

EPA's risk assessment methods have included methodology for an assessment of potential risks to listed species. Refer to the ESPP **Federal Register** Notice (67 FR 71549) for a more detailed description of how EPA assesses the risk to listed species.

EPA requires both new and existing pesticides to be supported by extensive information about the potential ecological risks of the pesticide product. Data requirements appear in EPA regulations at 40 CFR part 158. Studies conducted to generate data for EPA are subject to Good Laboratory Practice requirements that are designed to ensure that the results are reliable and of high quality. See 40 CFR part 160. EPA's scientists carefully review all data submissions and independently evaluate the potential risks of each pesticide. In situations raising novel or challenging scientific issues, EPA generally seeks outside peer review of its scientific assessments.

The Agency requires extensive toxicity and environmental fate data and uses this information, together with field reports of adverse effects on wildlife caused by pesticides and other relevant information, to evaluate the potential hazards to non-target species, including threatened and endangered species, for a pesticide intended for outdoor use. To assess potential hazard to non-target species, EPA requires a basic set of laboratory toxicity studies on an active ingredient using multiple surrogate species of birds, fish, aquatic invertebrates, non-target insects, and plants. In situations where additional, scientifically valid, toxicity data related to effects on wildlife and aquatic organisms are available, EPA will consider them in establishing the toxicity endpoint for risk assessment. It is EPA's policy to conduct risk assessments using the toxicity endpoint from the most sensitive species tested. EPA also requires data from a series of laboratory and field studies of the environmental fate of both the active ingredients in a pesticide product and typical formulations containing the active ingredient. These studies provide data on both the parent active ingredient, as well as its environmental degradates. The Agency combines these data, along with information about how the pesticide product is intended to be used, to develop an estimate of the potential concentrations of residues of the active ingredient and significant environmental degradates in the environment (the Estimated Environmental Concentration or EEC). In order to avoid underestimating risk, EPA makes assumptions designed not to understate potential exposure.

When assessing risks to listed species, EPA evaluates data and risks in a tiered fashion. The Agency compares its toxicity assessment of an active ingredient with the EEC. If the comparison demonstrates that the EEC is well below the amount of active ingredient that would be expected to cause harm to a particular species or critical habitat, EPA would conclude that the use of pesticide products containing that active ingredient would have "no effect" on listed species. Most of EPA's focus is on the potential risks from exposure to the active ingredient and its significant environmental degradates. EPA also has information, both on the other ingredients in pesticide products and on the formulations themselves, with which to assess the potential for increased risk. This ingredient- and formulation-specific information and many years of reviewing pesticide products support a general conclusion that inert ingredients in formulations usually do not make more than a negligible contribution to the overall environmental risks posed by a pesticide product formulation. If the initial comparison and subsequent refined assessments indicate that EPA's best estimate of the EEC for the active ingredient and/or significant environmental degradates could have toxic effects on a listed species, then EPA may require the pesticide sponsor to supply additional laboratory and/or field data in order to refine the risk assessment, require changes in the allowable use of the pesticide product that are sufficient to mitigate any potential risk, or determine it necessary to request initiation of consultation with the Services to obtain a Biological Opinion on actions that might be taken relative to reducing risk. Higher tier toxicity data may include studies on the effects of a pesticide on other wildlife species and plants or studies of longer durations of exposure. The Agency may occasionally require higher tier studies to be conducted in the field under simulated or actual use conditions. EPA may also require additional information to improve its estimate of potential exposure. Possible risk mitigation measures include changes in the manner or timing of pesticide applications, the rate or frequency of applications, or geographical restrictions on use.

D. The Endangered Species Act and Federal Agency Consultations with the Services

Section 7 of the ESA imposes obligations upon all Federal agencies whose actions may adversely impact listed species. Of particular relevance to

this ANPR, section 7(a)(2) directs all Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce (delegated to the Services), to ensure 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 that has been designated as critical ("critical habitat"). 16 U.S.C. 1536(a)(2). In meeting this requirement, each agency is required to use the "best scientific and commercial data available." 16 U.S.C. 1536(a)(2).

The Services adopted joint regulations set forth at 50 CFR part 402, which include procedural requirements. These regulatory provisions require action agencies to consult with the Services on all Federal actions that "may affect" a listed species or critical habitat. Consultation may be concluded "informally" if the action agency, with written concurrence from the Services, determines that the Federal action under consideration is "not likely to adversely affect" a listed species or critical habitat. 50 CFR 402.14(b)(1). "Formal" consultation is required on actions that are likely to adversely affect a listed species or critical habitat and when the Services disagree with an action agency's determination that the action is "not likely to adversely affect" the species or its critical habitat. During formal consultation, focus is on whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. 50 CFR 402.14(h).

By regulation, the consultation process reviews a variety of potential "effects" on listed species and habitat, including direct, indirect, and cumulative effects. "Direct effects" are those effects that will immediately flow from the proposed action. "Indirect effects" are those that will be caused by the proposed action, will occur later in time, but are still reasonably certain to occur. "Cumulative effects" are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the area affected by the proposed action. 50 CFR 402.02. Additionally, examination includes the effects of "interrelated" and "interdependent" actions. For a detailed explanation of these terms, please refer to the Consultation Handbook jointly published by NMFS and FWS, which further elaborates on the procedures followed by the Services when conducting section 7 consultations.