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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 (i) 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

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 reauest.
- (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,

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- (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

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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 reinitiate 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

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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.

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- (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 mav 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