

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