

**FISH AND WILDLIFE SERVICE
ADMINISTRATIVE PROCEDURE**

2.1 What is the purpose of this chapter? This chapter provides guidance for preparing rulemaking actions. The Departmental Manual at 318 DM also provides guidance on the requirements for drafting rules, Regulatory Action Alert forms, and other related documents.

2.2 How does a program office decide if a rule is necessary or advisable? To decide whether rulemaking is necessary or advisable, first determine whether adequate authority exists for us to publish a rule. If we have the authority, then ask yourself the following questions:

A. Why should the Service publish this rule? Consider why we need the regulation or what problem it will solve. Some reasons for rulemaking include:

- (1) A specific legislative requirement,
- (2) Program deficiencies identified as the result of an audit,
- (3) Chronic abuses or problems that need a remedy, or
- (4) A need to show the public that we will be consistent in the way that we administer our programs.

B. Are there any alternatives to rulemaking that are feasible? For the need you identified by asking the question above, consider the possible alternatives to rulemaking and whether or not they are feasible, such as a revision to the Fish and Wildlife Service Manual or other internal policy document.

2.3 What do I need to do before I begin drafting a rule? Before drafting Federal Register documents, you should review 318 DM and this Part (Part 202) of the Service Manual. You can find additional guidance at 1 CFR Parts 18, 21, 22, and 51. The Division of Policy and Directives Management (PDM) encourages program offices to consult with them before the program begins drafting documents. PDM has copies of all documents referenced in Part 202. Executive Order (E.O.) 12866, Regulatory Planning and Review, requires that you develop specific planning documents before drafting a rulemaking document:

A. Unified Agenda. E.O. 12866 requires that we publish the Unified Agenda of Regulatory and Deregulatory Actions, a list of anticipated rulemaking actions for the upcoming 12-month period.

- (1) PDM prepares the Service's portion of the Unified Agenda. PDM typically solicits data for the Unified Agenda from the program offices every February and August.
- (2) PDM provides Agenda Review Report forms to the programs on all the rulemaking actions we published in the previous Unified Agenda. The programs must update the information on these forms and return them to PDM.
- (3) Program offices must also alert PDM to new rulemaking actions that they anticipate publishing in some stage during the next 12 months. To do this, the programs need to complete a Regulatory Information Data form (FWS Form 3-2394) and send it to PDM.
- (4) Upon receiving a Regulatory Information Data form for a new planned action, PDM provides a Regulation Identifier Number (RIN) for the new rulemaking action (see 202 FW 1.6 for definition of a RIN).

B. Regulatory Alert. Program offices must:

- (1) Prepare a Regulatory Action Alert form (FWS Form 3-2188). This Department-mandated form describes a proposed rulemaking action, any possible controversy or sensitivity, and the anticipated

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publication date. It gives other Department of the Interior bureaus information that can help them decide if they want to participate in the development of the rule.

(2) Send the form to PDM. PDM sends it to the Department's Office of the Executive Secretariat and Regulatory Affairs (OES) for circulation to the other bureaus. FWS Form 3–2188 is available on our [Forms Web site](#).

C. OMB Regulatory Report. E.O. 12866 also requires that we work with the Office of Management and Budget (OMB) to designate significance for rulemaking actions.

(1) OMB reviews rules that they designate as significant. We cannot publish a significant rule in the Federal Register until OMB has reviewed and approved it. OMB makes the final determination of significance. Significant rules are those that meet any of the four parameters listed in 202 FW 1.6S (see definition of significant rule).

(2) We provide our initial determinations of significance to OMB through quarterly reports of upcoming regulatory actions. PDM prepares the Service report and submits it to OES for incorporation into a single Departmental report. OES sends the Department's report to OMB.

(3) When PDM requests data for the OMB regulatory report, the program offices must provide the data in the table format requested. See Exhibit 1 for an example of OMB regulatory report data format. The data include:

(a) The RIN of the rulemaking action, title, and CFR citation,

(b) The type/stage of the action,

(c) The designation of significance under E.O. 12866 (significant or not significant),

(d) Whether the action has a court-ordered or statutory due date and what that date is (and exactly what the due date requires—e.g., delivery to OFR, publication, etc.),

(e) Any OMB past response for this action on a prior OMB regulatory report,

(f) A brief description of the action,

(g) A point of contact and telephone number for more information, and

(h) The date the document will be ready for OMB review.

(4) OES sends the reports of upcoming regulatory actions to OMB on a quarterly basis, just before January 1, April 1, July 1, and October 1.

(5) OMB has 10 working days to respond to the regulatory report. PDM then advises the program offices if OMB has changed any of the designations that we have proposed. OMB generally designates rules as:

(a) Significant: OMB will formally review the rule, generally in 90 days or less, using the procedures in E.O. 12866,

(b) Not significant but needs informal review: OMB will conduct an informal review of the rule, generally in 10 days or less, or

(c) Not significant: OMB will not review the rule.

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(6) The program offices must track OMB's designations. When drafting a significant rule, the program offices must include certain language in the preamble. The language is found in 318 DM 3, Appendix 1.

2.4 What are the principles of regulation that a program office should consider before and during rulemaking? Keep the following principles, from E.O. 12866, in mind before and during rulemaking:

A. Identify the problem you intend to solve through rulemaking and assess the significance of that problem.

B. Examine whether existing regulations (or other laws) have created or contributed to the problem that you intend to correct through the new regulation and whether we should modify those regulations or other laws to achieve the intended goal of the regulation more effectively.

C. 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 that the public can use to make choices.

D. In setting priorities, consider the degree and nature of risks posed by various substances and activities within our jurisdiction.

E. Design the regulation in the most cost-effective manner to achieve the regulatory objectives. Consult our Division of Economics for assistance. In some cases, the Department's Office of Policy Analysis will also assist. Consider:

(1) Incentives for innovation, consistency, and predictability;

(2) Enforcement and compliance costs to the Government, regulated entities, and the public;

(3) Flexibility;

(4) Distributive impacts; and

(5) Equity.

F. Assess the costs and benefits of the intended regulation. Propose the regulation only when you determine that the benefits of the intended regulation justify its cost. Consult with the Division of Economics for help with this analysis.

G. Base regulatory decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

H. Identify and assess alternative forms of regulation and, to the extent feasible, specify performance objectives rather than specifying the behavior or manner of compliance that regulated entities must adopt.

I. Before proposing a rule, whenever feasible, work with and for State, local, and tribal governmental entities by:

(1) Seeking their views before imposing regulatory requirements that might significantly or uniquely affect them.

(2) Assessing the effects of the regulation on their governments, including the availability of resources to carry out any mandates.

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(3) Minimizing the burdens that uniquely or significantly affect them, consistent with achieving regulatory objectives.

(4) Keeping our regulatory actions consistent with related State, local, and tribal regulatory functions.

J. Avoid regulations that are inconsistent or incompatible with, or duplicative of, other Federal regulations.

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. Take into account, among other things and to the extent practicable, the costs of cumulative regulations.

L. Draft regulations so that they are simple and easy to understand, with the goal of minimizing the potential for uncertainty and any subsequent litigation.

2.5 Is it possible for a program office to draft a rule that is not included in the Unified Agenda or the OMB regulatory report? Yes; however, you should alert PDM about the rule as soon as possible so that it can notify OMB.

/sgd/ Daniel M. Ashe
DEPUTY DIRECTOR

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