Revised Method

for National Level Listed Species

Biological Evaluations of Conventional Pesticides

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Environmental Fate and Effects Division
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

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List of Acronyms

BAT	Base Acres Treated
BE	Biological Evaluation
BO	Biological Opinion
CAG	Crop Acres Grown
CDL	Cropland Data Layer
CoA	Census of Agriculture
ConUS	Contiguous United States
EC25	Concentration leading to 25% effect
EC50	Concentration leading to 50% effect
ECOFRAM	Ecological Committee on FIFRA Risk Assessment Methods
ECOS	Environmental Conversation Online System
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FGDC	Federal Geospatial Data Committee
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
GIS	Geographic Information System
HUC	Hydrologic Unit Code
LAA	Likely to Adversely Affect
LC50	Concentration leading to 50% mortality
LD50	Dose leading to 50% mortality
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
MA	May Affect
MC	Monte Carlo
NASS	National Agricultural Statistics Service
NE	No Effect
NLAA	Not Likely to Adversely Affect
NLCD	National Land Cover Dataset
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NRC	National Research Council
PCT	Percent Crop Treated
PPHD	Prey, Pollination, Habitat and/or Dispersal
PWC	Pesticide in Water Calculator
SAP	Scientific Advisory Panel
SEP	Standard Operating Procedures
SIAB	Science Information and Analysis Branch

SSD	Species Sensitivity Distribution
SUUM	Summary Use and Usage Memo
TIM	Terrestrial Investigation Model
UDL	Use Data Layer
USDA	United States Department of Agriculture

Introduction

Section 7(a)(2) of the Endangered Species Act (ESA) and its implementing regulations at 50 CFR Part 402 directs federal agencies, in consultation with the Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) (collectively referred to as "the Services"), to ensure that the discretionary actions they authorize, fund and carry out are not likely to jeopardize federally listed threatened or endangered (listed) species or destroy or adversely modify designated critical habitat of such species. The action related to pesticide registrations subject to ESA consultation may include those in registration or registration review[1].

The EPA conducts a biological evaluation (BE) to assess effects of the action on listed species and designated critical habitat. Step 1 of the BE is focused on approved uses (as defined on product labels) of a specific pesticide active ingredient, where the registration of the assessed pesticide's product labels is considered the action. The BE determines whether the registered uses of a pesticide active ingredient 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. For those species and critical habitat that EPA determines may be affected by the action, Step 2 of the BE also includes EPA's determination whether the action:

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

Formal consultation is triggered by a 'may affect' determination, unless the Services (responsible for the assessed species) concurs in writing with an action agency's determination that the action is NLAA. Otherwise, the action agency must engage in formal consultation to which the Services will respond with their biological opinion (BO) addressing the likelihood of jeopardy of the species and adverse modification of designated critical habitat and establishing what, if any, reasonable and prudent alternatives or measures are available for engaging in the action in a manner that avoids jeopardy or adverse modification. Action agencies must use their existing authorities to meet the substantive requirements of the ESA. For EPA's actions involving pesticides, the existing authority is the Federal Insecticide Fungicide Rodenticide Act (FIFRA).

EPA is using an iterative process for developing methods and conducting national-level BEs. In this approach, EPA has developed methods to inform and advance the development of national level BEs. The first approach was developed in 2015 and is referred to as the Interim Method,[2] which were applied

[1] At this time, EPA is not using the Revised Method for new pesticide use registration BEs for crops that are genetically modified to be tolerant to the assessed pesticide. Instead, consistent with the 2014 and 2019 Reports to Congress, EPA is using the 2004 Overview Document for these new use BEs. Cited documents available online at: https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf; https://www.epa.gov/sites/production/files/2020-01/documents/esa-report-12.20.19.pdf and https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf.

[2] https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf

to the first three national-level BEs (for chlorpyrifos, diazinon and malathion).[3] The document describing the Interim Method was general, and the first three pilot BEs included details regarding application of the Interim Method to those BEs. The Revised Method described in this document incorporates: recommendations from the National Research Council (NRC);[4] EPA's "lessons learned" during the first three pilot BEs; public comments provided through stakeholder meetings, through the docket on the draft BEs for chlorpyrifos, diazinon and malathion, and through the docket on the proposed Revised Method;[5] comments received during consultation with federally recognized tribes; and comments provided by FWS, NMFS and the US Department of Agriculture (USDA). Based on the aforementioned input, EPA notes the following major differences between the proposed (May 2019) and the final (March 2020) Revised Method. In the final (March 2020) Revised Method:

- The action area is based on pesticide use information (potential use sites from the pesticide labels) and the analysis in Step 1 does not incorporate usage data. Instead, the usage data is first incorporated as part of the Step 2 analysis framework;
- EPA will make NLAA (instead of NE) determinations for species that are considered extinct, have <1% overlap of range/critical habitat and the action area, or that have incomplete exposure pathways. These species will be included in informal consultation with the Services;
- EPA is working with the Services to identify species that are believed to be extinct;
- The requirement for a quantitative link between sublethal endpoints and "apical endpoints" (*i.e.,* survival, growth and reproduction) has been removed. In addition to apical endpoints, EPA will consider relevant sublethal endpoints strongly linked to apical endpoints;
- Additional details were provided to describe the Weight of Evidence and probabilistic methods;
- Uncertainties are described, along with assumptions made to address uncertainties and their directional implications for risk assessment;
- Species inhabiting federal lands are no longer considered in Step 1, but rather in the Weight of Evidence of Step 2.

On August 27, 2019, the Services published a final rule revising the regulations governing interagency cooperation (consultation) at Title 50, part 402, of the Code of Federal Regulations (see 84 FR 444976). Among other things, the final rule clarified definitions of the "effects of the action" and "environmental baseline;" clarified what is necessary for initiation of formal consultation and the analytical steps taken by the Services during consultation; and clarified the use of the phrase "activities reasonably certain to occur." The revised definition of "effects of action" clarifies that those effects include: "all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are cause by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur." (See 50 CFR 402.02). Activities that are reasonably certain to occur and consequences caused by the proposed action are further described at 50 CFR 402.17. The EPA will work with the Services to implement these Revised Methods in a manner consistent with the revised regulations.

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[3] 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

[4] 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.

[5] EPA released the proposed Revised Method for public comment in May 2019. The proposed Revised Method and submitted comments are available online at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0185

The Revised Method is intended to produce both a sustainable and scientifically sound risk assessment process to prepare pesticide BEs and to identify species that may be affected by the subject pesticide. The Revised Method for conducting BEs are not a regulation and, therefore, do not add, eliminate or change any existing regulatory requirements. This guidance is not binding on either EPA or any outside party, and the EPA may depart from the guidance on a case-by-case basis where circumstances warrant without prior notice. BEs conducted with the Revised Method will apply the methods described in this document, as appropriate, given the properties, uses, and usage of each assessed pesticide active ingredient. The BE process remains an iterative process. The methods applied to BEs will continue to evolve as EPA gains experience and as scientific methods and data improve. The EPA is applying a "day forward approach," by applying methods and available data to pesticide specific reviews relevant to the time when they are conducted. As new assessments on different pesticides are conducted, EPA will apply current methods and best available data. As the Revised Method evolves and is applied to BEs, EPA will continue discussions with the Services and USDA on the methods and how they are applied in specific BEs.

Overview of Revised Method

Three Step Process

As recommended by the NRC, the Interim Method 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[6] (**Table 1; Figure 1**) under Section 7 of the Endangered Species Act. The Revised Method includes this three-step process. Steps 1 and 2 are represented by the BE, which evaluates whether and how listed species and critical habitat are likely to be adversely affected by the proposed action, consistent with the regulations at 50 CFR Part 402. 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 relevant to Step 2.

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	Individual and field	Individual and field/landscape/watershed[1]	Population and landscape/watershed
Determination	No Effect/May Affect	Not Likely to Adversely Affect/Likely to Adversely Affect	No Jeopardy/Jeopardy[2]

[1] Although Step 2 is conducted at an individual level, consideration is given to the likelihood that an exposure and effect will occur. This step considers the proportion of a population exposed across the landscape/watershed and the distribution of exposures among individuals.
[2] This is the determination for listed species. The determination for designated critical habitats is "No Adverse Modification/Adverse Modification".

[6] These assessments will also consider those species that are currently proposed or candidates for listing and experimental populations.

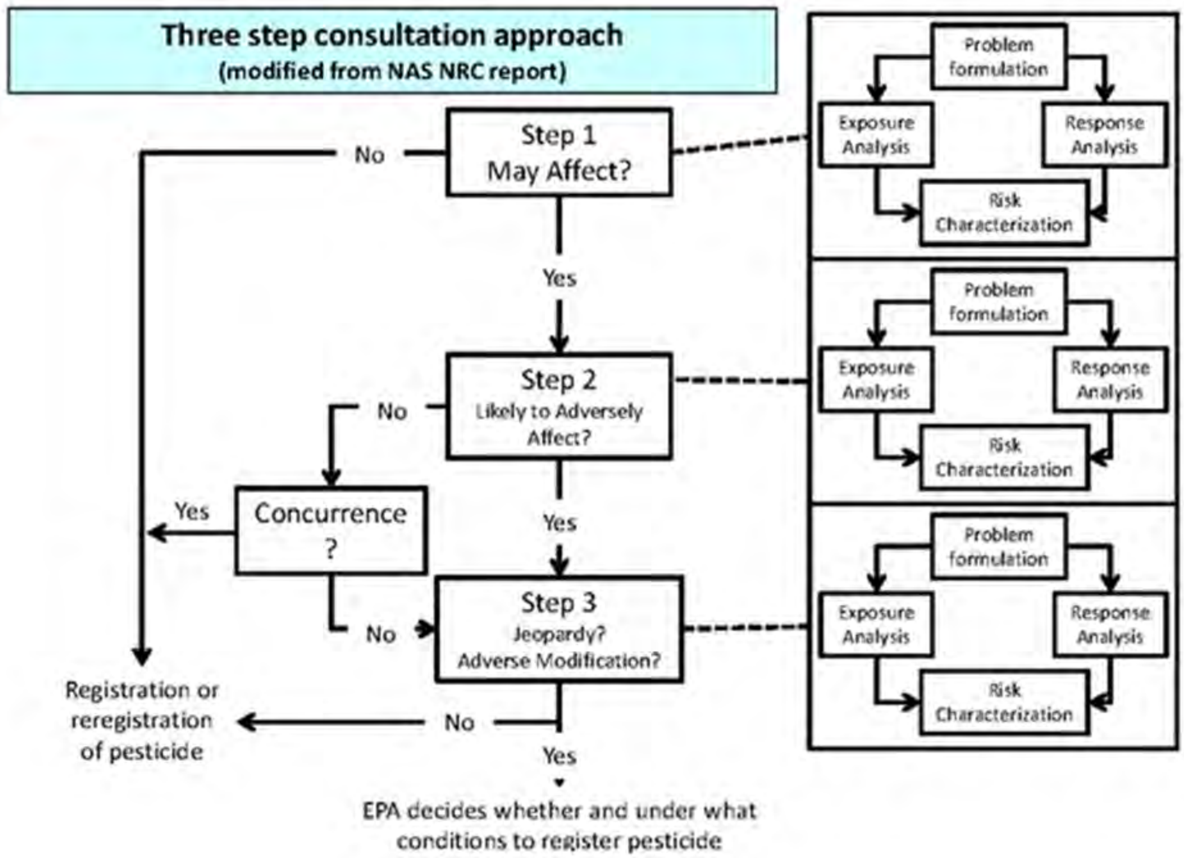

Figure 1. Three Step Section 7 Endangered Species Act Consultation Approach Based on a Figure in the National Academies of Science National Resource Council (2013) Report[7].

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 listed species' population. The scale of Step 3 is the landscape that represents the range of the listed species (also considered in Step 2). The BE informs the Services' BO. For listed species of which a pesticide is LAA for at least one individual, this analysis is structured to inform the BO, with appropriate modifications to account for population-level, landscape-scale assessments. Since this Revised Method document pertains to the BE, the approach presented here describes the processes for conducting Steps 1 and 2.

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 EPA's guidelines for ecological risk assessment (EPA 1998[8]). 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 pesticide being assessed is potentially used) with species range/designated critical

[7] 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

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

habitat. It uses conservative assumptions and is intended to screen out species that are not reasonably expected to be exposed (because they are outside of the action area) and no effect is expected. Step 2 uses a more refined spatial overlap (with specific pesticide use sites) to calculate the portion of the population exposed, considers life history information, 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 and to identify 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 in Step 3. The assessment methods for use by the EPA in the BEs for Steps 1 and 2 are described below.

Effects Determinations

Step 1 identifies which species and designated critical habitats are expected to be affected by the assessed pesticide at the individual level (warranting a "may affect" determination), and which species would not be affected by the pesticide (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. An 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 "completely beneficial."[9] These terms are defined by the Services as follows:

- Insignificant = based on best professional judgement, a person would not be able to meaningfully measure, detect, or evaluate insignificant effects. Insignificant effects should never reach the level where take[10] occurs.
- Discountable = those effects that are extremely unlikely to occur. Based on best professional 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 discernible, measurable, observable, and likely to occur. An LAA 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. LAA determinations are made when an effect from an exposure that is reasonably certain to occur is discernable and adverse. NLAA determinations by the EPA require concurrence from the Services. In cases where a species determination is LAA, formal consultation occurs and a Step 3 (population level, landscape scale) analysis is conducted by the Services, concluding in a BO. When an analysis leads to an NLAA determination with the Services' concurrence, no additional analysis is conducted for a species.

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[9] 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).

[10] 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)

Data to be used in Biological Evaluations

When developing a BE, the EPA will use the best available scientific and commercial data from a variety of sources, as required by the Endangered Species Act. This does not require EPA to conduct new studies and should not be read as requiring the best scientific data possible. Regarding the assessed pesticide, data are needed to describe the use, usage, fate and effects on organisms. For listed species, it is also necessary to understand the range, taxonomy and life history.

All spatial data, such as use sites and species location (*i.e.,* ranges and critical habitat) are projected into representative coordinate systems, selected to preserve area calculations. Seven representative projected coordinate systems are used, each one specific to the different regions under U.S jurisdictions. These regions include the contiguous United States (ConUS), Alaska (AK), Hawaii (HI), Puerto Rico (PR), United States Virgin Islands (VI), American Samoa (AS), Guam (GU), and the Commonwealth of the Northern Mariana Islands (CNMI). Each region has a unique representative projection with the exception of Guam and the Commonwealth of the Northern Mariana Islands that share the same projection.

At the time an BE is conducted, EPA will use the most up-to-date data that has been collected and processed. Each BE will identify the dates of the data sources so that they are reproducible. Specific data used in pesticide specific BEs (*e.g.,* spatial data, species life history, pesticide usage data) will be cited and summarized in the BEs. All data sources will be updated by EPA as needed for BEs.

Use and Usage Data

This document incorporates two distinct terms: pesticide "use" and "usage." Use data are based on registered labels and define crop or non-crop use sites to which a pesticide may be applied, along with the maximum application rates, method (*e.g.,* aerial or ground spray), re-treatment intervals and number of applications that may occur according to the labels. Step 1 relies entirely on use data. 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. The analysis in Step 2 incorporates both use and usage data.

As discussed below, potential pesticide use site layers, referred to as Use Data Layers (UDLs), represent the potential application sites for agricultural and non-agricultural uses. The spatial data used to generate these layers represent the best available landcover and land use data sets in the contiguous United States (ConUS) and the non-contiguous states and territories. Data sources representing the spatial footprints of potential use sites include USDA's Crop Data Layer (CDL)[11], US Geological Survey's

[11] 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.

National and Cover Dataset (NLCD)[12], USDA's Census of Agriculture[13], NOAA's C-CAPP[14] and others that may be relevant to the registered uses of the assessed pesticide. The Use Site Generation tool, version 2.1, was created by the EPA to assist develop the UDLs and Action Areas.

EPA obtains usage data from California's Pesticide Use Reporting database[15], USDA's National Agricultural Statistics Service (NASS)[16], The AgroTrak® Study from Kynetec USA[17], Inc., various market research reports from Kline and Company[18], other proprietary, commercial agricultural and non-agricultural data sources, and other federal agencies. Data may be obtained from other reliable sources, if applicable to a given pesticide.

Listed Species

Each BE will consider the current set of federally listed endangered and threatened species, as well as experimental populations and those species that are proposed and candidates for listing[19]. The BEs will also consider the current set of designated critical habitats. The Services provide data on listed species, as they are the experts on listed species range and biology, and thus represent the source of best available data on listed species. The Services provided spatial range and critical habitat data for each currently listed species and for experimental, candidate and proposed species. Those data are periodically updated in the Environmental Conservation Online System (ECOS)[20]. These species location files are needed to run the co-occurrence analysis, described below. Species locations files are standardized for projection, attributes including date updated, and formatted using the Processed GIS Data-Listed Species tool, version 1.1. The species input files used to in the co-occurrence analysis are generated from the processed files with the Co-occurrence Inputs tool, version 1.1.

EPA has also compiled life history information for each listed and candidate and proposed species included in a given assessment. Those data are collected from the Services documents for specific species (*e.g.,* listing decisions, 5-year reviews).

The Step 1 and Step 2 analyses both rely upon the best available estimate of a species' population size. The availability and quality of information on population size varies greatly among species. In this approach, the greater a population size, the lower the threshold (*i.e.*, a larger population number yields a more conservative approach). Therefore, to err on the side of the species, population estimates are rounded up to the next digit (*e.g.*, if the population size is 90, the value is represented as 100). If the

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[12] 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

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

[14] National Oceanic and Atmospheric Administration, Coastal Services Center. 1995-present. The Coastal Change Analysis Program (C-CAP) Regional Land Cover. Charleston, SC: NOAA Coastal Services Center. Accessed at https://coast.noaa.gov/digitalcoast/data/ccapregional.html

[15] Data may be accessed at https://calpip.cdpr.ca.gov/main.cfm

[16] Data may be accessed at https://www.nass.usda.gov/

[17] https://www.kynetec.com/solutions/agriculture

[18] https://www.klinegroup.com/market-research/research-agrochemicals-specialty-pesticides/

[19] https://ecos.fws.gov/ecp/species-query

[20] https://ecos.fws.gov/ecp/services

population size is not known, a conservative estimate of the population will be made based on available data for other species within the same taxon. **Table 2** represents the low – high range of population values for listed species for which data are available. The high-end range will be used in Step 1 when no population estimate is available for a given species. The low- and-high end range will both be used in the Weight of Evidence discussed below in Step 2.

Table 2. Estimated range of population sizes by taxon for listed species when no species-specific quantitative estimate is available. Ranges based on population sizes for listed species within the taxon where data are available.

Taxon	Low	High
Amphibians	100	10,000
Aquatic Invertebrates	1,000	100,000
Birds	100	10,000
Fish	100	10,000
Mammals	100	10,000
Plants	10	10,000
Reptiles	1,000	100,000
Terrestrial Invertebrates	1,000	100,000

Toxicity

Registrants submit data on the toxicity of a pesticide. EPA identifies data available in the open literature in the ECOTOX database[21]. EPA reviews toxicity data from registrant submissions and the open literature[22]. The toxicity values, or thresholds, will be based on those available from guideline studies classified as Acceptable or Supplemental (Quantitative) submitted to the EPA by registrants or from similarly classified open literature studies identified through the ECOTOX database. As part of the BE, EPA will evaluate whether environmental degradates are of concern using available empirical toxicity data and estimates of toxicity if necessary, from the ECOSAR model[23].

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 are strongly linked to apical endpoints. The decision to include a non-apical endpoint for a given species and chemical will be based on the best professional judgement of the risk assessor. Consistent with the recommendations of NRC, EPA is primarily 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 relevant sublethal endpoint to consider under this framework. The reproductive and growth effects that will be considered in the BE are the same as those 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 abnormalities, time to hatch, time to swim-up, pathological and histological observations,

[21] For additional information on ECOTOX see: https://cfpub.epa.gov/ecotox/
[22] 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
[23] https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model

lactation performance, and development of secondary sexual characteristics. Additional sublethal effects will be considered if they are strongly linked to survival, growth or reproduction. One way to apply this approach is through the use of a quantitative adverse outcome pathway[24], where effects at lower levels of organization (*e.g.,* biochemical) are linked to effects on survival, growth or reproduction. In this approach, the relationship between the magnitude change in the non-apical endpoint and the magnitude change in the apical (survival, growth or reproduction) endpoint would need to be established.

The reliance on endpoints representing survival, growth or reproduction (including sublethal endpoints that are strongly linked to survival, growth or reproduction) is different from what was done in the Interim Method for the first three BEs. The Revised Method is consistent with the need to identify effects that are reasonably certain to occur, as it is unknown whether organisms have compensatory mechanisms to prevent effects at lower levels of biological organization from manifesting in impacts to the individual. 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 include information on other sublethal endpoints (*e.g.*, changes to behavior or enzyme levels) for consideration by the Services. All endpoints (and their citations) 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. Due to the reasons discussed above, sublethal effects beyond reproductive and growth effects that are not clearly and strongly linked with survival and fecundity will not be considered in the BE analyses.

The mortality threshold is 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; note that the larger the population size, the lower the numerical threshold for mortality). The threshold for sublethal effects in animals and plants will be based on the lowest of the available no-observed adverse effect concentration or level (NOAEC/NOAEL) values for growth or reproduction (or other endpoint linked to survival or reproduction) with a corresponding LOAEC or LOAEL available for the taxon being assessed. **Table 3** summarizes the toxicity endpoints used for assessing effects in Step 1, as well as Step 2.

If sufficient toxicity endpoints are available for the same taxon and endpoint (*e.g.,* 96-h LC50 values for fish), a species sensitivity distribution (SSD) will be derived for that taxon and endpoint. Available toxicity data will be standardized as much as possible to remove variability that is not attributed to the species. The distribution with the best fit will be determined using the SSD toolbox[25].

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

[24] G.T. Ankley, R.S. Bennett, R.J. Erickson, D.J. Hoff, M.W. Hornung, R.D. Johnson, D.R. Mount, J.W. Nichols, C.L. Russom, P.K. Schmieder, P.K. Serrano, J.E. Tietge, D.L. Villeneuve. Adverse outcome pathways: a conceptual framework to support ecotoxicology research and risk assessment
Environ. Toxicol. Chem., 29 (2010), pp. 730-741

[25] http://www.epa.gov/chemical-research/species-sensitivity-distribution-toolbox

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 (discussed below). EPA has developed this method consistent with the ESA Section 7 regulations that require action agencies to consider 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 species with the smaller population would have fewer individuals impacted than the species with a larger population. In order to provide a greater level of protection for more critically endangered species, additional conservative considerations are incorporated into the final effects determinations for species with population sizes ≤100 individuals (additional details provided below).

When considering effects to a listed species that relies on animals (*i.e.,* for prey, pollination, habitat and/or dispersal), effects will be focused on mortality, growth or reproduction endpoints for the taxa relied upon. When considering the three types of endpoints, the most sensitive of the endpoints for a given taxon is used (considering the adjustment factors for mortality). For generalists, the mortality 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). In Step 1, the specific threshold for potential 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 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 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 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 effects when the ratio of the estimated concentration/mortality endpoint ≥0.1). In general terms, for listed species that are generalists, the effects threshold will represent roughly <10% decline in available prey. For species with obligate relationships, <0.1% mortality is expected in prey. For species with obligate relationships, the growth and reproduction endpoints are represented by the NOAEC or NOAEL. For species with general dependency upon a taxon for prey, pollination, habitat and/or dispersal (PPHD), but no obligate relationships, the LOAEC or LOAEL represent growth and reproduction thresholds. For sublethal effects, the threshold is equivalent to the endpoint (*i.e.,* factors of 0.1 and 0.5 are not applied).

Effects to a listed species depending upon plants (*e.g.*, for diet, habitat) is focused on plant growth. For habitat and plants eaten as dietary items, for generalists, the 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 could be 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 protective of listed species. A 50% change in plant growth or injury and a 25% detrimental effect, respectively, are the points at which plants will not generally recover to their full aesthetic value, economic value, or reproductive potential, as in the case of the maintenance of listed species[26,27]. 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 plants. For obligates, similar to the endpoints used to represent toxicity of a pesticide on listed species, the NOAEC associated with the lowest LOAEC for effects to plants will be used to address the potential for effects to PPHD. As discussed above, a more sensitive endpoint is chosen for obligate relationships to decrease the likelihood for failing to detect an effect. If sufficient plant toxicity data are available, SSDs may also be generated. **Table 3** summarizes the toxicity endpoints used for assessing effects in Steps 1 and 2.

EPA's Office of Water develops aquatic life criteria to represent acute and chronic thresholds for aquatic communities (fish, invertebrates and plants). If an aquatic life criterion is available for an assessed pesticide, the criterion will be characterized in the BE and discussed in the context of the relevant endpoints used for aquatic taxa (**Table 3**).

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 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.

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

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

Table 3. Description of toxicity endpoints used for Step 1 and 2 analyses. Many of these endpoints are from studies conducted following guideline toxicity studies[28]. As described in the text, mortality endpoints are used to calculate threshold values for listed species and taxa relevant to their PPHD.

Taxon	Exposure route(s)	Units of toxicity endpoints	Effects to listed species		Effects to Prey, Pollination, Habitat and/or Dispersal	
			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) • NOAEC/NOAEL (for growth or reproduction	• LD_{50}/LC_{50} or 5th percentile LD_{50}/LC_{50} from SSD (if available) • LOAEC/LOAEL (for growth or reproduction
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.
+If a suitable NOAEC is not available for the most sensitive test species, an ECx value may be used instead to represent the level where no effects are detected.
++If sufficient toxicity data are available (*e.g.,* for an herbicide), a SSD may be developed using terrestrial plant toxicity data.

[28] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines

Exposure

EPA created two tools to complete the spatial co-occurrences analysis between species location and the action areas/UDLs; the Chemical Independent Co-occurrence Result, version 1.1 and the Chemical Dependent Co-occurrence Results-MAGtool Tables, version 1.1. The chemical Independent Co-occurrence Results tool leverages the ESRI ArcGIS Tabulate Area tool, executed as a batch to determine the percent overlap of each UDL and action area with each species range and critical habitat. The Chemical Dependent Co-occurrence Results-MAGtool Tables tool generates the standard output tables summarized by UDL and species used in the BE by the MAGtool. This tool generates five different overlap scenarios that incorporate usage and species life history information into the co-occurrence results. The first scenario represents the unadjusted or chemical independent overlap, the 2nd and 3rd incorporates the chemical specific usage information and accounts for the redundancy in the UDL layers, and the 4th and 5th incorporates species life history information. These different overlap scenarios are used in Step 2 by the MAGtool in the calculation of the numbers of individuals exposed.

The Magnitude of Effect tool (MAGtool), version 2.1, was created by the EPA to assist in the determination of the magnitude of the effect of potential pesticide use. The output of the tool provides an estimate of the numbers of individuals of a given listed species (based on a specific population size and assuming that individuals are uniformly distributed in their range) which are potentially impacted due to mortality losses or adverse sublethal effects. Additionally, the number of individuals of the listed species impacted due to losses in their taxa representing their PPHD is predicted. The MAGtool combines toxicological information, species traits, exposure analysis and spatial results into one tool. It generates output on the number of individuals potentially impacted for species or critical habitat under different scenarios including variations in assumptions related to exposure, extent of pesticide usage on a crop, and extent of pesticide usage for the species.

Population and life history information that is incorporated into the MAGtool, including population size estimates, were obtained from FWS and NMFS documentation (described in **ATTACHMENTS 1-11 to 1-21** of the Chlorpyrifos, Diazinon and Malathion BEs[29]). As discussed below, the MAGtool uses EPA's standard models for assessing exposure to animals and plants located in terrestrial and aquatic habitats. Additional discussion of the MAGtool is included with the model documentation.[30]

Registrants submit data on the physical, chemical, fate and transport properties of a pesticide. Data available in the open literature may also be considered. These data are used to parameterize fate and transport models for estimating exposures in terrestrial and aquatic habitats relevant to listed species.

The sections below summarize models used to estimate exposures to organisms in terrestrial and aquatic habitats. Exposure estimates from these models are incorporated into the MAGtool. Over time, EPA expects to update the MAGtool and other models and tools described in this document. When a pesticide BE is conducted, it will incorporate the most current versions of models and tools intended for use in the BEs.

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[29] https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and

[30] https://www.epa.gov/endangered-species/models-and-tools-endangered-species-pesticide-assessments

Terrestrial Habitats

In the terrestrial environment, exposure is estimated for animals located on the treated area as well as on non-target areas adjacent to the treated area. Pesticide exposure to animals is quantified based on direct applications and spray drift transport. Measures of exposure are based on models that predict estimated exposure concentrations (EECs) using maximum labeled application rates and methods. In the Environmental Fate and Effects Division's (EFED) standard ecological risk assessment, the models used to predict EECs on food items of animals are T-REX (terrestrial plants and arthropods), T-HERPS and KABAM (aquatic plants, invertebrates and fish). Equations derived using deposition estimates from AgDRIFT are used to estimate spray drift deposition away from the treated area. These equations are parameterized using relevant reviewed environmental fate data and product labels. Supporting documentation for each model is available online at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.

Because the diets of listed species include food items that are not included in the current versions of T-REX (version 1.5.2) and KABAM (version 1.0), additional approaches were used that account for potential exposures through diet. These approaches rely upon established EPA models. For example, animals that consume mammals and birds were evaluated using an approach described for the T-HERPS tool[31] expanded to apply to birds and mammals. The earthworm fugacity model was used for species that consume soil-dwelling invertebrates.

In addition to dietary exposures, other routes will be considered for vertebrate animals, including consumption of contaminated drinking water, dermal contact or direct spray, and inhalation of volatilized residues or spray droplets. These methods are based on those used by the Terrestrial Investigation Model (TIM) and presented to the FIFRA Scientific Advisory Panel (SAP) in 2001 and 2004. For assessing effects to listed terrestrial invertebrates and effects to listed species that consume invertebrates (*i.e.,* terrestrial invertebrates represent prey of the listed species being assessed), a modified version of T-REX is used. This method is loosely based on the exposure method for bees that was developed by EPA, Canada's Pest Management Regulatory Agency (PMRA) and California's Department of Pesticide Regulation (CADPR) in 2012[32]. In this approach, dietary-based and contact-based exposures are assessed. For plants, exposure is assessed for areas adjacent to the treated area that receive spray drift and runoff from the treated area. The model used to derive runoff EECs relevant to terrestrial and wetland plants is TerrPlant. AgDRIFT equations are also used to estimate spray drift deposition away from the treated area.

Aquatic Habitats

The Pesticide in Water Calculator[33] (version 1.52) is used to estimate exposure in surface water. Nine generic habitat types are assessed (**Table 4**): three to simulate flowing waterbodies (Bins 2-4); three to simulate static waterbodies (Bins 5-7) and three to simulate estuarine/marine habitats (Bins 8-10). The habitats vary in depth, volume, and flow. Aquatic-associated terrestrial habitats (Bin 1) include riparian

[31] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-herps-version-10-users-guide-risk-amphibians-and
[32] https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf
[33] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic

habitats or other land-based habitats adjacent to waterbodies that may occasionally be inundated with surface water, provide habitat used by aquatic organisms and semi aquatic organisms, or influence the quality of the aquatic habitats. This habitat is not modeled explicitly using PWC. Each listed species assessed is assigned to the appropriate bin, based on habitat requirements. The daily average (*e.g.*, 1-in-15 year return frequency annual daily average EECs) and chronic (1-in-15 year return frequency annual 21-day and 60-day average EECs) for the different HUC 2 regions are estimated for the various use rates specified on the labels using the PWC, the appropriate scenario, and the associated aquatic bins (see **Table 4**). EPA currently lacks tools to model concentrations in tidal and marine environments. Generally, estimates developed for aquatic Bin 2 are used as surrogate exposure levels for intertidal nearshore waterbodies (Bin 8), and estimates developed using aquatic Bin 3 are used as surrogate exposure levels for subtidal nearshore waterbodies (Bin 9). Additionally, aquatic Bin 5 is used as a surrogate for tidal pools occurring during low tide (aquatic Bin 8). In each of these cases, other life history considerations may influence the surrogate bin assignments to vary by species.

Table 4. Generic Aquatic Habitats (bins).

Generic Habitat (bin #)	Depth (meters)	Width (meters)	Length (meters)	Flow (m^3/second)
Aquatic-associated terrestrial habitats (1)	NA	NA	NA	NA
Low-flow (2)	0.1	2	length of treated area	0.001
Moderate-flow (3)	1	8	length of treated area	1
High-flow (4)	2	40	length of treated area	100
Low-volume (5)	0.1	1	1	0
Moderate-volume (6)	1	10	10	0
High-volume (7)	2	100	100	0
Intertidal nearshore (8)	0.5	50	Length of treated area	NA
Subtidal nearshore (9)	5	200	Length of treated area	NA
Offshore marine (10)	200	300	Length of treated area	NA

length of treated area – The habitat being evaluated is the reach or segment that abuts or is immediately adjacent to the treated area. The habitat is assumed to run the entire length of the treated area.
NA = not applicable

Based on comments received on the modeling during the previous BEs, EFED will estimate EECs for various bins using two standard waterbodies that have been traditionally used. The standard farm pond is used to develop EECs for the medium and large static bins (*e.g.*, bins 6 and 7) and the index reservoir for the medium and large flowing bins (*e.g.*, bins 3 and 4). For the smallest flowing and static bins (bin 2 and 5), EFED will derive edge of field (treated area) exposure estimates, using the PWC edge of field calculator tool and the PRZM daily runoff file (*e.g.*, ZTS file). Aquatic EECs are summarized by species using the PWC postprocessor. Aquatic tools can be found under the ESA tools website.[34] Aquatic EECs resulting from spray drift only are estimated using the same equations derived from AgDRIFT and the original waterbody dimensions for the 6 aquatic bins.

Downstream transport

While downstream transport of a pesticide released into surface waters can occur, EPA does not currently have a quantitative tool to accurately account for the advection, dispersion, and dilution

[34] https://www.epa.gov/endangered-species/models-and-tools-endangered-species-pesticide-assessments

expected to occur as the pesticide mass moves downstream. Previous BEs assessed downstream effects by employing a screening approach, implemented using the Downstream Dilution tool; however, the tool was considered provisional (*i.e.,* it was not fully vetted; it was not 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[35]. Office of Pesticide Programs has also consulted with representatives at the Office of Water and the U.S. Geological Service for information on tools that may be available to predict downstream concentrations but was not able to identify any models that could be used to evaluate pesticide applications. Therefore, downstream transport will be assessed using a transparent qualitative approach.

In place of the Downstream Dilution tool, EPA will qualitatively evaluate the potential for downstream exposures to listed species associated with the medium and high-flowing bins. This evaluation will consider potential pesticide use in areas that are upstream and outside of the action area, as a pesticide may be transported from upstream locations where usage occurs. EPA will use ARCGIS and NHDPlus to evaluate monitoring data relevant to the assessed species to determine if any detections of the pesticide had occurred upstream or in the range or critical habitat. In Step 1 and in Step 2, if there are detections upstream, the available monitoring data will be considered in the determination for the species. If the determination is LAA, the monitoring data will be used to characterize the weight of evidence. EPA will continue to research modelling options to address downstream transport in a more quantitative way.

[35] https://www3.epa.gov/pesticides/nas/final/diazinon/appendix-3-5.docx

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

This section provides details on the process involved in Step 1. **Figure 2** depicts the decision tree that represents the Step 1 method, by which EPA makes its effects determinations of either "no effect" (NE) or "may affect" (MA). This process is carried out one species at a time for the assessed pesticide. The same process is used for each designated critical habitat. Details on each part (*i.e.,* 1a-1c) of Step 1 are provided below.

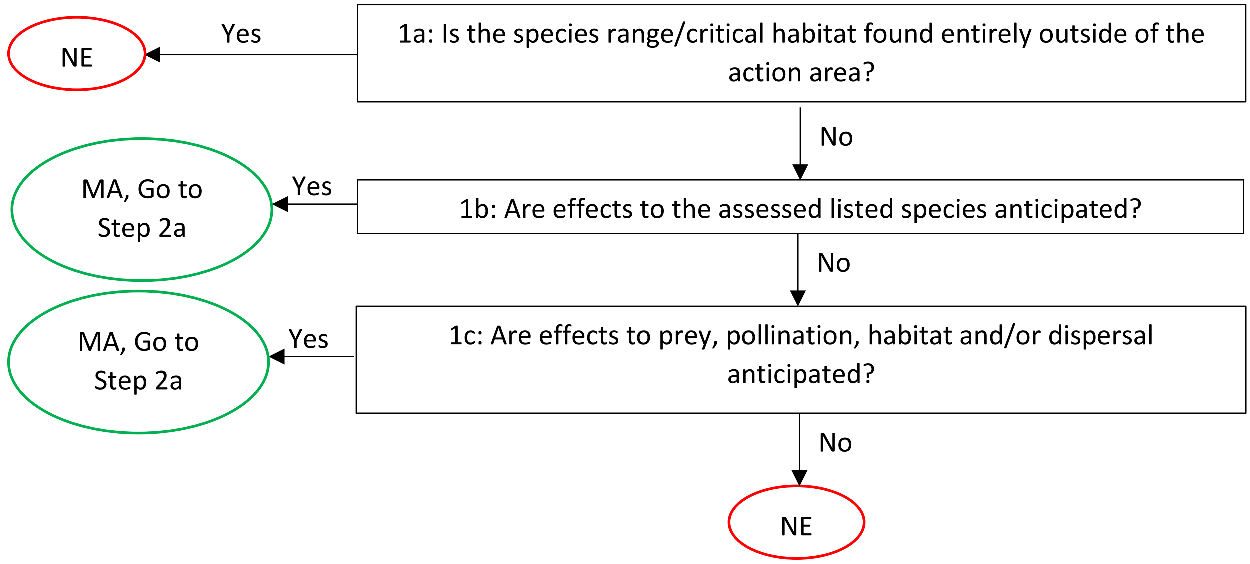

Figure 2. Step 1 framework for making No Effect (NE) and May Affect (MA) determinations. Species with NE determination do not require additional analysis (red ovals indicate stop). Species with MA determinations proceed to Step 2 (green ovals indicate proceed).

1a: Is the species range/critical habitat found entirely outside of the action area?

In this approach, if the species range or critical habitat is located entirely outside of the action area, a NE determination is made. An overlap analysis is conducted to determine the percent overlap of the species range/designated critical habitat with the spatially defined action area[36] (**Figure 3**[37]). 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" (See 50 C.F.R. § 402.02). This is the composite of all the areas where the pesticide 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 sites (based on the approved uses on pesticide product labels) that can be mapped spatially in the US and its territories, as

[36] The spatially defined action area is composed of use site that can be spatially mapped and reliably represent potential use sites that are approved on pesticide product labels. These use sites are from the best available data.
[37] **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 at the same 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.

well as the areas that potentially receive off-site transport from spray drift at exposure levels that are of toxicological concern (based on conservative exposure assumptions). Additional details are provided below on the relevant components of the action area (*i.e.,* the potential use sites and calculation of off-site transport zone). The source of the species range and critical habitat data is discussed above.

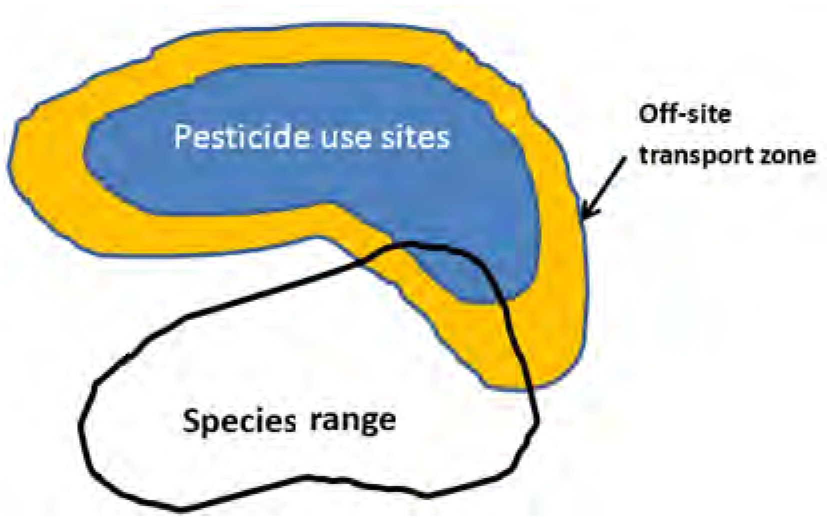

Figure 3. Listed Species Range and action area (*i.e*., Pesticide Use Site Plus Off-site Transport Zone) Overlap

Identifying pesticide use sites

At the beginning of Step 1, pesticide labels for an assessed pesticide active ingredient are reviewed, and a list of registered uses is compiled. Because use of a pesticide product that is inconsistent with the labeling is illegal, and EPA believes that users follow the label, the BE analysis does not include assumptions of misuse in the action being considered. The locations of potential pesticide use sites are defined with spatial data matched to uses defined on approved labels for the assessed pesticide. Spatial data for locations of potential use sites are obtained from numerous sources, with different sources providing data for different uses and locations. Agricultural crop uses in the ConUS are represented by an aggregated dataset based on the Cropland Data Layer (CDL), produced by the United States Department of Agriculture (USDA). The CDL is a land cover dataset that has over 100 cultivated crop classes. The spatial layer uses satellite imagery, which can be difficult to interpret. Therefore, EPA groups the individual CDL layers into 13 categories,[38] 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. 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 land cover represents the intended crops (*e.g.,* vegetable and ground fruits). This process uses the CDL error matrices from USDA to determine whether the accuracy can be improved with aggregation of crops typically confused with each other, reducing the uncertainty of the spatial footprints[39]. Multiple years of these UDLs are then

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[38] 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.
[39] Available on the USDA NASS CDL site in the FAQ section at https://www.nass.usda.gov/Research_and_Science/Cropland/sarsfaqs2.php#Section1_11.0

aggregated to further define locations where the crop could be grown across multiple years, then adjusted to meet or exceed the county-level NASS Census of Agriculture (CoA) acreage reports. 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 UDLs.

Non-crop uses (*e.g*., nurseries) on approved labels include a wide range of land cover and land use categories depending on the specific use. Each non-crop label use is considered and represented by the best available land cover or land use data. Initially, the National Land Cover Dataset (NLCD) is considered to represent non-crop label uses. When the NLCD is not appropriate for this purpose based on the specific uses being represented, 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 land cover class and would need to be mapped using a larger class (such as the "Developed" land cover class) which would significantly overestimate potential use sites. For these types of uses, for which EPA 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 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).

Prior to determining the action area, agricultural UDLs are masked based on the Census of Agriculture if no registered label use is grown in the county. These masked agricultural UDLs are combined with the non-crop UDLs to form the action area. The combined UDLs are then buffered for drift based on the process (see description in the next section, titled: off-site transport zone). Downstream transport due to runoff and spray drift is also discussed below.

Off-site transport zone

Toxicity thresholds and spray drift transport are used to determine how far effects to a listed species might extend from the edge of a use site. This considers registered pesticide label information describing use (*e.g.,* application rates and methods, label instructions for reducing spray drift) and current exposure models. The process for determining the spray drift transport area is described below.

In areas of overlap of the action area and an assessed species range, EPA assumes that taxa upon which a listed species is dependent may also be exposed. A listed species may be dependent upon other taxa for PPHD[40]. Taxa representing potential effects to PPHD for each listed species are selected based on life histories of the listed species (*e.g.*, declines in invertebrate prey will be used to assess effects to insectivores). The endpoint that results in the farthest distance from the treated field where any effect to the listed species or its PPHD may occur relative to a specific listed species will be used to determine the off-site transport distance for that species. This distance is capped at 2600 feet (the aerial limit of the AgDRIFT model; current version 2.1.1, December 2011) for several reasons discussed below.

[40] Sometimes commonly referred to as "indirect effects," which is different than the ESA definition of this term.

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[41]. EPA believes that spray drift deposition estimates and the limits of the AgDRIFT model are protective of listed species in considering downwind deposition and are the best available information to assess drift. The aerial deposition estimates are based on the maximum wind speed for a wind blowing perpendicular to the use sites in all directions. The estimates are derived for flat, bare-ground fields; therefore, canopy interception of the drift, either by the crop on the treated field or vegetation adjacent to the treated field, is not used to reduce the deposition estimates. Neutral stability conditions are employed, such that mixing is minimized and off-site transport maximized. Ground applications are modeled using empirically derived values using the high boom, very fine to fine drop size distribution, and values bounded by the 90th percentile of the data. Lastly, in both models, deposition estimates are based on 20 spray lines occurring perpendicular to the wind direction, sequentially adding to the 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.

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[42]), which generates estimated environmental concentrations (EECs) that may occur from various uses, typically at maximum use rates allowed on the label. The MAGtool incorporates AgDRIFT's deposition curves to assess exposures of terrestrial plants to pesticide deposited in terrestrial habitats by spray drift, simulating aerial and ground application, as well as spray blast applications to orchard crops. This area is represented by the farthest distance from a treated field based on endpoints for the species or its PPHD, which are included in **Table 3**. AgDRIFT's deposition curves are also used to estimate the amount of pesticide drift into adjacent waterbodies.

For broadcast applications that occur for non-crop uses, AgDRIFT's deposition curves and PWC are 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.

1b: Are effects to the assessed listed species anticipated? And, 1c: Are effects to prey, pollination, habitat and/or dispersal anticipated?

The purpose of these parts of Step 1 is to determine if a No Effect determination can logically be made for any species, based on the mode of action, estimated exposure and available toxicity data for the pesticide of interest. If the exposure of a pesticide is estimated to occur below levels where toxicity is observed in taxa relevant to an assessed species, then effects are not anticipated. For example, a pesticide that has no impact on plants at maximum application rates would not be expected to cause effects to plants. With this example, if the pesticide impacts some animals, there could be effects to listed plant species that rely upon animals (*e.g.*, for pollination, seed dispersal), so a NE determination may not be appropriate; however, for those listed plant species that do not depend upon animals, NE

[41] 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.
[42] 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

determinations may be made (because effects to the listed species or its PPHD would not be expected). To make this determination quantitatively, the Step 1 thresholds for the listed species and its PPHD (**Table 3**) are compared to the highest conservative EEC predicted for a species in the terrestrial or aquatic environment. As described above, the mortality thresholds represent the effect level relevant to an individual, accounting for the LD/LC50, slope and population size. If the EEC does not exceed an endpoint relevant to the assessed species, an NE determination can be made for that species.

For species or designated critical habitats that have an MA determination, a more refined analyses will be carried out in Step 2. The Step 2 methods are described in the next section.

Step 2 –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 Step 2 process, in which EPA makes 'likely to adversely affect' (LAA) or 'not likely to adversely affect' (NLAA) determinations for species and designated critical habitats with may affect determinations (from Step 1). Compared to Step 1, Step 2 includes more information and refinement to make a final effects determination. As discussed above, Step 1 reasonably relies upon 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. Many of Step 1's conservative assumptions (several are summarized in **Table 5**) are refined in Step 2, in part, by determining whether the consequence of the pesticide registration would not occur but for the proposed action and is reasonably certain to occur. A consequence or an activity must be clear and substantial for it to be considered reasonably certain to occur; it must be based on solid information. As discussed previously, adverse effects that are measurable, observable, and likely to occur to a species result in a LAA determination. Details on the Step 2 decision framework (**Figure 4**) are discussed below. Where possible, conservative assumptions (*e.g.,* population size) are used in Step 2, parts e, f and g because these parts are intended to screen out species where NLAA determinations can confidently be made with low effort. As EPA assesses a species through parts h and I of step 2, uncertainties and conservative assumptions are revisited, and EPA makes determinations based on the weight of the available evidence.

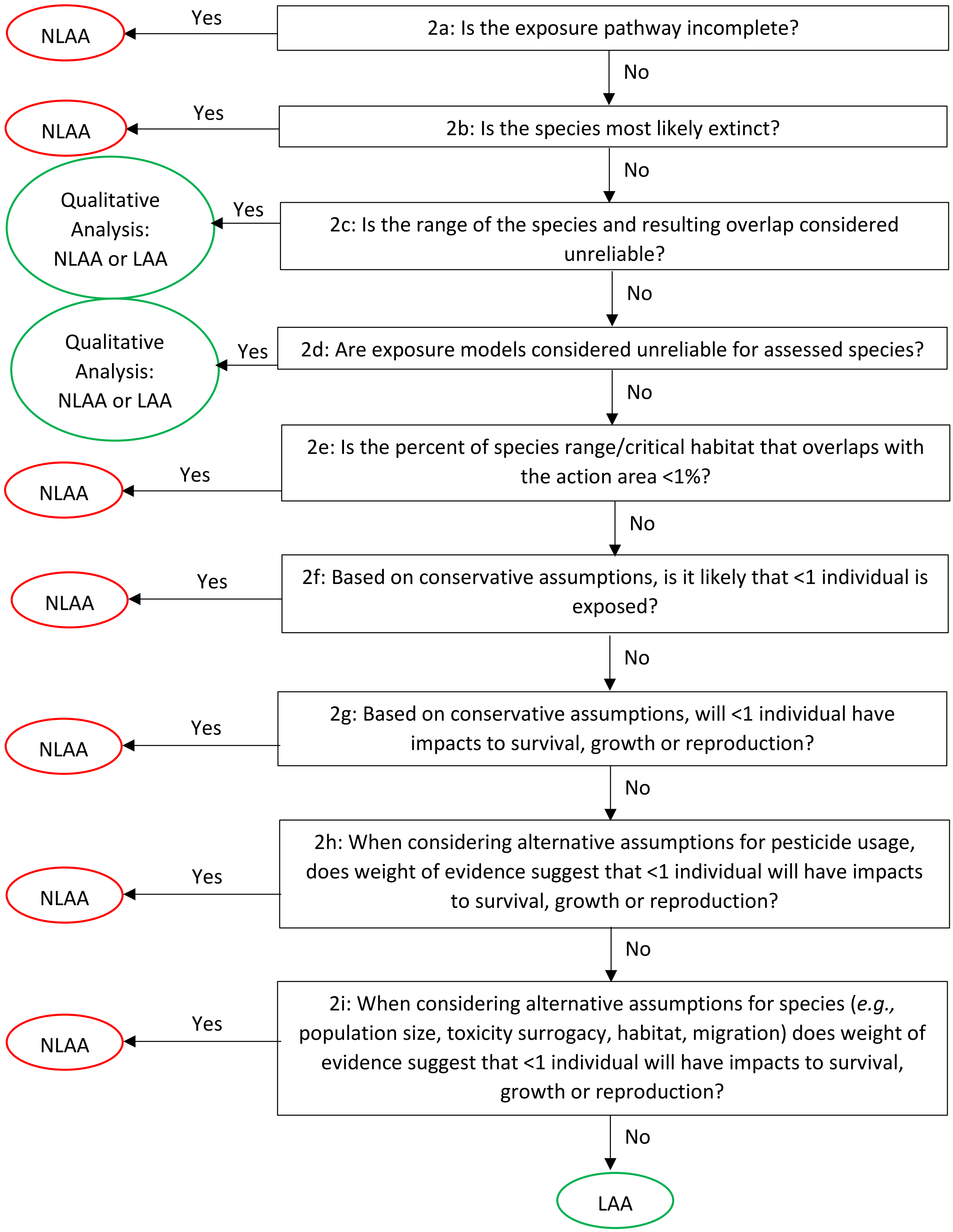

Figure 4. Step 2 framework for making Likely to Adversely Affect (LAA) and Not Likely to Adversely Affect (NLAA) determinations. Species with NLAA determinations do not require additional analysis (red ovals indicate stop at the part where the analysis concluded the determination was NLAA). Species with LAA determinations move on to Step 3 (green ovals indicate formal consultation). For species with LAA determinations at the end of part i, the information considered in parts h and i will be used to characterize the weight of evidence as either "strongest," "moderate" or "weakest."

2a: Is it reasonably certain that the exposure pathway is incomplete?

In Step 2, part a, the assessor considers whether the pathway to pesticide exposure is complete for an individual of a listed species or the taxa upon which it depends (*i.e.,* for prey, pollination, habitat and/or dispersal). In general, exposures to non-target animals and plants may occur through contact, consumption or inhalation. The pathways of exposure that are relevant to a given pesticide are dependent upon the application parameters and fate properties of a pesticide. An exposure pathway is considered incomplete when there is no reasonable expectation of continuity between the source of pesticide exposure and an individual organism of a listed species. In other words, the exposure pathway is considered incomplete if an individual of a listed species or organisms upon which it depends are not expected to be exposed through contact, consumption or inhalation. The assessor may consider characteristics of the listed species and uses of the pesticide in determining whether the exposure pathway is complete. Uses of a pesticide that result in incomplete exposure pathways (for all species) are not included in the action area for the assessed pesticide.

Regarding species characteristics, the following circumstances may lead to a conclusion that the exposure pathway is incomplete:

- Species whose ranges only occur on islands that are uninhabited by humans because pesticides are not reasonably expected to be applied in areas not inhabited by humans;
- Species that predominantly occur in the open ocean (*e.g.,* whales) or rely on ocean species (*e.g.,* seabirds) because their exposure to conventional pesticides is reasonably expected to be *de minimus*; and
- Terrestrial species that only occur in caves because it is not reasonably expected that pesticides applied outside of caves will reach terrestrial species or their prey.

In pesticide specific BEs, additional circumstances related to registered use patterns and species traits may lead to a conclusion that the exposure pathway is either complete or incomplete.

When the exposure pathway is incomplete, effects are not reasonably expected to occur. Therefore, an NLAA determination is made for species for which exposure pathways are incomplete.

2b: Is the species most likely extinct?

If a species is recommended by the responsible Service for delisting due to extinction and the Service concurs at the time the BE is being developed that this recommendation is still based upon the best scientific and commercial data available, EPA presumes in the BE that the species is extinct. Species are only presumed extinct after a recommendation to delist is made by the Services in a review document (*e.g.*, Recovery plan, 5-year review). Species categorized as presumed extinct will be periodically reviewed and updated as new information becomes available. EPA obtains information on these species from the Services.

NLAA determinations are made for species that are presumed extinct, as exposure from the action is not reasonably certain to occur, and, therefore, effects on the species are not anticipated.

2c: Is the range of the species and resulting overlap considered unreliable?

The species range data used in the overlap analyses are provided by the Services. The available range data vary in resolution. Some of the range data are at the sub-county level, with boundaries that are biological in nature (*e.g.,* are consistent with occurrence of specific habitat type). Some of the range data provided by FWS through ECOS follow geopolitical boundaries (*e.g.*, counties or states), rather than natural ones. For those range data that are at the county or state level, EPA will compare the data to the ranges contained within the FWS field offices' documentation for the specific species (*e.g.,* 5- year plans, listing documents). If the ranges from the two sources are consistent and seem consistent with the life history of the species (*e.g.*, top predators that utilize a variety of habitats are expected to have large ranges), the assessment will proceed to Step 2, part d. In cases where the ranges from ECOS and the field offices' documentation differ substantially and the resulting overlap with potential exposure areas would be considered unreliable, a quantitative overlap analysis is not conducted using the ECOS data. In those cases, EPA would make either a LAA or a NLAA determination based on a qualitative WoE.

2d: Are exposure models considered unreliable for assessed species?

The current exposure models used in this assessment may not capture exposures for all types of pesticide applications, all habitat types, or for all potential exposure routes relevant to listed species. Therefore, there may be uncertainty in some 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. 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. If the model estimates are not considered representative of the exposure of the species (due to an inconsistency in the exposure model and assessed species' habitat), a qualitative analysis will be conducted. In those cases, EPA would make either a LAA or a NLAA determination based on a qualitative WoE.

2e: Is the percent of overlap of the species range/critical habitat and the action area <1%?

The overlap analysis used in Step 1, part a is also used in Step 2, part d. 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 NLAA 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 Geographic Information System (GIS) data. There are three areas of the method impacted by these limitations: the species location files provided by the Services, the 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 or critical habitat, where the range and critical habitat files are not altered. There is no accuracy assessment available of the species location or designated critical habitat files, as recommended in National Spatial Data Infrastructure provided by the 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.

Action area: The primary spatial data source for the agricultural layers and non-agricultural layers are the CDLs, NLCD and the Coastal Change Analysis Program (C-CAP), which are consistent with 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 UDLs, 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, several 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. The composite of the potential use sites is buffered in all directions to represent the drift footprint (with the exception of the developed landcover, which is not buffered for spray drift). The combination of the potential use sites (*i.e.*, composite of all relevant UDLs for a given pesticide) and the drift footprint represents the action area. The 1% cutoff is applied only to the action area (which includes drift in all directions). The conservatism of the lack of consideration of usage data and the drift assumptions in the UDLs likely lead to high estimates of overlap of the action area and species range, reducing the likelihood 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 action area. The result of this analysis is the percent of the species range/designated critical habitat that overlaps with the 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. 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 use site data), an accuracy assessment has only been completed for the use site data sources, 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 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. 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. If the action area is represented by only a small cluster of pixels after temporal and use aggregation of the UDLs, this small cluster is below the smallest observable feature that can be reliably identified for this type of data, Landsat 30-meter imagery[43]. The action area considers all use sites as a whole (not individual use sites), and the overlap calculation includes drift to identify species <1%. The addition of the drift footprint is part of the assessment but not part of that Landsat imagery. Using the action area with the drift footprint to identify species <1% errs on the side of the species as spatial features that can be reliably identified are specific to the use sites layers prior to applying the drift footprint. The drift footprint is not part of the original imagery used to generate the UDLs, and the original data sets the accuracy of the results.

Figure 5 represents a map of an example species range with <1% overlap of the action area. The map is presented at a standard resolution for the use site data of 1: 100,000. In this example, the potential use site is represented by only a few 30 m pixels (a total of less than an acre). Because the action area involves buffering all potential use sites as far as 2600 feet from the edge of the field in all four cardinal directions, the ratio of the offsite transport zone to the use site can be as much as 2,000 to 1. Therefore, the majority of the overlap is represented by areas potentially receiving spray drift (not the use site). The overlap of the potential use sites and the species range is up to three orders of magnitude (*i.e.,* 2000x) lower than the action area overlap.

[43] https://coast.noaa.gov/data/digitalcoast/pdf/ccap-faq-regional.pdf

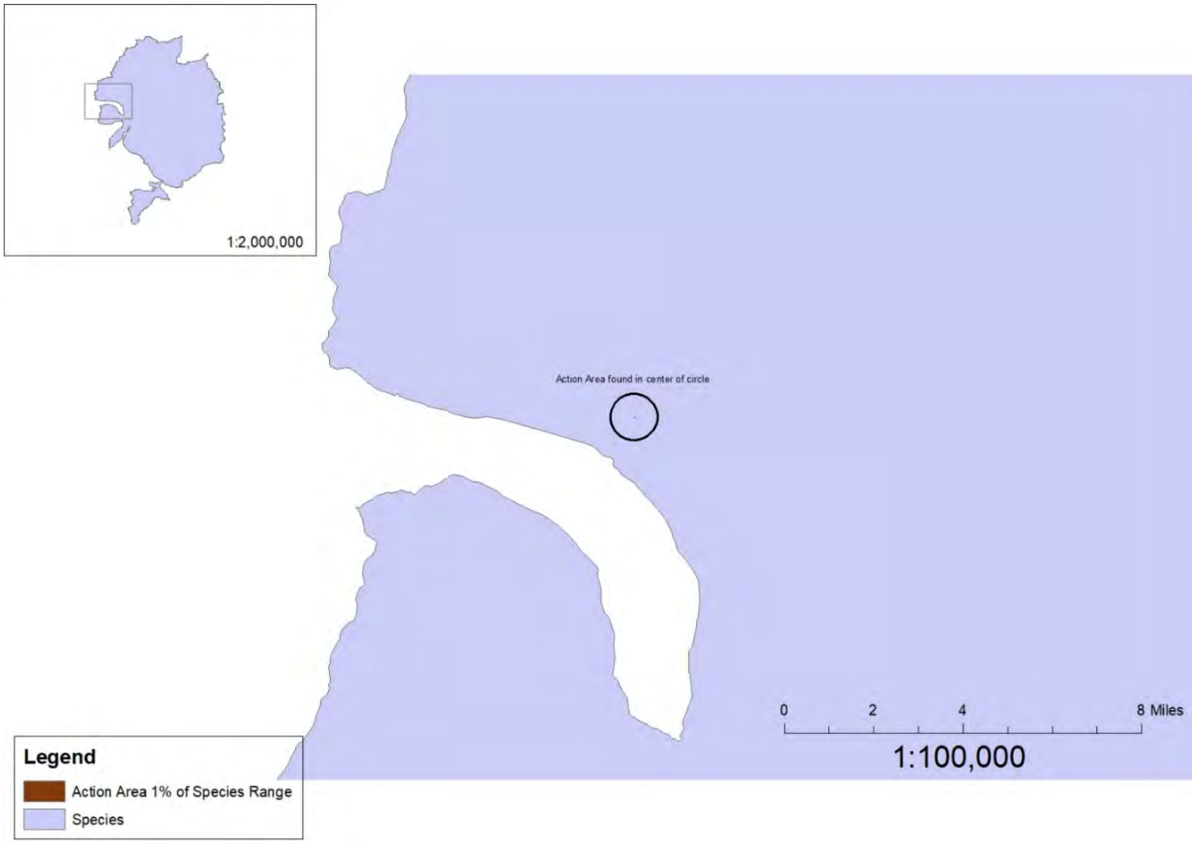

Figure 5. Example map that depicts 1% overlap of an action area (red) and generic species range (purple). Resolution is 1: 100,000.

The approach included here includes many conservative assumptions that result in overestimation of the extent of overlap of the action area and the species range or critical habitat. The method is intentionally designed that way to err on the side of protecting the species. **Table 5** summarizes the assumptions that are discussed above in establishing the action area and characterizes their conservative implications for the extent of overlap. When these conservative assumptions are taken together, an overlap of <1% is both unreliable and is expected to be much lower than 1%. If the overlap of the action area, plus drift does not reach a value of >1%, EPA does not believe this constitutes reliable information or a real potential for exposure. However, for these national level assessments NLAA determinations will be made to allow for additional feedback from the Services and the public.

Table 5. Summary of uncertainties and conservative assumptions employed in Step 2, part e.

Uncertainty	Step 2, part e Assumption	Implications of assumption
Exact population size is unknown due to limited availability of data or variability from year to year	Population size is rounded up when a population estimate is known; high-end value is used in cases where no population estimate is given	Population size is likely overestimated, resulting in overestimation of size of off-site transport zone (because the threshold for an individual is lower when more individuals are considered, resulting in greater estimate of drift distance)
The sensitivity of the assessed species relative to the tested species is unknown	Assessed species sensitivity is the same as the most sensitive tested species	For a taxon (*e.g.*, birds) where many species have been tested (relative to the number of species within the taxon), this is a conservative approach, as the range of sensitivities among species in the taxon is better defined. For a taxon where few species have been tested, the conservativeness of the approach is unknown.
The areas where specific crops are grown change from year to year.	Potential use sites are represented by an aggregated UDL, which includes labeled and non-labeled uses (*e.g.,* the entire vegetables and ground fruit UDL is used regardless of how many specific crops in that UDL are labeled uses) grown in any year over a 5-year period.	Within a given year, the area that represents potential use sites is overestimated.
Non-crop areas where pesticide applications may occur in ConUS and non- contiguous state and territories are uncertain	These areas are represented by broad classes of land (*i.e.,* Developed) which is inclusive of labeled and non-labeled use sites	Potentially treated area by a given pesticide is overestimated
Specific agricultural areas where pesticide applications may occur in the non- contiguous US states and territories are uncertain	These areas are represented by broad classes of land (*i.e., Agriculture*) which is inclusive of labeled and non-labeled uses. All potential use sites are assumed to be treated. Any crop within a UDL that has been grown at any time during a 5-year window is assumed to be treated.	Potentially treated area by a given pesticide is overestimated
Pixels on the edge of a UDL may or may not represent crop(s) within that UDL.	Any pixel indicating crop or non-crop from use site data sources are included in the analysis	Edge effect of potential use sites during spatial analysis is inflated. Edge effect is a well-documented uncertainty when classifying imagery caused by mixed classes in the window. These are areas of transition where the landscape may not represent a single land cover, resulting in different classification year to year. Temporal aggregation of the UDLs compounds the edge effect from individual years increasing area considered to be part of the UDL.
Pixels on the edge of a species range or critical habitat may or may	On the edges of the species range and critical habitat files, where a 30-meter pixel from the UDL would be partially within the species file, it is	Edge effect of species ranges and critical habitat during spatial analysis is inflated. This results in overestimates of overlap

Uncertainty	Step 2, part e Assumption	Implications of assumption
not represent the range/critical habitat of that species.	assumed the whole pixel is within the species range or critical habitat.	especially for species range and critical habitat files with irregular borders when this would occur more frequently
Locations of areas receiving spray drift are unknown.	Drift from the UDLs is based on minimum distance of the species to the closest use site, and extends in all directions	Since drift is expected to travel in the direction of wind (not in all directions from the treated area), drift is overestimated and more area will be found in the distance closer to the use site.
Extent of spray drift from application sites where effects may occur is uncertain	Most conservative application method (*i.e.*, aerial) and rate (highest single) and most sensitive toxicity endpoint (considering effects to the listed species and to PPHD) is used to model farthest off-site transport distance for a given species. Deposition is assumed to occur in all 4 directions around a field. The model is based on studies conducted in relatively flat areas with no barriers.	Spray drift deposition is over-estimated. Other factors that also overstate drift deposition include model parameterization using older spray drift nozzles than are currently used today.
Extent of off-site transport due to runoff and downstream transport is unknown	Assessment process assumes near stream assessment covers risks downstream.	For any aquatic species, located in medium and high-flowing waterbodies, where a NLAA determination is made, downstream impacts could still occur from use sites upstream of the species range. To address this, EPA will evaluate monitoring data upstream of the species range and critical habitat for these species, to determine if downstream impacts could occur. As this will be qualitative, there will be uncertainty as to whether the downstream effects would exceed the thresholds. Likewise, as monitoring data are typically not conducted at a daily timestep, there is uncertainty as to whether additional detectable concentrations are occurring.
It is uncertain whether an individual may be exposed when overlap is <1%	Assumptions used in the spatial analysis greatly overstate the potential for an exposure to occur. To avoid false negatives, overlap values >0.5 and <1.0% are rounded to 1.0%, so, an NLAA determination is not made in step 2, part e.	Overlap may be a false positive.
The specific location of the spray drift transport zone relative to potential use sites and species range is unknown (wind direction may change).	Buffering of UDLs for drift is done in all directions regardless of use. Drift is assumed to occur in all directions and the 1% cutoff after accounting for drift	A 900 square meter or 0.22 acres pixel representing a use site could represent as much as 2,044,920 square meters or 505 acres when considering aerial drift.

Uncertainty	Step 2, part e Assumption	Implications of assumption
The accuracy of the species range and critical habitat data is unknown	The accuracies of the species range and critical habitat data are the same as the CDL, NLCD and other use site data sources.	For specific ranges or critical habitats that are less accurate than the CDL or NLCD, a greater percent overlap would not be considered reliable. Since many species' ranges are at a coarser scale, it is likely that many species ranges are less accurate than CDL or NLCD (60 m accuracy). This means that the 1% cutoff will be more conservative than the datasets support.
Actual exposure levels are variable. Therefore, individuals may be exposed to different levels of pesticide	Species is exposed to highest EEC	This EEC may represent a small fraction of exposure in the action area, so it is considered conservative.

2f: Based on conservative assumptions, is it likely that <1 individual is exposed?

As discussed previously, Step 1's overlap analysis involved species range or critical habitat and potential use sites of the pesticide. The objective of the Step 2e through i analysis is to go from all possible use sites (in Step 1) to those sites where pesticide applications are reasonably likely to result in exposure to an individual of a listed species. Step 2f takes a more refined approach and considers available usage data when identifying the likely portion of a species range where pesticide exposure may occur. Different approaches will be employed for crop and non-crop uses due to differences in the nature of the available data. Step 1 focuses on the extent of overlap between the action area and the species range (or critical habitat), and when there is sufficient overlap and potential for effects, an MA determination is made. In Step 2, the number of individuals exposed and impacted is considered using the likely exposure area.

The Step 2f analysis, incorporates five types of exposure and effects data: 1) species range or critical habitat; 2) population size; 3) potential use sites; 4) pesticide usage data; and 5) off-site transport zone. The same population size and potential use sites used in Step 1 (both discussed above) are also used here in Step 2f. Additional information on species range and critical habitat and pesticide usage data are described below.

Species range and designated critical habitat

Species range and critical habitat data are provided by the Services. Species range and designated critical habitat spatial files are downloadable from the USFWS ECOS website and NMFS regional sites. The species range represents the areas where the population is thought or known to occur. The designated critical habitat represents areas that are essential to the conservation of a listed species, though the area does not need to be occupied at the time it is designated.

An overlap analysis of species range and likely exposure areas (including sites where the pesticide is directly applied and areas receiving off site transport) is conducted in Step 2 to estimate the number of individuals exposed. In Step 2, consideration is given to whether a species is expected to be found on an agricultural crop or non-crop use site. For those species that are not found on potential use sites[44] (*e.g.*, agricultural fields, residential areas) for habitat or resources, those non-relevant use sites will be removed from the overlap analysis. In cases where it is assumed that a listed species does not to use a crop or non-crop area, it is also assumed that it's PPHD is not exposed (on the use site). Exposure may still occur to species and taxa relevant to PPHD effects in areas that receive spray drift and runoff

EPA assumes that individuals of a listed species may be uniformly located throughout the entire range or critical habitat area (this assumes that all habitat is occupied). If the Services provide EPA with spatial data on the distribution of individuals of a species within the range or critical habitat or identify specific locations where densities of individuals are greater, the uniform distribution assumption will be refined for that species.

[44] 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).

Pesticide usage data

Usage data specify the location, magnitude, and type 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, while non-agricultural usage data may be summarized at the county, state, region or national level, depending on the data source. As noted earlier, BEs will include pesticide-specific usage data in making effects determinations. In absence of usage data, assumptions may need to be made, but these assumptions will be consistent with the ESA and Administrative Procedure Act standards. Accordingly, these assumptions must be clear and substantial and not be based on speculation.

EPA uses best available pesticide usage data from public (*e.g.,* USDA, California Pesticide Use Reporting) and proprietary (*e.g.*, Market Research Data and Non-Agricultural Market Research Data) sources. The proprietary sources are independent, commercial market research firms, which are not affiliated with any pesticide registrant or government agency. An analysis of available usage data, which includes use site specific usage statistics, is presented in a document called the National and State SIAB[45] Summary Use and Usage Memo (SUUM). EPA develops SUUMs for individual pesticide active ingredients and these SUUMs will be released with BEs. EPA evaluates the quality and relevance of usage data by assessing numerous variables to determine applicability, utility and soundness of the data[46,47] prior to incorporation into the BEs. One question EPA has received is about the reliability of historical usage data in predicting future use. EPA's method for forecasting relies upon the most recent usage data. EPA considers the most recent 5 years of data representative of current labeled uses. EPA publicly vetted the method used to predict future pesticide use at a FIFRA SAP meeting in 2002[48]. Considering advice from the SAP, the EPA determined that the methodology presented was most appropriate. EPA uses that methodology today.

This section focuses on application of the percent crop treated (PCT) to UDLs. PCT is estimated using the base acres treated (crop area that has been treated at least once with a given pesticide in a growing season) divided by the crop acreage grown (the total number of acres of a crop that was grown over the same time period). This is used to refine the spatial extent of the likely area of exposure. Other types of usage data (*e.g.*, typical application rates) are considered in Step 2, part h.

Agricultural crop uses

The available usage data represent the crops that, in combination, constitute more than 80% of agriculture acreage in the US. For many agricultural crop uses, usage data are available to quantify the PCT. The PCT will be used to adjust the extent of an area that may overlap with a listed species range. PCT data are available for specific crops and states. EPA will make available pesticide specific PCT data in SUUMs. EPA applies these data to crops based on the 13 agricultural UDLs discussed above.

Prior to adjusting the UDL overlap using the PCT data, EPA applies a series of steps to align the crops used to generate the PCTs in the SUUM with the crops found in each UDL. PCTs reported in the SUUM

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[45] Science Information and Analysis Branch in the Biological and Economic Analysis Division of EPA's Office of Pesticide Programs.
[46] https://www.epa.gov/quality
[47] https://www.epa.gov/sites/production/files/2013-10/documents/21050.pdf
[48] https://www.regulations.gov/docketBrowser?rpp=50&po=0&D=EPA-HQ-OPP-2002-0228

representing the same crop found in a UDL (*e.g.,* corn, cotton) require no additional calculations before adjusting the UDL with the PCT. Some UDLs contain many crops (*e.g.,* vegetables and ground fruit) and, therefore, have many PCTs reported in the SUUM representing individual crops within the UDL. In these cases, EPA calculates an aggregated PCT before adjusting the UDL. When calculating aggregated PCTs, crop information related to area grown for all crops within the UDL are extracted from either the SUUM or Census of Agriculture and used in the aggregated PCT calculation. The aggregated PCT accounts for all crops in the UDL and is used to adjust UDL overlap. This process is outlined below.

All 13 agricultural UDLs are adjusted by a PCT that is representative of the crops found in the UDL. For UDLs represented by single crops (*e.g.,* corn, cotton), there is no need to adjust the PCT provided in the SUUM because it directly represents the crops in the UDL. EPA applies the available PCT data from the SUUM for the crop directly to the total acres in the UDL for that state. The result is an estimate of the acres treated for the UDL (UDL acres treated = total UDL acres x PCT/100).

For each UDL representing multiple crops (*e.g.,* vegetable and ground fruit, non-citrus orchards), EPA calculates an aggregated PCT, which is then applied to the area in the UDL. EPA first calculates acres treated for each crop within a UDL based on the available usage data. Reported acres grown as reported in the SUUM or in the Census of Agriculture are extracted and used in the calculation for the treated acres. When available, the reported acres grown are extracted from the SUUM. For crops not found in the SUUM, this information is extracted from the Census of Agriculture. After calculating the treated acres for all crops in the UDL, completing the aggregated PCTs includes summing those treated acres then dividing by the total acres grown. The final aggregated PCT includes data for all crops relevant to the UDL. If a UDL contains crops that are not a registered use site for the pesticide, those crops are assigned a PCT of 0. EPA uses a PCT surrogacy method discussed below to assign PCTs to crops for registered use sites without usage data. With an aggregated PCT representing all crops in the UDL, EPA calculates acres treated for the UDL by multiplying this aggregated UDL PCT by the sum of the total acres from the UDL for that state; repeating this calculation for each UDL. The state treated acres for the state does not include counties where no registered crops are reported to be grown based on the Census of Agriculture.

$$PCT_{UDL\text{-}j} = \frac{Base\ acres\ treated}{Cropped\ total\ acres\ grown} = \frac{\sum_{i=1}^{n}(PCT_i * G_i)}{\sum_{i=1}^{n} G_i}$$

Where:

$PCT_{UDL\text{-}j}$ =	aggregated PCT (for UDL j in state)
j =	UDL for registered use pattern (*e.g.*, vegetables and ground fruit)
i =	crop (within UDL j) in state
n =	number of crops (within UDL j) with acres grown in state
PCT_i =	percent crop treated of crop i (from extended SUUM)
G_i =	acres of crop i (in state) (from extended SUUM or Census of Agriculture)

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 un-surveyed registered crops. For crops that are surveyed somewhere in the US but not in the state of interest, EPA will consider a surrogate PCT (*e.g.*, based on survey data for the same crop in other states, or the national PCT for the crop). For crops that are not surveyed anywhere, EPA will use a surrogate crop with surveyed data.

In order to adjust the overlap for a species range, EPA compares the UDL acres treated for the state to the number of acres within a species' range that overlaps with that UDL. If the number of UDL treated acres in a state is greater than or equal to the number of acres of UDL overlapping the species range, EPA will assume that all acres within the species range that overlap with the UDL are treated. Treated acres are only located in counties where registered, labeled use occurs for uses within a UDL as identified by Census of Agriculture. If the number of UDL treated acres is less than those overlapping with the species' range, EPA will assume that all treated acres for that UDL in a state occur within the range of a species. **Figure 6** illustrates how this approach assumes that treated acres within a state are concentrated within the species range. Other distribution assumptions for treated acres may be considered as part of the weight of evidence (see Step 2, part h discussion below).

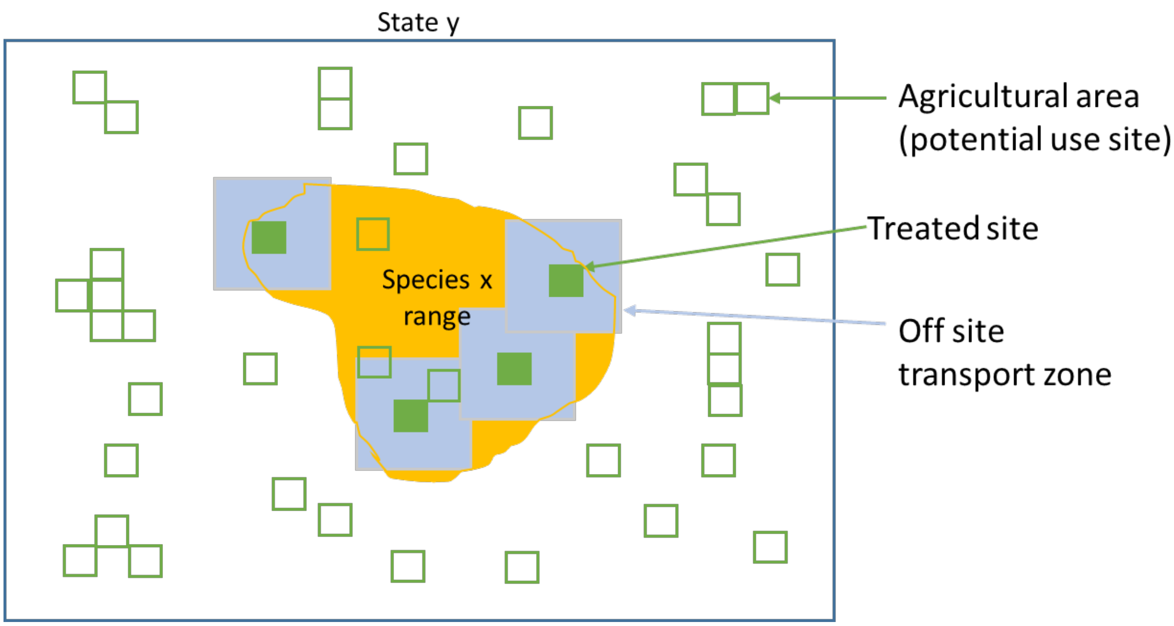

Figure 6. Conceptual illustration of approach for assigning treated acres to area relative to species range. In this example, PCT for the potential use site is 10%. Treated acres (green) are focused within range of assessed listed species (yellow). Grey areas represent off-site transport zone attributed to spray drift transport from treated acres.

Non-crop uses

Pesticides are registered for a wide variety of uses (*e.g.*, lawns and gardens in residential areas, forestry, rangelands, and nurseries) for which usage data are not captured in the same manner or with the same frequency as the aforementioned crop data. Data for these types of uses are varied in their availability and their characteristics. For example, usage data are available and reported in the SUUMs for several of these uses; however, they vary in scale (*e.g.*, regional, national). For non-crop uses, EPA will compile applicable data from a combination of sources, including production and sales data of formulated products, reported usage from proprietary sources (Agricultural Market Research Data) and from federal agencies (*e.g.,* Animal and Plant Health Inspection Service, Forest Service), 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 largest number of 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 pesticide is not in fact applied at a large scale to these UDLs. In cases where pesticide-specific usage data are not available for rangeland, and forestry, EPA will consider using USDA census data on usage of pesticide types for woodlands. For example, available usage data reported in the census for all insecticides could be used as a conservative surrogate for a specific insecticide (in the absence of pesticide-specific usage data for that use site). This approach, while still an overestimate (as this would represent applications of multiple pesticides in the pesticide type), is 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. EPA may supplement or replace this approach with available pesticide-specific usage data obtained from other sources, such as usage data reported by federal agencies.

For non-agricultural uses that are spatially represented by the developed land cover class (*e.g.,* residential, gardens, turf, ornamentals), usage data are also available, although in many cases, only at the regional or national level (and often only as acres treated or pounds applied rather than PCT). For applications that are not intended to be made directly to impervious surfaces (*e.g.,* to lawns), EPA will make a treated area assumption for the developed land cover class based on the percent of a typical lot that is not represented by impervious surfaces (*e.g.,* footprints of houses, driveways are assumed to not be treated). In these cases, EPA acknowledges that overspray to impervious surfaces can occur, and, as such, the treated area will include a small percent of the impervious surface. If data are available to provide robust usage data for residential areas (*e.g.*, from the Residential Exposure Joint Venture[49]), EPA may lower the percent treated area assumption. In some cases, usage data are available on a regional basis for uses relevant to the developed land cover class. In those cases, EPA will develop regional percent treated areas (PTAs).

On a pesticide specific basis, EPA will consider usage data available from other sources, as needed. Data will be reviewed to ensure that they meet the data quality standards of EPA and will be cited in the BEs.

Effects Determination

In this approach, EPA combines the potential use sites and the pesticide usage data to calculate the number of acres that are realistically expected to be treated. The off-site transport zone of the action area is adjusted to account for the proportion of treated acres relative to the potential use sites. The treated acres and adjusted off-site transport zone represent the exposure area. EPA calculates the proportion of the species range or critical habitat that overlaps with the exposure area and multiplies this proportion by the population size to calculate the number of individuals exposed. If <1 individual is exposed, EPA makes a NLAA determination. If 1 or more individuals are potentially exposed, then the species evaluation will move on to part 2g.

[49] https://www.epa.gov/pesticide-registration/prn-2011-1-residential-exposure-joint-venture

2g: Based on conservative assumptions, will <1 individual have impacts to survival, growth or reproduction?

This step involves a probabilistic analysis where several variables are distributed (*e.g.*, EECs, individual responses according to dose-response curve from toxicity data). Since the distributions of several variables related to usage and species are unknown, conservative assumptions related to these variables are employed here (point estimates are used instead of distributions). As discussed above, if an NLAA determination is not made in part g, some of these conservative assumptions may be revisited later in the Step 2 decision framework as a weight of evidence analysis.

The use of probabilistic methods was recommended by the NRC in all steps of the consultation process. In addition, the NRC 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 revisions in the new methodologies is the inclusion of a probabilistic analysis. Overall, this analysis is intended to introduce some basic probabilistic components into the effects determinations and is not intended to capture all potential variables that could be considered. **Table 6** summarizes many of the conservative assumptions that are still incorporated into Step 2, part g. As discussed below, a weight of evidence analysis may be considered later in Step 2 (parts h and i), where probabilistic analyses are also conducted using alternative assumptions for variables related to pesticide usage or the assessed species.

Table 6. Summary of uncertainties and conservative assumptions employed in Step 2, parts e and g. Many of these conservative assumptions are revisited in parts h and i.

Uncertainty	Step 2, part e and/or g Assumption	Implications of assumption
Locations of individuals of a listed species within range or critical habitat are not known	Individuals of a listed species are located uniformly throughout the range or critical habitat	If overlap occurs in areas where individuals are concentrated, number of exposed and impacted individuals could be underestimated. If overlap occurs in areas that are unoccupied, number of exposed and impacted individuals will be overestimated.
Mobile species (*e.g.,* animals) may move throughout range. They may move in and out of exposure areas.	It is assumed that individuals remain in the same location.	For pesticides that are not persistent and are acutely toxic, this is likely representative of exposures and effects. For chemicals that are persistent and cause sublethal effects, the estimated number of individuals impacted may be underpredicted because they would move between areas with and without pesticide exposure.
Locations of treated sites relative to species range is unknown	All treated acres for a potential use sites are located within range (or critical habitat) of species	Overlap of species range and use sites are likely overestimated, leading to an overestimate of the number of individuals exposed.
Total treated area is uncertain because it is calculated based on the temporally aggregated UDLs which overestimates the area where a crop could be found in a given year.	The temporal aggregation of crops UDLs results in an overestimate of where the crop is found in a given year due to common agricultural practices such as crop rotation and therefore overestimates the treated acres. Treated area for the state is calculated using the temporally aggregated layers based on usage data but acreage is not adjusted further to account for the overestimation of where the crop could be found for a given year.	The resulting area calculation based on a crop UDL is expected to be more area than grown for given year, resulting in more treated area than expected for a given year.
Location of the treated sites is unknown and therefore drift from the treated sites is unknown	Maximum drift distance from a use site, in all directions from all potential use sites are calculated	Calculating drift from all use sites and not just treated sites will overestimate the drift areas from treated sites. Drift from individual treated sites can't be calculated because the locations are unknown. Distances are adjusted to account for the overestimate (see discussions below).
The sensitivity of the assessed species relative to the tested species is unknown	Assessed species sensitivity is the same as the most sensitive tested species	For a taxon where many species are tested (relative to the number of species within the taxon), this is a conservative approach, as the range of sensitivities among species in the taxon is better known. For a taxon where few species are tested, the conservativeness of the approach is unknown.

Uncertainty	**Step 2, part e and/or g Assumption**	**Implications of assumption**
The size of a treated area that discharges into small flowing and static waterbodies is unknown	Edge-of-field estimates will be used as aquatic estimates for small flowing and static waterbodies	Aquatic concentrations for these waterbodies may be higher than those that actually occur. The estimated concentrations will be conservative and protective of the species
Use of PWC to model medium and high flowing waterbodies is uncertain	Use of the index reservoir, a validated EPA waterbody, to evaluate aquatic concentrations in medium and high flowing waterbodies	Aquatic concentrations for these waterbodies may be higher than those that actually occur but will be conservative and protective of the species, as the flowrate used in modeling the index reservoir is lower than that for the medium and high-flowing waterbodies, resulting in less dilution and removal from the waterbody.
The range in aquatic EECs resulting from different application dates is unknown/uncertain	Scaling factors were developed for single applications, which are assumed to be representative of scaling factors that would occur for multiple applications.	Scaling factors may over- or under-estimate changes in aquatic EECs based on using a different application date. However, the differences are not anticipated to be significant. The use of the scaling factor is expected to capture more of the potential variation in EECs than not using them.
The range in aquatic EECs resulting from different hydrologic soil conditions is unknown/uncertain	Scaling factors were developed to account for different hydrologic soil conditions. There is an equal probability of experiencing different hydrologic soil groups in the action area	Scaling factors may over- or under-estimate changes in EECs based on using a different hydrologic soil group. However, the differences are not anticipated to be significant and the use of the scaling factor is expected to capture more of the potential variation in EECs than not using them.
Extent of off-site transport due to runoff and downstream transport is unknown	Assessment process assumes near stream assessment covers risks downstream.	For any aquatic species, located in medium and high-flowing waterbodies, where an NLAA determination is made, downstream impacts could still occur from use sites upstream of the species range. To address this, EPA will evaluate monitoring data upstream of the species range for these species, to determine if downstream impacts could occur. As this will be qualitative, there will be uncertainty as to whether the downstream effects would exceed the thresholds. Likewise, as monitoring data are typically not conducted at a daily timestep, there is uncertainty as to whether additional detectable concentrations are occurring.

Consideration of effects from exposure and toxicity to an individual of a listed species

Probabilistic methods are incorporated 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 described herein draws conceptually from previously described methods, including several EPA Scientific Advisory Panels, where the methods were commented upon by experts (USEPA, 2000[50,51,52]; ECOFRAM, 1999[53,54]). The method also employs algorithms described in the USEPA Terrestrial Investigation Model (TIM; v. 3.0[55]).

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. For a refined assessment of risks, Tiers II-IV employ principles of probabilistic analysis with increasing levels of complexity and specificity. The 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 EPA's current standard, conservative, field-based models and various parameters that are influential to those models using known distributions. It is noted that there are other factors (*e.g.,* pesticide properties, agronomic practices, discrete distribution of aquatic species in water bodies, simultaneous variation of application rates at a field scale, etc.) that could impact the quantification of risk 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.

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

[51] 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. https://archive.epa.gov/scipoly/sap/meetings/web/pdf/probover.pdf

[52] U.S. Environmental Protection Agency (USEPA). 2000. Technical Progress Report of the Implementation Plan for Probabilistic Ecological Assessments: Terrestrial Systems. https://archive.epa.gov/scipoly/sap/meetings/web/pdf/probter.pdf

[53] ECOFRAM, Peer Input Workshop. 1999. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-committee-fifra-risk-assessment-methods#EcoPeerInput

[54] ECOFRAM, Terrestrial Workgroup. 1999. ECOFRAM Terrestrial Draft Report. May 10, 1999. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecofram-terrestrial-draft-report

[55] 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

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 EPA is considering 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 variables 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, represents 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 effects primarily on invertebrate and other animal taxa, it is anticipated the probabilistic analysis will be conducted only for terrestrial and aquatic animals as needed based on the tiered screening of species. For insecticides, probabilistic analyses will also be utilized to assess 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 toxicity data to determine the number of individuals with decreased survival, reproduction or growth. 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 or critical habitat based on the percent overlap with each zone, including being on site, in the off-site transport (drift) zone or in an area of the species range the pesticide is not expected to reach (unaffected area). 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 by randomly assigning the individual based on 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 resolution of the GIS data used for use sites. The likelihood of an individual of an assessed species being in that area of exposure would be equal 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 state, as well as the number of acres that receive spray drift from treated areas. As described in part 2h, different assumptions around how treated acres for the state are distributed relative to the species range will be considered (*e.g.,* all of the treated acres are within the area of overlap, outside the area of overlap, 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) [56] 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. These relevant waterbodies (see discussion of aquatic bins above) were developed and species assignments made by the Services. 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. The watershed for the index reservoir has been validated in previous Science Advisory Panels[57]. While it is acknowledged that the aquatic concentrations for the small static and the flowing waterbodies may be higher than those that actually occur, the estimated concentrations will be conservative and protective of the species.

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[56] 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
[57] USEPA. 1998. An Index Reservoir for Use in Assessing Drinking Water Exposure, Part IV of Proposed Methods for Basin-scale Estimation of Pesticide Concentrations in Flowing Water and Reservoirs for Tolerance Reassessment

Different distributions of maximum annual daily EECs, designed to represent the variability in EECs from year to year, will be considered, depending on if the species is located in flowing or static waterbodies. For the static and low-flow waterbodies, the distribution of maximum daily EECs from the 30 years of data is 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 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.

Other factors can also 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[58]. Simulations will be conducted with PWC to determine the EECs for single applications 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. 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.

A similar analysis is also conducted using different hydrologic soil group. Original PWC modeling used scenarios developed to represent hydrologic soil groups. The hydrologic soil groups used in the scenarios were considered 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. Using the metadata for the original PWC scenarios used to develop the ESA scenarios and the GLEAMS user guide[59], EPA estimated curve numbers for downgrades in hydrologic soil groups (*i.e.,* moving from a D group to a C group, etc.). Again, PWC modeling will be done using the original aquatic runs done for the BEs but will be done using the scenarios modified to represent different hydrologic soil groups. Scaling factors (which are pesticide and scenario specific) will be developed by comparing the EECs from the original PWC simulations to the modified simulations.

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 Hydrologic Unit Code (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*

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[58] USEPA. 2015. Background Document in Support of the Meeting of the FIFRA Scientific Advisory Panel on the Development of a Spatial Aquatic Model (SAM) for Pesticide Assessments. Available online at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2015-0424

[59] USDA. 2000. Groundwater Loading Effects of Agricultural Management Systems (GLEAMS).

This method is intended to be a simplified approach and require less processing time to capture the variability of these factors without needing to conduct Monte Carlo simulations using PWC. EPA acknowledges that there is uncertainty in the development of these scaling factors. For the application date approach, the approach only looks at the variation resulting from a single application, while the EECs for the original PWC runs were developed using multiple applications. As such, the original 1-in-10 year EECs may be reflective of runoff that is not related to the first application date and may be more reflective of additional applications. For the hydrologic soil group methods, the probability of the different soil factors is considered equal. However, based on the soil geology of a region, the probability of applications to soils with higher runoff may be higher than that for soils with lower runoff potential, and vice-versa. While growers typically try to minimize runoff and soil losses from their fields, it is uncertain to what level this occurs on a local scale near the species range. However, as mentioned earlier, the process is designed to provide a measure of the variation in these parameters, as well as more realistic EECs, while still being protective of the species.

Aquatic EECs resulting from spray drift are estimated using the same algorithms employed in the Tier I modules of AgDRIFT and the original waterbody dimensions for the 6 aquatic bins. 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 by randomly assigning the individual based on 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 within the range could be anywhere in the catchment, the assumption is conservatively made that the water body is directly next to the use site.

Available monitoring data will be used to qualitatively evaluate the potential for downstream exposure to listed species associated with the medium and high-flowing bins located in areas that have been removed from consideration (during Step 2). This evaluation will consider potential pesticide use in areas that are upstream and outside of the action area, as a pesticide may be transported from upstream locations where usage occurs. If there are detections upstream, the available monitoring data will be considered in the determination for the species (in Step 2, part i).

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 3**. 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, alternative scenarios will bound possible results by calculating the magnitude of mortality among exposed individuals at points on the species sensitivity distribution (*e.g.*, 5th, 50th percentile). 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. It is noted that the geomean will be evaluated in context of the LOAEC and the magnitude of effect at the LOAEC. For instance, if dose spacing is very wide and the LOAEC is associated with a significant effect (*e.g.*, >50% reduction in eggs laid) or if the geomean is greater than the EC25 for plants, the NOAEC or EC25 may be used in place of the geomean for Step 2.

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 as appropriate.

Consideration of effects to prey, pollination, habitat and/or dispersal

Since the focus of the assessment is on impacts to an individual of a listed species, EPA must consider effects to PPHD 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 effects to PPHD 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 terrestrial 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 effects endpoints for PPHD in **Table 3**). For species that rely upon animals (*i.e.,* for prey, pollination, habitat and/or dispersal), for non-obligate (*e.g.,* generalist) relationships, the specific threshold for potential effects to PPHD was set at one-half (0.5) of the mortality endpoint concentration (*i.e.*, there is a potential for effects to PPHD when the ratio of the estimated concentration/mortality endpoint ≥0.5) for the Step 1 analysis. In Step 2, in order to integrate variability in responses according to dose-response curve from toxicity data, the threshold for concern is set at 10% mortality predicted to the animal of concern. This is again 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) and the associated slope. 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 effects to PPHD 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 effects to PPHD when the ratio of the estimated concentration/mortality endpoint ≥0.1) for Step 1. Similar to non-obligate relationships, the threshold for concern is based on the % mortality prediction in order to integrate variability in responses according to the dose-response curve from toxicity data. For obligates the mortality threshold for concern is set at 1% mortality. 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 impacts on PPHD that result in 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 PPHD 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.

Effects Determinations

Although probabilistic analysis will be utilized with different assumptions later in the analysis, in this step (2g) of the method, probabilistic analyses will be completed using the conservative assumptions to identify those that are clearly NLAA. If the most conservative assumptions (*e.g.*, maximum labeled application rates, 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 1 individual impacted by PPHD effects at greater than the 95th percentile, then the determination is NLAA and no further analysis is warranted. If analyses find that both effects to the species and to PPHD are not likely for an individual of a listed species, a NLAA determination is made and no additional analyses are conducted. If this analysis results in >1 individual being affected, then EPA will proceed to part h of Step 2.

2h: When considering alternative assumptions for pesticide usage, does weight of evidence suggest that <1 individual will have impacts to survival, growth or reproduction?

In Step 2 parts e and g, conservative assumptions related to usage are applied in the probabilistic analysis (**Table 6**). In part h, the impact of those assumptions is considered. Additional probabilistic analyses are carried out with different assumptions related to the PCT applied and how treated acres are distributed within a state relative to the species range. In parts e and g, treated acres are concentrated within the species range and critical habitat (**Figure 6**) and the maximum PCT is applied. In part h, additional scenarios of PCT and distribution are considered including the use of an average PCT, the distribution of treated acres uniformly throughout the state (**Figure 7**) and the distribution approach where acres are concentrated outside of the species range (**Figure 8**). With all three distribution approaches, the off-site transport zone is adjusted for the proportion of treated acres and the overlap of the exposure area and the species is calculated. In the case of the distribution approach where acres are concentrated outside of the species range, if no treated acres occur within the species range, some acres representing spray drift may still overlap. In part h, the same probabilistic analysis discussed in part g is run several times using the following scenarios:

1) uniform distribution of treated acres (**Figure 7**), maximum PCTs;
2) treated acres concentrated outside of species range (**Figure 8**), maximum PCTs;
3) uniform distribution of treated acres (**Figure 7**), average PCTs;
4) treated acres concentrated outside of species range (**Figure 8**), average PCTs;
5) treated acres concentrated inside of species range (**Figure 6**), average PCTs;

(NOTE: the scenario considered in step 2, parts e and g is treated acres concentrated inside of species range, maximum PCTs)

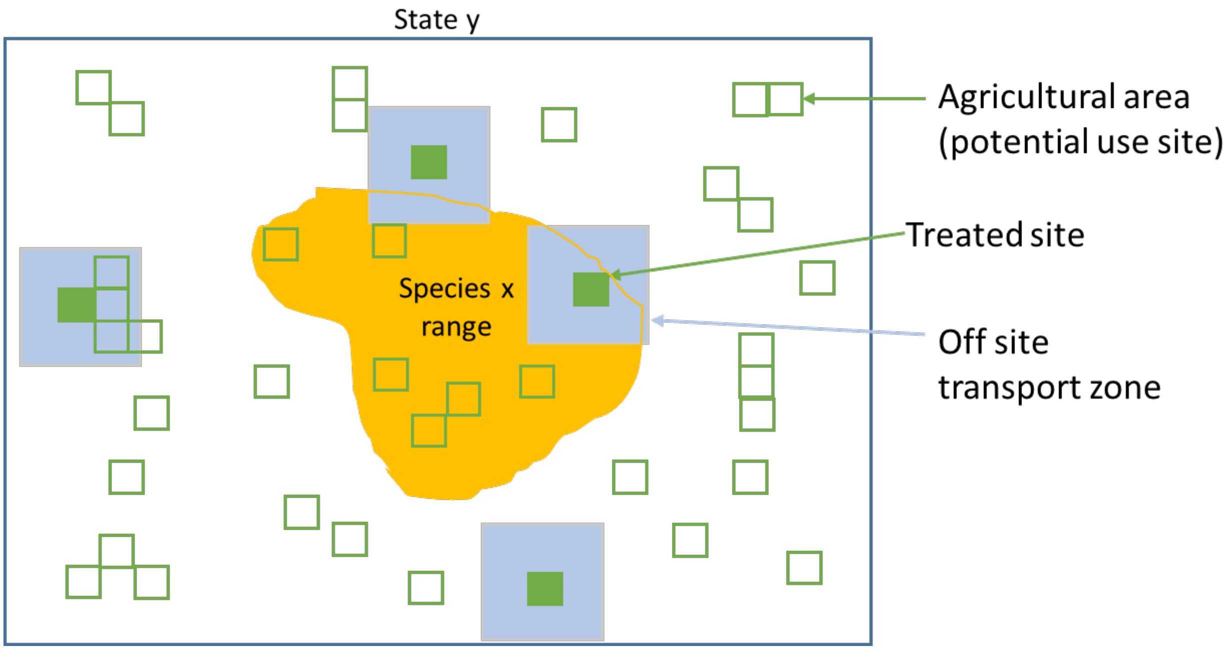

Figure 7. Conceptual illustration of approach for assigning treated acres to area relative to species range. In this example, PCT for the potential use site is 10%. Treated acres (green) are uniformly distributed throughout state. Grey areas represent off-site transport zone attributed to spray drift transport from treated acres.

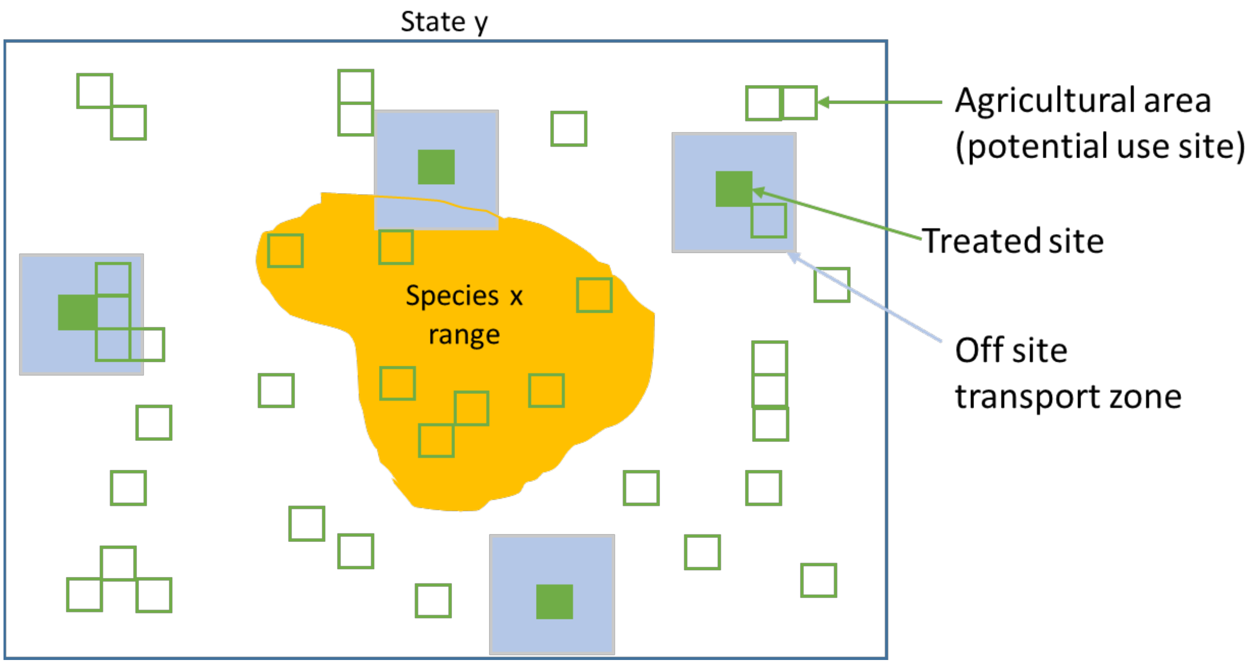

Figure 8. Conceptual illustration of approach for assigning treated acres to area relative to species range. In this example, PCT for the potential use site is 10%. Treated acres are concentrated outside of the species range. Grey areas represent off-site transport zone attributed to spray drift transport from treated acres.

As discussed previously, there are other types of usage data that may be relevant to consider (*e.g.*, typical application rates or methods). The analyses described in parts e and g both assume maximum exposure scenario based on product labels (*i.e.*, maximum rates are applied using the application method that results in the greatest off-site transport). If data are available that suggest that lower application rates are more often used or a pesticide is most often applied using ground spray and/or with nozzles that result in coarser droplet spectra, the impact of the conservative application parameters may be considered, and EPA may reassess using more typical rates or practices.

If the analysis indicates that 1 or more individuals are only impacted using the most conservative of the above scenarios, that suggests conservative assumptions influence the risk conclusions related to an individual. If the weight of evidence indicates that it is not likely that an individual through exposure to the pesticide or effects to its PPHD will be adversely affected, an NLAA determination will be made. For example, this may apply to a situation where the most conservative scenario modeled is not likely. If several of the above scenarios suggest that one or more individuals may be affected, additional weight of evidence analyses focused on assumptions related to the assessed species will be conducted in part 2i.

2i: When considering alternative assumptions for species (*e.g*., population size, toxicity surrogacy, habitat, migration), does weight of evidence suggest that <1 individual will have impacts to survival, growth or reproduction?

The final weight of evidence analysis considers uncertainties and alternative assumptions to variables related to the assessed species. Parts e, g and h utilize conservative assumptions related to population size, toxicity surrogacy, migration and dormancy and federal lands. In this weight of evidence analysis, alternative assumptions are employed. Like the previous parts, this analysis is also probabilistic. If only the conservative assumptions lead to the conclusion that one or more individuals may have impacts to survival, growth or reproduction through effects to the species or its PPHD, EPA may make an NLAA determination or reduce the confidence in the LAA determination. If the preponderance of evidence indicates that 1 or more individual is/are likely to be impacted, an LAA determination will be made.

Population Size

As discussed above for Step 2, part e, there is uncertainty associated with estimates of population size. To account for this uncertainty, probabilistic analyses are conducted in Step 2, parts g and h using conservative estimates of population size. In this analysis (for part i), lower bounds of the population size (**Table 2**) will also be considered.

For species with small populations (*i.e.,* ≤ 100), the most conservative assumptions are maintained. If the most conservative approach estimates 1 or more individuals being impacted, an LAA determination is made.

Confidence in the Toxicity Data (Surrogacy)

For parts g and h, the toxicity endpoints used in the analyses are largely from broad taxonomic groups (*e.g*., all birds, all mammals). Where the data allow, attempts will be 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. For each taxon conservative endpoints are used to represent effects to the listed species and PPHD (**Table 3**). EPA explored the option of considering more specific taxonomic groupings (*e.g*., using salmonid toxicity data to represent the toxicity to listed salmon species). What EPA found in preliminary analyses of the first three BEs (for chlorpyrifos, diazinon and malathion) is that for data-rich species that allowed for such an analysis, species within the same genus (*e.g*., *Rana sp*.[60]) or family (*e.g.,* Salmonidae[61]) were found throughout the species-sensitivity distribution for aquatic vertebrates.

Relying on conservative, taxa-based toxicity endpoints (when other tested species are available), introduces uncertainty into the assessments. It is unknown whether the assessed species is represented by sensitive or less sensitive tested species; however, it is not possible at this time to quantify the uncertainty associated with this surrogacy approach for each listed species. To explore the influence of the use of the most sensitive values on risk conclusions, when additional data are available for a taxon, they are used to calculate the likelihood one individual will be impacted. For example, the 50th percentile of the SSDs are used to determine if there are still risk concerns for an individual. Or alternative chronic toxicity endpoints may be considered to represent effects to reproduction.

In some cases, the similarity (or lack thereof) of the available test species to the assessed species will be considered. For example, laboratory rat toxicity data are often used to represent effects to listed mammals. Dose-based endpoints are scaled to adjust for body weight. Uncertainties may be limited when extrapolating from the tested rats (0.35 kg) to other rodents of similar sizes; however, the extrapolation may be greater for larger mammals that weigh several orders of magnitude more (*e.g.*, grizzly bears weigh >350 kg). Similar considerations may be made for PPHD effects. For example, many listed species inhabit forests; however, plant toxicity data are generally available for herbaceous species instead of woody plants.

In summary, uncertainties associated with the available toxicity data as they relate to the assessed species will be considered in the weight of evidence analysis.

Areas within range where individuals may be more likely to occur (based on habitat)

As previously discussed, none of the species range or critical habitat data provided by the Services to date include information on distribution of individuals within the range. Without that information, EPA assumes that individuals of a listed species are located uniformly throughout the entire range. It may be possible to refine this assumption using habitat preference information for a species and matching it to land cover data, such as the GAP/LANDFIRE National Terrestrial Ecosystems dataset from USGS. For example, species that only occur on beaches or in forest would be expected to be concentrated within those areas that are located within the range of the species. Another example would be to use known elevation restrictions of a species. Since habitat type or elevation are spatial data, a quantitative overlap analysis could be conducted for these listed species and a probabilistic analysis (as described in part g) could be carried out using an overlap of the areas where the species is likely to occur and the areas of pesticide exposure to supplement the results for the whole range. Alternatively, a qualitative analysis could be carried out by considering these factors.

[60] https://www3.epa.gov/pesticides/nas/final/chlorpyrifos/appendix-2-6.docx
[61] https://www3.epa.gov/pesticides/nas/final/diazinon/appendix-2-6.docx

Relationship between species habitat and exposure models

If the conceptual basis for the exposure models are substantially different than the habitat of the assessed species, this would lead to uncertainty in the estimated exposures and effects. For example, for species that dwell in the interior of forests and pesticides with no forestry uses, exposure would only be assessed using the AgDRIFT model. 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. Another example would be for species whose habitats are only located at elevations above potential use sites, only having exposure via drift.

Migration or Dormancy

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. For species that have a seasonal dormancy or migrate, further consideration may 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.

In the case of migration and dormancy, effects from exposure and toxicity to a listed species are considered. If there are concerns for PPHD effects due to impacts to species that are present when the listed species is not, migration and dormancy may not be relevant to consider. For instance, there would still be risk concerns if effects to a species habitat occur while it is not present and then the species may be impacted later when individuals are present.

Consideration of Overlap of Species Range/Critical Habitat with Federal Lands

Many listed species have ranges or critical habitats that have substantial overlap with federal lands. Federal agencies that own lands with listed species occurrences may be required under Section 7 to consult with the Services when applying pesticides to those lands. Therefore, there may be existing consultations relevant to assessed species. The likelihood that individuals of a species will be exposed to pesticides on federal lands will be considered, especially when consultations are already available. If a substantial portion of the species range overlaps with federal lands, this may influence the likelihood that an individual will be exposed and will be a factor considered in the overall weight of evidence.

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 or pesticides. 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 determination should be provided. The rationale should clearly state the specific reasons why the factors considered are believed to limit potential exposures and risk.

Confidence associated with LAA determinations

This assessment employs three categories (*i.e.,* strongest, moderate and weakest) to convey the confidence in the weight of evidence associated with an LAA determination. These categories are based on the extent to which assumptions related to pesticide usage or the species influence the likelihood that an individual will be impacted. Each category is described below along with some additional lines of evidence that may increase or decrease the confidence category. The three strength of evidence categories applied to LAA determinations are not used for NE or NLAA determinations. Given the conservative nature of the Step 1 analysis, EPA is confident that when a NE determination is made, there will be no effects to an individual of the assessed species. Similarly, because the Step 2 analysis is also conservative and the Weight of Evidence analysis errs on the side of the species when there is uncertainty, EPA is confident that when a NLAA determination is made, that an individual of a species is not likely to be adversely affected.

The strongest evidence in LAA determinations is represented by cases where assumptions related to usage (Step 2, part h) and species (Step 2, part i) are not expected to have a major influence on risk conclusions. The strongest evidence of LAA is represented by multiple lines of evidence that indicate that the assessed chemical is likely to adversely affect at least one individual of a listed species. A strong evidence of risk may be represented by a case where different distributions of treated acres, average PCTs and typical application rates still result in potential effects to one or more individuals. In this confidence category, there is a reasonable degree of certainty associated with the usage data relevant to the species (*e.g.,* agricultural data in ConUS), especially for the uses with the greatest likelihood of resulting in exposure (*i.e.,* those with the largest amount of overlap when potential use sites and usage data are considered). A strong evidence of risk may also be determined for a species (or critical habitat determination) when different population size assumptions and toxicity data still indicate that one or more individual may be impacted. In these cases, there is a high degree of confidence associated with the species range/critical habitat. In addition, the models used to estimate exposure are considered representative of the species habitat.

Moderate evidence in LAA determinations is represented by cases where some, but not all lines of evidence indicate that 1 or more individuals may be impacted; or there are uncertainties associated with the data that can influence the confidence in making an LAA determination. An example of moderate evidence may be a case where 1 individual is impacted with only some combinations of distribution of treated acres, max and average PCT and typical application rates. The moderate evidence category may also be appropriate when species specific parameters, such as population size or toxicity endpoints greatly impact the results and make the difference between greater than one or less than one individuals being impacted.

The weakest evidence in LAA determinations is represented by cases where there is evidence that an individual may be adversely affected; however, it is only supported by a few lines of evidence. In this case, only conservative assumptions related to usage (Step 2, part h) and species (Step 2, part i) lead to an estimate that one or more individuals may be adversely affected. Risk to an individual is concluded and an LAA determination is made; however, there is a substantial amount of uncertainty in making an LAA determination.

There are some additional lines of evidence that may increase the confidence category of a LAA determination. For example, the presence of reliable incident reports associated with labeled uses for the taxon representing the assessed species may increase confidence in LAA determinations because incident reports provide support for concluding that non-target organisms may be exposed at levels that may result in adverse effects. Also, presence of monitoring data relevant to the species that exceed toxicity thresholds (**Table 3**) for the species or its PPHD may increase confidence that in general adverse effects could occur. Similarly, mesocosm data may be used as a line of evidence in considering potential effects to PPHD.

There are several lines of evidence that may decrease the confidence category of a LAA determination. These considerations relate to the calculation of the likelihood that an individual may be impacted. First, if there are major uncertainties in the usage data associated with the uses that have the greatest degree of overlap, then confidence in an LAA determination may be reduced. For example, usage data in Hawaii and Puerto Rico overestimate the chemical specific usage because they are based on entire categories of pesticides (*e.g.,* insecticides) on broad landcover classes (*e.g.*, all agriculture). Second, uncertainty associated with the species range would reduce confidence in LAA determinations (*e.g.,* a species' range is based on political borders, but other data indicate that the range is more refined). Third, if the conceptual basis of the exposure models are substantially different than the habitat of the assessed species, this would also reduce confidence in the effects determinations. For example, reduced confidence in the exposure potential of a species may occur for an aquatic species that inhabits a near-shore estuarine/marine environment, and modeling is based on freshwater flowing waterbodies. Fourth, there is uncertainty associated with the surrogate test species used to define effects thresholds. For example, avian toxicity endpoints are used to represent effects to a listed reptile and terrestrial amphibian species. Although a necessary assumption given the paucity of reptile and amphibian species tested, there is uncertainty related to extrapolating toxicity thresholds across broad taxonomic groups. Lastly, there may be decreased confidence in an LAA determination when drift is the only contributor to exposure for a listed species, as there is uncertainty with the wind direction and wind speed in relationship to where the listed species may occur. There may be additional considerations related to the chemical or species that also impact the confidence in the LAA determination.

Summary

EPA is using an iterative process for developing methods and conducting national-level BEs for conventional pesticides. EPA, working with the other relevant agencies, believes it is important to continue to refine the pesticide consultation process using the best available information, and consistent with the ESA and its regulations implementing Section 7. This Revised Method is being applied to future pesticide biological evaluations that EPA conducts for listed species. This involves making one of three different determinations when considering the impacts of the pesticide on an individual of a listed species: No Effect, May Affect and Not Likely to Adversely Affect or May Affect and Likely to Adversely Affect. The method described in this document accounts for EPA's experience with applying previous methods for conducting listed species assessments, feedback from other federal agencies, public comments and recommendations from the NRC. The approach is broken into two steps, both of which include decision frameworks that are intended to conservatively and efficiently make NE or NLAA determinations, saving resources and time for those species that need greater consideration to decide if NLAA or LAA determinations are warranted. When deciding between the NLAA or LAA determinations, a weight of evidence approach is applied that includes probabilistic elements and considers impacts of conservative assumptions related to how and where the pesticide is used and assumptions related to the assessed species location and likelihood of exposure. This process will allow EPA to use of the best available information to confidently determine when a pesticide will have No Effect or is Not Likely to Adversely Affect an individual of a listed species. This will allow for identification of species where the pesticide is Likely to Adversely Affect an individual, communicate the confidence associated with the effects determinations, and provide additional information related to the potential impacts on the species under the scenarios evaluated that can then be assessed by the Services at the population level.