



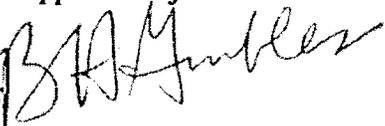
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
WATER

JAN 16 2009

**MEMORANDUM**

**SUBJECT:** Transmittal of *Recommended Approaches to Improve Endangered Species Act (ESA) Consultations on Approvals of State & Tribal Water Quality Standards*

**FROM:** Benjamin H. Grumbles  
Assistant Administrator 

**TO:** Water Management Division Directors  
Regions 1-10

I am pleased to transmit OW's *Recommended Approaches to Improve Endangered Species Act (ESA) Consultations on Approvals of State & Tribal Water Quality Standards*. The approaches recommended in this document reflect our collective experiences over the past decade or more in managing the ESA consultation process in the context of EPA's actions to approve State and Tribal Water Quality Standards (WQS). In large part because of the willingness of the regional offices to share experiences and work with OW and the Office of General Counsel, we are now able today to offer these recommendations which we expect will improve our ability to protect threatened and endangered species and critical habitat as we implement the Water Quality Standards Program. This document is designed to reflect EPA's continued commitment to meet the environmental goals of the ESA and to provide clear and specific information on how to most effectively comply with applicable consultation requirements.

The document:

- Recommends more consistently identifying the limited circumstances where EPA has no discretion to act upon listed species or critical habitat information in taking its approval action, since no consultation is required under these circumstances.
- Identifies more precisely the circumstances where a WQS approval action may affect listed species or critical habitat, since consultation is not required where an approval has "no effect."
- Recommends that we initiate *informal* consultation only for actions that are expected to generate a written Service concurrence with an EPA "not likely to adversely affect" finding within 60 days.
- Recommends that we use the *formal* consultation process for all other approval actions.

These recommendations continue to encourage Regions not to initiate consultation in situations where EPA has “no discretion;” specifically mentioned are WQS for human health criteria and antidegradation policies. OW is also recommending that we not initiate consultation in situations where there are no species in the action area and no observed effects on listed species based on available data (i.e., where there is no effect). The document also includes more specific recommendations on initiating formal consultations and interacting with the Services.

On December 16, 2008, revised ESA Interagency Consultation regulations were published in the Federal Register (73 FR 76272-76287). The Office of Science and Technology and the Office of General Counsel are currently reviewing these regulations and the supporting preamble explanation. However, the strategy and recommendations included in the attached document have been developed based upon current ESA statutory requirement and regulatory consultation provisions in effect prior to December 16<sup>th</sup>. Today’s recommendations are fully compatible with the new regulations, as well.

Development of this document, to capture regional and HQ experiences and best practices in order to improve the ESA consultation process, was initiated as a result of conversations with Division Directors, Regional Branch Chiefs, and technical staff regarding the often contentious and lengthy consultation process experienced as part of EPA’s required review of new or revised WQS packages. The attached document reflects substantial input as part of regular WQS Managers Association meetings, as well as comments on earlier drafts. I want to take this opportunity to express my appreciation for the detailed policy and technical input we have received throughout the process of developing these recommendations.

If you have any questions or need further information on the attached consultation recommendations, please do not hesitate to contact Ephraim King at 202-566-0430 or Denise Keehner at 202-566-1566, or have your staff contact Janita Aguirre at 202-566-0996.

Attachment

**Recommended Approaches to Improve Endangered Species Act Consultations  
On Approvals of State & Tribal Water Quality Standards  
January 16, 2009**

**I. Purpose**

EPA's review and approval of State, Tribal,<sup>1</sup> and Territorial Water Quality Standards (hereafter, State WQS) can trigger the need to consult with the Fish and Wildlife Service and the National Marine Fisheries Service (the Services) under section 7(a)(2) of the Endangered Species Act (ESA). This document outlines an improved approach for: (1) identifying when ESA consultation should be initiated for EPA approval actions, and (2) completing ESA consultations in a more effective and timely manner. Based on EPA's experience with the ESA consultation process to date, this approach will better focus EPA's resources and improve protections for federally-listed threatened and endangered species (together, "listed species") and their designated critical habitat under the Clean Water Act.

Some key elements of this improved approach are to:

- More consistently identify the limited circumstances where EPA has no discretion to act upon listed species or critical habitat information in taking its approval action, since no consultation is required under these circumstances.
- Identify more precisely the circumstances where a WQS approval action may affect listed species or critical habitat, since consultation is not required where an approval has "no effect."
- Initiate *informal* consultation only for actions that are expected to generate a written Service concurrence with an EPA "not likely to adversely affect" finding within 60 days.
- Use the *formal* consultation process for all other approval actions.

**II. Background**

Under CWA section 303(c) and 40 CFR 131.21(a), EPA is required to review and either approve or disapprove new or revised State WQS. The EPA action to approve new or revised WQS can trigger the need to consult with the Services under ESA section 7(a)(2). In the past, EPA has initiated the optional informal consultation process as the first step in the ESA consultation process for WQS approval actions under the CWA. In some instances, however, this practice of "automatically" initiating informal consultation has led EPA to expend resources and effort in initiating ESA consultations on actions where EPA had no discretion to act upon listed species and/or critical habitat information in taking its approval action and other actions where EPA's approval would have "no effect" on listed species. In a number of other cases, the decision to initiate *informal* consultation, rather than move directly into *formal consultation*, contributed to delays in WQS approvals and a reliance on making approvals "subject to" the results of incomplete ESA consultation. Accordingly, to focus EPA resources on better protecting listed species and critical habitat under the Clean Water Act in a more effective and timely manner, the Office of Water is recommending the approach outlined below.

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<sup>1</sup> Tribes found eligible to be treated in the same manner as a State (TAS) to administer the water quality standards program under section 518 of the Clean Water Act.

### **III. Consultation Steps**

#### **Step One: Analyze EPA's Discretion and the Possible Effects of Approval**

ESA consultation requirements do not apply to actions where EPA lacks discretion to protect species, consistent with the Services' regulations implementing ESA section 7(a)(2) at 50 CFR 402.03, or where an EPA action has no effect on listed species or critical habitat, consistent with 50 CFR 402.14(a). Where EPA makes a determination that an approval action falls in either the "no discretion" or "no effect" categories, EPA should detail its reasoning for the administrative record. Specifically, when determining whether consultation may be necessary, WQS Program managers should consider the following:

##### ***A. EPA's Discretion***

For ESA section 7(a)(2) to apply, EPA must be taking an action in which it has sufficient discretionary federal involvement or control to protect listed species. State WQS actions where EPA has concluded that it lacks such discretion include the following:

1. Approval of antidegradation policies that meet the requirements of 40 CFR 131.12.
2. Approval of water quality criteria to protect human health.

In the case of approvals of State antidegradation policies, EPA is not authorized to require anything more than the requirements listed in 40 CFR 131.12, and therefore it has no discretion to revise an otherwise approvable action to benefit listed species where the State submittal meets the requirements of 40 CFR 131.12. Similarly, human health water quality criteria are designed to protect humans, not plants and animals. EPA's discretion to act on a State submission is limited to determining whether the criteria ensure the protection of designated uses upon which the criteria are based (i.e., use by humans). Therefore, EPA has no discretion to revise an otherwise approvable human health criterion to benefit listed species.

##### ***B. The Effects of EPA Approval***

Where EPA's action to approve State WQS does not have any effect on listed species or critical habitat because there are no listed species or critical habitat in the action area that could be exposed to the relevant pollutant, no consultation is necessary.

Even where listed species are present in the action area, it is still possible that there would be no effect of the action in certain situations. For example, the circumstances may be such in the action area that the listed species will not be meaningfully exposed to a contaminant. As a second example, toxicity data may indicate that there are no effects to listed species at concentrations associated with the criteria levels, such as when the best data available show that toxic effects to a listed species do not occur until concentrations reach levels above the criteria levels. A concise administrative record of the basis of EPA's conclusion should be created in such cases to document that these circumstances apply. Of course, it is possible that EPA may determine that a WQS approval action has "no effect" on some listed species or critical habitat

but that it “may affect” others. In that case, consultation is only required for those species that may be affected.

**Step Two: Conduct Timely Informal or Formal Consultation Where Appropriate**

When the Region has determined that ESA section 7(a)(2) applies and that its approval of State WQS may affect listed species or designated critical habitat, EPA should consult with the Services. There are two different paths available when EPA initiates ESA consultation: informal consultation and formal consultation.

In informal consultation, EPA has the obligation to demonstrate that adverse effects are not likely. The optional informal consultation process is the recommended initial path *only* in situations where EPA determines that the approval is not likely to have adverse effects and the Service(s) written concurrence with EPA’s determination is expected within 60 days. This will be the case where ESA-related issues are relatively simple and straightforward. EPA has concluded that informal consultation is most appropriate and useful as a tool for workload management when both the Services and EPA can quickly and easily conclude that an EPA approval action is not likely to adversely affect listed species or designated critical habitat in the action area.

For all other situations, the recommended path is to skip the optional informal consultation and initiate formal consultation. Formal consultation operates under a framework of regulatory requirements and deadlines. Under the formal consultation process, the Services have the affirmative obligation of determining with a scientific basis whether EPA’s approval action is likely to jeopardize the continued existence of the species, will result in adverse modification of critical habitat, or is likely to cause incidental take -- while addressing any associated mitigation issues. Formal consultation by statute and regulation is to be completed within 135 days of initiation.

Since ESA formal consultation exceeds the CWA deadline of 60 days for EPA action to approve State WQS, Regions may need to rely upon the provisions of ESA section 7(d) which prohibit any irreversible commitment of resources that has the effect of foreclosing any alternatives to avoid potential jeopardy or adverse modification. Under the provisions of ESA section 7(d), EPA may issue an approval subject to ongoing consultation where the Region has determined that there will be no interim impacts of concern.

***A. When should EPA Regions choose informal consultation as the initial step?***

Regions should pursue informal consultation only in those cases where ESA-related issues are expected to be relatively straightforward and non-controversial, and where it is expected that the Services will concur within 60 days of EPA’s request for concurrence. The preamble to the consultation regulations states that an informal consultation “not likely to adversely affect” determination is appropriate for those activities that are found to have beneficial, discountable or insignificant effects on listed species or critical habitat. 51 FR 19,949 (June 3, 1986). In such cases, the following approach is suggested:

- a) Review the best data available and document whether the approval is “not likely to adversely affect” listed species and designated critical habitat.
- b) Send to the Services EPA’s technical evaluation along with a brief memo discussing the scope of information reviewed and summarizing the basis of the conclusion that the action is “not likely to adversely affect.”
- c) Request concurrence specifying a particular time period not to exceed 60 days.
- d) Where the Services are not able to concur within 60 days, formal consultation should be initiated.
- e) Where an EPA Region believes informal consultation should be extended beyond 60 days, the Office of Science and Technology (OST) requests that the Region notify the Director of the Standards and Health Protection Division of the rationale for the extension to ensure regional consistency regarding ESA consultation.

### ***B. When should EPA Regions utilize formal consultation?***

Formal consultation is recommended as a better and more appropriate *initial path* in situations where EPA does not expect the Services to concur in writing in a timely fashion with an EPA determination that approval is “not likely to adversely affect.” The regulations describing the ESA section 7 consultation procedures make clear that informal consultation is strictly an optional procedure. 50 CFR 402.13. Thus, EPA may proceed directly to initiating formal consultation without first attempting informal consultation.

Formal consultation is recommended as the most appropriate approach where:

- the WQS approval and/or the analysis of effects are complex,
- there is uncertainty or debate on what constitutes the best data available,
- EPA is unable to conclude that the action is “not likely to adversely effect” listed species<sup>2</sup>,
- there is otherwise reason to believe that the Services may disagree (or are likely to disagree) with EPA’s determination regarding the effects of the action.

### **The Formal Consultation Process**

The steps of formal consultation are described below with an outline of the regulatory requirements together with recommendations for conducting this process. It is important to recognize that in formal consultation, EPA’s biological evaluation and initiation package are prepared for the purpose of providing the best data available with EPA’s related analyses *for the Services’ use*. After subsequent discussions with EPA, the Services use this information to develop their own conclusion – their “biological opinion” -- regarding the likelihood of jeopardizing the continued existence of the species, adverse modification of critical habitat, or incidental take.

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<sup>2</sup> The only context in which the Services can authorize incidental take for a federal agency is under formal consultation.

## 1. Initiating formal consultation

To initiate formal consultation, EPA must provide the information specified in 50 CFR 402.14(c): (1) a description of the action, (2) a description of the specific area that may be affected, (3) the listed species and designated critical habitat in the specific area, (4) a description of how EPA's approval of State WQS may affect listed species or critical habitat, (5) an analysis of cumulative impacts, and (6) copies of all relevant reports, data and information.

The information provided must include the "best scientific and commercial data available." 50 CFR 402.14(d). There may be situations in which the Services may request additional data or analyses that are not readily available; in these situations it is recommended to initiate the consultation process and hold discussions about data or analyses during the formal consultation period rather than delaying initiation of consultation.

EPA can compile all of the information required by the regulation into a consultation package that includes: (1) a cover letter requesting initiation of formal consultation, and (2) a biological evaluation (BE) of the effects of the action.

### *a. The Cover Letter*

The cover letter requesting initiation should address the following procedural issues:

1. EPA's obligation to review and approve State WQS within statutory deadlines and the basis for EPA approval of the State's aquatic life criteria.
2. EPA's conclusion that the contents of the Agency's initiation package meet the requirements of 50 CFR 402.14(c) for initiation of formal consultation.
3. A confirmatory outline of any coordination with the Services on this particular action to date.
4. A clear delineation of EPA's specific expectations for how to conduct the formal consultation process including, for example:
  - a. EPA's understanding that formal consultation commences upon submission of EPA's complete consultation package, consistent with the definition of formal consultation at 50 CFR 402.02.
  - b. EPA's understanding that unless an extension is mutually agreed upon, formal consultation will be concluded and a biological opinion (BO) finalized within 135 days.
  - c. EPA's request that there be a meeting early in the 90-day consultation period to review EPA's analysis, discuss the Service's preliminary views on jeopardy and take, and discuss possible mitigation issues. 50 CFR 402.14(g)(5).
  - d. A request to review the draft BO prior to the end of consultation.
  - e. EPA's on-going commitment to actively support and expedite the consultation through meetings and quick responses so that the Services can deliver a final BO and conclude the consultation in a timely fashion.

***b. The Formal Consultation Package***

As briefly outlined above the following table provides a more detailed summary of what should be included in a consultation package delivered to the Services to initiate formal consultation under 50 CFR 402.14(c).

<b>What is Required</b>	<b>How to Comply</b>
1. Description of the action	Identify what you are approving.
2. Description of the specific area that may be affected	Identify where the standard applies.
3. The listed species and designated critical habitat in the specific area	Consult the FWS website at [ <a href="http://ecos.fws.gov/tess_public/">http://ecos.fws.gov/tess_public/</a> ] or the relevant Natural Heritage program occurrence data and develop a list of species that are currently known to occur in the area where the standards will apply.
4. Description of how the action may affect listed species or critical habitat	Include EPA's biological evaluation of the effects of the approval. EPA is responsible for considering the best scientific and commercial data available in this analysis.
5. Analysis of Cumulative Effects	Cumulative effects under the ESA are those effects of future State or private activities (not involving federal activities) that are reasonably certain to occur. 50 CFR 402.02. EPA's analysis should be brief and qualitative.
6. Relevant reports, including any biological assessment prepared	In addition to the biological evaluation, include tables that identify both the data that EPA used in the analyses of the effects of the action, as well as all other data that EPA considered but did not use.
7. Any other relevant available information on the action, the affected listed species, or critical habitat	The ESA regulations have a "placeholder" for anything else that would be relevant but which was not specifically listed previously.

2. Interacting with the Services

***a. Requests for Additional Data or Analyses from the Services***

Once EPA has submitted the initiation package to the Services, the Services may respond in writing that additional data or analyses are necessary to provide the information needed to allow the Services to formulate their BO. This response by the Services does not necessarily mean that the initiation criteria in 50 CFR 402.14(c) have not been met. Additional data or analyses should be provided to the Services if indeed the data or analyses submitted to the Services were incomplete or if it is practicable to gather the requested additional data. If EPA believes that it has already provided a complete package with the best data available, other relevant information, and the appropriate analyses to initiate consultation, EPA Regions should respond to the

Services' requests by explaining that it has complied with the requirements of 50 CFR 402.14(c), although it stands ready to work with the Services during the consultation period on any data or analytical issues.

***b. Initial Meetings and Review of the Draft Biological Opinion***

As indicated previously, in the cover letter initiating formal consultation EPA should include a request to review a draft of the Services' BO, preferably by a specified date. In addition, the Region should engage proactively with the Services after submitting the initial biological evaluation to review key issues that are likely to be addressed as part of the draft BO. These issues include whether the Services anticipate jeopardy of listed species, adverse modification of critical habitat, or take.<sup>3</sup>

Where the Services anticipate jeopardy or adverse modification, the draft BO will also include draft reasonable and prudent alternatives (RPAs). RPAs are defined in the Services regulations at 50 CFR 402.02:

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 are economically and technologically feasible, and that the [Service] believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Where the Services anticipates "take," it will be necessary for the Services to estimate the magnitude of the take and to specify reasonable and prudent measures (RPMs). RPMs are "actions the Director believes necessary or appropriate to minimize the impacts, i.e., amount or extent of incidental take." 50 CFR 402.02. In addition, RPMs "cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes." 50 CFR 402.14 (i)(3). Further, where the Services anticipate "take," the ESA regulations also require that the "action Agency report the progress of the action and its impact on the species to the Services as specified in the incidental take statement."

EPA should carefully consider the proposed RPAs and RPMs. RPAs and RPMs should relate to the approval action in question and not to all potential actions within EPA's authority. Any efforts to avoid jeopardy/adverse modification or to minimize take through RPAs and RPMs should generally be limited to actions that can be taken through the WQS review process, such as implementation recommendations.

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<sup>3</sup> "Jeopardize" is defined as an action that reasonably would be expected to reduce appreciably the chance of survival of a species by reducing the reproduction, numbers, or distribution of that species. 50 CFR 402.02. Adverse modification has been interpreted by FWS to depend on whether critical habitat "would remain functional (or retain the current ability for the primary constituent elements to be functionally established) to serve the intended conservation role for the species." See Acting FWS Director's Memorandum to Regional Directors (12/9/04). Take is defined to include actual injury or killing of individual listed animals. See e.g., 50 CFR 17.3 (defining "harm").

Promulgating federal WQS, revising national criteria or the State developing new criteria are not considered to be reasonable and prudent measures because these types of mitigation are beyond the scope of the action under consideration (i.e., the approval of the State WQS) and involve more than minor changes to the action. In addition, requiring additional research on toxic effects of pollutants to species is also not within the scope of the action and typically not appropriate for RPMs. See 51 FR 19,954 (June 3, 1986).

### *c. Elevation*

After EPA receives and reviews the draft BO, the Agency may disagree with the Services' conclusions regarding jeopardy, adverse modification, take and corresponding RPAs and RPMs. In the event that the Regional and Services representatives are not able to resolve significant disagreements, these disagreements should be elevated to higher levels of Regional management and if necessary, to the Headquarters offices of EPA and the Services. An elevation document should be prepared, jointly if possible by both EPA and the Services, describing the issue(s), and the positions of EPA and the Services with regard to the issue(s), and the basis for any technical differences. EPA can take the lead in preparing the elevation document in an effort to move the process forward.

### 3. Concluding Formal Consultation

Consultation is complete when the Services finalize and transmit the BO to EPA. When EPA Regions receive the final BO they should carefully review the document, in order to understand the technical basis for the Services' conclusions. EPA may or may not agree with the Services' conclusions about risk to the species, the technical basis for the Services' conclusions, or the suggested mitigation. If EPA does not agree with the BO or aspects of the BO, including the Services' interpretation of data or their technical analyses, EPA should document where EPA differs and why EPA differs as part of the administrative record for its action.

For example, if the Services determine that the action is likely to jeopardize a listed species, and EPA disagrees after giving careful consideration to the Services expert views, EPA may document the basis for the difference in the record for EPA's ultimate decision. Where EPA agrees there may be likely jeopardy, EPA may decide to implement the Services' suggested RPAs as written, develop its own RPAs, or implement a hybrid of the Services' and EPA-developed RPAs. Any proposal varying from the Services' RPA should include sound scientific support that the alternative will avoid likely jeopardy. EPA must inform the Services of the Agency's final decision on whether to approve the WQS where a jeopardy opinion is issued. See 50 CFR 402.15(b).

Similarly, EPA may disagree with a Services' finding that take will occur. In such a case, EPA may also believe that it may not be appropriate to implement the Services' RPMs. In addition, there may be situations where EPA agrees that take is reasonably likely but that the Services' RPMs appear inconsistent with the ESA regulations limiting the scope of RPMs. EPA may believe that it is inappropriate to implement an RPM that appears to lack a regulatory basis.

If the Region does not agree with an important aspect of a final BO and proposes not to implement its suggested mitigation alternative or measure, Headquarters requests that the Region discuss this with both OST and the Office of General Counsel, and that Headquarters and the Region review the written documentation of the disagreement and discuss the appropriate course of action prior to it being finalized.

