

AASHTO PRACTITIONER'S HANDBOOK

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COMPLYING WITH SECTION 7 OF THE ENDANGERED SPECIES ACT FOR TRANSPORTATION PROJECTS

This Handbook provides an overview of Section 7 consultation under the Endangered Species Act (ESA) and provides advice on carrying out Section 7 consultation for transportation projects. This Handbook focuses on the consultation process primarily from the perspective of the federal action agency and the applicant.

The Background Briefing section describes the legal framework for Section 7 consultation as defined in the ESA itself and in regulations issued by the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. This section includes a flow chart illustrating the four main steps in Section 7 consultation and the findings that can be made at each step.

The Key Issues to Consider section raises a series of questions for practitioners to consider when undertaking Section 7 consultation for a transportation project. This section can be used as a checklist when preparing for each step in Section 7 consultation.

The Practical Tips section provides advice on how to comply with Section 7 requirements as efficiently and effectively as possible. Issues covered in the Practical Tips section of the Handbook include:

- Preparing for Section 7 consultation
- Defining the action area and requesting or submitting a species list
- Assessing the effects of the proposed action on Section 7 resources
- Conducting formal consultation
- Conducting conference for proposed species and proposed critical habitat
- Coordinating Section 7 with the NEPA process and other requirements
- Complying with Section 7 following completion of the NEPA process

The Practitioner's Handbooks are produced by the Center for Environmental Excellence by AASHTO. The Center's Handbooks provide practical advice on a range of environmental issues that arise during the planning, development, and operation of transportation projects.

The Handbooks are primarily intended for use by project managers and others who are responsible for coordinating compliance with a wide range of regulatory requirements. With their needs in mind, each Handbook includes:

- key issues to consider;
- a background briefing;
- practical tips for achieving compliance; and
- a list of reference materials.

In addition, key regulations, guidance materials, and sample documents for each Handbook are posted on the Center's web site at <http://environment.transportation.org>.



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Documents

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Overview



This Handbook provides an overview of Section 7 consultation under the Endangered Species Act (ESA) as well as advice on carrying out Section 7 consultation for transportation projects. This Handbook is intended primarily for use by transportation agencies and their consultants and therefore focuses on the consultation process from the perspective of the Federal action agency and applicant.

This Handbook consists of four parts:

- **Background Briefing** provides an overview of the ESA as a whole and summarizes the four main steps in Section 7 consultation. This section also briefly discusses the relationship of Section 7 consultation to the National Environmental Policy Act (NEPA) process.
- **Key Issues to Consider** raises a series of questions for practitioners to consider when undertaking Section 7 consultation for a transportation project. This section can be used as a checklist when preparing for Section 7 consultation.
- **Practical Tips** provides advice on how to comply with Section 7 requirements as efficiently and effectively as possible. This section is organized according to the steps of the consultation process, from initiation through completion. It also addresses intersecting issues, such as how to coordinate Section 7 consultation with the NEPA process and other requirements.
- **Reference Materials** includes a list of key resource materials relevant to Section 7 consultation, including the statute, regulations, and important guidance, as well as links to additional materials on agency websites.

This Handbook also includes two appendices:

- **Appendix A** provides brief explanations of key terms and concepts in Section 7 consultation.
- **Appendix B** lists timeframes specified in the Section 7 regulations for various stages within the Section 7 consultation process.

For readability, this Handbook uses the following simplified terminology:

- **“Service”** refers to the U.S. Fish and Wildlife Service (USFWS) or the National Marine Fisheries Service (NMFS), as applicable. In general, “the Service” is used when describing an action that could be taken by either the USFWS or NMFS. The term “Services” is used when referring to both agencies together. The terms “USFWS” and “NMFS” are used when it is necessary to refer to a particular agency.
- **“Federal action agency”** refers to the Federal agency with responsibility for compliance with Section 7. The Section 7 regulations use the term “Federal agency” to refer to the agency with Section 7 consultation obligations, but “Federal action agency” is commonly used in practice to distinguish that agency from the USFWS and NMFS. As used in this Handbook, the “Federal action agency” also includes any State Department of Transportation (state DOT) that has assumed the responsibilities of a U.S. Department of Transportation (U.S. DOT) agency for Section 7 consultation pursuant to an assignment program.¹
- **“Listed” and “designated”** are used in this Handbook to refer to species listed and critical habitat designated under the ESA. In other words, these terms are used to refer to *federally listed* species and *federally designated* critical habitat. If context requires reference to a species listed under state law, the term “state-listed” is used.
- **“Section 7 resource”** is used in this Handbook to refer collectively to “listed and proposed species as well as designated and proposed critical habitat.” Where context requires, this Handbook refers specifically to listed species, proposed species, designated critical habitat, and proposed critical habitat, as applicable.

¹ See 23 USC 326 and 327.

- **“Finding”** and **“determination”** are used interchangeably in this Handbook to refer to a conclusion reached by a Federal action agency or the Services, as applicable, during Section 7 consultation. Both of these words are used in the Section 7 regulations, and the regulations do not give them different meanings.
- **“Section 7 regulations”** refers to the Services’ regulations that establish the procedures for Section 7 consultation (codified at 50 CFR Part 402).
- **“Services’ Section 7 Handbook”** refers to the Handbook issued by the Services as guidance for the Services’ staff on carrying out Section 7 consultation.² Note that the Services’ Section 7 Handbook was issued in 1998, and therefore it may not fully reflect the Services’ current interpretations, policies, and practices in all instances.

Finally, practitioners should keep in mind that Section 7 consultation practices and terminology vary somewhat among different states and regions of the country. In addition, Federal action agencies and the Services sometimes differ in their interpretations of the Section 7 regulations. As a result, it is possible that practitioners may encounter interpretations or practices that vary from those outlined in this Handbook. In those cases, practitioners should look to the Services and the Federal action agencies for direction. This Handbook should be used as a source of information only; it is not official agency guidance.

Background Briefing

This section provides background information that may be useful in understanding the recommendations provided in the Practical Tips section. This section includes:

- an overview of the ESA;
- Federal agency responsibilities under Section 7 of the ESA;
- Section 7 consultation process steps, including a flow chart; and
- relationship of Section 7 consultation to NEPA and other requirements.

Overview of the ESA

Purpose of the ESA. Enacted in 1973, the ESA creates a comprehensive regulatory regime that seeks to protect imperiled fish, wildlife, and plant species from extinction and to promote the recovery of those species and the ecosystems that support them, so that they no longer need protection under the statute.

USFWS and NMFS Roles. The two agencies primarily responsible for administering the ESA are the USFWS and NMFS. The USFWS, which is part of the U.S. Department of the Interior, is responsible primarily for terrestrial and freshwater organisms. NMFS, which is part of the U.S. Department of Commerce, is responsible for marine (ocean-dependent) species such as whales, seals, and salmon. The USFWS and NMFS share responsibility for turtles, Atlantic salmon, and Gulf sturgeon.

Requirement to List Species as Threatened or Endangered. Section 4 of the ESA gives the Services responsibility for listing fish, wildlife, and plant species as threatened or endangered.³ A species is listed as “threatened” if it “is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range”; a species is listed as “endangered” if it is “in danger of extinction throughout all or a significant portion of its range.”⁴ Any interested person can petition the Service to list, de-list, or re-classify a species.⁵ The listing process begins with a notice of proposed rulemaking published in the Federal Register. After an opportunity for public comment on the proposed listing, the Service may issue a final rule listing the species.

Requirement to Designate Critical Habitat. Section 4 of the ESA directs the Services to designate critical habitat for species that have been listed as threatened or endangered.⁶ As with a species listing, the designation of critical habitat occurs through a rulemaking process: a proposed rule is published in the Federal Register, followed by a public comment period, and then

² USFWS and NMFS, “Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act” (March 1998).

³ 16 USC 1533(a)(1).

⁴ 16 USC 1532(6) (definition of “endangered”) and 1532(20) (definition of “threatened”).

⁵ 16 USC 1533(b)(3).

⁶ 16 USC 1533(a)(3).

a final rule designating the critical habitat. All critical habitat designations identify specific geographic areas for that habitat. The statute requires critical habitat to be designated “concurrently” with the listing of a species, but in practice, there often is a delay in designating critical habitat, and there are many listed species for which no critical habitat has as yet been designated.

Requirement to Develop Recovery Plans. Section 4 of the ESA directs the Services to develop recovery plans for species that have been listed as threatened or endangered.⁷ A recovery plan, as the name suggests, is intended to help a species recover to the point that protection under the ESA is no longer needed. A recovery plan is developed through a public notice-and-comment process and typically includes recommendations for action by Federal and state agencies as well as private landowners and other stakeholders. A recovery plan’s recommendations are not binding, but they are intended to provide a common framework for efforts to promote recovery of the species. Binding requirements imposed under other provisions of the ESA may be based, in part, on recommendations in a recovery plan.

Prohibition against “Take” of Listed Fish and Wildlife Species. Section 9 of the ESA prohibits any individual from “taking” any federally listed fish or wildlife species without a permit.⁸ Practitioners should understand several key points about this prohibition:

- *The definition of “take” is very broad.* As defined in the ESA, “take” means to “harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.”⁹ The USFWS has defined the terms “harm” and “harass” as follows:
 - Harm means “significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering.”¹⁰
 - Harass means “an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns which include, but are not limited to, breeding, feeding or sheltering.”¹¹
- *Take can result from inadvertent acts, without any intention to cause harm to the species.* The term “incidental take” includes “takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.”¹²
- *Incidental take can be authorized by the Services.* The Services can authorize the incidental take of listed species under two distinct processes:
 - An “incidental take statement” is issued for federally funded or approved projects through Section 7 consultation. This statement is included in a Biological Opinion issued at the conclusion of formal consultation.
 - An “incidental take permit” is issued under Section 10 of the ESA for actions that do not require Section 7 consultation, such as many private development projects.¹³
- *The prohibition against take applies regardless of the project’s status.* The late discovery of a species, or the new listing of a species, could require an agency to engage in additional Section 7 consultation, even if the environmental review process is complete and project construction is under way. The need for additional consultation may require construction to halt in whole or in part.
- *The prohibition against “take” does not apply to plant species.* Plants are subject to different requirements, which prohibit various deliberate acts, such as removing listed plants from areas within Federal jurisdiction.¹⁴

Federal Agency Responsibilities under Section 7 of the ESA

Section 7 of the ESA includes several distinct requirements applicable to Federal agencies. These requirements include a “conservation obligation” in Section 7(a)(1), as well as the consultation requirements in Section 7(a)(2).

⁷ 16 USC 1533(f).

⁸ 16 USC 1538(a)(1).

⁹ 16 USC 1532(19).

¹⁰ 50 CFR 17.3.

¹¹ 50 CFR 17.3.

¹² 50 CFR 402.02.

¹³ 16 USC 1539(a)(1)(B).

¹⁴ 16 USC 1538(a)(2).

Conservation Obligation. Federal agencies have a duty under Section 7(a)(1) of the ESA to promote the conservation of threatened and endangered species.¹⁵ This general duty is in addition to the Federal agencies' consultation obligations under Section 7(a)(2). Federal agencies have broad discretion to decide how to carry out their conservation obligations. The Services describe this provision as requiring "proactive" efforts by Federal agencies to participate in the conservation and recovery of listed threatened and endangered species.¹⁶

Section 7 Consultation. Federal agencies are required under Section 7(a)(2) to engage in consultation with the Services before taking any action that has the potential to affect listed species or designated critical habitat.¹⁷ Federal agencies comply with this consultation requirement by following the procedures laid out in the Section 7 regulations.

Duty to Avoid Jeopardy to Listed Species. Section 7(a)(2) requires Federal agencies to ensure that their actions are not likely to jeopardize the continued existence of a listed threatened or endangered species.¹⁸ As part of formal consultation, the Services determine whether the proposed action would cause jeopardy to the species. The ESA includes a process for exempting Federal agencies from the jeopardy prohibition, but the exemption process has rarely been used.¹⁹

Duty to Avoid Destruction or Adverse Modification of Critical Habitat. Section 7(a)(2) also requires Federal agencies to ensure that their actions are not likely to destroy or adversely modify designated critical habitat.²⁰ As part of formal consultation, the Services determine whether the proposed action would adversely modify or destroy critical habitat. As with the jeopardy prohibition, the ESA includes a process for exempting Federal agencies from the prohibition against adversely modifying or destroying critical habitat.²¹ This exemption also has rarely been used.

Conference on Proposed Species and Proposed Critical Habitat. Section 7(a)(4) requires a process known as "conference" for species proposed for listing and for areas proposed for designation as critical habitat.²² Conference involves discussions between the Federal action agency and the Services, and it may result in issuance of a Conference Opinion, which is similar to a Biological Opinion. Important points to note:

- The Conference Opinion may include preliminary findings of "no jeopardy" and "no adverse modification or destruction" of critical habitat and a preliminary incidental take statement.
- The Conference Opinion also may include recommendations on ways to minimize or avoid adverse effects to proposed species or proposed critical habitat.
- The Federal action agency is not required to follow recommendations in a Conference Opinion.
- If a species is listed or critical habitat is designated before a project is fully implemented, the Federal action agency must review the action to determine whether formal consultation is required.
- If a Conference Opinion was previously issued, and there are no significant changes in the project or the affected environment, the Service can adopt the Conference Opinion as its Biological Opinion.²³ If so, the preliminary findings and the preliminary incidental take statement become final.

Consideration of Candidate Species. Federal agencies are encouraged, although not required, to consider the effects of their actions on species that have been identified by the Services as candidates for listing. The Section 7 regulations define a candidate species as "any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule."²⁴

¹⁵ 16 USC 1536(a)(1).

¹⁶ Services' Section 7 Handbook, p. 5–1.

¹⁷ 16 USC 1536(a)(2).

¹⁸ 16 USC 1536(a)(2).

¹⁹ 16 USC 1536(e)-(p).

²⁰ 16 USC 1536(a)(2).

²¹ See 16 USC 1536(e)-(p).

²² 16 USC 1536(a)(4).

²³ 50 CFR 402.10(d).

²⁴ 50 CFR 402.12(d).

Request for Species List and Preparation of Biological Assessment. Section 7(c) includes two requirements related to Section 7 consultation: requesting a species list and, in some cases, preparing a Biological Assessment.²⁵ As implemented by the Section 7 regulations, these requirements include the following steps:

- **Species List.** The Federal action agency must submit to the Services 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) the agency’s own list of such species and habitat for the Services’ review.²⁶ The Services must respond within 30 days of receipt, either by providing a species list or by concurring with or revising the species list submitted by the Federal action agency.²⁷
- **Biological Assessment.** If the proposed action is a “major construction activity” and listed species or designated critical habitat may be present in the action area, the Federal action agency must submit a Biological Assessment.²⁸ A “major construction activity” is a construction project for which an environmental impact statement (EIS) is required under NEPA.²⁹ A Biological Assessment evaluates the potential effects of the proposed action on any listed and proposed species and designated and proposed critical habitat that may be present in the action area. The Federal action agency may designate the applicant or non-Federal representative (e.g., a consultant) to prepare the Biological Assessment.

For a project that does not involve a “major construction activity,” a Biological Assessment is not required, but the Federal action agency is still required to assess the effects of the proposed action on any listed/proposed species and designated/proposed critical habitat that may be present in the action area. For such projects, the effects assessment may be documented in a Biological Assessment or an equivalent document, which is sometimes called a Biological Evaluation.

Section 7 Consultation Process Steps

The Section 7 consultation requirements are defined in Section 7(a)(2) of the statute and in the Section 7 regulations. The Services’ Section 7 Handbook provides additional guidance.

The main steps in Section 7 consultation are shown in the flow chart in Figure 1. Informal consultation steps are shown in blue, while formal consultation is shown in red; the color gray represents the initial step taken to determine whether consultation is required. As shown in the flow chart, findings must be made at the conclusion of each step. Based on those findings, consultation either ends or continues to the next step.

Keep in mind that this flow chart is a *simplified illustration* of the consultation process. The Section 7 regulations themselves do not specifically refer to consultation “steps” and in practice, the steps may overlap to some degree. Therefore, the flow chart should be used only as a general guide to the structure of the consultation process.

In addition, keep in mind that “*Section 7 resource*” is used in this Handbook to refer to any species for which consultation of any kind is required under Section 7. This term includes *listed and proposed* species as well as a *designated and proposed* critical habitat. When a more specific reference is needed, this Handbook refers to “listed” or “proposed” species as well as “designated” or “proposed” critical habitat.

²⁵ 16 USC 1536(c)(1).

²⁶ 50 CFR 402.12(c). The “action area” includes “all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.” 50 CFR 402.02.

²⁷ 50 CFR 402.12(d).

²⁸ See 16 USC 1536(c)(1) (“If the Secretary advises, based on the best scientific and commercial data available, that such species may be present, such agency shall conduct a biological assessment.”) The regulations limit this requirement to proposed actions involving a “major construction activity.” 50 CFR 402.12(b).

²⁹ See 50 CFR 402.02 (“‘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.”).

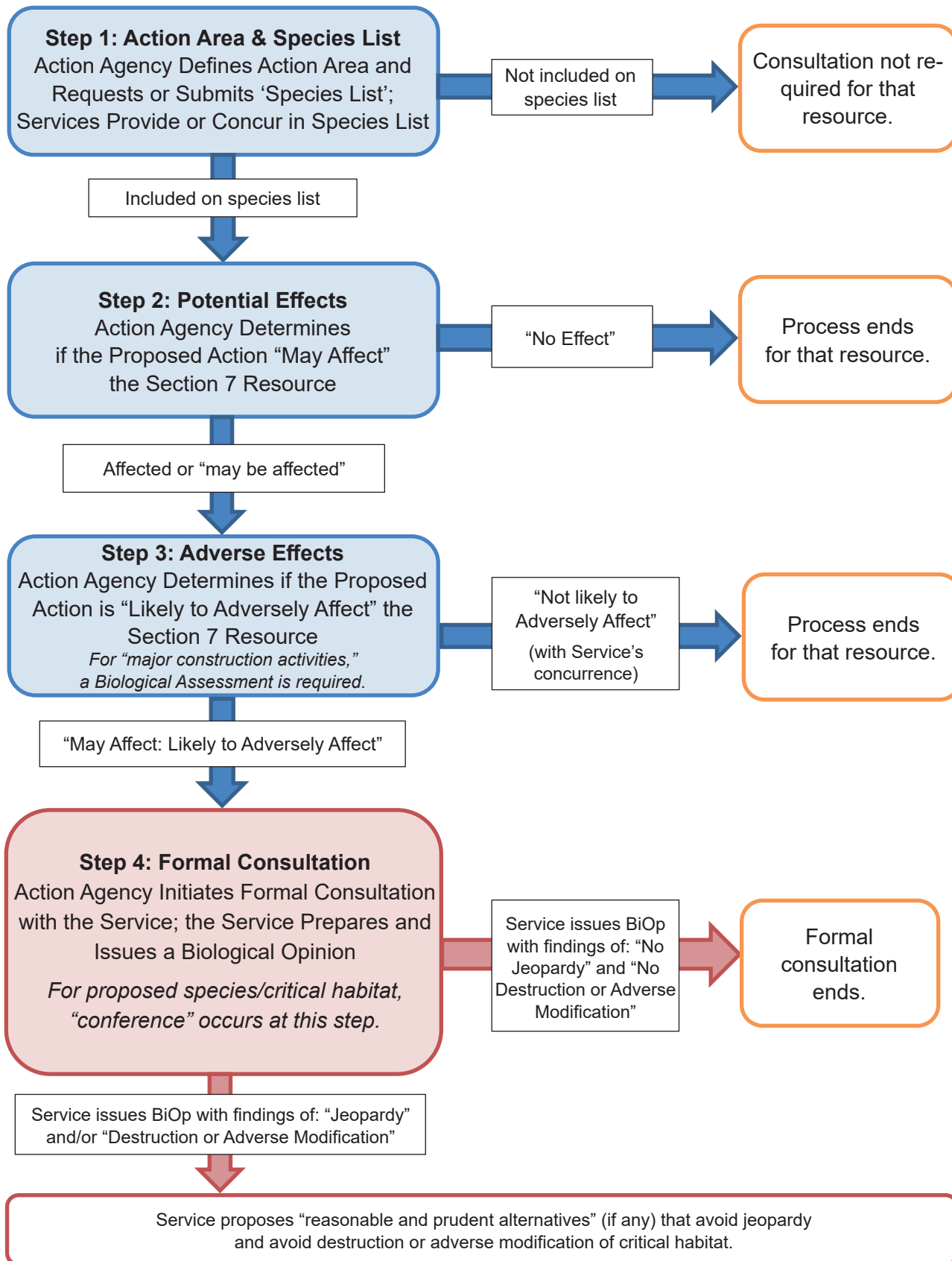


Figure 1: Simplified Illustration of Section 7 Process Steps

Step 1: Federal Action Agency Defines the Action Area and Requests or Submits a Species List

In this step, the Federal action agency defines the “action area” for the proposed action, and either requests a “species list” from the applicable Service office or submits a proposed species list to that office and requests the Service’s concurrence.³⁰ For species within the jurisdiction of the USFWS, species lists can be obtained on-line from the Information Planning and Conservation System (IPaC) database.³¹

Under the Section 7 regulations, the “action area” is defined as the geographic area within which direct and indirect project effects have the potential to occur.³² The species list must include all listed and proposed species and designated and proposed critical habitat that “may be present in the action area.”³³ In practice, the species list often includes species within a relatively broad geographic area (e.g., at the county level) to ensure that potentially affected species are not overlooked.

A species may be included on the species list based on the presence of “suitable habitat” for the species in the action area, even if individual members of the species have not been found in that area. Conversely, information showing that suitable habitat does not exist in the action area may support a finding or concurrence by the Service that the species is not present in the action area and therefore should not be included on the list. The term “suitable habitat” is not defined in the Section 7 regulations, but habitat generally is considered suitable if it is capable of supporting life activities of the species (e.g., breeding, sheltering, or feeding) at one or more life stages.

The Section 7 regulations require the species list to be re-verified if work on a Biological Assessment has not begun within 90 days after the list was provided,³⁴ and require that the Biological Assessment be completed within 180 days after acquisition of the species list.³⁵

Step 1 leads to one of the following outcomes with regard to each Section 7 resource:

- **Process ends at Step 1 for** any Section 7 resource (e.g., a listed species) that is not included on the species list received from, or concurred in by, the Service. The species list may need to be verified later in the NEPA process.
- **Process continues to Step 2 if** for any Section 7 resource that *is* included on the species list received from, or concurred in by, the Service.

Step 2: Federal Action Agency Determines if the Proposed Action “May Affect” the Section 7 Resource

In this step, the Federal action agency assesses the potential for the project to affect any Section 7 resources included on the species list developed in Step 1. This assessment focuses on whether the Section 7 resource may be affected *in any way*, not whether it will be adversely affected. For purposes of this assessment, the effects of the project include the effects of any “interrelated or interdependent” actions.³⁶

In general, this assessment will include the following:

- Describing the proposed action (including any interrelated or interdependent actions), including when and where the action will occur and any other information relevant to assessing effects on the Section 7 resource.
- Assessing whether the Section 7 resource will be directly or indirectly exposed to the effects of the proposed action. Direct or indirect effects on suitable habitat for a species may be considered to affect the species.
- If exposure is anticipated, assessing how the Section 7 resource will respond.

30 The requirement to request a species list is part of the process for preparing a Biological Assessment. See 50 CFR 402.12(a). Even if it is not clear whether a Biological Assessment will be needed, a species list still should be requested to obtain the information needed to comply with Section 7 consultation requirements.

31 IPaC is available at <https://ecos.fws.gov/ipac/>.

32 50 CFR 402.02 (definition of “action area”).

33 50 CFR 402.12(c).

34 50 CFR 402.12(e).

35 50 CFR 402.12(i).

36 See 50 CFR 402.02 (defining “effects of the action”). In general, interrelated and interdependent actions include other projects or activities that would not proceed “but for” the proposed action. See Appendix A of this Handbook for additional information about identifying interrelated and interdependent actions.



Step 2 leads to one of the following outcomes for each Section 7 resource:

- **Process ends at Step 2 if** the Federal action agency determines that the proposed action would have no effect on the Section 7 resource. This finding can be based on a determination that (1) the Section 7 resource will not be exposed to the direct or indirect effects of the proposed action (i.e., the resource is not in the action area); or (2) while exposure to those effects may occur (i.e., the resource is in the action area), there is no foreseeable linkage between an effect of the action and a response by the Section 7 resource.
- **Process continues to Step 3 if** the Federal action agency determines that the proposed action may affect the Section 7 resource, even if the effect is beneficial. A “may effect” determination normally is made whenever the evidence is insufficient to support an unequivocal finding of “no effect.”

The responsibility for making the “no effect” determination rests with the Federal action agency; the Services’ concurrence is not required.³⁷ A “no effect” finding made at this step should be revisited if new information relevant to the finding becomes available.

The assessment in Step 2 is analytically distinct from the assessment in Step 3, but in practice, Steps 2 and 3 often occur together and are included in the same Biological Assessment or equivalent document.

Step 3: Federal Action Agency Determines if the Proposed Action is Likely to Adversely Affect the Section 7 Resource

In this step, the Federal action agency assesses whether the proposed action is likely to adversely affect any Section 7 resource carried forward from Step 2. As in Step 2, this assessment includes effects of any interrelated or interdependent actions.

According to the Services’ Section 7 Handbook, an action is “not likely to adversely affect” if the effects are “completely beneficial, insignificant, or discountable.”³⁸ The Services define these terms as follows:

- beneficial effects are “contemporaneous positive effects without any adverse effects to the species”;
- insignificant effects “relate to the size of the impact and should never reach the scale where take occurs”—i.e., “[b]ased on best judgment, a person would not be able to meaningfully measure, detect, or evaluate” the effects; and
- discountable effects “are those extremely unlikely to occur”— i.e., “[b]ased on best judgment, a person would not expect discountable effects to occur.”³⁹

Step 3 leads to one of the following outcomes for each Section 7 resource:

- **Process ends at Step 3 if** the Federal action agency finds, and the Service concurs, that the proposed action is “not likely to adversely affect” the Section 7 resource. Concurrence by the Services must be documented in a concurrence letter, often referred to as a “letter of concurrence.”
- **Process continues to Step 4 if** the Federal action agency finds that the project is “likely to adversely to affect” the Section 7 resource or if the Service does not concur with the “not likely to adversely affect” finding.

The analysis and findings for Steps 2 and 3 normally occur at the same time and are documented together in the Biological Assessment (if prepared) or an equivalent document. Also note that this step can result in different findings for different resources—e.g., a “no effect” finding for one species and a “not likely to adversely affect” finding for another species.

Step 4: Federal Action Agency Conducts Formal Consultation with the Services; Services Issue a Biological Opinion

In this step, the Federal action agency engages in formal consultation with the Services regarding any species and/or critical habitat for which a finding of “likely to adversely affect” was made in Step 3. This step also includes “conference” with the Services regarding any proposed species and/or proposed critical habitat.

³⁷ An action agency may request concurrence from the Services in a no-effect finding. In practice, however, the Services often elect not to provide concurrence or non-concurrence in no-effect findings.

³⁸ Services’ Section 7 Handbook, p. 3–12.

³⁹ Services’ Section 7 Handbook, pp. 3–12 to 3–13.

This step begins when the Federal action agency submits an initiation package to USFWS and/or NMFS, as applicable. The initiation package typically consists of a letter requesting formal consultation, a copy of the Biological Assessment (if any), and any other relevant supporting documents, such as a large topographical map showing the affected area.⁴⁰ The Federal action agency is required to include the “best scientific and commercial data available or which can be obtained during the consultation” in the initiation package.⁴¹

The Service normally provides written acknowledgement to the Federal action agency within 30 days after receipt of the initiation package.⁴² As part of that communication, the Service advises the Federal action agency whether the Service considers the initiation package to be complete. If the package is deemed complete, the Service has 135 days from initial receipt of the package to complete consultation and provide the Biological Opinion. If the package is deemed incomplete, the Federal action agency is requested to submit additional information to the Service, either supplementing or superseding the initial package. The 135-day period for formal consultation starts when a complete initiation package is submitted to the Service.⁴³

Under the Section 7 regulations, Step 4 must be completed within 135 days unless the time period is extended.⁴⁴ An extension of the 135-day period requires agreement by the Federal action agency; an extension of more than 60 days requires agreement of the applicant as well.⁴⁵ In practice, it is common for consultation to extend beyond the 135-day period specified in the regulations, due to the Services’ budget and staffing constraints.

The Service may provide an opportunity for the Federal action agency and the applicant to review a draft of the Biological Opinion.⁴⁶ If a draft Biological Opinion is made available for review, it normally will be provided only after it has been reviewed by the Service’s legal counsel and is ready for signature. If the Federal action agency submits comments to the Service within 10 days before the Service’s deadline for issuing the Biological Opinion, the Service is automatically given a 10-day extension to issue the opinion.⁴⁷

The Service may also seek input from the Federal action agency in other ways during the preparation of a Biological Opinion—for example, by requesting additional information about the project to ensure that the project description in the opinion is accurate and complete. Depending on the extent of the request for additional information, the time period needed to complete the consultation may need to be extended.

Issuance of the Biological Opinion concludes the Section 7 consultation process. The opinion includes the following components:

- a description of the proposed action;
- a description of the potentially affected species and critical habitat;
- an analysis of the direct and indirect effects of the proposed action, including the effects of any interrelated or interdependent actions, on the potentially affected species and habitat;
- an analysis of cumulative effects on the potentially affected species and habitat;
- a determination as to whether the project is likely to jeopardize the continued existence of any listed species and a determination as to whether it would adversely modify or destroy any designated critical habitat;
- an incidental take statement, which includes “reasonable and prudent measures” and “terms and conditions”—requirements that must be met during project implementation for the incidental take statement to remain valid;

40 The types of information required to be included in the initiation package are listed in Section 402.14(c) of the Section 7 regulations.

41 50 CFR 402.14(d).

42 Services’ Section 7 Handbook, p. 4–6. Please note that this does not always occur. The Federal agency should stay in contact with the Service to determine when consultation can begin.

43 If the Federal agency believes the package is complete, the Federal agency could take the position that formal consultation was in fact initiated upon the date of submittal. The Section 7 regulations themselves do not provide a mechanism for resolving disputes over the completeness of the initiation package.

44 50 CFR 402.14(e). This 135-day period consists of 90 days for formal consultation plus an additional 45 days for the Service to prepare the Biological Opinion. The entire 135-day period is commonly referred to as formal consultation.

45 50 CFR 402.14(e).

46 50 CFR 402.14(g)(5).

47 50 CFR 402.14(g)(5).