Public Discussion Draft

STEP-WISE APPROACH TO ASSESSING POTENTIAL EFFECTS OF PESTICIDES ON LISTED SPECIES AND CRITICAL HABITAT

ROLES OF OPP DIVISIONS , THE SERVICES, AND EXTERNAL STAKEHOLDERS IN COLLECTING AND EMPLOYING BEST AVAILABLE INFORMATION

March 3, 2005

OVERVIEW

This document describes a "step-wise" or "tiered" approach to assessing the ecological risks of pesticides to species declared threatened or endangered under the Endangered Species Act (ESA) (listed species) and the critical habitat* [1] on which such species rely. The approach summarized below is described in considerably more detail in a document titled, "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations" (January 23, 2004) ("Overview document"). Cross-references to the Overview document appear at the start of each step. This paper also delineates the types of information needed for each step of the assessment; what source(s) supply the information; which division(s) in OPP participate in each step of the assessment; and what roles external stakeholders could play.

[1] Certain ESA terms are defined in the Glossary appearing at the end of this document. These terms appear with an asterisk following the first time they are used in the document.

General Principles. Several important principles underlie OPP's tiered approach to assessing the ecological risks to listed species and critical habitat. First, OPP intends to conduct an assessment that is both comprehensive and scientifically sound and that reliably evaluates whether a pesticide poses a risk to listed species or critical habitat. Second, if there is any risk, OPP will impose only those regulatory restrictions on the use of a pesticide that are necessary to ensure that use of a pesticide meets statutory standards under FIFRA and the ESA which will ensure protection of listed species. Third, recognizing the limited resources both of stakeholders and Agency risk assessment and risk management staff, OPP intends to conduct its assessments and reach regulatory conclusions as efficiently as possible. Therefore OPP intends to work collaboratively with key stakeholders, particularly the Services – the Fish & Wildlife Service in the Department of the Interior and the National Marine Fisheries Service in the National Oceanographic and Atmospheric Administration (NOAA Fisheries) at the Department of Commerce – to take best advantage of their special expertise.[2] Finally, OPP intends to make its assessments transparent so that all external stakeholders can review and appropriately comment on the assessments.

Summary of the 4 Step Process. Applying these principles, and consistent with EPA's Guidelines for Ecological Risk Assessment, OPP's approach emphasizes collecting and reviewing relevant, scientifically sound data on the toxicity of a pesticide available from both the public literature and registrants' submissions. Using these data, along with information available to assess potential exposure, EPA generates a "screening level" assessment of potential risk, comparing toxicity information and exposure estimates [**Step 1**]. As explained in the Overview document, this screening level assessment uses the best scientific and commercial data available, in conjunction with models, and assumptions in a manner designed not to underestimate potential risk. To the extent that Step 1 suggests there may be potential risks to species in particular taxa, OPP then reviews information on where a pesticide could be used and compares that with information on the location of listed species and critical habitat that could be affected by such use [**Step 2**]. OPP believes that this step-wise approach conserves resources and avoids the unnecessary collection or generation of data and the conduct of additional assessments when available information demonstrates that the pesticide use does not pose a risk to listed species and critical habitat.

If assessments in Steps 1 and 2 suggest that a pesticide might potentially have impacts on listed species or critical habitat, further data and /or analysis [**Step 3**] would be required. Before gathering additional information or conducting further analysis, however, it is essential for the risk assessment and risk management team to consider carefully the wide range of choices to develop a more refined assessment of risk that could definitively demonstrate whether the pesticide does (or does not) pose a risk. The strategy for Step 3 should consider what types of information would be most likely to refine the assessment, and the extent of the resources that

[2] Throughout this document where the "Service" is listed as a source of information, the particular information will be obtained directly from the Service or from materials produced by the Service, such as listing notices or critical habitat notices.

would be required to obtain and evaluate such information. To the extent possible, OPP should try to resolve risk issues as efficiently as possible.

If the refined, species-specific assessment in Step 3 indicates that a pesticide use will pose risks to listed species or critical habitat, EPA will need to consult with the appropriate Service(s). **Step 4** describes the additional work – identification of cumulative effects* and (at EPA's discretion) preparation of material relating to a draft Biological Opinion – that OPP needs to perform to initiate such consultation.

The different divisions in OPP need to work closely together throughout each step of the tiered assessment. Each division brings different expertise and has access to different types of information, all of which will likely come into play in addressing pesticides and endangered species. The level of involvement of each division depends on the type of analysis being conducted at each step. The following Table depicts what is summarized above and described in more detail in subsequent pages:

Table 1: Summary of Activities, Outputs, and Organizational Roles in the Step-Wise Approach to the Assessment of Potential Risks to Listed Species and Critical Habitat.

	Step 1	**Step 2**	**Step 3**	**Step 4**
Activity	Initial evaluation of the potential of the proposed or existing use of the pesticide to affect adversely different taxa of biological organisms, usually at a national scale.	Initial evaluation of potential overlap of areas affected by the pesticide use (action area*) and location of listed species and critical habitat.	Refined ecological risk assessment of particular pesticide use / species / habitat / exposure duration.	Assessment of cumulative effects and preparation of any package for consultation with the Service(s).
Output	Initial Risk Quotients (RQs) for different taxa, and either "No Effect" (NE) determinations or identification of the need for further analysis	Either NE or NLAA determinations based on the absence or limited nature of overlap of the action area and species / habitat location or the need for further analysis.	Refined risk assessments and either NE, Not Likely to Adversely Affect (NLAA), or Likely to Adversely Affect (LAA) determinations	Consultation package; possible ESA sec. 7(d) determination*
Lead Risk Management Division's role (RD, SRRD, AD, or BPPD)	To provide information on the pesticide's use pattern, to manage the problem formulation, and to negotiate any Risk Mitigation (RM) measures	To negotiate any Risk Mitigation (RM) measures	To lead the development of a plan for further refinement of the assessment and to negotiate any Risk Mitigation (RM) measures	To manage public participation
Risk Assessment Division's role (EFED, AD, or	To analyze the best available scientific (registrant & ECOTOX) data to calculate RQs and to make NE determinations, if	To perform an analysis of the extent of spatial overlap of the action area and the location of listed species / habitat	To develop a refined ecological risk assessment, focusing particularly on the refinement of modeled estimates of exposure and on the collection and analysis of additional species-	To analyze potential cumulative effects, to prepare the consultation package for the Services, and to prepare ESA

BPPD)	appropriate		specific information, and to make NE, NLAA, or LAA determinations, as appropriate.	section 7(d) determinations, as appropriate
BEAD role	To support the problem formulation for the ecological risk assessment	To provide information on the location of the pesticide use.	To manage the collection and analysis of pesticide use information used in the refined risk assessment.	None
Service's role	None	To provide information on species / habitat location and biology, particularly as it concerns potential indirect effects dependencies.	Through a Service Representative, to provide information on environmental baseline* and on the biological requirements of potentially affected species and critical habitat information	As requested, to assist in the development of any consultation package
External Stakeholders role[3]	To provide basic information on proposed or approved pesticide use patterns	On request, to provide information on location and other characteristics of pesticide use	On request, to provide information on location and other characteristics of pesticide use	

Once the species-specific risk mitigation measures, FEAD will assist in the dissemination of county bulletins containing such restrictions.

[3] While this document notes, here and elsewhere, opportunities for public input, those opportunities do not necessarily constitute the full extent of this participation. OPP is developing further information specific to opportunities for public input in which all such opportunities relative to endangered species risk assessments, will be described.

Considerations affecting the implementation of this approach. The approach described below represents the process that OPP intends to use routinely. Several factors influence how quickly and comprehensively OPP will implement this new approach for different chemical actions.

First, EPA is operating under statutory deadlines for making regulatory decisions on old chemicals through the reregistration program and on new products under the Pesticide Registration Improvement Act. OPP will continue to meet these deadlines, while performing as much of the ESA analysis as possible.

Second, because of the long lead time involved in conducting an ecological risk assessment, OPP may already have performed portions of its assessment for a chemical in a manner that does not track with the approach described below. OPP plans to implement these procedures for such assessments, to the extent possible, without delaying its regulatory decision-making. Team members should discuss how much of the new procedures to incorporate and when and how to do so while still adhering to current schedules and statutory deadlines. Teams should consult with division management as necessary. OPP recognizes that in some cases, it may not be possible to implement fully the new procedures for a particular chemical.

Third, resource considerations will necessitate a phasing in of portions of this new process. For FY 05, OPP has committed to complete full assessments and consult as appropriate with the Services for 12 active ingredients: aldicarb, carbofuran, the 9 rodenticides, and one yet-to-be-determined new active ingredient.[4] Additionally, OPP is committed to continuing litigation support on a variety of legal actions, including those focused on atrazine, Red Legged Frog, and Barton Springs salamander and continuing work in the Washington Toxics Coalition litigation. This suite of actions are the priority actions within OPP on which endangered species will be fully addressed. Beyond these priorities, endangered species assessments will be conducted to the extent pertinent divisions can dedicate resources to this effort. For example, in some situations EFED may include additional analysis consistent with the Overview document in its initial, screening level assessments of new active ingredients and other active ingredients undergoing reregistration such that NE or NLAA determinations may be made. For reregistration, with the exception of the 12 chemicals identified above, prior to moving beyond Step 2, teams should consult senior level (Division Director) management to determine the level of effort that can be supported and still meet statutory deadlines. Also, prior to initiating work on a given new active ingredient, new use, and Section 18 action, etc., the management from each appropriate division should discuss the extent of the effort necessary and determine whether the particular action can be supported and to what level of effort.

[4] In future years, the manner, pace, and extent of implementation of this process will depend on the level of resources available at the Services and EPA.

Finally, even though OPP may not immediately implement this new approach for all of its actions for some time, it is important for teams to look for and implement risk mitigation measures that achieve as much protection for listed species as possible within the constraints discussed above. Thus, teams should look for "low hanging fruit," i.e., situations in which the potential for adverse effects on a particular species or taxa can be shown, through further analysis, not to exist, and / or eliminated by imposition of practical risk mitigation measures. Such mitigation should be tailored to the extent that it can, to minimize the impact on agriculture and other pesticide users, while providing protection for the listed species.

STEP 1 – INITIAL LEVELS OF CONCERN ANALYSES
(Overview Document: Chapter V)
Timelines:
Conventional Registration: Completed for Team Meeting 2
Conventional Re-registration: Completed for Team Meeting 1
BPPD: Completed early in Phase III (Primary review)
AD:

Decision: Do any uses of the pesticide potentially result in exposures that EPA reasonably expects could equal or exceed the Levels of Concern (LOCs) for taxa of endangered aquatic life, plants, or wildlife? If no Endangered Species (ES) LOCs are exceeded for any taxonomic group, then EPA would expect no direct effects, indirect effects*, or effects on critical habitat to occur. EPA would make a determination that the pesticide use has "no effect" (NE) on listed species and critical habitat, and the ES analysis is completed. To the extent any exceedences of ES LOCs suggest a potential risk to listed species or critical habitat, move to Step 2. Also, does the screening level analysis suggest the need for extensive involvement of the Services?

Participants: regulatory divisions: AD, BPPD, RD, or SRRD (as appropriate)
risk assessors: EFED, AD, or BPPD (as appropriate);
support divisions: BEAD (for re-registration - label interpretation)

Information needs [sources of information]:

- standard registration package (use information from label, toxicity data, and exposure data) [appropriate regulatory division, registrant / applicant]
- data from ECOTOX [EFED]
- monitoring information [EFED, AD, or BPPD; others]
- risk characterization components (e.g., slope analysis, drift, etc.) [EFED, AD or BPPD]

Some information described in Table 2 may be used in Step 1, especially the information in Sections A and D that is readily available. Collection and utilization of information to produce an accurate and defensible effects determination with the least investment of resources is the overall objective.

Process: The initial problem formulation is completed with team members from the regulatory

division, the risk assessment division, and BEAD. During problem formulation, the team prepares a conceptual model and analysis plan. If, at this stage of the risk assessment (or any subsequent time), it appears likely that some uses may require refined (Step 3) assessments, the assessment team should include all of the above divisions through the rest of the steps. If the forecasted level of risk at the initial problem formulation stage suggests an assessment will reach Step 4 with multiple uses and species, the regulatory division should give a courtesy call to the Services to assist them in their workforce planning estimates.

The appropriate risk assessment division would perform a standard "screening level" assessment for the action. If initially calculated RQs for an action appear to exceed the ES LOCs, the pesticide use(s) potentially could cause direct effects, indirect effects, and / or effects on critical habitat. In such cases, EPA must consider during Step 1 potential risk assessment refinements and/or could consider risk-based mitigation measures (e.g., changes to the label accepted by the registrant), either (or both) of which might result in no exceedence of any ES LOCs. The lead risk assessment division would need to document the effectiveness of the risk mitigation measures, e.g., by recalculating exposure and the relevant RQs. EPA would then make a NE determination and the ES review would be completed. If, however, any ES LOCs are still exceeded, move to Step 2.

Output/Decisions: Risk assessment, following 'Overview Document' methods, that can support NE determinations for specific pesticide use (crop) / taxa / exposure duration or LOC exceedences for specified pesticide use (crop) / taxa / exposure duration. For the taxa/use/exposure subset with exceedences proceed to Step 2.

STEP 2 – IDENTIFICATION OF ACTION AREA AND ANY LISTED SPECIES / HABITATS POTENTIALLY AT RISK
(Overview document: Chapter V)
Timelines:
Conventional Registration: Completed prior to Team Meeting 3
Conventional Re-registration: Completed at Team Meeting 2
BPPD: Completed by end of Phase III (Primary review)
AD:

Decision: Is there overlap between the action area and potentially affected listed species / critical habitat that could preclude a "no effect" determination? EPA will identify the action area based on the location of the sites / crops on which the pesticide may lawfully be used and the potential for off-site movement of the pesticide. Unless EPA knows the species and its habitat are outside the action area (see below), EPA will consider a listed species potentially affected if EPA reasonably concludes: 1) the species belongs to a taxa for which the ES LOC is exceeded; or 2) the species depends on a non-listed species that belongs to a taxa for which the ES LOC is exceeded. EPA will consider a critical habitat potentially affected if any of the principal constituent elements belongs to a taxa for which EPA reasonably concludes exposure exceeds the ES LOC.

Participants: The risk assessment division (AD, BPPD, or EFED); BEAD (especially for re-

registration); the regulatory division (AD, BPPD, RD, or SRRD) [Services information sources]

Information needs [source]:

- Step 1 output [OPP's ecological risk assessment from Step 1]
- potential indirect effects dependency, i.e., what effects could a pesticide have on non-listed species that could indirectly affect a listed species [Services; EFED] will access]
- potential critical habitat dependency [Services; EFED will access]
- location of species that could be potentially affected either directly or indirectly (county level or spatial scale available in electronic format) [Services, FIFRA Endangered Species Task Force (FESTF),others; EFED will access]
- location of critical habitat (county level or spatial scale available in electronic format) [Services; EFED will access]
- location of pesticide use (county level or spatial scale available in electronic format) [BEAD, USDA, registrants, others]

Process: The risk assessment division will compare information on the location of listed species and critical habitat that could be affected by the pesticide uses identified in Step 1. If the action area does not overlap with any potentially affected critical habitat or listed species, then EPA would conclude that there would be "no effect" and the ES review would be completed. If the overlap is extremely limited, geographically or temporally, then EPA would conclude that the action is not likely to adversely affect the species and the ES review would be completed.

If any potentially affected listed species or critical habitat can reasonably be expected to occur within the action area, the pesticide use(s) potentially could cause direct effects, indirect effects, and / or effects on critical habitat. In such cases, EPA could consider additional risk assessment refinements and/or risk-based mitigation measures (e.g., changes to the label accepted by the registrant), either (or both) of which might result in no exceedence of any ES LOCs. EPA would then make a "no effect" determination and the ES review would be completed. If, however, any ES LOCs are still exceeded, move to Step 3.

To the extent other divisions do not participate in the development of an assessment, the lead risk assessment division should invite staff in those divisions to participate in internal peer review meetings or similar sessions that provide an opportunity to learn about the application of the risk assessment methodology to specific chemicals.

Output/Decisions: Risk assessment, following Overview document methods, that can support "no effect" or "not likely to adversely affect" determinations for specific pesticide use (crop) / taxa / exposure duration or LOC exceedences for specified pesticide use (crop) / taxa / exposure duration with potential overlap. If a NE or NLAA determination is not possible for some species/habitat/use at this stage of the process, proceed with that subset to Step 3.

STEP 3– SPATIALLY AND TEMPORALLY EXPLICIT ASSESSMENT OF RISK TO PARTICULAR SPECIES AND HABITAT

(Overview document: Chapters V and VI)
Timelines:
Conventional Registration: Completed with Final Risk Assessment Document to RD
Conventional Re-registration: Completed at Phase 1
BPPD: Completed by end of Phase III (Primary review)
AD:

Decision: based on a refined understanding of pesticide use, pesticide toxicity, and listed species and habitat, does the pesticide appear to pose a risk to listed species (direct or indirect) or critical habitat? Outcomes could include a "no effect" (NE) or "not likely to adversely affect" (NLAA) or a "likely to adversely affect" (LAA) determination for specific species, uses, and locations.

NOTE: Because the collection and analysis of additional information during this step often will involve considerable resources, once the team has prepared its strategy for refining the risk assessment, the team should check with OPP Division management for concurrence on the investment of those resources.

Participants: The risk assessment division (AD, BPPD, or EFED); BEAD; the regulatory division (AD, BPPD, RD, or SRRD); and, in some cases, the Services (Service Representative)

Information needs: The types of information potentially used in Step 3 include categories outlined in Table 2. The breadth and depth of the information needed for a specific regulatory action will depend on the nature of the risk assessment and potential mitigation options. Collection and utilization of specific information to produce an accurate and defensible effects determination with the least investment of resources is the overall objective.

NOTE: If EPA determines that any portion of the action is LAA for a particular species, EPA will request that Services provide "environmental baseline" information about that species and OPP will include that information in its determination. Depending on the nature of the risk evaluation, including the spatial extent of the action area, EPA may also request in some cases "environmental baseline" information to make a credible determination that the action is NLAA for a listed species or critical habitat.

Process: The team members from the risk assessment division, BEAD, the regulatory division, and, in some cases, the Service Representative should jointly prepare a strategy for refining the risk assessment. This strategy should describe whether to seek additional risk mitigation measures and / or to collect and analyze additional information to refine the risk assessment. In some cases, the team may find it helpful to consult stakeholders regarding the strategy; there is, however, no expectation that there will always be a formal opportunity for public participation at this stage. This team will use their best professional judgment to determine what course is most likely to produce the most reliable and accurate risk estimate and defensible effects determination (NE, NLAA or LAA) with the least investment of resources.

To the extent other divisions do not participate in the development of an assessment, the lead risk

assessment division should invite staff in those divisions to participate in internal peer review meetings or similar sessions that provide an opportunity to learn about the application of the risk assessment methodology to specific chemicals.

Output/Decisions: A risk assessment, following Overview document methods, that can support a NE, NLAA, or LAA determination for each well defined species, location, use pattern. If an LAA determination, then proceed to Step 4.

STEP 4 – CUMULATIVE EFFECTS EVALUATIONS AND CONSULTATION PACKAGES
(Overview document: Chapter VI)
Timelines:
Conventional Registration: Decision to enter consultation prior to PRIA deadline
Conventional Re-registration: Completed by issuance of the Reregistration Eligibility Determination (RED) or Interim RED
BPPD: Completed by end of Phase IV (Secondary review)
AD:

Decision: For a pesticide use that appears to be LAA, what level of risk does it pose when cumulative effects are considered and what incidental take* is likely? Also, what risk mitigation measures (reasonable & prudent alternatives to avoid jeopardy and reasonable & prudent measures to minimize incidental take) are appropriate?

Participants: the risk assessment division (EFED, AD or BPPD) (lead), Services, and the risk management division

Information needs:

- Step 3 outputs
- status of the species at particular sites
- information on other stressors

Output/Decisions: A consultation package for the Service(s) containing, at a minimum, an ecological risk assessment, following Overview Document methods, that supports LAA determinations, including evaluation of cumulative effects. In addition, OPP may also prepare a draft biological opinion, including conclusions regarding jeopardy, incidental take, and risk mitigation measures; possible ESA sec. 7(d) determinations.

SUBSEQUENT STEPS

Following the development of an ecological risk assessment that results in an NLAA determination, EPA has an option under the counterpart regulations either to consult informally with the Services or to make the NLAA determination without further informal consultation or written concurrence from the Services. EPA will make such determinations on a case-by-case basis, but OPP intends to move as quickly as practical to making NLAA determinations without imposing further on the Services' resources. If EPA makes an LAA determination, the Agency is required

to consult formally with the appropriate Service(s). EFED initiates consultation by sending a "consultation package" to the Service(s). This consultation package will contain the information developed through Steps 1- 4, along with a cover letter summarizing EPA's effects determinations.

Because EPA is committed to transparency and public participation, EPA intends to post its cover letters and consultation packages on the EPA website for endangered species and pesticides: www.epa.gov/pesticides/endanger/effects The public will also have an opportunity to submit comments on the risk assessment and associated materials.

After reviewing EPA's consultation package, the Service will develop a draft Biological Opinion which contains the Service's conclusions regarding the effects of the pesticide on listed species and critical habitat, the need for any reasonable and prudent alternatives to avoid jeopardy, the potential for incidental take of listed species, and reasonable and prudent measures to minimize such take. EPA intends to invite stakeholder comment on the draft Biological Opinion and to provide such comments, along with comments from EPA, to the Service for their consideration in developing a final Biological Opinion.

Finally, this document outlines only the assessment process for potential risk to listed species and does not address implementation of any necessary limitations on use of a pesticide that may be necessary as a result of this risk assessment process. The process for implementing use limitations necessary for the protection of listed species or their critical habitat will be published by OPP in a Federal Register notice, no later than the spring of 2005. That notice will describe how OPP will put in place enforceable use limitations that, when followed, will provide protection of listed species and critical habitat.

Table 2. Pesticide use/site, species, and toxicity information that can be used to develop and refine problem formulation (e.g., Federal action area definition; ecosystem potentially at risk definition, etc.) and refine risk characterizations at Steps 1, 2, and/or 3.

A. Use and Site Information

Type of Information (Either reflecting current conditions or label changes)	*Source(s)*	*Potential utility of information in refined assessment*
1. Location of pesticide use (described geographically or according to certain attributes)	BEAD State agencies FESTF[5] / registrants users	With species and critical habitat location (B.1.; C.1.), this can be used to show whether there is potential co-occurrence.
2. Timing of pesticide use	BEAD State agencies FESTF / registrants users	With species and critical habitat location (B.1.; C.1.), this can be used to show whether there is potential co-occurrence.
3. Amount of pesticide used	BEAD State agencies FESTF / registrants users	Can be used to show whether there is insufficient environmental loading to pose a potential risk.
4. Actual application rates	BEAD State agencies FESTF / registrants users	With other exposure information, can be used to recalculate EECs and LOCs
5. Local hydrogeological and	EFED	With other exposure

[5] Where FESTF IMS is indicated as a source of information, this refers to the FIFRA Endangered Species Task Force (FESTF) Information Management System IMS. The FESTF is a consortium of pesticide registrants who are satisfying a data requirement for species location information through development and submission to OPP of an information management system that will take advantage of specific species location information purchased from NatureServe and based upon specific information belonging to State Heritage Programs. The FESTF IMS is a compensable data submission and can be accessed for purposes of assessing and refining potential risks to listed species, ONLY for pesticide products belonging to member companies of the FESTF consortium or who have offered compensation to the FESTF consortium for the data.

meteorological conditions		information, can be used to recalculate EECs and LOCs
6. Label modifications	Applicant / registrant and OPP regulatory division	With other exposure information, can be used to recalculate EECs and LOCs

B. Listed Species Biological Characteristics – Direct effects analyses

Type of Information	*Source(s)*	*Potential utility of information in refined assessment*
1. Location of species (described geographically or according to certain attributes)	Services EFED FESTF / registrants	With location of pesticide use (A.1.), this can be used to show whether there is potential co-occurrence.
2. Timing of species presence	Services EFED FESTF / registrants	With timing of pesticide use (A.2.), this can be used to show whether there is potential co-occurrence.
3. Location of species life stages	Services FESTF / registrants	With location and timing of pesticide use (A.1.& 2), this can be used to show whether there is potential co-occurrence.
4. Listed species demographics	Services	With toxicity data (D.1 and D.2) significance of effects from potential exposure refined

C. Biological/Ecological information for indirect and critical habitat effects

Type of Information	*Source(s)*	*Potential utility of information in refined assessment*

1. Location of designated critical habitat	Services EFED	With location of pesticide use (A.1.), this can be used to show whether there is potential co-occurrence.
2.Identification of non-listed species that are principle constituent elements (PCEs)* of a critical habitat or that, if affected, could cause indirect effects on listed species	Services EFED	Can be used to show whether the pesticide may result in effects on the particular PCE or non-listed species upon which the listed species depends (D 1.).
3. Description of status of such non-listed species	Services	If the non-listed species / PCE is relatively abundant, EPA may employ a different LOC (i.e., endangered vs. non-endangered species LOC) for assessing indirect effects (D1.)
4. Age and life-stage specific dependencies (e.g., habitat, diet)	Services	Can be used to show that the specific timing of pesticide use does not indirectly affect a species or affect critical habitat (D2.)

D. Toxicity

Type of Information	*Source(s)*	*Potential utility of information in refined assessment*
1. Selection of surrogate species	EFED	Can be used to show that listed species is better represented by a different species than by the species used in developing the taxa LOC
2. LOC by life stage	EFED	Can be used to show a different level of risk for different life stages

Glossary of ESA Terms

Action Area:
All areas to be affected directly or indirectly by a Federal action and not merely the immediate area involved in the action.

Critical Habitat:
For a listed species,

(1) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of section 4 of the Endangered Species Act (Act), on which are found those physical or biological features (constituent elements) that are essential to the conservation of the species and may require special management considerations or protection; and
(2) specific areas outside the geographical area occupied by the species as described above, which are determined by the Secretary of Commerce or Interior as essential for the conservation of the species.

Cumulative Effects: Those effects of future State, tribal, local, or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation. Future Federal actions unrelated to the proposed action are not considered as cumulative effects because they require a separate consultation. It should be noted that this definition applies only to ESA section 7 analyses and should not be confused with the broader use of the term in other environmental laws.

Environmental Baseline Information: An analysis of the effects of past and ongoing human and natural factors leading to the current status of the species, its habitat (including designated critical habitat), and ecosystem within the action area. It is a "snapshot" of a species' health at a specified point in time and does not include the effects of the action under review in the consultation.

Incidental Take: The take of listed fish or wildlife species that results from, but is not the purpose of, carrying out an otherwise lawful activity conducted by a Federal agency or applicant. The term "take" is defined by the Act to mean "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." The Act does not prohibit incidental take of listed plants.

Indirect Effects: Those effects that are caused by or will result from the proposed action and are later in time, but are still reasonably certain to occur.

Principle Constituent Elements: those biological components present in the critical habitat of a listed species that are essential for the survival and recovery of the species.

Section 7(d) Determinations: While consulting, the Federal agency, and those acting under the authority of agency permits or licenses, shall not make any irreversible or irretrievable commitment of resources with respect to the Agency action, which has the effect of foreclosing

the formulation or implementation of any reasonable and prudent alternative measures which wold not violate subsection (a)(2). This means an agency and those acting under its authority, while in the process of consultation, cannot do anything that would irreversibly limit the development and implementation of measures to protect the listed species.