UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS DIRECTIVE	1232.4	11/20/01

REGULATIONS DEVELOPMENT AND CLEARANCE

I. PURPOSE

This directive:

A. Describes the process of forming docket teams, the functions of docket teams, and the responsibilities of members of docket teams.

B. Describes the documents docket teams develop and the laws and Executive orders governing FSIS regulations development.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

See Attachment 1 for a summary of laws and Executive orders governing regulations development.

V. ABBREVIATIONS AND FORMS

APA	Administrative Procedure Act
ANPR	Advance Notice of Proposed Rulemaking
NEPA	National Environmental Policy Act
OFO	Office of Field Operations
OGC	Office of General Counsel
OMB	Office of Management and Budget
OPPDE	Office of Policy, Program Development and Evaluation
OPHS	Office of Public Health and Science
OA	Office of the Administrator
RDDS	Regulations and Directives Development Staff, OPPDE
RFA	Regulatory Flexibility Act
SBREFA	Small Business Regulatory Enforcement Fairness Act of 1996

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OPI:
OPPDE – Regulations and Directives Development Staff

VI. FORMATION OF DOCKET TEAMS

A. *When is a docket team formed?*

The Deputy Administrator or Associate Deputy Administrator for OPPDE, the Assistant Deputy Administrator for Policy Analysis and Formulation, OPPDE, and the RDDS Director determine that there is a need to form a docket team when:

1. Legislation requires development of a rule.

2. The Administrator or other management requests development of or identifies the need for a rule or ANPR.

3. There is other good cause to establish a team.

B. *How is a docket team created?*

1. Once OPPDE management determines that a docket team is necessary, RDDS prepares a call memo for participation on the team. The memo is sent to the OA Staff Directors, the Deputy Administrators outside of OPPDE, and the OPPDE Assistant Deputy Administrators. The Staff Directors and Deputy Administrators assign staff members to participate in docket teams or delegate to other managers the authority to assign staff members to participate in docket teams. Managers should assign staff members to participate in docket teams in a non-discriminatory manner. The U.S. Department of Agriculture prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status.

2. Each OPPDE Assistant Deputy Administrator meets with the Directors in his or her program and decides whether to be represented on the team. Only staffs that have a direct and significant involvement in the subject of the docket that is to be developed should be represented on the team. RDDS will be represented on all docket teams. An OGC representative may participate on the docket team, when appropriate.

VII. DOCKET TEAM MEETINGS

A. *What is RDDS' role in docket team meetings?*

RDDS informs designated team members of proposed meetings. The RDDS analyst facilitates the work of the team, ensures that the team completes necessary documents, and ensures that the completed documents include required components. The RDDS economist collects economic data from the other team members and develops the economic analysis. The RDDS Director manages the docket team process, ensuring that appropriate offices and staffs are represented on the team, that the team works together effectively, and that the team develops the necessary documents.

B. ***What is the team leader's role?***

During the initial docket team meetings, the team chooses a leader who leads team meetings and informs the OPPDE Assistant Deputy Administrator for Policy Analysis and Formulation of the docket team's progress. The team leader may be the RDDS analyst or any other member of the docket team.

C. ***How will the responsibilities of each team member be determined?***

The docket team determines the responsibilities of each team member for contributing to the development of preliminary and rulemaking documents. If members of the docket team are unable to commit to completing the work, the team leader and RDDS analyst consult with the OPPDE Assistant Deputy Administrator for Policy Analysis and Formulation and the RDDS Director for guidance on how best to address the problem.

VIII. ROLES OF DOCKET TEAM MEMBERS

A. ***What is the RDDS analyst's role in developing the documents for which the team is responsible***?

The RDDS analyst ensures that the team completes necessary documents and that the completed documents include required components. To ensure that the documents include the required components, the RDDS analyst is responsible for development of or incorporation of legal analysis, risk assessment (when required), economic analysis, civil rights analysis, paperwork burden analysis and other analyses required by the statutes and Executive orders. (See Attachment 1.) Other docket team members assist in writing and developing these analyses.

B. ***What are the roles of the other members of the team?***

1. To help ensure that rulemaking documents are based on the best reasonably obtainable scientific, technical, and economic information, other docket team members assist in writing and developing the analyses required in rulemaking documents and other text in rulemaking documents. For example, team members from OPHS assist in drafting scientific information for these documents, such as information on pathogens or chemicals in foods and information on relevant epidemiology. Team members from OPHS may also be responsible for providing risk assessment information. Team members from OFO assist in drafting information on implementation of new regulations or current activities of inspection program personnel.

2. In general, docket team members from outside RDDS perform the following functions:

a. Inform their management officials of the docket team's work and present the views of their office or staff. Keeping management informed of the team's activities allows for the rapid mobilization of resources if necessary for the development of a rule.

b. Assist in the development of preliminary and rulemaking documents.

c. Assist in the preparation of interim reports describing the status of the docket team activities, including the identification of potential problems in meeting projected deadlines, as needed.

d. Draft text for the ANPR, proposed rule, or final rule, as needed, on a subject related to the docket team member's area of expertise.

e. Provide economic, technical, or public health data on a subject related to the docket team member's area of expertise when the data are available and the member has access to this data.

f. Provide assistance in responding to comments to ANPRs and proposed rules, as needed.

g. Provide input and technical assistance in developing FSIS directives that implement final rules. The staff members who participate as docket team members in developing rules would, if possible, serve as members of the directive development team.

IX. CLEARANCE OF DOCUMENTS

A. *Who is responsible for circulating documents through clearance?*

When the team completes work on a document, the RDDS analyst circulates the document through FSIS Deputy Administrators, OA Staff Directors, other appropriate FSIS managers, OGC, and the Departmental and OMB clearance processes. RDDS typically requests that FSIS management provide comments on the document within 5 business days of receipt of the document. The RDDS analyst ensures that the correct version of the document circulates through clearance.

B. *How will the docket team address comments from reviewing offices?*

The RDDS analyst advises the team leader of comments received on documents during the clearance process. The RDDS analyst and the team leader will work together to ensure that the responses to the comments are developed expeditiously, through unilaterally making changes, contacting individual team members, or reconvening the group. As the document is revised in response to comments, RDDS will send the revised versions of the document to the docket team.

C. ***Will members of the docket team meet with reviewing offices during the clearance process?***

If it is necessary to meet with Agency management, the Department, OGC, or OMB on a docket during the clearance process, the OPPDE Assistant Deputy Administrator for Policy Analysis and Formulation, in consultation with the RDDS Director, team leader, and RDDS analyst, will decide who will attend the meeting.

X. PRELIMINARY DOCUMENTS

The docket team develops preliminary documents before a regulation or ANPR is published. Preliminary documents are described as follows:

A. The docket team develops a **Preliminary Report** as quickly as possible. RDDS sends the report to the Deputy Administrator of OPPDE. Once the Deputy Administrator approves the preliminary report, it serves as the basis for development of the workplan, the unified regulatory agenda and regulatory plan, and the rule or ANPR under development. The preliminary report answers the following questions:

1. What is the purpose of the action? What is it intended to accomplish?

2. What is the public health risk or other issue (e.g., misbranding, regulations reform) being addressed and what evidence is there that the issue needs to be addressed?

3. Who will be affected by FSIS' proposed or final action (e.g., which industry segments, which consumers)?

4. What are the options for addressing the problem, and what is the evidence that each option will be effective? For rules that address public health risks, the report should present a range of possible mitigation strategies and a summary of available data on the potential effectiveness of each mitigation strategy.

5. What are the costs and benefits of each option (*brief description)*? How will they be estimated? What are the major areas of uncertainty in estimating costs and benefits? What is the relative public health risk with each option?

6. Is a risk assessment needed? If so, what type of risk assessment is needed?

7. What is the timetable for producing the workplan, other preliminary documents, and the ANPR, proposed rule, or final rule?

8. What are the resource requirements for developing the preliminary and rulemaking documents?

9. How will FSIS enforce the approach being proposed or adopted?

10. What measures will FSIS use to assess the success of the approach being proposed or adopted?

11. What other documents will FSIS need to develop to implement the approach being proposed or adopted?

12. What information is needed to develop the ANPR, proposed rule, or final rule and what are potential sources of this information?

B. The **Workplan** document is used to initiate a regulatory action.

1. The workplan provides a description of the contemplated regulatory action, including objectives, alternatives, and expected results of the regulatory action.

2. The information in the workplan is used to determine the regulatory classification of the regulatory action and designate the appropriate level of oversight. Six terms are used to classify regulatory actions with respect to the degree of oversight that will occur for a 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 and MAJOR as defined by subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996; and EXEMPT.

3. RDDS sends the workplan to the Deputy Administrator of OPPDE for review and signature and then to the Under Secretary for Food Safety for review and signature. The Under Secretary recommends a regulatory classification. The Department's Office of Budget and Policy Analysis then sends the workplan to OMB, and OMB provides the official regulatory classification.

C. **The Unified Regulatory Agenda and Regulatory Plan** are documents that are published in the Federal Register. Any rule that has a workplan that OMB has approved is included in the Unified Regulatory Agenda, which is published on a semi-annual basis. The Unified Regulatory Agenda includes a summary of the rule, the legal authority for the action, and any legal deadline for the action. Additional information on the rules that FSIS considers to be the most significant would be included in The Regulatory Plan, which is published annually.

XI. COMPONENTS OF AN ANPR

FSIS develops an ANPR when the Agency needs additional input from the public before it can develop a proposed rule. An ANPR typically includes:

A. Discussion of relevant existing regulations and statutes.

B. Regulatory changes FSIS is considering proposing.

C. Reasons that FSIS is considering regulatory changes.

D. Alternatives that FSIS is considering.

E. Preliminary discussion of costs and benefits of the changes being considered.

F. Request for comment.

XII. COMPONENTS OF A PROPOSED OR FINAL RULE

A proposed or final rule typically includes:

A. Preamble discussion of the provisions of the rule, and the need for and the statutory bases for the provisions.

B. A regulatory impact analysis estimating the future costs and benefits of the rule and discussion of regulatory alternatives considered. If the rule is designated "non-significant" or "exempt," a detailed regulatory impact analysis is not required.

C. A discussion of the estimated economic impact of the regulations on small businesses.

D. Statements addressing relevant Executive orders.

E. Proposed regulatory provisions or final regulatory provisions that will be codified in the Code of Federal Regulations.

F. A request for comment in a proposed rule, or, in a final rule, a summary of comments received to the proposed rule and FSIS' response to the comments.

G. A risk assessment of the rule for a "major" rule that affects human health, human safety, or the environment.

XIII. DIRECTIVES, NOTICES, AND COMPLIANCE GUIDES

A. *How do inspection-related directives relate to regulations?*

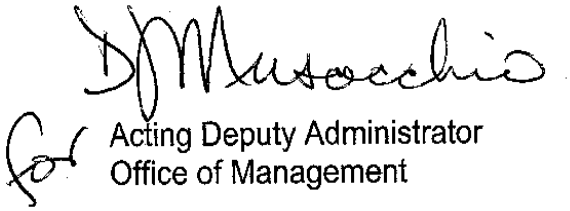
Inspection-related directives are documents that FSIS issues to provide instructions to its personnel in carrying out FSIS functions. FSIS may develop an inspection-related directive in conjunction with a final rule to provide instructions to inspection program personnel on how to perform functions necessary to implement new FSIS regulations. FSIS makes inspection-related directives available to regulated industry, but these directives are not regulations and do not carry the force of law. The staff members who participate as docket team members in developing a final rule would, if possible, serve as members of the directive development team for the final rule. RDDS is responsible for the clearance and issuance of inspection-related directives.

B. ***How does an inspection-related notice differ from an inspection-related directive?***

An inspection-related notice provides instructions and information to FSIS personnel on time-sensitive issues, one-time activities, and clarification of inspection-related directives. Notices expire one year after they are issued. Docket teams are not typically involved in the development of inspection-related notices. RDDS is responsible for the clearance and issuance of inspection-related notices.

C. ***When does FSIS develop compliance guides?***

In conjunction with proposed or final rules, FSIS may develop compliance guides that would assist the regulated industry's compliance with new requirements. For example, compliance guides may include methods proven to be effective at meeting pathogen reduction performance standards or other performance standards in proposed or final regulations. Members of the docket team assist in developing compliance guides related to the docket.



for Acting Deputy Administrator
Office of Management

Attachment

1 Summary of Laws and Executive Orders Governing Regulations Development

SUMMARY OF LAWS AND EXECUTIVE ORDERS GOVERNING REGULATIONS DEVELOPMENT

1. **Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act.** These statutes direct and authorize FSIS to carry out its inspection programs for meat, poultry, eggs, and egg products.

2. **Administrative Procedure Act.** The APA requires Federal Agencies to publish proposed rules in the Federal Register and provide for public participation in rulemaking. The APA also provides that proposed rules are not required in certain situations.

3. **Executive Order 12866, Regulatory Planning and Review.** This Executive order guides all Federal rulemaking. Importantly, it requires Agencies to conduct cost and benefit analyses for proposed and final regulations that are "significant" regulatory actions.

4. **Executive Order 12988, Civil Justice Reform.** This Executive order instructs Agencies to adhere to certain requirements in the development of new and revised regulations to avoid unduly burdening the court system.

5. **Unfunded Mandates Reform Act of 1995.** This Act requires Agencies to estimate the cost of Federal rulemaking to State, local, and tribal governments.

6. **Paperwork Reduction Act of 1995.** This Act requires Agencies to minimize the paperwork burden for individuals or other entities resulting from the collection of information by or for the Federal Government. This Act requires Agencies to assess the paperwork and reporting burden of proposed and final rules.

7. **Regulatory Flexibility Act.** The RFA requires Agencies to estimate the economic impact of their proposed and final regulations on small businesses and to attempt to minimize that impact.

8. **Small Business Regulatory Enforcement Fairness Act of 1996** (*Contains amendments to the APA and RFA*). Among other things, SBREFA requires agencies to publish an easily understood guide to assist small business to comply with regulations that undergo a required RFA analysis.

9. **The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354, Section 304).** This Act requires that any regulation published by USDA concerning human health, human safety or the environment and having an annual economic impact of at least $100 million in 1994 dollars contain a risk assessment and cost-benefit analysis.

10. **Departmental Regulation 1512-1, Regulatory Decisionmaking Requirements.** These regulations are intended to provide a consistent process for the development and review of all USDA regulatory actions.

11. **National Environmental Policy Act (42 U.S.C. 4321 et seq.) and the Council for Environmental Quality Regulations (40 CFR parts 1500-1508).** This Act and these regulations require Federal Agencies to conduct environmental impact analyses for regulatory actions. FSIS has been granted a categorical exclusion from NEPA requirements by USDA regulation (7 CFR 1b.4), unless "the agency head determines that an action may have a significant environmental effect."

12. **Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.** This Executive order requires Federal Agencies to consider the potential impact of regulations on environmental and health conditions in low-income and minority communities.

13. **Executive Order 13132, Federalism.** This Executive order requires agencies to submit a certification with all final rules that impose substantial direct compliance costs on State or local governments or that preempt state law.