

**§ 401.21**

**§ 401.21 Patents and inventions.**

Determination of the patent rights in any inventions or discoveries resulting from work under project agreements entered into pursuant to the Act shall be consistent with the "Government Patent Policy" (President's memorandum for Heads of Executive Departments and Agencies, August 23, 1971, and statement of Government Patent Policy as printed in 36 FR 16889).

**§ 401.22 Civil rights.**

Each application for Federal assistance, grant-in-aid award, or project agreement shall be supported by a statement of assurances executed by the Cooperator providing that the project will be carried out in accordance with title VI, Nondiscrimination in federally Assisted Programs of the Civil Rights Act of 1964 and with the Secretary's regulations promulgated thereunder.

**§ 401.23 Audits.**

The State is required to conduct an audit at least every two years in accordance with the provisions of Attachment P OMB Circular A-102. Failure to conduct audits as required may result in withholding of grant payments or such other sanctions as the Secretary may deem appropriate.

[49 FR 30074, July 26, 1984]

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AUTHORITY: 16 U.S.C. 1531 *et seq.*

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

**Subpart A—General**

**§ 402.01 Scope.**

(a) This part interprets and implements sections 7(a)-(d) [16 U.S.C. 1536(a)-(d)] of the Endangered Species Act of 1973, as amended ("Act"). Section 7(a) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical ("critical habitat"). Section

7(a)(1) of the Act directs Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or of Commerce, as appropriate, to utilize their authorities to further the purposes of the Act by carrying out conservation programs for listed species. Such affirmative conservation programs must comply with applicable permit requirements (50 CFR parts 17, 220, 222, and 227) for listed species and should be coordinated with the appropriate Secretary. Section 7(a)(2) of the Act requires every Federal agency, in consultation with and with the assistance of the Secretary, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat. Section 7(a)(3) of the Act authorizes a prospective permit or license applicant to request the issuing Federal agency to enter into early consultation with the Service on a proposed action to determine whether such action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Section 7(a)(4) of the Act requires Federal agencies to confer with the Secretary on any action that is likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat. Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat. Biological assessments are required under section 7(c) of the Act if listed species or critical habitat may be present in the area affected by any major construction activity as defined in § 404.02. Section 7(d) of the Act prohibits Federal agencies and applicants from making any irreversible or irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternatives which would avoid jeopardizing the continued existence of listed species or resulting in

the destruction or adverse modification of critical habitat. Section 7(e)-(o)(1) of the Act provide procedures for granting exemptions from the requirements of section 7(a)(2). Regulations governing the submission of exemption applications are found at 50 CFR part 451, and regulations governing the exemption process are found at 50 CFR parts 450, 452, and 453.

(b) The U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) share responsibilities for administering the Act. The Lists of Endangered and Threatened Wildlife and Plants are found in 50 CFR 17.11 and 17.12 and the designated critical habitats are found in 50 CFR 17.95 and 17.96 and 50 CFR part 226. Endangered or threatened species under the jurisdiction of the NMFS are located in 50 CFR 222.23(a) and 227.4. If the subject species is cited in 50 CFR 222.23(a) or 227.4, the Federal agency shall contact the NMFS. For all other listed species the Federal Agency shall contact the FWS.

#### § 402.02 Definitions.

*Act* means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 *et seq.*

*Action* means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

- (a) actions intended to conserve listed species or their habitat;
- (b) the promulgation of regulations;
- (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or
- (d) actions directly or indirectly causing modifications to the land, water, or air.

*Action area* means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

*Applicant* refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

*Biological assessment* refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

*Biological opinion* is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

*Conference* is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

*Conservation recommendations* are suggestions of the Service regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.

*Critical habitat* refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

*Cumulative effects* are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

*Designated non-Federal representative* refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

*Destruction or adverse modification* means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

*Director* refers to the Assistant Administrator for Fisheries for the National Marine Fisheries Service, or his or her authorized representative; or the Director of the U.S. Fish and Wildlife Service, or his or her authorized representative.

*Early consultation* is a process requested by a Federal agency on behalf

of a prospective applicant under section 7(a)(3) of the Act.

*Effects of the action* are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. (See § 402.17).

*Environmental baseline* refers to the condition of the listed species or its designated critical habitat in the action area, without the consequences to the listed species or designated critical habitat caused by the proposed action. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. The consequences to listed species or designated critical habitat from ongoing agency activities or existing agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.

*Formal consultation* is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

*Framework programmatic action* means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

*Incidental take* refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

*Informal consultation* is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

*Jeopardize the continued existence of* means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

*Listed species* means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11–17.12.

*Major construction activity* is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

*Mixed programmatic action* means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

*Preliminary biological opinion* refers to an opinion issued as a result of early consultation.

*Programmatic consultation* is a consultation addressing an agency's multiple actions on a program, region, or other basis. Programmatic consultations allow the Services to consult on the effects of programmatic actions such as:

(1) Multiple similar, frequently occurring, or routine actions expected to

be implemented in particular geographic areas; and

(2) A proposed program, plan, policy, or regulation providing a framework for future proposed actions.

*Proposed critical habitat* means habitat proposed in the FEDERAL REGISTER to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

*Proposed species* means any species of fish, wildlife, or plant that is proposed in the FEDERAL REGISTER to be listed under section 4 of the Act.

*Reasonable and prudent alternatives* refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

*Reasonable and prudent measures* refer to those actions the Director believes necessary or appropriate to minimize the impacts, *i.e.*, amount or extent, of incidental take.

*Recovery* means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

*Service* means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

[51 FR 19957, June 3, 1986, as amended at 73 FR 76286, Dec. 16, 2008; 74 FR 20422, May 4, 2009; 80 FR 26844, May 11, 2015; 81 FR 7225, Feb. 11, 2016; 84 FR 45016, Aug. 27, 2019]

#### § 402.03 Applicability.

Section 7 and the requirements of this part apply to all actions in which there is discretionary Federal involvement or control.

[74 FR 20423, May 4, 2009]

#### § 402.04 Counterpart regulations.

The consultation procedures set forth in this part may be superseded for a particular Federal agency by joint

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counterpart regulations among that agency, the Fish and Wildlife Service, and the National Marine Fisheries Service. Such counterpart regulations shall be published in the FEDERAL REGISTER in proposed form and shall be subject to public comment for at least 60 days before final rules are published.

#### § 402.05 Emergencies.

(a) Where emergency circumstances mandate the need to consult in an expedited manner, consultation may be conducted informally through alternative procedures that the Director determines to be consistent with the requirements of sections 7(a)–(d) of the Act. This provision applies to situations involving acts of God, disasters, casualties, national defense or security emergencies, etc.

(b) Formal consultation shall be initiated as soon as practicable after the emergency is under control. The Federal agency shall submit information on the nature of the emergency action(s), the justification for the expedited consultation, and the impacts to endangered or threatened species and their habitats. The Service will evaluate such information and issue a biological opinion including the information and recommendations given during the emergency consultation.

#### § 402.06 Coordination with other environmental reviews.

(a) Consultation, conference, and biological assessment procedures under section 7 may be consolidated with interagency cooperation procedures required by other statutes, such as the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*, implemented at 40 CFR parts 1500–1508) or the Fish and Wildlife Coordination Act (FWCA) (16 U.S.C. 661 *et seq.*). Satisfying the requirements of these other statutes, however, does not in itself relieve a Federal agency of its obligations to comply with the procedures set forth in this part or the substantive requirements of section 7. The Service will attempt to provide a coordinated review and analysis of all environmental requirements.

(b) Where the consultation or conference has been consolidated with the interagency cooperation procedures re-

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quired by other statutes such as NEPA or FWCA, the results should be included in the documents required by those statutes.

#### § 402.07 Designation of lead agency.

When a particular action involves more than one Federal agency, the consultation and conference responsibilities may be fulfilled through a lead agency. Factors relevant in determining an appropriate lead agency include the time sequence in which the agencies would become involved, the magnitude of their respective involvement, and their relative expertise with respect to the environmental effects of the action. The Director shall be notified of the designation in writing by the lead agency.

#### § 402.08 Designation of non-Federal representative.

A Federal agency may designate a non-Federal representative to conduct informal consultation or prepare a biological assessment by giving written notice to the Director of such designation. If a permit or license applicant is involved and is not the designated non-Federal representative, then the applicant and Federal agency must agree on the choice of the designated non-Federal representative. If a biological assessment is prepared by the designated non-Federal representative, the Federal agency shall furnish guidance and supervision and shall independently review and evaluate the scope and contents of the biological assessment. The ultimate responsibility for compliance with section 7 remains with the Federal agency.

#### § 402.09 Irreversible or ir retrievable commitment of resources.

After initiation or reinitiation of consultation required under section 7(a)(2) of the Act, the Federal agency and any applicant shall make no irreversible or ir retrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternatives which would avoid violating section 7(a)(2). This prohibition is in force during the consultation

process and continues until the requirements of section 7(a)(2) are satisfied. This provision does not apply to the conference requirement for proposed species or proposed critical habitat under section 7(a)(4) of the Act.

### Subpart B—Consultation Procedures

#### § 402.10 Conference on proposed species or proposed critical habitat.

(a) Each Federal agency shall confer with the Service on any action which is likely to jeopardize the continued existence of any proposed species or result in the destruction or adverse modification of proposed critical habitat. The conference is designed to assist the Federal agency and any applicant in identifying and resolving potential conflicts at an early stage in the planning process.

(b) The Federal agency shall initiate the conference with the Director. The Service may request a conference if, after a review of available information, it determines that a conference is required for a particular action.

(c) A conference between a Federal agency and the Service shall consist of informal discussions concerning an action that is likely to jeopardize the continued existence of the proposed species or result in the destruction or adverse modification of the proposed critical habitat at issue. Applicants may be involved in these informal discussions to the greatest extent practicable. During the conference, the Service will make advisory recommendations, if any, on ways to minimize or avoid adverse effects. If the proposed species is subsequently listed or the proposed critical habitat is designated prior to completion of the action, the Federal agency must review the action to determine whether formal consultation is required.

(d) If requested by the Federal agency and deemed appropriate by the Service, the conference may be conducted in accordance with the procedures for formal consultation in § 402.14. An opinion issued at the conclusion of the conference may be adopted as the biological opinion when the species is listed or critical habitat is designated, but only if no significant new information is de-

veloped (including that developed during the rulemaking process on the proposed listing or critical habitat designation) and no significant changes to the Federal action are made that would alter the content of the opinion. An incidental take statement provided with a conference opinion does not become effective unless the Service adopts the opinion once the listing is final.

(e) The conclusions reached during a conference and any recommendations shall be documented by the Service and provided to the Federal agency and to any applicant. The style and magnitude of this document will vary with the complexity of the conference. If formal consultation also is required for a particular action, then the Service will provide the results of the conference with the biological opinion.

#### § 402.11 Early consultation.

(a) *Purpose.* Early consultation is designed to reduce the likelihood of conflicts between listed species or critical habitat and proposed actions and occurs prior to the filing of an application for a Federal permit or license. Although early consultation is conducted between the Service and the Federal agency, the prospective applicant should be involved throughout the consultation process.

(b) *Request by prospective applicant.* If a prospective applicant has reason to believe that the prospective action may affect listed species or critical habitat, it may request the Federal agency to enter into early consultation with the Service. The prospective applicant must certify in writing to the Federal agency that (1) it has a definitive proposal outlining the action and its effects and (2) it intends to implement its proposal, if authorized.

(c) *Initiation of early consultation.* If the Federal agency receives the prospective applicant's certification in paragraph (b) of this section, then the Federal agency shall initiate early consultation with the Service. This request shall be in writing and contain the information outlined in § 402.14(c) and, if the action is a major construction activity, the biological assessment as outlined in § 402.12.

(d) *Procedures and responsibilities.* The procedures and responsibilities for

early consultation are the same as outlined in § 402.14(c)–(j) for formal consultation, except that all references to the “applicant” shall be treated as the “prospective applicant” and all references to the “biological opinion” or the “opinion” shall be treated as the “preliminary biological opinion” for the purpose of this section.

(e) *Preliminary biological opinion.* The contents and conclusions of a preliminary biological opinion are the same as for a biological opinion issued after formal consultation except that the incidental take statement provided with a preliminary biological opinion does not constitute authority to take listed species.

(f) *Confirmation of preliminary biological opinion as final biological opinion.* A preliminary biological opinion may be confirmed as a biological opinion issued after formal consultation if the Service reviews the proposed action and finds that there have been no significant changes in the action as planned or in the information used during the early consultation. A written request for confirmation of the preliminary biological opinion should be submitted after the prospective applicant applies to the Federal agency for a permit or license but prior to the issuance of such permit or license. Within 45 days of receipt of the Federal agency’s request, the Service shall either:

(1) Confirm that the preliminary biological opinion stands as a final biological opinion; or

(2) If the findings noted above cannot be made, request that the Federal agency initiate formal consultation.

#### § 402.12 Biological assessments.

(a) *Purpose.* A biological assessment shall evaluate the potential effects of the action on listed and proposed species and designated and proposed critical habitat and determine whether any such species or habitat are likely to be adversely affected by the action and is used in determining whether formal consultation or a conference is necessary.

(b) *Preparation requirement.* (1) The procedures of this section are required for Federal actions that are “major construction activities”; provided that

a contract for construction was not entered into or actual construction was not begun on or before November 10, 1978. Any person, including those who may wish to apply for an exemption from section 7(a)(2) of the Act, may prepare a biological assessment under the supervision of the Federal agency and in cooperation with the Service consistent with the procedures and requirements of this section. An exemption from the requirements of section 7(a)(2) is not permanent unless a biological assessment has been prepared.

(2) The biological assessment shall be completed before any contract for construction is entered into and before construction is begun.

(c) *Request for information.* The Federal agency or the designated non-Federal representative shall convey to the Director either (1) a written request for a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area; or (2) a written notification of the species and critical habitat that are being included in the biological assessment.

(d) *Director’s response.* Within 30 days of receipt of the notification of, or the request for, a species list, the Director shall either concur with or revise the list or, in those cases where no list has been provided, advise the Federal agency or the designated non-Federal representative in writing whether, based on the best scientific and commercial data available, any listed or proposed species or designated or proposed critical habitat may be present in the action area. In addition to listed and proposed species, the Director will provide a list of candidate species that may be present in the action area. Candidate species refers to any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule. Although candidate species have no legal status and are accorded no protection under the Act, their inclusion will alert the Federal agency of potential proposals or listings.

(1) If the Director advises that no listed species or critical habitat may be present, the Federal agency need not prepare a biological assessment

and further consultation is not required. If only proposed species or proposed critical habitat may be present in the action area, then the Federal agency must confer with the Service if required under § 402.10, but preparation of a biological assessment is not required unless the proposed listing and/or designation becomes final.

(2) If a listed species or critical habitat may be present in the action area, the Director will provide a species list or concur with the species list provided. The Director also will provide available information (or references thereto) regarding these species and critical habitat, and may recommend discretionary studies or surveys that may provide a better information base for the preparation of an assessment. Any recommendation for studies or surveys is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

(e) *Verification of current accuracy of species list.* If the Federal agency or the designated non-Federal representative does not begin preparation of the biological assessment within 90 days of receipt of (or concurrence with) the species list, the Federal agency or the designated non-Federal representative must verify (formally or informally) with the Service the current accuracy of the species list at the time the preparation of the assessment is begun.

(f) *Contents.* The contents of a biological assessment are at the discretion of the Federal agency and will depend on the nature of the Federal action. The following may be considered for inclusion:

(1) The results of an on-site inspection of the area affected by the action to determine if listed or proposed species are present or occur seasonally.

(2) The views of recognized experts on the species at issue.

(3) A review of the literature and other information.

(4) An analysis of the effects of the action on the species and habitat, including consideration of cumulative effects, and the results of any related studies.

(5) An analysis of alternate actions considered by the Federal agency for the proposed action.

(g) *Incorporation by reference.* If a proposed action requiring the preparation of a biological assessment is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may fulfill the biological assessment requirement for the proposed action by incorporating by reference the earlier biological assessment, plus any supporting data from other documents that are pertinent to the consultation, into a written certification that:

(1) The proposed action involves similar impacts to the same species in the same geographic area;

(2) No new species have been listed or proposed or no new critical habitat designated or proposed for the action area; and

(3) The biological assessment has been supplemented with any relevant changes in information.

(h) *Permit requirements.* If conducting a biological assessment will involve the taking of a listed species, a permit under section 10 of the Act (16 U.S.C. 1539) and part 17 of this title (with respect to species under the jurisdiction of the FWS) or parts 220, 222, and 227 of this title (with respect to species under the jurisdiction of the NMFS) is required.

(i) *Completion time.* The Federal agency or the designated non-Federal representative shall complete the biological assessment within 180 days after its initiation (receipt of or concurrence with the species list) unless a different period of time is agreed to by the Director and the Federal agency. If a permit or license applicant is involved, the 180-day period may not be extended unless the agency provides the applicant, before the close of the 180-day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why such an extension is necessary.

(j) *Submission of biological assessment.* The Federal agency shall submit the completed biological assessment to the Director for review. The Director will respond in writing within 30 days as to whether or not he concurs with the findings of the biological assessment.

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At the option of the Federal agency, formal consultation may be initiated under §402.14(c) concurrently with the submission of the assessment.

(k) *Use of the biological assessment.* (1) The Federal agency shall use the biological assessment in determining whether formal consultation or a conference is required under §402.14 or §402.10, respectively. If the biological assessment indicates that there are no listed species or critical habitat present that are likely to be adversely affected by the action and the Director concurs as specified in paragraph (j) of this section, then formal consultation is not required. If the biological assessment indicates that the action is not likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

### § 402.13 Informal consultation.

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

(c) If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(1) A written request for concurrence with a Federal agency's not likely to

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adversely affect determination shall include information similar to the types of information described for formal consultation at §402.14(c)(1) sufficient for the Service to determine if it concurs.

(2) Upon receipt of a written request consistent with paragraph (c)(1) of this section, the Service shall provide written concurrence or non-concurrence with the Federal agency's determination within 60 days. The 60-day timeframe may be extended upon mutual consent of the Service, the Federal agency, and the applicant (if involved), but shall not exceed 120 days total from the date of receipt of the Federal agency's written request consistent with paragraph (c)(1) of this section.

[74 FR 20423, May 4, 2009, as amended at 84 FR 45016, Aug. 27, 2019]

### § 402.14 Formal consultation.

(a) *Requirement for formal consultation.* Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) *Exceptions.* (1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under §402.12 or as a result of informal consultation with the Service under §402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under §402.11, is confirmed as the final biological opinion.

(c) *Initiation of formal consultation.* (1) A written request to initiate formal consultation shall be submitted to the Director and shall include:

(i) A description of the proposed action, including any measures intended to avoid, minimize, or offset effects of the action. Consistent with the nature and scope of the proposed action, the description shall provide sufficient detail to assess the effects of the action on listed species and critical habitat, including:

(A) The purpose of the action;  
 (B) The duration and timing of the action;  
 (C) The location of the action;  
 (D) The specific components of the action and how they will be carried out;  
 (E) Maps, drawings, blueprints, or similar schematics of the action; and  
 (F) Any other available information related to the nature and scope of the proposed action relevant to its effects on listed species or designated critical habitat.

(ii) A map or description of all areas to be affected directly or indirectly by the Federal action, and not merely the immediate area involved in the action (*i.e.*, the action area as defined at § 402.02).

(iii) Information obtained by or in the possession of the Federal agency and any applicant on the listed species and designated critical habitat in the action area (as required by paragraph (c)(1)(ii) of this section), including available information such as the presence, abundance, density, or periodic occurrence of listed species and the condition and location of the species' habitat, including any critical habitat.

(iv) A description of the effects of the action and an analysis of any cumulative effects.

(v) A summary of any relevant information provided by the applicant, if available.

(vi) Any other relevant available information on the effects of the proposed action on listed species or designated critical habitat, including any relevant reports such as environmental impact statements and environmental assessments.

(2) A Federal agency may submit existing documents prepared for the pro-

posed action such as NEPA analyses or other reports in substitution for the initiation package outlined in this paragraph (c). However, any such substitution shall be accompanied by a written summary specifying the location of the information that satisfies the elements above in the submitted document(s).

(3) Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12.

(4) Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area, a programmatic consultation, or a segment of a comprehensive plan. The provision in this paragraph (c)(4) does not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole.

(d) *Responsibility to provide best scientific and commercial data available.* The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) *Duration and extension of formal consultation.* Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

(2) The information that is required to complete the consultation, and

(3) The estimated date on which the consultation will be completed. A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) *Additional data.* When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) *Service responsibilities.* Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status and environmental baseline of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to

whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1) through (3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data

available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) *Biological opinions.* (1) The biological opinion shall include:

(i) A summary of the information on which the opinion is based;

(ii) A detailed discussion of the environmental baseline of the listed species and critical habitat;

(iii) A detailed discussion of the effects of the action on listed species or critical habitat; and

(iv) The Service's opinion on whether the action is:

(A) Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion).

(2) A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(3) The Service may adopt all or part of:

(i) A Federal agency's initiation package; or

(ii) The Service's analysis required to issue a permit under section 10(a) of the Act in its biological opinion.

(4) A Federal agency and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service's biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. The Federal agency

and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat, and other relevant factors to determine whether an action or a class of actions is appropriate for this process. The Federal agency and the Service may develop coordination procedures that would facilitate adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service, if appropriate, as the Service's biological opinion in fulfillment of section 7(b) of the Act.

(i) *Incidental take.* (1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, *i.e.*, the amount or extent, of such incidental taking on the species (A surrogate (*e.g.*, similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or

any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinstate consultation immediately.

(5) Any taking which is subject to a statement as specified in paragraph (i)(1) of this section and which is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(6) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) *Conservation recommendations.* The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) *Incremental steps.* When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(1) *Expedited consultations.* Expedited consultation is an optional formal consultation process that a Federal agency and the Service may enter into upon mutual agreement. To determine whether an action or a class of actions is appropriate for this type of consultation, the Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat and other relevant factors. Conservation actions whose primary purpose is to have beneficial effects on listed species will likely be considered appropriate for expedited consultation.

(1) *Expedited timelines.* Upon agreement to use this expedited consultation process, the Federal agency and the Service shall establish the expedited timelines for the completion of this consultation process.

(2) *Federal agency responsibilities.* To request initiation of expedited consultation, the Federal agency shall provide all the information required to initiate consultation under paragraph (c) of this section. To maximize efficiency and ensure that it develops the

appropriate level of information, the Federal agency is encouraged to develop its initiation package in coordination with the Service.

(3) *Service responsibilities.* In addition to the Service's responsibilities under the provisions of this section, the Service will:

(i) Provide relevant species information to the Federal agency and guidance to assist the Federal agency in completing its effects analysis in the initiation package; and

(ii) Conclude the consultation and issue a biological opinion within the agreed-upon timeframes.

(m) *Termination of consultation.* (1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

[51 FR 19957, June 3, 1986, as amended at 54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015; 84 FR 45016, Aug. 27, 2019]

#### **§ 402.15 Responsibilities of Federal agency following issuance of a biological opinion.**

(a) Following the issuance of a biological opinion, the Federal agency shall determine whether and in what manner to proceed with the action in light of its section 7 obligations and the Service's biological opinion.

(b) If a jeopardy biological opinion is issued, the Federal agency shall notify the Service of its final decision on the action.

(c) If the Federal agency determines that it cannot comply with the requirements of section 7(a)(2) after consultation with the Service, it may apply for an exemption. Procedures for exemption applications by Federal agencies and others are found in 50 CFR part 451.

#### **§ 402.16 Reinitiation of consultation.**

(a) Reinitiation of consultation is required and shall be requested by the Federal agency or by the Service, where discretionary Federal involvement or control over the action has been retained or is authorized by law and:

(1) If the amount or extent of taking specified in the incidental take statement is exceeded;

(2) If new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered;

(3) If the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or

(4) If a new species is listed or critical habitat designated that may be affected by the identified action.

(b) An agency shall not be required to reinitiate consultation after the approval of a land management plan prepared pursuant to 43 U.S.C. 1712 or 16 U.S.C. 1604 upon listing of a new species or designation of new critical habitat if the land management plan has been adopted by the agency as of the date of listing or designation, provided that any authorized actions that may affect the newly listed species or designated critical habitat will be addressed through a separate action-specific consultation. This exception to reinitiation of consultation shall not apply to those land management plans prepared pursuant to 16 U.S.C. 1604 if:

(1) Fifteen years have passed since the date the agency adopted the land management plan prepared pursuant to 16 U.S.C. 1604; and

(2) Five years have passed since the enactment of Public Law 115-141 [March 23, 2018] or the date of the listing of a species or the designation of critical habitat, whichever is later.

[51 FR 19957, June 3, 1986, as amended at 84 FR 45017, Aug. 27, 2019]

#### **§ 402.17 Other provisions.**

(a) *Activities that are reasonably certain to occur.* A conclusion of reasonably certain to occur must be based on

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clear and substantial information, using the best scientific and commercial data available. Factors to consider when evaluating whether activities caused by the proposed action (but not part of the proposed action) or activities reviewed under cumulative effects are reasonably certain to occur include, but are not limited to:

(1) Past experiences with activities that have resulted from actions that are similar in scope, nature, and magnitude to the proposed action;

(2) Existing plans for the activity; and

(3) Any remaining economic, administrative, and legal requirements necessary for the activity to go forward.

(b) *Consequences caused by the proposed action.* To be considered an effect of a proposed action, a consequence must be caused by the proposed action (i.e., the consequence would not occur but for the proposed action and is reasonably certain to occur). A conclusion of reasonably certain to occur must be based on clear and substantial information, using the best scientific and commercial data available. Considerations for determining that a consequence to the species or critical habitat is not caused by the proposed action include, but are not limited to:

(1) The consequence is so remote in time from the action under consultation that it is not reasonably certain to occur; or

(2) The consequence is so geographically remote from the immediate area involved in the action that it is not reasonably certain to occur; or

(3) The consequence is only reached through a lengthy causal chain that involves so many steps as to make the consequence not reasonably certain to occur.

(c) *Required consideration.* The provisions in paragraphs (a) and (b) of this section must be considered by the action agency and the Services.

[84 FR 45018, Aug. 27, 2019]

## Subpart C—Counterpart Regulations for Implementing the National Fire Plan

SOURCE: 68 FR 68264, Dec. 8, 2003, unless otherwise noted.

## 50 CFR Ch. IV (10–1–23 Edition)

### § 402.30 Definitions.

The definitions in § 402.02 are applicable to this subpart. In addition, the following definitions are applicable only to this subpart.

*Action Agency* refers to the Department of Agriculture Forest Service (FS) or the Department of the Interior Bureau of Indian Affairs (BIA), Bureau of Land Management (BLM), Fish and Wildlife Service (FWS), or National Park Service (NPS).

*Alternative Consultation Agreement (ACA)* is the agreement described in § 402.33 of this subpart.

*Fire Plan Project* is an action determined by the Action Agency to be within the scope of the NFP as defined in this section.

*National Fire Plan (NFP)* is the September 8, 2000, report to the President from the Departments of the Interior and Agriculture entitled “Managing the Impact of Wildfire on Communities and the Environment” outlining a new approach to managing fires, together with the accompanying budget requests, strategies, plans, and direction, or any amendments thereto.

*Service Director* refers to the FWS Director or the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration.

### § 402.31 Purpose.

The purpose of these counterpart regulations is to enhance the efficiency and effectiveness of the consultation process under section 7 of the ESA for Fire Plan Projects by providing an optional alternative to the procedures found in §§ 402.13 and 402.14(b) of this part. These regulations permit an Action Agency to enter into an Alternative Consultation Agreement (ACA) with the Service, as described in § 402.33, which will allow the Action Agency to determine that a Fire Plan Project is “not likely to adversely affect” (NLAA) a listed species or designated critical habitat without formal or informal consultation with the Service or written concurrence from the Service. An NLAA determination for a Fire Plan Project made under an ACA, as described in § 402.33, completes the Action Agency’s statutory obligation to consult with the Service for that Project. In situations where the Action

Agency does not make an NLAA determination under the ACA, the Action Agency would still be required to conduct formal consultation with the Service when required by § 402.14. This process will be as protective to listed species and designated critical habitat as the process established in subpart B of this part. The standards and requirements for formal consultation under subpart B for Fire Plan Projects that do not receive an NLAA determination are unchanged.

**§ 402.32 Scope.**

(a) Section 402.33 establishes a process by which an Action Agency may determine that a proposed Fire Plan Project is not likely to adversely affect any listed species or designated critical habitat without conducting formal or informal consultation or obtaining written concurrence from the Service.

(b) Section 402.34 establishes the Service's oversight responsibility and the standard for review under this subpart.

(c) Nothing in this subpart C precludes an Action Agency at its discretion from initiating early, informal, or formal consultation as described in §§ 402.11, 402.13, and 402.14, respectively.

(d) The authority granted in this subpart is applicable to an Action Agency only where the Action Agency has entered into an ACA with the Service. An ACA entered into with one Service is valid with regard to listed species and designated critical habitat under the jurisdiction of that Service whether or not the Action Agency has entered into an ACA with the other Service.

**§ 402.33 Procedures.**

(a) The Action Agency may make an NLAA determination for a Fire Plan Project without informal consultation or written concurrence from the Director if the Action Agency has entered into and implemented an ACA. The Action Agency need not initiate formal consultation on a Fire Plan Project if the Action Agency has made an NLAA determination for the Project under this subpart. The Action Agency and the Service will use the following procedures in establishing an ACA.

(1) *Initiation:* The Action Agency submits a written notification to the Serv-

ice Director of its intent to enter into an ACA.

(2) *Development and Adoption of the Alternative Consultation Agreement:* The Action Agency enters into an ACA with the Service Director. The ACA will, at a minimum, include the following components:

(i) A list or description of the staff positions within the Action Agency that will have authority to make NLAA determinations under this subpart C.

(ii) Procedures for developing and maintaining the skills necessary within the Action Agency to make NLAA determinations, including a jointly developed training program based on the needs of the Action Agency.

(iii) A description of the standards the Action Agency will apply in assessing the effects of the action, including direct and indirect effects of the action and effects of any actions that are interrelated or interdependent with the proposed action.

(iv) Provisions for incorporating new information and newly listed species or designated critical habitat into the Action Agency's effects analysis of proposed actions.

(v) A mutually agreed upon program for monitoring and periodic program evaluation to occur at the end of the first year following signature of the ACA and periodically thereafter.

(vi) Provisions for the Action Agency to maintain a list of Fire Plan Projects for which the Action Agency has made NLAA determinations. The Action Agency will also maintain the necessary records to allow the Service to complete the periodic program evaluations.

(3) *Training:* Upon completion of the ACA, the Action Agency and the Service will implement the training program outlined in the ACA to the mutual satisfaction of the Action Agency and the Service.

(b) The Action Agency may, at its discretion, allow any subunit of the Action Agency to implement this subpart as soon as the subunit has fulfilled the training requirements of the ACA, upon written notification to the Service. The Action Agency shall at all

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times have responsibility for the adequacy of all NLAA determinations it makes under this subpart.

(c) The ACA and any related oversight or monitoring reports shall be made available to the public through a notice of availability in the FEDERAL REGISTER.

### § 402.34 Oversight.

(a) Through the periodic program evaluation set forth in the ACA, the Service will determine whether the implementation of this subpart by the Action Agency is consistent with the best available scientific and commercial information, the ESA, and section 7 regulations.

(b) The Service Director may use the results of the periodic program evaluation described in the ACA to recommend changes to the Action Agency's implementation of the ACA. If and as appropriate, the Service Director may suspend any subunit participating in the ACA or exclude any subunit from the ACA.

(c) The Service Director retains discretion to terminate the ACA if the Action Agency fails to comply with the requirements of this subpart, section 7 of the ESA, or the terms of the ACA. Termination, suspension, or modification of an ACA does not affect the validity of any NLAA determinations made previously under the authority of this subpart.

## Subpart D—Counterpart Regulations Governing Actions by the U.S. Environmental Protection Agency Under the Federal Insecticide, Fungicide and Rodenticide Act

SOURCE: 69 FR 47759, Aug. 5, 2004, unless otherwise noted.

### § 402.40 Definitions.

The definitions in § 402.02 are applicable to this subpart. In addition, the following definitions are applicable only to this subpart.

(a) *Alternative consultation agreement* is the agreement described in § 402.45.

(b) *Effects determination* is a written determination by the U.S. Environmental Protection Agency (EPA) ad-

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ressing the effects of a FIFRA action on listed species or critical habitat. The contents of an effects determination will depend on the nature of the action. An effects determination submitted under § 402.46 or § 402.47 shall contain the information described in § 402.14(c) and a summary of the information on which the determination is based, detailing how the FIFRA action affects the listed species or critical habitat. EPA may consider the following additional sections for inclusion in an effects determination:

(1) A conclusion whether or not the FIFRA action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and a description of any reasonable and prudent alternatives that may be available;

(2) A description of the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures; and

(3) A summary of any information or recommendations from an applicant. An effects determination shall be based on the best scientific and commercial data available.

(c) *FIFRA action* is an action by EPA to approve, permit or authorize the sale, distribution or use of a pesticide under sections 136–136y of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 *et seq.* (FIFRA). In any consultation under this subpart, EPA shall determine the nature and scope of a FIFRA action.

(d) *Listed species* is a species listed as endangered or threatened under section 4 of the Act.

(e) *Partial biological opinion* is the document provided under § 402.47(a), pending the conclusion of consultation under § 402.47(b), stating the opinion of the Service as to whether or not a FIFRA action is likely to jeopardize the continued existence of one or more listed species or result in the destruction or adverse modification of one or more critical habitats, and describing

the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures.

(f) *Service Director* refers to the Director of the U.S. Fish and Wildlife Service or the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration.

(g) *Service Representative* is the person or persons designated to participate in advance coordination as provided in this subpart.

[69 FR 47759, Aug. 5, 2004, as amended at 84 FR 45018, Aug. 27, 2019]

#### § 402.41 Purpose.

The purpose of these counterpart regulations is to enhance the efficiency and effectiveness of the existing consultation process under section 7 of the Endangered Species Act (Act), 16 U.S.C. 1531 *et seq.*, by providing Fish and Wildlife Service and the National Marine Fisheries Service (referred to jointly as “Services” and individually as “Service”) and EPA with additional means to satisfy the requirements of section 7(a)(2) of the Act for certain regulatory actions under FIFRA. These additional means will permit the Services and EPA to more effectively use the scientific and commercial data generated through the FIFRA regulatory process as part of the best scientific and commercial data available to protect listed species and critical habitat. The procedures authorized by these counterpart regulations will be as protective of listed species and critical habitat as the process established in subpart B of this part.

#### § 402.42 Scope and applicability.

(a) *Available consultation procedures.* This subpart describes consultation procedures available to EPA to satisfy the obligations of section 7(a)(2) of the Act in addition to those in subpart B of this part for FIFRA actions authorized, funded, or carried out by EPA in which EPA has discretionary Federal involvement or control. EPA retains discretion to initiate early, informal, or formal consultation as described in §§ 402.11, 402.13, and 402.14 for any

FIFRA action. The procedures in this subpart may be employed for FIFRA actions as follows:

(1) Interagency exchanges of information under § 402.43 and advance coordination under § 402.44 are available for any FIFRA action.

(2) Alternative consultation under § 402.45 is available for a listed species or critical habitat if EPA determines the FIFRA action is not likely to adversely affect the listed species or critical habitat.

(3) Optional formal consultation under § 402.46 is available for any FIFRA action with respect to any listed species or critical habitat.

(4) The special procedures in § 402.47 are available for consultations on FIFRA actions that will be unusually complex due to factors such as the geographic area or number of species that may be affected by the action.

(5) EPA shall engage in consultation as to all listed species and critical habitat that may be affected by a FIFRA action, and may in its discretion employ more than one of the available consultation procedures for a FIFRA action that may affect more than one listed species or critical habitat.

(6) EPA shall engage in consultation on actions involving requests for emergency exemptions under section 18 of FIFRA that may affect listed species or critical habitat, and may choose to do so under § 402.05 or other provisions of this subpart or subpart B of this part. Any required formal consultation shall be initiated as soon as practicable after the emergency is under control. For the purposes of § 402.05(b) the definition of formal consultation in § 402.02 includes the procedures in § 402.46.

(7) EPA must prepare a biological assessment for a FIFRA action to the extent required by § 402.12.

(8) EPA must comply with § 402.15 for all FIFRA actions.

(9) After a consultation under this subpart has been concluded, EPA shall reinstate consultation as required by § 402.16 as soon as practicable after a circumstance requiring reinstatement occurs, and may employ the procedures in this subpart or subpart B of this part in any reinstated consultation.

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(b) *Exchanges of scientific information.* As part of any of the additional consultation procedures provided in this subpart, EPA and the Services shall establish mutually-agreeable procedures for regular and timely exchanges of scientific information to achieve accurate and informed decision-making under this subpart and to ensure that the FIFRA process considers the best scientific and commercial data available on listed species and critical habitat in a manner consistent with the requirements of FIFRA and ESA.

#### § 402.43 Intagency exchanges of information.

EPA may convey to the Service a written request for a list of any listed species or critical habitat that may be present in any area that may be affected by a FIFRA action. Within 30 days of receipt of such a request the Service shall advise EPA in writing whether, based on the best scientific and commercial data available, any listed species or critical habitat may be present in any such area. EPA may thereafter request the Service to provide available information (or references thereto) describing the applicable environmental baseline for each species or habitat that EPA determines may be affected by a FIFRA action, and the Service shall provide such information within 30 days of the request.

#### § 402.44 Advance coordination for FIFRA actions.

(a) *Advance coordination.* EPA may request the Service to designate a Service Representative to work with EPA in the development of an effects determination for one or more listed species or critical habitat. EPA shall make such a request in writing and shall provide sufficient detail as to a FIFRA action planned for consultation to enable the Service to designate a representative with appropriate training and experience who shall normally be available to complete advance coordination with EPA within 60 days of the date of designation. Within 14 days of receiving such a request, the Service shall advise EPA of the designated Service Representative.

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(b) *Participation of Service Representative in preparation of effects determination.* The Service Representative designated under paragraph (a) of this section shall participate with EPA staff in the preparation of the effects determination identified under paragraph (a) of this section. EPA shall use its best efforts to include the designated Service Representative in all relevant discussions on the effects determination, to provide the designated Service Representative with access to all documentation used to prepare the effects determination, and to provide the designated Service Representative office and staff support sufficient to allow the Service Representative to participate meaningfully in the preparation of the effects determination. EPA shall consider all information timely identified by the designated Service Representative during the preparation of the effects determination.

#### § 402.45 Alternative consultation on FIFRA actions that are not likely to adversely affect listed species or critical habitat.

(a) *Consultation obligations for FIFRA actions that are not likely to adversely affect listed species or critical habitat when alternative consultation agreement is in effect.* If EPA and the Service have entered into an alternative consultation agreement as provided below, EPA may make a determination that a FIFRA action is not likely to adversely affect a listed species or critical habitat without informal consultation or written concurrence from the Director, and upon making such a determination for a listed species or critical habitat, EPA need not initiate any additional consultation on that FIFRA action as to that listed species or critical habitat. As part of any subsequent request for formal consultation on that FIFRA action under this subpart or subpart B of this part, EPA shall include a list of all listed species and critical habitat for which EPA has concluded consultation under this section.

(b) *Procedures for adopting and implementing an alternative consultation agreement.* EPA and the Service may enter into an alternative consultation agreement using the following procedures:

(1) *Initiation.* EPA submits a written notification to the Service Director of its intent to enter into an alternative consultation agreement.

(2) *Required contents of the alternative consultation agreement.* The alternative consultation agreement will, at a minimum, include the following components:

(i) *Adequacy of EPA Determinations under the ESA.* The alternative consultation agreement shall describe actions that EPA and the Service have taken to ensure that EPA's determinations regarding the effects of its actions on listed species or critical habitat are consistent with the ESA and applicable implementing regulations.

(ii) *Training.* The alternative consultation agreement shall describe actions that EPA and the Service intend to take to ensure that EPA and Service personnel are adequately trained to carry out their respective roles under the alternative consultation agreement. The alternative consultation agreement shall provide that all effects determinations made by EPA under this subpart have been reviewed and concurred on by an EPA staff member who holds a current certification as having received appropriate training under the alternative consultation agreement.

(iii) *Incorporation of new information.* The alternative consultation agreement shall describe processes that EPA and the Service intend to use to ensure that new information relevant to EPA's effects determinations is timely and appropriately considered.

(iv) *Incorporation of scientific advances.* The alternative consultation agreement shall describe processes that EPA and the Service intend to use to ensure that the ecological risk assessment methodologies supporting EPA's effects determinations incorporate relevant scientific advances.

(v) *Oversight.* The alternative consultation agreement shall describe the program and associated record keeping procedures that the Service and EPA intend to use to evaluate EPA's processes for making effects determinations consistent with these regulations and the alternative consultation agreement. The alternative consultation agreement shall provide that the Serv-

ice's oversight will be based on periodic evaluation of EPA's program for making effects determinations under this subpart. Periodic program evaluation will occur at the end of the first year following signature of the alternative consultation agreement and should normally occur at least every five years thereafter.

(vi) *Records.* The alternative consultation agreement shall include a provision for EPA to maintain a list of FIFRA actions for which EPA has made determinations under this section and to provide the list to the Service on request. EPA will also maintain the necessary records to allow the Service to complete program evaluations.

(vii) *Review of Alternative Consultation Agreement.* The alternative consultation agreement shall include provisions for regular review and, as appropriate, modification of the agreement by EPA and the Service, and for departure from its terms in a particular case to the extent deemed necessary by both EPA and the Service.

(3) *Training.* After EPA and the Service enter into the alternative consultation agreement, EPA and the Service will implement the training program outlined in the alternative consultation agreement to the mutual satisfaction of EPA and the Service.

(4) *Public availability.* The alternative consultation agreement and any related oversight or monitoring reports shall be made available to the public to the extent provided by law.

(c) *Oversight of alternative consultation agreement implementation.* Through the program evaluations set forth in the alternative consultation agreement, the Service will determine whether the implementation of this section by EPA is consistent with the best scientific and commercial information available, the ESA, and applicable implementing regulations. The Service Director may use the results of the program evaluations described in the alternative consultation agreement to recommend changes to EPA's implementation of the alternative consultation agreement. The Service Director retains discretion to terminate or suspend the alternative consultation agreement if, in using the procedures in this subpart,

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EPA fails to comply with the requirements of this subpart, section 7 of the ESA, or the terms of the alternative consultation agreement. Termination, suspension, or modification of an alternative consultation agreement does not affect the validity of any NLAA determinations made previously under the authority of this subpart.

### § 402.46 Optional formal consultation procedure for FIFRA actions.

(a) *Initiation of consultation.* EPA may initiate consultation on a FIFRA action under this section by delivering to the Service a written request for consultation. The written request shall be accompanied by an effects determination as defined in § 402.40(b) and a list or summary of all references and data relied upon in the determination. All such references and data shall be made available to the Service on request and shall constitute part of the Service's administrative record for the consultation. The time for conclusion of the consultation under section 7(b)(1) of the Act is calculated from the date the Service receives the written request from EPA. Any subsequent interchanges regarding EPA's submission, including interchanges about the completeness of the effects determination, shall occur during consultation and do not extend the time for conclusion of the consultation unless EPA withdraws the request for consultation.

(b) *Additional information determination.* For an effects determination prepared without advance coordination under § 402.44, the Service may determine that additional available information would provide a better information base for the effects determination, in which case the Service Director shall notify the EPA Administrator within 45 days of the date the Service receives the effects determination. The notification shall describe such additional information in detail, and shall identify a means for obtaining that information within the time period available for consultation. EPA shall provide a copy of the Service Director's notification to any applicant. EPA may thereafter revise its effects determination, and may resubmit the revised effects determination to the Service. If EPA advises the Service it

will not resubmit a revised effects determination to the Service, its initiation of consultation on the effects determination is deemed withdrawn.

(c) *Service responsibilities.* (1) Within the later of 90 days of the date the Service receives EPA's written request for consultation or 45 days of the date the Service receives an effects determination resubmitted under paragraph (b) of this section, and consistent with section 7(b)(1) of the Act, the Service shall take one of the following actions:

(i) If the Service finds that the effects determination contains the information required by § 402.40(b) and satisfies the requirements of section 7(b)(4) of the Act, and the Service concludes that the FIFRA action that is the subject of the consultation complies with section 7(a)(2) of the Act, the Service will issue a written statement adopting the effects determination; or

(ii) The Service will provide EPA a draft of a written statement modifying the effects determination, which shall meet the requirements of § 402.14(i), and as modified adopting the effects determination, and shall provide a detailed explanation of the scientific and commercial data and rationale supporting any modification it makes; or

(iii) The Service will provide EPA a draft of a biological opinion finding that the FIFRA action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, and describing any reasonable and prudent alternatives if available.

(2) If the Service acts under paragraphs (c)(1)(ii) or (c)(1)(iii) of this section, EPA shall, on request from an applicant, provide the applicant a copy of the draft written statement or draft biological opinion received from the Service. The Service shall at the request of EPA or an applicant discuss with EPA and the applicant the Service's review and evaluation under this section, and the basis for its findings. EPA and any applicant may submit written comments to the Service within 30 days after EPA receives the draft written statement or opinion from the Service unless the Service, EPA and any applicant agree to an extended deadline consistent with section 7(b)(1) of the Act.

(3) The Service will issue a final written statement or final biological opinion within 45 days after EPA receives the draft statement or opinion from the Service unless the deadline is extended under section 7(b)(1) of the Act.

(d) *Opinion of the Secretary.* The written statement or opinion by the Service under paragraphs (c)(1) or (c)(3) of this section shall constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act.

(e) *Delegation of Authority for Service decisions.* Any written statement modifying an effects determination or any biological opinion issued under this section shall be signed by the Service Director and such authority may not be delegated below the level of Assistant Director for Endangered Species (FWS) or Director of Office of Protected Resources (NOAA Fisheries).

**§ 402.47 Special consultation procedures for complex FIFRA actions.**

(a) *Successive effects determinations.* If EPA determines after conferring with the Service that consultation on a FIFRA action will be unusually complex due to factors such as the geographic area or number of species that may be affected by the action, EPA may address the effects of the action through successive effects determinations under this subpart addressing groupings or categories of species or habitats as established by EPA. EPA may initiate consultation based upon each such effects determination using the procedure in § 402.46(a), and the provisions of § 402.46(b) and (c) shall apply to any such consultation. When consultation is conducted under this section, the written statement or opinion provided by the Service under § 402.46(c) constitutes a partial biological opinion as to the species or habitats that are the subject of the consultation. While not constituting completion of consultation under section 7(a)(2), EPA retains authority to use such a partial biological opinion along with other available information in making a finding under section 7(d) of the Act.

(b) *Opinion of the Secretary.* After conclusion of all consultation on the FIFRA action, the partial biological

opinions issued under paragraph (a) of this section shall then collectively constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act except to the extent a partial biological opinion is modified by the Service in accordance with the procedures in § 402.46(c). The Service shall so advise EPA in writing upon issuance of the last partial biological opinion for the consultation.

**§ 402.48 Conference on proposed species or proposed critical habitat.**

EPA may employ the procedures described in § 402.10 to confer on any species proposed for listing or any habitat proposed for designation as critical habitat. For the purposes of § 402.10(d), the procedures in § 402.46 are a permissible form of formal consultation.

**PART 403—TRANSFER OF MARINE MAMMAL MANAGEMENT AUTHORITY TO STATES**

Sec.

- 403.01 Purpose and scope of regulations.
- 403.02 Definitions.
- 403.03 Review and approval of State request for management authority.
- 403.04 Determinations and hearings under section 109(c) of the MMPA.
- 403.05 State and Federal responsibilities after transfer of management authority.
- 403.06 Monitoring and review of State management program.
- 403.07 Revocation and return of State management authority.
- 403.08 List of States to which management has been transferred.

AUTHORITY: 16 U.S.C. 1361 *et seq.*, as amended by Pub. L. 97-58.

SOURCE: 48 FR 22456, May 18, 1983, unless otherwise noted.

**§ 403.01 Purpose and scope of regulations.**

The regulations contained in this part implement section 109 of the Act which, upon a finding by the Secretary of compliance with certain requirements, provides for the transfer of marine mammal management authority to the states.

(a) The regulations of this part apply the procedures for the transfer of marine mammal management authority