

applied on any approved site throughout the United States. Thus, a single registration encompasses multiple separate decisions by EPA. The ESA currently requires a Federal agency to ensure that its "actions" do not jeopardize protected species or adversely modify critical habitat. The Services' regulations state that "[a]ny request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given area or a segment of a comprehensive plan." 50 CFR 402.14(c). Thus, EPA and the Services have discretion to determine the scope of the regulatory action subject to both formal and informal consultations. Please comment on the advantages and disadvantages of using counterpart regulations or other mechanisms to give EPA and the Services more flexibility to define the scope of EPA's consultation with respect to a specific regulatory action. For example, please comment on whether it would be appropriate to have the ability to define EPA's proposed action in a way that would limit a consultation on a registration decision to: A particular geographical area, a particular ingredient in a pesticide formulation, or a particular use of a pesticide product.

3. *The contents of a consultation package.* The ESA requires that "each agency shall use the best scientific and commercial data available." ESA sec. 7(a)(2). The Services' consultation regulations specify that a written request to initiate formal consultation shall contain:

- (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 statements, environmental assessments, or biological assessments prepared; and
- (6) Any other relevant available information on the action, the affected listed species, or critical habitat. 50 CFR 402.14(c).

The Services' regulations define "cumulative effects" to mean "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." 50 CFR 402.02. The consultation regulations do not establish any requirements with respect to the content

of a request for an informal consultation.

Please comment on:

- The meaning of the statutory phrase, "best scientific and commercial data available," with respect to the type of information EPA should be required to include in a review package.
- The advantages and disadvantages of issuing counterpart regulations to modify the existing requirements in 50 CFR 402.14(c).
- Whether the same requirements apply to review packages submitted for informal consultation as for formal consultation or whether informal consultation packages should be subject to any regulatory requirements since they are informal.
- Given that most EPA actions involve multiple pesticide uses that may range from regional to national in scope, what is the most effective and efficient way to address the concept of "cumulative effects" as defined under the Services regulations at 50 CFR 402.02?

4. *The time frame for completing formal and informal consultation on pesticide regulatory actions.* The ESA sets a goal of 135 days for concluding a formal consultation, but also contains provisions that allow the action agency and the Services to agree, in certain circumstances, to extend the deadline for completing the consultation. See ESA sec. 7(b). Neither ESA nor the Services' consultation regulations establish a time frame for completion of informal consultations.

Please comment on the advantages and disadvantages of:

- Establishing specific time frames for concluding formal consultations on pesticide regulatory decisions, including the possibility of a shorter time frame and what action by EPA should trigger the start of a time period for formal consultation.
- Establishing specific time frames for concluding informal consultations on pesticide regulatory actions and what action by EPA should trigger the start of a time period for informal consultation.
- Defining specific circumstances under which the time frames should be extended and what those circumstances might be.

5. *Identify and establish procedures for dealing with an "emergency" for purposes of emergency consultation and other expedited review.* The Services' consultation regulations contain provisions allowing consultation to be conducted in an expedited manner in "emergency circumstances." 50 CFR 402.05. This provision applies to "situations involving acts of God, disasters, casualties, national defense or

security emergencies, etc." The regulations state that expedited consultation may be conducted in any manner consistent with ESA, and that formal consultations "shall be initiated as soon as practicable after the emergency is under control." Under FIFRA, EPA may issue exemptions to States or Federal agencies to allow the use of an unregistered pesticide when "emergency conditions exist which require such exemption." FIFRA sec. 18.

Please comment on whether these and other types of regulatory actions taken by EPA's pesticide programs should be considered "emergencies" that would justify conducting any required ESA consultation in an expedited manner. For example, if consultation with the Services were required, should emergency consultation provisions apply to:

- Petitions for emergency exemptions under FIFRA sec. 18?
- Notifications to EPA of State issuance of "special local needs" registrations under FIFRA sec. 24(c)?
- Other circumstances giving rise to a need for expedited review?

Are there any circumstances where no review by the Services is appropriate, for example, when the action is taken to address a public health emergency as described in 40 CFR part 166, under FIFRA?

6. *Clarify the role of the Services.* As discussed in Unit II.D., ESA and existing consultation regulations describe the role that the Services play in providing advice and opinions on the impact of agency actions on protected species and their critical habitat.

What are the advantages and disadvantages of using counterpart regulations or other mechanisms to establish additional responsibilities for the Services, for example, by specifying that the Services should assist EPA in developing the information base for consultation or by specifying the types of information that the Services should provide to EPA? What other responsibilities, if any, should the Services assume? Should counterpart regulations (or some other mechanism) establish a process that a Service follows to ensure that, when different parts of its organization issue Biological Opinions on the same pesticide and/or species, its Biological Opinions are consistent? If so, how should that process operate?

7. *Clarify the term "applicant" and the participation afforded to applicants.* The current consultation regulations define the term "applicant," as a person "who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action."