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 ei-
- (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.

$\S\,402.12$ 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

§ 402.12

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.

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