Next Steps in Endangered Species Risk Assessments

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Abstract

As an integral part of its registration review program, U.S. Environmental Protection Agency (EPA) is conducting screening-level endangered species risk assessments for pesticides. These assessments, which evaluate potential effects on endangered birds, non-target mammals, fish, aquatic invertebrates, and non-target plants, typically consist of EPA's standard, national-level screening risk assessments for pesticides. These screening-level assessments are inherently intended to be conservative, so if a pesticide-use combination passes this initial assessment, there is a relatively high degree of confidence that those uses of the product will not adversely impact endangered or threatened species. However, if the use of a product fails this initial assessment, the conclusion should not be that use of the product is likely to adversely impact endangered species; rather, the conclusion should be that the risk assessment should be refined. However, EPA does not conduct a refined assessment. Instead, those uses of the product that fail the initial assessment may be referred to the Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS; collectively, the Services) for further evaluation in a Biological Opinion (BiOp). The Services' approach to risk assessments of pesticides differs considerably from the approach that EPA and registrants typically use. Therefore, registrants are encouraged to conduct a higher-tier risk assessment to evaluate the potential for uses of a product that fails a screening-level risk assessment to impact endangered species. A higher-tier risk assessment can involve several levels of refinement. This paper provides examples of several types of refinements, including more detailed, specific use information, more specific information relating to endangered species that may be impacted, refinements in potential exposure, and refinements in toxicity endpoints, that can be used to address endangered species concerns.

Introduction

As an integral part of its registration review program for pesticides, EPA is conducting national-level, screening-level endangered species risk assessments. These risk assessments include evaluations of potential effects on endangered species belonging to the following major taxonomic groups: mammals, birds, freshwater and estuarine fish, freshwater and estuarine invertebrates, and non-target terrestrial and aquatic plants. Unless specific data are available on amphibians and reptiles, these taxonomic groups are covered by using assessments for fish and birds as surrogates. While EPA typically does not conduct risk assessments for possible effects on insects, EPA has conducted assessments for effects on endangered insect species.

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Risk Assessment Process

For these national-level endangered species assessments, EPA relies on its standard screening-level risk assessment procedures for pesticides. These procedures include using modeling to estimate exposure:

- GENEEC and PRZM-EXAMS for aquatic organism exposure (fish, aquatic-phase amphibians, aquatic invertebrates, and aquatic plants);
- T-REX and T-HERPS for avian, mammalian, reptilian, and terrestrial-phase amphibian exposure;
- TerrPlant for terrestrial plant exposure.

Since these models are used for screening-level exposures, the models are intentionally and inherently conservative. New EPA screening-level models for estimating potential exposures through inhalation, drinking water, and dermal exposure have also recently become available.

Risk quotients (RQs), are calculated for each major taxonomic group that is evaluated. Acceptable RQs for endangered species assessments include an additional level of safety, and therefore represent more stringent criteria for acceptable RQs (e.g., passing the screening-level assessment) than the criteria applied for acceptable RQs for non-endangered species (Table 1).

Table 1. EPA's levels of concern for acute effects on endangered and non-endangered species

Taxonomic Group	Endangered Species	Non-Endangered Species
Mammals	RQ ≥0.1	RQ ≥0.5
Birds	RQ ≥0.1	RQ ≥0.5
Fish	RQ ≥0.05	RQ ≥0.5
Reptiles	RQ ≥0.1	RQ ≥0.5
Amphibians	RQ ≥0.1(terrestrial phase) RQ ≥0.05 (aquatic phase)	RQ ≥0.5
Aquatic Invertebrates	RQ ≥0.05	RQ ≥0.5
Terrestrial Plants	RQ ≥1.0 (based on NOEL)	RQ ≥1.0 (based on EC25)
Aquatic Plants	RQ ≥ 1.0 (based on NOEC)	RQ ≥1.0 (based EC50)
Insects	Unclear	Unclear

Therefore, if a product and use combination passes the screening-level assessment, there is a high degree of confidence that those uses will not adversely impact endangered species when the product is used according to label directions.

The EPA screening-level assessments are conducted at the level of each of the major taxonomic groups evaluated (e.g., birds, fish, mammals, terrestrial plants), not at lower taxonomic levels, and the assessments are conducted at the national level, not more specific regional levels. For endangered species, EPA may conclude that a product and use combination is:

- not likely to affect endangered species belonging to a given major taxonomic group;
- may affect but is unlikely to adversely affect endangered species within a major taxonomic group, or
- that the pesticide and use combination may affect and is likely to adversely affect endangered species within a major taxonomic group.

If EPA concludes that a pesticide and use combination is likely to adversely affect endangered species within a major taxonomic group, then EPA is required to refer the pesticide to the Services for further evaluation.

The Services' approach to conducting risk assessments differs from EPA's approach, and generally, registrants are not as familiar with the Services' approach as with EPA's approach to risk assessments. For example, in its Pacific salmon assessments, NMFS has focused on potential exposure of salmon in shallow, off-channel habitats, and has recently also focused on potential indirect effects through effects on salmon food supply, and potential physiological effects arising from cholinesterase inhibition. Thus, the Services' approach represents a "black box" to many in the regulated pesticide community. The end result of the Services assessment is the issuance of a Biological Opinion (BiOp) that includes Reasonable and Prudent Alternatives (RPAs) and Reasonable and Prudent Measures (RPMs) that may significantly curtail or limit pesticide use in certain areas. While EPA is not required to incorporate the Services recommendations into its registration decisions, users may be in potential jeopardy if a product is used in a manner or area that is not consistent with the Services recommendations, due to lack of "incidental take" coverage.

However, if a pesticide and use combination fails the screening-level assessment, the conclusion should not be that use of the product is likely to affect endangered species that belong to the major taxonomic group which failed the screening-level assessment. Rather, the conclusion should be that risks to endangered species within taxonomic groups that fail a screening-level assessment should be that the product and use should undergo a more detailed, higher-tier evaluation. Often, a more detailed, in-depth assessment can alleviate concerns about potential effects to endangered and non-endangered species.

Higher Tier Risk Assessment Options

EPA will not refine the screening-level risk assessment; that is the registrant's responsibility. A number of options are available for refining screening-level risk assessments for endangered species on both the exposure and the receptor sides of the risk equation. Table 2 lists some of these options, and some of these options are discussed below.

Table 2. Options for refining screening-level risk assessments

Refinement Option	Source for Additional Data
Overlap of crop/use pattern with species distribution	County level, USDA data, State agricultural data, FESTF[1] data (some sub-county level data available)
Species habitat information	FWS data, NMFS data, Literature data, FESTF (summary information)
Species diet information	Literature data
Information on actual use of product	USDA data, Registrant data[2]
GIS proximity analysis	State agricultural data, Land use data
Field data	Registrant data[2], EPA review data
Residue data	Registrant data[2]
Water monitoring data	USGS data, State data

[1]FIFRA Endangered Species Task Force
[2]Data considered confidential

Refinements to risk assessments can be tiered; some endangered species assessments can be adequately refined by incorporating just one refinement option, while other endangered species assessments require multiple levels of refinement. The initial tier of refinement focuses on determining whether there is geographic overlap between a pesticide use area (including an area to which runoff may occur from a use area), and the species of concern.

- Geographic distribution of species of concern compared to the geographic distribution of the use pattern and crop of concern. This represents the initial refinement to a national-level, screening-level risk assessment. The initial analysis is conducted at the county level, and often results in a number of endangered species being eliminated from concern due to a lack of overlap.
- Detailed information from growers and trade organizations concerning how a product is actually used on a crop, compared to default, maximum-use assumptions. For uses in California, this step includes specific data collected by California on the locations and amounts of products used.
- Incorporation of regional field data into modeling of estimated exposure for specific regions (e.g., dissipation data, specifics on soil types).
- Incorporation of product-specific residue data into estimating potential exposures. This is particularly helpful for non-persistent products, and products that are soil-incorporated or watered into the soil.
- Use of water monitoring data in estimating potential exposures (note that both EPA and the Services have reservations regarding monitoring data, but these data often provide a useful perspective on modeling results).
- Incorporation of GIS information regarding the proximity of agricultural crop use areas to aquatic sites or terrestrial habitats of concern.
- Use of species sensitivity distributions, actual data, or closely -elated surrogates of preferred feed species or feed items.
- Incorporation of detailed information on the species of concern into the assessment, including habitat and dietary information. This refinement often provides key information on whether, and if so, how an endangered species may use agricultural habitat, or habitat adjoining agricultural habitat.

Conclusions

Standard screening-level risk assessments are inherently conservative, and thus may easily result in a product and use pattern combination being predicted to affect endangered species within certain major taxonomic groups. At this stage, registrants should consider conducting a more detailed, higher-tier risk assessment for endangered species preliminarily identified as potentially affected by use of their product. A number of options exist for refining endangered species risk assessments. Refined assessments often substantially reduce the number of potentially-affected species, which can then result in less stringent restrictions being proposed for registered uses.