DRAFT EPA Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides

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Introduction

Section 7(a)(2) of the Endangered Species Act (ESA) directs federal agencies to ensure that the actions they authorize, fund and carry out are consistent with the Act. Specifically, it requires agencies to consult with the Fish and Wildlife Service (FWS), National Marine Fisheries Service (NMFS), or both to ensure agency actions are not likely to jeopardize federally listed threatened or endangered species or destroy or adversely modify designated critical habitat of such species. The action related to pesticide registrations subject to ESA consultation may be registration or registration review of a pesticide.

Potential risks a pesticide may pose to a listed species and any designated critical habitat associated with the Agency's action are evaluated in a biological evaluation (BE) conducted by the action agency. The BE determines whether the pesticide's registration will have 'no effect' on the species or designated critical habitat or 'may affect' the species or designated critical habitat. The Services regulations provide that the consultation obligation is triggered when an agency action 'may affect' one or more listed species or designated critical habitat. May affect is not a defined term, but the Services have provided guidance suggesting it is any effect on a listed species that is reasonably certain to occur. If EPA determines the pesticide 'may affect' the species, it refines its assessment to determine whether the pesticide's use:

- "may affect, but is **not** likely to adversely affect" the species or designated critical habitat (NLAA); or
- "may affect and is likely to adversely affect" the species or designated critical habitat (LAA).

LAA determinations are made when an effect from a potential exposure that is reasonably certain to occur is adverse. This may or may not be a quantitative determination and is described in more detail in subsequent sections in this document.

Once the consultation obligation is triggered by a 'may affect' determination, agencies may engage in either formal or informal consultation. Under the Services regulations, informal consultation can be concluded if the action agency (1) finds that the action is Not Likely to Adversely Affect (NLAA) and (2) the Services concurs in writing. Otherwise, the agency must engage in formal consultation to which the Services will respond with their biological opinion addressing the likelihood of jeopardy and adverse modification and establishing what, if any, reasonable and prudent alternatives are available for engaging in the action in a manner that avoids jeopardy. If the Services find jeopardy, action agencies must use their existing authorities (*e.g.*, FIFRA) to meet the substantive requirements of the ESA.

This document describes proposed revisions to the interim methods used to conduct effects determinations as documented in EPA's BEs for federally threatened and endangered species for pesticides. This proposal is intended to describe methods that will generally be used in the evaluation of potential risks from pesticides to listed species. However, the risk assessment methods are not a regulation and, therefore, do not add, eliminate or change any existing regulatory requirements. Conclusions within a BE will be made on a case- by- case basis that reflects the properties and use patterns of each active ingredient. As such, every aspect of the proposal may not always be applicable in a biological evaluation. The risk assessment process remains an iterative process. As such, if during the course of the evaluation information indicates that aspects of this method are not appropriate and different assessment methods or assumptions are suitable, then they may be utilized as appropriate. These methods are intended to be used by EPA for making effects determinations under registration review, which will also be used to inform biological opinions from the Fish and Wildlife Service and the National Marine Fisheries Service.

Overview

Consistent with the pilot process for developing methods and conducting national-level biological evaluations (BEs), EPA has revisited the method used in the first three BEs (for chlorpyrifos, diazinon and malathion)[1] and has proposed refinements to the interim method. The revised method is summarized in this document. In revising the interim methods for the BEs, EPA considered public comments provided through stakeholder meetings and submitted to the docket for the pilot draft BEs, as well as National Research Council (NRC)[2] recommendations. In addition, EPA considered lessons learned during the development of the first three BEs. The objective of the proposed revised method is to produce both a sustainable and scientifically defensible risk assessment process to prepare BEs. This method is designed to identify species that may be affected by the subject pesticide and whether they are likely to be adversely affected. This method is consistent with the requirements of the ESA and its implementing regulations, in a manner that remains consistent with the NRC recommendations, while being responsive to regulatory mandates and public input and that will result in protections for those species.

As recommended by the NRC, the interim methods that were developed by EPA and the Services involve a three-step consultation process to evaluate the potential risk to Federally-listed threatened and endangered (listed) species[3] (see **Figure 1**) under Section 7 of the Endangered Species Act. Steps 1 and 2 are represented by the BE, which evaluates whether an individual of a listed species is reasonably expected to be exposed to a pesticide, and, if so, distinguishes effects that are likely to adversely affect (LAA) an individual of a species from those that are not likely to adversely affect (NLAA) an individual. Effects that result in a LAA determination are those that are measurable or observable, and likely to occur. Steps 1 and 2 are focused on assessing risks to an **individual** of a listed species. Therefore, the spatial scale of Steps 1 and 2 is relevant to an individual, which is considered the field level, including the site of application and the potential areas around the application sites where effects may occur (**Table 1**). Because Step 2 also considers a distribution of exposures among individuals of a population, the landscape scale is also relevant to Step 2. For the first three pilot assessments, a field scale assessment was conducted without much consideration of the likelihood or extent of exposure occurring or the potential variability and uncertainty in the underlying data used in the assessment. The proposed advancements to the interim method attempt to consider systematically these factors in a meaningful way in Steps 1 and 2 of the consultation process.

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[1] Copies of the first three biological evaluations (chlorpyrifos, diazinon and malathion) can be found at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and

[2] National Research Council of the National Academies (NRC) (2013). Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press. Washington, DC. Pp. 175.

[3] These assessments will also consider those species that are currently proposed or candidates for listing.

Step 3 is the "biological opinion", which determines whether an adverse effect will jeopardize the continued existence of a species or destroy or adversely modify its designated critical habitat. The scale is no longer at an individual level and is focused on assessing risks to the species' **population** that is listed as endangered or threatened. The scale of Step 3 is the landscape that represents the range of a listed species (also considered in Step 2). The BE informs the Services' biological opinion. For listed species of which a pesticide is LAA for at least one individual, this analysis is structured to inform the biological opinion, with appropriate modifications to account for population-level, landscape-scale assessments. Since this document pertains to the BE, the approach presented here describes the processes for conducting Steps 1 and 2; therefore, additional descriptions of Steps 1 and 2 are included below.

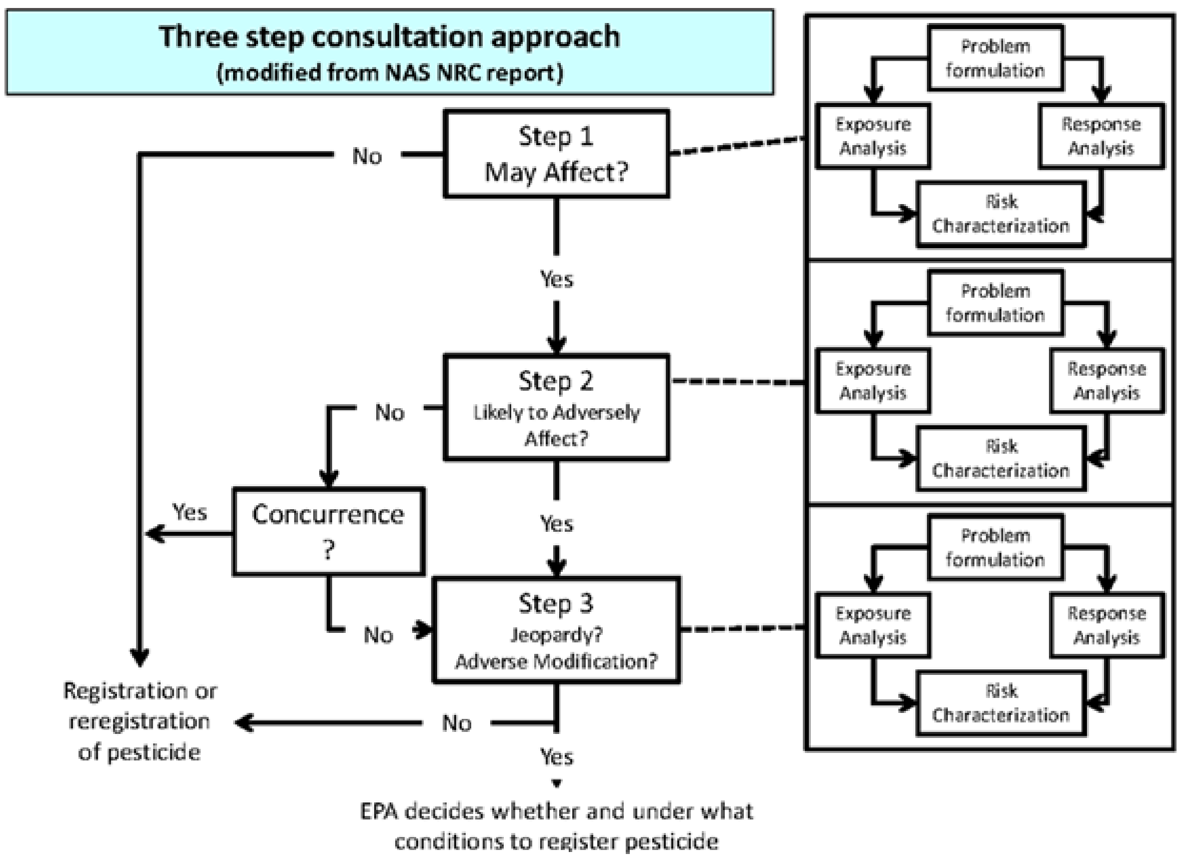

Figure 1. Three Step Section 7 Endangered Species Act Consultation Approach Based on a Figure in the National Academies of Science National Resource Council (2013) Report[4].

[4] National Research Council. 2013. *Assessing Risks to Endangered and Threatened Species from Pesticides*. Washington, DC: The National Academies Press. https://doi.org/10.17226/18344

Table 1. Overview of the 3-Step Section 7 Endangered Species Act Consultation Process

TOPIC	STEP 1	STEP 2	STEP 3
Assessment	Biological Evaluation	Biological Evaluation	Biological Opinion
Scale[1]	Individual/field	Individual/field and landscape	Population/landscape/watershed
Determination	No Effect/May Affect	Not Likely to Adversely Affect/Likely to Adversely Affect	No Jeopardy/ Jeopardy[2]

[1] Although Step 1 and Step 2 are conducted at an individual level, consideration is given to the likelihood that exposure is reasonably certain to occur in Step 1 and the potential consequence of that exposure in the effects determination in Step 2.
[2] This is the determination for listed species. The determination for designated critical habitats is "No Adverse Modification/Adverse Modification".

Step 1 identifies which species and designated critical habitats are reasonably expected to be affected by the proposed action at the individual-level (warranting a "may affect" determination), and which species would not be affected by the proposed action (warranting a "no effect" determination). Any species and/or designated critical habitat that warrants a "no effect" determination is not considered further. Any species and/or critical habitat that warrants a "may affect" determination in Step 1 continues to Step 2 for further analysis.

Step 2 determines whether use of the assessed pesticide is either "not likely to adversely affect" (NLAA) or "likely to adversely affect" (LAA) a single individual of a listed species or designated critical habitat. A NLAA determination can be made if the assessment finds that the effects of a pesticide on an individual of a listed species is "insignificant," "discountable," or "wholly beneficial."[5] These terms are defined by the Services as follows:

- Insignificant = based on best judgement, a person would not be able to meaningfully measure, detect, or evaluate insignificant effects. Insignificant effects should never reach the level where take[6] occurs.
- Discountable = those effects that are extremely unlikely to occur. Based on best judgement a person would not expect discountable effects to occur.
- Beneficial = are contemporaneous positive effects without any adverse effects (even short term) to the species.

Based on these definitions, EPA concludes whether adverse effects on a single individual of a listed species in the context of an effects determination are measurable, observable, and likely to occur. The likely to adversely affect finding is an EPA determination that it is reasonable to conclude, based on the weight of the evidence, that an individual is likely to be adversely affected. This may or may not be a quantitative determination. The EPA determination requires concurrence from the Services.

In cases where a species determination is LAA, a Step 3 (population level, landscape scale) analysis is conducted by the Services. When an analysis leads to an NLAA determination with the Services' concurrence, no additional analysis is conducted for a species. Steps 1 and 2 are described in greater detail in the following sections.

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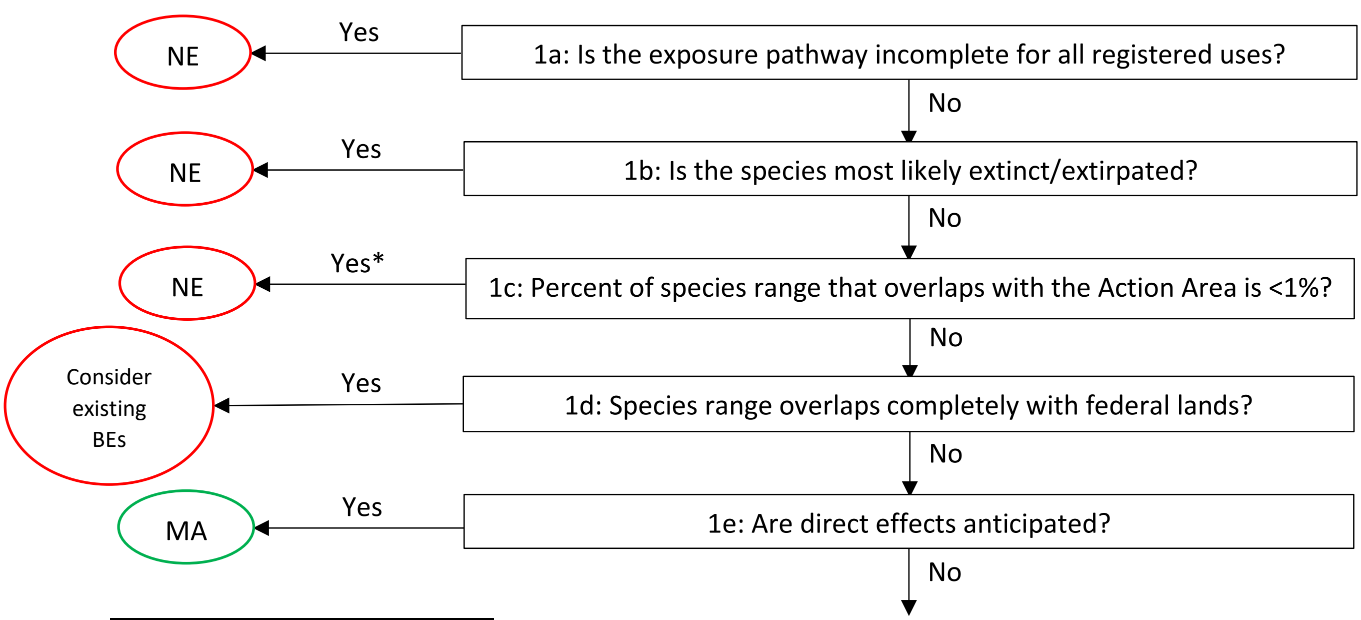
[5] Based on the Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities under Section 7 of the Endangered Species Act (FWS and NMFS, 1998).
[6] From Section 3(18) of the Federal Endangered Species Act: "The term 'take' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." (https://www.fws.gov/midwest/endangered/glossary/index.html)

Each of the three steps of the process includes four components: problem formulation, effects characterization, exposure analysis and risk characterization (**Figure 1**). This is based on the guidelines for ecological risk assessment (EPA 1998[7]). Although each step in the process has a similar framework and relies largely upon a common data set, those data are used in a different manner in each step. Step 1 is intended to be a conservative screen that is heavily reliant upon overlap of areas of effect (based on where the chemical being assessed is likely to be used) with species range/critical habitat. It uses conservative assumptions and is intended to screen out species that are not reasonably expected to be exposed and are, therefore, not of concern for the assessed pesticide. Step 2 uses a more refined spatial-overlap with specific chemical use sites that considers life history information and detailed toxicity data and potential exposure concentrations. Step 2 is intended to identify those species for which it is likely that an individual will be adversely impacted. The method of Step 2 is designed to screen out those species where impacts to an individual are not measurable, observable, or likely to occur. This allows for a more focused list of species that will be carried forward to the more resource-intensive analysis carried out in Step 3. The assessment processes proposed for use in the BEs for each step are described below.

Step 1 – Proposed Method to Differentiate May Affect (MA) from No Effect (NE) Determinations

This section provides details on how Step 1 is proposed to be conducted. **Figure 2** depicts the decision tree that represents the Step 1 method, by which species determinations are either "no effect" (NE) or "may affect" (MA). This process is carried out one species at a time for each pesticide. The same process is carried out for the designated critical habitat. Details on each part (1a-1f) of Step 1 are provided below.



[7] USEPA. 1998. Guidelines for ecological risk assessment. United States Environmental Protection Agency, Risk Assessment Forum. EPA/630/R-95/002F.

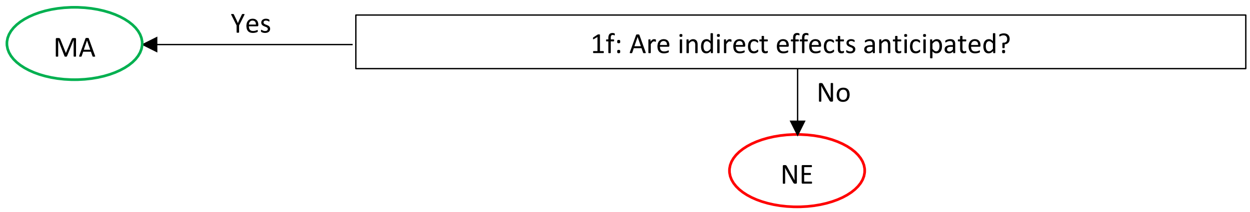


Figure 2. Step 1 proposed decision framework for making No Effect (NE) and May Affect (MA) determinations. Species with NE determination do not require additional analysis (red ovals indicate stop). Species with MA determinations proceed to Step 2 (green ovals indicate proceed).
***NE determinations are made if any qualitative analysis (relevant to species) is not expected to substantially increase the overlap of use sites with species range. The resolution of the available spatial data does not allow for quantification of overlaps <1% (see 1c for details).**

1a: Is the exposure pathway incomplete for all registered uses? In Step 1a, the assessor considers whether the pathway to pesticide exposure is complete. This may consider species characteristics and uses of the chemical. Examples of species characteristics that would result in an incomplete exposure pathway (where applications and/or exposures are unlikely to occur) include: species found only on uninhabited islands and species with habitats that are inconsistent with pesticide exposure. Additionally, uses with incomplete exposure pathways (*e.g.*, indoor uses; termiticide bait stations; *etc*.) are not included in the Action Area for the assessed pesticide. An NE determination is made for species for which all exposure pathways are incomplete, based on considerations of species traits and/or registered pesticide use patterns.

1b: Is the species most likely extinct or extirpated? For species that are still listed but are most likely extinct or extirpated from the United States, NE determinations are made. NE calls are made for these species, as exposure from the action is not reasonably certain to occur, and, therefore, no effects on the species are anticipated. A species is considered most likely extinct or extirpated if it:

- is presumed by the Services to be extinct,
- no longer occurs in the US,
- has not been observed for decades in the US, or
- exists only in captivity and has no designated critical habitat.

Whether or not a species is most likely extinct or extirpated is based on available information provided by the Services (*e.g.*, 5-year review). Once a species is identified as being "most likely extinct" or "most likely extirpated", a NE determination will be made for that species for future pesticides assessed. This list will be periodically updated as new information becomes available.

1c: Percent of species range that overlaps with the Action Area is <1%? For the remaining species (that are not NE from parts a and b), an overlap analysis is conducted to determine the percent overlap of the species range/designated critical habitat with the spatially defined Action Area[8] (**Figure 3**). The Action Area is defined as "all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action." For pesticide use and applications, this is the composite of all the areas where the chemical may possibly be used, based on the best available data, and associated areas of potential effects. The spatially defined Action Area is a depiction of pesticide use

[8] The spatially defined Action Area is composed of landcovers that can be spatially mapped and reliably represent potential use sites that are on registered labels. These landcovers are from the best available data.

sites (based on the registered labels and usage data) that can be mapped spatially in the US and its territories, as well as the areas that potentially receive off-site transport at exposure levels that are of toxicological concern (based on conservative exposure assumptions). Note that throughout this document when reference is made to “direct effects” or “indirect effects”, the term “direct effects” refers to toxic effects of a chemical on an individual of the assessed listed species and the term “indirect effects” refers to impacts to the prey and/or habitat upon which listed species rely. These terms do not refer to the regulatory definitions of the terms under ESA, which describe the direct and indirect effect of the action.

Additional details are provided below on the relevant components of the Action Area (*i.e.,* the potential use sites, application of usage data and calculation of off-site transport areas of concern). Also discussed below is the source of the species range data.

Figure 3 is a simplification as, for many species, the overlap of range and Action Area will occur in different areas and may not overlap in time. The overlap may take the form of several disconnected areas, likely representing several different fields and off-site transport areas. The fields and surrounding areas of effect will likely differ in size and shape.

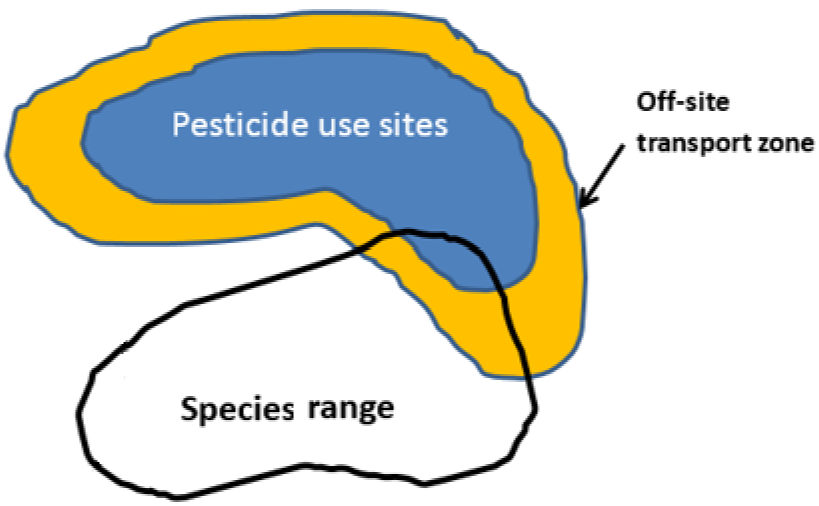


Figure 3. Listed Species Range and Action Area (*i.e.*, Pesticide Use Site Plus Off-site Transport Zone) Overlap

Species range

The species range used in the overlap analyses are provided by the Services. As these spatial data layers are expected to change over time, the date on which the files were received from the Services will be referenced as part of the spatial analyses. When a critical habitat has been designated for a listed species, the spatial file for the designated critical habitat will also be used to make the determination for the critical habitat.

Identifying pesticide use sites

Pesticide use sites are defined using two types of data. The first type are spatial data representing potential use sites matched to uses defined on registered labels for the assessed pesticide. The second type are usage data based on documented recent past applications of the assessed pesticide. These two types of data are further discussed below.

Note that this section relies on two distinct terms: pesticide "use" and "usage." Use data are based on registered labels and define crops or non-crop uses to which a pesticide may be applied, along with the maximum application rates, method (*e.g.,* aerial or ground spray), intervals and numbers of applications that may occur according to the labels. Usage data describe documented applications of a pesticide, including information such as actual application rates and timing, and spatial distribution of applications (usually based on survey data). The key difference between use and usage is potential applications vs. actual applications.

Potential use sites

Spatial data for locations of potential use sites are obtained from numerous sources, with different sources providing data from different uses and locations. Agricultural crop uses in the 48 conterminous states are represented by an aggregated dataset based on the Cropland Data Layer (CDL), produced by the United States Department of Agriculture (USDA)[9]. The CDL is a land cover dataset that has over 100 cultivated crop classes. The spatial layer is interpreted from satellite imagery, which can be difficult to interpret. Therefore, the Agency groups the individual CDL layers into 13 categories,[10] referred to as Use Data Layers (UDLs), to improve the accuracy of the data and to help ensure that agricultural fields that are mis-identified with respect to the crop being grown are captured in the aggregated spatial layer. These grouped CDL layers are referred to as UDLs (use data layers). In this approach, high confidence crops (*e.g.,* corn, wheat) are represented individually, while lower-confidence crops (*e.g.,* onions, tomatoes) are grouped in order to increase the confidence that the landcover represents the intended crops (*e.g.,* vegetable and ground fruits). The agricultural classes are further refined by comparing county level National Agricultural Statistics Service (NASS) Census of Agriculture (CoA) acreage reports to county level CDL acreages, and layers are adjusted to meet or exceed the acres reported in the Census of Agriculture. This approach results in an overestimate of where a crop is likely to be found for a given year due to common agricultural practices such as crop rotation and the aggregating of individual CDLs. This is discussed further below.

Non-crop label uses (*e.g*., nurseries) include a wide range of land cover and land use categories depending on the specific use to be spatially represented. Each label use is considered and represented by the best available land cover data. Initially, the National Land Cover Dataset (NLCD)[11] is considered to

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[9] USDA National Agricultural Statistics Service Cropland Data Layer. 2013-2017. Published crop-specific data layer [Online]. Available at https://www.nass.usda.gov/Research_and_Science/Cropland/SARS1a.php (accessed 3/2018; verified 3/2019). USDA-NASS, Washington, DC.

[10] Categories include: corn, cotton, rice, soybeans, wheat, vegetables and ground fruit, other grains, other row crops, other crops, pasture/hay, citrus, vineyards and other orchards.

[11] Homer, C.G., Dewitz, J.A., Yang, L., Jin, S., Danielson, P., Xian, G., Coulston, J., Herold, N.D., Wickham, J.D., and Megown, K., 2015, Completion of the 2011 National Land Cover Database for the conterminous United States-Representing a decade of land cover change information. Photogrammetric Engineering and Remote Sensing, v. 81, no. 5, p. 345-354

represent non-crop label uses. When the NLCD is inadequate, other data sources are used as appropriate.

Often there are uses for which reliable data are not available to map the locations of the use sites. For example, a fly bait spread around enclosed dumpsters would not have a specific landcover class and would need to be mapped using a larger class (such as the "Developed" landcover class) which would significantly overestimate potential use sites. For these types of uses, for which one cannot reliably define the spatial footprint of use, but complete exposure pathways are expected to occur for an individual of a listed species, a qualitative spatial analysis will be carried out. For the fly bait example, the spatial extent of the fly bait use would need to be evaluated in the context of the other labeled uses that were assessed quantitatively (*i.e*., whether the use area is already accounted for by uses quantitatively assessed).

Pesticide usage data

Usage data specify the location and magnitude of applications of a given pesticide. These data are pesticide specific and vary by use site and by scale (*e.g.,* state, national level). Agricultural crop usage data are summarized at the state level. EPA uses best available pesticide usage data from public (*e.g.,* USDA, California Pesticide Use Reporting) and proprietary sources (Agricultural Market Research Data) and provides this data in a document called the National and State Summary Use and Usage Memo (SUUM). Prior to incorporation into the biological evaluations, EPA evaluates the quality and relevance of usage data by assessing numerous variables to determine applicability, utility and soundness of the data. One criticism we have received on the utility of the usage data is that it does not necessarily predict future use. EPA's method for forecasting relies upon the most recent usage data (generally the last 5 years of available data) and uses those data to make regulatory decisions. The most recent 5 years of data are still considered representative of current labeled uses.

In Step 1, the potential agricultural crop use sites are mapped, as described above, using the 13 agricultural UDLs. All relevant agricultural UDLs are identified based on labeled uses. Two data sources, the NASS Census of Agriculture and the SUUM, are used to remove areas from the agricultural UDLs prior to combining all potential use sites, both agricultural crop and the non-crop, into the Action Areas to generate the initial footprint.

1. The NASS Census of Agriculture is used to identify registered crops based on labeled uses that are grown at a county level. If all labeled uses within a UDL are not grown in a county according to the NASS Census of Agriculture, then the county is removed from the UDL.
2. Based on the SUUM, if a state reported no usage (surveyed but no documented usage) for all labeled uses in a UDL, the state is removed from the UDL.

In this approach, areas that have either not grown **any** of the labeled crop uses or that have not reported usage for **any** of the currently labeled uses are not considered to meet the standard that the effect of the action is reasonably expected to occur in those areas.

Not all agricultural crop uses are surveyed. In addition, the same crops are not surveyed in all states. Thus, past usage data for the assessed chemical are not available for some crop-state combinations. In these cases where there are no survey data, the potential use site corresponding to the appropriate landcover category will remain in the pesticide use area footprint for the Step 1 analysis.

The approach applied for non-crop uses cannot necessarily be applied in the same manner as described previously for agricultural crop uses due to differences in available landcover and usage data. Examples of non-crop uses include residential areas (*e.g.,* applications to turf), nurseries (*i.e.,* ornamental applications), and forestry. For non-crop areas, usage data are available at different scales (*e.g.,* state, region or nation). Therefore, when usage data are available for a registered non-crop use, modifications may not be able to be made to the potential use site footprint unless usage at a national level is ***de minimis*** (*i.e.,* very unlikely to occur) or if sufficient surveyed data are available that indicate no usage for a given use occurs in the US. In that case, the UDL representing the entire use could be removed from the pesticide use site footprint. There may also be some non-crop uses where data become available to allow EPA to identify areas where a particular pesticide or labeled use is or is not reasonably expected to occur.

After removing areas from the agricultural crop and non-crop UDLs using the above process, all UDLs are combined into the Action Area. The Action Area is buffered for drift based on the process described in the next section, off-site transport zone.

Off-site transport zone

Toxicity thresholds and spray drift transport are used to determine how far effects might extend from the edge of a use site. The process for selecting these thresholds is described below.

In areas of overlap of the Action Area and the species range, we assume that taxa upon which a listed species is dependent are also exposed. Taxa representing potential indirect effects endpoints will be selected based on life histories of a given listed species (*e.g.*, declines in invertebrate prey will be used to assess indirect effects to insectivores). The endpoint that results in the farthest distance from the treated field where any direct or indirect effect may occur relative to a specific species will be used to determine the Action Area for that species. This distance is capped at 2600 feet (the aerial limit of the AgDRIFT model; current version 2.1.1, December 2011). AgDRIFT is an empirical model based on deposition studies that were conducted in the 1990s and upper-level drift estimates for aerial applications derived from the AGDISP model[12]. EPA believes that spray drift deposition estimates of AgDRIFT are conservative and the limits of the model are protective in considering downwind deposition. While deposition beyond the limits of the models can occur under extreme circumstances, estimation of deposition should be limited to the extent of the model because the AgDRIFT model is a regression of interpolated values and going outside the bounds of that interpolation is uncertain. Species with less than 1% overlap of direct use and drift (discussed further below) based on the most sensitive relevant taxon will generally be an NE. The "less than 1% overlap" approach is discussed in a following next section.

Standard EPA models will be used to calculate off site exposure concentrations. Measures of pesticide exposure to aquatic animals and plants in surface water are simulated with the Pesticide in Water Calculator (PWC, current version 1.52, February 2016[13]), which generates estimated environmental concentrations (EECs) that may occur from various uses, typically at maximum use rates allowed on the label. AgDRIFT is used to assess exposures of terrestrial plants to pesticide deposited in terrestrial

[12] Teske, M., Bird, S., Ray, S. , Esterly, D., Perry, S. 2003. A User's Guide for AgDRIFT® 2.0.07: A Tiered Approach for the Assessment of Spray Drift of Pesticides, Regulatory Version. CDI Report No. 01-02. February 2003.
[13] USEPA. 2016. Pesticide in Water Calculator User Manual for Versions 1.50 and 1.52. February 25, 2016. https://www.epa.gov/sites/production/files/2016-05/documents/pwc_user_manual_v1_50and1_52.pdf

habitats by spray drift, simulating aerial and ground application, as well as spray blast applications to orchard crops. AgDRIFT is also used to estimate the amount of drift of pesticide into adjacent waterbodies. This area is represented by the farthest distance from a treated field based on the direct and indirect effects endpoints included in **Table 2**.

For broadcast applications that occur for non-crop uses, AgDRIFT and PWC will also be used to estimate off site transport due to runoff and spray drift. For non-crop uses that do not involve broadcast applications (*e.g.*, granular applications via a shaker can, spot applications via a spray wand), spray drift will not be assessed, as the amount of pesticide being transported off site due to spray drift is considered *de minimis* and the AgDRIFT model is not designed to assess such applications.

While downstream transport of a pesticide release into surface waters can occur, EPA does not currently have a tool to accurately account for the advection, dispersion, and dilution expected to occur as the pesticide mass moves downstream. The first three BEs did assess downstream effects by employing a screening approach, implemented using the Downstream Dilution tool; however, the tool was considered provisional [*i.e.,* it has not been fully vetted (it has not been made available to the public) or validated], and overly conservative (*i.e.*, EPA used Bin 2 EECs as a starting point and assumed that, as the concentrated mass of pesticide moved down the stream, there was no dissipation or dispersion of the concentration, unless the next watershed had no use in it). For more information on the downstream dilution methodology, consult Appendix 3-5 of the diazinon BE[14]. Where use patterns are extensive, and thus would occur in a large area, the impacts of downstream transport are not expected to significantly affect the removal of a species from consideration during Steps 1 and 2 of the BE and would only result in additional resources being used. In place of the Downstream Dilution tool, EPA will qualitatively evaluate the potential for downstream impacts to aquatic species in the medium and high-flowing bins located in areas that have been removed from consideration during Steps 1 and 2 based solely on usage data, as pesticide may be transported from upstream states where usage occurs to states where there is no usage.

Toxicity thresholds

The toxicity values, or thresholds, will be based on those available from studies classified as Acceptable or Supplemental (Quantitative) submitted to the EPA by registrants or from similarly classified open literature studies identified through the ECOTOX[15,16] database. Toxicity data used in the Step 1 and 2 analyses will be based on apical endpoints (*i.e.*, survival, growth or reproduction) or other sublethal effects that can be quantitatively linked to apical endpoints. EPA is using toxicity endpoints quantifying effects to survival and reproduction of listed species. Because of the well-understood general links between the effects of decreased growth on reproduction and survival, EPA believes that growth is an important sublethal endpoint to consider under this framework. The reproductive and growth effects that will be considered in the BE are the same as those required in EPA's ecological effects test guidelines. The endpoints are broad and include, but are not limited to, the following: individual parental and offspring growth, rate of maturation, embryo/egg production, embryo viability, egg

[14] Available online at: https://www3.epa.gov/pesticides/nas/final/diazinon/appendix-3-5.docx
[15] For additional information on ECOTOX see: https://cfpub.epa.gov/ecotox/
[16] For information on how open literature studies are evaluated and classified, see: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open

abnormalities, time to hatch, time to swim-up, pathological and histological observations, lactation performance, and development of secondary sexual characteristics. Additional sublethal effects will be considered if they can be quantitatively linked to survival, growth or reproduction. This approach is different from what was done in the Interim method for the first three BEs; however, the revised approach is consistent with the recommendations of the NRC, which stated:

> *"An adverse effect should be defined by the degree to which an organism's survival or reproduction is affected; thus, assessing the effects of a pesticide on a listed species requires quantifying the effect of the pesticide on survival and reproduction of the species in the wild." [p. 132]*

EPA will not be excluding information on other sublethal endpoints (*e.g.*, changes to behavior or enzyme levels). All endpoints related to survival and all sublethal effects from studies that pass the ECOTOX screen will be provided in the BEs as an appendix and will be available to the Services for consideration. However, due to the reasons discussed above, sublethal effects beyond reproductive and growth effects that are not quantitatively tied to survival and fecundity will not be considered in the BE analyses.

For direct effects to an individual of a listed species, the mortality threshold is used to determine the Step 1 spray drift distance, calculated as the concentration/dose that represents death to 1 out of the population (*i.e*., the concentration likely to result in the death of at least one individual in the population). For Step 1, the "no effect" threshold for sublethal effects in animals and plants will be based on the lowest no-observed adverse effect concentration or level (NOAEC/NOAEL) for growth or reproduction with a corresponding LOAEC available for the taxon being assessed. **Table 2** summarizes the toxicity endpoints used for assessing direct effects in Step 1, as well as Step 2 (the latter is discussed below). The spray drift distance for Step 1 is based on the more sensitive endpoint of the mortality or sublethal threshold. The mortality threshold for listed animals will be the concentration that results in at least one predicted death based on: 1) the LD_{50}/LC_{50} that corresponds to the lower fifth percentile of a species sensitivity distribution (SSD; if available) or the most sensitive LD_{50}/LC_{50} value available for the taxon being assessed; 2) the slope of the dose-response curve (if a slope is not available, the standard default slope of 4.5 will be used); and 3) the population size of the species being assessed (if the population size is not known, a conservative estimate of the population will be made based on available data). EPA has developed this method to be consistent with the ESA Section 7 regulations that task action agencies with considering impacts of their actions on an individual of a listed species. In this approach, if there are two species and all things are equal (*e.g.*, percent of population exposed, magnitude of mortality among exposed individuals), except their population sizes, the smaller population would have fewer individuals impacted than the species with a larger population.

When considering indirect effects for listed species that rely on animals (*e.g*., as prey or pollinators), effects will be focused on mortality endpoints for the taxa relied upon. For generalists, the endpoints will be based on the LD_{50}/LC_{50} that corresponds to the lower fifth percentile of an SSD (if available) or the most sensitive LD_{50}/LC_{50} value available for the animal taxa relied upon (using the most sensitive taxon). The specific threshold for potential indirect effects for generalist species that rely on animals is set at one-half (0.5) of the mortality endpoint concentration (*i.e*., there is a potential for indirect effects when the ratio of the estimated concentration/mortality endpoint ≥ 0.5). This ratio is the same level of concern for animal mortality used by EPA to conduct pesticide risk assessments under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For listed species that are obligates with an animal species (*i.e.*, they cannot survive and/or complete their life-cycle without the obligate species), similar endpoints are used for determining the potential for indirect effects; however more conservative thresholds are used (to decrease the chance of failing to detect an effect that may be present). In the case of obligates, the species threshold for potential indirect effects for obligate species that rely on animals is set at one-tenth (0.1) of the mortality endpoint concentration (*i.e.*, there is a potential for indirect effects when the ratio of the estimated concentration/mortality endpoint ≥0.1).

Indirect effects to a listed species depending upon plants (*e.g.*, for diet, habitat) is focused on growth. For habitat and plants eaten as dietary items, for generalists, the indirect threshold will be based on the most sensitive EC_{50} value for aquatic plants and the EC_{25} value for terrestrial plants. In this approach, it is assumed that a 50% decline in biomass of the most sensitive tested aquatic species and a 25% decline in the most sensitive terrestrial species would constitute an effect that is meaningful to the survival, growth or reproduction of a listed species. Again, these are the same levels of concern used by EPA in FIFRA pesticide risk assessments and is meant to be protective. Based on standard evaluation procedures (SEP) developed by EPA in 1986[17,18] for aquatic plants and terrestrial plants, a 50% change in plant growth or injury and a 25% detrimental effect, respectively, are the points at which plants will not recover to their full aesthetic value, economic value, or reproductive potential, as in the case of the maintenance of endangered or threatened species. It is notable that this threshold is only applied to a generalist species and is still based on the most sensitive endpoint of the tested terrestrial or aquatic plant. For obligates, similar to the direct endpoints for listed species, the NOAEC associated with the lowest LOAEC will be used to address the potential for indirect effects. As discussed above, a more sensitive endpoint is chosen for obligate relationships to decrease the likelihood for failing to detect an effect. **Table 2** summarizes the toxicity endpoints used for assessing indirect effects in Step 1.

Reduced animal testing is a priority for EPA. Scientific advancements exist and are being developed that allow for better predictions of potential hazards for risk assessment purposes without the use of traditional methods that rely on animal testing. EPA is aggressively pursuing these new approach methodologies. As the methodologies mature, endpoints from studies using non-animal test methods that are scientifically sound, fit for purpose in risk assessment, and represent toxicological thresholds on apical endpoints will be incorporated into the BE process.

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[17] Hazard Evaluation Division, Standard Evaluation Procedure, Non-Target Plants. USEPA. Office of Pesticide Programs. June 1986

[18] Hazard Evaluation Division, Standard Evaluation Procedure, Non-Target Plants: Growth and Reproduction of Aquatic Plants…", OPP, June 1986

Table 2. Description of toxicity endpoints used for Step 1 and 2 analyses.

Taxon	Exposure route(s)	Units of toxicity endpoints	Direct Effects (to taxon)		Indirect Effects (listed species relies upon taxon)	
			Mortality	**Growth/Reproduction**	**Obligate relationship**	**General**
Birds*	Diet Dermal Inhalation Drinking water	mg a.i./kg-bw mg a.i./kg-food lb a.i./A	Lowest available LD$_{50}$/LC$_{50}$ or 5th percentile LD$_{50}$/LC$_{50}$ from SSD (if available)	Step 1: NOAEC from lowest LOAEC Step 2: Geomean of the Lowest quantitative NOAEC and LOAEC	Lowest available LD$_{50}$/LC$_{50}$ or 5th percentile LD$_{50}$/LC$_{50}$ from SSD (if available)	Lowest available LD$_{50}$/LC$_{50}$ or 5th percentile LD$_{50}$/LC$_{50}$ from SSD (if available)
Mammals	Diet Dermal Inhalation Drinking water	mg a.i./kg-bw mg a.i./kg-food lb a.i./A				
Fish**	Respiration contact	µg a.i./L				
Aquatic invertebrates	Respiration contact	µg a.i./L				
Terrestrial invertebrates	Diet Contact	µg a.i./individual µg a.i./g-diet mg a.i./kg-bw mg a.i./kg-soil lb a.i./A				
Aquatic plants – non-vascular	Contact	µg a.i./L	Not applicable	Not applicable (no listed species)	Step 1: NOAEC from lowest LOAEC Step 2: Geomean of the Lowest quantitative NOAEC and LOAEC	Lowest quantitative EC50
Aquatic plants - vascular	Contact	µg a.i./L	Not applicable	Step 1: NOAEC from lowest LOAEC Step 2: Geomean of the Lowest quantitative NOAEC and LOAEC		
Terrestrial plants – monocots	Contact (seedling emergence)	lb a.i./A	Not applicable			Lowest quantitative EC25
Terrestrial plants - dicots	Contact (seedling emergence)	lb a.i./A	Not applicable			

*Same endpoints used to represent terrestrial phase amphibians and reptiles, unless taxon-specific data are available.

**Same endpoints used to represent aquatic phase amphibians, unless taxon-specific data are available.

Use of <1% Overlap for NE determinations

For Step 1, the overlap analysis is completed for all species range/designated critical habitat and the Action Area including the potential areas of effect (using ArcGIS current version 10.3.1). The result of this analysis is the percent of the species range/designated critical habitat that overlaps with the spatially defined Action Area and is referred to as percent overlap. In this calculation, the denominator is the area of the species range/critical habitat and the numerator is the area of overlap. The effects determination for any listed species or designated critical habitat whose range overlaps <1% with the area of effects, after considering the quantitative and qualitative (those not quantitatively defined in the Action Area) analyses, will be an NE determination.

The cutoff of 1% is based on the precision of the available data. As recommended by the NRC, the spatial analysis leverages authoritative geospatial data to increase accuracy and reliability. Authoritative data was defined by the NRC as,

> *"…geospatial data on any scale need to meet three criteria: availability from a widely recognized and respected source, public availability, and inclusion of metadata that are consistent with the standards of the National Spatial Data Infrastructure (NSDI)—a federal interagency program [Federal Geospatial Data Committee (FGDC)] to organize and share spatial data and to ensure their accuracy [page 10]."*

Even when relying on authoritative data sources there are limitations with GIS data. There are three areas of the method impacted by these limitations: the species location files provided by the Services, the Use Data Layers (UDLs), and the overlap analysis or quantitative spatial analysis conducted to combine the species locations information with the UDLs. The accuracies of the available spatial data need to be accounted for in evaluating the results of the overlap analysis. In this analysis, the 1% cutoff is based on the level of accuracy of the UDLs, and includes conservative assumptions related to the Action Area and drift. Additional details are provided below.

Species location files: At this time, the "best available species location information" is represented by the files provided to EPA by the Services. The 1% cutoff is applied to the overlap based on the full extent of the range; range files are not altered. There is no accuracy assessment available of the species location files, as recommended in National Spatial Data Infrastructure provided by the Federal Geospatial Data Committee (FGDC). The lack of an accuracy assessment introduces uncertainty related to reporting accuracy of a spatial analysis, which should be based on the lowest level of accuracy among the datasets used.

Use Data layers (UDLs): The primary spatial data source for the agricultural layers is the Cropland Data Layers (CDL), which meets the NRC report definition of authoritative data as previously described. To address some of the uncertainty inherent to the CDL, individual crops are combined into 13 general crop categories or Use Data Layers (UDL), temporally aggregated across multiple years, and then expanded to meet or exceed the area reported in the Census of Agriculture. These final UDLs represent anywhere the crop could be found. However, this is an overestimate of where a crop is likely to be found for a given year due to common agricultural practices such as crop rotation and the aggregating of individual CDLs to form UDLs. For non-agricultural uses, a number of data sources were used, leveraging national level GIS data with accuracy assessments when available. All agricultural and non-agricultural UDLs are combined into a composite layer to generate the Action Area. The Action Area is buffered to represent the drift footprint in all directions. The 1% cutoff is applied only to the Action Area and includes drift in all directions. The conservatism of the UDLs, Action Area, and drift assumptions, likely lead to high estimates of overlap reducing the risk that a species will drop below the 1% overlap cut-off only because it is artificially large, *e.g.* county range files.

Overlap analysis: The third area impacted is the quantitative overlap analysis, or the analysis performed to combine species location and UDLs. The result of this analysis is the percent of the species range/designated critical habitat that overlaps with the spatially defined Action Area or UDL and is referred to as percent overlap. In this calculation, the denominator is the area of the species range/critical habitat and the numerator is the area of overlap. When conducting this type of quantitative spatial analysis, it is important to consider the limits of the GIS data used in the analysis, so the results do not represent accuracy and precision beyond the limits of the data. Calculating the total area of the species range is only one part of the overlap equation.

Of the two data sources included in the overlap (range data and CDL data), an accuracy assessment has only been completed for the CDL, which followed the guidance on accuracy and precision of GIS data outlined by the FGDC to assign the limits of the data. The CDL meets the standards for a 60-meter accuracy to no decimal places (*e.g.,* not to 60.0 meters). This accuracy value directs the number of appropriate decimal places to report when conducting a quantitative spatial analysis. In this case, based on the 60-meter accuracy, reporting overlap below whole numbers, or 1% overlap after rounding, would be beyond the limits or exactness of the data. To report results down to multiple decimal places, the accuracy of the underlying data would also need be accurate to a fraction of meter.

Use of 1% as a cutoff is conservative given the assumptions related to the Action Area and drift discussed previously that lead to an overestimate of potential use areas. Also, because the FGDC recommends reporting accuracy based on the least accurate dataset, in cases where species ranges may be more accurate, 1% would still apply. However, in cases where species range data are at a county level or other coarse scale, the accuracy of the overlap analysis would be lower (*i.e.,* an appropriate cutoff may be >1%).

Therefore, any overlap <1% is not considered reliable. Cases where overlap is <1% when considering all the spatially defined uses combined will likely be represented by overlaps of clusters with only a few pixels and EPA does not believe this constitutes reliable information.

1d: Species range overlaps completely (≥99%) with federal lands?

ESA Section 7 requires all federal agencies to consult with the Services for any of their actions that may affect a listed species or their designated critical habitats. Therefore, the determination for any listed species or critical habitat that has a range occurring completely (*i.e.,* >99%) on federal lands will be evaluated in the context of existing consultation obligations, as appropriate protections may already be in place.

This will:

1) conserve government resources by avoiding analysis that is not needed (*i.e.*, not all federal agencies will apply all pesticides to federal lands),
2) minimize duplication of work and

3) rely on the local expertise of the federal agencies applying pesticides to their lands to avoid adversely affecting listed species.

1e: Are direct effects anticipated? And, 1f: Are indirect effects anticipated?

The purpose of this part of Step 1 is to determine if a No Effect determination can logically be made for any species, based on the mode of action and available toxicity data for the pesticide of interest. For example, a pesticide that has no impact on plants at maximum application rates would not be expected to cause direct effects to plants. With this example, if the pesticide impacts some animals, there could be indirect effects to listed plant species that rely upon animals (*e.g.*, for pollination), so an NE determination may not be appropriate; however, for those listed plant species that do not depend upon animals, NE determinations may be made (because direct and indirect effects would not be expected).

For species or designated critical habitats that have a MA determination as a result of parts 1e or 1f of Step 1, more refined analyses will be carried out in Step 2. The Step 2 methods are described in the next section.

Step 2 – Proposed Method to Differentiate May Affect and Likely to Adversely Affect (LAA) from May Affect and Not Likely to Adversely Affect (NLAA)

The framework depicted in **Figure 4** represents the major parts of Step 2, in which ‘likely to adversely affect’ (LAA) or ‘not likely to adversely affect’ (NLAA) determinations are made for species and critical habitats with may affect determinations (from Step 1). Compared to Step 1, Step 2 includes more information, refinement and effort to come to a determination. As discussed above, Step 1 relies upon reasonably conservative assumptions to identify species for which no effect is expected and those species for which an individual may be affected. Step 2 involves refinements to the conservative approach employed in Step 1, with the intent of determining whether an individual of a species is or is not likely to be adversely affected by the assessed pesticide. As discussed previously, adverse effects that are measurable, observable, and likely to occur to a species results in a LAA determination. Details on the Step 2 decision framework (**Figure 4)** are discussed below.

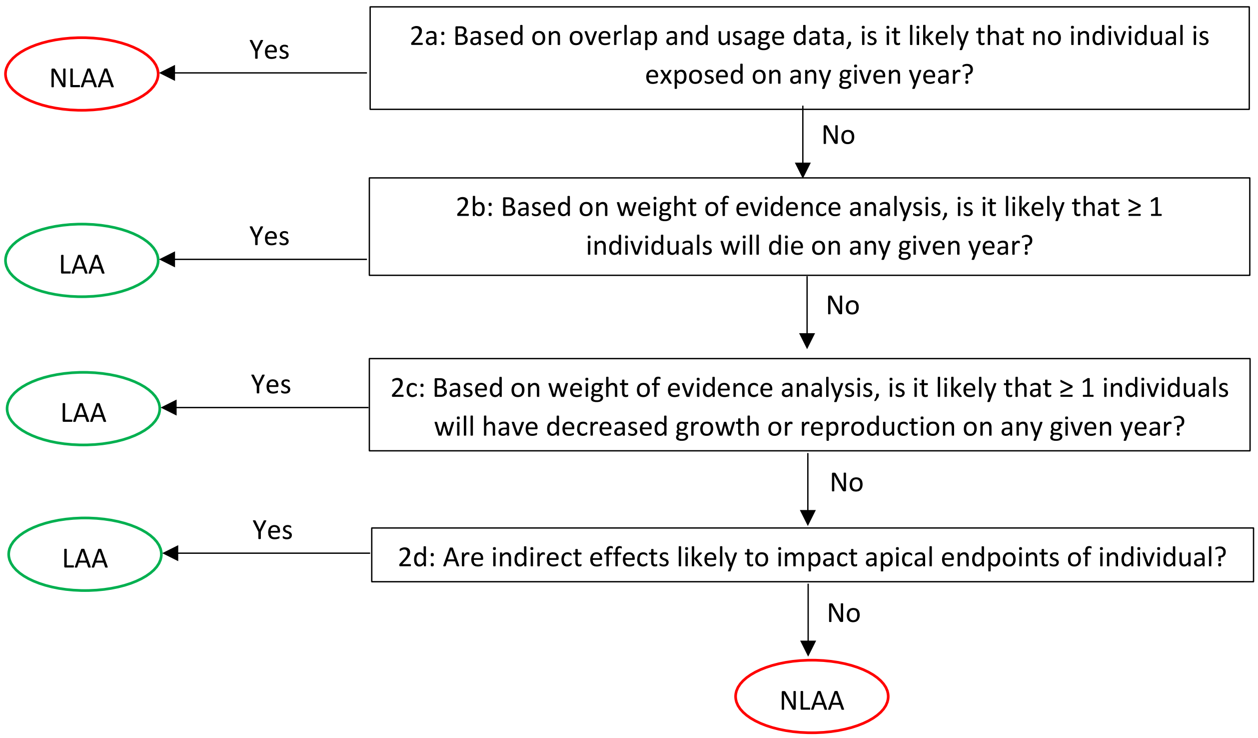

Figure 4. Step 2 decision framework for making Likely to Adversely Affect (LAA) and Not Likely to Adversely Affect (NLAA) determinations. Species with NLAA determinations do not require additional analysis (red ovals indicate stop). Species with LAA determinations move on to step 3 (green ovals indicate proceed). Once an LAA determination is made, no additional analyses are carried out for a species.

2a: Based on overlap and usage data, is it likely that no individual is exposed on any given year?

As discussed previously, Step 1 broadly incorporated usage data by removing counties if the NASS Census of Ag indicates no labeled uses in the UDL are grown and removing states with surveyed usage data indicating no usage from those potential UDLs. The objective of this analysis is to go from all possible use sites (in Step 1) to those sites where pesticide applications are likely (in Step 2) to result in exposure to an individual of a listed species. Step 2 takes a more refined approach to incorporating available usage data. As with Step 1, different approaches will be employed for crop and non-crop uses due to differences in the nature of the available data.

Species range

In Step 2, regarding the species range and anticipated location in the range, consideration is given to a species expected use of an agricultural crop or non-crop use site. For those species that are not found on and do not use potential use sites[19] (*e.g.*, agricultural fields, residential, forests) for habitat or resources, those use sites will be removed from the overlap. In cases where a listed species is determined not to use a crop or non-crop area, it is also assumed that the taxa relevant to indirect effects are also not exposed on-site (*i.e.*, exposure would only occur off site due to spray drift or runoff transport). However, exposure may still occur to species and taxa relevant to indirect effects in areas that receive spray drift and runoff and these areas are still considered in the analysis. In this approach, it is assumed that indirect effects are only relevant to a listed species in areas where that listed species occurs.

Agricultural crop uses

In addition to the methods applied in Step 1 with the application of the NASS Census of Agriculture and the SUUM to remove areas from the agricultural UDLs where usage in not expected, Step 2 continues to build on the usage data to apply it in a more quantitative manner. For agricultural crop uses, usage data are available for many uses to quantify the percent of crop acreage that has been treated (PCT). The PCT can be used to adjust the extent of an area that may overlap with a listed species. PCT data are available for specific crops and states. These data are applied to the 13 agricultural UDLs discussed above. For categories represented by single crops (*e.g.,* corn, cotton), the available PCT data for a given state are applied directly to the acres grown in that state to calculate the acres treated (acres treated = acres grown x PCT). For those categories representing multiple crops (*e.g.,* vegetable and ground fruit, non-citrus orchards), an aggregated PCT is calculated. This is accomplished by first calculating the acres treated for each crop relevant to the UDLs based on the available usage data, summing these treated acres, then dividing by the total acres grown for the all crops relevant to the UDLs. For crops with usage data, the acres grown are extracted from the SUUM, for crops without usage the acres grown are extracted from the Census of Agriculture (USDA-NASS, 2012) [20]. Acres treated of the UDL is calculated by multiplying this aggregated PCT by the area of the UDL for the state. The application of the PCT occurs after removing counties from a UDL if that county only includes acres for crops within a UDL that are not registered.

As noted previously in Step 1, some uses are not surveyed at all and some uses are only surveyed in some states. In such cases, a surrogate assumption may be used. For crops that are surveyed somewhere in the US but not in the state of interest, a surrogate PCT (*e.g.*, based on survey data for the same crop in nearby states, or the national PCT for the crop) will be considered. For crops that are not surveyed anywhere, a surrogate crop with surveyed data will be used if appropriate. For an unsurveyed crop, the PCT may be derived from crops with similar agronomic practice.

The aggregate PCT is used to calculate the total number of acres treated within a state for each UDL (PCT x total acres within a UDL = total acres treated for a UDL). The total acres treated will be compared to the number of acres within a species' range that overlaps with that UDL. If the number of treated acres in a state is > number of acres of UDL overlapping the species range, it will be assumed that all acres within the species range that overlap with the UDL are treated. Treated acres are only placed in counties where registered labeled use occur for the UDL as identified by Census of Agriculture.

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[19] This is determined by considering available life history of a species, particularly habitat as well as reported observations of the species on these use sites. Life history and observations are from species-specific documentation published by the Services (e.g., recovery plans, 5-year plans).

[20] USDA NASS. 2012. Census of Agriculture. Available at: www.nass.usda.gov/AgCensus/ (accessed 3/2019, verified 3/2019). USDA-NASS, Washington, DC.

If the number of treated acres is less than those overlapping with the species' range, it will be assumed that all treated acres for that UDL in a state occur within the range of a species. **Figure 5** illustrates how this approach assumes that treated acres within a state are concentrated within the species range.

After treated acres are attributed to the species range, the overlap due to spray drift transport is adjusted to account for the reduced number of treated acres. Basing drift on each individual use layer greatly overestimates the drift overlap, as many of these areas will overlap with each other. Therefore, as discussed in Step 1, overlap due to drift is based on buffering the Action Area in all directions. However, in Step 2, a composite factor will be applied to the drift area based on the aggregated PCTs for a state for agricultural UDLs, and any factor adjustments possible for the non-crop UDLs. This composite factor will be used to scale the number of acres impacted by off-site drift and subsequently lower the total predicted overlap with a species range due to drift. The off-site distance to which drift is buffered will be based on the uses relevant to the species within the state. The UDL with the highest number of acres treated in a state will be used to determine the method of application and maximum application rates for calculating drift distances.

The total number of acres within the species range that are treated or receive spray drift for each state will be added up and divided by the total number of acres represented by the species range. This can be considered the percent of the species range that may be exposed to the pesticide of interest. That value can be multiplied by the best available population size estimate to determine the number of individuals potentially exposed. If <1 individual is exposed, a NLAA determination is made. If 1 or more individuals are potentially exposed, then the weight of evidence analysis will be conducted as described in part 2b. Note that part of the weight of evidence (discussed below) will employ alternative assumptions of how treated acres may be distributed relative to the range of the species in cases where the species range is small relative to the range of the state. For example, rather than assuming that all treated acres within the state are concentrated within a species range, it could be assumed that they are uniformly distributed throughout the state.

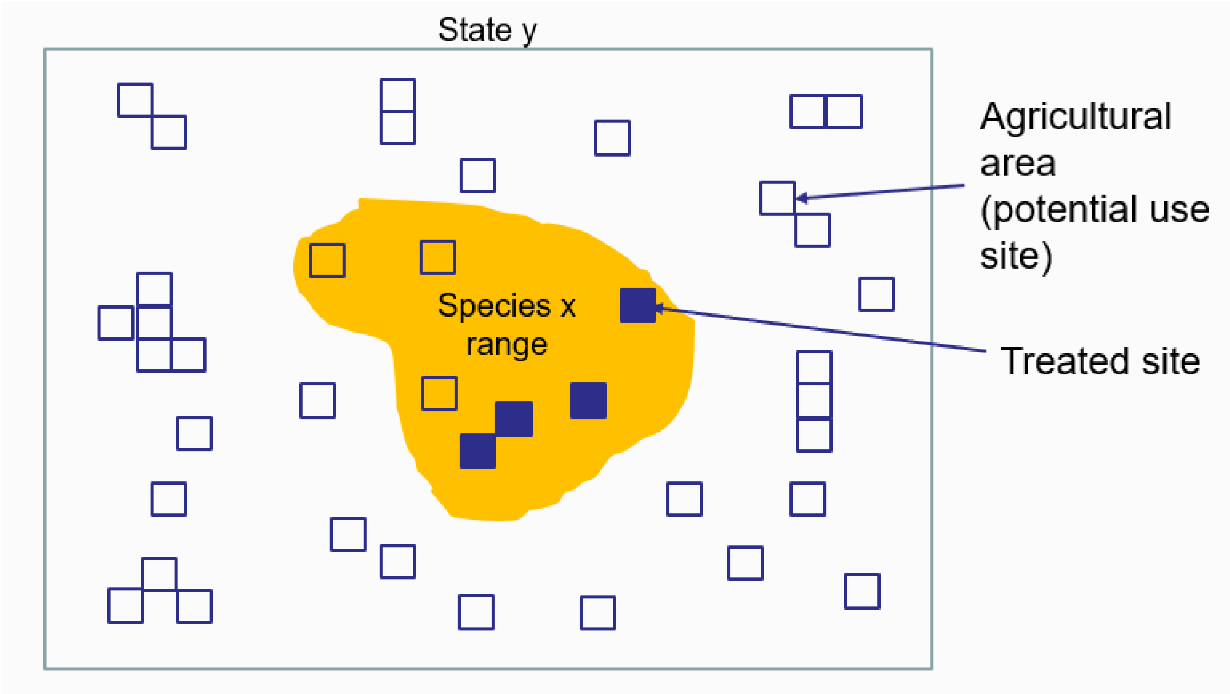

Figure 5. Conceptual illustration of approach for assigning treated acres to area relative to species range. In this example, PCT for the potential use site is 10%.

Non-crop uses

Pesticides are registered for a wide variety of uses that are not agricultural (*e.g.*, turf and ornamentals in residential areas, forestry, rangelands, and nurseries). Data for these types of uses are varied in their availability and their characteristics. For example, usage data are available in the SUUMs for several of these uses; however, they vary in scale (*e.g.*, regional, national). For non-crop uses, EPA intends to compile data from a combination of reliable sources, including production and sales data of formulated products (reported under section 7 of FIFRA), reported usage from federal agencies (*e.g.,* APHIS, US Forest Service), and proprietary sources (Agricultural Market Research Data), as available and appropriate to inform the extent and location of usage.

Of the uses described as "non-crop," those that are represented by the rangeland and forestry spatial footprints have the greatest extent of overlap with the most listed species. For these cases, assuming that all of these lands are treated (in the absence of usage data) potentially represents a gross overestimate of overlap. This assumption could lead to erroneous conclusions when a chemical is not in fact applied at a large scale to these UDLs. In cases where chemical specific usage data are not available for rangeland, and forestry, EPA will consider using USDA census data for woodlands for broad classes of pesticides. For example, available usage data reported in the census for all insecticides could be used to represent a specific insecticide. This is assumed to be an overestimate, as this would represent applications of multiple insecticides; however, it would be a more reasonable estimate than assuming that all acres of these uses are treated. In this case, a similar approach as discussed above for agriculture, would be used in applying state-level usage data to the rangeland and forestry footprints. This approach may be supplemented or replaced with chemical specific usage data obtained from other sources, such as formulated product sales data and usage data reported by federal agencies.

For uses that are spatially represented by the developed landcover class (*e.g.,* residential, gardens, turf, ornamentals), usage data are also available at the national level. EPA is currently investigating an approach for adjusting the percent of residential land expected to be treated by accounting for the proportion represented by impervious surfaces (which are not expected to be treated). A treated area assumption will be made for these areas based on the percent of a typical lot that is not represented by impervious surfaces (*e.g.,* houses, driveways). If product-specific sales data or other reliable survey information are available to provide robust usage data for residential areas, the percent treated area assumption may be lowered. In some cases, usage data are available on a regional basis for uses relevant to the developed landcover class. In those cases, regional percent treated areas (PTAs) may be developed.

For nurseries and other landcovers with a limited spatial extent, the 100% treated assumption will be reconsidered for those species with >1% overlap. This is because the spatial extent of this use is small and only overlaps with a limited number of species. Therefore, this use is not expected to lead to substantial exposure with the majority of species. There are a handful of species with measurable (*i.e.*, >1%) overlap with this use. In those cases, the percent of the area likely to be treated will be considered as part of the weight of evidence. Factors to consider in the weight of evidence include the portion of the use site (*e.g.*, nursery) represented by surfaces expected to be treated and available usage data from NASS or other sources discussed above.

2b: Based on weight of evidence, is mortality likely for 1 (or more) individuals? And, 2c: Based on weight of evidence, is it likely that ≥ 1 individuals will have decreased growth or reproduction on any given year?

In keeping with the need to determine whether the use of a pesticide is likely or not likely to adversely affect an individual of a listed species (through direct effects), this portion of the analysis relies upon a weight of evidence that contains probabilistic elements. The goal of this approach is to account for major factors that influence the potential exposure of an individual of a listed species and to account for variation in individual sensitivity.

In addition to the probabilistic assessment of likelihood of exceedance of exposure concentrations associated with a toxic effect (described further below), this approach focuses on: 1) information that could impact potential exposure to the pesticide being assessed; 2) assumptions and uncertainties associated with the current assessment process and available information; and, 3) consideration of the confidence in the available information and tools related to the specific species/critical habitat being assessed. The list of factors considered in this WoE approach is not exhaustive. The factors discussed here were determined to have the greatest potential impact on the effects determinations and are achievable with available resources (determined using a preliminary exploration of a subset of approximately 50 species). The factors considered include: timing of application related to the dormancy or migration pattern of the species, precision of the species range data, dietary considerations, confidence in the exposure estimates and confidence in the toxicity data. These are discussed in detail below. The process is set up as a tiered process, where conservative approaches are set up to identify species for which NE or NLAA determinations can reasonably be made using limited effort and refinement. As a species proceeds through step 2, refinements to the broad assumptions are made in order to more clearly understand the species-specific risk picture and uncertainties associated with the available data and assessment. This is intended to decrease uncertainty in the effects determinations and will increase the level of complexity, necessary data, and analysis as a species proceeds from lower to higher tiers. This tiered framework is a standard practice, where resources (time, personnel, data) are limited and must be used as efficiently as possible. Similar tiered frameworks have been discussed at FIFRA SAPs[21].

Timing of Applications Relative to a Species' Dormancy State or Migration Pattern:

Dormancy State:

Some listed species enter seasonal dormancy states normally related to low temperatures in the winter (*e.g*., hibernation, torpor, or diapause). These dormancy states can impact potential exposures of individuals to pesticides because they are associated with decreased metabolism and cessation of eating or drinking. Additionally, animals that enter seasonal dormancy states normally are found in protected areas (*e.g*., caves, underground burrows, tree crevices) that could limit pesticide exposures – especially via spray drift. Because most dormancy states are related to late fall, winter, and spring, this factor should be considered for any pesticide applications made during these times of year in areas where individuals of a species may enter into one of the dormancy states.

For any pesticide uses that occur in late fall/winter/spring:

- The assessor will determine if the species that overlaps with the use(s) enters into a dormancy state during the time the applications are most likely made. This will be based on information provided in FWS or NMFS documents (*e.g.,* the species profiles included in the BE, recovery plans or 5-year reviews) (**Figure 6**) and available pesticide use and usage information.
    - If the species is most likely dormant during the expected pesticide applications to a given use, the assessor will consider the exposure potential low and will remove this use from consideration.
        - The assessor will then determine if there are any other uses that overlap with species range.
            - If there are no other uses, the assessor will make an NLAA determination (because the overall exposure to the pesticide is likely low)
            - If there are other uses, the assessor will continue the analyses with the remaining uses
    - If the species is not likely dormant during the expected pesticide applications, the assessor will continue the analyses, considering other factors relevant to the Weight of Evidence (discussed below).

[21] FIFRA SAP. 2000. SAP Report No. 2000-02. A Set of Scientific Issues being Considered by the Environmental Protection Agency Regarding: Session I. Implementation Plan for Probabilistic Ecological Assessment: A Consultation. August 2. http://www.epa.gov/scipoly/sap/meetings/2000/april/freportapril572000.pdf

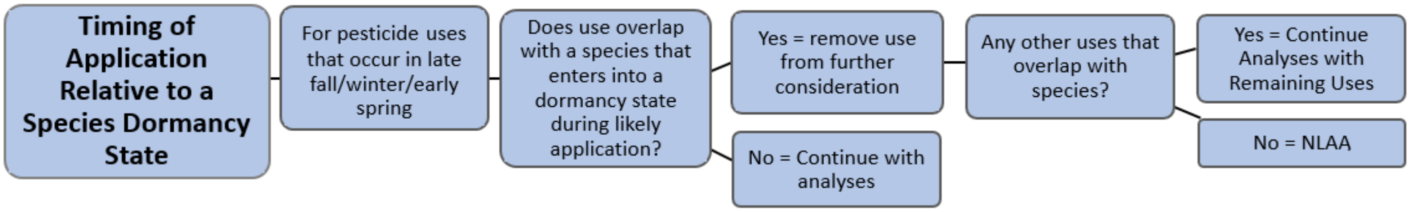

Figure 6. Consideration of Dormancy state.

Migration Pattern:

Some listed species migrate (the seasonal movement of animals from one geographic area to another). The species range data that are currently available for use in the overlap analyses include the entire range of a species, without distinguishing seasonal variability. Therefore, for species that migrate, further consideration will be made to determine if individuals of a species are expected to be in an area when the pesticide being assessed is most likely applied. This will only apply to those species that have all individuals of the population migrate during a given season (*e.g.*, population of listed bird species migrates from a wintering area to a separate breeding area), not to those species where only portions of the population migrate (*e.g.,* anadromous fish species where some individuals of the population move between fresh and salt water, largely depending on age). In the former, areas of the range are completely vacant of individuals of the population during parts of the year; whereas, in the latter, individuals of a population can be found throughout the range throughout the year.

For all pesticide uses;

- The assessor will determine if the species being assessed migrates. The initial focus will be on birds, because many listed species within this taxon are known to migrate. In addition, this analysis could also include species from other taxa where all individuals migrate within the same season. Again, this will be based on information provided in FWS or NMFS documents (*e.g.*, the species profiles included in the BE, recovery plans or 5-year reviews) (see **Figure 7**).
    - If the species migrates, the assessor will identify where the species is found during the time when the pesticide applications are most likely made.
        - The assessor will repeat and continue all of the overlap analyses, only including the portion of the range with potential exposure (*i.e.*, that part of the range where the timing of the applications is expected to overlap with the locations of individuals of the species).
        - The effects determination will be based on the results of the analysis using only the portions of the range where the species is when the applications are likely made.
    - If the species does not migrate (at all or at the same time), the assessor will continue the analyses with the entire range.

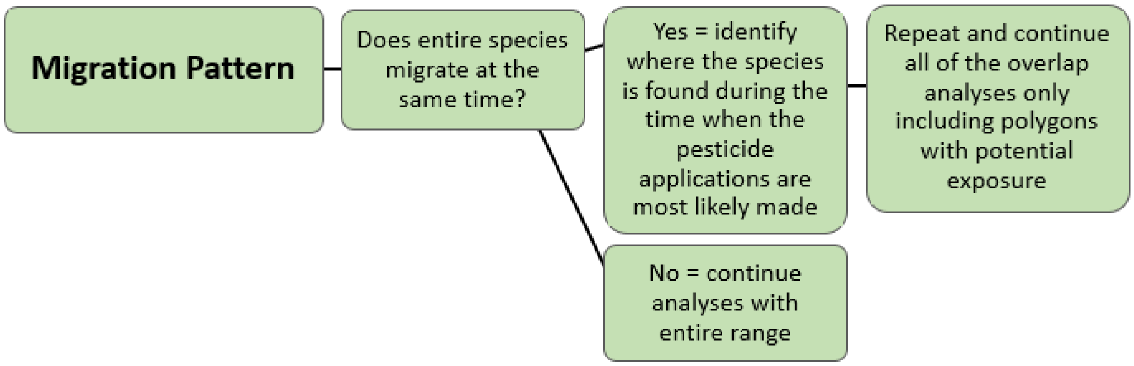

Figure 7. Consideration of Migration Pattern.

Precision of the Species Range Data (GIS Layers):

The available species range data varies in granularity (*e.g.*, county-level, township-range level). In addition, some of the available range data are delineated along geopolitical boundaries and include specific areas where the species is not likely found. Because the proposed process is highly dependent on an understanding of the overlap of the species range with likely pesticide applications, the assessor will consider the precision of the available species range data.

For all pesticide uses:

- The assessor will determine if the available species range is wholly or partially at the county and/or state-level. The focus is on county and state-level ranges because these are geopolitical boundaries that are easily identified, and an initial analysis indicated that a large portion of the available range layers are at this level of granularity (see **Figure 8**).
    - If yes, the assessor will determine if the species can be found in many habitat types, meaning a refined range may look very similar to the state or county range data available (*e.g.*, bats, wide-ranging carnivores). Again, this determination will be based on information provided in FWS or NMFS documents (*e.g.*, the species profiles included in the BE, recovery plans or 5-year reviews).
        - If yes, the assessor will continue with the analyses
        - If no, the assessor will continue with the following steps:
            - Explore the available Services' documents (*e.g.*, recovery plans, 5-year reviews) in ECOS (https://www.fws.gov/endangered/) to determine where in the county(s)/state(s) the species is most likely located.
            - Determine if the species is only found on federal lands based on available species location descriptions.
                - If yes, the species will be treated as if the species is only found on federal lands (*i.e.*, no further analyses will be conducted)
                - If no, determine if the species is found overlapping with or near (within 2600 ft of) a potential use site(s). The 2600 ft limit is based on the limits of the spray drift models available; beyond this limit potential effects cannot be determined. Because the overlap analysis using a supplemental species range (*i.e.,* one limited to specific habitats) relies on a suitable habitat crosswalk

between described species habitats and GAP[22] landcovers (which is not currently available), this analysis will be qualitative.

- If no, the exposure potential is considered low and the assessor will make an NLAA determination
- If yes, determine if the potential use site(s) overlapping with or near the species range is wholly within a non-federal protected area (*e.g.*, state park, state forest). If so, this will be considered qualitatively in the overall risk determination (considering the totality of the available data and all other analyses).
  - If no, continue with analyses
  - If yes (or it cannot be determined), determine if the species is only found in a specific habitat. If so, the overlap analysis will be repeated and will be limited to the part of the species range that contains the specific habitat. As a proof of concept, the analysis will initially focus on species found only on 'beaches' based on the National Vegetation Classification Macro Group and Ecological System/Land use classes of the GAP Landcover layer. Other levels of the National Vegetation Classification can be considered if needed as the process expands to other habitat types.
  - If no, continue with analyses

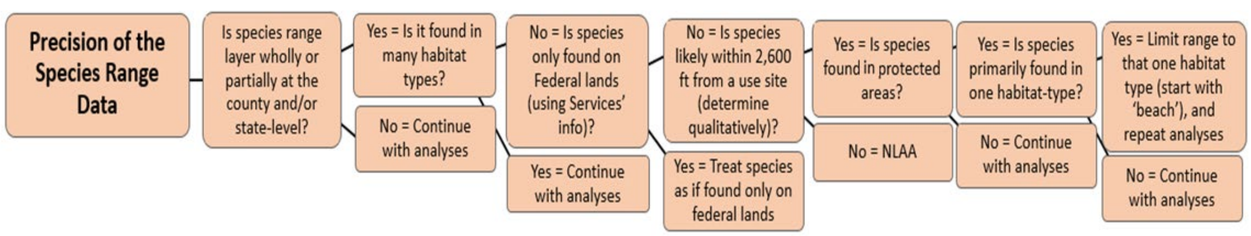

Figure 8. Consideration of the Precision of the Species Range Data.

Dietary Considerations:

The quantitative analysis of Step 1 and the beginning parts of Step 2 (a-c) involving dietary exposures for terrestrial species is based on the most conservative dietary item. In other words, if a species eats from more than one dietary category, the category that results in the highest exposure value is used in the exposure model. Although this is a conservative approach, it may not represent the most likely exposure for a species that does not rely equally on each food category. Many species, even those that are

[22] The USGS Gap Analysis Project (GAP) which consists of mapping three data layers — land cover, predicted distributions of vertebrate species, and a stewardship layer depicting both location and conservation status of protected areas. More information at: https://gapanalysis.usgs.gov/

generalists, have food preferences and may rely more heavily on particular food items. This preference can vary seasonally and/or by life stage. Therefore, for any species that has food preferences, a refined dietary analysis that focuses on the preferred food items will be considered.

For all pesticide uses:

- The assessor will determine if a species relies on specific dietary item(s) (throughout the year or during times associated with pesticide applications). The identification of dietary preferences will be based on information provided in FWS or NMFS documents (*e.g.*, the species profiles included in the BE, recovery plans or 5-year reviews) (see **Figure 9**).
    - If yes, the assessor will focus the dietary exposure analysis on that particular food item(s). If the risks associated with the preferred dietary item(s) are below the levels of concern, then an NLAA determination will be made for the species. If the risks associated with the preferred dietary item(s) are above the levels of concern, then continue with the analyses [focusing on the preferred dietary category(ies)].
    - If no, continue with analyses.

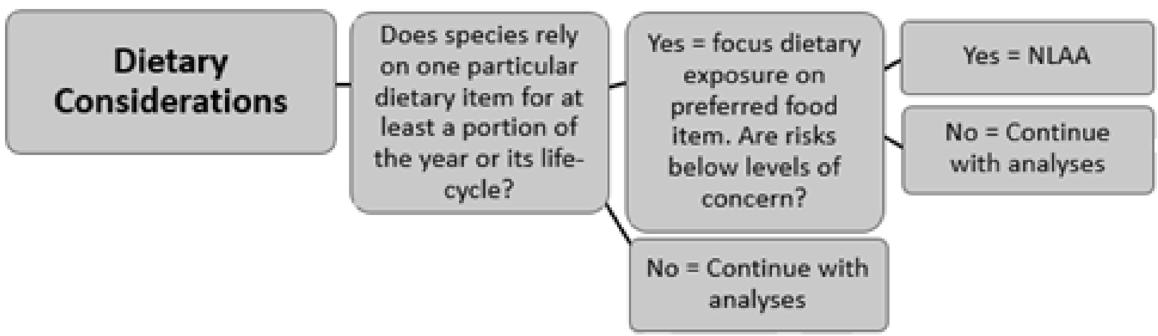

Figure 9. Consideration of a Species Dietary Preferences.

Confidence in the Exposure Assessments:

The current exposure models used in this assessment were not designed to estimate exposures for all types of pesticide applications; all habitat types; or for all potential exposure routes. Therefore, there may be uncertainty in the exposure values being used for a particular species based on what potential uses it may overlap with, what type of habitat it is found in, or what the main potential exposure route(s) might be. Although the uncertainties associated with these factors cannot be quantitatively assessed at this time, they should be considered qualitatively in the effects determination.

For species and critical habitats that have not been determined to be NE or NLAA based on the above analyses, the assessor will consider how well the conceptual model of the relevant exposure model(s) matches up with the specific species being assessed. For example, if an aquatic species is typically found in a much larger water body than the one being modeled, the actual exposure values may be lower than the estimated values. If it is determined that the estimated exposures may be higher or lower than those being estimated for a species, it should be described, with a rationale, and considered in the effects determination. An example for a terrestrial habitat would be a forest dwelling species. For chemicals that do not have forestry use, the AgDRIFT model would be used to estimate pesticide exposure via drift. The conceptual basis of AgDRIFT is a relatively flat, unimpeded field and adjacent area, where drift is not intercepted by trees or other geographic features. Therefore, AgDRIFT would be expected to overestimate drift exposure to species that dwell in the interior of forest.

Confidence in the Toxicity Data (Surrogacy):

The toxicity endpoints used in the analyses are largely from broad taxonomic groups (*e.g.*, all birds, all mammals). Where the data allow, attempts are made to rely on more granular taxonomic groupings – *e.g.*, separating aquatic-phase amphibians out from fish; separating saltwater fish species from freshwater fish; or separating mollusks from other aquatic invertebrates.

We explored the option of considering more specific taxonomic groupings (*e.g.*, using salmonid toxicity data to represent the toxicity to listed salmon species). What we found in our preliminary analyses with several pesticides, is that for data-rich species that allowed for such an analysis (*e.g.*, salmonids), even species within the same genus were often found throughout the species-sensitivity distribution for a broader taxonomic group. Additionally, the search and evaluation of toxicity data for all listed species, even at the family-level, would be resource prohibitive.

Relying on toxicity data from broad taxonomic groups does introduce uncertainty into the assessments. However, it is not possible at this time to quantify the uncertainty associated with this surrogacy approach for each listed species; or to even determine if a specific species being assessed would be more or less sensitive than the surrogate toxicity values being used would suggest. Therefore, we are relying on toxicity data from the more sensitive species within each taxonomic group to help ensure we are being protective of each listed species.

Other Factors:

The factors discussed above are general and are meant to apply to a broad range of species. There may be other important factors that could impact the effects determinations that are specific to one or a few species. For species and critical habitats that have not been determined to be NE or NLAA based on the above analyses, the assessor will consider other species-specific information that could potentially influence exposures and risks. If any of the species-specific factors are believed to limit potential exposures and risks to a level that would result in an NE or NLAA determination, the NE or NLAA determination should be made and a rationale for the call should be provided. The rationale should clearly state the specific reasons why the factors considered are believed to limit potential exposures and risk (see **Figure 10**).

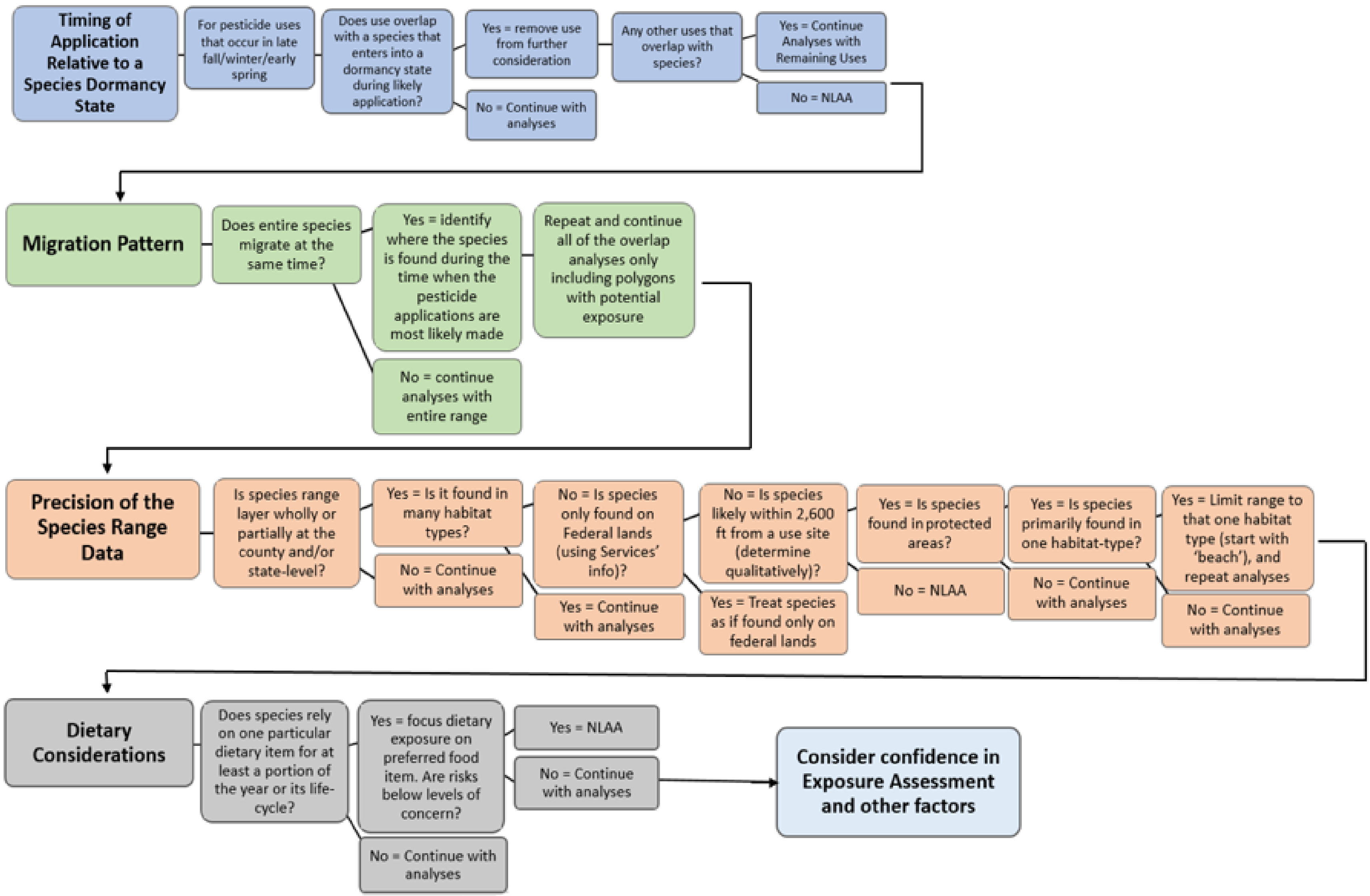

Figure 10. Additional Exclusion Criteria Approach.

Probabilistic Analysis

The use of probabilistic methods was recommended by the NRC in all steps of the consultation process. In addition, they recommended that uncertainty be integrated into the exposure and effects analyses so that the impacts of uncertainty on risk can be recognized and considered. One of the major changes to the interim method that are reflected here include a probabilistic analysis. It is the EPA's opinion that this type of analysis is consistent with the NRC recommendations and allows for consideration of the likelihood that an individual will be adversely affected, which is the goal of step 2 (*i.e.,* to determine whether a pesticide is likely or not likely to adversely affect an individual).

Probabilistic methods are incorporated as part of the weight of evidence to determine the likelihood of exposure and effects to an individual of a listed species. The goal of the probabilistic analysis is to more fully capture and characterize variability in the range of potential risks that can occur based on the inherent variability in the most influential input parameters used in EPA's models. In contrast to deterministic methods, the probabilistic analysis will consider distributions of exposure concentrations as well as toxicological responses among individuals (*i.e.*, differences in individuals sensitivities influencing the likelihood of individual mortality). The method proposed herein draws conceptually from previously described methods, including several EPA Scientific Advisory Panels and other documents (USEPA, 2000[23,24,25]; ECOFRAM, 1999[26,27,28]). The method also employs algorithms described in the USEPA Terrestrial Investigation Model (TIM; v. 3.0[29]).

As described in the TIM technical manual (Appendix I; USEPA 2015), conceptually, an ecological risk assessment, or in this case a biological evaluation, may be conducted using a Tiered framework (Tiers I-IV) where the level of complexity of the analyses increases through the ascending Tiers. A deterministic Tier I analysis, using a screen of the maximum exposure values to threshold ecological values, is conducted in Step 1 of the process (Step 1e: Are direct effects anticipated? Step 1f: Are indirect effects anticipated?). For a refined assessment of risks, Tiers II-IV employ principles of probabilistic analysis with increasing levels of complexity and specificity. The proposed method described herein can be considered a Tier II probabilistic analysis. In this approach, variability in some of the more influential input parameters is quantified, including potential EECs, exposure scenarios and individual species sensitivities. The method is based on EFED's current standard, conservative field-based models and

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[23] U.S. Environmental Protection Agency (USEPA). 2000. Technical Progress Report of the Implementation Plan for Probabilistic Ecological Assessments: Aquatic Systems. http://www.epa.gov/scipoly/sap/meetings/2000/april/probaq.pdf

[24] U.S. Environmental Protection Agency (USEPA). 2000. A Progress Report for Advancing Ecological Assessment Methods in OPP: A Consultation with the FIFRA Scientific Advisory Panel. Overview Document. http://www.epa.gov/scipoly/sap/meetings/2000/april/probover.pdf

[25] U.S. Environmental Protection Agency (USEPA). 2000. Technical Progress Report of the Implementation Plan for Probabilistic Ecological Assessments: Terrestrial Systems. http://www.epa.gov/scipoly/sap/meetings/2000/040500_mtg.htm

[26] ECOFRAM, Aquatic Workgroup. 1999. ECOFRAM Aquatic Report. May 4, 1999. www.epa.gov/oppefed1/ecorisk/index.htm

[27] ECOFRAM, Peer Input Workshop. 1999. http://www.epa.gov/oppefed1/ecorisk/ecorisk_ecofram.htm#EcoPeerInput

[28] ECOFRAM, Terrestrial Workgroup. 1999. ECOFRAM Terrestrial Draft Report. May 10, 1999. www.epa.gov/oppefed1/ecorisk/index.htm

[29] USEPA. 2015. Technical Description and User's Guidance Document for the Terrestrial Investigation Model (TIM), Version 3.0 BETA. United States Environmental Protection Agency, Office of Pesticide Programs. Available online at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#tim

varies parameters that are influential to those models using known distributions. It is noted that there are other factors (*e.g.,* chemical properties, discrete distribution of aquatic species in water bodies, simultaneous variation of application rates at a field scale, etc.) that could impact risks that are not currently being integrated into the probabilistic approach. These types of higher-level Tier III-IV analyses may be developed in the future.

Probability simulation (Monte Carlo Analysis)

In the analysis, referred to as a Monte Carlo (MC) analysis, thousands of individuals of a species are simulated in order to represent the full range of combinations of variables considered in the probabilistic approach. In the MC analysis, one individual is simulated at a time, with a random value being drawn from each distribution that is included in the probabilistic approach. This simulation is completed over and over, each time using a different set of random input values drawn from the probability functions. Depending upon the number of uncertainties and the ranges specified for them, the simulation may require thousands or tens of thousands of recalculations to fully describe the variability associated with an analysis. The Monte Carlo simulation produces a distribution of possible outcome values, each with an associated probability of occurrence.
For the Monte Carlo analysis completed herein, the number of simulations completed will be determined by the variables simulated (*e.g.*, 10,000 runs may be completed to fully describe the variability associated with an analysis, but less runs may be necessary to capture this variability). This is not meant to represent specific individuals in the population; rather, we are trying to represent the potential variability in terms of exposure and responses that are relevant to those individuals. Therefore, it is necessary in some cases to simulate more individuals than are in the population. Impact to individuals in the population will be calculated post analysis by applying the predicted impact to the known population size. For many insecticides, which tend to have direct effects primarily on invertebrate and other animal taxa, it is anticipated the probabilistic analysis will be conducted for only terrestrial and aquatic animals as needed based on the tiered screening of species. For insecticides, probabilistic analyses will also be utilized to assess indirect effects to listed plants or animals due to impacts to animals on which those species depend. For herbicides, which are expected to impact plants, probabilistic approaches to assessing exposure of animals will also be considered, where appropriate, as well as consideration of alternative toxicity assumptions based on available data.

Different approaches are used for terrestrial and aquatic habitats due to differences in available models, habitat characteristics and species behavior. Both approaches integrate exposure information with dose-response acute toxicity data to determine the likelihood of mortality to an individual. For chronic effects, this analysis calculates the likelihood that a sublethal effect endpoint (for growth or reproduction) is exceeded. Details on the exposure and effect considerations of the probabilistic analysis are provided below.

Exposure Analysis

In determining exposure concentrations, individuals of a species will be randomly assigned to areas of their range proportional to the percent overlap of the species range with each zone, including being on site, in the off-site transport (drift) zone or in an area of the species range not impacted by the pesticide. The exposure will be based on a residue value selected from a distribution of concentrations relevant to the diet of the organism or aquatic exposure concentrations and the organism's spatial location (*e.g.,* on-field, 60-90 m from field). Exposure analyses are conducted differently for species that inhabit terrestrial and aquatic environments. For those that inhabit both of these environments (*e.g.*, amphibians), each habitat is assessed separately and considered in the overall assessment of the species.

Terrestrial habitats

In the terrestrial environment, dietary exposure will be drawn from a distribution of concentrations on food items that are relevant to a species. These concentrations account for variability in residues on food items located on treated use sites or in the spray drift area. On field, the concentrations will be based on a residue value randomly selected from a distribution of exposure concentrations relevant to the diet of the organism using the means and standard deviations as outlined in the TIM manual, which are the same residue values incorporated in EFED's standard terrestrial exposure tools. Off field, the same principle will apply, but the dose received by the individual will be decreased based on the distance from the edge of the field (calculated according to AgDRIFT deposition curves; estimated exposures would be reduced by the percent reduction estimates from AgDRIFT). For example, if a species is assigned to a location that corresponds to a deposition of 50% of the application rate, then the distribution of potential pesticide concentrations will be 50% lower than on-field concentrations.

The probability of an individual being in any zone (zones defined as on the use site, in the off-site transport zone or in an unaffected area) will be simulated as proportional to the percent overlap of the species range with each zone. Off-site drift will be analyzed in increments of 30-meter distances away from a treated field, based on the size of a pixel in the GIS spatial analysis. The likelihood of an individual of an assessed species being in that area would be proportional to the overlap of the species range with that zone and the exposure concentration would be drawn from the distribution of predicted EECs at that distance. For example, using the uniform distribution assumption, if there is a 7% overlap of the use site with a species range, an individual of a species has a 7% chance of being in that area. Usage data, in the form of the PCT, will be used to inform the total number of acres that could possibly be treated within a species range. As described in the usage section above, different assumptions around how treated acres are distributed within a state in relation to the species range will be considered (*e.g.,* all of the treated acres are within the area of overlap with the range, outside the area of overlap with the range or uniformly distributed throughout the area).

The approach for assessing terrestrial exposure uses several approaches already incorporated into TIM, which is EFED's Tier II and III model for assessing risks of pesticides to birds. The approach used here will use a simplified version of the method integrated into TIM. Much of this method has been discussed at several FIFRA SAPs (see Appendix I of TIM manual) [30] and integrated into risk assessments used for FIFRA decisions.

Aquatic habitats

In the aquatic environment, exposure concentrations will be drawn from predicted EECs within a relevant size water body for a species. Relevant size water bodies are represented by aquatic bins described in the biological evaluations (BEs) conducted for chlorpyrifos, diazinon, and malathion. For this refined method, fewer bins will be modeled: bins 2 and 5 will be represented by edge of field runoff; bins 3 and 4 are represented using the index reservoir; and bins 6 and 7 are represented using the standard farm pond. Different distributions of EECs will be considered, including maximum annual daily or time-weighted average (*e.g.*, 21-day or 60-day) EECs and the distribution of EECs will represent the variability in maximum EECs from year to year. Different methods are used for species depending on if

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[30] USEPA. 2015. Technical Description and User's Guidance Document for the Terrestrial Investigation Model (TIM), Version 3.0 BETA. United States Environmental Protection Agency, Office of Pesticide Programs. Available online at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#tim

they are in flowing or static waterbodies. For the static and low-flow flowing waterbodies, the distribution of maximum daily EECs from the 30 years of data are used based on the assumption that a species will not leave that static bin and could be exposed to the maximum exposure concentrations for a given year. For medium and high-flow flowing waterbodies, there will be movement of the species, as well as the water, within the water bodies and there is higher variability and uncertainty in the expected exposure concentrations. In this case, the distribution of daily EECs based on the 90-day window around the maximum annual daily concentration will be used in the analysis.

Numerous other factors can impact the actual concentrations in a water body under varied application times, rates and conditions. To try and capture some of this variability, the influence of 2 additional factors, application date and hydrologic soil group, will be considered in the distribution of EECs. These factors were chosen as they can have a substantial impact on EECs and are expected to vary considerably in real world applications. Simulations will be conducted with PWC to determine the EECs for 1 application at the maximum application rate using the date associated with the month with the maximum precipitation within a realistic application window for each scenario and bin (details on bins and modeling assumptions provided in the exposure chapter analysis section of pilot BEs). The same simulations are run using alternate application dates that would fall within a reasonable application window (generally April to August, or the relevant application window for the area). Factors are developed that relate the EEC associated with the original chosen application date to the randomly selected application date. For example, if the EEC from the original analysis based on a May 1 application date was 80 µg/L and the randomly selected date yielded an EEC of 70 µg/L, the factor applied would be 0.875 (70/80 = 0.875). A distribution of factors is created based on all the variable dates modeled. Similarly, an analysis is conducted using a different hydrologic soil group. Original PWC modeling used a hydrologic soil group that was conservative and generated high levels of runoff. The sensitivity analysis will look at hydrologic soil groups which may reduce the runoff from a use site, resulting in lower EECs. In the Monte Carlo analysis, EECs are then drawn from the distribution of original EECs (modeled at the maximum application rates and wettest predicted month for the HUC) and multiplied by a randomly drawn factor developed from a variable application date and variable hydrologic soil group sensitivity analysis. Resulting EECs are defined by the equation below.

*Exposure value EEC = EEC from max labeled rate run*app date factor*soil factor*

This method is intended to be a more simplified approach to capturing the variability of these factors without needing to conduct separate PWC runs for each variable every time an EEC is sampled from the distribution in the Monte Carlo analysis.

Aquatic EECs resulting from spray drift only are estimated using the same algorithms employed in the Tier I modules of AgDRIFT. Estimates of the average drift across the waterbody width at 30-meter distances away from a treated field are developed and the product of this average drift and the application rate, divided by the depth of the waterbody, results in a short-term average concentration in the waterbody due to spray drift. Similar to the terrestrial analysis, the percent overlap is used as a surrogate for the percent of the species exposed to an EEC in all water bodies. Locations of individuals will be similarly modeled with the water body located next to the use site (receiving direct runoff) or in the spray drift zone from 0 to 2600 ft. The probability of an individual being in any zone will be simulated as proportional to the percent overlap of the species range with each zone. For individuals of a species within the area of direct overlap with a use site, the individual would be considered to be adjacent to the use site, and exposure EECs would be equal to those directly from the PWC output. For individuals of a species within the spray drift area, EECs will be decreased based on the distance from the edge of the field at 30 m increments and calculated with AgDRIFT as described above. It is important to note that aquatic species ranges are not based just on the water body a species occupies, but the entire catchment that feeds that water body. Therefore, while any direct overlap of a use site with the range could be anywhere in the catchment, the assumption is conservatively made that the water body is directly next to the use site.

Toxicity Analysis

Under both the terrestrial and aquatic simulations, a distribution of sensitivities among individuals will be considered when determining the likelihood of mortality. Toxicity data considered in the Step 2 analysis are listed in **Table 2**. The mortality endpoint of concern will be based on the dose-response curve for a given toxicity endpoint (*e.g.*, LD_{50} representing the 5^{th} percentile of species sensitivity distribution and associated slope). Additionally, "what-if" scenarios will bound possible results by calculating the magnitude of mortality among exposed individuals at points on the species sensitivity distribution (*e.g.*, 5^{th}, 50^{th} percentile) and the confidence limits of the selected LD_{50}. Similar to the method used in TIM, a sensitivity will be ascribed to each individual based on the LD_{50}/LC_{50} and the dose response curve for the selected LD_{50}.

For sublethal effects, the geomean of the lowest quantitative NOAEC and LOAEC will be used to determine the likelihood of exceeding this value, given the distribution of exposure concentrations. If only a LOAEC is available, the LOAEC is used in the simulation.

As noted earlier in Step 1, given the priority for EPA to pursue incorporation of methods that reduce whole animal testing, endpoints from studies using non-animal test methods that are scientifically sound, fit for purpose in risk assessment, and represent toxicological thresholds on apical endpoints will be incorporated into the BE process.

Effects Determinations

Probabilistic analyses will be completed using the most conservative and least conservative assumptions initially to identify those that are clearly NLAA or LAA. If the most conservative assumptions (*e.g.*, maximum labeled application rates, use of upper bound Kenaga values, all treated acres inside overlap with the species range, etc.) in the probabilistic analysis predict less than 1 mortality or less than 1 individual exceeding the sublethal endpoint or less than the indirect threshold at greater than the 95^{th} percentile, then the call is NLAA and no further analysis is warranted. Conversely, if the least conservative assumptions (*e.g.*, typical application rate, single application per year, use of mean Kenaga values, maximum number of treated acres outside overlap with the species range, etc.) predict greater than 1 mortality or greater than 1 individual exceeding sublethal endpoint or exceedance of the indirect thresholds at greater than the 95^{th} percentile, the species call is LAA and no further analysis is warranted. If the prediction is between these two extremes, then additional factors might be considered to make the determination (*e.g.,* output based on upper bound vs. mean EECs for terrestrial effects, variation based on placement of treated acres within or outside the species range, impact of aquatic scenario selection for crop groups, etc.). Aquatic scenario selection is important as some UDLs have multiple PWC scenarios that could be applied, and due to differences in EECs among scenarios, exposure could vary depending upon the scenario used to represent the UDL. Consideration may also be given to additional output along the distribution (*e.g.,* 90^{th} and 70^{th} percentiles).

Output for the species will provide probability density functions. In the output, in addition to the likelihood of impacting more than one individual being provided for a Step 2 determination, the most likely number of impacted individuals will be provided. This will presumably provide useful information to carry over into the Step 3 analysis where impacts across the population are considered.

Overall, this analysis is intended to introduce some basic components of probabilistic analysis into the effects determinations and is not intended to capture all potential variables that could be considered. Additionally, the results of this analysis are considered as part of the weight of evidence and will be interpreted in light of other species considerations (*e.g.,* suitability of conceptual model to species habitat, representativeness of species range, behavior of species, etc.) to make the final effects determination.

2d: Are indirect effects likely to impact apical endpoints of an individual?

Since the focus of the assessment is on impacts to an individual of a listed species, it is necessary for indirect effects to be considered in the context of whether impacts to taxa relied upon by the species may result in an impact to an individual of the listed species. Therefore, the focus of this analysis is on indirect effects that may impact apical endpoints of a listed individual. For habitat requirements or for species with plants included in their diets, a 50% decline in growth of aquatic plants or a 25% decline in growth of plants (based on most sensitive tested species) is assumed to result in decreased cover/availability of food and decreased likelihood of survival/growth of a listed individual (see indirect effects endpoints in **Table 2**). For species that rely upon animals (*e.g.*, for diet, pollination, seed dispersal), for non-obligate relationships, the specific threshold for potential indirect effects is set at one-half (0.5) of the mortality endpoint concentration (*i.e.*, there is a potential for indirect effects when the ratio of the estimated concentration/mortality endpoint ≥0.5). The mortality endpoint is based on the lower 5th percentile LD_{50}/LC_{50} of the SSD (if available) or the lowest available LD_{50}/LC_{50} for the taxa that are relied upon (using the most sensitive taxon). Again, this is meant to be protective at a community-level for non-listed species.

For obligate relationships, more conservative assumptions are made, so the obligate species is treated as if it were a listed species. The effects endpoints (mortality for animals and growth for plants), and thresholds for potential indirect effects for obligate species that rely on animals is set at one-tenth (0.1) of the mortality endpoint concentration (*i.e.*, there is a potential for indirect effects when the ratio of the estimated concentration/mortality endpoint ≥0.1). The 'range' of the obligate species will be assumed to overlap with the range of the listed species to which it is obligated.

When assessing the potential for indirect effects to an individual of a listed species, EPA will consider diet, habitat and other types of effects. When assessing exposure to terrestrial animal prey (vertebrates or invertebrates) or pollinators, central tendency exposure estimates (*i.e.,* mean) will be used to represent potential exposure to dietary items located within the territory of an animal. The mean was chosen as it is assumed to represent the concentration across the area where the prey may inhabit. For aquatic food items, daily average EECs generated by PWC will be compared to toxicity endpoints. If an animal's diet includes multiple food items, the food item representing the most conservative scenario will be used in the assessment of indirect effects, although the magnitude of a reduction in food availability as a whole may be considered as well. Impacts to habitat that may be relevant to animals (*e.g.*, dependency upon mammal burrows) will be assessed using the same method. Additionally, some of the weight of evidence considerations discussed above (*e.g.,* confidence in exposure estimates, confidence in toxicity data, probabilistic analysis, etc.) could be applied to the indirect effects assessment in a similar manner.

If direct and indirect effects are not likely for an individual of a listed species, a NLAA determination is made and no additional analyses are conducted. For all species with LAA determinations, Step 3 analyses will be carried out as part of the Biological Opinions (BO). In Step 3, the Services will determine whether impacts to individuals are likely to result in population-level consequences (*i.e.*, jeopardy, for listed species, or adverse modification, for designated critical habitats).