

In those circumstances where a Federal agency cannot conclude that its actions will have “no effect” on listed species or critical habitat, but can conclude that its actions are “not likely to adversely affect” listed species or critical habitat, Service regulations provide that if the relevant Service concurs in writing on that determination the agency need not engage in further, (i.e., formal) consultation with the Service. 50 CFR 402.13. The concurrence approach, in these situations, serves as a Service opinion or interpretation that the agency has satisfied its section 7(a)(2) obligations regarding such actions.

Under these circumstances the Services have determined, by regulation, that formal consultation is unnecessary for individual agency actions in order for Federal agencies to satisfy their section 7(a)(2) obligations. While this regulatory regime currently applies to, and is generally appropriate for, a wide variety of Federal agency actions, there may be circumstances where the mission and expertise of a particular agency, or a particular office within an agency, may lend itself to the development of alternative or additional informal processes. EPA’s regulation of pesticides may be one such instance. As explained in Unit II.C., one of EPA’s core functions in the regulation of pesticides under FIFRA is the development of extensive ecological risk assessments, including an evaluation of the effects that pesticide use may have on various plant and animal taxa. As a result, EPA may possess sufficient information and analytical expertise to make informed determinations as to whether a pesticide is “not likely to adversely affect” a listed species or critical habitat. For this reason, EPA and the Services think it is appropriate to consider whether there is a need for either further consultation or Service concurrence in those situations where EPA determines that use of a pesticide is “not likely to adversely affect” listed species or critical habitat.

This ANPR therefore seeks comment on whether to pursue, through counterpart regulations or other mechanisms, either of the two following potential approaches to conducting consultation on pesticide regulatory actions: (1) If EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, no further consultation would be required; or (2) where EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, EPA would continue to consult with the Services but EPA would not need to obtain the written concurrence of the

Services to satisfy its section 7(a)(2) obligations.

EPA and the Services welcome comments on these alternate approaches and specifically request that commenters consider the following in developing their submissions:

- The administrative and programmatic advantages and disadvantages of these approaches.
- In connection with such regulations, what, if any, criteria should the Services establish which, if met, would support one or both of the approaches.
- Whether in connection with such regulations it would be appropriate or necessary to change any of EPA’s data requirements, risk assessment methods, or criteria for evaluating potential risks to protected species.
- Whether there are additional changes to the informal consultation process that may be warranted.

3. *Focused review by the Services during consultation.* The immediately preceding alternative explores amendments to the circumstances under which informal consultation would be necessary. This alternative considers potential approaches to consultation that would focus review provided by the Services once formal or informal consultation had been initiated. It is predicated on the assumption that in the development of this rulemaking, EPA’s practices and policies would be reviewed and, where necessary revised to ensure that the data and analyses EPA obtains and uses provide the best available information on the effects on threatened and endangered species. As discussed earlier, EPA has extensive information available with which to assess and mitigate potential risks to listed species and their critical habitat and EPA has developed considerable expertise in these areas. Based on this expertise, therefore, in the case of pesticide regulatory actions, this alternative proposes that the Services would rely on EPA’s assessment of effects. Thus in the case of pesticide regulatory actions, the Services would rely on EPA’s assessment.

When consultation is necessary, an approach would be to provide for a more focused review of EPA pesticide submissions by the Services. This approach would provide for a rebuttable presumption regarding the adequacy of the effects analysis in an EPA request to initiate consultation. There are many potential standards that could be applied to determine whether the effects analysis would be deemed adequate (see 50 CFR 402.14(c)). This ANPR identifies three:

- Whether EPA had considered the most current and best available scientific, commercial, and technical information on listed species and their habitat and that the determinations were not arbitrary and capricious.

- Whether there was clear and convincing information warranting a different conclusion as to the effects of the proposed registration.
- Whether there is substantial evidence to support EPA’s effects determinations.

EPA and the Services are seeking comments on this approach and specifically request that commenters consider the following questions in developing their submissions:

- What are the administrative and programmatic advantages and disadvantages of this overall approach?
- What are the administrative and programmatic advantages and disadvantages of specific provisions?
- What are other possible appropriate evidentiary or procedural provisions?
- Should the Services establish criteria which, if met, would justify such an approach?
- Would it be appropriate to change any of EPA’s data requirements, risk assessment methods, or criteria for evaluating potential risks to protected species?

B. Modifications of the Existing Framework Under FIFRA and the ESA to Increase the Effectiveness, Efficiency, and Flexibility of the Existing Interagency Process

1. *Modification of EPA’s approach to assessing potential risk to protected species.* EPA routinely receives and evaluates extensive scientific information on the potential hazards of and exposure to pesticide active ingredients as part of its registration and reregistration processes. Unit II.C. contains an overview of this evaluation process and EPA’s ESPP Notice describes the risk assessment process in more detail. Please comment on whether there is a need to modify the current assessment process for evaluating the potential risks to protected species, including whether there should be any changes to EPA’s data requirements, assessment algorithms, or criteria for judging whether the use of a pesticide poses a potential risk to listed species.

2. *Scope of a consultation.* EPA’s registration and reregistration decisions typically involve one or more pesticide products containing a specific active ingredient. A single pesticide product is generally registered for use on multiple crop and/or non-crop sites and may be