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.
- TerPlant 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.

However, if a pesticide and use combination fails the screening-level assessment, the conclusion should not be that 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 using the product that failed 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 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 taxonomic endpoints, that can be used to address endangered species concern.

Introduction

As an integral part of its registration review program for pesticides, EPA is conducting national-level, screening-level species risk assessments. These risk assessments include evaluations on the potential for a product to adversely affect endangered species belonging to the following major taxonomic groups: mammals, birds, fish, freshwater and estuarine invertebrates, and non-vascular 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 assessments on non-vascular aquatic plants for possible effects on insects, EPA has conducted assessments on certain major taxonomic groups of endangered insect species.

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’ approach is the issuance of a Biological Opinion (BiOp) that includes Reasonable and Prudent Alternatives (RPAs) and Reasonable and Prudent Measures (RPMs) that may significantly affect 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 be reevaluated at a higher-tier level. 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 refinements of 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

<table>
<thead>
<tr>
<th>Refinement Option</th>
<th>Science for Additional Data</th>
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</thead>
<tbody>
<tr>
<td>Overlap of crop/usage pattern with species habitat</td>
<td>habitat information</td>
</tr>
<tr>
<td>Exposure/ionization at field sites</td>
<td>pesticide information</td>
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<tr>
<td>Species diet information</td>
<td>Pesticide data, NMFS data, literature data, teratogenicity data</td>
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<tr>
<td>Effects of product</td>
<td>Pesticide data, NMFS data, literature data, teratogenicity data</td>
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<tr>
<td>GIS proximity analysis</td>
<td>Pesticide data, NMFS data, literature data</td>
</tr>
<tr>
<td>Water monitoring data</td>
<td>Pesticide data, NMFS data, literature data</td>
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Refrinements to risk assessments can be tiered; some endangered species assessments can be adequately refined by classifying the area of concern based on geographic overlap between the registration area (including an area to which runoff may occur from a use area), and the species of concern. Examples of these refinements include:

- 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, species 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 data is collected by the California Department of Pesticide Regulation.
- Incorporation of regional field data into modeling of estimated exposure for specific regions (e.g., dissipation data, specific 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 exposure areas (note that this type of data may not 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 crops to use areas to aquatic sites or terrestrial habit of concern.
- Use of species sensitivity distributions, actual data, or closely related 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

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 and non-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 a product. A number of key information exists 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.

Cliff Habig, Compliance Services International

Next Steps in Endangered Species Risk Assessments

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