

Title 50: Wildlife and Fisheries

PART 402—INTERAGENCY COOPERATION—ENDANGERED SPECIES ACT OF 1973, AS AMENDED

Contents

Subpart A—General

- §402.01 Scope.
- §402.02 Definitions.
- §402.03 Applicability.
- §402.04 Counterpart regulations.
- §402.05 Emergencies.
- §402.06 Coordination with other environmental reviews.
- §402.07 Designation of lead agency.
- §402.08 Designation of non-Federal representative.
- §402.09 Irreversible or irretrievable commitment of resources.

Subpart B—Consultation Procedures

- §402.10 Conference on proposed species or proposed critical habitat.
 - §402.11 Early consultation.
 - §402.12 Biological assessments.
 - §402.13 Informal consultation.
 - §402.14 Formal consultation.
 - §402.15 Responsibilities of Federal agency following issuance of a biological opinion.
 - §402.16 Reinitiation of formal consultation.
-

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

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.

Note from Section 7 Training LLC - This document represents the 50 CFR 402 regulations before the 2019 revisions and thus is the set of regulations applicable after the 2019 revisions were vacated by court order on July 5, 2022. Original source information was reformatted for this document. Refer to Code of Federal Regulations at <https://www.ecfr.gov/current/title-50/chapter-IV> (once it has been updated to reflect the vacatur) as authoritative source.

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 for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

Director refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

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 refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. 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. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.

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.

Note from Section 7 Training LLC - This document represents the 50 CFR 402 regulations before the 2019 revisions and thus is the set of regulations applicable after the 2019 revisions were vacated by court order on July 5, 2022. Original source information was reformatted for this document. Refer to Code of Federal Regulations at <https://www.ecfr.gov/current/title-50/chapter-IV> (once it has been updated to reflect the vacatur) as authoritative source.

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.

§402.03 Applicability.

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

§402.04 Counterpart regulations.

The consultation procedures set forth in this part may be superseded for a particular Federal agency by joint 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 required 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 irretrievable 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 irretrievable 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 developed (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. 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. 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.

(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.

§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. A written request to initiate formal consultation shall be submitted to the Director and shall include:

- (1) A description of the action to be considered;
- (2) A description of the specific area that may be affected by the action;
- (3) A description of any listed species or critical habitat that may be affected by the action;
- (4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statement, environmental assessment, or biological assessment prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat.

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. 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 or a segment of a comprehensive plan. This does not relieve the Federal agency of the requirements for considering the effects of the action 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 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) Formulate its biological opinion as to whether the action, taken together with cumulative effects, 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 taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

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

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

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

(3) The Service's opinion on whether the action is 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, the action is 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). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(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.

(l) *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.

§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 formal consultation.

Reinitiation of formal 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:

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

(b) 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;

Note from Section 7 Training LLC - This document represents the 50 CFR 402 regulations before the 2019 revisions and thus is the set of regulations applicable after the 2019 revisions were vacated by court order on July 5, 2022. Original source information was reformatted for this document. Refer to Code of Federal Regulations at <https://www.ecfr.gov/current/title-50/chapter-IV> (once it has been updated to reflect the vacatur) as authoritative source.

(c) 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

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