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Preamble to Regs.

#76-86

Part II

Department of the Interior

Fish and Wildlife Service

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 402

Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule

AGENCIES: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule.

SUMMARY: This final rulemaking establishes the procedural regulations governing interagency cooperation under section 7 of the Endangered Species Act of 1973, as amended (the "Act"). The Act requires Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce, to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species. The Endangered Species Act Amendments of 1978, 1979, and 1982 (the "Amendments") changed the consultation requirements of section 7. This final rulemaking amends the existing rules governing section 7 consultation by implementing the changes required by the Amendments and by incorporating other procedural changes designed to improve interagency cooperation.

EFFECTIVE DATE: July 3, 1986.

FOR FURTHER INFORMATION CONTACT: Marvin E. Moriarty, Acting Chief, Office of Endangered Species, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240 (703–235–2771); or Charles Karnella, Protected Species Division, Office of Protected Species and Habitat Conservation, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce, Washington, D.C. 20235 (202–634–7461).

SUPPLEMENTARY INFORMATION:

Background

On January 4, 1978, the Department of the Interior, through the United States Fish and Wildlife Service (FWS), and the Department of Commerce, through the National Marine Fisheries Service (NMFS), established procedures for the Act's consultation process by implementing the interagency cooperation requirements of section 7 (50 CFR Part 402, "1978 rule"). The consultation process is designed to assist Federal agencies in complying with the requirements of section 7 and provides such agencies with advice and guidance from the Secretary on whether an action complies with the substantive requirements of section 7.

The Secretaries of the Interior and Commerce (the "Secretary") share responsibilities for conducting consultations pursuant to section 7 of the Act. Generally, marine species are under the jurisdiction of the Secretary of Commerce and all other species are under the jurisdiction of the Secretary of the Interior. Authority to conduct consultations has been delegated by the Secretary of the Interior to the Director of the FWS and by the Secretary of Commerce to the Assistant Administrator for Fisheries, NMFS, National Oceanic and Atmospheric Administration.

Section 7(a)(1) of the Act authorizes Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or Commerce, depending on the species involved, to utilize their resources in furtherance of the purposes of the Act by carrying out programs for the conservation of endangered species and threatened species ("listed species") listed pursuant to section 4 of the Act.

Section 7(a)(2) of the Act requires Federal agencies, in consultation with and with the assistance of the Secretary, to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat of such species which has been designated as critical ("critical habitat"). Although Federal agency authority and responsibility under section 7 have remained virtually intact from the 1973 Act, the Amendments made significant procedural changes in the section 7 consultation procedures.

The 1978 Amendments formalized the process for the issuance of the Secretary's opinion ("biological opinions"), and required that the opinion include "reasonable and prudent alternatives" in cases where the proposed Federal action, in the opinion of the Secretary, would jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its critical habitat. The 1978 Amendments also added section 7(c), requiring the preparation of biological assessments in appropriate instances. section 7(d) of the Act, also added by the 1978 Amendments, prohibits a Federal agency or any involved permit or license applicant, after initiation of consultation, from making an irreversible or irretrievable commitment of resources which would foreclose the adoption of any reasonable and prudent alternatives.

Perhaps the most significant part of the 1978 Amendments was the creation of the Endangered Species Committee, which is authorized to grant exemptions from the requirements of section 7(a)(2) in appropriate cases. Regulations governing the submission of exemption applications and consideration of such applications by the Endangered Species Committee are presently codified at 50 CFR Parts 450–453. Although this final rule on consultation procedures does not deal directly with exemptions, good faith adherence to the consultation requirements of section 7 is a statutory prerequisite for entry into the exemption process.

The 1979 Amendments slightly altered the Federal agency's substantive obligation under section 7(a)(2) from insuring that its action "does not jeopardize" listed species or adversely modify the critical habitat of such species to insuring that its action "is not likely to jeopardize" such species or critical habitat. Congress expressly provided that the consultation and resultant biological opinion be based upon the "best scientific and commercial data available." These changes made the consultation process more flexible and established a reasonable information standard to be followed by the NMFS and FWS (the "Service") and other Federal agencies. The 1979 Amendments added a requirement that all Federal agencies confer with the Secretary on all actions that are likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat.

The 1982 Amendments also established several new processes under section 7. First, a new subsection 7(b)(4) allows for the issuance of an "incidental take statement" along with a biological opinion. This "incidental take statement" operates to exempt the Federal agency and any permit or license applicant involved from the section 9 "taking" prohibitions under the Act *if* the subsequent implementation of the action is consistent with the terms and conditions of the incidental take statement.

Second, the 1982 Amendments provide an opportunity for permit or license applicant involvement in all

phases of the consultation procedures. A prospective permit or license applicant may request Federal agencies to initiate consultation in advance of filing for any needed license or permit, *if* they have reason to believe that their proposed actions may affect listed species or critical habitat. This new provision, under section 7(a)(3), for "early consultation" allows a prospective applicant the opportunity to discover, and attempt to resolve, potential endangered or threatened species conflicts early in the planning stage of the proposed action—a time at which alterations in project plans could involve much less expense and delay.

Further involvement of the applicant in the consultation procedures is provided by the requirement that the applicant be involved in time extensions. Congress amended section 7(c) to require the Federal agency to give written notice to the applicant explaining why any extension of the biological assessment deadline is needed. If formal consultation under section 7(a)(2) is extended by the Service and the Federal agency for up to 60 days, the Service must provide the applicant with a written explanation of the reasons for extension. Any extension past 60 days must be approved by the applicant. Clearly, the permit or license applicant plays an active role in the consultation process. The final rule recognizes this increased role of the applicant while retaining the requirement that formal communications flow between the Federal agency and the Service during the consultation process.

In order to implement these Amendments to section 7 and to otherwise improve the interagency cooperation process, the Service published a proposed rule on June 29, 1983 (48 FR 29990–30004). Although the Service originally specified a 60-day comment period for these revised section 7 regulations, the comment period was extended until September 30, 1983. The Service received approximately 70 comments from other Federal agencies, State governmental agencies, private organizations, and other individuals and entities on the proposed rule.

After careful consideration of these comments, the Service has modified the regulations to clarify the consultation process and to improve the overall organization of the regulations. These technical changes are more fully explained in the section-by-section analysis below and were made to accommodate concerns raised in the public comments.

General Comments

The majority of the comments received on the proposed rule focused on particular regulatory provisions or concepts. These specific comments are discussed in the section-by-section analysis. However, several commenters expressed general concerns with the proposed rule or addressed matters that went beyond the scope of the proposal.

These general comments ranged from praise for the comprehensiveness of the proposal to criticism for the proposal's alleged failure to require the level of analysis and protection mandated by the Act. The Service believes that this final rule properly and accurately implements the Amendments to the Act and affords the protection mandated by section 7.

The House of Representatives Committee on Merchant Marine and Fisheries ("House Committee"), which oversees the implementation of the Act, submitted comments on the proposed rule. The Committee commended the Service in its efforts to translate complex legislation into agency policy and noted specific areas that it believed did not conform to the legislative intent. These matters have been clarified in the final rule.

One commenter was concerned that the proposed rule confused the informal (nonmandatory) consultation components with the formal (required) components of the consultation process. To clarify this matter, the Service has distinguished optional procedures from required procedures in the final rule. For example, the conference procedures (§ 402.10) are required for Federal actions that are likely to jeopardize proposed species or proposed critical habitat and the formal consultation procedures (§ 402.14) are required for actions that may affect listed species or critical habitat. Additionally, biological assessments (§ 402.12) are required for "major construction activities." Early consultation (§ 402.11) and informal consultation (§ 402.13) are optional procedures and are clearly designated as such in the final rule.

Concerned about increased paperwork burdens and potential time commitments resulting from the proposal, one commenter complained that the proposed rule is burdensome, unnecessary, and unacceptable. The commenter noted that additional protection for listed species or their habitat would not result from these alleged increases in administrative burdens, and it urged that currently used processes be maintained. The Service emphasizes that the proposal was not intended to increase in any way the paperwork burden of Federal agencies or any other participant in the consultation process. Moreover, the purpose of the proposal was to implement the Amendments to the Act in such a way as to streamline the consultation process while maintaining the protections afforded species under section 7. The concern of the commenter has been addressed to the extent possible by the Service's effort to clarify the consultation process in this final rule. Because section 7 imposes certain requirements on Federal agencies, any burdens recognized in this final rule are a creature of statutory law as implemented by these regulations.

Two commenters asserted that the Act protects habitat only when it is designated as the critical habitat of a listed species and, therefore, the Service must identify areas of critical habitat for all listed species to assure adequate protection. It is true that the Service has not designated critical habitat for all listed species. The Service has consistently taken the position that it is not prudent to designate critical habitat for a species if to do so would increase the risk that the species might be taken or would otherwise not benefit the species. *See* 50 CFR 424.12(a). However, the commenters ignore the fact that section 7 protections attach to both designated critical habitat and to each individual of a listed species within the jurisdiction of the United States or on the high seas. An action could jeopardize the continued existence of a listed species through the destruction or adverse modification of its habitat, regardless of whether that habitat has been designated as "critical habitat." Thus, the failure of the Service to designate critical habitat for a given species does not automatically mean that its habitat is without protection.

Two States commented that Federal agencies charged with implementing the Act should recognize and cooperate with the States in resolving water resource issues within the context of section 7. Consistent with the Department's "good neighbor" policy, one commenter encouraged the Service to actively include affected States in any consultation process. The Service intends to cooperate with all State and local agencies to resolve water resource issues consistent with the requirements of the Act. The Service stands ready to receive any and all comments, data, or other input from any affected States that are interested in a particular section 7 consultation. However, consultation takes place between the Service, the Federal agency and, where applicable, a Federal permit or license applicant.

Several commenters stated that the proposal goes beyond the scope of the Act, thereby placing unjustifiable burdens on applicants and Federal agencies. They claimed that the rules would usurp Federal agency authority. One commenter questioned the ultimate authority of the Service to issue binding procedural regulations under section 7. In no way does the Service intend to use the consultation procedures of section 7 to establish substantive policy for Federal agencies. The Service performs strictly an advisory function under section 7 by consulting with other Federal agencies to identify and help resolve conflicts between listed species and their critical habitat and proposed actions. As part of its role, the Service issues biological opinions to assist the Federal agencies in conforming their proposed actions to the requirements of section 7. However, the Federal agency makes the ultimate decision as to whether its proposed action will satisfy the requirements of section 7(a)(2). The Service recognizes that the Federal agency has the primary responsibility for implementing section 7's substantive command, and the final rule does not usurp that function. The Service is satisfied that the final rule is within the scope of the authority provided in the Act.

Moreover, the Service is responsible for interpreting section 7 and for establishing a consultation process that is both uniform and consistent with statutory requirements. This issue was addressed in the preamble to the 1978 rule:

> The FWS and NMFS are authorized under the Act to issue such regulations as they deem appropriate for the conservation of listed species. The two Services believe that these procedural regulations promote the conservation of listed species by implementing a uniform general framework as the starting point for consultation. Once the mandatory consultation has taken place, however, the ultimate responsibility for determining agency action in light of section 7 still rests with the particular Federal agency that was engaged in consultation. In this fashion, a standardized consultation process is established which preserves ultimate agency administrative control over its activities or programs.

43 FR 870, 871 (Jan. 4, 1978). These procedural regulations do not dictate results but prescribe a process by which the Service will consult in keeping with the Act.

Several commenters stated that Congress did not intend that the Service interpret or implement section 7, and believed that the Service should recast the regulations as "nonbinding guidelines" that would govern only the Service's role in consultation. The Service notes that Congress reviewed with approval the section 7 regulations issued on January 4, 1978, when deliberating over the 1978 Amendments to the Act. *See* H.R. Conf. Rep. No. 1804, 95th Cong., 2d Sess. 18 (1978). Also, the Service was urged by the House Committee, through its comments on the proposed rule, to press forward with the issuance of this final rule. The Service is satisfied that it has ample authority and legislative mandate to issue this rule, and believes that uniform consultation standards and procedures are necessary to meet its obligations under section 7. However, the Service is aware that some Federal programs may require a modified consultation process, and therefore the Service has provided for the issuance of counterpart regulations under § 402.04.

Several general comments were received regarding programmatic adjustments and coordination. One commenter suggested that the Service maintain cumulative summaries of consultation activities in the Washington Office. The Service maintains copies of all biological opinions and monitors the issuance of biological opinions in an effort to ensure consistency and accuracy of findings. The Service submits that current review mechanisms are adequate and that, although the maintenance of cumulative consultation summaries might be useful, the increased costs are not justified.

Another commenter urged increased public participation in the consultation process, including: (1) Public notice of each request for consultation; (2) public notice of the agenda for each consultation; (3) public notice of consultation results; (4) public comment periods; and, (5) prescribed rights to appeal by the public. Nothing in section 7 authorizes or requires the Service to provide for public involvement (other than that of the applicant) in the "interagency" consultation process. Moreover, due to the statutory time constraints imposed on the consultation procedures, it would not be practicable to implement such detailed public participation measures. Public participation may be provided within the Federal agency's decisionmaking process. However, that is a function of the agency's regulations or substantive legislation and not an issue to be raised in the context of consultation.

Finally, several questions were raised as to what rules will apply to pending consultations once the final rule becomes effective. The Service does not anticipate any dramatic change in procedure or additional burdens on Federal agencies because the statutory changes to section 7 have been in effect throughout the development of the final rule. When this rule becomes effective, all pending and future consultations must comply with the requirements of these regulations. The Service will cooperate with the Federal agencies and any applicants to ensure that there are no undue delays in ongoing consultations.

Section-by-Section Analysis

The following portion of the preamble explains the final rule, covering the substantive issues of each section, noteworthy modifications from the proposed rule, significant changes from the 1978 rule, and responses to public comments. To assist the reader, Table 1 presents a citation to each subsection of the proposed rule with appropriate cross-references to the location of that provision in the final rule and in the 1978 rule.

TABLE 1.—CROSS-REFERENCE OF SECTION 7 REGULATORY PROVISIONS: PROPOSAL—FINAL—1978 RULE

Proposal	Final	1978 Rule
§ 402.01(a)–(e)	§ 402.01(a)–(b)	§ 402.01
§ 402.02 Definitions	§ 402.02 Definitions	§ 402.02 Definitions.
(none)	—"Act"	(none)
—"Action"	—"Action"	—"Activities or programs"
—"Action area"	—"Action area"	(none)
—"Adversely affect"	(none)	(none)
—"Applicant"	—"Applicant"	(none)
—"Biological assessment"	—"Biological assessment" and "Major construction activity"	(none)
—"Biological opinion"	—"Biological opinion"	(none)
—"Conference"	—"Conference"	(none)
—"Conservation"	(none)	(none)
—"Conservation recommendations"	—"Conservation recommendations"	(none)
—"Consultation process"	(none)	(none)
—"Critical habitat"	—"Critical habitat"	—"Critical habitat": § 402.05

TABLE 1.—CROSS-REFERENCE OF SECTION 7 REGULATORY PROVISIONS: PROPOSAL—FINAL—1978 RULE—Continued

Proposal	Final	1978 Rule
—"Cumulative effects"	—"Cumulative effects"	(none)
—"Designated non-Federal representative"	—"Designated non-Federal representative"; § 402.08	(none)
—"Destruction or adverse modification"	—"Destruction or adverse modification"	—"Destruction or adverse modification"
—"Director"	—"Director"	—"Director or Regional Director"
—"Early consultation"	—"Early consultation"	(none)
—"Effects of the action"	—"Effects of the action"	(none)
—"Federal agency"	(none)	—"Federal agency"
—"Formal consultation"	—"Formal consultation"	(none)
—"Further discussion"	(none)	(none)
—"Incidental take"	—"Incidental take"	(none)
—"Informal consultation"	—"Informal consultation"	(none)
—"Jeopardize the continued existence of"	—"Jeopardize the continued existence of"	—"Jeopardize the continued existence of"
—"Listed species"	—"Listed species"	—"Listed species"
—"Preliminary biological opinion"	—"Preliminary biological opinion"	(none)
—"Proposed critical habitat"	—"Proposed critical habitat"	(none)
—"Proposed species"	—"Proposed species"	(none)
—"Reasonable and prudent alternatives"	—"Reasonable and prudent alternatives"	(none)
(none)	—"Reasonable and prudent measures"	(none)
—"Recovery"	—"Recovery"	—"Recovery"
—"Service"	—"Service"	(none)
§ 402.03	§ 402.03	§ 402.03
§ 402.04	§ 402.04	§ 402.04(f)
§ 402.05	§ 402.05(a)–(b)	(none)
§ 402.10(a)	§ 402.06(a)	§ 402.04(b)(1)
——(b)	§ 402.06(a)	(none)
——(c)	(none)	(none)
——(d)	§ 402.07	§ 402.04(b)(2)
§ 402.11	§ 402.09	§ 402.04(a)(3)
§ 402.12(a)	§ 402.13(a)–(b)	§ 402.04(a)
——(b)	§ 402.12(a)–(k)	§ 402.04(c), (d)
§ 402.13(a)–(c)	§ 402.10(a)–(e)	(none)
§ 402.14	§ 402.11	(none)
§ 402.15(a)	§ 402.14(a)	§ 402.04(a)
——(b)	§§ 402.11(f), 402.14(b)(2)	(none)
——(c)	§§ 402.13(a), 402.14(b)	§ 402.04(a)
——(d)	§ 402.14(c)–(d)	——(a), (c), (d)
——(e)	——(e)	——(e), (f)
——(f)	——(g)	——(e)
——(g)	——(h)	——(e)
——(h)	——(h)–(j)	——(e)
——(i)(1)	§ 402.13(a)	(none)
——(i)(2)–(4)	§§ 402.14(7), 402.15(b)	(none)
——(j)(1)	——(f)	§ 402.04(f)
——(j)(2)	——(k)	(none)
——(k)	——(a)	§ 402.04(a)
§ 402.16	(none)	(none)
§ 402.17(a)	§ 402.15(a)	§ 402.04(g)
——(b)	§ 402.15(c)	(none)
——(c)	§ 402.06(b)	§ 402.04(g)
§ 402.18	§ 402.16	§ 402.04(h)
§ 402.19	§ 402.14(i)	(none)

Subpart A—General

Section 402.01 Scope.

This section describes the purpose and scope of these regulations. Section 402.01 of the proposed rule contained an introductory paragraph and five subsections that were largely repetitive of other sections of the rule. These repetitive passages have been deleted from the final rule, and minor editorial corrections have been made.

Several commenters noted that, although § 402.01 acknowledges the language of section 7(a)(1) of the Act, no guidance is provided to enable Federal agencies to meet their conservation responsibilities under the Act. Claiming that the rules are silent as to Federal agency management programs required for the recovery of listed species, one commenter advised the Service to add a statement in the rule that would insure that Federal agencies address recovery as well as detrimental effects through consultation. According to another commenter, this statement may include a request that Federal agencies issue policies and procedures to implement their authority under section 7(a)(1).

The Service notes that it is beyond the scope of these regulations to address how other Federal agencies should implement and exercise their authority to carry out conservation programs for listed species under section 7(a)(1). However, the Service stands ready to assist any Federal agency in developing and carrying out conservation programs. The Service cautions that all Federal actions including "conservation programs" are subject to the consultation requirements of section 7(a)(2) if they "may affect" listed species or their critical habitats. If the Service agrees, through informal consultation, that the action is not likely to adversely affect the species, then formal consultation is not required [see § 402.13(a)–(b)]. Each Federal agency has the responsibility to implement its authority under section 7(a)(1). Further, any conservation program must comply with applicable permit requirements to the extent that such actions involve the taking of listed species. "Take," as defined in the Act, means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.

The 1978 rule extended the scope of section 7 beyond the territorial limits of the United States to the high seas and foreign countries. The proposed rule cut back the scope of section 7 to the United States, its territorial sea, and the outer continental shelf, because of the apparent domestic orientation of the consultation and exemption processes resulting from the Amendments, and because of the potential for interference with the sovereignty of foreign nations.

Several commenters asserted that the rules should continue to have extraterritorial effect. The scope of these regulations has been enlarged to cover Federal actions on the high seas but has not been expanded to include foreign countries. The Service finds that, because it already has jurisdiction under section 9(a)(1)(C) of the Act to regulate the taking of a listed fish or wildlife species on the high seas by all persons subject to the jurisdiction of the United States, concomitant jurisdiction under section 7 is implicit from Congressional concern that compliance with a section 7 incidental take statement not result in a taking violation under section 9(a)(1)(C), as provided in section 7(o)(2).

Although consultations on Federal actions in foreign countries will not be conducted under this rule, the Service maintains its strong commitment to the preservation of species and habitat worldwide. The Service will continue to list species which are found outside of United States jurisdiction when they are determined to be endangered or threatened.

Furthermore, Congress, in the International Environment Protection Act of 1983, 22 U.S.C. 2151q, made a finding that "the extinction of animal and plant species is an irreparable loss with potentially serious environmental and economic consequences for developing and developed countries alike." Accordingly, it places the preservation of species "through limitations on the pollution of natural ecosystems, and through the protection of wildlife habitats" as an "important objective of the United States development assistance." In furtherance of this policy, an Interagency Task Force was established to develop a national strategy for the protection and conservation of biological diversity in developing countries. The task force did not specifically recommend that international assistance activities be subject to consultation requirements, but did cite section 7(a)(2) in recommending that Federal agencies "should continue to adopt policies withholding support for certain types of projects that degrade or destroy fragile or protected lands." Until enacted by Congress, however, the recommendations of the task force will not be implemented in these regulations for the reasons stated above.

One commenter urged the Service to change the standard for initiating a section 7(a)(4) conference from "likely to jeopardize" to "would adversely affect." The regulation tracks the statute, and the Service lacks the authority to make the requested change. The same commenter noted that the section 7(d) sentence referred to a "*would* avoid jeopardizing" standard. (Emphasis theirs.) Again, the Service adopts the regulation as in keeping with the statutory standard.

Another commenter stated that biological opinions need only be required after formal consultation under section 7(a)(2) of the Act and that this should be clarified in the rule. The Service disagrees because the statute requires that a "written statement" containing the Secretary's opinion be issued after the conclusion of both early and formal consultation. The rule has been amended slightly to clarify this requirement.

The commenter also requested that the sentence in proposed § 402.01(d) dealing with section 7(d) be amended by adding "measures" after the phrase "reasonable and prudent alternative[s]" to bring the regulation in line with the statute. The Service declines to make this change because it would tend to confuse "reasonable and prudent alternatives" that are included in jeopardy biological opinions with "reasonable and prudent measures" that are included in an incidental take statement under section 7(b)(4) of the Act. The proposed language describing the section 7(d) prohibition accurately implements the Act and is adopted in this final rule.

Section 402.02 Definitions.

This section sets out definitions of terms that are used throughout these regulations. As noted in Table 1, many definitions have been added to those included in the 1978 rule. Only comments which specifically addressed the definitions used in these regulations are discussed in this section. These terms are further discussed as they pertain to the consultation procedures in the appropriate, subsequent sections.

A definition of "Act" has been added to the final rule. It refers to the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

The definition of "action" parallels the former definition of "activities or programs," a term that predated the Amendments. Several changes have been made in the definition of "action" to accommodate public comments: First, the definition is expanded to cover activities occurring on the high seas. (*See* § 402.01 segment of the Preamble.) Second, the phrase "actions that are intended to conserve listed species or their habitat" was restored from the 1978 rule because of the decision to require Service review of all Federal actions that may affect listed species or their critical habitat. (*See* § 402.14 segment of the Preamble.) The Service declines to define further or to delete the reference to actions that "indirectly cause modifications to the land, water, or air" in this definition. The concept of indirect effects is adequately addressed in the discussion of "cumulative effects" and "effects of the action."

The definition of "action area" is adopted from the proposed rule. Several commenters criticized the vagueness or apparent expansiveness caused by the reference to indirect effects in this definition. The definitions of "cumulative effects" and "effects of the action" further clarify the scope of "indirect effects."

The Service is not able to define specific spatial and temporal limits for the concept of indirect effects that would satisfy every conceivable situation, and believes that sufficient understanding of the term exists so that confusion will not occur. "Action area" is not limited to the immediate area involved in a Federal action.

"Applicant," an abbreviated term including all permit or license applicants, was defined in the proposed rule because of the increased role of permit or license applicants in the consultation process. Although the Act defines "permit or license applicant" in section 3(12), the Act's definition is of limited use in the consultation context because it focuses on the exemption process under section 7. The definition in the proposed rule broadly defines "applicant" as "any person who requires formal approval or authorization from a Federal agency as a prerequisite to conduct the action." Thus, applicants would include those seeking permits, licenses, leases, letters of authorization, and any other form of authorization or approval issued by a Federal agency as a prerequisite for carrying out the action.

One commenter suggested that the definition of applicant be amended to allow prospective permit applicants to participate in section 7 consultations involving the promulgation of regulations governing permit issuance. The applicant (or prospective applicant) is involved in the consultation process as a result of a specific permit or license application. The applicant may provide input regarding its concerns in the Federal agency's rulemaking process through the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* Further, a prospective applicant could request early consultation through the Federal agency under § 402.11 of this rule on its prospective application during the course of agency rulemaking, if it desires early notice of potential conflicts and if it meets the requirements of these

regulations. This would involve interaction with the Service, but it would be limited in scope to the prospective application for the permit at issue, not a general consultation on the pending rulemaking. In response to another comment, the Service takes the position that it will not expand "applicant" to include those seeking funding from Federal agencies, unless the request for funding is coupled with a requirement that the person obtain Federal approval or authorization as a prerequisite for carrying out the action for which funding is sought. Finally, one commenter asked that the scope of the definition be expanded to include corporations, Federal agencies, and all other legal entities. The Service believes that the use of the word "person" in the definition satisfies the commenter's concern because of the broad definition of that term in section 3(13) of the Act. To clarify this point, the Service added a reference to the Act's definition of "person" in the definition of "applicant" in the final rule.

The definition of "biological assessment" in the final rule, derived from §§ 402.02 and 402.12(b)(4)(ii) of the proposed rule, clarifies that the assessment must include an evaluation of potential impacts. One commenter criticized the "vagueness" of the definition of "biological assessment" in the proposed rule, stating that it was unclear as to how a Federal agency would determine which species or critical habitat may be in the action area and how the agency would evaluate potential effects. The Service believes that this definition is adequate and that the process-oriented format in § 402.12 of the regulations adequately explains the scope and procedure of the biological assessment requirement.

The proposed definition of "biological opinion" has been adopted in these final rules. A biological opinion is the document that states the Service's opinion 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. One commenter suggested a third possible conclusion for biological opinions: "insufficient information to issue an opinion." The commenter argued that such a conclusion would eliminate the risk that the Service takes when issuing an opinion based on arguably inadequate data. The Service declines to add this third option. The legislative history of the Act is clear in requiring the Service to make a decision on the issue of likely jeopardy at the conclusion of formal consultation. The Service will not sidestep this obligation, but instead will conclude either "jeopardy" or "no jeopardy" based on the best available data.

The definition of "conference" has been adopted as proposed. One commenter suggested that the conference not include recommendations to minimize or avoid adverse effects since they are not required by section 7(a)(4) of the Act. The commenter believed that such recommendations might result in legal action if not adopted. The Service, however, believes it has the responsibility not only to identify impacts but also to identify measures that would reduce those impacts.

The definition of "conservation" contained in the proposed rule was derived from the Act's definition in section 3(3). One commenter, characterizing the Service's interpretation of "conservation" as opposing the purposes of the Act and potentially encouraging the "further decline" of listed species, urged the Service to adopt the strict language of the statutory definition. The Service's definition in the proposed rule in no way discouraged recovery. In fact, the proposed definition tracked the statute except for its interpretation of "the point at which the measures provided pursuant to this Act are no longer necessary" as being equivalent to "the point at which [the species] may be removed from the Lists . . . ." The basic goal of the Act is to recover listed species through conservation measures. Bringing a species to the point at which the Act's protective measures are no longer necessary is the same as bringing the species to the point at which delisting is appropriate. However, to avoid any misunderstanding, the Service has deleted the definition from the final rule and will rely solely on the definition contained in section 3(3) of the Act. The Service declines specifically to include habitat modification (improvement or restoration), "off-site mitigation," captive propagation, and species reintroduction in the list of conservation methods and procedures, as suggested by certain commenters. Such activities are already adequately provided for in the Act's definition.

The term "conservation recommendations" was introduced in the proposed rule and explains the Service's role in helping agencies meet their section 7(a)(1) responsibilities. Several commenters feared that the Service would employ conservation recommendations to require Federal agencies to reformulate their actions that had received "no jeopardy" biological opinions. This is not the purpose of conservation recommendations. They are nonbinding suggestions that a Federal agency may elect to implement in its proposed action. These recommendations should be consistent with the general scope, magnitude, and duration of a Federal action that is not likely to jeopardize a listed species or destroy or adversely modify its critical habitat. The Service, in answering the concerns noted above, is satisfied that it has clarified its position and that the regulatory definition should not be deleted. The Service has chosen to retain this definition with limited, technical changes because it believes that the opportunity to provide conservation recommendations, including minor design modifications, may minimize possible adverse effects and may avoid future section 7 conflicts for subsequent Federal actions in the same action area.

One commenter confused "conservation recommendations" with "reasonable and prudent alternatives" and believed that recommendations to *reduce* adverse impacts would violate section 7(a)(2), absent the granting of an exemption. The obligation of Federal agencies under section 7(a)(2) is to insure that the actions they authorize, fund, or carry out are not likely to *jeopardize* listed species or destroy or adversely modify their critical habitat. A showing of "adverse effect" does not necessarily violate section 7(a)(2), because the jeopardy standard is the ultimate barrier through which Federal agencies may not pass in conducting their actions. "Reasonable and prudent alternatives" represent avenues of fulfilling the action without violating the jeopardy standard. "Conservation recommendations" involve voluntary measures that the Federal agency has the discretion to undertake to avoid or reduce adverse effects of a proposed action that otherwise complies with the provisions of section 7(a)(2).

The definition of "consultation process" has been deleted from the final rule because it tended to confuse the statutory requirements and optional processes and because it added little to the public's understanding of the process. The definition in the proposed rule could have led persons to believe that early consultation and informal consultation are required, sequential steps of the overall consultation process. As discussed above, the only required components of the consultation process are a "conference" for proposed species, a "formal consultation" for listed species, and a biological assessment for "major construction activities."

The "critical habitat" definition contained in the proposed rule only referred to those sections of 50 CFR Parts 17 and 226 that contain the lists of those areas so designated. The mechanics of the designation process are more properly considered under the section 4 regulations (50 CFR Part 424). For purposes of determining whether any of their actions is likely to destroy or adversely modify critical habitat, Federal agencies involved in section 7 consultations need only be aware of those areas that have been designated by the Service as critical habitat. Two commenters requested that a definition of critical habitat be included in the final rule. The Service notes that the requested definition is contained in the Act and need not be repeated here.

"Cumulative effects" and "effects of the action" are defined in § 402.02 of the final regulations. Under § 402.14(g) (3) and (4) of the final rule, the Service will consider both the "effects of the action" subject to consultation and "cumulative effects" of other activities in determining 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.

In determining the "effects of the action," the Director first will evaluate the status of the species or critical habitat at issue. This will involve consideration of the present environment in which the species or critical habitat exists, as well as the environment that will exist when the action is completed, in terms of the totality of factors affecting the species or critical habitat. The evaluation will serve as the baseline for determining the effects of the action on the species or critical habitat. The specific factors that form the environmental baseline are given in the definition of "effects of the action," as requested by some commenters.

"Effects of the action" include the direct and indirect effects of the action that is subject to consultation.

"Indirect effects" are those that are caused by the action and are later in time but are still reasonably certain to occur. They include the effects on listed species or critical habitat of future activities that are induced by the action subject to consultation and that occur after that action is completed. In *National Wildlife Federation* v. *Coleman*, 529 F.2d 359 (5th Cir. 1976), the Court of Appeals for the Fifth Circuit found that "indirect effects" which can be expected to result must be considered under section 7 of the Act. In that case, the court enjoined completion of a highway because the Department of Transportation failed to consider the effects to the endangered sandhill crane from future private development that would result from construction of the highway. The Service will consider the effects to listed species from such future activities that are reasonably certain to occur under the analysis of "indirect effects." The Service's approach will be consistent with *National Wildlife Federation* v. *Coleman*, and the Service declines to narrow the scope of its review (as requested by one commenter) in light of existing case law.

Effects of the action also include direct and indirect effects of actions that are interrelated or interdependent with the proposal under consideration. 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 significant independent utility apart from the action that is under consideration. As noted by one commenter, the "but for" test should be used to assess whether an activity is interrelated with or interdependent to the proposed action.

One commenter urged the Service to exclude Federal actions that have completed consultation from the environmental baseline unless it can be shown that the actions are reasonably certain to occur. The Service declines to adopt this suggestion. In issuing its biological opinion on an action, the Service's finding under section 7(a)(2) entails an assessment of the degree of impact that action will have on a listed species. Once evaluated, that degree of impact is factored into all future section 7 consultations conducted in the area. These impacts will continue to be considered as part of the environmental baseline unless the Service receives notice from the Federal agency that the proposed action will not be implemented or unless the biological opinion on the proposed action is no longer valid because reinitiation of consultation is required.

In response to one comment, the Service notes that Federal actions that have proceeded through early consultation and that have received "no jeopardy" preliminary biological opinions should be factored into the environmental baseline. These actions, to be eligible for early consultation, had to be nonspeculative, feasible actions, and, because the preliminary biological opinion can later be confirmed as a final biological opinion, this initial review and conclusion by the Service must be considered in other section 7 consultations.

The term "cumulative effects" means those effects on the species caused by other projects and activities unrelated to the action under consultation that the Service will consider in formulating its biological opinion on the subject action. One commenter opposed the proposed definition of cumulative effects by arguing that the Act does not require an analysis of cumulative effects in a section 7 consultation. Citing section 7(c), the commenter noted that biological assessments may be limited to an examination of effects of "such action" on listed species. The commenter urged the Service to strike cumulative effects analysis from this rule because few Federal agencies have the capability to recognize or assess cumulative effects of State or private actions contemporaneously with conducting section 7 consultation. According to the commenter, the Service, as the expert on current status of listed species, should keep watch on these State and private activities that come on line in a particular action area. The Service responds that a Federal agency, when evaluating the environmental impacts of a proposed action, must comply with NEPA. Since this compliance includes an analysis of cumulative effects, the Service believes that it is the Federal agency's responsibility to develop this information. The cumulative effects analysis conducted in compliance with the broad definition under NEPA may be submitted to the Service by the Federal agency when initiating formal consultation. The Service can use this analysis and apply its narrower definition of cumulative effects when analyzing whether a proposed action, along with cumulative effects, violates section 7(a)(2) of the Act.

Other commenters, while not opposing the applicability of cumulative effects analysis to section 7 consultations, believed that the proposed scope of "cumulative effects" and "effects of the action" were too narrow. These commenters generally suggested that cumulative effects should include the effects of all reasonably foreseeable future Federal, State, and private actions. They stated that this scope would be more in line with that mandated under NEPA and argued that any lesser review could detrimentally affect endangered species. The commenters adamantly opposed any limitation on the foresight employed by the Service or Federal agencies that they believed would result from the proposal's construction of cumulative effects.

Section 7 consultation will analyze whether the "effects of the action" on listed species, plus any additional,

cumulative effects of State and private actions which are reasonably certain to occur in the action area, are likely to jeopardize the continued existence of that species. Based on this analysis, the Federal agency determines whether it can proceed without exceeding the jeopardy standard. If the jeopardy standard is exceeded, the proposed Federal action cannot proceed without an exemption. This is a substantive prohibition that applies to the Federal action involved in the consultation. In contrast, NEPA is procedural in nature, rather than substantive, which would warrant a more expanded review of cumulative effects. Otherwise, in a particular situation, the jeopardy prohibition could operate to block "nonjeopardy" actions because future, speculative effects occurring after the Federal action is over might, on a cumulative basis, jeopardize a listed species. Congress did not intend that Federal actions be precluded by such speculative actions.

Future Federal actions proposed for the same area would have to be separately evaluated under section 7 and could not occur unless they were able, in their own right, to avoid jeopardizing the continued existence of the affected species or destroying or adversely modifying critical habitat. Since all future Federal actions will at some point be subject to the section 7 consultation process pursuant to these regulations, their effects on a particular species will be considered at that time and will not be included in the cumulative effects analysis. However, those future State or private actions (*i.e.*, no Federal agency involvement) that are "reasonably certain to occur" must be factored into section 7(a)(2) evaluations. The Service agrees that cumulative effects that are reasonably certain to occur will be considered in determining the likelihood of jeopardy. The final rule is amended accordingly, to clarify the duty to consider cumulative effects.

One commenter thought that the "reasonably certain to occur" standard was far too narrow and that it should be amended to cover actions where proposals have been made, and implementation schedules have been established. This suggestion would open the door for speculative actions to be factored into the "cumulative effects" analysis, adding needless complexity into the consultation process and threatening potential Federal actions which pose minimal adverse impacts of their own with possible "jeopardy" opinions due to speculative, State or private projects that may never be implemented. For State and private actions to be considered in the cumulative effects analysis, there must exist more than a mere possibility that the action may proceed. On the other hand, "reasonably certain to occur" does not mean that there is a guarantee that an action will occur. The Federal agency and the Service will consider the cumulative effects of those actions that are likely to occur, bearing in mind the economic, administrative, or legal hurdles which remain to be cleared. The Service declines to alter its "cumulative effects" definition to include State or private actions that are not likely to occur.

One issue was raised concerning the application of cumulative effects analysis to water projects. A commenter contended that State and private projects that possess senior water rights under State water law and that can "reasonably be expected to occur" concurrently with the Federal action should be considered as cumulative effects. The Service notes that any State or private project (*i.e.*, no Federal agency involvement) that is reasonably certain to occur must be considered during the analysis of cumulative effects. Further, the Service believes that Federal actions, whether authorized, funded, or carried out by Federal agencies, that possess senior water rights should be considered while analyzing the effects of the action. In order to determine the effects of the action when a water project is the subject of consultation in a State which follows the prior appropriation doctrine, the project's operation plan should indicate the priority of the project's water rights under State law and account for the future effects of senior conditional water rights.

On a related matter, the Associate Solicitor's opinion on the scope of cumulative effects cited in the proposed rule provided, in part, that only those effects of other projects that are reasonably certain to occur *prior* to the completion of the Federal action subject to consultation under section 7(a)(2) should be considered during formal consultation. This statement has been interpreted by some to exclude from cumulative effects analysis those future State and private actions that, while "reasonably certain to occur," would not be completed *before* the completion of the Federal action subject to consultation. Such an interpretation places undue emphasis on the use of the word "prior" while ignoring the central concept that the Associate Solicitor's opinion intended to project: that a proposed State or private activity be "reasonably certain to occur" in order to be taken into account during cumulative impact analyses. If such a State or private project satisfies the "reasonable certainty" test, then it should be considered in the cumulative impact analysis, even if it would go on line sometime after completion of the federally authorized, funded, or carried out project which was the subject of consultation. To the extent that the Associate Solicitor's opinion created the opposite impression, the Service takes this opportunity to clarify this point.

Moreover, as suggested by some commenters, and for the reasons outlined above, the Service has deleted its reference to the Interior Department position on "cumulative effects" in 88 I.D. 903 (1981) in the definition section. The Service disagrees with the commenter who stated that the citation to the legal opinion in the proposed definition denied the public meaningful comment on these regulations. The policy was widely known, and it was explained in the preamble to the proposed rule. The Associate Solicitor's opinion on "cumulative effects" is published in Interior Decisions, a publication available to the general public. Finally, the opinion does not represent a policy change subject to Administrative Procedure Act (APA) informal rulemaking proceedings. It represented Interior's legal interpretation of the scope of "cumulative effects" under section 7, adopted and published in 1981 in keeping with APA requirements. 5 U.S.C. 552(a). Therefore, no reproposal is needed on this issue.

The definition of "designated non-Federal representative" is adopted from the proposal in part. First, in response to a comment, the Service explains that the non-Federal representative may conduct informal consultations (§ 402.13) and/or prepare biological assessments (§ 402.12). However, Federal agencies cannot delegate their role in initiating formal consultation, a conference, or early consultation. The second sentence of the proposed definition has been deleted, but a new § 402.08 has been added to further explain the role of the designated non-Federal representative.

The proposed definitions of "destruction or adverse modification" and "jeopardize the continued existence of" received a lot of attention from commenters. Both definitions contained, as did the 1978 rule, the phrase "survival and recovery." The final rule retains the language of the proposed definitions, except for the changes noted below. Also connected with these terms is the definition of "recovery." The "recovery" of a listed species means that the status

of the species has improved to the point at which it may be removed from the Lists of Endangered and Threatened Wildlife and Plants.

The principal controversy involving the "jeopardy" and "destruction or adverse modification" definitions was that, under the proposed rule, to find that an action is likely to jeopardize a listed species or result in the destruction or adverse modification of critical habitat, the Service must identify detrimental impacts to "both the survival and recovery" of the listed species. The conjunction "and" was used in the 1978 rule's definitions of these phrases, but the word "both" was added by the proposed rule to emphasize that, except in exceptional circumstances, injury to recovery alone would not warrant the issuance of a "jeopardy" biological opinion. The Service adopts these definitions substantially without change from the proposed rule; this does not represent a change in policy, as one commenter charged, because the Service has internally interpreted the "jeopardy" standard as requiring detrimental impacts to the continued existence of a species under a joint survival and recovery concept. Other Federal agencies are assured that the same "jeopardy" standard under which their actions have been evaluated in the past will be continued under this final rule.

Several commenters urged the Service to strike the "and" and insert "or" in the definitions of "jeopardy" and "destruction or adverse modification." They argued that injury to recovery for an already depleted species would require the issuance of a jeopardy opinion. They also remarked that the Service's position disregarded the conservation requirements of the Act, failed to adequately protect critical habitat, operated to weaken or nullify recovery efforts, and otherwise violated the purposes and policies of the Act.

These commenters misconstrued the Service's role in conducting consultations under section 7(a)(2) of the Act. The purpose of consultation is to identify conflicts between proposed Federal actions and the "jeopardy" standard of section 7(a)(2). The "continued existence" of the species is the key to the jeopardy standard, placing an emphasis on injury to a species' "survival." However, significant impairment of recovery efforts or other adverse effects which rise to the level of "jeopardizing" the "continued existence" of a listed species can also be the basis for issuing a "jeopardy" opinion. The Service acknowledges that, in many cases, the extreme threats faced by some listed species will make the difference between injury to "survival" and to "recovery" virtually zero.

One commenter disagreed that actions adversely affecting survival of a species will also always adversely affect its recovery. The commenter did not cite examples where an action that jeopardized "survival" of a species would not jeopardize its "recovery." The Service is not aware of any examples and believes that it would be very difficult to recover a species whose survival had been placed in jeopardy. The very concept of "jeopardy" is that a Federal agency should not authorize, fund, or carry out an action that would injure a listed species' chances for survival to the point that recovery is not attainable. If survival is jeopardized, recovery is also jeopardized. As noted above, though, these concepts are generally considered together in analyzing effects, and it is difficult to draw clear-cut distinctions.

The concept of "survival" is discussed above, but is not defined in the Act or in these regulations. Two commenters felt that "survival" should be defined in the regulations, and one urged the Service to adopt the following specific definition:

> "Survival" for a species means retention of a sufficient number of individuals and/or populations with necessary habitat to insure that the species will keep its integrity in the face of genetic recombination and known environmental fluctuations.

The Service agrees with the criteria set out in the above definition, but declines to adopt a regulatory definition for "survival" because this concept varies widely among listed species. The Service will apply the statutory standard of jeopardy to the continued existence of a species on a case-by-case basis, taking into account the particular needs of and the severity and immediacy of threats posed to a listed species. The Service is not attempting to predetermine the results of any future consultations by announcing these interpretations of the "jeopardy" standard, but instead is emphasizing what "jeopardy" is and how it should be applied in the section 7(a)(2) process.

One commenter urged the Service to go further and forbid any Federal action to proceed, regardless of a "no jeopardy" finding, if the proposed action would adversely affect the recovery of a listed species. Numerous commenters cited sections 2(c)(1), 3(3), and 7(a)(1) of the Act as authority for the Service to ban Federal agency actions that "violate the requirement to conserve endangered species."

The commenters misinterpret the statutory changes which the Amendments have made to section 7, and they misconstrue court decisions which have noted the apparent "heightened" responsibility of the Secretary. The Service will undertake programs for the conservation of listed species and will consult with other Federal agencies attempting to do the same. The Service will not, nor does it have the authority to, mandate how or when other Federal agencies are to implement their responsibilities under section 7(a)(1), nor is the Service authorized to issue a biological opinion under section 7(a)(1) of the Act. Section 7(a)(1) has a limited purpose under the Act: to authorize Federal agencies to factor endangered species conservation into their planning processes, regardless of other statutory directives.

In contrast, section 7(a)(2) contains the mandatory "jeopardy" standard. The prohibitory features of section 7, and the exemption process added by the 1978 Amendments, focus on the provisions of section 7(a)(2). Although there is no express legislative history directly weighing and comparing the relative strengths of section 7(a)(1) with 7(a)(2), there can be no doubt that Congress considered the jeopardy standard of section 7(a)(2) as being the substantive cornerstone of section 7:

> The term "is likely to jeopardize" is used because the *fundamental* obligation of section 7(a) of the act is that Federal agencies insure their actions do not jeopardize the continued existence of an endangered or threatened species.

S. Rep. No. 151, 96th Cong., 1st Sess. 4 (1979) (emphasis added). Congress intended that the "jeopardy" standard be the ultimate barrier past which Federal actions may not proceed, absent the issuance of an exemption. The commenters' argument would require Federal actions to halt if they failed to conserve listed species, a result clearly not intended by Congress. Congress intended that actions that do not violate section 7(a)(2), or actions receiving an exemption from the requirements of that subsection, be allowed to proceed.

Commenters argued that it would be a violation of section 7(a)(1) for the Service to issue a "no jeopardy" biological opinion for a proposed Federal action that would have an adverse effect on the recovery of a listed species. As previously stated, the Service lacks authority to issue biological opinions under that subsection, and the Act does not mandate particular actions to be taken by Federal agencies to implement 7(a)(1). Furthermore, adverse effects not

rising to the level of "jeopardizing the continued existence" of a listed species cannot be the basis for issuing a jeopardy opinion.

The Service disputes two commenters' assertions that "the Service now proposes to allow the 'continued existence' of a listed species to reach a state of likely jeopardy." The Service has followed and will continue to follow the policy of strictly applying the jeopardy standard of section 7(a)(2) in the consultation process. The Service has not and will not relax the statutory standard.

One commenter stated that limiting the definition of "destruction or adverse modification" to critical habitat is illogical. This limitation is mandated by the strict language of section 7(a)(2) and cannot be altered by the Service, although habitat destruction can be the basis for a jeopardy opinion in appropriate cases.

Another commenter requested that examples be given of actions that might indirectly alter critical habitat. The Service responds with the following examples of indirect alteration of critical habitat (which is not intended as an exclusive list): ground water pumping that occurs on land adjacent to the critical habitat area, but nevertheless diminishes essential ground water levels within the critical habitat; air pollution created by an action not occurring directly on the critical habitat area that causes a deterioration of essential air quality levels in the critical habitat; contamination of water supply within the critical habitat caused by release of toxic substances outside of the critical habitat area; etc.

In the definition of "jeopardize the continued existence of," one commenter suggested the word "could" be substituted for "would" in the phrase "would be expected, directly or indirectly, to reduce appreciably the likelihood of . . . the survival and recovery of listed species . . . ." Such a change would be an unwarranted deviation from the language of the 1978 rule in light of subsequent Amendments to the Act. The Service retains the substance of the proposed language, but does delete the phrase "or otherwise adversely affecting the species" because, as several commenters suggested, the phrase is confusing and adds nothing to the definition.

In response to several comments, the Service has modified the definition of "recovery" to make it clear that recovery is not attained until the threats to the species as analyzed under section 4(a)(1) of the Act have been removed. The protective measures provided for listed species under the Act are no longer needed if endangered or threatened status is no longer applicable to a species under section 4(a)(1).

The definition of "Director" has been modified by the addition of the phrase "or his authorized representative" after "the FWS regional director" and "Assistant Administrator for Fisheries" to accommodate present and future delegations of authority to carry out certain consultation responsibilities. Although the Minerals Management Service requested that all Outer Continental Shelf (OCS) section 7 biological opinions issued by the FWS be signed by the Washington Office, the authority to sign such opinions will remain with the regional offices because they have been staffed specifically to conduct all interagency consultations and to sign the resulting biological opinions.

The term "early consultation" was included in the proposed rule pursuant to the provisions of section 7(a)(3). This section authorizes the Service to consult with Federal agencies at the request of prospective applicants, prior to the submission of the permit or license application to that Federal agency. The definition has been modified to reference the appropriate section of the Act.

One commenter requested that, instead of using the term "early consultation," the Service refer to this process as "consultation on behalf of prospective applicants." The commenter was concerned that, by calling this pre-application process "early consultation," the Service would fail to alert Federal agencies and applicants of the need to determine impacts to endangered or threatened species early in the planning stages of all of their actions, regardless of whether the consultation is early, informal, or formal. The Service retains the label "early consultation" due to its convenience, its frequent use in the committee reports on the 1982 Amendments, and its common acceptance within and outside the Service. The Service believes that the language provided in §402.14(a), advising Federal agencies to review their actions at the earliest possible time, provides adequate safeguards to address the commenters' concerns.

The definition of "Federal agency" has been deleted since it is defined in section 3(7) of the Act. The Service declines to expand the statutory definition to accommodate one commenter's concern. The statutory definition adequately provides notice that all departments, agencies, and instrumentalities of the United States come within the scope of section 7. The Service will not interpret this term further in the final rule.

The definition of "formal consultation" has been modified to specify that it is the consultation required under section 7(a)(2) of the Act. Other minor, technical changes have also been made. The phrase "after it has been determined, through informal consultation with the Service, that its action may adversely affect listed species or critical habitat" has been deleted from the proposed definition because, as recommended by some commenters, informal consultation is strictly an optional process. Although the Federal agency may elect to enter into informal consultation to determine if formal consultation is required, the Federal agency can initiate formal consultation any time that it determines its action may affect listed species or critical habitat.

"Further discussion" was an optional process included in the proposed rule. It provided the Federal agency and any applicant the opportunity to continue consultation after the issuance of a biological opinion in order to discuss with the Service any reasonable and prudent alternatives and any conservation recommendations. Recommendations and alternatives could be refined or developed during these discussions, and consultation would terminate with the Federal agency's written notice of its final decision on the action. Because of concerns expressed by commenters, this provision contained in proposed §402.16 has been deleted from the final rule.

Although several commenters supported this provision, many opposed further discussion contending that it is unnecessary, that all reviews and discussions should occur prior to the issuance of the biological opinion, that it extends consultation beyond the statutory time limits, and that it lacks statutory authority. Although the process was optional, some commenters believed that there was an implication that the Federal agency or applicant would have a duty to engage in further discussion.

Although further discussion has been deleted, the Service is available to discuss the biological opinion, any reasonable and prudent alternatives, and any conservation recommendations with the Federal agency and any applicant on an informal basis. If revisions to the opinion are necessary, consultation can be reinitiated and a revised opinion issued.

"Incidental take" has been clarified in the final rule as those takes that result from, but are not the purpose of,

carrying out an otherwise lawful activity conducted by the Federal agency or the applicant. As requested by one commenter, the Service explains that otherwise lawful activities are those actions that meet all State and Federal legal requirements except for the prohibition against taking in section 9 of the Act. The Service believes that the definition, as clarified in the final rule, is adequate.

The definition of "informal consultation" has been clarified in the final rule to indicate that it is an optional process that includes all discussions, correspondence, etc., between the Service, Federal agency, and designated non-Federal representative prior to formal consultation. To address one commenter's concerns, "if required" has been included after "formal consultation" to clarify that formal consultation is not always required after informal consultation. Through informal consultation, a Federal agency may determine that formal consultation is not required.

The definition of "listed species" is adopted as proposed. Contrary to the concern of one commenter, aquatic invertebrates are not excluded from this definition, because all listed species in 50 CFR 17.11–17.12 are specifically included.

The definition of "major construction activity" was included in the definition of biological assessment in the proposed rule and is adopted substantially as proposed. As suggested by many commenters, it has been made a separate definition. Whether a Federal action is a major construction activity, as defined in these regulations, is the standard used for determining whether a Federal agency must prepare a biological assessment. A "major construction activity" is defined as a construction project (or other undertaking having similar physical impacts) that is a major Federal action significantly affecting the quality of the human environment for purposes of NEPA. The term encompasses dams, buildings, pipelines, roads, water resource developments, channel improvements, and other such undertakings which significantly modify the physical environment.

A vast array of comments were received concerning the scope of a major construction activity that requires the preparation of a biological assessment. Several commenters noted that only major Federal actions requiring the preparation of an environmental impact statement (EIS) pursuant to NEPA should require the preparation of a biological assessment under section 7(c) of the Act. Other commenters argued that assessments can only be required for major Federal actions involving construction activities, and suggested that the phrase "or other undertakings having similar physical impacts" be eliminated from the definition. Four commenters thought that the standard in the proposed rule was too narrow, because the limitation to major Federal actions, and/or the limitation to construction projects and other undertakings having similar physical impacts, were arbitrary and without legal basis. The Service has adopted the definition of major construction activity as proposed for the reasons set out below.

The legislative history of section 7(c) of the Act plainly focused the mandatory duty to prepare biological assessments on "major Federal actions . . . designed primarily to result in the building or erection of dams, buildings, pipelines and the like." H.R. Conf. Rep. No. 697, *supra*. The two-pronged regulatory test adopted in this rule—major Federal action *and* construction project (or other undertaking having *similar* physical impacts)—clearly tracks the quoted language from the Conference Report to the 1979 Amendments. The Service will not require biological assessments for projects that are not major Federal actions for purposes of NEPA. Further, the Service will not require biological assessments for actions that do not involve construction or activities having physical impacts similar to construction, such as dredging, blasting, etc. This limitation derives support from the 1979 Conference Report reference to actions designed *primarily to result* in the building or erection of various projects. These other "potentially destructive activities," H.R. Rep. No. 1625, *supra*, having physical impacts similar to construction projects, will require the preparation of an assessment, but only if they are major Federal actions for purposes of NEPA.

The Service declines to limit the scope of the definition of a major construction activity to major Federal actions involving construction projects, because other potentially destructive activities that are major Federal actions may have similar physical impacts and should be included. The Service is confident that the courts will be able to apply this standard consistent with the Act and the legislative history.

Contrary to the belief of one commenter, the Service has not abrogated its authority under section 7(c). That commenter urged the Service to change this rule by requiring biological assessments "for actions that, taking into consideration cumulative effects, may be 'potentially destructive.' " Citing a February 1980 legal opinion issued by the Assistant Solicitor for Fish and Wildlife, Department of the Interior, the commenter noted that cumulative effects may trigger the requirement that an assessment be prepared, although the Service must defer to the Federal agency's decision on whether a major Federal action exists. Contending that Congress would have used the word "shall" instead of "may" in the last sentence of section 7(c)(1) if it had intended that assessments be required only for major Federal actions for purposes of NEPA, the commenter argued that the definition of "major construction activity" should be expanded:

> "Major Construction activity" means any planned, temporary, or permanent physical modification to the environment. Examples of such projects include but are not limited to, dredging, drilling, filling, mining, site preparation, road construction, the erection of structures such as dams and buildings, or any other potentially destructive activities.

The commenter's suggested language goes well beyond the above-cited legislative history of the Act which clearly limited the biological assessment requirement to major Federal actions within the meaning of NEPA that are construction projects or that involve similar physical impacts. Further, the legal opinion of the Assistant Solicitor cited by the commenter does not support the commenter's argument because that opinion dealt with cumulative effects of a proposed *construction* project and a basic rule of NEPA case law that cumulative impacts of an action can trigger the requirement that an EIS be prepared. Thus, the basic elements of this rule's requirements—major Federal action (*e.g.*, EIS, or the functional equivalent, required) *and* construction project (or activity involving similar physical impacts)—were assumed to be appropriate standards by the Assistant Solicitor. The use of the word "may" instead of "shall" in section 7(c) means nothing more than Congressional intent that the duty to coordinate these review processes is discretionary with the Federal agency.

As requested by one commenter, the final definition clearly states that an action must be both a major Federal action for purposes of NEPA *and* a construction project (or other activity involving similar impacts). Therefore, it plainly follows that, although dams, pipelines, etc. are construction activities, a biological assessment is not

required unless the action is also a major Federal action.

Two commenters argued that OCS leasing, exploration, and development/production activities should be exempt from the section 7(c) requirement because such an analysis is presently covered by NEPA compliance as addressed in the Outer Continental Shelf Lands Act. Other commenters agreed with the Service that biological assessments would be required for development/production activities on the OCS, and, generally, would not be required for leasing and exploration activities that do not involve a significant modification of the physical environment. The Service adopts its position as proposed, because no exemption exists under section 7(c) if a biological assessment is required for an action. In some instances, OCS exploration activities may require the preparation of a biological assessment; *e.g.*, major Federal action involving exploration through construction of artificial gravel islands. However, in most cases major Federal exploration activities on the OCS will involve the drilling of test wells, actions that will not require the preparation of assessments.

The definition of "preliminary biological opinion" is adopted as proposed.

The definition of "proposed critical habitat" is adopted as proposed with the addition of the phrase "or revised" after "designated." The commenter that suggested this correction accurately noted that proposals may be made to designate or revise critical habitat under section 4 of the Act.

The definition of "proposed species" is adopted as proposed.

"Reasonable and prudent alternatives" is defined in the final rule. Section 7(b) of the Act requires the Service to include reasonable and prudent alternatives, if any, in a "jeopardy" biological opinion. An alternative is considered reasonable and prudent only if it can be implemented by the Federal agency and any applicant in a manner consistent with the intended purpose of the action, and if the Director believes it would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat of such species. Further, the Service should be mindful of the limits of a Federal agency's jurisdiction and authority when prescribing a reasonable and prudent alternative. An alternative, to be reasonable and prudent, should be formulated in such a way that it can be implemented by a Federal agency consistent with the scope of its legal authority and jurisdiction. However, the Service notes that a Federal agency's responsibility under section 7(a)(2) permeates the full range of discretionary authority held by that agency; *i.e.*, the Service can specify a reasonable and prudent alternative that involves the maximum exercise of Federal agency authority when to do so is necessary, in the opinion of the Service, to avoid jeopardy. The Service recognizes that economic and technological feasibility are factors to be used in developing reasonable and prudent alternatives, as requested by one commenter. The definition of "reasonable and prudent alternatives" has been amended to reflect these considerations. If there are no alternatives that meet the definition of "reasonable and prudent alternatives," the Service will issue a "jeopardy" biological opinion without alternatives.

Two commenters stated that reasonable and prudent alternatives should include mitigation measures designed to reduce adverse effects, *i.e.*, conservation recommendations. One of those commenters urged the Service to limit the scope of recommended alternatives to those "consistent with the scope, magnitude, and duration of the project as well as the extent of its adverse effects." First, because there is a distinction between "reasonable and prudent alternatives" (that satisfy section 7(a)(2)) and "conservation recommendations" (that are authorized by section 7(a)(1)), the Service declines to include conservation measures within the scope of the definition. Second, the Service agrees that reasonable and prudent alternatives should be consistent with the intended purpose of the action and should therefore be economically and technologically feasible, but the Service cannot limit its range of choices to the criteria suggested by the commenter. Reasonable and prudent alternatives must cover the full gamut of design changes that are economically and technologically feasible for an action, independent of who is sponsoring the action.

Two commenters asked that "reasonable and prudent measures" be defined, and the Service has inserted a definition in the final rule. This addition clarifies the distinction between "reasonable and prudent alternatives" included in a "jeopardy" biological opinion and "reasonable and prudent measures" provided in an incidental take statement. The Service agrees with several commenters that reasonable and prudent measures are not the same as reasonable and prudent alternatives. Substantial design and routing changes—appropriate only for alternatives to avoid jeopardy—are inappropriate in the context of incidental take statements because the action already complies with section 7(a)(2). The commenter that advocated an "alternatives" approach for reasonable and prudent measures misapplied the legislative history of the 1982 Amendments. Reasonable and prudent measures were intended to minimize the level of incidental taking, but Congress also intended that the action go forward essentially as planned. Therefore, the Service believes that they should be minor changes that do not alter the basic design, location, duration, or timing of the action. The section 7 obligations of Federal agencies are not expanded by the application of reasonable and prudent measures, which strictly govern the scope of the section 9 exemption for incidental takings.

The definition of "Service" is adopted as proposed.

Section 402.03 Applicability.

This section, which explains the applicability of section 7, implicitly covers Federal activities within the territorial jurisdiction of the United States and upon the high seas as a result of the definition of "action" in §402.02. The explanation for the scope of the term "action" is provided in the discussion under §402.01 above.

Section 402.04 Counterpart Regulations.

The Service has retained the counterpart regulations section of the 1978 rule as the new §402.04 that authorizes the drafting of joint counterpart regulations by Federal agencies and the Service. "These counterpart regulations would allow individual Federal agencies to 'fine tune' the general consultation framework to reflect their particular program responsibilities and obligations." 43 FR 870, 871 (Jan. 4, 1978).

Counterpart regulations must be published first as proposed rules with a minimum 60-day public comment period. Such counterpart regulations must retain the overall degree of protection afforded listed species required by the Act and these regulations. Changes in the general consultation process must be designed to enhance its efficiency without eliminating ultimate Federal agency responsibility for compliance with section 7. As long as the general consultation process is used as a starting point, Federal agencies can anticipate little difficulty in securing approval of the Service for counterpart regulations.

One Federal agency commented that the counterpart regulation process is a time-consuming alternative. The Service admits that informal rulemaking takes time and effort, but believes that the "fine tuning" that could occur through the development of counterpart regulations might, in the long run, provide a solid return in time and resources saved through the use of a more compatible consultation procedure.

Section 402.05 Emergencies.

Section 402.05 provides a modified consultation procedure for the Service to respond to emergency situations. This provision applies to situations involving acts of God, casualties, disasters, national defense or security emergencies (added to the rule in response to public comments), etc.

Upon request by the Federal agency, the Service may carry out consultation through procedures other than those provided under these regulations, as long as such emergency procedures are consistent with sections 7(a)–(d) of the Act. This allows, for example, consultation through informal means (*e.g.*, a telephone call) and, therefore, rapid responses to emergency situations.

Several commenters suggested that specific procedures should be set out to provide guidance to Federal agencies facing emergency situations. One commenter suggested that consultation could be initiated informally, such as through a telephone call, and the Service could then communicate its information and recommendations over the telephone. Because of the severe time constraints inherent in an emergency, this informal approach is the method the Service anticipates will be used by a Federal agency to conduct a consultation for a *bona fide* emergency. One commenter felt that minimum requirements should include "documentation of the nature of the emergency and justification for an expedited consultation." The Service agrees and has required, in a new paragraph (b) to this section, that the nature of the emergency and the justification for using an expedited process be documented and forwarded to the Service. However, the Service has not required that this be done during the emergency or expedited consultation, as this may not always be possible. The new paragraph (b) requires that the Federal agency conduct an "after the fact" consultation. The Service will evaluate the information submitted by the Federal agency, *i.e.*, the nature of the emergency actions, justification for the expedited consultation, and an evaluation of the impacts to listed species and critical habitat, and issue a biological opinion including the information and recommendations given during the emergency consultation. This will serve not only to document fully the consultation, but may assist the Federal agency in responding to similar emergencies.

One commenter argued that, when dealing with a fire, flood, earthquake, or storm, there is not enough time or opportunity for a Federal agency to undertake consultation through an alternate process determined by the Director to be consistent with section 7 The Service notes that the utmost flexibility is needed to handle the most extreme emergencies and believes that the informal process outlined in this section would satisfy the commenter's concern for the availability of prompt consultation and decisionmaking in emergency situations.

The Service further recognizes that it is sometimes necessary to take immediate steps to contain, limit, or alleviate an emergency in order to protect health, safety, and welfare prior to initiating any form of consultation. However, the Service would like to stress the fact that its early involvement is important in order to take advantage of its expertise in minimizing the effects of emergency response activities on endangered and threatened species. Federal agencies must exercise discretion when responding to an emergency as to when to consult with the Service. This will depend on the nature of the emergency and the actions that are immediately required. The Federal agency should contact the Service as soon as practicable, keeping in mind the informal nature of emergency consultation and Service expertise in minimizing the impacts of emergency response activities on endangered and threatened species.

Section 402.06 Coordination with Other Environmental Reviews.

This section on coordination with other environmental reviews contains paragraphs (a) and (b) of § 402.10 and paragraph (c) of § 402.17 of the proposed rule. The substance of these paragraphs has been adopted, but the format has been altered.

These regulations, following the 1978 rule, allow Federal agencies to coordinate their consultation, conference, and biological assessment responsibilities under the Act with the agency's responsibilities under other statutes such as NEPA (42 U.S.C. 4321 *et seq.*) or the Fish and Wildlife Coordination Act (FWCA, 16 U.S.C. 661 *et seq.*). The Service encourages Federal agencies to coordinate these responsibilities, but believes it is preferable to allow Federal agencies to do so in a manner that best conforms to their particular actions and which they believe is most efficient. Therefore, the sentences in the proposed § 402.10(b) stating that biological assessments *should* be incorporated into the documents required by other statutes (such as NEPA) have been dropped from the final rule.

Several commenters applauded these paragraphs because the coordination of environmental reviews would reduce duplication of paperwork and save time. One commenter requested guidance on how a NEPA review of endangered species issues should be conducted. The Service is not in a position to provide criteria that will ensure adequate NEPA compliance on endangered species issues. The Service suggests that the commenter contact the Council on Environmental Quality, the agency in charge of NEPA compliance, to obtain such information.

Another commenter expressed concern that, in simplifying the consultation process, safeguards should be used to avoid potential abuse and substantive problems. The commenter feared that, without safeguards, NEPA compliance might be construed as being less necessary on endangered species matters. The Service is also concerned that it retain sufficient review capability to identify potential conflicts between proposed Federal actions and listed species. Therefore, it has slightly altered its consultation procedures in this final rule to ensure that all Federal actions that "may affect" listed species receive some degree of review under informal or formal consultation.

The concluding sentences of paragraph (a) emphasize that although, for example, a biological assessment can be incorporated into an EIS, the procedures of these regulations also must be satisfied to ensure adequate and timely analyses during the section 7 consultation process. These sentences also express the intent of the Service to avoid a fragmented analysis of environmental concerns through the Service's direct efforts to provide a coordinated review. The Service declines to delete these sentences as requested by several commenters.

Under paragraph (b), the Service agrees with a comment that the biological opinion should be stated in the final environmental impact statement or environmental assessment. A statement of the opinion may be a summary of its findings and conclusions, contrary to the fear of one commenter that the entire opinion must be repeated

in the text of the NEPA document. The Service does feel that the entire opinion should be attached as an exhibit to the NEPA document if completion time permits.

Section 402.07 Designation of Lead Agency.

This section, which governs the designation of a lead agency, is adopted from §402.10(d) of the proposed rule. One commenter requested that the section be amended so that only the lead agency is required to notify the Director that it will be conducting consultation on behalf of itself and all other cooperating agencies. The Service has adopted this suggestion.

Section 402.08 Designation of Non-Federal Representative.

A new §402.08 has been added to the final rule to clarify the role of the designated non-Federal representative and was derived from §§ 402.02 and 402.12 (a) and (b)(5) of the proposed rule. Because the designated non-Federal representative may or may not be the applicant, there is a difference in the role the representative can play in the consultation. If the representative is not the applicant, the information-gathering functions, through informal consultation (§402.13) and/or through the preparation of a biological assessment (§402.12), is the full extent of its participation. However, if the representative is an applicant, its role in consultation is two-fold. As the representative, it may conduct the information-gathering functions identified above; as the applicant, it may continue its participation into formal consultation.

If an applicant is involved and does not desire to be the designated non-Federal representative, the Federal agency and the applicant must agree on the party to be designated. The Director shall be notified, in writing, if a non-Federal entity has been designated to represent the Federal agency for the informal consultation or biological assessment procedures.

One commenter stated that prior notice to the Director of the designation of a non-Federal representative is unnecessary. The Service disagrees because there is a legitimate need for it to be certain of the Federal agency's concurrence in the representation. However, the Service notes that there is a degree of flexibility here; *i.e.*, designation in advance for a continuous action or for a group of related actions is acceptable. In response to one comment, the Service agrees that the designated non-Federal representative may only submit a species list under the biological assessment procedures (§ 402.12) if the Federal agency has, previously to or simultaneously with this notice, provided its written designation to the Director.

Another commenter questioned the Service's authority to conduct informal consultations with non-Federal representatives in place of the Federal agencies. The Service acknowledges that the Federal agency must retain the responsibility to initiate formal consultation along with its ultimate responsibility to ensure that its actions are not likely to jeopardize listed species, but the designation of a representative by the Federal agency to conduct informal consultation does not lessen these responsibilities or eliminate the Federal agency's duty to review its actions. Instead, the designation of a representative allows the Federal agency to coordinate all of its environmental reviews, thereby saving time and resources to obtain a single, comprehensive analysis of the action and its potential impacts. The agency must still review the work product and independently reach its own conclusions and decisions. The representative does the ground work (data compilation and synthesis); the Federal agency cannot delegate its duty to review, analyze, and formally consult.

Concerned that a conflict of interest could exist if applicants were allowed to be designated as non-Federal representatives, one commenter cited 40 CFR 1506.5(c) (NEPA regulation) as authority for eliminating applicants from the field of potential representatives. The Service declines to make the suggested change for the following reason. Section 7(c)(2) itself recognizes that exemption applicants (including permit or license applicants) may prepare biological assessments in cooperation with the Service and under the supervision of the Federal agency. This express statutory opportunity for "interested parties" (as applicants would always be) to prepare biological assessments runs counter to the NEPA rule and shows the clear Congressional intent in favor of full applicant involvement in the section 7 process. Although applicants may fill the role of non-Federal representatives, the ultimate responsibility for compliance with section 7 remains with the Federal agency. In response to one commenter, the regulations have been changed to eliminate the requirement that the Federal agency "participate in the preparation" of the biological assessment. The Service believes that the Federal agency may fulfill its responsibilities by providing guidance and supervision, and by independently reviewing and evaluating the work product of the applicant. Responsibility for carrying out negotiations with the Service may not be delegated to the applicant/representative, as suggested by this commenter. In addition, Federal agencies cannot delegate their role in initiating formal consultation, conference, or early consultation.

Section 402.09 Irreversible and Irretrievable Commitment of Resources.

Section 7(d) of the Act provides that, after initiation of consultation required under section 7(a)(2), the Federal agency and any applicant shall make no irreversible or irretrievable commitment of resources with respect to the Federal action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternatives that would avoid violation of section 7(a)(2). This prohibition does not apply to actions affecting proposed species or proposed critical habitat. This mandatory restriction on commitment of resources is set out in §402.09 of the final rule (formerly §402.11 of the proposal). In response to comments, the language of the proposed rule was corrected to conform more closely to section 7(d). Another commenter requested that the sentence dealing with section 7(d) be amended by adding "measures" after the phrase "reasonable and prudent alternative[s]" to bring the regulation in line with the statute. The Service declines to make this change because it would tend to confuse "reasonable and prudent alternatives" that are included in jeopardy biological opinions with "reasonable and prudent measures" that are included in an incidental take statement under section 7(b)(4) of the Act. The proposed language describing the section 7(d) prohibition accurately implements the Act and is adopted in this final rule.

The proposed rule addressed the duration of the section 7(d) prohibition as follows:

> This requirement exists until: a "no jeopardy" biological opinion is issued by the Service . . . ; the Federal agency adopts reasonable and prudent alternatives; or an exemption is granted under section 7(h).

Proposed rule, 48 FR 29990, 30000 (June 29, 1983), *proposed to be codified at* 50 CFR 402.11. Several commenters asked for a clarification or expansion of these criteria that terminate section 7(d) restrictions. Noting that the Act is silent as to when the section 7(d) prohibition ceases, one commenter contended that the prohibition should end when consultation is terminated. Another commenter, concerned that the proposed language would deprive Federal

agencies of the responsibility and authority to determine compliance with section 7(a)(2), urged the addition of a fourth criterion that would terminate the section 7(d) prohibition if "the Federal agency determines that its proposed action will not jeopardize the continued existence of endangered and threatened species or adversely affect critical habitat." Another commenter went further and urged the Service to adopt other criteria where Federal agency compliance with section 7(a)(2) would remove the section 7(d) restriction. Two other commenters felt that the second criterion—adoption of reasonable and prudent alternatives—must be restricted to those recommended by the Service. They opposed allowing the Federal agency to formulate its own "reasonable and prudent alternatives" without Service approval in order to avoid the prohibition of section 7(d).

The commenters raise valid concerns that illustrate the need to reexamine the duration of the prohibition against the irreversible and irretrievable commitment of resources. First, the Service recognizes that, although its biological opinions issued by authority of section 7(b) are entitled to great deference, the ultimate decision of whether to proceed with an action in light of section 7 responsibilities rests with the Federal agency. The proposed language did preempt Federal agency discretion by placing an agency that disagreed with the conclusion of the Service's biological opinion in the awkward position of facing section 7(d) restrictions on its action, even though it had determined through its own analysis that the section 7(a)(2) standards were satisfied. Second, case law indicates that section 7(d)'s proscriptive force continues while Federal agency efforts to conform its action to the requirements of section 7(a)(2) are "ongoing." *See North Slope Borough* v. *Andrus*, 642 F.2d 589, 611 n.143 (D.C. Cir. 1980); *Conservation Law Foundation of New England, Inc.* v. *Andrus*, 623 F.2d 712, 714 n.1 (1st Cir. 1979). The final rule has been amended to provide that the section 7(d) prohibition is in force during consultation and continues until the requirements of section 7(a)(2) are satisfied.

Therefore, if a Federal agency receives a "no jeopardy" biological opinion from the Service or chooses any reasonable and prudent alternative recommended by the Service, the requirements of section 7(a)(2) are met and the section 7(d) prohibition expires. If the Federal agency disagrees with a "jeopardy" biological opinion or chooses an alternative not provided by the Service based on its own analysis, then the validity of the Federal agency's "no jeopardy" finding will decide whether section 7(a)(2) has been satisfied and whether section 7(d) no longer applies. If it is later determined that the finding is not valid, the Federal agency would be taking the risk of noncompliance with the Act.

Finally, one commenter asked that this section be amended to require Federal agencies to give written notice to the Service verifying that neither it nor any applicant involved has made any irreversible or irretrievable commitment of resources during consultation. The Act does not provide such authority, except arguably in the exemption process. A mandatory section 7(d) notice has not been adopted in this final rule regarding consultation procedures because section 7(d) is strictly prohibitory in nature and not consultative.

Subpart B—Consultation Procedures

There are five primary components within the section 7 consultation procedures—conference, early consultation, biological assessment, informal consultation, and formal consultation. Of these, only conference, formal consultation, and biological assessments may be required. Although a Federal agency may elect to use several of these procedures, they do not represent a mandatory, sequential process. As requested by one commenter, the following is a brief abstract of each component of the consultation process.

If a Federal agency determines that its action is likely to jeopardize the continued existence of any *proposed* species or result in the destruction or adverse modification of *proposed* critical habitat, the Federal agency is required to "confer" with the Service under §402.10. The purpose of a conference is to identify and resolve potential conflicts between an action and proposed species or critical habitat. The Service will make advisory recommendations on ways to minimize or avoid adverse effects. If the proposed species or proposed critical habitat is subsequently listed or designated, respectively, then the Federal agency must consider whether formal consultation under §402.14 is required.

"Early consultation" is an optional process that may be requested through the Federal agency by a prospective applicant to determine whether its proposed action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. Early consultation occurs prior to a formal application for a Federal permit or license. Such early consultation is conducted between the Service and the Federal agency in cooperation with the prospective applicant. At the request of the prospective applicant, early consultation is initiated by the Federal agency responsible for issuing the permit or license and is generally conducted and concluded in the manner prescribed for "formal consultation." If the action is a "major construction activity," the biological assessment requirement of §402.12 must be satisfied before early consultation is initiated. After concluding early consultation, the Service will deliver its preliminary biological opinion to the Federal agency and the prospective applicant.

After formal application is made for the permit or license but before its issuance, the Federal agency should submit to the Service a written request that the preliminary biological opinion be confirmed as a final biological opinion under section 7(a)(2). If the Service determines that no significant changes have occurred in either the proposed action or the information available since early consultation, no new impacts are anticipated, and no new species have been listed or critical habitat designated since early consultation, it will confirm that the preliminary biological opinion remains accurate and shall be treated as a final biological opinion issued under section 7(b) of the Act. Consultation will terminate in accordance with §402.14(*l*). However, if the Service is unable to confirm the preliminary biological opinion due to any of the reasons outlined in §402.11, formal consultation on that action must be initiated under §402.14.

"Biological assessment" requirements apply to all major construction activities as defined in these regulations. Even if not required, Federal agencies may voluntarily prepare a biological assessment to assist them in fulfilling their section 7 responsibilities. Also, any person who wishes to apply for an exemption may voluntarily prepare such an assessment in cooperation with the Service and under the supervision of the appropriate Federal agency.

A biological assessment contains information concerning listed or proposed species or designated or proposed critical habitat that may be present in the action area and an evaluation of any potential effects of the action on such species and habitat. A biological assessment should be used in determining whether formal consultation or a conference is required.

"Informal consultation" includes all the contacts (discussions, correspondence, etc.) between the Federal agency or its designated non-Federal representative and the Service that take place prior to the initiation of any necessary formal consultation. Informal consultation may be used by the Federal agency in determining whether formal consultation under §402.14 or a conference under §402.10 is required.

"Formal consultation" is required under section 7(a)(2) of the Act. A Federal agency must initiate formal consultation if it determines that its action "may affect" any listed species or its critical habitat unless it determines through informal consultation or biological assessment procedures, with the written concurrence of the Service, that its action "is not likely to adversely affect" such species or habitat. If the action is a "major construction activity," the biological assessment requirement must be satisfied before formal consultation may begin. Formal consultation is concluded within 90 days or extended in accordance with the provisions of §402.14. Within 45 days after concluding formal consultation, the Service will deliver its biological opinion stating whether or not the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. If formal consultation results in a "jeopardy" biological opinion, reasonable and prudent alternatives, if any, will be included in the opinion.

These procedures are discussed more fully below, together with the sections governing post-consultation responsibilities of Federal agencies and the factors that require reinitiation of formal consultation. Specific public comments are treated on a section-by-section basis.

Section 402.10 Conference on Proposed Species or Proposed Critical Habitat.

The 1979 Amendments added the requirement in section 7(a)(4) that Federal agencies confer with the Service on any Federal action that is likely to jeopardize the continued existence of any *proposed* species or result in the destruction or adverse modification of *proposed* critical habitat. The purpose of this requirement is to identify and resolve potential conflicts between an action and proposed species or proposed critical habitat at an early point in the decisionmaking process. Conferences will be conducted on an informal basis between the Federal agency and the Service. The Service will make recommendations, if any, to minimize or avoid adverse effects of the action on proposed species or proposed critical habitat. These recommendations are advisory in nature, because the "jeopardy" prohibition of section 7(a)(2) does not apply until the species is listed or the critical habitat is designated. However, the Federal agency and any applicant should give serious consideration to implementing the recommendations since, if the species is later listed or critical habitat designated, the Federal agency must review its action, regardless of its stage of completion, to determine whether consultation is required. In certain instances the Federal agency and the Service may conduct the conference in such a thorough manner that it would satisfy the consultation requirements of section 7(a)(2) if the proposed listing or designation is subsequently completed.

The conference procedures are not repetitive of work performed in the preparation of a biological assessment, as suggested by three commenters. First, the conference requirement applies to all Federal actions, while the biological assessment requirement only applies to actions that are "major construction activities." Second, the conference requirement applies to proposed species and proposed critical habitat, whereas biological assessments are required only when listed species or critical habitat may be present in the action area (although proposed species or proposed critical habitat should be covered in the assessment if they also may be present in the action area). Thus, the conference process fills the need to alert Federal agencies of possible steps that the agency might take at an early stage to adjust their actions to avoid jeopardizing a proposed species. The Service strongly encourages the implementation of the recommendations so the action would not violate section 7(a)(2) if the species is listed or the critical habitat designated.

After reviewing a biological assessment or other available information, the Service may determine that a conference is required for the proposed species or proposed critical habitat. A sentence has been added to the new paragraph (b) of §402.10 [proposed §402.13(a)] to point out the Service's responsibility to request a Federal agency to confer after a review of available information. The last sentence of the proposed paragraph (a) has been deleted since the new §402.08 clearly defines the role of the designated non-Federal representative. The Service declines to take the position that it can "require" the initiation of a conference, because the Federal agency bears the ultimate responsibility to assess the likelihood of jeopardy to proposed species by its actions. However, the Service will vigilantly review biological assessments and other available information and fulfill its duty to make Federal agencies aware of their responsibilities under the Act.

The Service emphasizes the need for Federal agencies to confer because such efforts may not only minimize or avoid injury to proposed species but might also prevent the halting of an action if the species is subsequently listed:

> Obviously, Federal agencies irreversibly committing resources and foreclosing alternatives to an action that is likely to jeopardize a proposed species do so with the risk that the species will eventually be formally listed and the prohibitions of section 7 will become applicable. The conferees do not believe that any Federal agency or permittee should make any irreversible or irretrievable commitments of resources for the purpose or with the intent of foreclosing otherwise reasonable alternatives or in order to secure an exemption pursuant to section 7(h).
>
> H.R. Conf. Rep. No. 697, 96th Cong., 1st Sess. 13 (1979).

There is no requirement that Federal agencies confer with the Service on species that are candidates for listing proposals. However, for the reasons identified by Congress in the Conference Report to the 1979 Amendments on proposed species, the Service encourages Federal agencies to confer informally on candidate species when deemed appropriate to avoid jeopardy and to avoid potential economic loss through project modification if the species is later listed.

Several specific changes were recommended for proposed paragraph (a) [paragraphs (a) and (b) in the final rule]. One commenter felt that the reference to "potential endangered species conflicts" was too restrictive. The Service agrees that the proposed rule might have been construed so as to exclude threatened species. Therefore, the sentence has been adjusted to refer to all potential conflicts.

One commenter urged the Service to change the standard for initiating a section 7(a)(4) conference from "likely to jeopardize" to "would adversely affect." The regulation tracks the statute. The Service lacks the authority to make the requested change.

Several commenters urged the Service to make provisions for applicant involvement in the conference process. The Service agrees, and has added language in paragraphs (a), (c), and (e) of §402.10 to ensure that applicants have an opportunity to participate in the

conference, and that they receive a copy of the conclusions documented by the Service.

Another commenter asked that time limits be established for the conference process. The Service declines to establish time limits for the conference requirement. The timing of the section 7(a)(4) process is, in part, dictated by the progress of the proposed rulemaking to list a species or to designate critical habitat. Regardless of any time limits that the Service could establish, the conference requirement expires and consultation is required if the listing or critical habitat designation becomes final. The Service finds no reason to impose rigid time frames for conferences.

Paragraph (c) defines the nature and content of the conference. Basically, a "conference" involves informal discussions on the identification and possible avoidance or minimization of potential adverse effects to proposed species or proposed critical habitat from a Federal action. The reference to "informal discussions" should not be confused with "informal consultation," which is a distinct, but optional, component of consultation.

The Service declines to modify paragraph (c) by changing "advisory" recommendations to "conservation" recommendations, as suggested. Such a change may confuse conference with formal consultation, the required procedure in which discretionary "conservation recommendations" may be given. The Service also declines to adopt suggested provisions that would (1) require advisory recommendations to be made in every conference, (2) force the Service to notify the Federal agency of the date on which a final decision will be made on a listing proposal, or (3) require the Service to initiate emergency rulemaking proceedings to list a species or designate critical habitat if the Federal action is likely to jeopardize the species. Although required, conference is an informal process that has no substantive force. To force every conference into a regimented structure would be counterproductive and contrary to the intent of the Act. When appropriate, the Service will make advisory recommendations on ways to avoid or minimize adverse effects to proposed species or proposed critical habitat. During the conference, the Service will apprise the Federal agency of the progress of the listing or critical habitat proposal and will attempt to notify the Federal agency when the listing or critical habitat proposal becomes final. Emergency rulemaking is provided for under section 4(b)(7) of the Act and will be used if appropriate under the circumstances.

One commenter suggested that the conference involve all of the steps of formal consultation, but on an informal basis so that if the listing becomes final, the conclusions and recommendations derived from the conference could be adopted as a final biological opinion. In some cases, a thorough, well-prepared conference might elucidate sufficient conclusions and recommendations to serve as the biological opinion, upon the final listing of a species. While section 7(a)(4) does not require Federal agencies to follow the section 7(a)(2) process for proposed species or proposed critical habitat, or specifically provide for the conversion of conference "conclusions and recommendations" into a final biological opinion [in contrast to explicit authority under section 7(b)(3)(B) for the conversion of preliminary biological opinions into final biological opinions], such a procedure is available to the Federal agency and the Service in appropriate instances.

If the information necessary to conduct a formal consultation is available at the conference stage, and if a formal procedure is deemed appropriate by both the Federal agency *and* the Service, the conference may be conducted through a procedure equivalent to formal consultation; the results, or opinion, derived from a "formal" conference may be adopted as the biological opinion when the proposed listing or designation is completed. It should be noted that the conference conclusions and recommendations would only be adopted as the biological opinion in those instances where no new data are developed, including that developed during the rulemaking process on the proposed listing or designation of critical habitat, and no changes to the Federal action are made which would alter the content of that opinion. By providing procedures which allow for a more extensive conference that may later be adopted as the biological opinion, the Service does not intend to expand upon the requirements of section 7(a)(4). Rather, this procedure is an option available to the Federal agency and the Service to help avoid conflicts and expedite consultation if the proposed species or critical habitat is listed or designated. Therefore, a new paragraph (d) is added to this final rule to acknowledge the availability of a "formal" conference procedure.

Paragraph (e) of §402.10 discusses the documentation of the results of the conference. If the action involves only proposed species or proposed critical habitat, a copy of the recommendations will be forwarded by the Service to the Federal agency and any applicant. If an action also involves formal consultation on listed species or critical habitat, the Service will provide the recommendations on proposed species or proposed critical habitat with the biological opinion. As requested by some commenters, the final rule has been clarified to state that the conclusions of a conference will be provided with the biological opinion rather than made an integral part of ("consolidated in") the opinion. The Service does not intend that the informal nature of the conference be changed or that any of the requirements of formal consultation under section 7 be imposed on Federal agencies with respect to proposed species or proposed critical habitats unless the Federal agency specifically requests a more formal procedure. Early initiation of these discussions increases the chances of resolution of potential conflicts.

Section 402.11 Early Consultation.

The 1982 Amendments added a provision to the consultation process [section 7(a)(3)] designed to identify and to minimize, early in the planning stage of an action, potential conflicts between the action and listed species. These early consultation provisions authorize the Service to consult with Federal agencies at the request of and in cooperation with prospective applicants regarding the impact of proposed actions on listed species or critical habitat. These provisions are incorporated into the final regulations in §402.11 (§402.14 of the proposed rule). The intent of this provision is to involve the Service and State and local planning and conservation entities in the planning stages of actions. The Service believes that early consultation will be helpful in establishing a mechanism for early resolution of potential conflicts. Congress did not intend that this provision be used to authorize consultation for speculative or remote actions but rather only on actions which are likely to occur. The regulations require prospective applicants to provide sufficient information describing the project, its location, the scope of activities associated with it, and the anticipated impacts to listed species to enable the Federal agency and the Service to conduct meaningful early consultations.

The opportunity for an early consultation should expedite the permitting and other regulatory processes associated with actions requiring Federal authorizations.

Contrary to the interpretation of one commenter, early consultation is not a required process, but rather is an optional step that a prospective applicant can take to factor in section 7 considerations during the initial planning stage. Although early consultation contains most of the features of formal consultation, the Service declines to adopt the suggestion to place the early consultation provisions within the formal consultation section as a "special case." Early consultation, unlike formal, is not required and occurs before any application for a permit or license is filed, whereas formal consultation is a post-application process when applicants are involved. These differences are significant and merit the separation of these distinct processes into separate sections. However, because of the extensive similarities in the procedures for early and formal consultation, the final rule has been substantially modified in format to reference appropriate paragraphs in § 402.14 (formal consultation) to avoid repetition of these commom features. Although this has greatly shortened the early consultation section, the requirements and procedures have not been altered substantively.

One commenter was confused over the parameters of early consultation and informal consultation (§ 402.13). Informal consultation is a post-application process, as is formal consultation; early consultation is a pre-application process. There is no overlap. Designated non-Federal representatives can carry out informal consultation, and they can also carry out the biological assessment process if an assessment is required during the early consultation. Although only Federal agencies conduct early consultation directly with the Service, non-Federal representatives may continue to play a role in the data-gathering function of consultation.

Several commenters believed that proposed § 402.14 took away the prospective applicant's right to request early consultation and to make the initial determination of possible impacts to listed species or critical habitat. The proposed rule preserved the prospective applicant's right to request early consultation but provided the Federal agency with the responsibility for determining impacts to listed species or critical habitat. In response to comments, the final rule has been rearranged to clarify the primary role of the applicant in making the initial determination and request to the Federal agency. However, the applicant's rights under section 7(a)(3) of the Act are not unqualified, and the ultimate burden is on the applicant to meet certain threshold criteria.

Paragraph (a) of § 402.11 outlines the purpose of early consultation and is adopted substantially as proposed in § 402.14(b) and the first sentence of § 402.14(c). The legislative history is clear that the prospective applicant must be involved to the greatest extent practicable in every aspect of the early consultation process. H.R. Conf. Rep. No. 835, 97th Cong., 2d Sess. 28 (1982). One commenter expressed concern that it may not be possible to have the applicant involved in every meeting and telephone call between the Federal agency and the Service. Therefore, acknowledging the practical limitations on involving the applicant in all consultation contacts (but still recognizing the need for continuous communication with the applicant), the second sentence of paragraph (a) now reads that the prospective applicant should be involved "throughout" (instead of "in every aspect of") the consultation process.

Paragraph (b) of § 402.11 sets out the threshold conditions that must be satisfied before early consultation can be initiated and is derived from proposed § 402.14(c). As suggested by one commenter, the prospective applicant's request for early consultation should be made in writing to the Federal agency.

The "may adversely affect" threshold for initiating early consultation has been expanded to "may affect." This action was taken because the more restrictive standard unnecessarily limited access to this early review procedure, especially since at the early planning stage of an action the exact nature of a possible effect could be difficult to define.

Section 402.14(c) of the proposal established that the Federal agency ensure that the following conditions be met prior to initiation of early consultation:

(1) there must be a definitive proposal outlining the action and its effect;

(2) it must be shown that the action is technologically, administratively, and legally feasible;

(3) it must be shown that the applicant possesses adequate economic resources to conduct the action; and

(4) it must be shown that the applicant possesses some property interest in the proposed site on which the action will occur.

Numerous comments were received on these criteria. Three commenters urged the Service to strike all four conditions because of their unreasonableness and the Service's lack of authority to impose them on applicants. Other commenters criticized conditions (2) and (3) due to their ambiguity. Contending that enforcement of these conditions would preclude early consultation in many cases, the commenters noted that the information needed to meet these conditions is not available at the time that early consultation is most useful. The commenters also attacked condition (4), regarding the need to show an ownership interest in land, because early consultation would normally occur prior to the selection of an exact location for the project. Two commenters stated that conditions (1) and (2) are adequate for screening serious actions. One commenter suggested that only two criteria be addressed in determining eligibility for early consultation: scope of the project, and possible effects on listed species.

The Service was given explicit authority in section 7(a)(3) of the Act to issue guidelines that would prevent speculative or undefined actions from triggering early consultation.

> The Committee expects that the Secretary will exclude from such early consultation those actions which are remote or speculative in nature and to include only those actions which the applicant can demonstrate are likely to occur . . . . The Committee further expects that the guidelines will require the prospective applicant to provide sufficient information describing the project, its location, and the scope of activities associated with it to enable the Secretary to carry out a meaningful consultation.

H.R. Rep. No. 567, 97th Cong., 2d Sess. 25 (1982).

The final rule retains proposed condition (1) that requires the nature and effect of a prospective action to be defined. Without adequate information, early consultation would be meaningless. Proposed condition (2) has been modified in the final rule to require that the prospective applicant certify that it intends to implement its proposal, if authorized. This will prevent highly speculative actions from entering early consultation. The Service believes that these two conditions are reasonable and will allow Federal agencies and the Service to focus their attention on concrete, feasible actions through meaningful, early consultations.

Proposed conditions (3) and (4) described above have been deleted. The Service agrees that these conditions went beyond the normal pre-application information-gathering practices of Federal agencies and that they might have discouraged early consultations unnecessarily.

Paragraph (c) of § 402.11 is adopted from proposed § 402.14(a) and the introductory paragraph of proposed § 402.14(d). This paragraph governs initiation of early consultation by the Federal agency if the prospective applicant complies with paragraph (b).

Paragraph (d) of § 402.11 governs the procedures for conducting early consultation. To eliminate unnecessary regulatory language, this paragraph cross-references the items in § 402.14(c)–(j), since the general consultation requirements are the same as for formal consultation. The proposed rule repeated these requirements in § 402.14 (d) through (i).

One commenter argued that the Service exceeded its authority in proposed paragraph (d)(3) by telling Federal agencies how to meet their responsibilities by requiring Federal agencies to involve the applicant in the data-gathering function. Although this is not included in the final rule, the Federal agency has an underlying responsibility to involve the applicant in every aspect of the early consultation to the extent possible. Moreover, the applicant may be the primary source of data used in the consultation.

If the action is a major construction activity, then a biological assessment must be prepared in accordance with § 402.12 before the request for early consultation is submitted, as is required for formal consultation. This is a change from proposed § 402.12(b)(10), which made the biological assessment optional during early consultation. The Service agrees with the comment that, for major construction activities, a meaningful early consultation must include the preparation of a biological assessment because the preliminary biological opinion issued after early consultation may be confirmed as the final biological opinion. Therefore, if early consultation is requested for a major construction activity, the Federal agency must complete a biological assessment under § 402.12 prior to submitting its request for early consultation.

The time limits and extension provisions for formal consultation are incorporated by reference as the requirements for early consultation. Several commenters felt that the "mutually agreed upon" language of the proposal [§ 402.14(e)] was too loose and that definitive time limits were needed. The Service agrees and has adopted the time limits for formal consultation to apply to early consultation as well. The Service notes that, for major construction activities, the time period will not begin to run until the biological assessment under § 402.12 is completed. Because time deadlines have been adopted, there is no need to require a written notice that consultation has been concluded, as requested by one commenter.

Proposed § 402.14(i) concerned requests by the Service for additional data, and did not require the addition of a written notice procedure for obtaining an extension. This is now required, as requested by one commenter, by incorporating the formal consultation requirements.

Proposed § 402.14(f) recognized that the Service's responsibilities during early consultation are the same as those that exist during formal consultation. The final rule retains this provision by reference. The Service is opposed to limiting the scope of its analysis of impacts during early consultation, and it is also opposed to limiting the free flow of communication among it, the Federal agency, and the applicant. Therefore, the comment suggesting that draft preliminary biological opinions not be released to the Federal agency or the prospective applicant is rejected. This is not an issue that can be dealt with on an ad hoc basis, depending on the program experience with particular agencies or regions. The policy behind early consultation is clear: full involvement of all parties, including the prospective applicant, to identify and eliminate conflicts at the earliest possible stage of a project.

Paragraph (e) of § 402.11 provides that the contents and conclusions of a preliminary biological opinion are the same as for a biological opinion issued after formal consultation in § 402.14(i). One commenter stated that biological opinions need only be issued after formal consultation under section 7(a)(2) of the Act and that this should be clarified in the rule. The Service disagrees because a "written statement" containing the Secretary's opinion is required to be given after the conclusion of both early and formal consultation. However, there is an important difference in these two types of opinions: the former has no independent, operative significance, while the latter states the Service's "final" judgment on the impacts of an action. The preliminary biological opinion, issued after the conclusion of early consultation, has no operative force until it is later confirmed by the Service under section 7(b)(3)(B) of the Act, just before the action is to be taken.

One commenter said that it is inappropriate to include an incidental take statement with a preliminary biological opinion. The Service believes that input on incidental take is essential to adequately assist the applicant in planning its action. It would be unfair to force the applicant to wait until the time for confirmation of the preliminary biological opinion to receive its first notice on the terms and conditions that must be complied with and the amount and extent of permissible incidental take. No harm results to the species by providing this statement in the preliminary biological opinion because, as stated in the rule, it does not constitute a permit to take. The "taking" exemption under section 7(o)(2) does not occur until the preliminary biological opinion is later confirmed as a final opinion under § 402.11(f).

Paragraph (f) of § 402.11 is adopted from proposed §§ 402.15(b) and 402.18(a). This paragraph acknowledges that, if certain findings are made by the Service, a preliminary biological opinion may be confirmed as a final biological opinion after formal application for a Federal license or permit is made. The rule requires the Service to make its decision on confirmation within 45 days after receipt of the Federal agency's request. As requested by one commenter, both the request and the Service's response must be in writing.

Section 402.12 Biological Assessment.

This section explains the biological assessment requirements under section 7(c) of the Act and the process that must be followed in its preparation. The requirement that biological assessments be prepared in advance of certain consultations under section 7(a)(2) was added by the 1978 Amendments. Although the Service has, as a matter of agency practice, been requiring the preparation of biological assessments in appropriate cases under the authority of section 7(c), this final rule consolidates all regulatory requirements pertaining to biological assessments.

The proposed rule addressed the biological assessment provisions in §§ 402.01(c) and 402.12(b). In response to public comments, the Service has merged these sections in the final rule into § 402.12. The new format clarifies the requirements and procedures for preparing biological assessments. Although the organization of these provisions has been changed substantially, the substance of the regulation is, except for minor amendments, the same as that presented in the proposed rule.

The informal consultation and biological assessment processes were both presented in § 402.12 of the proposed rule. This confused several commenters who believed that biological assessments could only be performed in conjunction with informal consultations. To eliminate this

confusion, the biological assessment provisions are placed in a separate section, immediately before informal consultation. Although a Federal agency may prepare a biological assessment while involved in informal consultation with the Service, there is no requirement that it do so.

References to conference, early consultation, and formal consultation in proposed §402.12 (b)(7) (third through fifth sentences) and (b)(10) have been deleted because cross-references to the biological assessment requirement have been inserted in §§402.10, 402.11, and 402.14 to explain the interrelationship of these processes.

The purpose of a "biological assessment," as stated in §402.12(a), is to evaluate the potential effects of the action on listed or proposed species or designated or proposed critical habitat and determine whether any such species and habitat are likely to be adversely affected by the action. Biological assessments are designed to assist Federal agencies in "determining whether section 7(a)(2) consultation should be initiated by identifying endangered or threatened species that may be present in the area affected by their proposed project and by identifying the impacts of those projects on such species." H.R. Rep. No. 697, 96th Cong., 1st Sess. 14 (1979). Such assessments are designed to promote the "early discovery of and elucidation" of potential endangered and threatened species conflicts with proposed agency actions. These reviews should take place well before the agency exercises its discretion to authorize, fund, or carry out an action. H.R. Rep. No. 1625, 95th Cong., 2d Sess. 20 (1978).

One commenter asked that a reference be inserted for preparation of "preliminary biological assessments." The Service does not require advance review of draft biological assessments; the requested procedure would add to statutory requirements. Therefore, the addition has not been made.

Section 402.12(b)(1) of the final rule acknowledges that the Act exempts from the biological assessment requirement those actions for which contracts were let or construction was started on or before the effective date of the 1978 Amendments. One commenter argued that the assessment requirement must not be retroactive, but should apply only to current actions as of the issuance of the final rule. The Service must follow the Act on this point and adopt the rule as proposed. This will not operate to the disadvantage of any Federal agency involved in a section 7 consultation, because the Service has been requiring the preparation of biological assessments since the effective date of the 1978 Amendments.

Section 402.12(b)(1) also recognizes that virtually any Federal agency, State or local agency, private organization, or individual (potential exemption applicants) may voluntarily prepare a biological assessment consistent with the procedures set forth in this section to assist it in fulfilling its section 7 responsibilities. One commenter urged the Service to delete the sentence referring to voluntary preparation of assessments in proposed §402.12(b)(1) because consultation is terminated if a biological assessment is not *required*. The commenter's statement is only true for an action if no listed species or critical habitat are present in the proposed action area. The placement of that sentence in the proposed rule was confusing, and thus the final rule has been clarified. The Service would like to make it clear, however, that whether a biological assessment is required or voluntary bears no relation to whether a conference or formal consultation is required under §§402.10 or 402.14, respectively. The assessment is a tool used to identify impacts to species or habitat so that a decision can be made as to whether a proposed action is likely to adversely affect listed species or critical habitat. The biological assessment can be used to determine whether a conference or formal consultation is required.

The Act provides that any person who may wish to apply for an exemption from the requirements of section 7(a)(2) may voluntarily conduct such an assessment, in cooperation with the Service and under the supervision of the appropriate Federal agency. These potential exemption applicants must follow the procedures described in §402.12. Under section 7(h)(2), an exemption is not permanent unless a biological assessment has been prepared. A permanent exemption remains in force for a particular Federal action regardless of the listing of additional species in the action area, whereas an ordinary exemption is limited to the species involved in the section 7 consultation. Paragraph (b)(1) acknowledges these statutory provisions.

Therefore, the Service retains the flexibility inherent in paragraph (b)(1) that allows for the preparation of biological assessments in those instances where they are not specifically required by this rule. Although requested by another commenter, the Service declines to set guidelines for the exercise of discretion by other Federal agencies or applicants on the decision to voluntarily prepare assessments.

Paragraph (b)(2) has been added in response to public comments. The limitation in section 7(c)(1) of the Act on entering contracts or starting construction on an action while the preparation of a biological assessment is pending has been included in these regulations. This construction restriction applies to all actions involving the preparation of a biological assessment.

The fact that a biological assessment is not required for all actions does not mean that listed or proposed species or designated or proposed critical habitat receive less protection. Federal agencies still have an obligation to review all of their actions to determine whether formal consultation under §402.14 is required. In addition, Federal agencies must confer on actions that are likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat.

One commenter asked that Federal agencies be required to document any finding of "no effect" on listed species or critical habitat for actions not involving the preparation of a biological assessment. The Service has no authority to impose such a requirement, but does encourage Federal agencies to use their NEPA documentation to illustrate their analysis of Endangered Species Act issues.

The Service reserves the right to request that an agency prepare a biological assessment. One commenter questioned the right of the Service to request assessments when such are not otherwise required by the Act. Another commenter feared that the Service would routinely request field studies with many of the characteristics of biological assessments, regardless of the action's potential effects, the acceptability of a general field reconnaissance, or the obligation of the Service to provide guidance and data. The Service's request for a biological assessment or for field studies is not of mandatory effect; a Federal agency may reject any such request. The Service recognizes that consultation involves a two-way flow of information. It will always strive to provide data that are available and to assist in designing or in conducting studies (within budgetary constraints and available staffing) or in gathering data through consultation.

Paragraph (c) of §402.12 covers the request by a Federal agency for a species list from the Service. This paragraph was adopted from §402.12(b)(1) (first sentence) of the proposed rule. Paragraph (d) of §402.12

involves the Director's issuance of a species list. This paragraph was adopted from §402.12(b)(2) of the proposed rule.

The biological assessment process begins when a Federal agency decides that its action is a major construction activity, as discussed in these regulations, or it decides that it will voluntarily prepare a biological assessment. The Federal agency or the designated non-Federal representative requests information on whether listed or proposed species or designated or proposed critical habitat may be present in the action area. Within 30 days of receipt of that inquiry, the Director will respond with a list of any such species and critical habitat that may be present, as well as the available data (or references thereto). This may include recommendations for studies or surveys that may assist in the preparation of the biological assessment.

Contrary to the contentions of several commenters, the request for a species list is mandatory under section 7(c) for any major construction activity, unless the Federal agency forwards its own list for the Director's concurrence as explained below. This is not a burdensome requirement, even for apparent "no effect" actions, since the entire process, including the Director's response that no listed species or critical habitat occurs in the action area, may be carried out without delay through the NEPA process.

In response to comments, the final regulations explicitly allow the Federal agency or the designated non-Federal representative to proceed with the preparation of the biological assessment prior to receiving a species list from the Service. In this situation, the Federal agency or the designated non-Federal representative is required to notify the Director in writing as to the species and critical habitat that are being included in the assessment. As recommended by three commenters, the Service will respond to this notification in writing within 30 days as to whether it concurs with the species and critical habitat to be covered in the biological assessment.

One commenter suggested that an applicant should have an opportunity to informally request a species list to assist it during the planning stage of a project. Then, if the applicant begins preparation of a biological assessment within 90 days of receipt of this "informal" list, the commenter thought that the Service should not amend the list at a later time. The commenter appears to be advocating an opportunity for early consultation, which is provided for under §402.11 of this final rule.

Nevertheless, the request that a species list not be modified once issued might backfire on the applicant, because §402.14 requires consultation on all listed species and critical habitat that may be affected by a Federal action. Even if a species is inadvertently omitted from the species list and biological assessment, the Act nevertheless requires that it must be considered in satisfying the requirements of section 7(a)(2). Thus, the sooner the Service notifies the applicant of additional species to be included in a required biological assessment, the sooner the consultation will be completed.

In addition to listed or proposed species or designated or proposed critical habitat, the Service will include candidate species in the species list. Candidate species are those species being considered for listing but not yet the subject of a proposed rule. This will inform the Federal agency and any applicant of potential proposals for listing. Candidate species have no legal status and are accorded no legal protection under the Act, and thus the Federal agency need not include them in a biological assessment. However, should a candidate species become proposed or listed prior to completion of the action, a conference or formal consultation may be required.

Several commenters asked that species lists be "site-specific" and not regional in scope. One of these commenters urged the Service to include only species actually known or believed to occur in the action area. The Service agrees that the species list should be tailored to the action area and that field personnel should take care that the list is not overinclusive. However, the Act requires the Service to provide a list of all listed or proposed species that "may be present" in the action area. Thus, migratory species that "may be present" at some point within the action area must be included in the species list.

Another commenter said that the Service should include only species in the list that it believes may be affected by the action. This approach is not consistent with section 7(c), which requires a disclosure of all species that "may be present" in the action area. The comment would also eliminate the Federal agency's right to make an initial evaluation of possible effects to each species.

One commenter's conclusion that a determination of no adverse effect after receipt of the species list, but before preparation of the assessment, eliminates the need to prepare the assessment and concludes consultation is erroneous. The biological assessment is used to determine whether an activity "is likely to adversely affect" listed species or critical habitat. Consultation does not conclude unless the Service concurs in writing with the finding of the biological assessment indicating that the action is not likely to adversely affect listed species or critical habitat.

The Service has clarified paragraph (d)(1) to accommodate the concern of the House Committee that biological assessments not be required on major construction activities affecting proposed species or proposed critical habitat only. However, if a species list includes both listed and proposed species, each must be considered in the biological assessment as required by section 7(c) of the Act.

Concerned that the Federal agency should receive all information during the assessment process, one commenter asked that the species list be delivered to both the Federal agency and its designated non-Federal representative due to the agency's responsibility to supervise the preparation of the assessment. The Service declines to include this requirement in the rule, but will forward a copy to the Federal agency, if requested. It is the Federal agency's responsibility to decide whether it wants to designate a non-Federal representative, and if one is designated, the species list will be sent to the representative as requested by the Federal agency.

Several commenters suggested that the Service's ability to recommend "necessary" studies or surveys would contravene the "best available scientific and commercial data" standard of section 7(a)(2). The Service agrees that the proposed language may have implied that additional studies or surveys were required or necessary to complete the assessment. Therefore, the sentence is changed to state that the Service may recommend studies or surveys that it believes would assist in the preparation of the assessment. A new sentence is also added to clarify that such a recommendation 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. This change preserves the Service's prerogative to request further studies if deemed appropriate, while recognizing the ultimate responsibility of the Federal agency to secure the best available data. Two commenters suggested that the request for studies be limited to studies necessary to locate and assemble already existing data. The Service declines to so limit the scope of studies it may request.

Paragraph (e) of §402.12 is carried over from §402.12(b)(3) of the proposal.

It requires a party preparing a biological assessment to verify its species list with the Service if, after 90 days from the receipt of or concurrence with the species list, it has yet to commence the preparation of the assessment. A written verification, as suggested by one commenter, is not required since that would be tantamount to issuing a second species list, contrary to the informal nature of this verification step. The Federal agency may, on its own, document the verification received under this paragraph in its administrative record. As requested by one commenter, the Service has distinguished the initiation of the biological assessment time period (time of receipt of or concurrence with a species list) from the point at which actual preparation of the assessment is begun.

Based on comments received, a new paragraph (f) entitled "contents" has been added. Some commenters argued that Federal agencies should be required to include certain minimum research methods or activities in the preparation of a biological assessment. One commenter suggested that preparers of biological assessments should:

(a) conduct a scientifically sound on-site inspection of the area affected by the action, which must, unless otherwise directed by the Service, include a detailed survey of the area to determine if listed or proposed species are present or occur seasonally and whether suitable habitat exists within the area for either expanding the existing population or potential reintroduction of populations;

(b) interview recognized experts on the species at issue, including those within the Fish and Wildlife Service, the National Marine Fisheries Service, State conservation agencies, universities and others who may have data not yet found in scientific literature;

(c) review literature and other scientific data including recovery plans if available to determine the species' distribution, habitat needs, and other biological requirements;

(d) review and analyze the effects of the action on the species, in terms of individuals and populations, including consideration of the indirect and cumulative effects of the action on the species and habitat;

(e) analyze alternate actions that may provide conservation measures; and

(f) conduct any studies necessary to fulfill the requirements of (a) through (e) above.

The Service agrees that assessments should be as complete and thorough as possible, but declines to impose strict minimum standards that all biological assessments must satisfy. The above-listed activities, which may be performed in preparing an assessment, are endorsed by the Service as items that a model assessment would include. However, the nature of the Federal action may not warrant carrying out all of these research activities or studies, and some of the steps may not be technologically feasible in certain cases. Therefore, the new paragraph (f) only contains suggestions of what a Federal agency may include in a biological assessment.

One commenter asked the Service to explain the difference between the degree of information needed in a biological assessment and the degree of information needed to initiate formal consultation when the action does not require the preparation of an assessment. In both cases the overall information standard is the same: "best scientific and commercial data available." The difference arises in the process. If a biological assessment is prepared, it must include not only the data but also a synthesis of the data involving an analysis of the effects of the action. Basically, the assessment serves as an analytical instrument and can be used by the Federal agency "to build its case" as to whether a particular action is likely to adversely affect a listed species or its critical habitat. If the Service concurs with a determination of "not likely to adversely affect," then formal consultation is not required. If an assessment is not required, the Federal agency need only submit data to the Service to initiate formal consultation pursuant to § 402.14(c).

Paragraph (g) of § 402.12, which deals with the authority to incorporate earlier biological assessments by reference as the assessment for a current proposal, is adopted from the last two sentences of proposed § 402.12(b)(1). In those instances where a proposed Federal action is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may not need to prepare a new biological assessment.

One commenter requested that language be added to clarify that a previous biological assessment being incorporated by reference could have been part of a prior EIS or area-wide assessment. The Service declines to make the change noting that the form of the previous biological assessment (whether in an EIS or other document) has no bearing on whether it meets the conditions for incorporation by reference.

In response to comments, the conditions that must be met for incorporation by reference are clarified. The biological assessment requirement may be fulfilled by incorporating by reference the earlier biological assessment and supporting data 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 critical habitat designated or proposed for the action area; and (3) the biological assessment has been supplemented with any relevant changes in information.

Condition (1) has been expanded to allow incorporation by reference if the proposed action involves similar impacts (rather than no new impacts). The term "or administrative unit" has been deleted as it is substantially the same as "geographic area." The Service adds "for the action area" at the end of condition (2) to clarify the scope of the certification. Finally, condition (3) is changed to allow Federal agencies to incorporate a former biological assessment by reference while supplementing it with any relevant changes in information. This change clarifies the intent behind this paragraph.

Paragraph (h) of § 402.12, which cross-references permit requirements under the Act that may apply to the preparation of a biological assessment, is adopted as proposed in § 402.12(b)(4)(i). The Service believes that the references in the rule are adequate to alert Federal agencies and/or designated non-Federal representatives of the need to consider applicable permit requirements, rather than include the appropriate section 10 permit requirements in these regulations, as suggested by one commenter. Certain field work might involve the take (*i.e.*, harassment, harm, etc.) of listed species which, absent a permit, would violate sections 9 or 4(d) of the Act. To avoid possible violations, the Federal agency or non-Federal representative should apply for and obtain a section 10 permit for such field work. Those individuals carrying out field studies or other research without a permit during the section 7 consultation process are subject to the prohibitions of the Act and other applicable wildlife laws. The Service emphasizes that permits should be obtained if takings of any listed species are anticipated.

Paragraph (i) of § 402.12 specifies the time period for completing a biological assessment and sets out the requirements for any needed extension. This paragraph is taken substantially from § 402.12(b)(8) of the proposed rule.

Two commenters asked that the rule require written notices of all extensions, regardless of whether an applicant is involved. A written notice from the Federal agency to the applicant is required if an extension is agreed upon between the Service and the Federal agency, and such written notice must be provided by the Federal agency prior to

the expiration of the 180-day time period. However, the Service declines to require a written notice if an applicant is not involved in the consultation, because responsibility for the preparation and completion of the biological assessment rests with the Federal agency. The Service will defer to the needs and judgment of the Federal agency which can document the extension in its administrative record.

Another commenter asked that the Service explain that the 180-day time period begins on the date of receipt of the species list (or the date of receipt of the Director's concurrence with the Federal agency species list). This change has been made since it clarifies when the time period begins and is consistent with the intent of this paragraph.

As noted above, if an 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 an extension is necessary. The applicant has no remedy to expedite the preparation of the biological assessment under section 7(c) of the Act. Thus, the 180-day time period is subject to an indefinite extension at the Federal agency's prerogative. The Service lacks statutory authority to impose an appeal process to review extensions, as requested by two commenters.

Paragraph (j) of § 402.12, which requires the submission of completed biological assessments to the Director for review, is adopted from proposed § 402.12(b)(4)(iii). In response to two comments, the Director will make a written response within 30 days after receiving the complete assessment as to whether or not the Service concurs with the findings in the assessment. This change provides Federal agencies with a written record acknowledging the Service's receipt of the biological assessment and indicating the results of the Service's review.

A new sentence is added to this paragraph to clarify that the Federal agency may initiate formal consultation concurrently with the submission of the assessment to the Director.

In response to one comment, the Service declines to substitute "Service" for "Director" in this paragraph. It is important that the Director or his authorized representative directly receive the biological assessment for review so that a timely review can be facilitated.

Paragraph (k) of § 402.12, governing the use of a completed biological assessment, is derived from § 402.12(b)(7) of the proposed rule. Once the biological assessment has been completed, the Federal agency must consider whether formal consultation should be initiated or if a conference is necessary. Three commenters noted that a written notice of concurrence should be issued by the Director if the Service agrees with the Federal agency's finding that its action is not likely to adversely affect listed species or critical habitat (*i.e.*, the Service concurs in writing that formal consultation is not needed). This comment has been accommodated by appropriate changes to paragraphs (j) and (k).

The proposed § 402.12(b)(5), "Assistance from other sources," has not been included in the biological assessment section of the final rules. The substance of this paragraph has been included in the final § 402.06 dealing with designated non-Federal representatives. The first two sentences have been deleted since a Federal agency may obtain assistance from any source to aid in the preparation of a biological assessment (or other aspect of consultation), and it does not need to be authorized in these regulations. One commenter suggested that the Service be included as a source of information; however, assistance from the Service is already included in appropriate sections of the regulations.

Section 402.13 Informal Consultation.

Informal consultation is an optional procedure that includes all contacts between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required. It is designed primarily to except from the formal consultation process those proposed actions which, upon further informal review, are found not likely to adversely affect a listed species or critical habitat. If the Service concurs with such a determination, formal consultation is not required. The final rule is adopted largely by combining proposed §§ 402.12(a), 402.15(c), and 402.15(i)(1), into one composite statement of the purpose and scope of informal consultation.

Several commenters disagreed on the scope of informal consultation. One commenter felt that informal consultation should include all dialogue between the Service, the Federal agency, and any designated non-Federal representative in determining whether formal consultation is required. Another commenter recommended that informal consultation be available if listed species are found in the action area. The Service believes that informal consultation encompasses all of these communications between the Service, the Federal agency, and the designated non-Federal representative, as well as others. The Service is available for informal consultation at any time; the decision on whether to seek informal consultation is that of the Federal agency. The Service agrees that, if requested as a part of informal consultation, it should participate in NEPA scoping meetings.

The Service declines to specify uniform levels of contact that must be followed in conducting informal consultations. Existing relationships between the Service's field or regional offices and particular Federal agencies mandate maximum flexibility. The present system is working well and efficiently addresses the needs of other Federal agencies, and it is therefore retained.

Because informal consultation is an optional process that is under the control of the Federal agency as to its initiation and duration, the Service declines to require notices of initiation and/or termination. Such a step would merely place paperwork burdens on the Federal agency in an otherwise voluntary process.

As noted in § 402.12, biological assessments are required for major construction activities. To clarify a procedural point, the Service notes that the biological assessment process may be conducted simultaneously with informal consultation if desired by the Federal agency, or the Federal agency may choose to undertake the biological assessment without any informal consultation. Whether or not a biological assessment is required, the Federal agency may choose to enter into informal consultation.

In response to many comments, the Service has made numerous adjustments throughout these regulations to eliminate references to informal consultation as a prerequisite to formal consultation. The Service agrees that such a process would not be workable, both as a result of limited consultation resources and the need to respect Federal agency program discretion. As previously noted, the proposed rule required formal consultation if the action "may adversely affect" listed species or critical habitat. "Beneficial" actions were excused from formal consultation if the Service concurred during the mandatory informal consultation. Since informal consultation has been made strictly an optional process in this final rule, the Service retains, from the 1978 rule, the "may affect" trigger for formal consultation in § 402.14 of the final rule.

Under this final rule, if a Federal agency determines that its action "may affect" listed species or critical habitat, then formal consultation is required unless an exception applies. One exception is that a Federal agency may, through informal consultation, utilize the expertise of the Service to evaluate the agency's assessment of potential effects or to suggest modifications to the action to avoid potential adverse effects. If, as a result of informal consultation, the Federal agency determines, and the Service concurs, that the action (or modified action) is "not likely to adversely affect" listed species or critical habitat, then formal consultation is not required. The consultation process would terminate with the written concurrence of the Service. Therefore, through this informal consultation process, those activities which are found to have beneficial, discountable, or insignificant effects upon listed species or their critical habitats could be deemed to be in compliance with section 7(a)(2) without formal consultation. If a "not likely to adversely affect" determination cannot be made during informal consultation, then formal consultation is required for those Federal actions that "may affect" listed species or their critical habitat.

In short, the final rule retains the general requirement for formal consultation if the Federal agency determines that its action "may affect" listed species or critical habitat. The Federal agency may, however, through voluntary informal consultation with the Service, forego formal consultation and promptly implement actions that the agency and the Service agree are not likely to adversely affect listed species or critical habitat. The Service finds that this reformulation of the consultation process is not significantly different from the current practice, except that, as a result of informal consultation, biological opinions will no longer be required for actions that "are not likely to adversely affect" listed species or critical habitat.

The Service could not accommodate all concerns expressed on this issue. Two commenters contended that the "may adversely affect" standard for initiating formal consultation yielded too much discretion to action agencies. They stated that such a threshold would shift the benefit of the doubt from one in favor of the listed species to one in favor of the Federal agency's action. Noting the Service's expertise on wildlife issues, the commenter urged the Service to reverse this shift. As noted above, the Service did not intend to reverse the burden of proof with the focus on "adverse effects." The goal is to reduce procedural barriers for actions which the Service believes are not likely to have an adverse effect, while retaining full protection for listed species or critical habitat. The changes noted above address these commenters' concern. However, other commenters who suggested a shift in the burden of proof cannot be accommodated. The commenters that urged a "would adversely affect" standard for triggering formal consultation, a standard that might be interpreted as requiring a showing of effects that destroy or adversely modify critical habitat or are likely to jeopardize the continued existence of listed species, are requesting a trigger for formal consultation that the Service believes is too close to the "jeopardy" standard of section 7(a)(2). The threshold for formal consultation must be set sufficiently low to allow Federal agencies to satisfy their duty to "insure" under section 7(a)(2). Therefore, the burden is on the Federal agency to show the absence of likely, adverse effects to listed species or critical habitat as a result of its proposed action in order to be excepted from the formal consultation obligation.

The Service believes that informal consultation is extremely important and may resolve potential conflicts (adverse effects) and eliminate the need for formal consultation. Through informal consultation, the Service can work with the Federal agency and any applicant and suggest modifications to the action to reduce or eliminate adverse effects. If a Federal agency modifies its action so that the action is not likely to adversely affect listed species or critical habitat, then formal consultation is not required.

Section 402.14 Formal Consultation.

These regulations require Federal agencies to review their actions to determine whether they "may affect" listed species or critical habitat. Formal consultation procedures must be initiated if such a situation exists, unless, with the written concurrence of the Service, the Federal agency determines through informal consultation and/or through the biological assessment process that its action is not likely to adversely affect listed species or critical habitat. As noted above in regard to § 402.13, the final rule adopts the "may affect" standard of the 1978 rule, with a special provision allowing actions "not likely to adversely affect" to by-pass the formal consultation process as a result of informal consultation with the Service.

Paragraph (a) of § 402.14 sets out the requirements for formal consultation. This paragraph is a composite of paragraphs (a) and (k) of proposed § 402.15. Paragraph (b), which sets out the exceptions to the initiation requirement of (a), was taken primarily from proposed §§ 402.12(b)(7) and 402.15 (b) and (c).

The Service declines to substitute "may" for "shall" in describing the Federal agency's responsibilities in paragraph (a), as requested by one commenter. Federal agencies have an obligation under section 7(a)(2) of the Act to determine whether their actions may affect listed species and whether formal consultation is required under these regulations. However, the Service does not intend to mandate the timing of this review, which is solely at the discretion of the Federal agency. Early review of its actions is to the advantage of the Federal agency so that compliance with section 7 can be attained without undue delays to its action.

Paragraph (a) also includes a provision for the Director to request a Federal agency to enter into consultation. Two commenters asked that the final rule empower the Director to require a Federal agency to consult. Although the Service will, when appropriate, request consultation on particular Federal actions, it lacks the authority to require the initiation of consultation. The determination of possible effects is the Federal agency's responsibility. The Federal agency has the ultimate duty to ensure that its actions are not likely to jeopardize listed species or adversely modify critical habitat. The Federal agency makes the final decision on whether consultation is required, and it likewise bears the risk of an erroneous decision.

The last sentence of proposed § 402.15(a), dealing with Service assistance to Federal agencies, has been deleted as it is more appropriately addressed in the preamble. The Federal agency may obtain information and advice from the Service, but this is a supplement to, and not a substitute for, formal consultation. The Service believes that there should be a continuous dialogue between the Service and the Federal agency involving the exchange of information and assistance as part of the formal consultation.

Unless a Federal agency chooses to avail itself of the exceptions in paragraph (b), it must initiate formal consultation if its proposed action "may affect" listed species or critical habitat. Any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement, as suggested

by one commenter. However, although informal consultation is not required, a Federal agency may use that process and/or the biological assessment process to remove an action that "is not likely to adversely affect" listed species or critical habitat from the formal consultation requirement.

Proposed paragraph (c), a "no adverse effect" exception, was attacked as weakening the Act. One commenter remarked that this procedure unrealistically allows Federal agencies to determine the presence of a "detrimental effect," through informal consultation, when the precise objective of formal consultation is to reach that same goal. The Service does not agree, because formal consultation is conducted to determine if an action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Adverse effects may exist without constituting jeopardy. However, the Service has changed the trigger for formal consultation to "may affect" with certain exceptions contained in paragraph (b).

The exceptions in paragraph (b) are derived from the "will not adversely affect" exception in proposed §402.15(c) and from the confirmation of the preliminary biological opinion in proposed §402.15(b). The first exception is modified to "not likely to adversely affect" to make the biological assessment provisions compatible with the formal consultation provisions. Under section 7(c) of the Act, a biological assessment is completed to facilitate compliance with the consultation provisions of section 7(a)(2) by identifying whether any species or critical habitat is "likely to be affected." If the Federal agency determines, with Service concurrence, that its action is not likely to adversely affect any listed species or critical habitat, there is no need for formal consultation.

Imposing the time delays and information responsibilities of formal consultation on such actions would not provide any additional protection to listed species or critical habitat and may discourage interagency cooperation. Regulatory flexibility is appropriate here to eliminate undue burdens. By requiring the Service's "written concurrence" with a "not likely to adversely affect" finding as a prerequisite to invoking the exception to formal consultation, the Service believes it has retained adequate review authority through informal consultation. If the information made available during informal consultation is not sufficient to make this determination, formal consultation is required. The case of *Romero-Barcelo* v. *Brown*, 643 F.2d 835 (1st Cir. 1981), *rev'd on other grounds sub nom. Weinberger* v. *Romero-Barcelo*, 456 U.S. 305 (1982), does not preclude this change. That decision interpreted the 1978 rule but did not set a minimum threshold for initiation of formal consultation under the Act. Paragraphs (a) and (b), as adopted, are totally within the statutory authority of the Service.

The other exception to the general formal consultation requirement is the confirmation of a preliminary biological opinion as the final biological opinion. If early consultation takes place, the Service will issue a preliminary biological opinion. When the prospective applicant applies for a Federal permit or license, the Federal agency may request that the Service confirm the preliminary biological opinion as the final biological opinion that would have been issued after formal consultation. If the Service reviews the proposed action and finds no significant changes in the action as planned and no significant changes in the information used during early consultation, such a confirmation will be issued. Consultation is required if the preliminary biological opinion is not confirmed.

Paragraph (c) of §402.14 specifies the required contents of a request for formal consultation. This paragraph is adopted substantially from proposed §§402.12(b)(7) and 402.15(d).

According to one commenter, the information requirements of paragraph (c), which apply to all actions involved in formal consultation, lack statutory authority. The Service cites the obligation to use the "best scientific and commercial data available" and the overall responsibility to consult in good faith under section 7(a)(2) as ample authority for the information requirements. Proposed item (vi), requiring a list of Federal agencies that have jurisdiction in the action area and how they may be affected, is too broad since much of this information would be unrelated to the consultation. Other Federal actions that are interrelated or interdependent would be discussed along with the effects of the action. Therefore, this item is not included in the final rule. The remaining items are essential in determining the parameters of the action, the extent, duration, and severity of its impacts, and the effects of other actions in the action area. The Service retains these essential information requirements, although it has noted under subparagraph (5) that only "relevant" reports, including environmental impact statements, etc., need be supplied, because consultations will in most cases be completed prior to the production of final NEPA documentation for the subject action.

The concluding sentences of paragraph (c) permit Federal agencies, subject to the Director's approval, to tailor their requests for consultation to a particular segment of a comprehensive plan, so long as the effects of the action as a whole are considered. To clarify this passage, as requested by one commenter, the Service uses the example of the management, pursuant to a comprehensive plan, of a National Wildlife Refuge that is inhabited by a listed species. Section 7 consultation may be undertaken on a segment of that management program, such as big-game hunting, and a biological opinion will be issued on that phase of the program only. However, in formulating its biological opinion, the Service must consider the effects, including indirect effects, of the action as a whole, and cumulative effects of unrelated management programs in reaching the conclusion of "jeopardy" or "no jeopardy." The concluding passage of paragraph (c) illustrates the flexibility inherent in the formal consultation process and the care with which the protections of section 7 are preserved.

Paragraph (d) of §402.14 repeats the required information standard of section 7(a)(2): "best scientific and commercial data available." This paragraph is adopted essentially without change from proposed §402.15(d)(2), except that, pursuant to public comment, the Service changed "biological information" to "scientific and commercial data" to bring the language of the regulation in line with the Act. One commenter suggested that the phrase "or which can be developed during the consultation process" be removed from this paragraph. The Service has modified the wording to state that the information referred to in this paragraph is information that can be obtained during the consultation. We believe that information could become available at any time during the consultation, and such information should be submitted to the Service for its consideration. The legislative history of the 1979 Amendments supports this provision. H.R. Conf. Rep. No. 697, 96th Cong., 1st Sess. 12 (1979). The Service is satisfied that this paragraph adequately mandates the use of the best available scientific and commercial data, requires Federal agencies to supply this data at any time during formal consultation, and recognizes that this information requirement is a Federal agency

responsibility—not an obligation of the Service.

Paragraph (d) of § 402.14 also adopts a portion of § 402.15(d)(3) of the proposed rule that requires the Federal agency to provide any applicant with the opportunity to participate in formal consultations, including submitting information for consideration during the consultation. The remainder of proposed § 402.15(d)(3) was deleted because it duplicated other parts of the final rule.

Paragraph (e) of § 402.14 establishes the time period for conducting formal consultations and explains the process for extending the consultation period. The paragraph is adopted substantially as proposed in § 402.15(e), with certain technical, clarifying amendments.

The Amendments changed the timing requirement on the conclusion of formal consultation from the 60 days originally established by the 1978 rule to a maximum of 90 days or to such time periods as discussed below. If an applicant is involved, the Service and the Federal agency may mutually agree to extend consultation for up to 60 additional days without the consent of the applicant, provided that the Service submits to the applicant, before the close of the initial 90-day period 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. The biological opinion must be delivered to the Federal agency and any applicant promptly after the conclusion of formal consultation (within 45 days).

One commenter suggested that a provision be added that would require the Service to issue a notice concluding formal consultation with a finding that it has sufficient information to prepare a biological opinion. The Service declines to adopt this comment. At the end of the 90-day period (unless extended), the parties to the consultation realize that the Service has but 45 days to deliver its biological opinion to the Federal agency and any applicant. A mandatory notice of "sufficient information" might be, in some cases, misleading by creating the impression that additional information or studies may not be advisable. The Service must develop its biological opinion based upon the best scientific and commercial data available regardless of the "sufficiency" of that data. Therefore, the suggested change does not accurately reflect the legal framework within which the Service must operate.

The Service has defined the statutory directive to issue biological opinions "promptly after" the conclusion of formal consultation as requiring the delivery of a biological opinion to the Federal agency and any applicant within 45 days. Several commenters agreed with this stipulated deadline as long as the applicant retains some control over extensions. Other commenters felt that the 45-day period was excessive, and they argued that the opinion drafting period should either be worked out with mutually-agreeable extensions or the opinion should be issued by the end of the consultation period. The Service retains the 45-day drafting period as consistent with the statutory requirement and as a necessary time period to further refine biological opinions after the conclusion of formal consultation.

One sentence has been added to paragraph (e) to acknowledge the ability of the Service and the Federal agency, where no applicant is involved, to extend consultation for a mutually-agreeable time period. This clarification satisfies the request of one commenter.

Paragraph (f) of § 402.14, which governs Service requests for additional information, is adopted from § 402.15(j)(1) of the proposed rule. The Service declines to rename this paragraph "extension of consultation" because that topic is generally covered in paragraph (e).

In some cases, the Service may determine that additional information would enhance the formulation of its biological opinion. To cover this situation, the final rule adopts the procedures discussed by Congress in the legislative history of the 1979 Amendments. S. Conf. Rep. No. 697, 96th Cong., 1st Sess. 12 (1979). When additional data is believed to be advantageous, the Service will request an extension of formal consultation. When the Service requests such an extension, it will identify the types of additional data sought for assisting consultation. The Service will, to the extent practicable, and within existing budgetary and personnel restrictions, provide assistance in planning studies, furnishing relevant data, and providing recommendations that may be necessary to obtain the additional data. The responsibility for conducting and funding any studies, however, belongs to the Federal agencies or the applicant and not to the Service.

The comments received on this paragraph covered a wide spectrum of opinion as to the breadth of the Service's authority to request additional data. Some commenters questioned the statutory authority of the Service under this provision, and they erroneously interpreted the Service's ability to *request* additional data as the authority to *require* an extension of formal consultation to obtain such data. Their position was that additional data was not a valid reason for seeking an extension of formal consultation and that additional data should only be sought when obtaining it would not delay the consultation and when the Service is willing to fund the studies. Another commenter went further, suggesting that the request for additional data be treated as an extraordinary measure that should be invoked "reluctantly and only on rare occasions." The commenter said that the Service should affirmatively state that existing data is presumed to be adequate and that the Service bears the burden of demonstrating inadequacy before seeking additional data.

On the other end of the spectrum, several commenters faulted the Service for not requiring an extension so that additional data could be obtained under this paragraph. Citing the Federal agency's statutory duty to use the "best scientific and commercial data available" and the decision in *Roosevelt Campobello International Park Commission* v. *EPA*, 684 F.2d 1041 (1st Cir. 1982) ("*Pittston* case"), these commenters noted that Federal agencies are required by section 7(a)(2) to do "all that [is] practicable" to develop information for the consultation. *Pittston* case, *supra*. According to the commenters, the proposed rule gave too much discretion to Federal agencies in controlling the information used in the consultation process.

The Service adopts the proposed rule because it recognizes the need for an opportunity to request additional data while deferring to the Congressional intent that consultation have a definite end point. Additional data may be requested by the Service, but the Service is not relieved of its duty to issue a biological opinion unless appropriate time extensions are obtained under paragraph (e).

However, Federal agencies and applicants are cautioned that they bear the burden under section 7(a)(2) to show that they have obtained the best available scientific and commercial data. This is not the Service's burden or obligation, but the Service does have the responsibility to alert the Federal agency and any applicant of areas where additional data would provide a better information base from which to

formulate a biological opinion. This advice from the Service is intended to help the Federal agency to better satisfy its duty to *insure* that its action is not likely to jeopardize listed species or adversely modify critical habitat.

A Service request for additional data will not be used as a vehicle for burdening applicants with unnecessary studies and inordinate delays, as feared by one commenter. As in the *Pittston* case, these requests will be limited to readily obtainable data that would assist the Service in formulating its biological opinion. In paragraph (f), as in *Pittston*, a distinction must be made between requests for special research projects and requests for routine, customary data collection activities. Moreover, paragraph (f) does not take the final decision regarding the acquisition of additional data away from the Federal agency. The agency still has the discretion to reject the Service's request for additional data provided it is not arbitrary or capricious in doing so. The paragraph has been clarified to state that the Federal agency, when collecting additional data, shall do so to the extent practicable and within the timeframe of the agreed upon extension.

The Service, in requesting additional data, will not comment as to the overall adequacy of the Federal agency's data. It is the agency's burden to obtain credible data. The Service's request for additional data, just as the Federal agency's inability to complete any agreed upon collection of data, should not be interpreted as evidence that the Federal agency has failed to meet the information standard of section 7(a)(2); it would merely represent the Service's belief that the additional data would improve the consultation data base so that it could issue the best biological opinion possible. The Service, therefore, has added language to the final rule to clarify this provision.

As discussed above, if an extension is not agreed to in accordance with paragraph (e), the Service shall issue a biological opinion based on the best scientific and commercial data made available during the consultation. The Conference Report to the 1979 Amendments states that in this situation, the Federal agency has a continuing responsibility to make a reasonable effort to develop additional data. H.R. Conf. Rep. No. 697, 96th Cong., 2d Sess. 12 (1979). By initiating informal consultation with the Service at an early stage of the development of a proposed action, the Federal agency would, in most cases, minimize the need to request an extension of formal consultation because of a lack of data.

In formulating its biological opinion, the Service must provide the "benefit of the doubt" to the species concerned, H.R. Conf. Rep. No. 697, *supra*, at 12. In addition, a biological opinion must be developed within the consultation timeframe based upon the best scientific and commercial data available. Though requested by several commenters, the Service is not authorized to condition its "no jeopardy" opinions with "safeguards" or to issue "may jeopardize" opinions in retaliation for an agency refusal to extend consultation or to develop additional data.

The Service was requested to publish availability notices for biological opinions to facilitate public participation in the conservation of listed species. For the reasons noted previously in response to a general comment, the Service declines to impose such a requirement on itself as an amendment to paragraph (f).

Paragraph (g) of §402.14, which sets out the Service's responsibilities during formal consultation, is adopted from proposed §402.15(f) with only minor changes to clarify the Service's responsibilities. The public comments concerning paragraph (g) focused on the fifth item: the responsibility to discuss the availability of reasonable and prudent alternatives. The Service is committed to working closely with Federal agencies and any applicants in the development of reasonable and prudent alternatives. However, the Service is unable to agree that a draft reasonable and prudent alternative should be excluded from the biological opinion if the Federal agency disagrees as to its reasonableness, as suggested by one commenter. The Service will, in most cases, defer to the Federal agency's expertise and judgment as to the feasibility of an alternative. Nevertheless, in those instances where the Service disagrees with a Federal agency's assessment of the reasonableness of its alternatives, the Service must reserve the right to include those alternatives in the biological opinion if it determines that they are "reasonable and prudent" according to the standards set out in the definition in §402.02; the Service cannot abdicate its ultimate duty to formulate these alternatives by giving Federal agencies control over the content of a biological opinion.

Paragraph (g) provides for Federal agency and applicant review of the basis for any finding contained in draft biological opinions, including the availability of reasonable and prudent alternatives. Four commenters requested that the final rule clarify whether an applicant was entitled to receive a copy of the draft biological opinion. The Service believes that the applicant should participate in the review and should receive a copy of the draft opinion from the Federal agency. The final rule includes this provision.

The release of draft opinions to Federal agencies and any applicants (through the Federal agency) facilitates a more meaningful exchange of information. Review of draft opinions may result in the development and submission of additional data, and the preparation of more thorough biological opinions. Two commenters opposed the release of draft biological opinions. Although they were supportive of open communication and mediation between the Service and the Federal agency during the consultation time period, the commenters opposed Federal agency review of draft opinions because agencies could bring pressure on the Service to modify a particular reasonable and prudent alternative or to convert the opinion's conclusion from "jeopardy" to "no jeopardy." If there were any discussions needed regarding the reasonable and prudent alternatives, noted the commenters, this could be done in "further discussion" after the issuance of the biological opinion. The Service disagrees that Federal agency review of draft biological opinions will result in "rewritten" biological opinions, unless valid biological reasons mandate a change. Federal agency review of draft opinions helps ensure the technical accuracy of the opinion, and may save time and resources by resolving these issues early. The Service believes that the availability of draft biological opinions is a meaningful process and has retained it in the final rule. As noted previously in the "Definitions" section, "further discussion" has been deleted from this rule. Thus, through the discussions between the Service and the Federal agency and any applicant during formal consultation and the provision to review draft biological opinions, the exchange of information for the development of reasonable and prudent alternatives is sufficient.

The proposed rule stated that the 45-day deadline for delivery of the final biological opinion would be suspended while the Federal agency retained the draft opinion. Several commenters complained that such a suspension would violate the statutory deadlines for concluding formal consultation and that the applicant would be powerless to force an end to the consultation. Although the proposed rule provided

that, "[i]f the draft biological opinion is not returned to the Service within a reasonable period of time, the Service will issue a final biological opinion," the Service agrees that the meaning of "a reasonable period of time" requires clarification. Therefore, to accommodate these comments, the Service now requires the Federal agency to secure the applicant's written consent to an extension for a specified time period if the 45-day deadline is to be suspended while the draft opinion is under review. If no extension is agreed to, the biological opinion will be issued within 45 days of the conclusion of formal consultation.

Another commenter suggested that the Service be required to deliver its biological opinion within the Federal agency's NEPA timeframe so that the biological opinion can be included without delaying the release of the agency's NEPA document. The Service will attempt to coordinate all environmental reviews with the consultation. However, special timing problems under other Federal statutes, or failure to enter into the consultation process early in the planning stage of an action, is not a justification for altering the required timeframe established under the Act. If a particular Federal agency needs special procedures to handle its consultation responsibilities, the Service urges the development of counterpart regulations under § 402.04.

Paragraph (g) has also been modified to reflect that the Service, in formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, 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.

Paragraph (h) of § 402.14, which deals with the contents of a biological opinion, is adopted with minor, technical corrections from proposed § 402.15 (g)-(h). The final rule distinguishes that information or material which will be included in a biological opinion from that which will be provided with a biological opinion.

The biological opinion will 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 as to 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. The biological opinion will conclude that either: (1) the action is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion), or (2) the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion).

If a "jeopardy" biological opinion is issued, the Service must identify and include reasonable and prudent alternatives, if any, that will avoid jeopardy and that the Federal agency or applicant can implement. If the Service is unable to develop reasonable and prudent alternatives, it will indicate that, to the best of its knowledge, there are no such alternatives that would satisfy the standard of section 7(a)(2).

Paragragh (i) of § 402.14, which governs incidental taking under section 7(b)(4) of the Act, is adopted essentially as proposed in § 402.19. This paragraph is included in the formal consultation section of the final rule because of the direct relationship between final biological opinions and incidental take statements.

The 1982 Amendments changed section 7(b) to include provisions concerning incidental taking of species. The new provisions included in sections 7(b)(4) and 7(o)(2) of the Act are designed to resolve the situation where a Federal agency or an applicant has been advised, through a biological opinion, that the proposed action or the adoption of the reasonable and prudent alternative(s), will not violate section 7(a)(2) of the Act, but the proposed action (or adopted alternative) will result in taking individuals of a listed species incidental to the action. The new provision states that, if the action complies with specified terms and conditions, the resulting incidental take will not be a violation of any "taking" prohibitions established by section 4(d) or 9(a)(1) of the Act.

As noted in the public comments, the availability of an "incidental" taking exemption through the section 7 consultation process is a welcome clarification made by the 1982 Amendments. However, many commenters requested additional guidance on this subject, and several felt that the proposed rule was cumbersome and burdensome. The Service believes that the following discussion will clarify the incidental take provision and explain the incentives for compliance with sections 7(a)(2) and 7(b)(4) of the Act.

If an agency action receives a "no jeopardy" biological opinion, or if the Federal agency adopts any reasonable and prudent alternative provided in a "jeopardy" biological opinion, then the action may proceed in compliance with section 7. An incidental take statement will be provided with the biological opinion when the activity may incidentally take individuals of a listed species but not so many as to jeopardize their continued existence. If the action proceeds in compliance with the terms and conditions of the incidental take statement, then any resulting incidental takings are exempt from the prohibitions of section 4(d) or 9 of the Act. No permit is required of the Federal agency or any applicant in carrying out the action, as one commenter contended. The biological opinion, plus the incidental take statement, operate as an exemption under section 7(o)(2) of the Act. However, this exemption is limited to actions taken by the Federal agency or applicant that comply with the terms and conditions specified in the incidental take statement. Compliance with these terms and conditions is mandatory to qualify for the exemption from section 4(d) or 9 of the Act. "Actions that are not in compliance with the specified measures . . . remain subject to the prohibition against takings that is contained in section 9." S. Rep. No. 418, 97th Cong., 2d Sess. 21 (1982). Therefore, the Service cannot make these terms discretionary, as urged by one commenter.

Paragraph (i)(1) states that, where incidental takings may occur, the Service will provide with the biological opinion to the Federal agency and applicant a written statement that: (i) specifies the impact, *i.e.*, amount or extent, of such anticipated incidental take of the species that does not violate section 7(a)(2), (ii) specifies those reasonable and prudent measures necessary or appropriate to minimize such impact, (iii) 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 in order to implement the reasonable and prudent measures specified under (ii) above, and (iv) specifies the procedures to be used to handle or dispose of any individuals of a species actually taken. Several comments were received on these elements of the incidental take statement.

Because, in some cases, exact numerical limits on the amount of permissible incidental taking will be difficult to determine, the Service may, in accordance with (i)(1)(i), specify the extent of anticipated take that will not violate section 7(a)(2) of the Act. The impact of a particular action may only

be predictable in terms of the extent of land or marine area that may be affected. Precise numbers of individuals that may be taken are preferable to descriptions of the extent of disruption and will be provided when they can be computed. However, the Service reserves the flexibility in the rule so that the most appropriate standard for an individual consultation can be used. The Service declines to endorse the use of numerical amounts in all cases over the use of descriptions of extent, because for some species loss of habitat resulting in death or injury to individuals may be more deleterious than the direct loss of a certain number of individuals. Likewise, the Service declines to incorporate into the final rule the comment that would focus take levels on population numbers and recovery plan guidelines, if available. One commenter suggested that two figures or levels be specified: "the expected and the acceptable amount or extent" of take. This approach offers the benefit of giving a "caution" signal to Federal agencies or applicants as they approach a possible problem with the incidental takings resulting from the action. Steps could be taken to correct the course of the action before the threshold of reinitiation (level of maximum anticipated take) is exceeded. The Service recognizes the merit of this approach but does not require that it be followed under the final rule because it may not be appropriate for all Federal actions.

Paragraph (i)(1)(ii) states that the incidental take statement shall specify those reasonable and prudent measures necessary to minimize the level of incidental take. For the reasons discussed under the definition of reasonable and prudent measures, the Service has added a new paragraph (i)(2) to the final rule to clarify that reasonable and prudent measures may only involve minor changes that do not alter the basic design, location, duration, or timing of the action. Should the Service believe that the way to minimize the incidental takings is through research, an explanation of how such research will accomplish this will be included. Any research-related reasonable and prudent measure shall be subject to the limitations in paragraph (i)(2).

Paragraph (i)(1)(iii) provides that reporting requirements must be included in the terms and conditions of an incidental take statement. As explained in paragraph (i)(3), these reporting requirements will be tailored to the nature of the particular Federal action and will, to the extent possible, be limited to existing reporting requirements.

Under 50 CFR 13.45 (FWS) and 222.23(d) (NMFS), there are provisions concerning reporting requirements for any taking of threatened or endangered species. These reporting requirements are not limited to annual reports, and may vary in accordance with the particular needs of the species as set forth in the incidental take statement. Congress did not prohibit the imposition of new reporting requirements, contrary to the assertion of one commenter.

Another commenter said that the disposal procedures in item (i)(1)(iv) should refer to "specimens" taken, not to species taken. The Service has accommodated the commenter's concern by inserting "individuals of a species" in item (iv).

Paragraph (i)(4) requires the Federal agency or the applicant to immediately request reinitiation of formal consultation if the specified amount or extent of incidental take is exceeded. One commenter argued that the Service is allowing the "jeopardy" ceiling to be exceeded in (i)(4). The Service disagrees; however, the Service agrees that the amount or extent of take should not be set at the threshold of likely jeopardy. If the establishment of such a high taking level were necessary to cover all impacts of a proposed action, it is questionable whether the issuance of a "no jeopardy" opinion is appropriate. It is not expected that the level of incidental take anticipated for most "no jeopardy" actions would come close to the section 7(a)(2) barrier.

Congress recognized this in the House Report to the 1982 Amendments:

> If the specified impact on the species is exceeded, the Committee expects that the Federal agency or permittee or licensee will immediately reinitiate consultation since the level of taking exceeds the impact specified in the initial section 7(b)(4) statement. In the interim period between the initiation and completion of the new consultation, the Committee would not expect the Federal agency or permittee or licensee to cease all operations unless it was clear that the impact of the additional taking would cause an irreversible and adverse impact on the species.

H.R. Rep. No. 567, 97th Cong., 2d Sess. 27 (1982). Exceeding the level of anticipated taking does not, by itself, require the stopping of an ongoing action during reinitiation of consultation. The Federal agency must make this ultimate decision, taking into consideration the prohibitions of sections 7(a)(2) and 7(d). Further, the Service will enforce the taking prohibitions of section 4(d) or 9 if the continuation of an action, after the anticipated level of incidental take has been reached, results in additional takings of listed species.

This provision for incidental take in no way affects a Federal agency's responsibility under section 7(a)(2) to ensure that its action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. The Service agrees with one commenter that the basis for the conclusion that incidental take will not violate section 7(a)(2) should be included with the biological opinion.

Paragraph (j) specifies that the Service may provide any conservation recommendations with the biological opinion. Several commenters objected to the inclusion of conservation recommendations in the biological opinion, and questioned whether these recommendations were to have binding force. The comment submitted by the House Committee summarized these concerns:

> While the proposed regulations conform to the statute regarding the recommending of "reasonable and prudent alternatives" only where jeopardy is found, they also inject a totally new concept referred to as "conservation recommendations." Although we do not argue with the appropriateness of wildlife agencies recommending measures that could be taken to lessen a project's impact on endangered or threatened species, it should be made clear in the regulations that failure to abide by these recommendations does not result in a violation of section 7(a)(2) of the Act. In addition, while the language of section 7(a)(1) does direct all Federal agencies to "utilize their authorities in furtherance of the purposes of [the Act] by carrying out programs for the conservation of endangered species and threatened species", we do not believe that it was intended that section 7(a)(1) require developmental agency actions to be treated as conservation programs for endangered or threatened species. We also do not believe that all of the conservation recommendations of the Secretary have to be followed for this requirement to be met. Such an interpretation would render the much debated provisions of section 7(a)(2) redundant and essentially meaningless and bring about endless litigation.
>
> Accordingly, we suggest that any conservation recommendations be transmitted to action agencies separate from biological opinions and that the regulations state plainly that failure to accept or implement the recommendations does not constitute a violation of section 7 of the Act.

The Service agrees with the Committee's comments and has amended the proposed rule accordingly. Discretionary conservation recommendations will be provided with the biological opinion as a separate statement rather than as an integral part

of the opinion. In this rule, conservation recommendations [402.14(j)] are discussed separately from biological opinions [402.14(h)]. A sentence has been added at the conclusion of paragraph (j) to emphasize the advisory, non-binding nature of conservation recommendations.

Paragraph (k) of §402.14, which deals with incremental steps, is adopted with minor, technical changes from proposed §402.15(j)(2). Paragraph (k) applies, at the option of the Federal agency, in situations where a statute authorizes the Federal action to be taken in incremental steps. Such circumstances existed in *North Slope Borough* v. *Andrus*, 642 F.2d 589 (D.C. Cir. 1980), involving development of oil and gas resources on the OCS and possible impacts to the bowhead whale. In view of this decision, these regulations provide that a Federal agency may proceed with incremental steps toward completion of the entire 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.

In response to one comment, the Service acknowledges that the incremental step process can only be invoked at the option of the Federal agency, regardless of the Service's preference. If the Federal agency chooses not to use the incremental step process, the Service must render its biological opinion for the entire action.

Several commenters thought that this provision should be deleted. Some thought the subject should be handled through counterpart regulations or limited strictly to Outer Continental Shelf Lands Act cases. Another commenter stated that the incremental step approach is ill-advised because it is difficult to halt a project at its final stage after substantial resources have been invested. Finally, two commenters criticized the approach as a vehicle granting the Service veto power at any stage of the Federal action.

Paragraph (k) is retained in the final rule for several reasons. First, the Service adopts paragraph (k) because it provides a viable consultation approach sanctioned by the court in *North Slope Borough* v. *Andrus*, *supra*. The Service has clarified the final rule to show that it will not deprive a Federal agency of the opportunity to consult on incremental steps if requested. Second, the risk of section 7(a)(2) and 7(d) noncompliance should not be diminished because the incremental step approach is used. Monetary investments or other actions that do not foreclose the adoption of reasonable and prudent alternatives do not violate section 7(d). If a "jeopardy" opinion is issued at any step of the overall action, a prompt remedy can be sought through the exemption procedure. Third, consulting in incremental steps can be a valuable tool for developing information as an action progresses.

Oil and gas development on the OCS is a multistaged, long term action that provides a good example of the utility of an incremental step consultation. The Federal action occurs in discrete stages: the lease sale, exploration activities, and development/production activities. Any analysis of the impacts of development/production would be mere speculation without knowing what tracts will be leased and without the information on the extent of the petroleum reserves discovered during the exploration phase. As the scope and location of the ultimate action is further refined, the Federal agency will have the opportunity to conduct studies designed to determine the effects of that particular action in that particular area.

The Service is sympathetic to the commenter's concern that applicants might face an arduous series of consultations under paragraph (k), whereas a prompt consultation on the entire action would avoid a series of reviews by the Service. The Service reminds applicants that they may, in appropriate instances, avail themselves of the early consultation procedure to obtain a preapplication review of the remaining steps of the Federal action.

Under paragraph (k), biological opinions concluding "no jeopardy," or Service concurrence letters finding that a step "is not likely to adversely affect," must eventually cover each step of the incremental process. This does not mean that separate opinions must be issued for each step—several steps may be covered in one opinion (*e.g.*, OCS leasing and exploration activities)—but instead that each step must eventually satisfy section 7(a)(2) of the Act. A "jeopardy" opinion issued at any stage not only applies to that step but to the entire project as well. Once a "jeopardy" opinion is issued (unless the Federal agency adopts a reasonable and prudent alternative provided by the Service), paragraph (k) is inapplicable and the ordinary consultation process applies, allowing access to the exemption process. The commenter that contended that this approach is tantamount to a usurpation of Federal agency statutory authority ignores the fact that this process is at the option of the Federal agency and that the net effect of the Service's action is to cause the consultation to revert to a treatment of the action as a whole. The Federal agency may disagree with the Service's "jeopardy" finding, but it cannot continue to consult on an incremental basis on remaining steps in the action.

One commenter insisted that an action can be halted only if new information that was not previously known becomes available during a later stage of the incremental step consultation. However, the Service's responsibility to determine "jeopardy" or "no jeopardy" places no weight on when, where, or how data that is of compelling force in its analysis were developed. The Service cannot ignore data and permit a listed species to become jeopardized because someone "missed" a piece of information during an earlier step of the consultation. One of the criteria for reinitiation of formal consultation is whether new information reveals effects of the action that may affect a listed species or critical habitat in a manner or to an extent not previously considered. Therefore, incremental step consultations are not the only consultations subjected to this requirement.

Finally, one commenter objected to the requirement for obtaining sufficient data, noting an alleged absence of statutory authority. Again, paragraph (k) is not a creature of statute, but instead was developed so that consultations could be initiated and focused on a step-by-step review of segmented Federal actions—especially those where, in the absence of additional information, the final determination of "likely jeopardy" for the entire action would be highly speculative if consultation were not limited to the initial step or steps. The development of sufficient information is crucial to the ultimate success of the incremental step process, and, therefore, cannot be eliminated from the rule. The Federal agency must have sufficient information to show that its action is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Section 402.14(l) covers the termination of formal consultation. Adopted from proposed §402.15(i)(2)–(4), paragraph (l) was retained in the section

on formal consultation because §402.14 is the primary mandatory procedure of Part 402.

The proposed rule provided that consultation terminated with the issuance of a "no jeopardy" opinion unless further discussion took place, and, if a "jeopardy" opinion was issued, consultation terminated with the Service's receipt of the Federal agency's decision on the action. This notice requirement was criticized by several commenters as unnecessary and as extending consultation beyond the legal timeframe. As discussed under the "Definitions" section above, further discussion has been deleted as a formal step in the consultation process. Further, to accommodate the concerns, consultation terminates with the issuance of the biological opinion, whether "jeopardy" or "no jeopardy." However, the Service believes that the Federal agency notice of final action with respect to "jeopardy" opinions represents a minimal burden and has retained it under §402.15—"Responsibilities of Federal agency following issuance of a biological opinion." The Service agrees that a copy of the NEPA record of decision would meet the notice provisions of §402.15(b); the Service disagrees that this approach causes problems with NEPA compliance.

Finally, one commenter suggested that written notice be required to terminate consultation if a Federal agency or applicant decides to cancel plans for the action that is the subject of the consultation. The Service agrees that a written notice of termination is preferred, and has adopted the commenter's suggestion in paragraph (l)(2).

Section 402.15 Responsibilities of Federal Agency Following Issuance of a Biological Opinion.

Following the receipt of the Service's biological opinion, the Federal agency will make its final decision on the action. Section 402.15 describes the steps that the Federal agency should take after consultation is concluded. Paragraphs (a) and (c) of this section are adopted substantially without change from proposed §402.17. Paragraph (b) is adopted from proposed §402.15(i)(3) (last sentence).

Several commenters asked that the Federal agency be required to provide a statement of its reasons if it has chosen to disregard the Service's biological opinion. The Service declines to implement this request, because it remains the responsibility of each Federal agency to insure that it is in compliance with section 7(a)(2) and that it has established an administrative record for a given activity which demonstrates such compliance.

Federal courts have accorded Service biological opinions great deference. It, therefore, is incumbent upon a Federal agency to articulate in its administrative record its reasons for disagreeing with the conclusions of a biological opinion. But this is a matter which is primarily controlled under the provisions and judicial interpretations of the Administrative Procedure Act, not these regulations. Thus, the requested modification would add nothing that is not already required as a matter of administrative law.

Paragraph (c) points out the availability of an exemption process if the Federal agency determines that its proposed action cannot comply with section 7(a)(2). Although not covered in §402.15, the applicant may also pursue an exemption if it receives a final denial of its application as a result of a "jeopardy" biological opinion. The Service disagrees with one commenter that the applicant may seek an exemption if the Federal agency issues the permit or license with conditions related to section 7 considerations. The Act requires a final agency denial, and the issuance of a "jeopardy" biological opinion on the action, as predicates for an applicant's entry into the exemption process. See sections 3(12) and 7(g)(1) of the Act.

Section 402.16 Reinitiation of Formal Consultation.

Reinitiation of formal consultation is required in certain instances as specified in §402.16. The reinitiation requirement applies only to actions that remain subject to some Federal involvement or control. In the case where a permit or license had been granted, reinitiation would not be appropriate unless the permitting or licensing agency retained jurisdiction over the matter under the terms of the permit or license or as otherwise authorized by law.

In response to one comment, the Service notes its lack of authority to require Federal agencies to reinitiate consultation if they choose not to do so. Nevertheless, the Service shall request reinitiation when it believes that any condition described in this section applies.

Pursuant to several public comments, several minor changes have been made to §402.16 (proposed §402.18). Proposed paragraph (a), dealing with nonconfirmation of preliminary biological opinions, was deleted since it is more properly covered in the discussion of early consultation. The standard for reinitiation on incidental take statements is clarified in new paragraph (a). Paragraph (c) is clarified to show that changes to the action that do not cause effects different from or additional to those considered in the biological opinion will not require reinitiation of formal consultation.

Summary

The Amendments made significant changes in the consultation requirements of section 7, and the Service believes that a consistent response by the Federal agencies to those Amendments, as implemented by this final rule, will facilitate successful compliance with section 7 of the Act. The Service believes that these regulations will serve as an effective tool for the early resolution of potential conflicts involving listed species.

The primary authors of this final rule are Michael Young and Nancy Sweeney, Department of the Interior; Patricia Carter, Patricia Montanio, and Michael Gosliner, Department of Commerce.

The Department of the Interior, as lead agency in the development of these regulations, has prepared an environmental assessment in conjunction with this rulemaking. On the basis of the environmental assessment, it has been determined that this is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 (implemented at 40 CFR Parts 1500–1508). Therefore, an environmental impact statement need not be prepared. These procedural regulations simply provide a uniform approach for consultation required by section 7 of the Act. Compliance with the procedures in these regulations will not have any significant, direct, or indirect adverse environmental impact. It also has been determined that these regulations do not constitute major rules as defined in Executive Order 12291. The Department of the Interior has certified, under the terms of the Regulatory Flexibility Act (5 U.S.C. 601), that these regulations will not have a significant economic impact on a substantial number of small entities. The regulations are directed at Federal actions. The costs to small entities are those involved with timing and data gathering, if requested by the Federal agency. Even if the costs were passed on, the analysis under the Regulatory Flexibility Act has concluded that they are not substantial. The Department has determined that these rules do not contain "collection of information" or recordkeeping

requirements as defined by the Paperwork Reduction Act. The analyses under Executive Order 12291, the Regulatory Flexibility Act, and NEPA are available to the public at the Office of Endangered Species, U.S. Fish and Wildlife Service, at the address listed above.

List of Subjects in 50 CFR Part 402

Endangered and threatened wildlife, Fish, Intergovernmental relations, Plants (agriculture).

Regulation Promulgation

Accordingly, the Service revises 50 CFR Part 402 to read as follows:

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

Subpart A—General

Sec.

402.01 Scope.
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402.10 Conference on proposed species or proposed critical habitat.
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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.

"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 both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.

"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.

"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)].

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

"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)–(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 may 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), 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 of the species;

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

(iii) 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 (ii) above; and

(iv) 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(FWS) and 222.23(d)(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.

(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;

(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.

Dated: December 12, 1985.

William P. Horn,

Assistant Secretary for Fish and Wildlife and Parks.

Dated: January 30, 1986.

William G. Gordon,

Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration.

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