placed on the more important regulatory actions; (3) provides agencies a mechanism for requesting that certain types of rulemakings may be exempt from OMB review; (4) provides that rulemakings classified by OMB as not-significant are not subject to formal OMB review; (5) requires that rulemakings classified by OMB as significant or economically significant be supported by substantial documentation in the form of impact statements, assessments, and analyses; (6) sets forth time limits for OMB review of regulatory actions; and (7) requires agencies to review existing significant regulations to determine if they should be modified or eliminated to bring an agency's regulatory program into greater alignment with the President's regulatory priorities and principles.

The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, title III, section 304, requires that for each proposed major regulation (any regulation that the Secretary of Agriculture estimates is likely to have an annual impact on the economy of the United States of \$100 million in 1994 dollars) the primary purpose of which is to regulate issues of human health, human safety, or the environment, USDA publish an analysis of the risks addressed by the regulation and costs and benefits of the regulation.

The Unfunded Mandates Reform Act of 1995 requires agencies to assess the impact of regulations containing Federal mandates. Title II of the Act requires Federal agencies, before promulgating a proposed rulemaking that is likely to result in a final rule that contains a Federal mandate that may result in the expenditure by State, local, or tribal governments in the aggregate, or by the private sector, of \$100 million or more adjusted annually for inflation, in any one year, to prepare, among other things, an assessment of the anticipated costs and benefits of the mandate and the effect of the mandate on health, safety, and the natural environment. The Act, however, does not apply to any provisions in regulations with respect to seven stated areas, including the enforcement of certain Constitutional or statutory rights.

Since this Departmental Regulation was revised in December 1995, there have been additional and significant changes in Government-wide and USDA policy and practice regarding the development and review of regulatory actions. Most notably, these changes are reflected in the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Public Law No. 104-121)(SBREFA).

SBREFA amends the Regulatory Flexibility Act (5 U.S.C. 601-612)(RFA) to provide small entities that are adversely affected or aggrieved by final agency action the right to seek judicial review of the agency's compliance with various requirements of the RFA. It also provides specific procedures for Congressional review of final agency rules and for enacting Resolutions of Disapproval voiding such rules. SBREFA also requires agencies to develop, in certain instances, small entity compliance guides and programs for informal small entity guidance.

The Congressional review provisions of SBREFA require agencies to submit for review each final rule, as well as other documentation to Congress and to the Comptroller General (General Accounting Office) before a rule can take effect. SBREFA also requires that certain analyses related to the rule be submitted to the Comptroller General and be available to Congress. The Act has a specific definition of the term "rule" which may include more than those agency actions subject to notice and comment rulemaking. Also, SBREFA may delay the effective dates of major rules, which the Act broadly and uniquely defines.

Accordingly, we are revising this Departmental Regulation on Regulatory Decisionmaking Requirements to make changes necessitated by SBREFA and to incorporate all applicable Executive Orders, directives, and related material affecting regulations that have been issued since December 21, 1995, including Executive Order 12988, "Civil Justice Reform," dated February 5, 1996.

DEPARTMENTAL REGULATION		NUMBER: 1512-1
SUBJECT: Regulatory Decisionmaking Requirements	DATE: March 14, 1997	OPI: Office of Budget and Program Analysis

1 PURPOSE

This Departmental Regulation is intended to provide a consistent process for the development and review of all regulatory actions. It covers the full rulemaking cycle, starting when the need for a regulatory action is first identified, and carries through drafting (including analytic requirements); technical, legal, policy, and external review; preliminary publication in the FEDERAL REGISTER, receipt of public comment, and final publication for inclusion in the CODE OF FEDERAL REGULATIONS. Further, this Departmental Regulation is intended to ensure that USDA regulatory actions do not impose unreasonable costs on society, but rather foster economic growth; respect the role of State, local, and tribal governments; and are effective, consistent, sensible, and understandable.

This Departmental Regulation identifies requirements of Executive Order 12866, "Regulatory Planning and Review," and other applicable Executive Orders, applicable requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, and the Paperwork Reduction Act of 1995, and other statutes and regulations which must be considered in the rulemaking process. This Departmental Regulation assigns regulatory development and review responsibilities to USDA officials and agencies, and establishes internal procedures to accomplish the following goals:

- a Adoption of a development and review policy that provides a streamlined process for the review of rulemakings determined to be non-significant under E.O. 12866;
- b Early oversight of regulatory actions to assure consistency with Administration policy;
- c Thorough analysis and documentation of impacts, costs, and benefits to assure that the most cost effective means, which is consistent with any applicable statutes, of accomplishing the objective is chosen; and

- d Review of all regulatory actions to assure consistency with the substantive and procedural requirements of law and applicable Executive Orders. Section 1 of Executive Order 12866, "Statement of Regulatory Philosophy and Principles," provides guidance on the Administration's regulatory policy.

This Departmental Regulation, DR 1512-1, is intended only to improve the internal management of USDA and is not intended to create any right or benefit, substantive or procedural, enforceable at law or equity by a party against USDA, its agencies, instrumentalities, officers, employees, or any other person.

2 SPECIAL INSTRUCTIONS

This Departmental Regulation supersedes DR 1512-1, "USDA Regulatory Decisionmaking Requirements," dated December 21, 1995.

3 DEFINITIONS

- a **RULE OR REGULATION.** An agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describe the procedure or practice requirements of an agency. However, (1) formal rulemaking (rules required by statute to be made on the record after opportunity for an agency hearing), (2) regulations issued with respect to military or foreign affairs functions of the United States, and (3) any regulations relating to agency organization, management, or personnel, are specifically excluded from notice and comment rulemaking.

A more detailed discussion of the term "rule" and the exemptions to notice and comment rulemaking is found in Appendix B of this Departmental Regulation, "Further Guidance On The Initiation Of A Rulemaking."

For purposes of Congressional review under subtitle E of SBREFA, the term "rule" is defined in section 8 of this Departmental Regulation.

- b **REGULATORY ACTION.** Any substantive action by an agency (normally published in the FEDERAL REGISTER) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advanced notices of proposed rulemaking, and notices of proposed rulemaking.

c **REGULATORY CLASSIFICATION.** Six terms are used to categorize regulatory actions with respect to the degree of oversight that will occur for any particular regulatory action. The terms are: **NON-SIGNIFICANT**, **SIGNIFICANT**, **ECONOMICALLY SIGNIFICANT**, two definitions of **Major**: **MAJOR** as defined by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354); **MAJOR** as defined by subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. No. 104-121) and **EXEMPT**.

- (1) **NON-SIGNIFICANT.** Those regulatory actions for which an agency head has oversight and do not trigger any of the effects described in section 3c(2), (3), (4) or (5) of this Departmental Regulation.
- (2) **SIGNIFICANT.** Those regulatory actions for which an Under or Assistant Secretary has oversight and are likely to result in a rule that may:
 - (a) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
 - (b) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
 - (c) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.
- (3) **ECONOMICALLY SIGNIFICANT.** Those regulatory actions that are likely to result in a rule that may have an annual affect on the economy of \$100 million or more, OR adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Under or Assistant Secretary will have oversight over these actions.
- (4) **MAJOR** (as defined by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994). Those regulatory actions that the Secretary of Agriculture estimates are likely to have an annual impact on the economy of the United States of \$100 million in 1994 dollars; AND the primary purpose of which is to regulate issues of human health, human safety, or the

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environment. All major regulatory actions are economically significant, but not all economically significant regulatory actions are major. The primary distinction between economically significant and major regulatory actions is that the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 requires USDA to conduct an analysis for major regulatory actions which is not required to be conducted for economically significant regulatory actions. Required analyses are discussed in section 6 of this Departmental Regulation, "Documentation and Analysis Requirements for Regulations." Under or Assistant Secretary will have oversight over these actions.

- (5) MAJOR (as defined by the Small Business Regulatory Enforcement Fairness Act of 1996, subtitle E, Congressional Review). Those regulatory actions which are likely to result in a rule that has an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; OR significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. This definition of major is similar, but not identical to, the definition of economically significant and the definition of major as associated with risk assessment in the Federal Crop Insurance Reform and USDA Reorganization Act of 1994. This definition of major is only applicable to determinations under subtitle E of SBREFA regarding Congressional review of agency rules. Under or Assistant Secretary will have oversight over these actions.
- (6) EXEMPT. Those regulatory actions for which an agency head has oversight and that OMB has exempted from review under Executive Order 12866 because the regulatory actions are highly routine and/or concern non-sensitive subject matter. Exempt regulatory actions must be reviewed by the OGC. Exempt regulatory actions may, after appropriate clearances, be published in the FEDERAL REGISTER without any further consultation with OMB. When appropriate, an agency, working through the Office of Budget and Program Analysis (OBPA), may petition OMB for exemptions.

- d **WORKPLAN.** The document used to initiate a regulatory action. The workplan provides a description of the contemplated regulatory action, including objectives, alternatives, and expected results of the regulatory action. The information in the workplan is used to determine the regulatory classification of the regulatory action and designate the appropriate level of oversight. The front side of the workplan form has been designed to provide the information needed by OMB for its classification review. The workplan also provides source information for the creation of entries in the Regulatory Agenda and/or Regulatory Plan, as well as the information needed for opening a record in the USDA regulatory tracking system. Finally, the workplan offers the Under or Assistant Secretaries the opportunity to provide additional instructions to the drafting agency, including instructions that the Under or Assistant Secretary is to review a non-significant regulation before publication in the Federal Register. The workplan format and instructions for its completion are found at Figure 1.
- e **ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPRM).** A regulatory action issued before an agency is ready to issue a notice of proposed rulemaking. An ANPRM is often used by an agency as a vehicle to obtain public views regarding the necessity for rulemaking or to obtain public participation in the formulation of a notice of proposed rulemaking.
- f **NOTICE OF PROPOSED RULEMAKING (NPRM).** A regulatory action issued to inform the public that an agency is proposing a regulation. The NPRM includes either the terms or substance of the proposed rule, or a description of the subjects and issues involved; a reference to the legal authority under which the rule is proposed; and a statement of the manner in which, and time during which, the public may participate in the rulemaking process. NPRMs normally provide the public with a 60 day period in which to submit written comments regarding the NPRM.
- g **INTERIM FINAL RULE.** A final rule that is not preceded by a NPRM, but that provides the public with an opportunity to participate in the rulemaking proceeding after the final rule has been published. Interim final rules may only be used when the agency for good cause finds (and incorporates the findings and a brief statement of the reasons for the findings in the interim final rule) that a prior NPRM would be impracticable, unnecessary, or contrary to the public interest.
- h **FINAL RULE.** A regulatory action issued to make effective a regulatory change. The final rule includes a statement of the basis and purpose for the rule; a discussion of the comments received; the agency's response to comments received; and the reasons for the agency's response to comments received.

The final rule is normally effective not less than 30 days after the date of publication of the final rule in the FEDERAL REGISTER.

- i DIRECT FINAL RULE. A regulatory action that expedites noncontroversial CHANGES to an EXISTING regulation. Rules that are believed to be noncontroversial and unlikely to result in adverse comments may be published in the FEDERAL REGISTER as direct final rules. A more detailed discussion of the use of direct final rules is found at Appendix E in this Departmental Regulation.
- j ROUTINE NOTICE. Non-regulatory actions that are published in the FEDERAL REGISTER to inform the public of planned meetings, public hearings, extensions of comment periods, or other information or actions which are not designed to implement, interpret, or prescribe law or policy or describe procedure or practice requirements of an agency.

4 ABBREVIATIONS

OBPA	Office of Budget and Program Analysis
OCE	Office of the Chief Economist
OGC	Office of the General Counsel
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
ORACBA	Office Of Risk Assessment and Cost- Benefit Analysis (Reports to OCE)
USDA	The United States Department of Agriculture

5 RESPONSIBILITIES

a AGENCY HEADS will:

- (1) Inform the appropriate Under or Assistant Secretary of contemplated regulatory actions using the workplan format (see Figure 1 for an illustration of the format and instructions for completion);
- (2) Develop for review and classification by OMB an appropriate summary of regulatory actions (see section 6(a)(3)(A) of Executive Order 12866) that are under development and are planned for publication within a 60 to 90 day timeframe, and recommend the level of significance for each regulatory action, including whether the action is major as defined by section 3(c) (4) and (5) of this Departmental Regulation, described in the summary.
(These summaries are forwarded to OMB through OBPA at approximately six week intervals);

- (3) Prepare and review regulatory actions within their scope of responsibility;
- (4) Perform required analyses for these regulatory actions;
- (5) Ensure that these regulatory actions meet the requirements of this Departmental Regulation, the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act of 1995, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, title III, section 304, and any other relevant statutes and Executive Orders;
- (6) Complete the Executive Order 12866 Submission (see Figure 2);
- (7) Submit all regulatory actions requiring OMB approval to OMB through OBPA;
- (8) Approve economically significant, major, and significant regulatory actions prior to forwarding such actions and accompanying analyses for Department level review and clearance through OGC and OBPA;
- (9) Prepare the information memorandum for the Secretary and Deputy Secretary for economically significant and major regulatory actions as required by section 7b(3) of this Departmental Regulation;
- (10) Comply with the requirements of the Small Business Regulatory Enforcement Fairness Act of 1996 as required by sections 8 and 10 of this Departmental Regulation;
- (11) Comply with the requirements of section 1.27 of USDA's Administrative Regulations (7 C.F.R. § 1.27) regarding rulemaking and other notice procedures (see Appendix J);
- (12) Maintain for each regulatory action a complete file of documents relevant to the regulatory action including comments received as required by section 6g of this Departmental Regulation;
- (13) Update current entries and develop new entries, where appropriate, for the USDA Unified Regulatory Agenda on a continuing basis to ensure that all entries are reflective of planned regulatory activities for the 12-month period following the publication of the April and October regulatory agenda respectively. Workplans will be used by all agencies as the basis for providing new agenda entries and entries for the Annual Regulatory Plan;

- (14) Develop and update on a continuing basis the USDA draft Annual Regulatory Plan to ensure that the plan is reflective of the most important significant regulatory actions that the agency plans to pursue during the year covered by the Plan;
- (15) Promptly advise OBPA when a regulatory action under review by OMB has been withdrawn by the agency, revised based on an OMB request, or returned to the agency for reconsideration;
- (16) Approve non-significant regulatory actions and routine notices for publication in the FEDERAL REGISTER;
- (17) Designate a regulatory officer/coordinator as the principal point of contact within the agency on regulatory matters;
- (18) Maintain and execute up-to-date plans for reviewing existing regulations as required by section 5 of Executive Order 12866 to ensure that reviews are conducted on a timely basis, and needed modifications to existing regulations are made; and
- (19) Maintain adequate records of conclusions of reviews made pursuant to section 5a(18) of this Departmental Regulation.

b UNDER SECRETARIES AND ASSISTANT SECRETARIES will:

- (1) Review agency workplans for contemplated regulatory actions;
 - (a) Designate the level of significance for contemplated regulatory actions as one or more of the following:
 - 1 Non-Significant
 - 2 Significant
 - 3 Economically Significant
 - 4 Major (Public Law 103-354)
 - 5 Major (Public Law 104-121)
 - (b) Direct the development or termination of the regulatory action, as warranted.
 - (c) Indicate on the workplan any additional analyses that may be appropriate or any other instructions pertinent to the development process.

After the appropriate Under or Assistant Secretary completes review of a workplan as provided in this section, the signed workplan and any other documents which provide information on the contemplated regulatory action and the designation of the significance of the contemplated regulatory action are to be returned to OBPA. OBPA will provide the appropriate agency with the signed original workplan, and for workplans designated as economically significant or major as defined by section 3(c)(4) of this Departmental Regulation, a copy to ORACBA.

- (2) Approve regulatory cost-benefit assessments as required by section 6 of this Departmental Regulation for economically significant, major, and significant regulatory actions;
 - (3) Approve and clear all significant, economically significant, and major regulatory actions for transmittal to OMB for review and release for publication in the FEDERAL REGISTER unless delegations of authority provide approval authority to other USDA officials;
 - (4) Approve agency submissions for the ANNUAL REGULATORY PLAN, and SEMI-ANNUAL REGULATORY AGENDA; and
 - (5) Approve agencies' plans for the review of existing significant regulations as required by section 5 of Executive Order 12866.
- c THE CHIEF INFORMATION OFFICER will:
- (1) Review all "significant" regulatory actions which contain information collection or recordkeeping requirements for compliance with the Paperwork Reduction Act of 1995; and
 - (2) Assist agencies with the identification of information collection and recordkeeping requirements and with the submission of information collection requests under the Paperwork Reduction Act of 1995 to OMB for approval.

d THE ASSISTANT SECRETARY FOR ADMINISTRATION will:

Assist with the development of civil rights impact statements, as requested, and review impact statements relating to regulatory actions having significant civil rights impact.

e STAFF ORGANIZATIONS will:

Lend their specific expertise and an element of independent oversight to the drafting and review process. The staff organizations consist of the Office of the Chief Economist, the Office of the General Counsel, and the Office of Budget and Program Analysis.

(1) THE OFFICE OF THE CHIEF ECONOMIST will:

- (a) Review regulatory cost-benefit assessments on economically significant, major, and significant regulatory actions to ensure that: (1) the analytical techniques used are adequate; (2) the analysis is accurate; (3) analytical requirements in section 6 of this Departmental Regulation have been met; (4) reasonable alternatives have been considered; and (5) any appropriate risk assessments have been conducted. For major rules as defined by section 3(c)(4) of this Departmental Regulation, the Director of ORACBA will coordinate the design of the required risk assessment and cost-benefit analysis with the responsible agency, assist in its preparation, and review and approve the analysis and assessment to ensure that the requirements of P.L. 103-354 are met. If it is not practicable to conduct an analysis as required by P.L. 103-354, the Director of ORACBA will provide in the applicable proposed major regulation an explanation of why the analysis was not conducted; and
- (b) Review workplans that have been designated economically significant or major to ensure appropriate and timely identification of all major rulemakings.

(2) THE OFFICE OF THE GENERAL COUNSEL will:

- (a) Review regulatory actions for legal sufficiency. This review includes a review of any justifications for the publication of a final rule without prior public participation, for the publication of a notice of proposed rulemaking with an abbreviated comment period, or for the publication of an interim final rule. Regulatory actions will also be reviewed for conformity with laws, regulations, and USDA policy;

- (b) Assist agency staff, as needed, in drafting regulatory actions;
- (c) In the event the lowest cost alternative is not chosen for a significant or economically significant regulatory action, review the adequacy of the explanation of the legal reasons why such alternatives were not adopted;
- (d) Review regulatory actions for compliance with Executive Order 12866 "Regulatory Planning and Review";
- (e) Review regulations and notices of proposed rulemaking for compliance with Executive Order 12612, "Federalism Considerations in Policy Formulation and Implementation," and determine whether the preparation of a federalism assessment by an agency is required;
- (f) Review regulations and notices of proposed rulemaking for compliance with Executive Order 12630, "Government Actions and Interference With Constitutionally Protected Property Rights," and the Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings with Respect to Proposed Regulatory Actions;
- (g) Review regulations and notices of proposed rulemaking for compliance with sections 3(a) and 3(b)(2) of Executive Order 12988 "Civil Justice Reform";
- (h) Review all regulations for compliance with section 1 of Executive Order 12875, "Enhancing the Intergovernmental Partnership";
- (i) Review all regulation for compliance with Title 11 of Public Law 104-4, Unfunded Mandates Reform Act of 1995;
- (j) Review regulations and notices of proposed rulemakings for compliance with Executive Order 12606 "The Family" to assess potential impact on family well-being; and
- (k) Review all regulations and notices of proposed rulemaking for compliance with the requirements of the Regulatory Flexibility Act (5 U.S.C 601 et seq.).

- (3) THE OFFICE OF BUDGET AND PROGRAM ANALYSIS will:
- (a) Review and clear economically significant, major, and significant regulatory actions and all required analyses as described in section 6 of this Departmental Regulation, OMB guidelines, and any other pertinent documents;
 - (b) Ensure that all regulatory actions are consistent with policy and budget constraints;
 - (c) Advise Under or Assistant Secretaries on contemplated regulatory actions, including levels of significance;
 - (d) Assist agencies in the development and clearance of all regulatory actions and accompanying analyses;
 - (e) Provide to ORACBA workplans that have been designated economically significant and/or major as defined in sections 3(c) (3) and (4) of this Departmental Regulation to ensure appropriate and timely identification of all proposed major regulations;
 - (f) Facilitate the clearance of regulatory actions through OMB; respond to inquiries from OMB; inquire of OMB staff regarding the status of regulatory actions under review, highlighting as necessary, regulatory actions experiencing clearance delays; maintain records of transmittals to OMB and clearances by OMB; promptly notify agencies of OMB decisions regarding the classification, withdrawal, or revisions to any regulatory action;
 - (g) Produce the USDA Unified Regulatory Agenda as required by the Regulatory Flexibility Act and Executive Order 12866; and the Annual Regulatory Plan as required by Executive Order 12866; and
 - (h) Transmit memoranda as required by section 5a(9) of this Departmental Regulation regarding economically significant and major regulatory actions, to the Secretary and Deputy Secretary. Provide copies of regulatory actions as required and follow-up on any instructions issued resulting from the review of regulatory actions.

6 DOCUMENTATION AND ANALYSIS REQUIREMENTS FOR REGULATIONS

Agencies have responsibility for preparation of regulatory actions and analyses in compliance with the law and this Departmental Regulation, and for maintaining necessary decisionmaking records. This section lists requirements applicable to most regulatory actions in order of the stages of development of a regulatory action.

The requirements listed in this section are not applicable to every regulatory action or class of regulatory actions. The requirements are as follows:

- a **SUMMARY INFORMATION TO POLICY OFFICIALS ON CONTEMPLATED REGULATORY ACTIONS.** Agencies submit summary information on contemplated regulatory actions to policy officials via the workplan process. Workplans must be prepared for all regulatory actions which are required to be submitted to OMB and reviewed under Executive Order 12866. These regulatory actions include advance notices of proposed rulemakings, notices of proposed rulemakings, interim final rules, and any final rules for which a workplan has not previously been approved by the cognizant policy official. The appropriate Under or Assistant Secretary's designation of non-significant, significant, economically significant, or major must be recorded on the workplan. Workplans are not prepared for routine notices such as announcements of meetings, public hearings, extension of comment periods, and other notices that are not regulatory actions. Information that must be provided on the workplan include:
- (1) complete and detailed descriptions of contemplated regulatory actions so that the appropriate regulatory classification can be determined;
 - (2) the identification of the analyses necessary for the contemplated regulatory action. (Analyses applicable to regulatory actions are discussed in this section); and
 - (3) the identification in the "Special Handling Requirement" section of any statutory or judicial deadlines, any other time constraints, any non-typical matter that is relevant, or any particular sensitivities associated with the contemplated regulatory action.

(Workplans will be forwarded for the approval of the appropriate Under or Assistant Secretary through OBPA.)

- b **COMPLIANCE WITH THE PAPERWORK REDUCTION ACT OF 1995 (P.L. 104-13) AND 5 CFR PART 1320 (CONTROLLING PAPERWORK BURDENS ON THE PUBLIC).** Agencies preparing regulatory actions that would impose new information collections or change existing OMB approved information collections must ensure that they have complied with the requirements in the Act, 5 CFR Part 1320, and OMB policies regarding such collections of information. Agency program, regulatory liaison, and reports management personnel involvement in the early stage of regulatory development facilitates clearances. In addition:
- (1) As provided in section 9 of this Departmental Regulation, agencies must complete an Executive Order 12866 Submission to transmit the regulatory action for OMB review and clearance. A completed OMB-83-1, Paperwork Reduction Act Submission (see Figure 6) and a justification statement must be submitted to OMB through the Chief Information Officer for information collection requirements that are included in the regulatory action. Departmental Regulation 3410-1, INFORMATION COLLECTION ACTIVITIES, provides detailed instructions concerning the preparation, review, and clearance associated with information collection activities.
 - (2) Agencies must include the existing OMB control number within the regulatory action for any information collection requirements published in the FEDERAL REGISTER. The number must be displayed in such a manner that it will be included in the regulatory text in the CODE OF FEDERAL REGULATIONS for regulations that appear there (see Figure 3).
- c **ANALYTICAL REQUIREMENTS.** A single, unified analytical statement should be completed where possible to meet all applicable analytic requirements. This analysis document should contain subsidiary headings that indicate the types of analyses included. Figure 4 provides a model clearance signature sheet to be used for analyses and regulatory actions. The analytic requirements which may be applicable to regulatory actions and the conditions under which they are applicable are as follows (this list includes the key requirements, but is not exhaustive):

(1) DECISION CRITERIA AND COST-BENEFIT ASSESSMENT
REQUIREMENTS FOR ALL REGULATIONS

Section 1(b) of Executive Order 12866 states that all agencies shall to the extent permitted by law and where applicable, adhere to the following principles in developing their regulatory programs:

- (a) Identify the problem that the agency intends to address through the regulatory process and assess the significance of that problem;
- (b) Examine whether existing regulations (or other law) have created or contributed to the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the regulatory goal more effectively;
- (c) Identify and assess available alternatives to direct regulation;
- (d) In setting regulatory priorities, consider to the extent reasonable, the degree and nature of the risks posed by various substances or activities within agency jurisdiction;
- (e) Design regulations in the most cost effective manner to achieve the regulatory objective when it is determined that a regulation is the best available method of achieving the regulatory objective;
- (f) Assess both the costs and benefits of the intended regulation and propose or adopt a regulation only upon a reasoned determination that the benefits of the regulation justify its costs;
- (g) Base decisions regarding the need for and consequences of a regulation on the best reasonably obtainable scientific, technical, economic, and other information;
- (h) Identify and assess alternative forms of regulation and, to the extent feasible, specify performance objectives that regulated entities must adopt;
- (i) Seek, whenever feasible, views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities;

- (j) Avoid regulations that are inconsistent, incompatible, or duplicative with other agency regulations or those of other federal agencies;
 - (k) Tailor regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; and
 - (l) Draft regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.
- (2) **COST-BENEFIT ASSESSMENT FOR MAJOR (Public Law 104-121 (SBREFA), ECONOMICALLY SIGNIFICANT, AND SIGNIFICANT REGULATORY ACTIONS**

Executive Order 12866 requires that a regulatory cost-benefit assessment be performed on all economically significant and significant regulatory actions. Public Law 104-121 requires that a regulatory cost-benefit assessment be prepared for all major regulations. See the guidelines provided in Appendix C for such analyses.

Each preliminary and final regulatory cost benefit assessment for significant regulatory actions shall contain sufficient information to meet the requirements in section 6c(1) of this Departmental Regulation, as well as the following information required by section 6(a)(3)(B) of Executive Order 12866:

- (a) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need;
- (b) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

Each preliminary and final regulatory cost/benefit assessment for major regulatory action as defined by section 3c(5) of this Departmental Regulation and economically significant regulatory actions shall contain sufficient information to meet the requirements in sections 6c(1), 6c(2)(a), and 6c(2)(b) of this Department Regulation, as well as the following information required by section 6(a)(3)(C) of Executive Order 12866;

- 1 An assessment, including the underlying analysis of benefits anticipated from the regulatory action (such as but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias), together with, to the extent feasible, a quantification of those benefits;
 - 2 An assessment, including the underlying analysis of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety and the natural environment), together with, to the extent feasible, a quantification of those costs; and
 - 3 An assessment, including the underlying analysis of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation of why the planned regulatory action is preferable to the identified potential alternatives.
- (3) REGULATORY ANALYSES FOR MAJOR REGULATIONS THAT ADDRESS ISSUES OF HUMAN HEALTH, HUMAN SAFETY, OR THE ENVIRONMENT

Public Law 103-354, Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, title III, section 304 establishes certain analysis requirements which address risk assessment and cost-benefit analysis. Proposed regulations which meet the Act's definition of major, whose

primary purpose is to regulate issues of human health, human safety, or the environment, must include an analysis with as much specificity as practicable of:

- (a) the risk, including the effect of the risk, to human health, human safety, or the environment, and any combination thereof, addressed by the regulation, including where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive;
- (b) the costs associated with the implementation of, and compliance with, the regulation;
- (c) where appropriate and meaningful, a comparison of that risk relative to other similar risks regulated by USDA or another Federal agency, resulting from comparable activities and exposure pathways (such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or nonpreventability of risks); and
- (d) the quantitative and qualitative benefits of the regulation, including the reduction or prevention of risk expected from the regulation.

The analysis should also contain a statement that the Secretary of Agriculture evaluated: (1) whether the regulation will advance the purpose of protecting against the risk, including the effect of the risk to human health, human safety, or the environment, and any combination of those risks and, where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive; and (2) whether the regulation will produce benefits and reduce risks to human health, human safety, or the environment, and any combination thereof, in a cost-effective manner as a result of the implementation of and compliance with the regulation, by local, State, and Federal governments, and other public and private entities, as estimated.

Guidelines for the preparation of risk assessment and cost-benefit analyses are found in Appendix C to this Departmental Regulation.

(4) REGULATORY FLEXIBILITY ANALYSIS OR CERTIFICATION

- (a) The Regulatory Flexibility Act requires agencies to evaluate the impact of a contemplated regulation on small entities. If the agency head CAN certify under 5 U.S.C. 605 that a proposed or final rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, the certification, along with a statement providing the factual basis for the certification, must be published in the FEDERAL REGISTER at the time of publication of either the notice of proposed rulemaking or final rule. The requirements of section 6c(4)(b) and (c) of this Departmental Regulation apply to a proposed or final rule if the head of the agency CANNOT certify that the rule will not have a significant economic impact on a substantial number of small entities.
- (b) Except as provided in section 6c(4)(a) of this Departmental Regulation, when an agency is required by section 5 U.S.C. 553, or any other law, to publish a notice of proposed rulemaking, the agency must prepare and make available for public comment an initial regulatory flexibility analysis.

The analysis or a summary of it must be published in the FEDERAL REGISTER at the time that the notice of proposed rulemaking is published. The initial regulatory flexibility analysis must contain:

- 1 a description of the reasons why action by the agency is being considered;
- 2 a succinct statement of the objectives of, and legal basis for, the proposed rule;
- 3 a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- 4 a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record;

- 5 an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule;
 - 6 a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of the applicable statutes, the analysis shall discuss significant alternatives such as--

 - a the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
 - b the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
 - c the use of performance rather than design standards; and
 - d an exception from the coverage of the rule, or any part thereof, for such small entities.
- (c) Except as provided in section 6c(4)(a) of this Departmental Regulation, when an agency publishes a final rule under 5 U.S.C. 553, after being required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking, the agency must prepare a final regulatory flexibility analysis. The final regulatory flexibility analysis or summary thereof shall be published in the FEDERAL REGISTER and made available to members of the public. The final regulatory flexibility analysis must contain:
- (1) a succinct statement of the need for, and objectives of, the rule;
 - (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

- (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
 - (4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
 - (5) description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.
- (d) Those responsible for the preparation of a regulatory flexibility analysis should consult the Regulatory Flexibility Act (5 U.S.C. 601- 612) for defined terms relevant to the analysis as well as the scope of any judicial review available.
- (5) ENVIRONMENTAL ASSESSMENTS AND ENVIRONMENTAL IMPACT STATEMENTS (EA, EIS). Section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.) requires all Federal agencies to include in proposals for major Federal actions significantly affecting the quality of the human environment, a detailed statement on the environmental impact of the proposed action, any adverse environmental effects of implementation, and alternatives to the proposed action. General NEPA requirements for EA and EIS documents are set forth in 7 CFR 3100 and 40 CFR Parts 1500-1508. Agencies may have issued implementing regulations to apply NEPA to their specific types of actions. Some agencies, whose rulemakings do not involve environmental considerations, may be exempt from the provisions of this analytic requirement (see 7 CFR 1b.4 for the listing of exempt USDA agencies).
- (6) CIVIL RIGHTS IMPACT ANALYSIS. When an agency head determines that a decision is, "a major policy action having a significant civil rights impact", a civil rights impact analysis must be completed and, in addition to other clearances, the regulation

and analysis must be submitted to the Assistant Secretary for Administration for review. Elements of the analysis include evaluation of impacts of the action, alternative approaches to minimize unfavorable civil rights impact and an equal housing opportunity assessment, where appropriate.

The Assistant Secretary for Administration can provide technical assistance and informal advice to agencies regarding the applicability of a civil rights impact analysis to specific regulatory actions.

- (7) **ANALYSIS OF REGULATORY IMPACT ON THE FAMILY.** Section 1 of Executive Order 12606, "Family Policymaking Criteria and Regulations," states that in formulating and implementing policies and regulations that may have significant impact on family formation, maintenance, and general well-being, executive departments and agencies shall, to the extent permitted by law, assess such measures in light of the considerations enumerated in the Executive Order. The Executive Order further provides that executive departments and agencies shall identify proposed regulatory and statutory provisions that may have significant potential negative impact on family well-being and provide adequate rationale as to why the proposal should be submitted.
- (8) **FEDERALISM ASSESSMENT.** Executive Order 12612, "Federalism Considerations in Policy Formulation and Implementation," establishes a number of fundamental federalism principles which are to guide executive departments and agencies when they formulate and implement regulations that have substantial direct effects on the States, the relationship between the national government and the States, and the distribution of power and responsibilities among the various levels of government. A federalism assessment is required for those regulations and notices of proposed rulemaking that are determined by OGC to have sufficient federalism implications to warrant such assessment.
- (9) **ANALYSIS OF THE IMPACT OF REGULATORY ACTIONS ON CONSTITUTIONALLY PROTECTED PROPERTY RIGHTS.** Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," states that fundamental principles of good Government and responsible fiscal management require that Government decisionmakers evaluate carefully the effect of their actions on constitutionally protected property rights. The Executive Order and the Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings contain general principles to guide

executive departments and agencies in formulating or implementing policies (including regulations) that have taking implications, and provide criteria and procedures to be followed when implementing such policies.

- (10) **CIVIL JUSTICE REFORM.** Section 3 of Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. These requirements include eliminating drafting errors and ambiguity. Proposed regulations also shall be written to minimize litigation, shall provide a clear legal standard for affected conduct, and shall promote simplification and burden reduction. Section 3(b)(2) of the Executive Order instructs agencies to review all regulations against a "litigation checklist" of specific issues (such as preemptive effect and retroactivity). In addition, section 3(c) of the Executive Order requires that regulations and notices of proposed rulemaking be reviewed to determine that either they meet the applicable standards provided in section 3(b) of the Order or that it is unreasonable to require the regulation or notice of proposed rulemaking to meet those standards.
- (11) **ENHANCING THE INTERGOVERNMENTAL PARTNERSHIP.** Executive Order 12875 is intended to "reduce the imposition of unfunded mandates upon State, local, and tribal governments." Section 1 of Executive Order 12875 requires Federal agencies that impose unfunded mandates upon State, local or tribal governments through a regulation that is not specifically required by statute to (1) assure that funds necessary to pay the direct costs incurred by the State, local, or tribal government are provided by the Federal Government or (2) describe the extent of the agency's prior consultations with affected units of government, the nature of their concerns, any written submissions from them, and the agency's position supporting the need to issue the regulation containing the mandate.
- (12) **ASSESSMENT OF THE IMPACT OF REGULATIONS CONTAINING FEDERAL MANDATES.** Title II of the Unfunded Mandates Reform Act of 1995 (P.L. 104-4, 109 Stat. 64) requires Federal agencies to, before promulgating a general notice of proposed rulemaking that is likely to result in a final rule that includes any Federal mandate that may result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more (adjusted annually for inflation) in any one year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, prepare a written statement. The statement must identify the

provision of Federal law under which the rule is being promulgated and provide a qualitative and quantitative assessment of the anticipated costs and benefits to State, local, and tribal governments or the private sector, as well as the effect of that Federal mandate on health, safety, and the natural environment.

(a) The assessment must also include:

- (1) an analysis of the extent to which costs to State, local, and tribal governments may be paid with Federal financial assistance (or otherwise paid for by the Federal Government);
- (2) the extent to which Federal resources are available to carry out the intergovernmental mandate;
- (3) if feasible, estimates of the future compliance cost of the Federal mandate;
- (4) if feasible, estimates of any disproportionate budgeting effect of the mandate upon particular regions of the Nation or particular State, local, or tribal governments, urban or rural or other types of communities, or particular segments of the private sector;
- (5) if feasible, estimates of the effect on the national economy; and
- (6) information regarding the extent of the agency's prior consultation with elected representatives of affected State, local, and tribal governments, a summary of comments and concerns of elected representatives of State, local, and tribal governments regarding the proposed regulations, and a summary of the agency's evaluation of the comments and concerns.

(b) For rulemakings that require a written statement:

- (1) prior to issuing the rule, the agency must identify and consider a reasonable number of regulatory alternatives and SELECT the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. However, if the head of an agency publishes with a final rule an explanation of why the least costly, most cost-effective, or least burdensome method of achieving the objectives of the

rule was not adopted, or if the provisions of the least costly, most cost-effective or least burdensome alternative are inconsistent with law, the least costly, most cost-effective, or least burdensome alternative does not have to be selected; and

- (2) a summary of the information contained in the statement must be published along with the regulation.
- (c) The Unfunded Mandates Reform Act of 1995 (Public Law 104-4, 109 Stat. 64) contains additional provisions with which agencies must comply as part of the rulemaking process. In particular, Title II of the Act sets forth certain requirements for consultation with State, local, and tribal governments on regulatory proposals containing significant Federal inter-governmental mandates. OMB has issued a memorandum which provides guidelines and instructions for implementing these consultation requirements. The full text of the OMB memorandum, as published in the FEDERAL REGISTER, is found as Appendix H.
- (d) Rulemakings that incorporate requirements specifically set forth in law do not have to comply with the assessment requirements of Public Law 104-4.

(13) OTHER ANALYSIS REQUIRED BY LAW OR REGULATIONS

d NOTICE AND PUBLIC COMMENT

- (1) GENERAL POLICY. As required by the Administrative Procedure Act, USDA is committed to providing the public reasonable opportunity to participate in rulemakings. Generally, comment periods for proposed regulations should not be less than 60 days. When an emergency or other good reason exists, a period of less than 60 days may be used. OGC must be consulted early in the decisionmaking process for advice regarding the justification for an abbreviated comment period.

Regulations may also be issued on an emergency basis with no prior opportunity for comment if there is GOOD CAUSE not to solicit comments on the rule and the reason is set forth in the rule as published, as provided in 5 U.S.C. 553(b). This "good cause" exception to notice and opportunity for public comment is to be construed narrowly and used only in unusual circumstances. In addition, OGC must be consulted early in the decisionmaking process for advice regarding the applicability of the "good cause" exception to the rulemaking. Rules published in accordance with

the "good cause" exception should generally be issued as interim final rules and comments solicited following publication of the regulation.

- (2) **REGULATORY FLEXIBILITY ACT NOTICE AND COMMENT REQUIREMENTS.** When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule will assure that small entities have been given the opportunity to participate in the rulemaking process through techniques such as the:
- (a) Initial notice of the rule in the Unified Agenda of Federal Regulations;
 - (b) Inclusion in an advanced notice of proposed rulemaking, if issued, a statement that the contemplated proposed rule may have a significant economic effect on a substantial number of small entities;
 - (c) Publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;
 - (d) Direct notification of interested small entities;
 - (e) Conduct open conferences or public hearings concerning the rule which small entities can attend; and
 - (f) Adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.
- e **MEMORANDUM SUMMARIZING THE RULE AND ITS IMPACT FOR ECONOMICALLY SIGNIFICANT AND MAJOR RULES.** This memorandum should be prepared by the agency for the Secretary and Deputy Secretary for each economically significant or major regulatory action and transmitted through OBPA when the rulemaking package is approved by the agency head (see section 7b(3) of this Departmental Regulation).
- f **GENERAL CONTENT REQUIREMENTS FOR FEDERAL REGISTER RULEMAKING DOCUMENTS.** General requirements are set out in 1 CFR Part 18, and are discussed in detail in the "Document Drafting Handbook" available from the Office of the Federal Register. Appendix A of this Departmental Regulation provides a checklist useful in the preparation of proposed or final rulemaking documents.

- g RULEMAKING FILE. Agencies will maintain a file for each regulatory action. The rulemaking file shall contain copies of all FEDERAL REGISTER notices regarding the regulatory action, background data on which the regulatory action is based, analyses conducted by the agency, written comments received from the public, summaries or transcripts of any meeting or hearings, written comments received from OMB, and any other data which will be considered in the decision to promulgate a final regulation.

7 DEPARTMENT CLEARANCE PROCEDURES

a REQUIREMENTS FOR ALL REGULATIONS

- (1) Agencies are responsible for preparation of regulations in accordance with this Departmental Regulation, instructions of the cognizant Under or Assistant Secretary, Executive Order 12866, and other relevant requirements.
- (2) OGC will review ALL regulatory actions for legal sufficiency, including those that are exempt from OMB review as defined in section 3c(6) of this Departmental Regulation.
- (3) The Chief Information Officer will review all significant regulatory actions that have information collection requirements. Agency staff shall consult with agency clearance officers during the drafting of a regulation that contains any information collection requirements to ensure that the requirements of the Paperwork Reduction Act of 1995 and the regulations implementing that Act are being met in a timely manner. 5 CFR part 1320 specifically requires that collections of information contained in proposed rules MUST be submitted to OMB for approval not later than the day of publication of the notice of proposed rulemaking in the FEDERAL REGISTER. OMB may request the information collection submission sooner. Information collection requests contained in regulations MAY NOT be put into effect until OMB has given approval.
- (4) Advance copies of regulatory actions may be sent to OMB only with the prior review of OGC and OBPA.
- (5) Exempt regulatory actions may, after clearance by an agency head, be published in the FEDERAL REGISTER without any further consultation with OMB. When appropriate, an agency, working through OBPA may petition OMB for additional exemptions.

- b SPECIAL REQUIREMENTS FOR SIGNIFICANT, ECONOMICALLY SIGNIFICANT, AND MAJOR REGULATIONS. In addition to the requirements of section 7a of this Departmental Regulation, significant, economically significant, and major regulatory actions must be handled as follows:
- (1) Agencies are responsible for preparation of a regulatory assessment and other required analyses, subject to the direction of the appropriate Under or Assistant Secretary.
 - (a) OGC clears only the regulatory action for both legal sufficiency and policy considerations (the policy clearance concurrence by OGC may, in some instances, at the discretion of the appropriate Associate General Counsel, be obtained after the agency head clearance);
 - (b) Agency head clears the regulatory action and required analyses;
 - (c) OBPA clears the regulatory action and required analyses;
 - (d) OCE clears only the required analyses;
 - (e) The Chief Information Officer clears significant regulations containing information collection requirements,
 - (f) Assistant Secretary for Administration clears the regulatory action and analyses for any applicable civil rights impact; and
 - (g) Under or Assistant Secretary clears the regulatory action and required analyses.
 - (2) Officials who clear regulatory actions should sign and date the appropriate clearance sheet(s), stating the officials' name and title.

Note: Significant and economically significant regulatory actions are similar in characteristics, with the notable exception that the latter category of regulatory action is likely to result in a rule that may have an annual effect on the economy of \$100 million or greater or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Therefore, the analytic requirements for economically significant regulatory actions are more rigorous than those for significant

regulatory actions. Agencies must prepare an analysis that meets the requirements of section 6(a)(3)(B) of E.O. 12866 for each significant regulatory action and an analysis that meets the requirements of that section as well as section 6(a)(3)(C) for each economically significant regulatory action. In addition, for major regulations, as defined by SBREFA (see sections 3c(5) and 8d of this Departmental Regulation), an analysis that meets the requirements of sections 6a(3)(B) and (C) of E.O. 12866 must be prepared if such a regulation is significant under the Executive Order. For each proposed major regulation the primary purpose of which is to regulate issues of human health, human safety, or the environment, the agency must prepare and publish in the FEDERAL REGISTER the analysis required under section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, as well as an analysis that meets the requirements of sections 6(a)(3)(B) and (C) of E.O. 12866.

- (3) Agencies will prepare an information memorandum for the Secretary and Deputy Secretary that summarizes economically significant and major regulatory actions and their impact. The memorandum will accompany the rulemaking package sent to OBPA when the agency head has cleared the package. OBPA will make the summary available to the Secretary and Deputy Secretary who can then advise OBPA of those regulatory actions they wish to review. If they have not advised OBPA of their intention to review a regulatory action by the time the Under or Assistant Secretary has cleared it, the regulatory action may be transmitted to OMB without further review. It is recommended that the key contents of the memorandum be taken from the overview section of the analysis.

c SPECIAL REVIEW REQUIREMENTS FOR SELECTED NON-SIGNIFICANT REGULATIONS.

In addition to the requirements of section 7a of this Departmental Regulation, the Secretary or Deputy Secretary may choose to review or take some other action relative to non-significant regulatory actions which they may identify from summary regulatory activity lists provided by OBPA. As and when this occurs, OBPA will advise the appropriate subcabinet officer and the agency involved and make arrangements to provide the non-significant regulatory action requested.

8 CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

- a The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)(P.L. 104-121, Title II, subtitle E) requires that agencies **SUBMIT** for review **ALL FINAL** rules to each House of Congress and the Comptroller General (General Accounting Office) before such rules can take effect.

In addition to a copy of the rule, agencies must **SUBMIT** a report containing (see Figure 5):

- (1) a concise general statement relating to the rule, including whether it is a major rule (as defined in SBREFA); and
 - (2) the proposed effective date of the rule.
- b On the same date as the agency submits the rule and other information to Congress and to the Comptroller General, the agency must also **SUBMIT** to the Comptroller General and **MAKE AVAILABLE** upon request to each House of Congress:
- (1) a complete copy of the cost-benefit analysis of the rule, if any, as provided in section 6c of this Departmental Regulation;
 - (2) information concerning the agency's actions relative to certain requirements of the Regulatory Flexibility Act, as provided in sections 6c and d of this Departmental Regulation;
 - (3) information concerning the agency's actions relative to the Unfunded Mandates Reform Act of 1995, as provided in section 6c of this Departmental Regulation; and,
 - (4) any other relevant information or requirements under any other law and any other Executive Order as provided in section 6c of this Departmental Regulation.
- c The agency must cooperate with the Comptroller General in his preparation of reports on each major rule to Congress. The Comptroller General's reports will include an assessment of whether the agency provided to the Comptroller General and made available to Congress the required information, as provided in section 8b of this Departmental Regulation.

d SBREFA specifically defines Rule, Major Rule, and Non-Major Rule.

- (1) Rule. For purposes of the Congressional review provisions of SBREFA, the term "rule" has the meaning given the term in the Administrative Procedure Act (5 U.S.C. 551), except that rule does not include - -
 - (a) any rule or particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing;
 - (b) any rule relating to agency management or personnel; or
 - (c) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

Thus, the term "rule" may include more than those agency actions subject to notice and comment rulemaking. Agencies should consult the definition of rule in the Act, which is attached as Appendix I to this Departmental Regulation.

- (2) Major Rule. Any rule that the Administrator of the Office of Information and Regulatory Affairs of OMB finds has resulted in or is likely to result in:
 - (a) an annual effect on the economy of \$100,000,000 or more;
 - (b) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or
 - (c) significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

This term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.

- (3) Non-Major Rule. Any rule which is not covered by the definition of major is a non-major rule.

e Effective Date of Non-Major Rules

A non-major rule takes effect on the date provided for by the agency promulgating the rule, provided the agency has submitted for review the rule and other required information to Congress and the Comptroller General. However, Congress may disapprove of the rule pursuant to the procedures set forth in SBREFA. Any non-major rule that takes effect and which Congress later disapproves by joint resolution shall be treated as if it had never taken effect. See section 8j of this Departmental Regulation.

f Effective Date of Major Rules

SBREFA's Congressional review provisions contain specific procedures for rules which are determined to be major and may delay the effective date of such rules. Generally, major rules will not take effect before Congress has had at least 60 days to review them.

- (1) A major rule shall take effect on the LATEST of three possible dates:
- (a) the later of the date occurring 60 "session" days after the date on which--
 - 1 the Congress receives the report submitted by the Comptroller General; or
 - 2 the rule is published in the FEDERAL REGISTER, if so published;
 - (b) if Congress passes a joint resolution of disapproval of the rule, and the President vetoes that resolution, the effective date of the rule would be the earlier of the date--
 - 1 on which either House of Congress votes and fails to override the veto of the President; or
 - 2 occurring 30 session days after the date on which the Congress receives the veto and objections of the President;
 - (c) the date the rule would have otherwise taken effect, if not for the Congressional review requirement (unless a joint resolution of disapproval is enacted).

- (2) The effective date of a major rule, however, can not be delayed beyond the date on which either House of Congress votes to reject a joint resolution of disapproval.

g Exceptions to the delay of effect of major rules.

Any rule--

- (1) that establishes, modifies, opens, closes, or conducts a regulatory program for a commercial, recreational, or subsistence activity related to hunting, fishing, or camping; or
- (2) for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public comment procedures are impracticable, unnecessary, or contrary to the public interest--

shall take effect on the date the agency promulgating the rule determines.

h In addition to the exceptions stated above, a rule that would have its effectiveness delayed because of the Congressional review requirements may take effect sooner if the President determines by Executive Order, and submits written notice of such determination to Congress, that the rule should take effect because it is:

- (1) necessary due to an imminent threat to health or safety or other emergency;
- (2) necessary for the enforcement of criminal laws;
- (3) necessary for national security; or
- (4) issued pursuant to any statute implementing an international trade agreement.

Note: A rule which takes effect in this manner is subject to Congressional disapproval in the same way as any other rule.

i Any major rule which the agency determines comes within one of the exceptions stated in sections 8g or 8h of this Departmental Regulation may take effect on the date determined by the agency; provided, however, that the agency complies with the requirements to submit for review the rule and other required information.

- j A rule that does not take effect (or does not continue) because of a joint resolution may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution.
- k See Appendix I for additional information regarding the Congressional review requirements and the Congressional disapproval procedures in SBREFA.

9 OMB CLASSIFICATION AND CLEARANCE REQUIREMENTS

As required in the Executive Order 12866, regulatory actions subject to this Departmental Regulation must be submitted to OMB for review, classification, and/or clearance (where appropriate) prior to publication in the FEDERAL REGISTER. The procedures for submission of regulatory actions to OMB follows:

- a Documents Required for Rulemaking Classification by OMB. As required in section 5a(2) of this Departmental Regulation, on a periodic basis the agency shall submit to OMB through OBPA, a summary via the workplan of its planned regulatory actions which are expected to be promulgated within a 60 to 90 day timeframe. Each summary (see Figure 1) must include complete, understandable descriptions of the regulatory action so that an informed classification decision can be made by OMB. Summaries must be provided to OMB for classification at EACH stage of development of the regulatory action, i.e., advance notice of proposed rulemaking, notice of proposed rulemaking, interim final rule, and final rule. See section 6 of the OMB guidance on implementing Executive Order 12866.
- b Documents Required for Regulations Clearing OMB. OMB requires the submission of regulatory actions in triplicate (original and two copies) with each copy accompanied by a completed Executive Order 12866 Submission (see Figure 2). The Executive Order 12866 Submission must be signed by the "Program Official" for the agency (the agency head or his or her designee) and the "Authorized Regulatory Contact" (normally the responsible division director or regulatory management official of the agency). OBPA is responsible for transmitting these documents to OMB.

In addition, the agency must provide two copies of each regulatory action, the Executive Order 12866 Submission, and a copy of the completed clearance sheet (see Figure 4) to OBPA.

- c OMB Classification and Clearance Timetable: In accordance with Executive Order 12866 OMB has:
- (1) 10 WORKING days in which to classify the level of significance for a regulatory action. Requests for expedited classification will be permitted for regulatory actions which must be published in the FEDERAL REGISTER immediately. A justification must accompany each request for an expedited classification;
 - (2) 10 WORKING days to review notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a notice of proposed rulemaking; and
 - (3) 90 CALENDAR days to review all other regulatory actions, unless OIRA has previously reviewed the action and there has been no material change in the facts and circumstances upon which the regulatory action is based. In such cases, the OIRA review time is limited to 45 CALENDAR days. The 45-day time limit will apply for the most part to only final regulations that have been reviewed in the notice of proposed rulemaking or interim final rule stage.

The review process may be extended by the Director of OMB by no more than 30 days. Such extension must be provided to the Department's Regulatory Policy Officer in writing. In addition, the review process may be extended at the request of the Secretary.

- d Notification of OMB Classification and Clearance. OBPA acts as liaison with OMB and will advise agencies of OMB classification and clearance of regulatory actions. When OBPA receives information from OMB the agencies will be promptly notified.

10 SMALL ENTITY CONSIDERATIONS

- a COMPLIANCE GUIDES PROVIDED TO SMALL ENTITIES. Subtitle A of the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121) (SBREFA) requires that:
- (1) for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under 5 U.S.C. 604, the agency must publish one or more guides, entitled "small entity compliance guides." These guides shall explain in plain language likely to be understood by affected small entities the actions a small entity is required to take to comply with a rule or group of rules. Agencies may prepare separate guides for groups of similarly affected small entities.

Where appropriate, and if resources are available, agencies are authorized to develop guides that integrate both State and Federal regulations;

- (2) agencies shall make available to small entities compliance guides and other information relating to statutes and regulations which effect small entities; and
- (3) the content of the small entity compliance guides may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages in any civil or administrative action against a small entity.

b **INFORMAL SMALL ENTITY GUIDANCE.** Subtitle A of SBREFA also requires:

- (1) whenever appropriate, that agencies have programs to answer inquiries by small entities concerning compliance with statutes and regulations within their jurisdiction. It shall be the practice of USDA agencies, when appropriate, to answer questions regarding the interpretation and application of the law to specific sets of facts supplied by a small entity;
- (2) each USDA agency regulating small entities shall establish and maintain a program for responding to inquiries from small entities; and
- (3) in any civil or administrative action against a small entity, guidance given by an agency applying the law to facts provided by the small entity may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against such small entity.

c **CIVIL PENALTY PROVISIONS FOR SMALL ENTITIES.** Subtitle B of SBREFA requires agencies to establish programs or policies that provide for reductions or, where appropriate, waivers of civil penalties for violations of statutory or regulatory requirements by small entities. As part of its program or policy, an agency may consider a small entity's ability to pay in imposing a penalty.

- (1) USDA policy on civil penalty provisions for small businesses, as set forth in the Secretary's Memorandum 3031-1 (October 12, 1995), is consistent with SBREFA. The Secretary's Memorandum describes the circumstances under which an agency may waive all or a portion of a penalty which would otherwise be imposed on a small business. The USDA policy is to be applied to all small entities covered by SBREFA, including small businesses.

- (2) The Secretary's Memorandum 3031-1 and the President's April 21, 1995, Memorandum which it implements are contained in Appendixes D to D-2 of this Departmental Regulation.

11 REVIEW OF EXISTING REGULATIONS

Objectives. The objectives of the review of existing regulations, as stated in Executive Order 12866, are to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and industries; to determine whether regulations promulgated by the USDA have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with current regulatory priorities and principles set forth in Executive Order 12866, within applicable law; and to otherwise improve the effectiveness of existing regulations.

To achieve the above objectives, existing regulations are to be reviewed on an ongoing basis.

Under and Assistant Secretaries are responsible for assuring that reviews are accomplished.

The following requirements must be met:

- a Regulatory Review Plans. Agencies will maintain regulatory review plans which establish priorities for review of existing regulations. Generally, significant, economically significant, and major regulations should be given the highest level of priority in any review plan. The regulatory review plans will provide for the review of existing regulations every 5 years. Regulatory review plans and changes or amendments to the plans must be approved by the appropriate Under or Assistant Secretary.
- b Criteria for Review. Agencies will review regulations according to the following factors as well as such other factors as they believe are appropriate:
 - (1) The continued need for the regulation;
 - (2) The nature of comments or petitions received concerning the regulation from the public;
 - (3) The complexity of the regulation;

- (4) The extent to which the regulation overlaps, duplicates, or conflicts with other federal regulations, and, to the extent feasible, with State and local government regulations;
 - (5) The length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the areas affected by the regulation; and
 - (6) The extent to which there is opportunity to reduce governmental or nongovernmental burdens while still achieving statutory objectives and requirements.
- c. Conclusion of Review. The agency head will determine, on the basis of the review, whether regulations should be continued without change, revised, or rescinded. A rulemaking file shall be created for each review so that records can be maintained on the reviews and determinations.

If regulations are found to need revision or rescission, the agency should initiate rulemaking actions, which are subject to the requirements of this Departmental Regulation, including preparation of regulatory impact analyses required for significant, economically significant, and major regulations. (See section 6 of this Departmental Regulation.)

12 USDA SEMI-ANNUAL UNIFIED REGULATORY AGENDA AND ANNUAL REGULATORY PLAN

The USDA SEMI-ANNUAL UNIFIED REGULATORY AGENDA is mandated by Executive Order 12866 and the Regulatory Flexibility Act. These mandates require Federal agencies, in April and October of each year, to submit to OMB for review and publication in the FEDERAL REGISTER a regulatory agenda, listing all rulemaking actions that the agency expects to conduct or review during the 12-month period covered by the agenda. This agenda includes, at a minimum, any plans to publish or otherwise implement an advance notice of proposed rulemaking, notice of proposed rulemaking, or a final rule, or any plans to conduct a review pursuant to 5 U.S.C. 610 or section 4 of Executive Order 12866. Agencies may incorporate the information required under 5 U.S.C. 602 into these agendas. The USDA REGULATORY PLAN is mandated by section 4(c) of Executive Order 12866. Executive Order 12866 requires Federal agencies, once each year, to prepare and submit to OMB for review and publication, a Regulatory Plan of the most significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Regulatory Plan, which will be published as a separate section (but part) of the fall Unified Regulatory Agenda, will provide in-depth descriptions of the most important significant regulatory actions the agency proposes to pursue during the year to which it pertains.

OBPA will oversee and coordinate both the Semi-Annual Unified Regulatory Agenda and the annual Regulatory Plan for submission to OMB. (Instructions for the completion of the Agenda and the Plan are provided by OMB via the semi-annual call memorandum.) OMB will arrange for publication in the FEDERAL REGISTER. When these documents are published, OBPA will distribute copies of the documents to the Chief Counsel for Advocacy of the Small Business Administration, and to small entities or their representatives or publications likely to be obtained by small entities as required by 5 U.S.C. 602.

UNITED STATES DEPARTMENT OF AGRICULTURE
Regulatory Review Workplan

Workplan _____
OMB Review _____

(Agency Name)

Date: _____

DESIGNATION OF SIGNIFICANCE: (Under/Asst. Secy.)

Special Handling Requirements

- ___ NON-SIGNIFICANT
- ___ NON-SIGNIFICANT (Policy Oversight)
- ___ SIGNIFICANT
- ___ ECONOMICALLY SIGNIFICANT
- ___ MAJOR - (Public Law 103-354) - ORACBA
- ___ MAJOR - (Public Law 104-121) - SBREFA

Cleared OMB:
Designation: _____ Date: _____

Signature: (Under/Asst. Secy)

Date

RIN #

Work Plan # - Date: _____

Descriptive Title

Description of Proposed Action: (Need for Government Action, Objectives, Alternatives, Expected Results): (Attach additional sheet if necessary)

Schedule: (Enter dates)

Pre-Notice: _____ Proposal: _____ Hearings/Meetings: _____ Final: _____

Direct Final: _____ Other: _____

Additional Instructions from Under or Assistant Secretary:
(for use at the discretion of policy official)

Required Analysis: (check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Cost/Benefit Analysis | <input type="checkbox"/> Regulatory Flexibility Analysis |
| <input type="checkbox"/> Assessment of Alternatives | <input type="checkbox"/> Civil Rights Impact Analysis |
| <input type="checkbox"/> Family Impact Analysis | <input type="checkbox"/> Federalism Assessment |
| <input type="checkbox"/> Risk Assessment | <input type="checkbox"/> Property Rights Assessment |
| <input type="checkbox"/> Unfunded Mandate Analysis
and Consultation | |

Agency Contact: (Name, mailing address, phone)

Agency Head Approval:

Signature: _____ **Date:** _____

Comment:

WORKPLAN - INSTRUCTIONS

WORKPLAN FORMAT: The revised form is intended to take advantage of the computer assisted information handling capabilities available to most agencies. Agencies are requested to develop an "on-screen" format for the preparation of the workplans. The format must reasonably conform with the sample provided in order to assure uniformity and consistency of information; and also serve as an important aid in the review process.

PURPOSE OF THE WORKPLAN: The Workplan, when properly completed, provides the agency head, subcabinet official, and other reviewing parties a succinct statement of an contemplated regulatory action. The Workplan is designed to serve five purposes:

- 1 Summarizes the objectives, possible alternatives, ways to accomplish the objectives, and probable effects of each alternative so that policy officials will have a clear understanding of the contemplated regulatory action early in the development process;
- 2 Provides information useful for the designation of the significance of the regulatory action determining if the action is major and designation of the appropriate level of oversight;
- 3 Provides initial identification of regulatory actions which will be included in the Regulatory Agenda and/or Regulatory Plan;
- 4 Provides a description of the contemplated regulatory action (side 1 of the Workplan form) that is sufficient for purposes of the OMB classification review; and
- 5 In the aggregate (both sides of the Workplan form) provides the information necessary for initiation of an entry into USDA's regulatory tracking system.

WHEN TO COMPLETE A WORKPLAN: The Workplan is normally the action that initiates the rulemaking process. The Workplan must be completed sufficiently early in the regulatory development process to permit the Under or Assistant Secretary to provide direction to the development process or, on occasion, terminate the process before substantial resources have been expended. Submission of the Workplan should PRECEDE any drafting of the regulatory action and/or any analysis.

Most of the blocks on the Workplan form are self-explanatory. However, a few extra words of instruction may help identify the information which should be included on the Workplan form.

DESIGNATION OF SIGNIFICANCE: This block is for use by the cognizant Under or Assistant Secretary. The agency may want to make a classification recommendation in the "Description" block. Note that a significance designation of major has been added to accommodate the analysis requirements found in section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354) and to accommodate the requirements of the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121). The definitions of terms found in the designation of significance block can be found in section 3 of this Departmental Regulation.

SPECIAL HANDLING REQUIREMENTS: Indicate any special action that may be necessary as a result of particular sensitivities or time constraints (such as statutory or judicial publication deadline) associated with the regulatory action.

DESCRIPTION OF PROPOSED ACTION: Summarize objectives, i.e., what the regulatory action is intended to achieve and why Government action is necessary to achieve the objectives. Where possible, regulatory alternatives should be examined and the likely economic, budget, and other effects noted. Special effort should be made to identify innovative techniques and flexible alternatives designed to achieve the objectives at a minimum cost and risk. Reasonable alternatives outside the Government's current statutory authority should be included so that possible legislative alternatives can be considered in the overall review context.

ADDITIONAL INSTRUCTIONS: For use by the appropriate Under or Assistant Secretary to provide any additional guidance as necessary. Agency heads will ordinarily clear not significant regulatory actions for publication in the FEDERAL REGISTER. If the reviewing Under or Assistant Secretary has a continuing interest in further reviewing the regulatory action before OMB review or publication, the Under or Assistant Secretary should so indicate in this space on the form.

EXECUTIVE ORDER 12866 SUBMISSION

Important

Please read the instructions on the reverse side before completing this form.

For additional forms or assistance in completing this form, contact the OIRA Docket Library, [202] 395-6880, or your OIRA Desk Officer.

Send three copies of this form and supporting material to:

Office of Information and Regulatory Affairs
 Office of Management and Budget
 Attention: Docket Library, Room 3201
 725 17th Street N.W.
 Washington, DC 20503

1. Agency/Subagency originating request	2. Regulation Identifier Number (RIN)
3. Title	
4. Stage of Development <input type="checkbox"/> Prerule <input type="checkbox"/> Proposed Rule <input type="checkbox"/> Interim Final Rule <input type="checkbox"/> Final Rule <input type="checkbox"/> Final Rule – No material change <input type="checkbox"/> Notice <input type="checkbox"/> Other _____ Description of Other	5. Legal Deadline for this submission a) <input type="checkbox"/> Yes <input type="checkbox"/> No b) Date ____/____/____ DD MM YY c) <input type="checkbox"/> Statutory <input type="checkbox"/> Judicial
6. Economically Significant	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
7. Agency Contact (person who can best answer questions regarding the content of this submission)	
Phone ()	

Certification for Executive Order 12866 Submissions	
The authorized regulatory contact and the program official certify that the agency has complied with the requirements of E.O. 12866 and any applicable policy directives.	
Signature of Program Official	Date
Signature of Authorized Regulatory Contact	Date

INSTRUCTIONS FOR REQUESTING OMB REVIEW UNDER EXECUTIVE ORDER 12866

GENERAL

Please make sure to answer all questions and have the appropriate officials sign the form.

1. Agency/Subagency

Provide the name of the agency or subagency originating the request. For most Cabinet-level agencies, a subagency designation is also necessary. For non-Cabinet agencies, the subagency designation is generally unnecessary.

EXAMPLE

1. Agency/Subagency originating request

Department of the Interior
National Park Service
or
Office of Personnel Management

2. Regulation Identifier Number (RIN)

The RIN is the means by which rules are linked across the Unified Agenda of Federal Regulations (Agenda), the Regulatory Plan, and Executive Order 12866.

RINs are assigned to items in the Agenda by the Regulatory Information Service Center (Center). For E.O. 12866 submissions that have not appeared in the Agenda, the agency must obtain a RIN from the Center. The RIN is a prerequisite to the regulatory action being logged in at OIRA.

EXAMPLE

2. Regulation Identifier Number (RIN)

1024-AA12

3. Title

Please provide a brief title that describes, as specifically as you can, the subject of this rulemaking. Avoid using general headings or the title of the CFR part for your rulemaking. To the extent possible, you should keep the title the same as in the Agenda. Also, you should use the same title for all stages of a rulemaking.

4. Stage of Development

Check the stage of development for this action.

Check "Prerule" when the action submitted for review seeks to determine whether or how to initiate rulemaking. Examples include ANPRMs and reviews of existing regulations.

Check "Proposed Rule" when the action submitted will be published in the Proposed Rules section of the Federal Register (for example, an NPRM).

Check "Interim Final Rule" when the action submitted will be published in the Rules and Regulations section of the Federal Register with an Action caption of Interim Rule or Interim Final Rule.

Check "Final Rule" when the action submitted will be published in the Rules and Regulations section of the Federal Register and there have been material changes in the facts and circumstances upon which the previous action was based.

Check "Final Rule - No material change" when the action submitted is associated with a previous request (for example, an NPRM) and there has been no material change in the facts and circumstances upon which the previous action was based.

Check "Notice" when the action submitted will be published in the Notices section of the Federal Register.

Check "Other" when the action does not meet the criteria of any of the above categories. (Indicate on the line provided what type of action you are submitting; for example, a policy statement.)

5. Legal Deadline for This Submission

The deadline is for the regulatory action in this submission only and not for any future or past action in this rulemaking proceeding.

a) Indicate whether the action submitted is subject to any specific legal deadline. For example, if this submission is for an NPRM and the Final Rule stage has a deadline, check No. If this submission is for the Final Rule, check Yes.

b) If 5a is Yes, provide the month, day, and year of the deadline for this action (whether past or future).

c) If 5a is Yes, indicate whether the deadline is statutory or judicial.

6. Economically Significant

Check Yes if the action submitted will likely have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health and safety, or State, local, or tribal governments or communities. (Section 3 (f)(1) of E.O. 12866.)

7. Agency Contact

Provide the name and telephone number of the agency person best able to answer questions regarding the content of this submission.

FIGURE 3**DISPLAY OF OMB CONTROL NUMBER FOR REGULATIONS
CONTAINING INFORMATION COLLECTION REQUIREMENTS**

(The OMB control number is assigned by OMB and identifies specific collections of information that is contained in or required by a regulation that an agency is permitted to collect from the public.)

EXAMPLE 1

The OMB Control Number May Be Placed Parenthetically At The End Of The Appropriate Section As Shown Below.

Section 264.51 Purpose and implementation of contingency plan.

- (a) Each owner or operator must have a contingency plan for his facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil or surface water.
- (b) The provisions of the plan must be carried out immediately whenever there is a fire, explosion or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment. (Approved by the Office of Management and Budget under control number 2050-0011.)

OR

EXAMPLE 2

The OMB Control Number May Be Displayed In the Regulatory Text Of A Section Devoted to OMB Control Numbers As Shown Below.

Section 1942.500 OMB Control Number

The information collection requirements in this regulation have been approved by the Office of Management and Budget and assigned OMB control number 0575-0132.

FIGURE 4

CLEARANCE PAGE USED FOR SIGNIFICANT, ECONOMICALLY SIGNIFICANT AND MAJOR RULES AND COST/BENEFIT ASSESSMENTS

	_____		_____	(clears both the regulation and applicable analyses)
(Name), AGENCY HEAD (Name agency)	Date			

	_____		_____	(clears regulation only)
(Name) FOR THE OFFICE OF THE GENERAL COUNSEL	Date			

	_____		_____	(clears both the regulation and applicable analyses)
(Name), DIRECTOR OFFICE OF BUDGET AND PROGRAM ANALYSIS	Date			

	_____		_____	(clears analysis only)
(Name), CHIEF ECONOMIST	Date			

	_____		_____	(clears regulation only)
(Name), CHIEF INFORMATION OFFICER	Date			

	_____		_____	(clears regulation and any analysis for civil rights impacts)
(Name), ASSISTANT SECRETARY FOR ADMINISTRATION	Date			

	_____		_____	(clears both the regulation and applicable analyses)
(Name) UNDER OR ASSISTANT SECRETARY	Date			

Note 1: Prepare one signature sheet for rule review and approval and for review and approval of the analysis. List only those signature blocks on the clearance page that are necessary for the particular rulemaking package. The parenthetical material, and notes on this page should not appear on actual clearance page.

Note 2: Show a separate signature line for each Under or Assistant Secretary that must clear each document.

Congressional Review Rulemaking Report
(P.L. 104-121)

USDA Agency _____

Rule Title _____

Submission Date: _____ Major: Y/N Workplan Number: _____

Proposed Effective Date: _____ RIN Number: _____

General Statement/Summary * : (For major regulations include who will be affected and impact on economic growth) _____

The attached final rule includes the indicated materials (as applicable) See also P.L. 104-121, Title II, Subtitle E, Section 251, "Congressional Review."

- Copy of Rule
- Cost Benefit Analysis
- Unfunded Mandates Analysis
- Regulatory Flexibility Analysis
- Risk Assessment
- Assessment of Alternatives
- Family Impact Analysis
- Civil Rights Impact Analysis
- Federalism Assessment
- Property Rights Assessment

Other Consideration For Reviewers: _____

For Additional Information or Questions Contact:

Name: _____ Phone: _____ Fax: _____

* If necessary, attach an additional sheet.

70 52 30

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW Washington, DC 20503

<p>1. Agency/Subagency originating request</p>	<p>2. OMB control number b. <input type="checkbox"/> None a. _____ - _____</p>
<p>3. Type of information collection (check one)</p> <p>a. <input type="checkbox"/> New collection</p> <p>b. <input type="checkbox"/> Revision of a currently approved collection</p> <p>c. <input type="checkbox"/> Extension of a currently approved collection</p> <p>d. <input type="checkbox"/> Reinstatement, without change, of a previously approved collection for which approval has expired</p> <p>e. <input type="checkbox"/> Reinstatement, with change, of a previously approved collection for which approval has expired</p> <p>f. <input type="checkbox"/> Existing collection in use without an OMB control number</p> <p><i>For b-f, note Item A2 of Supporting Statement instructions</i></p>	<p>4. Type of review requested (check one)</p> <p>a. <input type="checkbox"/> Regular submission</p> <p>b. <input type="checkbox"/> Emergency - Approval requested by: ____ / ____ / ____</p> <p>c. <input type="checkbox"/> Delegated</p> <p>5. Small entities Will this information collection have a significant economic impact on a substantial number of small entities? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>6. Requested expiration date a. <input type="checkbox"/> Three years from approval date b. <input type="checkbox"/> Other Specify: ____ / ____</p>
<p>7. Title</p>	
<p>8. Agency form number(s) (If applicable)</p>	
<p>9. Keywords</p>	
<p>10. Abstract</p>	
<p>11. Affected public (Mark primary with "P" and all others that apply with "X")</p> <p>a. <input type="checkbox"/> Individuals or households d. <input type="checkbox"/> Farms</p> <p>b. <input type="checkbox"/> Business or other for-profit e. <input type="checkbox"/> Federal Government</p> <p>c. <input type="checkbox"/> Not-for-profit institutions f. <input type="checkbox"/> State, Local or Tribal Government</p>	<p>12. Obligation to respond (Mark primary with "P" and all others that apply with "X")</p> <p>a. <input type="checkbox"/> Voluntary</p> <p>b. <input type="checkbox"/> Required to obtain or retain benefits</p> <p>c. <input type="checkbox"/> Mandatory</p>
<p>13. Annual reporting and recordkeeping hour burden</p> <p>a. Number of respondents _____</p> <p>b. Total annual responses _____</p> <p> 1. Percentage of these responses collected electronically _____ %</p> <p>c. Total annual hours requested _____</p> <p>d. Current OMB inventory _____</p> <p>e. Difference _____</p> <p>f. Explanation of difference</p> <p> 1. Program change _____</p> <p> 2. Adjustment _____</p>	<p>14. Annual reporting and recordkeeping cost burden (in thousands of dollars)</p> <p>a. Total annualized capital/startup costs _____</p> <p>b. Total annual costs (O&M) _____</p> <p>c. Total annualized cost requested _____</p> <p>d. Current OMB inventory _____</p> <p>e. Difference _____</p> <p>f. Explanation of difference</p> <p> 1. Program change _____</p> <p> 2. Adjustment _____</p>
<p>15. Purpose of information collection (Mark primary with "P" and all others that apply with "X")</p> <p>a. <input type="checkbox"/> Application for benefits e. <input type="checkbox"/> Program planning or management</p> <p>b. <input type="checkbox"/> Program evaluation f. <input type="checkbox"/> Research</p> <p>c. <input type="checkbox"/> General purpose statistics g. <input type="checkbox"/> Regulatory or compliance</p> <p>d. <input type="checkbox"/> Audit</p>	<p>16. Frequency of recordkeeping or reporting (check all that apply)</p> <p>a. <input type="checkbox"/> Recordkeeping b. <input type="checkbox"/> Third party disclosure</p> <p>c. <input type="checkbox"/> Reporting</p> <p> 1. <input type="checkbox"/> On occasion 2. <input type="checkbox"/> Weekly 3. <input type="checkbox"/> Monthly</p> <p> 4. <input type="checkbox"/> Quarterly 5. <input type="checkbox"/> Semi-annually 6. <input type="checkbox"/> Annually</p> <p> 7. <input type="checkbox"/> Biennially 8. <input type="checkbox"/> Other (describe) _____</p>
<p>17. Statistical methods</p> <p>Does this information collection employ statistical methods?</p> <p style="text-align: center;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>18. Agency contact (person who can best answer questions regarding the content of this submission)</p> <p>Name: _____</p> <p>Phone: _____</p>

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8 (b) (3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;
- (e) Its implementation will be consistent and comparable with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b) (3):
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);
- (i) It uses effective and efficient statistical survey methodology; and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Deputy Administrator	Date
Signature of Senior Official or designee	Date

73 58 53

APPENDIX A

Outline for Preamble and Text for Notices and Regulatory Actions

This outline is provided to serve as a checklist to be used in the preparation of rulemaking documents for publication in the FEDERAL REGISTER. Not all items are necessary or appropriate for all types of regulations. Refer to the FEDERAL REGISTER DOCUMENT DRAFTING HANDBOOK for specific requirements concerning document preparation for publication in the FEDERAL REGISTER.

HEADINGS

- Billing Code
- Agency Name
- CFR Title and Parts
- RIN Number
- Descriptive Title

PREAMBLE REQUIREMENTS

AGENCY: Agency or staff office of USDA.

ACTION: Indicate the type of action such as Notice of Proposed Rulemaking; Final Rule; Prenotice; or Advance Notice of Proposed Rulemaking.

SUMMARY: Summarize the action (required by 1 CFR 18.12) by briefly describing:

The action being taken.

The circumstances creating the need for the action.

The intended effects of the action.

DATES: State all relevant dates including any of the following:

Comment deadlines. (Period should be not less than 60 days for notices of proposed rulemaking unless an emergency or other reason warrants a shorter period.)

Dates and times of hearings or meetings and their locations.

Coordinate this with the information in "Addresses," below.

Effective date for interim final rules and final rules.

25 307-1 666

- ADDRESSES:** Identify all necessary addresses.
- Name(s) and address(es) to which comments should be sent.
- Addresses of hearings and of individuals to contact for examining any material available to the public, to place items on an agenda and to reserve space.
- FOR FURTHER INFORMATION:** Identify the name and telephone number of knowledgeable agency official who the public can contact for further information.
- Indicate the availability of any analytical statements relating to the action.
- SUPPLEMENTARY INFORMATION:** Assure that (1) legal statements required for this action are made and (2) readers who are not expert in the subject area will understand the action.
- State the OMB classification for the rule. If the rule is classified as economically significant or significant, include the following language in the preamble, where appropriate: THIS RULE HAS BEEN DETERMINED TO BE SIGNIFICANT OR ECONOMICALLY SIGNIFICANT AND WAS REVIEWED BY THE OFFICE OF MANAGEMENT AND BUDGET UNDER EXECUTIVE ORDER 12866. If the rule is classified as not significant, include the following language in the preamble, where appropriate: THIS RULE HAS BEEN DETERMINED TO BE NOT SIGNIFICANT FOR PURPOSES OF EXECUTIVE ORDER 12866 AND THEREFORE HAS NOT BEEN REVIEWED BY THE OFFICE OF MANAGEMENT AND BUDGET.
- Some agencies have classes of rulemakings that are exempt from the provisions of Executive Order 12866. Such exemptions are granted by petitioning OMB. If a rule is being published that falls within an OMB exemption class, include the following language in the preamble, where appropriate: THIS RULE HAS BEEN DETERMINED TO BE EXEMPT FOR THE PURPOSES OF EXECUTIVE ORDER 12866, AND THEREFORE HAS NOT BEEN REVIEWED BY THE OFFICE OF MANAGEMENT AND BUDGET.

If the regulatory action is economically significant or significant, briefly summarize the preliminary or final Cost-Benefit Assessment including risk assessment if the regulatory action is major as defined by section 3(c)(4) of this Departmental Regulation.

Certify the inapplicability of the Regulatory Flexibility Analysis requirement or indicate that it applies and whether an analysis has been conducted.

Indicate what other analytical requirements are applicable, if any.

If the rule is major as defined by section 3(c)(4) of this Departmental Regulation, include the following language in the preamble where appropriate: "THIS RULE HAS BEEN DETERMINED TO BE MAJOR AS PROVIDED BY P.L. 103-354, AND THE ANALYSES HAVE BEEN REVIEWED AND APPROVED THE DIRECTOR OF THE OFFICE OF RISK ASSESSMENT AND COST BENEFIT ANALYSIS."

Indicate the official program number and title listed in the catalogue of Federal Domestic Assistance and the and the applicability of Executive Order 12372 which requires intergovernmental consultation.

If an action is being issued as an emergency without prior comment or without any comment period, explain the reasons.

If the action is an emergency, explain the basis for that determination and, if the emergency is such that compliance with Executive Order 12866 is not practicable, the reasons why it is not practicable. Explain the need for governmental action and the USDA's objectives or alternative objectives with respect to the problem.

Summarize the major alternative actions considered, their technical and financial feasibility, and their expected direct and indirect economic, public health and safety, environmental, and social effects. Identify the favored or final alternative, and reasons.

Discuss the highlights of the action, clarify complexities, and draw the public's attention to new provisions, as appropriate.

Indicate any information collection requirements contained in the action as required by the Paperwork Reduction Act of 1995.

For final regulations, summarize comments received, if any, and USDA's response.

List of Subjects in Part _____ (CFR Index Terms)

Words of Issuance (required for all rulemaking documents)

Text of Regulations or Action

Definitions:

Amendatory Language

Table of Contents (if necessary)

Authority Citation

Text

Identify in the text of the regulations the OMB control number for each information collection requirement mentioned. The number may be identified by placing it in parentheses at the end of the appropriate section of the regulatory text or display the number in the regulatory text of a section devoted to OMB control numbers. (See Figure 3.)

Signature--Note that all significant, major, and economically significant regulatory actions must be signed by an Under Secretary or Assistant Secretary or above.

APPENDIX B

Further Guidance On The Initiation Of A Rulemaking

1 PURPOSE.

This appendix is to reemphasize to USDA agencies the requirement that all decisions made to issue Departmental Regulations (nonregulation) are taken in full compliance with the Administrative Procedure Act. In particular, agencies must avoid the issuance of a Departmental Regulation when a rulemaking would have been the proper course of action. To assist in an agency decision regarding whether to write a Departmental Regulation or conduct a rulemaking proceeding in accordance with the Administrative Procedure Act, the following explanatory text is provided, most of which has been excerpted from an OGC working paper entitled, AN INFORMAL GUIDE TO RULEMAKING, July 15, 1994. The material presented below focuses on the definition of a rule. The full text of the informal guide may be obtained from the OGC Division that provides legal services to your agency. If an action under consideration meets the definitional conditions described below, then the matter must be developed in conformance with the USDA rulemaking procedures detailed in DR 1512-1.

Under the Administrative Procedure Act, a rulemaking is an agency action which regulates future conduct. Rulemaking is legislative in nature because it operates in the future, and because it is primarily concerned with policy considerations. The objective of a rulemaking proceeding is the implementation or prescription of law or policy for the future.

The Administrative Procedure Act categorizes rules as: (1) "rules of particular applicability" (rules which apply or will apply to only a single individual or entity); (2) "rules of general applicability" (rules which affect or will apply to industry or other members of the public in general); (3) "rules of practice or procedure" (rules which affect the way the agency conducts its business and which affect private parties only to the extent they do business with the agency); (4) "substantive rules" (rules which effect conduct, rights, and duties); (5) "interpretive rules" (rules which define the views of the agency regarding the meaning of its mandated functions, particularly the statutes it administers and the regulations which it has promulgated); (6) "general statements of policy" (agency statements which advise the public prospectively of the manner in which the agency proposes to exercise its discretionary power); and (7) "rules of agency organization" (rules which describe an agency's central and field organization, the places at which, the agency employees from whom, and the method whereby, the public may obtain information, make submittal or requests and obtain decisions). The Administrative Procedure Act rulemaking procedures are not applicable to rules that involve: (1) military or foreign affairs functions of the United States; or (2) a matter relating to agency

management or personnel or to public property, loans, grants, benefits, or contracts. However, as articulated in Secretary Hardin's memorandum of July 20, 1971, it is USDA's policy to apply the Administrative Procedure Act's informal rulemaking procedures to matters relating to public property, loans, grants, benefits, and contracts.

As contrasted with rules, Departmental Regulations are used to issue policies, procedures, and guidance which have general applicability to an agency, but are not binding on the industry or members of the general public. Most typically agency directives:

- * Establish program goals, objectives, and policies:
- * Delegate authority or assign responsibility;
- * Establish or change organizational structure;
- * Initiate or prescribe courses of action for the execution of missions and programs; and
- * Establish procedures, standards, guides, or methods of performing duties, functions or operations.

When consideration is being given to the choice between drafting a Departmental Regulation or a rule and there is any uncertainty regarding which approach is most appropriate to the matter at hand, the agency should consult with the OGC Division that provides legal services to the agency.

APPENDIX C

Guidelines for Preparing Risk Assessments and Preparing Cost-Benefit Analyses (Significant, Economically Significant, or Major Regulatory Actions)

To the extent possible, the ORACBA will ensure USDA agencies employ the principles identified in this Departmental Regulations for conducting risk assessments and other activities related to the analysis of risks. Within the rulemaking framework, risk analysis, regulatory impact analysis, and cost-benefit analysis are often closely linked. These analyses will be consolidated when necessary and beneficial to regulatory review, priority setting, and policy making.

The following format is recommended for the use of USDA agencies when preparing risk assessments and cost-benefit analysis. USDA agencies utilize different methods for cost-benefit analysis and risk assessment. USDA programs are directed to a multiplicity of hazards. Methods used in cost-benefit and risk assessment should reflect the diversity of the hazards.

- 1 TITLE
- 2 BACKGROUND
- 3 OVERVIEW

Provide brief overview of the problem and significant issues pertinent to rulemaking. For example, discuss whether the problem is a result of market failure, or other compelling action, and show how the regulatory action is to alleviate the condition. Discuss whether alternative measures can address the problem including the judicial system and regulation at the state or local level. State compelling arguments if the cause for regulatory action is not a result of market failure.

OBJECTIVES.

State the need for and objectives of the regulatory action. Describe performance measures, versus design standards, to be included in the regulatory action.

REGULATORY OR RISK MANAGEMENT OPTIONS.

Summarize the alternative approaches considered and evaluated, the risks associated with each alternative, and major uncertainties and unknowns associated with each alternative. The potential benefits and groups or entities affected should also be identified. Summarize the reasons for selecting the proposed alternative.

STATUTORY AUTHORITY.

Quote appropriate brief passages to show that the regulatory action is consistent with statute and with program objectives.

RISK ASSESSMENT.

A risk assessment is the identification of the hazard, an evaluation of the extent to which a group of people or resource has been exposed to the hazard, and a determination of the magnitude of harm to human health, human safety, and the environment. A risk assessment relies on methods which use reasonably obtainable and sound scientific, technical, economic, and other information regarding the nature and magnitude of risk to individuals, groups, or resources that are exposed. The information and analysis used in conducting the risk assessment is available to the public upon request.

HAZARD IDENTIFICATION.

Hazard identification is a consideration of whether exposure to a substance, activity, or event (e.g., a food borne pathogen, or a crop production practice on environmentally sensitive land) can cause potential harm or an adverse outcome. It is an identification of what might go wrong, why, and how.

The hazard identification should accurately identify and objectively analyze the available information and data regarding the hazard.

EXPOSURE ASSESSMENT.

An exposure assessment evaluates the extent to which an individual, group, or the environment is likely to be exposed to the particular hazard and the types of conditions under which it is likely to occur.

To the extent practicable, the assessment should identify the magnitude, frequency, duration, and route(s) of exposure.

RISK.

Risk is the likelihood and magnitude of the consequences should the hazard occur. It is defined by answering two questions: What is the probability that the hazard will occur? How serious are the consequences if the hazard does occur?

The likelihood of occurrence of an unwanted event may be described both quantitatively and/or qualitatively. Some estimate of the uncertainty associated with the estimate of likelihood is necessary. The description of risks can include a discussion of probabilities of an adverse occurrence and the magnitude of its consequences, uncertainties, conflicting data and opinions, and extrapolations.

The seriousness of the consequences should the hazard occur is often expressed in monetary terms. However, other methods of expressing the magnitude of the consequences may also be appropriate.

RISK CHARACTERIZATION.

A risk characterization includes, but is not limited to, the following information concerning risk:

- (1) Risk Substitution. New types of hazards may be introduced as the assessed risk is regulated.
- (2) Comparison of Risks. Place the nature and magnitude of the risks being analyzed in context, including appropriate comparisons with other risks that are regulated by the agency, as well as risks that are familiar to the general public.
- (3) Social and Differential Population Effects. Some hazards, the proposed mitigation of them, or changes in the regulations relating to policies and programs may have vastly different effects on various segments of the population. To the extent that there are definable social effects, it is appropriate to characterize the risks for both the full population at risk, and for highly exposed or sensitive subpopulations.

LEVEL OF UNCERTAINTY AND UNKNOWNNS.

- (1) Classify the information used in a risk assessment. A risk assessment should clearly identify and make distinctions among the data and information used in risk assessment. If the data is from a published paper, reference should be made to the source.

If the data or estimates are based on expert opinion, that should also be noted. Anecdotal information used as part of the risk assessment

should be identified as such.

- (2) Assumptions, default values, and judgements should be clearly identified. The rationale for assumptions and judgements, and their influence on the risk assessment, should be clearly explained.
- (3) Uncertainty must be specified for the risk estimates.
- (4) There should be a clear explanation of how data is evaluated in the risk assessment, including an explanation of the model used.

PEER REVIEW

A peer review of the risk assessment may be conducted to ensure that the highest professional standards are maintained.

COST-BENEFIT ANALYSIS

Analysis of the costs and benefits of regulatory alternatives should follow the guidelines and procedures identified in Departmental Regulation 1512-1, Executive Order 12866, and executive guidance for regulatory analysis.

ALTERNATIVE MEASURES.

For regulatory actions consisting of a series of related, but separable provisions, review the effects of key alternatives for each significant provision. The most important alternative approaches to a problem should be discussed and a manageable number subjected to cost-benefit analysis.

- (1) **Performance-Based Measures.** It is preferable to identify the desired objective level of performance, or tolerable (acceptable) levels of risk, and allow the regulated party to achieve the objective in a cost-effective manner. Design-based measures limit innovative approaches to meet objectives.
- (2) **Sensitivity of Measures.** Options should be provided to reflect different conditions among segments of the regulated group.

- (3) Levels of Stringency and Compliance. Measures considered may include different levels of stringency, methods for ensuring compliance, and dates for compliance. These should be examined to reduce regulatory burden. The description of measures should evaluate whether the measure can be better implemented at the State or local level and whether the measure interferes with State and local governments.

COSTS AND BENEFITS.

For each of the major risk management alternatives or regulatory options subject to similar review, calculate the following:

- (1) Net Social Welfare. The criterion for the choice of regulatory alternatives is the greatest gain in net social welfare. The calculation of benefits and costs includes economic, social, environmental, costs of compliance, regulatory burden, and risk valuation (below). Costs and benefits should be quantified to the extent possible but may include non-quantifiable consequences. Costs and benefits should be discounted in accordance with applicable law, regulations, and Executive Orders.
- (2) Risk Valuation. The results of the risk characterization are quantified in terms of the monetary consequences of the outcomes. Risk valuation should specifically quantify the avoidance of adverse outcomes that may be regarded as benefits. The analysis is encouraged to recognize a broad range of qualitative factors including social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distributions of benefits and costs. Risk valuations should be conducted in a manner consistent with the intent of a risk assessment and which contributes to cost-benefit analysis.
- (3) Probability Analysis. Regulations requiring risk assessments, those whose primary purpose is to regulate issues of human health, human safety, or the environment, can have unintended consequences because underlying conditions are subject to change. USDA agencies are encouraged to identify the likelihood of alternative conditions and the effect on the variability of expected net benefits. In most situations, it will be sufficient to calculate the expected value of the reduction in risk, the expected value of benefits, or a reasonable set of "high" and "low" values reflecting uncertainty in the estimates.

- (4) Other Significant Effects. Other factors to consider that may be nonquantifiable include distributional effects among geographic, social, and economic groups; market structures and systems; competition, terms of trade, productivity, and other concerns. Provide summary tables and identify data sources as appropriate.

RISK MANAGEMENT ALTERNATIVES

Risk management is USDA's decision making process whereby risk-related scientific, technical, and economic information is considered along with other factors--political, social, distributional impacts--to analyze and compare alternatives and select the regulatory response which best satisfies the objectives.

For each of the alternative approaches considered and evaluated, the analysis should summarize the social benefits and costs of each. Separately, it should summarize the risk assessment for each alternative, as well as major uncertainties and unknowns. The potential benefits and costs to specific groups or entities affected should also be identified. It should conclude by summarizing the reasons for selecting the proposed alternative.

EVALUATION BY THE SECRETARY OF AGRICULTURE

By law, the Secretary is required to evaluate whether the regulation advances the purpose of protecting against the identified risk, and produces benefits and reduces risks to human health, human safety, or the environment and any combination thereof in a cost effective manner as a result of the implementation of and compliance with the regulation, by local, State, and Federal governments, and other public and private entities as estimated.

PUBLIC COMMENT

Provide a summary and analysis of public comments received and of responses to comments. Describe procedures to encourage exchange of information about the analysis and especially the risk assessment, and to ensure that risk communication principles have been employed.

APPENDIX D

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

October 12, 1995

SECRETARY'S MEMORANDUM 3031-1

WAIVER OF PENALTIES FOR SMALL BUSINESS AND CUTTING FREQUENCY OF REPORTS

1 BACKGROUND

The Secretary administers a number of statutes that authorize the Secretary to impose penalties for violations of those statutes, of regulations issued under those statutes, and of contracts and agreements executed under those statutes. The Secretary administers a number of programs under which the public is required, by regulation or policy, to provide USDA with regularly scheduled reports. The President issued a memorandum on April 21, 1995, to the heads of executive branch agencies directing that each:

- a use his or her discretion to waive the imposition of all or a portion of penalties on small businesses;
- b cut by one-half the frequency with which regularly scheduled reports are required, by rule or policy, to be provided to the United States Government; and
- c submit a plan to the Director of the Office of Management and Budget describing the actions the agency will take to implement the penalty waiver policy and the reporting frequency policy described in the President's April 21, 1995, memorandum.

2 PURPOSE

- a This Memorandum implements the President's policy to waive penalties for small businesses and to reduce the frequency of reports required to be made by the public.

DISTRIBUTION: 30

OPI: OGC

- b Neither the President's policy to waive penalties for small businesses and to reduce the frequency of reports required to be made by the public nor this Memorandum applies to:
- (1) matters related to law enforcement, national security, or foreign affairs;
 - (2) the importation or exportation of prohibited or restricted items;
 - (3) United States Government taxes, duties, fees, revenues, or receipts; or
 - (4) USDA agencies whose principal purpose is the collection, analysis, and dissemination of statistical information.

3 DEFINITIONS

For the purposes of this Memorandum, the following terms shall have the meanings set forth in this paragraph.

- a Administering agency. The USDA agency that administers the statute, regulation, contract, or agreement under which penalties may be imposed.
- b Corrective action. Action taken by a small business to correct a violation or to achieve compliance.
- c Covered penalty. Any penalty that may be imposed for a violation of a statute, regulation, contract, or agreement for which:
- (1) the violator has made a good faith effort to comply with the statute, regulation, contract, or agreement that has been violated;
 - (2) the violation does not constitute a violation of criminal law;
 - (3) the violation did not result in a significant threat to health, safety, or the environment;
 - (4) the violation can be corrected or the violator can achieve compliance;

- (5) an adjudicatory action has not been instituted;
and
 - (6) the Secretary is permitted by law or has discretion under applicable statutes, regulations, contracts, or agreements to waive all or a portion of the penalty.
- d Good faith effort to comply with the statute, regulation, contract, or agreement that has been violated. Conduct that results in a violation of a statute, regulation, contract, or agreement, but circumstances surrounding the violation indicate that: (1) the violator did not know that the conduct constituted a violation and the violator did not intend to commit the violation; (2) the violator made every reasonable effort to comply with the statute, regulation, contract, or agreement; or (3) the violator knew that the conduct constituted a violation, but due to circumstances beyond the violator's control it was impossible for the violator to comply, and the violator brought the violation to the attention of appropriate USDA officials in an expeditious manner. (The term good faith effort to comply with the statute, regulation, contract, or agreement that has been violated does not include any circumstance in which: the violation was malicious; the violator had previously been found to have violated the same statute, regulation, contract, or agreement; or the violator had previously been informed that the conduct that resulted in the violation is prohibited by statute, regulation, contract, or agreement.)
- e Penalty. Any sanction that may be imposed directly by the Secretary. (The term penalty does not include: liquidated damages; any restitution for damages suffered by USDA; any action that either permanently or temporarily excludes a small business from entering into a transaction with USDA; or any sanction that may be imposed by a USDA grantee or subgrantee even if the sanction may be imposed as a result of conditions required by USDA for the grant.)
- f Penalty Modification Coordinator. The individual appointed by a USDA agency in accordance with paragraph 5 of this Memorandum.

- g Secretary. The Secretary of the United States Department of Agriculture or any individual to whom the Secretary delegates authority.
- h Significant threat to health, safety, or the environment. Any conduct that is likely to result in:
 - (a) death, injury, illness, or spread of diseases or pests to any human, animal, or plant; or
 - (b) material harm to the environment.
- i Small business. Any sole proprietorship, joint venture, partnership, corporation, association, or other legal entity that:
 - (a) employed 500 or fewer individuals at the time of the alleged violation; or
 - (b) in the tax year immediately preceding the alleged violation, had gross receipts of \$ 1,000,000 or less.
- j USDA. The United States Department of Agriculture.

4 WAIVER OF PENALTIES

- a If a penalty may be imposed on a small business by the Secretary, the administering agency shall determine whether the penalty is a covered penalty. If the administering agency determines the penalty to be a covered penalty, the administering agency shall:
 - (1) provide a copy of this Memorandum to the small business on which the penalty may be imposed; and
 - (2) notify the small business that the imposition of all or a portion of a penalty can be waived as agreed by the small business and the agency, if corrective action can be achieved within the time to be established in the sole discretion of the administering agency. The penalty shall be waived, in whole or in part, if the administering agency and the small business agree in writing as to the waiver of the penalty, the administering agency establishes the time

within which corrective action is to be taken, and the small business takes corrective action within the time established by the administering agency.

- b If the small business takes corrective action, but fails to do so within the time established in accordance with paragraph 4a(b) of this Memorandum by the administering agency, the administering agency may reduce the amount of any monetary penalty that may be imposed for the violation up to the amount spent by the small business for corrective action. When determining whether to reduce a monetary penalty in accordance with this subparagraph, the administering agency shall take into account the time in which the small business took corrective action and any difficulties the small business encountered when doing so.
- c Any administering agency that waives a penalty in accordance with paragraph 4a or 4b of this Memorandum shall issue a written statement to the small business stating that corrective action has been taken, that the imposition of all or a portion of the penalty has been waived, the manner in which the penalty has been waived, and the amount or type of any remaining penalty that may be imposed.
- d The use of appropriate alternative dispute resolution techniques to assist in the determination whether a penalty will be waived as authorized by this Memorandum is encouraged.
- e Each Under or Assistant Secretary shall submit a quarterly report, starting January 1, 1996, to the Secretary of Agriculture describing actions taken pursuant to this Memorandum. Each quarterly report must include each penalty that has been waived during the quarter, the manner in which each penalty has been waived, the corrective action taken by the small business, and the amount or type of any remaining penalty.

5 PENALTY MODIFICATION COORDINATOR

Each administering agency that administers any program under which the Secretary is permitted by law or has discretion to waive the imposition of a penalty shall appoint a Penalty Modification Coordinator who shall be responsible for the implementation of

paragraphs 4 and 6 of this Memorandum in the administering agency.

6 NOTIFICATION

- a Each Penalty Modification Coordinator shall provide to each employee of the administering agency who has authority to assess penalties or to recommend the assessment of penalties:
 - (1) a copy of this Memorandum; and
 - (2) the name, address, and telephone number of the Penalty Modification Coordinator, who shall be available to answer questions concerning the implementation of this Memorandum posed by agency employees.
- b Small businesses shall be notified of this Memorandum by publication of this Memorandum in the Federal Register.

7 REPORTING FREQUENCY

- a Except as provided in paragraph 7c of this Memorandum, each agency shall reduce by at least one-half the frequency with which regularly scheduled reports required, by regulation or policy in effect on April 21, 1995, must be provided to USDA.
- b Policy changes necessary to comply with paragraph 7a of this Memorandum shall be implemented no later than November 1, 1995. Regulatory changes necessary to comply with paragraph 7a of this Memorandum shall be effective no later than January 1, 1996.
- c The frequency with which regularly scheduled reports shall be provided to USDA shall not be reduced pursuant to paragraph 7a of this Memorandum if:
 - (1) the frequency with which the report is provided to USDA is required by statute;
 - (2) the report is required to be provided to USDA as a condition of continued employment with USDA, execution

of a contract with USDA, or receipt of a loan, grant, guarantee, or benefit from USDA; or

- (3) the Secretary of Agriculture determines that the reduction of the frequency with which the regularly scheduled report is provided to USDA - is not legally permissible; would not adequately protect health, safety, or the environment; would be inconsistent with achieving regulatory flexibility or reducing regulatory burdens; or would impede the effective administration of a USDA program.

8 EFFECTIVE DATE

This Memorandum shall be effective on October 10, 1995.

9 EFFECT ON OTHER AGENCY PENALTY WAIVER POLICIES

To the extent that any administering agency policy regarding the waiver of covered penalties is inconsistent with this Memorandum, the policy shall be revoked or modified to conform to this Memorandum no later than November 1, 1995. To the extent that any administering agency regulations regarding the waiver of covered penalties is inconsistent with this Memorandum, the regulations shall be revoked or modified to conform to this Memorandum no later than January 1, 1996. This Memorandum does not affect any administering agency policy to waive penalties that is not inconsistent with this Memorandum.

10 TERMINATION OR MODIFICATION

This Memorandum may be terminated or modified by the Secretary of Agriculture at any time.

11 JUDICIAL REVIEW

This Memorandum is intended only to improve the internal management of USDA and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, USDA, the officers or employees of the United States or USDA, or any other person. Neither this

March 14, 1997

Memorandum nor the waiver of any penalty in accordance with this Memorandum shall affect the date on which the imposition of a penalty shall be considered to be final agency action for the purposes of judicial review.



DAN GLICKMAN
SECRETARY

APPENDIX D-1

THE WHITE HOUSE

WASHINGTON

April 21, 1995

MEMORANDUM FOR THE SECRETARY OF STATE
 THE SECRETARY OF THE TREASURY
 THE SECRETARY OF DEFENSE
 THE ATTORNEY GENERAL
 THE SECRETARY OF THE INTERIOR
 THE SECRETARY OF AGRICULTURE
 THE SECRETARY OF COMMERCE
 THE SECRETARY OF LABOR
 THE SECRETARY OF HEALTH AND HUMAN SERVICES
 THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
 THE SECRETARY OF TRANSPORTATION
 THE SECRETARY OF ENERGY
 THE SECRETARY OF EDUCATION
 THE SECRETARY OF VETERANS AFFAIRS
 THE ADMINISTRATOR, ENVIRONMENTAL PROTECTION
 AGENCY
 THE ADMINISTRATOR, SMALL BUSINESS ADMINISTRATION
 THE SECRETARY OF THE ARMY
 THE SECRETARY OF THE NAVY
 THE SECRETARY OF THE AIR FORCE
 THE DIRECTOR, FEDERAL EMERGENCY MANAGEMENT AGENCY
 THE ADMINISTRATOR, NATIONAL AERONAUTICS AND SPACE
 ADMINISTRATION
 THE DIRECTOR, NATIONAL SCIENCE-FOUNDATION
 THE ACTING ARCHIVIST OF THE UNITED STATES
 THE ADMINISTRATOR OF GENERAL SERVICES
 THE CHAIR, RAILROAD RETIREMENT BOARD
 THE CHAIRPERSON, ARCHITECTURAL AND TRANSPORTATION
 BARRIERS COMPLIANCE BOARD
 THE EXECUTIVE DIRECTOR, PENSION BENEFIT GUARANTY
 CORPORATION

SUBJECT: Regulatory Reform - Waiver of Penalties and
 Reduction of Reports

On March 16, I announced that the Administration would implement new policies to give compliance officials more flexibility in dealing with small business and to cut back on paperwork. These Governmentwide policies, as well as the specific agency actions

4-21-95 10:00

I announced, are part of this Administration's continuing commitment to sensible regulatory reform. With your help and cooperation, we hope to move the Government toward a more flexible, effective, and user friendly approach to regulation.

A. Actions: This memorandum directs the designated department and agency heads to implement the policies set forth below.

1. Authority to Waive Penalties. (a) To the extent permitted by law, each agency shall use its discretion to modify the penalties for small businesses in the following situations. Agencies shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time period appropriate to the violation in question. For those violations that may take longer to correct than the period set by the agency, the agency shall use its enforcement discretion to waive up to 100 percent of the financial penalties if the amounts waived are used to bring the entity into compliance. The provisions in paragraph 1(a) of this memorandum shall apply only where there has been a good faith effort to comply with applicable regulations and the violation does not involve criminal wrongdoing or significant threat to health, safety, or the environment.

(b) Each agency shall, by June 15, 1995, submit a plan to the Director of the Office of Management and Budget ("Director") describing the actions it will take to implement the policies in paragraph 1(a) of this memorandum. The plan shall provide that the agency will implement the policies described in paragraph 1(a) of this memorandum on or before July 14, 1995. Plans should include information on how notification will be given to frontline workers and small-businesses.

2. Cutting Frequency of Reports. (a) Each agency shall reduce by one-half the frequency of the regularly scheduled reports that the public is required, by rule or by policy, to provide to the Government (from quarterly to semiannually, from semi-annually to annually, etc.), unless the department or agency head determines that such action is not legally permissible; would not adequately protect health, safety, or the environment; would be inconsistent with achieving regulatory flexibility or reducing regulatory burdens; or would impede the effective administration of the agency's program. The duty to make such determinations shall be nondelegable.

(b) Each agency shall, by June 15, 1995, submit a plan to the Director describing the actions it will take to implement the policies in paragraph 2(a), including a copy of any determination that certain reports are excluded.

B. Application and Scope: 1. The Director may issue further guidance as necessary to carry out the purposes of this memorandum.

2. This memorandum does not apply to matters related to law enforcement, national security, or foreign affairs, the importation or exportation of prohibited or restricted items, Government taxes, duties, fees, revenues, or receipts; nor does it apply to agencies (or components thereof) whose principal purpose is the collection, analysis, and dissemination of statistical information.

3. This memorandum is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees.

4. The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

APPENDIX D-2

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

MEMORANDUM

TO: Subcabinet Officials
Agency Administrators

FROM: Dan Glickman
Secretary *Dan Glickman* OCT 12 1995

SUBJECT: Secretary's Memorandum 3031: Waiver of Penalties for Small Business
and Cutting Frequency of Reports

In a Memorandum dated April 21, 1995 (Attachment 1), the President directed that new policies be implemented to give compliance officials more flexibility in dealing with small business and to cut back on paperwork. The latter requirement will be dealt with in the near future.

Under cover of this correspondence, I am issuing the subject Secretary's Memorandum (Attachment 2) to implement the requirements of the President's Directive. I ask your full and prompt cooperation with the Memorandum, which becomes effective on October 10, 1995. In particular, your attention is directed to three requirements:

1. Paragraph 4e. Waiver of Penalties, which establishes a quarterly reporting requirement;
2. Paragraph 5, which deals with the appointment of a Penalty Modification Coordinator; and
3. Paragraph 6, which deals with public notification of the policy established by this Memorandum. Arrangements will be made for Federal Register publication, but I want each agency to undertake outreach activities with their small business clients.

Regulatory reform continues to be a major priority of the President. The Department has made major contributions to this initiative, particularly through its participation in the recently concluded National Performance Review (NPR) project. Our work has been favorably commented on by the Vice President's Office and the Office of Management and Budget (OMB). I want to express my appreciation to each of you for the leadership you provided to that important undertaking. The tangible benefits of our effort can only be realized if we hold to the commitments made in our NPR report to the President. I urge each of you to continue the excellent work you have started by following up on the commitments resulting from the recent review of all Departmental regulations.

Attachments (2)

APPENDIX E DIRECT FINAL RULEMAKING

Agencies are encouraged to use innovative and/or streamlined approaches in the regulatory process whenever practicable. It is clear from considerable experience with OMB classification reviews that a significant majority of USDA regulatory actions are being classified not significant. This situation suggests that there may be a substantial body of rulemakings which are candidates for the Direct Final (DF) rulemaking process. Agencies which intend to use Direct Final rulemaking must publish a policy statement in the FEDERAL REGISTER before proceeding with publishing DF rulemaking documents.

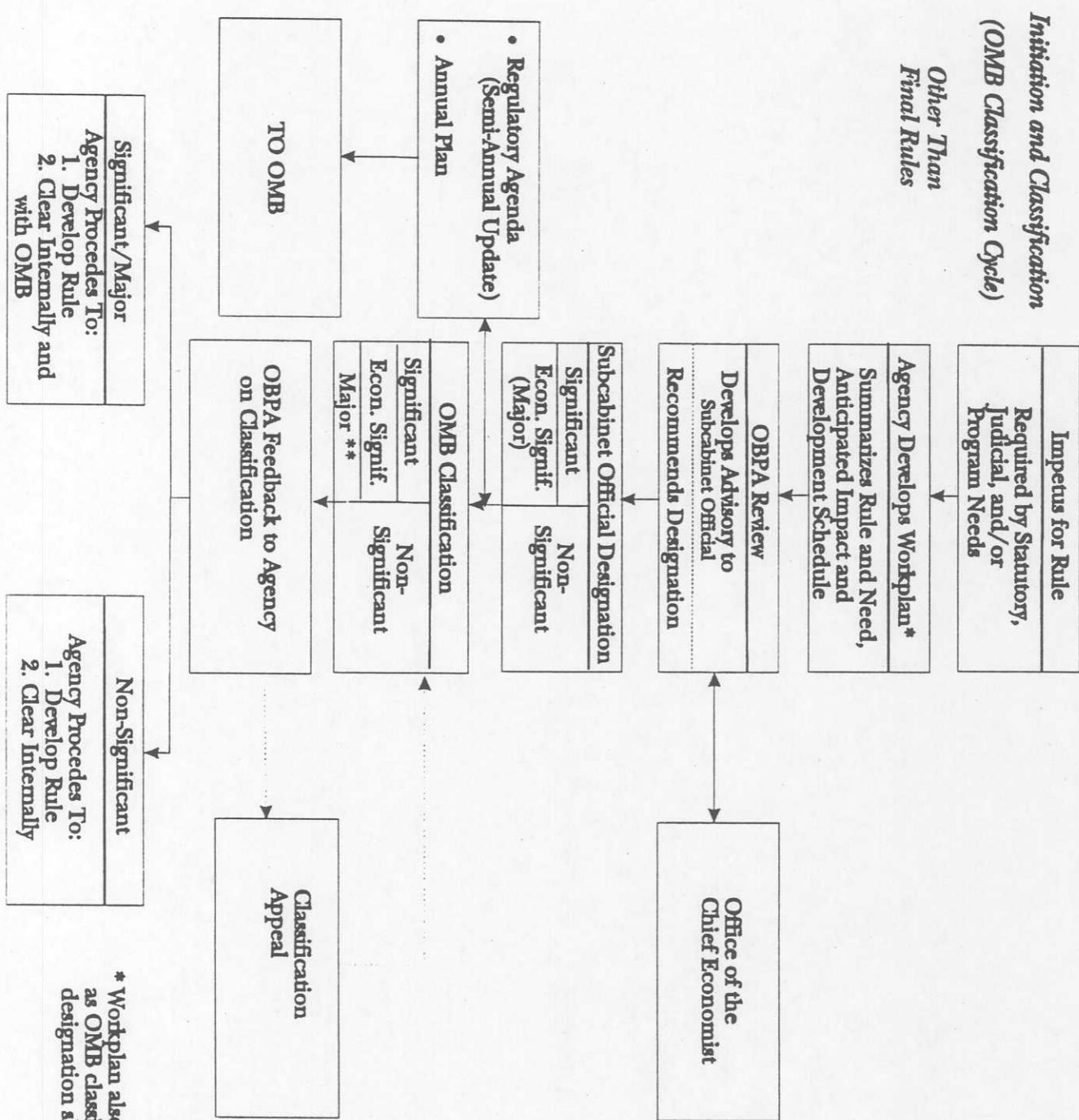
The following information on DF rulemaking is taken from a paper prepared by the OGC entitled, "Informal Guide to Rulemaking," July 15, 1994.

A voluntary device that may be used by agencies to expedite noncontroversial CHANGES to regulations is the direct final rule. Rules that an agency believes are noncontroversial and unlikely to result in adverse comments may be published in the FEDERAL REGISTER as direct final rules. This direct final rule advises the public that no adverse comments are anticipated, and that, unless a written adverse comment is received or written notice of intent to submit an adverse comment is received within a specified period of time (generally 30 days), the revision made by the direct final rule will be effective within a specified period of time (generally 60 days) from the date the direct rule is published in the FEDERAL REGISTER. If the agency receives a written adverse comment or notice of intent to submit a written adverse comment within the prescribed time, a notice of withdrawal of the direct final rule is published in the FEDERAL REGISTER and the agency proceeds with notice and comment rulemaking.

If the agency receives no adverse comments or notice of intent to submit an adverse comment, the agency publishes a notice in the FEDERAL REGISTER stating that no adverse comments and no notices of intent to submit adverse comments were received on the direct final rule and confirming that the direct final rule is effective on the date stated in the direct final rule.

The DF approach is currently being used by some USDA agencies and a significant body of written information is available to assist an agency that may wish to explore the applicability of DF in their rulemaking environment. Agencies that would like to use the DF rulemaking process should contact the OGC Division that provides legal services to the agency. OBPA regulatory staff is also available to facilitate agency inquiries regarding the DF process.

USDA REGULATION DEVELOPMENT PROCEDURE



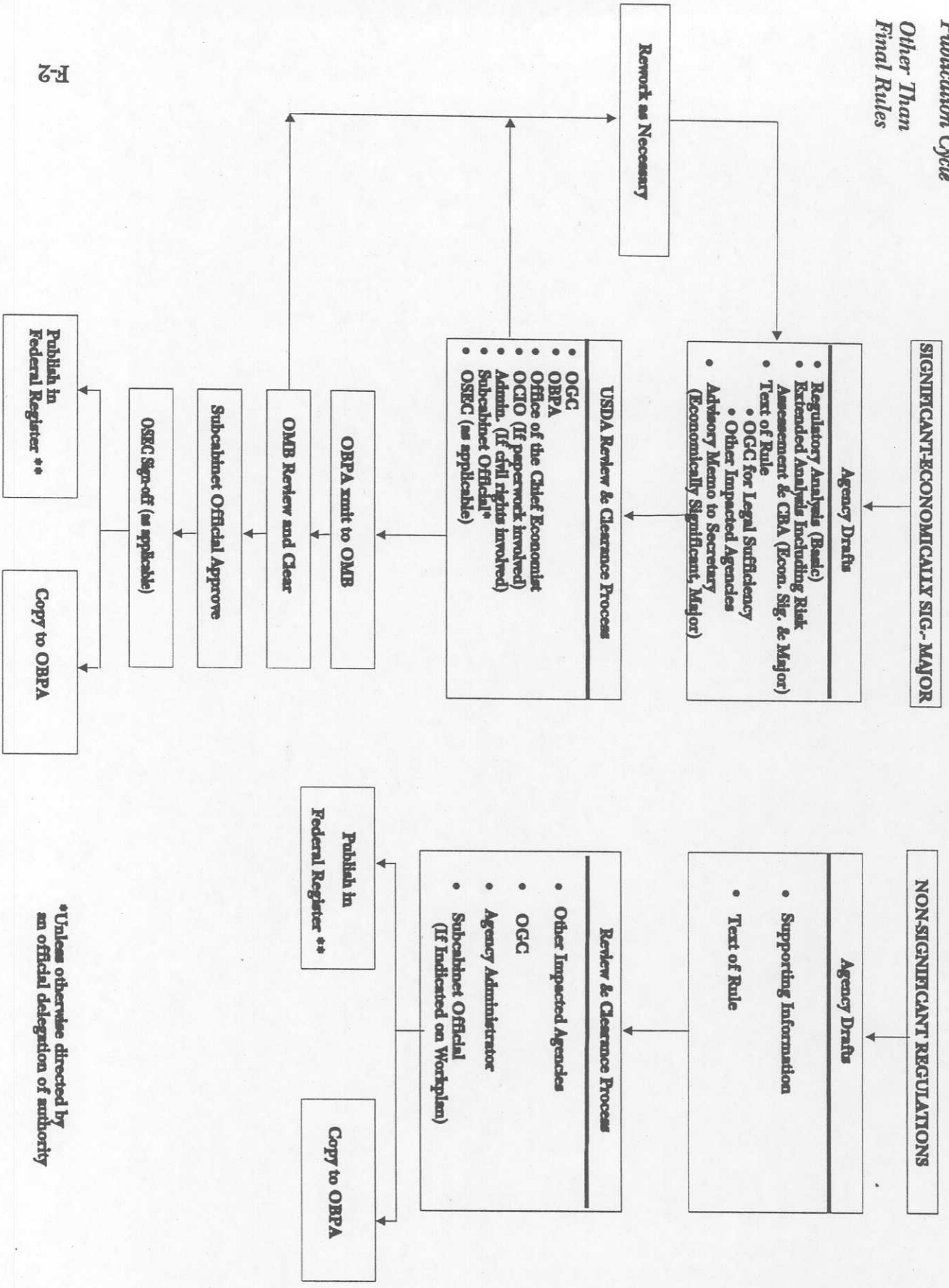
* Workplan also functions as OMB classification designation sheet

** Per SBREFA, See section 8(b), of the Departmental Regulation

*Development and
Publication Cycle
Other Than
Final Rules*

USDA REGULATION DEVELOPMENT PROCEDURE

APPENDIX G



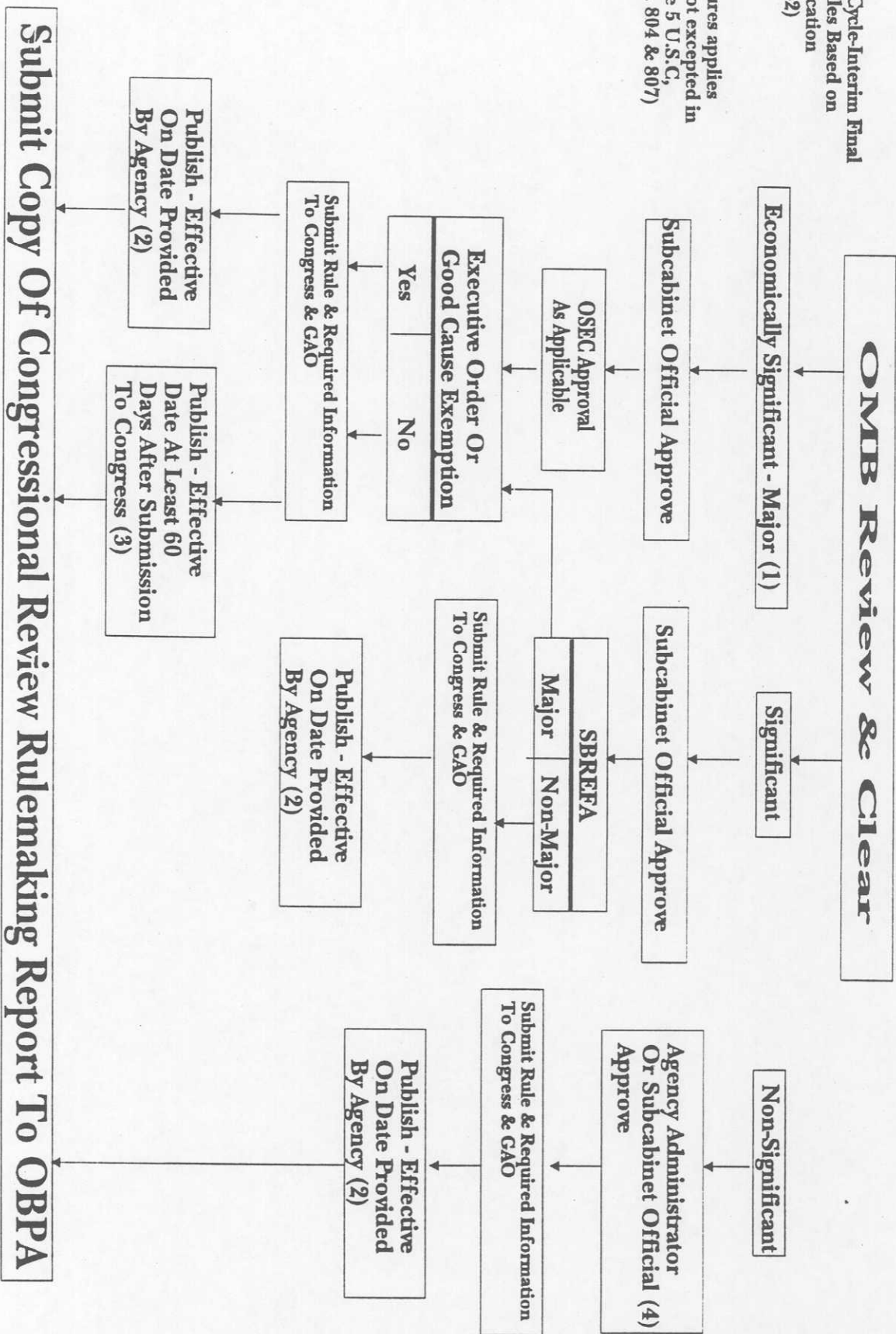
*Unless otherwise directed by an official delegation of authority

** See chart on page F-3 for processing Interim Final and Final Rules

USDA REGULATION DEVELOPMENT PROCEDURE

Publication Cycle-Interim Final and Final Rules Based on Prior classification (See page G-2)

This procedure applies to all rules not excepted in SBREFA (See 5 U.S.C. Chap. 8, Sec. 804 & 807)



F-3

(1) All rules classified as "Major" under the USDA Reorganization Act will be SBREFA "Major."

(2) Congress may still take adverse action before or after the effective date. See Appendix J.

(3) Assuming Congress takes no adverse action. See Appendix J.

(4) If indicated on Worksheet.

Executive Order

Monday
October 4, 1993

APPENDIX G

Part VIII

The President

Executive Order 12866—Regulatory
Planning and Review

1512-1

Presidential Documents

Title 3—

Executive Order 12866 of September 30, 1993

The President

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the 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, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation

is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) *The Agencies.* Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) *The Office of Management and Budget.* Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by this Executive order.

(c) *The Vice President.* The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President and the Vice President may, from time to time, consult.

Sec. 3. Definitions. For purposes of this Executive order: (a) "Advisors" refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected

to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law: (a) *Agencies' Policy Meeting.* Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.

(b) *Unified Regulatory Agenda.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) *The Regulatory Plan.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) *Regulatory Working Group.* Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) *Conferences.* The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regula-

tions promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) *Agency Responsibilities.* (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion, and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory

actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) *OIRA Responsibilities.* The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did

not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without

March 14, 1997

any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. Agency Authority. Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

William Clinton

THE WHITE HOUSE,
September 30, 1993.

[FR Doc. 93-24523
Filed 10-1-93; 12:12 pm]
Billing code 3195-01-M

Editorial note: For the President's remarks on signing this Executive order, see issue 39 of the *Weekly Compilation of Presidential Documents*.

Dated at Rockville, Maryland, this 22th day of September 1995.

For the Nuclear Regulatory Commission.
 Ledyard B. Marsh,
 Director, Project Directorate I-1, Division of
 Reactor Projects—/II Office of Nuclear
 Reactor Regulation.
 [FR Doc. 95-24224 Filed 9-28-95; 8:45 am]
 BILLING CODE 7590-01-P

OFFICE OF THE FEDERAL REGISTER

Procedures for Publication of Federal Register Documents During a Funding Hiatus

AGENCY: Office of the Federal Register.
ACTION: Notice of special procedures.

SUMMARY: Due to the possibility of a lapse in appropriations and in accordance with the provisions of the Antideficiency Act, as amended by Public Law No. 101-508, 104 Stat. 1388 (31 U.S.C. 1341), the Office of the Federal Register (OFR) announces special procedures for agencies submitting documents to be published in the Federal Register.

In the event of an appropriations lapse, the OFR would be required to publish documents directly related to the performance of governmental functions necessary to address imminent threats to the safety of human life or protection of property. Since it would be impracticable for the OFR to make case-by-case determinations as to whether certain documents are directly related to activities that qualify for an exemption under the Antideficiency Act, the OFR will place responsibility on agencies submitting documents to certify that their documents relate to emergency activities authorized under the Act.

During a funding hiatus affecting one or more Federal agencies, the OFR will remain open to accept and process documents authorized to be published in the daily Federal Register in the absence of continuing appropriations. An agency wishing to submit a document to the OFR during a funding hiatus must attach a transmittal letter to the document which states that publication in the Federal Register is necessary to safeguard human life, protect property, or provide other emergency services consistent with the performance of functions and services exempted under the Antideficiency Act.

Under the August 16, 1995 opinion of the Office of Legal Counsel of the Department of Justice, exempt functions and services would include activities such as those related to the constitutional duties of the President,

food and drug inspection, air traffic control, responses to natural or manmade disasters, law enforcement and supervision of financial markets. Documents related to normal or routine activities of Federal agencies, even if funded under prior year appropriations, will not be published.

At the onset of a funding hiatus, the OFR may suspend the regular three-day publication schedule to permit a limited number of exempt personnel to process emergency documents. Agency officials will be informed as to the schedule for filing and publishing individual documents.

FOR FURTHER INFORMATION CONTACT:
 Richard Claypoole or Michael White,
 (202) 523-4534.

Authority

The authority for this action is 44 U.S.C. 1502 and 1 CFR 2.4 and 5.1.

Dated: September 28, 1995.

Richard L. Claypoole,

Director of the Federal Register.

[FR Doc. 95-24535 Filed 9-28-95; 11:09 am]

BILLING CODE 1505-02-M

OFFICE OF MANAGEMENT AND BUDGET

Guidelines and Instructions for Implementing Section 204, "State, Local, and Tribal Government Input," of Title II of Public Law 104-4

AGENCY: Office of Management and Budget.

ACTION: Memorandum for Heads of Departments and Agencies.

SUMMARY: On March 22, 1995, the President signed into law the "Unfunded Mandates Reform Act of 1995" (P.L. 104-4). This notice provides guidance to agencies on the Act.

FOR FURTHER INFORMATION CONTACT: Jeff Hill, 395-7340.

Attached to this notice is the material for inclusion in the Federal Register.

Dated: September 25, 1995.

John B. Arthur,

Assistant Director for Administration.

Memorandum for the Heads of Departments and Agencies

FROM: Alice M. Rivlin, Director.

SUBJECT: Guidelines and Instructions and Implementing Section 204, "State, Local, and Tribal Government Input," of Title II of P.L. 104-4.

On March 22, 1995, President Clinton signed into law the "Unfunded Mandates Reform Act of 1995" (P.L. 104-4) (the "Act"). Section 204(a) of the Act requires that—

"Each agency shall, to the extent permitted in law, develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals containing significant Federal intergovernmental mandates."¹

Section 204(b) of the Act provides an exemption from the Federal Advisory Committee Act (5 U.S.C. App.) for intergovernmental consultations involving intergovernmental responsibilities or administration.

Section 204(c) requires the President to issue guidelines and instructions to Federal agencies "for appropriate implementation" of both of these provisions "consistent with applicable laws and regulations." In accordance with the President's delegation of authority,² OMB is today issuing those guidelines and instructions.³

I. The Process for Intergovernmental Consultation

It is important that this intergovernmental consultation process not only achieves meaningful input, but also builds a better understanding among Federal, State, local, and tribal governments. As described in Part II, below, the process required by the Federal Advisory Committee Act is not to act as a hindrance to full and effective intergovernmental consultation.

A. What Agencies Are Covered?

The process for intergovernmental consultation called for by Section 204(a) applies to all Federal agencies (as

¹ The Act's consultation requirement builds on that set forth by President Clinton on October 26, 1993, in Executive Order No. 12875. In order "to reduce the imposition of unfunded mandates upon State, local, and tribal governments," the Executive order requires agencies, when they seek to impose unfunded mandates upon State, local, or tribal governments through a regulation, to provide to the Director of the Office of Management and Budget "a description of the extent of the agency's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, any written communications submitted to the agency by such units of government, and the agency's position supporting the need to issue the regulation containing the mandate" (Sec. 1(a)(2)).

² See 60 Fed. Reg. 45039 (August 29, 1995).

³ Portions of these guidelines and instructions are based on OMB Memorandum M-94-10, entitled "Guidance for Implementing E.O. 12875, 'Reduction of Unfunded Mandates,'" issued by Director Leon E. Panetta on January 11, 1994. These guidelines and instructions are not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees. Neither are these guidelines and instructions intended, nor should they be construed, to limit the availability of any exclusion from the Federal Advisory Committee Act contained in that Act or any applicable regulations.

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defined in 5 U.S.C. 551(1)), with the exception of independent regulatory agencies.

B. When Should Intergovernmental Consultations Take Place?

Intergovernmental consultation should take place as early in the regulatory process as possible. Except where the need for immediate agency action precludes prior consultation, consultation should occur before publication of the notice of proposed rulemaking or other regulatory action proposing a significant Federal intergovernmental mandate. Consultation should continue after publication of the regulatory action initiating the proposal. Except in exceptional circumstances where the need for immediate action precludes prior consultation, consultation must occur prior to the formal promulgation in final form of the regulatory action.

C. With Whom Should Agencies Consult?

The statute directs agencies to develop an effective process to ensure that "elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf)" who wish to provide meaningful and timely input are able to do so.

Each agency needs to develop an intergovernmental consultation process for that agency. To do so, the agency should first develop a proposal for that process, and consult with State, local, and tribal governments (as appropriate) concerning this proposed process, as soon as possible.

One approach an agency may wish to adopt is to designate a person or an office through which intergovernmental consultation should be coordinated. Another approach is for an agency to instruct those responsible for developing a rule to seek out the views of elected officers of their designated employees. An agency may also wish to develop other effective means of generating meaningful input or expand those that it already has. An agency will be able to obtain the fullest range of meaningful input from State, local, and tribal governments by undertaking the following kinds of consultation.

(1) Heads of Government

Agencies should seek to consult with the highest levels of the pertinent government units, e.g., the Office of the Governor, Mayor, or Tribal Leader (or their designated employees with authority to act on their behalf). These officials are the ones elected to represent the people and are the ones

that the public holds directly accountable for the actions of those government units.

(2) Both Program and Financial Officials

Many regulatory agencies have functional counterparts in State, local, and tribal governments, e.g., those government officials who implement or enforce regulatory responsibilities required in whole or part by the Federal agency. These local officials tend to be those most familiar with the Federal agency's regulatory program, and should be consulted as a source of important information concerning the likely effects of, or effective alternatives to, Federal regulatory proposals.

In addition, agencies should consult with those State, local, and tribal officials most directly responsible for ensuring the funding of compliance with the Federal mandate, e.g., the applicable treasury, budget, tax-collection, or other financial officials. These officials are institutionally responsible for balancing the competing claims for scarce State, local, or tribal resources.

(3) Washington Representatives

It is also important that Federal agencies consult with Washington representatives, where available, of associations representing elected officials. These Washington representatives often know which local elected officials are the most knowledgeable about, interested in, or responsible for, implementing specific issues, regulations or programs, and can ensure that a broad range of government officials learn of and provide valuable insight concerning a proposed intergovernmental mandate.

(4) Small Governments

Agencies should make special efforts to consult with officials of small governments, and to develop a plan for such consultation under section 203 of Title II of the Act. Agencies may wish to consider several mechanisms for reaching small governments, including special task forces, periodic mailings through small government associations, or communication through rural development councils.

D. How Much Consultation Should There Be?

The scope of intergovernmental consultation should be based on common sense and be commensurate with the significance of the action being taken. The more costly, the more potentially disruptive, the more broadly applicable, the more controversial the proposed Federal intergovernmental

mandate—the more consultation there should be. An agency should decide the extent of its consultation on a case-by-case basis; a one-size-fits-all prescription is neither appropriate nor desirable.

E. What Should Be the Content of Consultation?

Agencies should seek views of State, local, and tribal governments regarding costs, benefits, risks, and alternative and flexible methods of compliance regarding their regulatory proposals. Agencies should also seek views on potential duplication with existing laws or regulations at other levels of government, and on ways to harmonize their rules with State, local and tribal policies and programs.

To assist with these consultations, agencies should first estimate the direct costs to be incurred by the State, local, or tribal governments in complying with the mandate and then inform the affected governmental units of these cost estimates. Estimates should cover both up-front and recurring costs, for a reasonable number of years after the rule is to be put into effect. To the extent practicable, agencies should make reasonable efforts to disaggregate these cost estimates as they affect the various levels of government, or otherwise provide the criteria by which those affected can disaggregate the cost estimates in order to determine the potential costs to themselves. Where quantitative estimates are not feasible, agencies should work with other levels of government to discern and discuss qualitative costs.

Agencies should also consult on and estimate the benefits expected from the mandate for States, localities, tribes, and their residents and businesses. Estimates should cover both up-front and recurring benefits for a reasonable number of years after the rule is to be put into effect. To the extent practicable agencies should make reasonable efforts to disaggregate these benefit estimates as they affect the various levels of government, or otherwise provide the criteria by which those affected can disaggregate the benefit estimates in order to determine the potential benefit to themselves. Where quantitative estimates are not feasible, agencies should work with other levels of government to discern and discuss qualitative benefits.

Agencies should also, during the consultative process, seek views on the expected method of compliance. Governmental units may have suggestions as to how to achieve the Federal regulatory objective in a way that is more effective, efficient flexible.

and consistent with State, local, and tribal governmental regulatory and other functions.

F. How Should Agencies Integrate These Intergovernmental Consultations into the Rulemaking Process?

It is important for agencies to integrate these consultation activities into the ongoing rulemaking process. The cost and benefit estimates, any additional viable suggestions received during the pre-notice consultations, and the agency plan to carry out intergovernmental consultation should be included in the preamble to the notice of proposed rulemaking. Publication of consultation plan in the Federal Register will assure that those governmental units that are not contacted directly will have access to the same cost and benefit estimates as those who were contacted directly, and have the opportunity to make their concerns known. Similarly, and consistent with E.O. 12875, any preamble transmitted to the Federal Register on or after October 2, 1995, should include, as of the particular stage of the rulemaking, the extent of the agency's prior consultations with representatives of affected State, local, and tribal governments, the nature of their concerns, any written communications submitted to the agency by such units of government, and the agency's position supporting the need to issue the regulation containing the mandate.

G. What Compliance Reports Should Agencies Submit to OMB?

Under Section 208 of the Act, OMB is required to submit a report to Congress on agency compliance with the requirements of Title II of the Act, which includes the intergovernmental consultation requirement, on or before March 22, 1996, and annually thereafter. Accordingly, agencies should provide the Administrator of the Office of Information and Regulatory Affairs, by January 15, 1996, and annually on that date thereafter, a written report of each agency's compliance with Title II of the Act. The report should include a description of the process established by the agency to ensure meaningful input, as well as a description of agency consultations with State, local, and tribal governments for each proposed and final rule "containing significant Federal intergovernmental mandates." As part of the report to be submitted by January 15, 1996, agencies should also describe the plans they have developed to consult with small governments, under Section 203 of Title II of the Act.

II. The Exemption From the Federal Advisory Committee Act

In order to facilitate the consultation process, section 204(b) of the Act provides an exemption from the Federal Advisory Committee Act ("FACA") (5 U.S.C. App.) "for the exchange of official views regarding the implementation of public laws requiring shared intergovernmental responsibilities or administration."⁴ This exemption applies to all Federal agencies subject to FACA, and is not limited to the intergovernmental consultations required by Section 204(a) but instead applies to the entire range of intergovernmental responsibilities or administration. In accordance with the legislative intent, the exemption should be read broadly to facilitate intergovernmental communications on responsibilities or administration.

This exemption applies to meetings between Federal officials and employees and State, local, or tribal governments, acting through their elected officers, officials, employees, and Washington representatives, at which "views, information, or advice" are exchanged concerning the implementation of intergovernmental responsibilities or administration, including those that arise explicitly or implicitly under statute, regulation, or Executive order.⁵

The scope of meetings covered by the exemption should be construed broadly to include any meetings called for any purpose relating to intergovernmental responsibilities or administration. Such meetings include, but are not limited to, meetings called for the purpose of seeking consensus; exchanging views, information, advice, and/or recommendations; or facilitating any other interaction relating to intergovernmental responsibilities or administration.

The guidance given above should help determine when a meeting qualifies under Section 204(b) of the Act for an exemption from the FACA. We also note that meetings that do not meet these guidelines for an exemption may nonetheless not be subject to the FACA in the first instance. Accordingly, to

⁴ House Conference Report 104-78 (March 13, 1995), p. 40.

⁵ Specifically, this exemption from FACA applies where—

"(1) meetings are held exclusively between Federal officials and elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf), acting in their official capacities; and

"(2) such meetings are solely for the purposes of exchanging information, or advice relating to the management or implementation of Federal programs established pursuant to public law that explicitly or inherently share intergovernmental responsibilities or administration."

determine whether there is even a need for an exemption from the FACA, agencies should also consult the FACA itself, as well as the General Service Administration's regulations at 41 CFR Subpart 101-6.10, and the court decisions construing the FACA.

It is important that agencies make their best efforts to implement these guidelines and instructions. As the Conference Report stated, "an important part of efforts to improve the Federal regulatory process entails improved communications with State, local, and tribal governments. Accordingly, this legislation will require Federal agencies to establish effective mechanisms for soliciting and integrating the input of such interests into the Federal decision-making process."⁶

If agencies have any questions concerning these guidelines and instructions, they should contact the Administrator of the Office of Information and Regulatory Affairs, or her staff. OMB will provide additional guidance as experience and need dictate.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-36272; File No. SR-OCC-95-01]

Self-Regulatory Organizations; the Options Clearing Corporation; Notice of Withdrawal of a Proposed Rule Change

September 22, 1995.

On January 23, 1995, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ a proposed rule change clarifying OCC's Rules regarding the unavailability of current index values. Notice of the proposed rule was published in the Federal Register on March 17, 1995.² On September 19, 1995, OCC filed a request that the proposed rule change be withdrawn.³

¹ House Conference Report 104-78 (March 13, 1995), p. 40.

² 15 U.S.C. 78s(b)(1) (1988).

³ Securities Exchange Act Release No. 35472 (March 10, 1995), 60 FR 14473 (File No. SR-OCC-95-01).

⁴ Letter from James C. Yong, First Vice President and General Counsel, OCC, to Jerry Carpenter, Assistant Director, Division of Market Regulation, Commission, (September 15, 1995).

APPENDIX I

Subtitle E—Congressional Review

SEC. 251. CONGRESSIONAL REVIEW OF AGENCY RULEMAKING.

Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

“CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

- “Sec.
- “801. Congressional review.
- “802. Congressional disapproval procedure.
- “803. Special rule on statutory, regulatory, and judicial deadlines.
- “804. Definitions.
- “805. Judicial review.
- “806. Applicability; severability.
- “807. Exemption for monetary policy.
- “808. Effective date of certain rules.

“§ 801. Congressional review

Reports.

“(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

- “(i) a copy of the rule;
- “(ii) a concise general statement relating to the rule, including whether it is a major rule; and
- “(iii) the proposed effective date of the rule.

“(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

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“(i) a complete copy of the cost-benefit analysis of the rule, if any;

“(ii) the agency’s actions relevant to sections 603, 604, 605, 607, and 609;

“(iii) the agency’s actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

“(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

“(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

“(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency’s compliance with procedural steps required by paragraph (1)(B).

Reports.

“(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General’s report under subparagraph (A).

“(3) A major rule relating to a report submitted under paragraph (1) shall take effect on the latest of—

Effective dates.

“(A) the later of the date occurring 60 days after the date on which—

“(i) the Congress receives the report submitted under paragraph (1); or

“(ii) the rule is published in the Federal Register, if so published;

Federal Register, publication.

“(B) if the Congress passes a joint resolution of disapproval described in section 802 relating to the rule, and the President signs a veto of such resolution, the earlier date—

“(i) on which either House of Congress votes and fails to override the veto of the President; or

“(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President; or

“(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

“(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

Effective date.

“(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by operation of this chapter beyond the date on which either House of Congress votes to reject a joint resolution of disapproval under section 802.

Effective dates.

“(b)(1) A rule shall not take effect (or continue), if the Congress enacts a joint resolution of disapproval, described under section 802, of the rule.

“(2) A rule that does not take effect (or does not continue) under paragraph (1) may not be reissued in substantially the same form, and a new rule that is substantially the same as such a

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rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.

“(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of subsection (a)(3) may take effect, if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

“(2) Paragraph (1) applies to a determination made by the President by Executive order that the rule should take effect because such rule is—

“(A) necessary because of an imminent threat to health or safety or other emergency;

“(B) necessary for the enforcement of criminal laws;

“(C) necessary for national security; or

“(D) issued pursuant to any statute implementing an international trade agreement.

“(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under section 802 or the effect of a joint resolution of disapproval under this section.

“(d)(1) In addition to the opportunity for review otherwise provided under this chapter, in the case of any rule for which a report was submitted in accordance with subsection (a)(1)(A) during the period beginning on the date occurring—

“(A) in the case of the Senate, 60 session days, or

“(B) in the case of the House of Representatives, 60 legislative days,

before the date the Congress adjourns a session of Congress through the date on which the same or succeeding Congress first convenes its next session, section 802 shall apply to such rule in the succeeding session of Congress.

“(2)(A) In applying section 802 for purposes of such additional review, a rule described under paragraph (1) shall be treated as though—

“(i) such rule were published in the Federal Register (as a rule that shall take effect) on—

“(I) in the case of the Senate, the 15th session day,

or

“(II) in the case of the House of Representatives, the 15th legislative day,

after the succeeding session of Congress first convenes; and

“(ii) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

“(B) Nothing in this paragraph shall be construed to affect the requirement under subsection (a)(1) that a report shall be submitted to Congress before a rule can take effect.

“(3) A rule described under paragraph (1) shall take effect as otherwise provided by law (including other subsections of this section).

Federal Register,
publication.

Effective date.

“(e)(1) For purposes of this subsection, section 802 shall also apply to any major rule promulgated between March 1, 1996, and the date of the enactment of this chapter.

“(2) In applying section 802 for purposes of Congressional review, a rule described under paragraph (1) shall be treated as though—

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“(A) such rule were published in the Federal Register on the date of enactment of this chapter; and

Federal Register,
publication.

“(B) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

“(3) The effectiveness of a rule described under paragraph (1) shall be as otherwise provided by law, unless the rule is made of no force or effect under section 802.

“(f) Any rule that takes effect and later is made of no force or effect by enactment of a joint resolution under section 802 shall be treated as though such rule had never taken effect.

“(g) If the Congress does not enact a joint resolution of disapproval under section 802 respecting a rule, no court or agency may infer any intent of the Congress from any action or inaction of the Congress with regard to such rule, related statute, or joint resolution of disapproval.

“§ 802. Congressional disapproval procedure

“(a) For purposes of this section, the term ‘joint resolution’ means only a joint resolution introduced in the period beginning on the date on which the report referred to in section 801(a)(1)(A) is received by Congress and ending 60 days thereafter (excluding days either House of Congress is adjourned for more than 3 days during a session of Congress), the matter after the resolving clause of which is as follows: ‘That Congress disapproves the rule submitted by the _____ relating to _____, and such rule shall have no force or effect.’ (The blank spaces being appropriately filled in).

“(b)(1) A joint resolution described in subsection (a) shall be referred to the committees in each House of Congress with jurisdiction.

“(2) For purposes of this section, the term ‘submission or publication date’ means the later of the date on which—

“(A) the Congress receives the report submitted under section 801(a)(1); or

“(B) the rule is published in the Federal Register, if so published.

Federal Register,
publication.

“(c) In the Senate, if the committee to which is referred a joint resolution described in subsection (a) has not reported such joint resolution (or an identical joint resolution) at the end of 20 calendar days after the submission or publication date defined under subsection (b)(2), such committee may be discharged from further consideration of such joint resolution upon a petition supported in writing by 30 Members of the Senate, and such joint resolution shall be placed on the calendar.

“(d)(1) In the Senate, when the committee to which a joint resolution is referred has reported, or when a committee is discharged (under subsection (c)) from further consideration of a joint resolution described in subsection (a), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for a motion to proceed to the consideration of the joint resolution, and all points of order against the joint resolution (and against consideration of the joint resolution) are waived. The motion is not subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the joint resolution is agreed

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to, the joint resolution shall remain the unfinished business of the Senate until disposed of.

“(2) In the Senate, debate on the joint resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 10 hours, which shall be divided equally between those favoring and those opposing the joint resolution. A motion further to limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the joint resolution is not in order.

“(3) In the Senate, immediately following the conclusion of the debate on a joint resolution described in subsection (a), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the Senate, the vote on final passage of the joint resolution shall occur.

“(4) Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a joint resolution described in subsection (a) shall be decided without debate.

“(e) In the Senate the procedure specified in subsection (c) or (d) shall not apply to the consideration of a joint resolution respecting a rule—

“(1) after the expiration of the 60 session days beginning with the applicable submission or publication date, or

“(2) if the report under section 801(a)(1)(A) was submitted during the period referred to in section 801(d)(1), after the expiration of the 60 session days beginning on the 15th session day after the succeeding session of Congress first convenes.

“(f) If, before the passage by one House of a joint resolution of that House described in subsection (a), that House receives from the other House a joint resolution described in subsection (a), then the following procedures shall apply:

“(1) The joint resolution of the other House shall not be referred to a committee.

“(2) With respect to a joint resolution described in subsection (a) of the House receiving the joint resolution—

“(A) the procedure in that House shall be the same as if no joint resolution had been received from the other House; but

“(B) the vote on final passage shall be on the joint resolution of the other House.

“(g) This section is enacted by Congress—

“(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of a joint resolution described in subsection (a), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

“(2) with full recognition of the constitutional right of either House to change the rules (so far as relating to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

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“§ 803. Special rule on statutory, regulatory, and judicial deadlines

“(a) In the case of any deadline for, relating to, or involving any rule which does not take effect (or the effectiveness of which is terminated) because of enactment of a joint resolution under section 802, that deadline is extended until the date 1 year after the date of enactment of the joint resolution. Nothing in this subsection shall be construed to affect a deadline merely by reason of the postponement of a rule’s effective date under section 801(a).

“(b) The term ‘deadline’ means any date certain for fulfilling any obligation or exercising any authority established by or under any Federal statute or regulation, or by or under any court order implementing any Federal statute or regulation.

“§ 804. Definitions

“For purposes of this chapter—

“(1) The term ‘Federal agency’ means any agency as that term is defined in section 551(1).

“(2) The term ‘major rule’ means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—

“(A) an annual effect on the economy of \$100,000,000 or more;

“(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

“(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.

“(3) The term ‘rule’ has the meaning given such term in section 551, except that such term does not include—

“(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing;

“(B) any rule relating to agency management or personnel; or

“(C) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

“§ 805. Judicial review

“No determination, finding, action, or omission under this chapter shall be subject to judicial review.

“§ 806. Applicability; severability

“(a) This chapter shall apply notwithstanding any other provision of law.

“(b) If any provision of this chapter or the application of any provision of this chapter to any person or circumstance, is held

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invalid, the application of such provision to other persons or circumstances, and the remainder of this chapter, shall not be affected thereby.

“§ 807. Exemption for monetary policy

“Nothing in this chapter shall apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.

“§ 808. Effective date of certain rules

“Notwithstanding section 801—

“(1) any rule that establishes, modifies, opens, closes, or conducts a regulatory program for a commercial, recreational, or subsistence activity related to hunting, fishing, or camping, or

“(2) any rule which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest,

shall take effect at such time as the Federal agency promulgating the rule determines.”.

SEC. 252. EFFECTIVE DATE.

5 USC 801 note.

The amendment made by section 351 shall take effect on the date of enactment of this Act.

SEC. 253. TECHNICAL AMENDMENT.

The table of chapters for part I of title 5, United States Code, is amended by inserting immediately after the item relating to chapter 7 the following:

“3. Congressional Review of Agency Rulemaking 801”.

Rules and Regulations

Federal Register

Vol. 60, No. 246

Friday, December 22, 1995

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Parts 1 and 1b

Departmental Proceedings, Judicial Proceedings, and NEPA Policy

AGENCY: Office of the Secretary of Agriculture, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Administrative Regulations—Departmental Proceedings, the Administrative Regulations—Judicial Proceedings, and the National Environmental Policy Act regulations as part of the United States Department of Agriculture's (USDA) regulatory reinvention initiative to improve its regulations. This final rule updates and corrects references to statutes, regulations, USDA agencies, and USDA officials; removes gender specific references; removes unnecessary regulations; and makes minor nonsubstantive changes for clarity.

EFFECTIVE DATE: This final rule is effective January 22, 1996.

FOR FURTHER INFORMATION CONTACT: William Jenson, Senior Counsel, Regulatory Division, Office of the General Counsel, USDA, room 2422, South Building, 14th Street and Independence Avenue SW., Washington, DC 20250, (202) 720-2453.

SUPPLEMENTARY INFORMATION:

Background

The President directed the heads of all departments and agencies to review all regulations and eliminate or revise those that are outdated or otherwise in need of reform. The Department completed its review and submitted a report on the review to the Office of Management and Budget on June 1, 1995. The review included USDA's Administrative Regulations—

Departmental Proceedings (7 CFR, part 1, subpart B); Administrative Regulations—Judicial Proceedings (7 CFR, part 1, subpart C); and National Environmental Policy Act regulations (7 CFR, part 1b). The Department found that these regulations contain outdated and incorrect references to statutes, regulations, USDA agencies, and USDA officials; unnecessary provisions; gender specific references; and provisions that could be clarified by making minor nonsubstantive changes. This final rule updates and corrects references to statutes, regulations, USDA agencies, and USDA officials; removes gender specific references; removes unnecessary regulations; and makes minor nonsubstantive changes for clarity.

7 CFR, Part 1, Subpart B

This final rule amends 7 CFR, part 1, subpart B, by adding a citation to the statutory authority for the subpart. This final rule also amends §§ 1.26, 1.27, 1.28, and 1.29 in 7 CFR, part 1, subpart B.

Section 1.26(c) provides that “[c]hapter 11 of title 18, United States Code prohibits employees and former employees from representing others under certain circumstances. See § 0.735-41 of this subtitle for illustrations.” Section 1.26(c) is unnecessary and has no effect and is therefore removed. In addition, this final rule makes minor nonsubstantive amendments to 7 CFR 1.26 (a), (b)(2), and (b)(3) for clarity and to remove gender specific references.

Section 1.27 sets forth the Department policy with respect to the availability of written submissions in response to certain notices published by the Department. Sections 1.27 (a) through (d) appear by their terms to apply only to written submissions in response to notices of proposed rulemaking published by the Department. However, § 1.27(e) provides that, despite the limiting language in § 1.27 (a) through (d), the policy announced in § 1.27 applies to written submissions in response to any published notice which solicits, or affords interested members of the public an opportunity to submit, written views with respect to any proposed action relating to any program administered by the Department regardless of the fact that the issuance of a rule may not be contemplated.

Further, this final rule amends the provisions regarding the confidentiality of written submissions. Sections 1.27 (c) and (d) provide for confidentiality if making the submission public would have an adverse effect on the submitter by reason of: (1) Disclosing trade secrets, processes, operations, style of work or apparatus; (2) disclosing the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures; or (3) exposing the submitter to substantial disadvantage in business or employment. This confidentiality provision was written before the enactment of the Freedom of Information Act. The confidentiality provision in § 1.27 (c) and (d) includes agency records that the Department may not be able to withhold under the Freedom of Information Act. Therefore, § 1.27 is amended to provide that confidentiality may be given to written submissions only if they may be withheld under the Freedom of Information Act.

Further still, this final rule amends § 1.27 by setting forth the scope of the Department policy at the beginning of § 1.27, eliminating the inaccurate limiting language currently found in § 1.27 (a) through (d), and making other minor nonsubstantive changes for clarity.

Section 1.28 contains an inaccurate reference to a provision of the Administrative Procedure Act. This final rule amends § 1.28 to correct that inaccurate reference.

Section 1.29(a) provides that the “Administrator, Agricultural Marketing Service may delegate the authority to issue subpoenas in connection with investigations being conducted under the Packers and Stockyards Act, as amended and supplemented (7 U.S.C. 181-229), to the Deputy Administrator, Packers and Stockyards, Agricultural Marketing Service.” Since § 1.29(a) was issued, the Department has been reorganized and the references to Department officials in § 1.29(a) are no longer accurate. This final rule amends this provision within § 1.29(a) to correct the references to Department officials.

In addition, this final rule amends other provisions in § 1.29(a), and §§ 1.29(b)(1)(iii), (b)(2), and (b)(3) for clarity and to remove gender-specific references and surplusage.

pg 105 + 106 + 107

7 CFR, Part 1, Subpart C

This final rule amends 7 CFR, part 1, subpart C, by adding a citation to the statutory authority for the subpart. This final rule also amends § 1.41 in 7 CFR, part 1, subpart C, to remove a gender-specific reference and to remove a provision that requires service of process to be made upon the General Counsel to enforce child support or alimony payments owed by employees of the Department. This provision is removed because the regulations related to service of legal process for the enforcement of child support and alimony owed by Department employees are set forth in 5 CFR, part 581.

7 CFR, Part 1b

This final rule amends the authority citation for 7 CFR, part 1b, to remove inaccurate references to the Federal Register.

Section 1b.1 contains inaccurate references to regulations and an inaccurate reference to the Council on Environmental Quality. This final rule corrects those inaccuracies.

Section 1b.2(a) describes the purposes of some of the Department's programs and the methods by which some of these programs are conducted. Section 1b.2(a) is unnecessary and has no effect and is therefore removed. In addition, this final rule makes minor, nonsubstantive amendments to 7 CFR 1b.2 paragraphs (c), (d), and (e) for clarity; to remove inaccurate references to regulations, the Under Secretary, Natural Resources and Environment, and the Agricultural Council on Environmental Quality; and to remove surplusage.

Section 1b.3(c) is amended to correct a cross reference.

Section 1b.4 lists agencies that are excluded from the requirement to prepare procedures to implement the National Environmental Policy Act and categorically excluded from the preparation of environmental assessments and environmental impact statements unless the agency head determines that an action may have a significant environmental effect. Since § 1b.4 was published, the Department has been reorganized and some of the listed agencies no longer exist. This final rule corrects the list of Department agencies in § 1b.4 and makes minor nonsubstantive changes for clarity.

Notice and Comment

This rule makes only minor nonsubstantive amendments to the regulations in order to update and correct incorrect references, remove

gender-specific references, remove unnecessary provisions, and clarify existing regulations. The rule will not have any effect on the public and no public participation is expected. Therefore, notice and public procedure with respect to this rule are unnecessary, and there is good cause under 5 U.S.C. 553 to make this rule effective without opportunity for public participation.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This final rule updates and corrects references to statutes, regulations, USDA agencies, and USDA officials; removes gender-specific references; removes unnecessary provisions; and makes minor nonsubstantive changes for clarity. This final rule will not have any economic impact.

Under these circumstances, the Secretary has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all state and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects**7 CFR Part 1**

Administrative practice and procedure, Agriculture, Antitrust, Blind, Claims, Concessions, Cooperatives, Equal access to justice, Federal buildings and facilities, Freedom of information, Lawyers, Privacy.

7 CFR Part 1b

Environmental policy statements.

Accordingly, 7 CFR parts 1 and 1b are amended as follows:

PART 1—ADMINISTRATIVE REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 5 U.S.C. 301, unless otherwise noted.

§ 1.26 [Amended]

2-3. Section 1.26 is amended as follows:

a. In paragraph (a), by removing the words "The provisions of this section apply" and by adding the words "This section applies" in their place; and by removing the words "such provisions, or any part thereof" and by adding the words "this section, or any part of this section" in their place.

b. In paragraph (b)(2), by removing the word "he" and adding the words "the Secretary" in its place each time it appears; and by removing the word "him" and adding the words "the person" in its place.

c. In paragraph (b)(3), by removing the words "his employment he" and adding the words "employment with the Department the employee or former employee" in their place; and by removing the word "him" and adding the words "the employee or former employee" in its place.

d. By removing paragraph (c).

§ 1.27 [Amended]

4. Section 1.27 is revised to read as follows:

§ 1.27 Rulemaking and other notice procedures.

(a) This section shall apply to:

- (1) Notices of proposed rulemaking;
- (2) Interim final rules;
- (3) Advance notices of proposed rulemaking; and

(4) Any other published notice that solicits, or affords interested members of the public an opportunity to submit, written views with respect to any proposed action relating to any program administered in the Department regardless of the fact that the issuance of a rule may not be contemplated.

(b) Each notice identified in paragraph (a) of this section shall indicate the procedure to be followed with respect to the notice, unless the procedure is prescribed by statute or by published rule of the Department. Each notice shall contain a statement that advises the public of the policy regarding the availability of written submissions by indicating whether paragraph (c), (d), or (e) of this section is applicable to written submissions made pursuant to the notice.

(c) All written submissions made pursuant to the notice shall be made

available for public inspection at times and places and in a manner convenient to the public business.

(d)(1) Any written submission, pursuant to a notice, may be held confidential if the person making the submission requests that the submission be held confidential, the person making the submission has shown that the written submission may be withheld under the Freedom of Information Act, and the Department official authorized to issue the notice determines that the submission may be withheld under the Freedom of Information Act.

(2) If a request is made in accordance with paragraph (d)(1) of this section for confidential treatment of a written submission, the person making the request shall be informed promptly in the event the request is denied and afforded an opportunity to withdraw the submission.

(3) If a determination is made to grant a request for confidential treatment under paragraph (d)(1) of this section, a statement of the specific basis for the determination that will not be susceptible of identifying the person making the request will be made available for public inspection.

(e) If the subject of the notice is such that meaningful submissions cannot be expected unless they disclose information that may be withheld under the Freedom of Information Act, the notice shall so indicate and contain a statement that written submissions pursuant to the notice will be treated as confidential and withheld under the Freedom of Information Act. *Provided*, That the policy regarding availability of written submissions set forth in this paragraph may only be used with the prior approval of the Secretary, or the Under Secretary or Assistant Secretary that administers the program that is the subject of the notice.

§ 1.28 [Amended]

5. Section 1.28 is amended by removing the phrase "the provisions of section 4(d) of the Administrative Procedure Act (60 Stat. 239; 5 U.S.C. 1003(d))" and adding the reference "5 U.S.C. 553(e)" in its place.

§ 1.29 [Amended]

6. Section 1.29 is amended as follows:
a. By revising paragraph (a) to read as set forth below.
b. In paragraph (b)(1)(iii), by adding the word "her," immediately after the word "his".
c. In paragraph (b)(2), by adding the words "or she" immediately after the word "he"; and by removing the word "therein" and adding the words "in the subpoena" in its place.

d. In paragraph (b)(3), by removing the reference "(5 U.S.C. 301)."

§ 1.29 Subpoenas relating to investigations under statutes administered by the Secretary of Agriculture.

(a) *Issuance of subpoena.* (1) When the Secretary is authorized by statute to issue a subpoena in connection with an investigation being conducted by the Department, the attendance of a witness and the production of evidence relating to the investigation may be required by subpoena at any designated place, including the witness' place of business. Upon request of any representative of the Secretary involved in connection with the investigation, the subpoena may be issued by the Secretary, the Inspector General, or any Department official authorized pursuant to part 2 of this title to administer the program to which the subpoena relates, if the official who is to issue the subpoena is satisfied as to the reasonableness of the grounds, necessity, and scope of the subpoena. Except as provided in paragraph (a)(2) of this section, the authority to issue subpoenas may not be delegated or redelegated by the head of an agency.

(2) The Administrator, Grain Inspection, Packers and Stockyards Administration, may delegate the authority to issue subpoenas in connection with investigations being conducted under the Packers and Stockyards Act (7 U.S.C. 181-229), to the Deputy Administrator, Packers and Stockyards Programs.

§ 1.41 [Amended]

7-8. Section 1.41 is amended as follows:

- a. In the third sentence, by removing the word "he" and adding the words "the officer" in its place.
- b. By removing the last sentence.

PART 1b—NATIONAL ENVIRONMENTAL POLICY ACT

9. The authority citation for part 1b is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 4321 *et seq.*; E.O. 11514, 3 CFR, 1966-1970 Comp., p. 902, as amended by E.O. 11991, 3 CFR, 1978 Comp., p. 123; E.O. 12114, 3 CFR, 1980 Comp., p. 356; 40 CFR 1507.3.

§ 1b.1 [Amended]

10. Section 1b.1 is amended as follows:

- a. In paragraph (a), by removing the words "This subpart" and adding the words "This part" in their place; by removing the words "Council of" and adding the words "Council on" in their place; and by removing the words "The

subpart" and adding the words "This part" in their place.

b. In paragraph (b), by removing the word "subpart" and adding the word "part" in its place:

§ 1b.2 [Amended]

11. Section 1b.2 is amended as follows:

- a. By removing paragraph (a).
- b. In paragraph (c), by removing the words "the provisions of this subpart" and adding the words "this part" in their place; and by removing the words "the provisions of NEPA" and adding the word "NEPA" in their place.
- c. In paragraph (d), the first sentence, by removing the word "Assistant" and adding the word "Under" in its place; and by removing the reference "(7 CFR 2.19(b))".
- d. In paragraph (d), the second sentence, by removing the words "Assistant Secretary, through the USDA Natural Resources and Environment Committee" and adding the words "Under Secretary, NR&E, through the Agricultural Council on Environmental Quality" in their place.
- e. In paragraph (e), the first sentence, by removing the word "subpart" and adding the word "part" in its place.
- f. In paragraph (e), the third sentence, by removing the word "Assistant" and adding the word "Under" in its place.
- g. By redesignating paragraphs (b), (c), (d), and (e) as paragraphs (a), (b), (c), and (d), respectively.

§ 1b.3 [Amended]

12. In § 1b.3, paragraph (c) is amended by removing the words "above and in" and adding the words "in paragraphs (a) of this section and" in their place.

13. Section 1b.4 is revised to read as follows:

§ 1b.4 Exclusion of agencies.

(a) The USDA agencies and agency units listed in paragraph (b) of this section conduct programs and activities that have been found to have no individual or cumulative effect on the human environment. The USDA agencies and agency units listed in paragraph (b) of this section are excluded from the requirements of preparing procedures to implement NEPA. Actions of USDA agencies and agency units listed in paragraph (b) of this section are categorically excluded from the preparation of an EA or EIS unless the agency head determines that an action may have a significant environmental effect.

(b)(1) Agricultural Marketing Service

4150 DAE

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- (2) Economic Research Service
- (3) Extension Service
- (4) Federal Corp Insurance Corporation
- (5) Food and Consumer Service
- (6) Food Safety and Inspection Service
- (7) Foreign Agricultural Service
- (8) Grain Inspection, Packers and Stockyards Administration
- (9) National Agricultural Library
- (10) National Agricultural Statistics Service
- (11) Office of the General Counsel
- (12) Office of the Inspector General

Done in Washington, DC, this 8th day of December, 1995.

Dan Glickman,

Secretary of Agriculture.

FR Doc. 95-30674 Filed 12-21-95; 8:45 am]

BILLING CODE 3410-01-M

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. 95-048DF]

RIN 0583-AC03

Use of the Fast Antimicrobial Screen Test for Bob Veal Calves

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to permit the use of the Fast Antimicrobial Screen Test (FAST) in its bob veal calf residue testing program. Under FSIS' residue testing program, carcasses of bob veal calves are subject to specific regulatory requirements for residue testing by FSIS inspectors to assure that adulterated meat does not enter human food channels. Until recently, the Calf Antibiotic and Sulfonamide Test (CAST) was the only official test authorized for use in the bob veal calf residue testing program. FSIS has now developed FAST, which is an enhanced and equally effective version of CAST that provides results after 6 hours of incubation, compared to 18-24 hours of incubation for CAST. This action will permit the use of FAST in lieu of CAST under FSIS' bob veal calf residue testing program.

DATES: This rule will be effective on February 20, 1996, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before January 22, 1996. If FSIS receives adverse comments or notice of intent to submit adverse comments, FSIS will withdraw this rule and publish a proposed rule for public comment.

ADDRESSES: Send an original and two copies of written comments to: FSIS Docket Clerk, Docket #95-048DF, Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

SUPPLEMENTARY INFORMATION:

Background

In June 1984, as a result of findings of increased levels of sulfonamide and antibiotic residues in young calves, FSIS promulgated an interim rule (49 FR 23602; affirmed 50 FR 32162) that amended the Federal meat inspection regulations (9 CFR parts 309, 310 and 318) by establishing an intensified residue testing program for bob veal calves (calves up to 3 weeks in age or 150 pounds in weight). FSIS was concerned with findings of increased levels of sulfonamide and antibiotic residues in young calves, and undertook an emergency rulemaking to decrease the likelihood that adulterated meat would enter into human food channels. FSIS determined that carcasses and parts thereof from bob veal calves are adulterated under the Federal Meat Inspection Act if they bear or contain sulfonamide or antibiotic residues other than in accordance with tolerances established by the Food and Drug Administration.

In the interim rule, FSIS stated that CAST, a swab bioassay test, would be the official test used to screen carcasses of bob veal calves. In trial testing, FSIS had found CAST to be extremely reliable in detecting violative levels of antibiotics and sulfonamides in animal tissues.

FSIS has recently developed a new test that, like CAST, is designed to detect the presence of sulfonamide and antibiotic residues in animal tissues. FAST is similar to and is performed in a similar manner to CAST. The major advantage of FAST is that test results can be obtained in 6 hours, instead of the 18-24 hour period required for CAST. FSIS' in-plant trial testing of FAST has shown that FAST is equivalent to CAST in detecting sulfonamide and antibiotic residues in animal tissues.¹

Therefore, FSIS is amending § 310.21 to add FAST as an alternative to CAST for use by inspectors in testing carcasses and parts of bob veal calves for sulfonamide and antibiotic residues.

¹ Results of the in-plant trial for FAST are available for review in the Office of the FSIS Docket Clerk, Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

Effective Date

This rule is being published without a prior proposal because this action is viewed as noncontroversial, and FSIS does not anticipate any adverse public comments will be received. This rule will be effective 60 days after the date of publication in the **Federal Register** unless FSIS receives written adverse comments or written notice of intent to submit adverse comments within 30 days of the date of publication of this rule in the **Federal Register**.

If FSIS receives adverse comments or notice of intent to submit adverse comments, FSIS will withdraw this rule and publish a proposed rule for public comment.

If no adverse comments are received, FSIS will publish a notice in the **Federal Register** confirming that the rule is effective on the date indicated.

Executive Order 12866

This rule is considered not significant and therefore has not been reviewed by the Office of Management and Budget.

Effect on Small Entities

The Administrator, FSIS, has determined that this rule will not have a significant impact on a substantial number of small entities. The rule permits the use of an alternate test, which can provide results in less than half the time than the original test. Carcasses that test negative could be released on the day of slaughter, which will modestly benefit the meat industry.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

List of Subjects in 9 CFR part 310

Meat inspection, Residue testing.

For the reasons discussed in the preamble, FSIS is amending part 310 of the Federal meat inspection regulations (9 CFR Part 310) as follows:

PART 310—[AMENDED]

1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

2. The introductory text and footnote to paragraph (c) of § 310.21 are revised to read as follows:

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APPENDIX K

BIBLIOGRAPHY

- Administrative Procedure Act, 5 U.S.C. 551 et seq.
- Regulatory Flexibility Act, 5 U.S.C. 601 et seq.
- National Environmental Policy Act, 42 U.S.C. 4321 et seq.
- Negotiated Rulemaking Act of 1990, 5 U.S.C. 561 et seq.
- Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
- Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, 109 Stat. 48.
- Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, Pub. L. 103-354, 108 Stat. 3178.
- Exec. Order No. 12498, "Regulatory Planning Process," 50 Fed. Reg. 1,036.
- Exec. Order No. 12606, "The Family," 52 Fed. Reg. 34,188.
- Exec. Order No. 12612 "Federalism Considerations in Policy Formulation and Implementation," 52 Fed. Reg. 41,685.
- Exec. Order No. 12630, "Governmental Actions and Interference With Constitutionally Protected Property Rights," 53 Fed. Reg. 8,859.
- Exec. Order No. 12866, "Regulatory Planning and Review," 58 Fed. Reg. 51,735.
- Exec. Order No. 12875, "Enhancing the Intergovernmental Partnership," 58 Fed. Reg. 58,093.
- Exec. Order No. 12988, "Civil Justice Reform," 61 Fed. Reg. 4729.
- Office of The Federal Register, Legal Drafting Style Manual, March 1978 Interim Edition.
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- Administrative Conference of the United States, A Guide to Federal Agency Rulemaking, 2nd Edition (Office of the Chairman 1991).
- USDA Office of the General Counsel, Informal Guide to Rulemaking, July 15, 1994.