

Response to Public Comments Received on
Proposed Revised Method
for National Level Endangered Species Risk Assessments
for Biological Evaluations of Conventional Pesticides

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1. Introduction

On May 16, 2019, EPA released a proposed, Revised Method that included advancements to the first iteration of the Interim method used to evaluate potential risks to federally threatened and endangered species. EPA received public comments on the proposed Revised Method through August 15, 2019, which included a 45-day extension of the original public comment period. From July-October 2019, EPA conducted tribal outreach during the public comment period, followed by formal tribal consultation. EPA requested comments on the overall method and on four specific aspects of the Revised Method, including: incorporation of usage data, probabilistic analyses, use of a Weight of Evidence approach, and application of a 1% overlap threshold (based on overlap of species ranges and the Action Area) for making no effect determinations. The sections below summarize the comments received during the public comment period, as well as EPA responses to these public comments. Because EPA was seeking comments on the Revised Method, comments received that were not on the Revised Method (*e.g.*, on specific pesticide active ingredients, on Biological Opinions, etc.) are not addressed here.

A total of 80 comments were submitted¹. Several of those were either duplicate submissions or requests for extensions of the public comment period. Forty-six comments that pertained to the Revised Method were submitted by varying stakeholders, including: Chairs of the House Committee on Natural Resources, state and county governments, federally recognized tribes, wastewater treatment and stormwater agencies, mosquito control organizations, pesticide registrants or registrant groups/affiliates, grower groups or affiliates, environmental non-governmental organizations and unaffiliated individuals (**Appendix A**). The sections below summarize comments received (sometimes grouping similar comments made by different submitters) and the EPA responses. Comments are organized by the four topic areas on which EPA requested comment, general comments on the method, additional comments on other topic areas and additional (future) reviews of the Revised Method.

EPA appreciates the input provided during the public comment period and during tribal consultation. When updating the Revised Method document, EPA carefully considered these comments. Based on the input from the public, tribes as well as the Services and USDA, 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;

¹ Available at: <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0185>

- Species inhabiting federal lands are no longer considered in Step 1, but rather in the Weight of Evidence of Step 2.

2. Summary of Comments and EPA Responses on Four Topics for which EPA Requested Feedback

2.1. Pesticide usage data

Comment 1: Responsible Industry for a Sound Environment, Lee County Mosquito Control District, Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau, Minor Crop Farmer Alliance, Pesticide Policy Coalition, FIFRA Endangered Species Task Force and Crop Life America expressed support for inclusion of usage data into the BEs. Some indicated that these data are an accurate reflection of how pesticides are likely to be used and incorporate the “best scientific and commercial data available” as required by the Endangered Species Act (ESA).

EPA response: *EPA agrees that incorporation of usage data allows for a more accurate reflection of how pesticides are likely to be used. Since this allows for a more accurate estimate of the likelihood that an individual of a listed species will be exposed, EPA believes these represent the best available information and has incorporated these data into Step 2 of the Revised Method.*

Comment 2: Xerces Society, Northwest Center for Alternatives to Pesticides (and 8 other groups), Defenders of Wildlife and Center for Biological Diversity, Washington State Department of Agriculture expressed concerns about incorporation of usage data into Step 1 of the Biological Evaluation (BE), where either a No Effect (NE) or May Affect (MA) determination is made. These commenters were concerned that excluding potential use sites from consideration in Step 1 is not sufficiently conservative and may mistakenly result in NE determinations if a pesticide should be applied in an area where it has not historically been used (according to usage data).

EPA response: *The proposed Revised Method included usage data in the derivation of the Action Area. EPA has changed the Revised Method so that usage data are no longer incorporated into Step 1. EPA has incorporated usage data into Step 2 of the Revised Method. When usage data (i.e., PCT, average rate, application timings, etc...) are incorporated into the risk assessment, the best available, scientifically valid data are used. EPA believes that data on pesticide usage represent critical information for determining whether an individual of a listed species is likely to be exposed and adversely impacted, which is the goal of Step 2.*

Comment 3: Washington State Department of Agriculture commented that usage data should not be used in the establishment of Action Areas. They commented that they “would like to see usage data utilized more heavily in Step 2 with traditional modeling for risk assessments, if the usage data is locally collected for the specific crops grown in that area.” They added: “The Step 2 process could use a probabilistic modeling approach and consider labeled rates, including the maximum labeled rate, along with other variables and also incorporate an evaluation of usage data into the Weight of Evidence approach.”

EPA response: *As stated above, several commenters expressed concerns about incorporation of usage data into Step 1 of the Biological Evaluation (BE), where either a No Effect (NE) or May Affect (MA)*

determination is made. These commenters were concerned that excluding potential use sites from consideration in Step 1 is not sufficiently conservative and may mistakenly result in NE determinations if a pesticide should be applied in an area where it has not historically been used (according to usage data). EPA has incorporated usage data into Step 2 of the Revised Method. When usage data (i.e., PCT, average rate, application timings, etc...) are incorporated into the risk assessment, the best available, scientifically valid data are used.

Comment 4: Xerces Society, Northwest Center for Alternatives to Pesticides (and 8 other groups), Center for Biological Diversity, Trout Unlimited, OR and individuals expressed concerns about consideration of usage data in Step 2, which is where Not Likely to Adversely Affect (NLAA) and Likely to Adversely Affect (LAA) determinations are made. Commenters indicated that labels should be used to represent potential use sites and to define maximum application rates.

EPA response: *EPA believes that data on pesticide usage represent critical information for determining whether an individual of a listed species is likely to be exposed and adversely impacted, which is the goal of Step 2. EPA also believes that the data on pesticide usage is the best available data with which to forecast future use. The alternative assumption is that all potential use sites are treated simultaneously, which is not realistic or representative of what is happening in the field, historically. Incorporation of usage data in Step 2 allows the EPA to use “real world” data to determine whether a pesticide is LAA or NLAA a listed species and if LAA, which uses are of greatest concern. EPA believes that available usage data described in the Revised Method are consistent with the ESA standard for use of the “best scientific and commercial data available.”*

Comment 5: Several commenters Northwest Indian Fisheries Commission, Xerces Society, Center for Biological Diversity, Trout Unlimited (OR) and Northwest Center for Alternatives to Pesticides (and 8 other groups) stated that incorporation of usage data is contrary to the recommendations of the National Research Council (NRC)². In regard to usage data, the NAS provided the following statement (p. 70):

“Pesticide application rate is another important source of uncertainty. Despite a label's explicit application specifications, such as 1 lb of material per acre for corn fields, users commonly apply lower quantities according to the severity of their weed or pest infestation. However, Steps 1 and 2 of the ESA process (Figure 2-1) should ensure that no potentially unsafe pesticide applications are ignored. Accordingly, an exposure modeler can only assume that a given pesticide is applied at the maximum allowable rate. Furthermore, in Step 3 of the process (Figure 2-1), the Services cannot reasonably be expected to use information that suggests that substantially lower application rates are used unless supporting data are available. Such data must include statistical descriptions of the spatially and temporally distributed application rates. Moreover, some measures would have to be taken to ensure that a use pattern could not dramatically increase in any particular season or locale (for example, because of crop shifts). Only then could exposure modelers use such knowledge to obtain EECs with associated uncertainties. For now, pesticide use is probably an inaccurate input for exposure analysis; registration and labeling are not well suited for solving this exposure-analysis bias.”

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

EPA response: *The National Research Council addressed application parameters (i.e., maximum rate) but not usage intensity (i.e., how much is likely to be applied over a geographic area). Consistent with this recommendation, EPA is conducting the Step 1 analysis based on maximum application rates defined on the labels. EPA is also using maximum application rates in Step 2 as well as an analysis involving typical application rates that is intended to evaluate the potential influence of differences in application rates on risk conclusions.*

Since the purpose of the Step 2 analysis is to distinguish between whether a pesticide is likely or not to adversely affect an individual, it is critical to determine the likelihood of exposure to an individual. A pesticide label includes instructions for an application to a single field, orchard or other use site (e.g., garden). In order to determine the likelihood of exposure and resulting effect to an individual, it is necessary to consider the extent of usage across the multiple use sites. Assuming that all potential use sites are treated is not a realistic scenario and does not allow for true consideration of the likelihood of exposure and effects to an individual. Usage data represent the best available information to address this need (e.g., from the American Mosquito Control Association). On the pilot BEs for malathion, chlorpyrifos, and diazinon, EPA had previously received public comments recommending the incorporation of usage data. EPA reviewed those recommendations and determined that usage data would provide the best available information to evaluate potential exposure across multiple use sites.

Comment 6: Generic Endangered Species Task Force agreed with the use of the most recent 5 years of usage data to represent current uses (with the exception of label changes). Crop Life America commented that EPA should use average usage over a five-year period or account for trends in usage. Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau and the Pesticide Policy Coalition expressed support for the use of national and state level from the past 5 years so that areas where pesticides are not applied may be identified. The National Cotton Council supported incorporation of the most recent 5 years of usage data. They expressed criticism that the data do not predict future use, including reduction of use.

EPA response: *EPA uses the best available data to forecast future usage when conducting its risk assessments, including BEs. EPA encourages stakeholder engagement from early on in the risk assessment process.*

Comment 7: Attorneys General from ten states and Washington DC criticized the reliance of the proposed Revised Method “on incomplete and unreliable crop and past usage data in predicting future use even though there are wide data gaps in each of EPA’s selected sources, past usage is not necessarily indicative of future usage, and, in some cases, more comprehensive data are available.”

EPA response: *EPA believes that data on pesticide usage represent critical information for determining the likelihood of whether an individual of a listed species will be exposed and adversely impacted, which is the goal of Step 2. Incorporation of usage data allows the EPA to use “real world” data to determine whether a pesticide is LAA or NLAA a listed species and, if LAA, which uses are of greatest concern. EPA considers all available, scientifically credible data that meet our established quality standards.*

The EPA currently uses historical usage data to forecast future pesticide usage at the national level for dietary risk assessments. The forecast method being used was publicly vetted through a FIFRA Scientific Advisory Panel (SAP) in 2002. This method forecasts national pesticide usage for an active ingredient on individual crops.

Comment 8: Washington State Department of Agriculture commented that EPA did not propose a method to account for new uses and label changes. FIFRA Endangered Species Task Force indicated that a method should be developed for estimating usage of new active ingredients (based on usage of products that may be displaced).

EPA response: *The Revised Method is being used to assess chemicals in EPA's registration review program and uses for those chemicals. In the case of new active ingredients or new uses, the PCT refinements described would not be applicable. Other usage refinements (e.g., typical rates, reapplication interval, etc...) would also not be applicable because there would be no chemical-specific historical usage data. Nevertheless, there are other approaches that could be considered that may allow assessments to be refined, yet remain adequately protective. For example, forecasting approaches to predict percent crop treated based on market leaders. The suitability of alternative approaches will need to be evaluated on a case-by-case basis.*

Comment 9: Defenders of Wildlife and individuals commented that EPA needs to predict future usage over the 15-year time period of registration review for a pesticide. Several commenters expressed concerns about the validity of incorporating historical usage data, especially only 5 years, as a basis for calculating future usage. Commenters wondered how EPA would account for changes in crops and pest pressure. Center for Biological Diversity (and 37 other groups) indicated that usage is not expected to be stable over time and cannot be predicted. The Northwest Indian Fisheries Commission commented "As a snapshot in time, past market reports are a poor predictor of future pesticide usage in a context of crop rotations, climate variability, shifting crop patterns, and regulatory and other changes in relation to competing pesticides. Market reports are insufficient to inform pesticide application registrations for a 15-year period. EPA should retain reliance on labeled use to determine action areas."

EPA response: *As stated above, several commenters expressed concerns about incorporation of usage data into Step 1 of the Biological Evaluation (BE), where either a No Effect (NE) or May Affect (MA) determination is made. These commenters were concerned that excluding potential use sites from consideration in Step 1 is not sufficiently conservative and may mistakenly make NE determinations if a pesticide should be applied in an area where it has not historically been used (according to usage data). EPA agrees that usage data should not be incorporated into Step 1. The Revised Method now incorporates usage data into Step 2.*

EPA believes that data on pesticide usage represent critical information for determining the likelihood of whether an individual of a listed species will be exposed and adversely impacted, which is the goal of Step 2. Incorporation of usage data allows the EPA to use "real world" data to determine whether a pesticide is LAA or NLAA for a listed species and if LAA, which uses are of greatest concern.

The EPA currently uses historical usage data to forecast future pesticide usage at the national level. The current forecast method was publicly vetted through a FIFRA Scientific Advisory Panel (SAP) in 2002. The method forecasts national pesticide usage for an active ingredient on individual crops. EPA has evaluated the use of historical usage data to forecast future usage and currently uses this method for dietary assessment. In specific circumstances, EPA agrees that historical data are likely to be inadequate indicators of future pesticide usage. Introduction of a novel key pest (e.g., Asian Citrus Psyllid and huanglongbing in citrus in Florida is one example), market shifts due to the introduction of a pesticide tolerant crop, new uses, and certain other events have the potential to increase (or decrease) usage relative to historical observations, making some pesticide usage forecasts unsuitable for risk assessment

use in certain circumstances. EPA considers these factors to reduce the likelihood that unreliable forecasts of pesticide usage are used in assessments

EPA is assessing ways to present information about pesticide usage data and usage forecasting, while still fulfilling our obligations to protect the individual commercial, proprietary data points.

Comment 10: Several commenters expressed concerns about the use of proprietary sources of usage data that were proposed for incorporation into the Revised Method. Commenters included the Washington State Department of Fish and Wildlife, Florida Department of Agriculture and Consumer Services, Xerces Society, Northwest Center for Alternatives to pesticides (and 8 other groups), Center for Biological Diversity (and 37 other groups) and individuals. Concerns were expressed about a lack of transparency surrounding the source and the methods used to collect the usage data. Concerns were also expressed about the accuracy, completeness, reliability and quality of these data and the degree to which EPA has reviewed these data.

EPA response: *EPA uses a combination of proprietary and publicly available usage data. The primary publicly available usage data sources include: USDA NASS, California Pesticide Use Reporting, USDA APHIS, and the USDA Forest Service. Proprietary agricultural usage data are obtained from an agricultural market research company, Kynetec USA, Inc, which is an independent company that is not affiliated with pesticide registrants or government agencies. Similarly, non-agricultural data are obtained from Kline and company, a private, commercial source, as well as other private, commercial sources, governmental agencies, and public sources. EPA has evaluated the data and determined that they meet the EPA Quality System Policy (CIO 2106.0) and contracted proprietary sources are required to provide EPA with documented quality assurance procedures.*

While both the survey methodology and sampling strategy are proprietary and trade secret, EPA provides transparency by supplying a general description of the survey methodology and sampling strategy. Also, the pesticide usage estimate data that are used in the BEs are summarized (i.e., averaged and rounded) in the SUUMs that are released publicly with the draft BEs in the docket, to the fullest extent allowed by our contractual agreements. In addition, EPA is evaluating ways to present information about pesticide usage data and usage forecasting, while still fulfilling our obligations to protect the individual commercial, proprietary data points.

As stated above, EPA has evaluated the use of historical usage data to forecast future usage and currently uses this method for dietary assessment. In specific circumstances, EPA agrees that historical data are likely to be inadequate indicators of future pesticide usage. Introduction of a novel key pest (e.g., Asian Citrus Psyllid and huanglongbing in citrus in Florida is one example), market shifts due to the introduction of a pesticide tolerant crop, new uses, and certain other events have the potential to increase (or decrease) usage relative to historical observations, making some pesticide usage forecasts unsuitable for risk assessment use in certain circumstances. EPA considers these factors to reduce the likelihood that unreliable forecasts of pesticide usage are used in assessments.

Comment 11: Northwest Center for Alternatives to Pesticides (and 8 other groups) pointed to California as having a more complete usage data set.

EPA response: *The California Pesticide Use Reporting (PUR) data are more complete for California, both in terms of the use sites covered and the percent of users participating, than either the Kynetec AgroTrak® or USDA NASS California data sets; however, the PUR data also have limitations. For example,*

while the data are more complete for California, there are reporting inconsistencies between counties and in the way that some parameters are recorded, which make using the California PUR data unreliable for some usage statistics in certain circumstances. As an example, when a pesticide is applied multiple times to a fraction of the same field, those applications are generally considered to be to unique portions of the field, which may overestimate the Base Acres Treated, inflating the PCT. Also, despite mandatory reporting requirements, not all required pesticide users report.

EPA considers the strengths and limitations of all data available and uses the best available data in a scientifically appropriate manner. Surveys are not intended to be a complete accounting of every occurrence of an event. Properly designed surveys provide an accurate appraisal of the intended measures. The usage estimates from both the USDA NASS and Kynetec USA, Inc. are intended to provide usage estimates for the coterminous United States. The California PUR data cover only California and analogous datasets are not available for other states at this time. EPA considers all available usage data of acceptable quality in our analyses. Thus, information from California PUR, USDA NASS, Kynetec USA, Inc., and other pertinent sources are combined to provide the most comprehensive understanding of pesticide usage possible. The analysis and sources used are provided in the SUUM for each pesticidal active ingredient.

Comment 12: Xerces Society commented that seed treatment usage data may be unreliable. They referred to the following statement by the USGS: “Beginning 2015, the provider of the surveyed pesticide data used to derive the county level use estimates discontinued making estimates for seed treatment application of pesticides because of complexity and uncertainty.” They added: “It is not clear if this usage data source (Kynetec AgroTrack data) is the one of the primary sources that the EPA will also use. While the NASS Agricultural Chemical Use Program did start surveying for seed treatments in 2015, the survey focuses only on a subset of crops which is rotated by year.”

EPA response: *EPA agrees with Xerces Society that seed treatment usage data are currently very limited in scope and scale. The BEs developed for pesticidal active ingredients that have registered seed treatment uses will need to account for this data gap or new information will need to be identified and the quality of those data verified before use.*

Comment 13: Northwest Center for Alternatives to Pesticides (and 8 other groups) expressed concerns that available data underrepresent pesticide usage for non-agricultural uses.

EPA response: *Non-agricultural usage data are available for a limited set of uses from a commercial, proprietary data source. EPA has evaluated the data and determined that they meet the EPA Quality System Policy (CIO 2106.0) and have documented quality assurance procedures. EPA considers additional information that is provided through the public comment process, and will incorporate data of acceptable quality in an appropriate manner.*

Comment 14: The California Department of Pesticide Regulation commented “EPA’s proposed ‘action area’ approach for incorporating pesticide-specific usage data into No Effect determinations process is overly broad and inaccurately estimates the acres affected.” They indicated that the grouping of crops into 13 UDLs can affect precision of how minor crops are represented. They commented that their Pesticide Use Reporting system can “distinguish pesticides and their use rates to the geographic square mile for approximately 400 different crops, with some crops further divided by postharvest use such as fresh versus processing.”

EPA response: As stated above, several commenters expressed concerns about incorporation of usage data into Step 1 of the Biological Evaluation (BE), where either a No Effect (NE) or May Affect (MA) determination is made. These commenters were concerned that excluding potential use sites from consideration in Step 1 is not sufficiently conservative and may mistakenly result in NE determinations if a pesticide should be applied in an area where it has not historically been used (according to usage data). EPA has incorporated usage data into Step 2 of the Revised Method. When usage data (i.e., PCT, average rate, application timings, etc...) are incorporated into the risk assessment, the best available, scientifically valid data are used.

Grouping of CDLs into UDLs is a conservatism built into the Revised Method. In circumstances where additional refinement is warranted, incorporation of California PUR data may allow for greater precision and refinement of assessments.

Comment 15: Generic Endangered Species Task Force agreed that if there is no acreage in a given county (based on Census of Agriculture) or no usage data (as captured in the Summary Use and Usage Memo) for a state, “the ‘effect of the action’ is not reasonably expected to occur in those areas, and can therefore be excluded from the overlap analysis.” BASF indicated that with this approach, “the potential for refinement seems limited, particularly for UDLs containing a large number of individual agricultural uses.”

EPA response: As a point of clarification, EPA views the absence of acreage for a registered use of a pesticide in a county as reasonable grounds for excluding from the overlap analysis all treated acreage for those use sites from the state(s). Geographic areas that are unsurveyed or surveyed, but without reported usage, should not be excluded from the overlap analysis. Those areas should be included in the overlap analysis, if an appropriate surrogacy method is available it should be applied or 100% crop treated may be used in the absence of an appropriate surrogacy method.

Comment 16: Defenders of Wildlife recommended that EPA describe the available usage data and how data gaps will be addressed. The default assumption should be that all lands are included, unless there are sufficient data to do otherwise.

EPA response: EPA is providing several documents with each draft, and final BE that will describe and characterize the pesticide usage data sources used in the assessment. These documents are the usage data crosswalk and SUUM.

In the absence of sufficient data of an acceptable quality for the use site in the state of interest or information to develop an estimate based on surrogate data, the EPA uses conservative assumptions. In very few cases EPA does consider a default assumption of 100 PCT as a reasonable approximation of the likely usage of a pesticide.

Comment 17: Wastewater and Stormwater Treatment Agencies indicated that EPA could use sales and usage data collected annually by the California Department of Pesticide Regulation to improve urban pesticide usage estimates. Reported use and total annual sales data may be accessed at: <https://www.cdpr.ca.gov/dprdatabase.htm>. While the Center for Biological Diversity objected to the use of sales data to represent pesticide usage as it is not known where and when the sold pesticide was used.

EPA response: EPA considers California Pesticide Use Reporting data in assessments, as appropriate. EPA agrees with CBD that pesticide sales data, including those available from California Department of Pesticide Regulation, are of limited use in characterizing the timing and location of pesticide usage. Pesticide sales data can provide some information regarding the scale of usage for a pesticide. For example, historical sales for an established pesticide may be useful in ground truthing the reasonableness of estimated usage that rely on multiple conservative assumptions. One example could be comparing sales data to usage modeled for a year and finding that the single year modeled exceeds the 20-year sales total for the AI. Such an outcome suggests that the model is highly conservative overall. Of course, at a local level, the model may be less conservative than indicated by the disparity between the sales and modelled usage estimates.

Comment 18: Several groups discussed additional data sources of pesticide usage data. The Washington State Department of Agriculture indicated that they collect data on pesticide usage. They commented that “we typically find that pesticide applicators are most often utilizing the maximum label rates.” Several Grower Groups or Affiliates commented that EPA should engage stakeholders to obtain additional usage data. The American Mosquito Control Association indicated that they are willing to provide additional data on pesticide usage. They noted that “mosquito control districts do not often spray entire counties. They also noted that “mosquito populations requiring control are often localized,” with changes over time in the locations of these populations due to different factors, including “demographics, land development, and changing rainfall patterns.”

EPA response: EPA always welcomes the submission of additional pesticide usage information to better inform its assessments. EPA welcomes additional dialogue with stakeholders on the issue of usage data in environmental risk assessments and always welcomes the submission of additional pesticide usage information that grower groups can provide, which improves characterization. EPA Office of Pesticides also holds Environmental modeling Public Meetings to provide a public forum for pesticide registrants, other stakeholders, and EPA to discuss current issues related to pesticide fate, transport and exposure for risk assessments in a regulatory context. The October 2019 meeting focused on incorporation of usage data into environmental exposure and ecological risk assessments (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0879-0175>).

Comment 19: The Pesticide Policy Coalition, Generic Endangered Species Task Force, BASF and Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau indicated that EPA should use sub-state (e.g., county level) usage data when available. Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau indicated that Oregon State University Extension Service Staff are creating county level data sets. Generic Endangered Species Task Force pointed out two examples of sub-state data, including Kynetic AgroTRAK® Crop Reporting Districts and California Department of Pesticide Regulation Pesticide Use Report (PUR) data. BASF also pointed to California Department of Pesticide Regulation’s PUR and USDA data.

EPA response: EPA uses the best available, scientifically reliable data to inform our assessments. Statistically robust sub-state level data could be considered, if those data were available. In some circumstances those data are available for limited uses or over a limited geographic range, but not to the extent necessary for general incorporation into the BEs using the Revised Method.

EPA always welcomes information to better inform our decisions. EPA reminds all stakeholders that intend to generate data intended to supplement the information available to the Agency to consider

EPA's data quality standards and ensure that the data generated are of an appropriate quality and scope to be used by EPA.

Comment 20: Generic Endangered Species Task Force pointed out two examples of sub-state data, including Kynetic AgroTRAK® Crop Reporting Districts and California Department of Pesticide Regulation Pesticide Use Report (PUR) data. BASF also pointed to California Department of Pesticide Regulation's PUR and USDA data.

EPA response: *EPA has a comprehensive knowledge of the AgroTrak® study from Kynetec USA, Inc., USDA NASS, and California PUR pesticide usage data. Those PCT data are not consistently suitable for use below the state level on an annual basis. The reasons for this vary across source and year. For example, the number of samples at the substate level may be insufficient to provide the statistical power necessary in all of the 5-years or data collection inconsistencies over time may make sub-state level usage estimates unreliable. EPA uses the best available, scientifically reliable data to inform our assessments. Statistically robust sub-state level data could be considered, if those data were available. In some circumstances those data are available for limited uses or over a limited geographic range, but not to the extent necessary for general incorporation into the BEs using the Revised Method.*

Comment 21: The Northwest Center for Alternatives to Pesticides (and 8 other groups) criticized the state level usage data and PCT calculation because “within a state, PCT may vary significantly due to varying pest pressure or other reasons (for example, some pesticides are not permitted for use on certain soil types). As a result, overall PCT calculated at a state level may ignore large variations, and those variations may have significance for listed species.”

EPA response: *EPA uses the best available, scientifically reliable data to inform our assessments. Statistically robust sub-county level data could be considered, if those data were available. In some circumstances those data are available for limited uses or over a limited geographic range, but not to the extent necessary for incorporation in the revised method.*

EPA agrees that variations may occur for a pesticide within a state due to pest pressures or use restrictions. EPA addresses that uncertainty in the conservative manner by which the treated acres for approved uses are allocated to the overlap between the species range and the use sites.

Comment 22: Crop Life America provided a case study involving malathion, where county level usage data were applied. CLA suggested that EPA adopt this approach.

EPA response: *The county level usage estimates proposed by CLA are from USGS usage estimates that are derived from the AgroTrak® Study from Kynetec USA, Inc. This is the same proprietary agricultural pesticide usage data used by EPA. USGS created the Estimated Annual Agricultural Pesticide Use maps as part of the National Water-Quality Assessment (NAWQA) Project. In the documentation on USGS' website (<https://water.usgs.gov/nawqa/pnsp/usage/maps/about.php>), which accompanies the maps, USGS states:*

*Pesticide-use estimates from this study are suitable for making national, regional, and watershed estimates of annual pesticide use; however, the reliability of these estimates generally decreases with scale. **For example, detailed interpretation of where and how much use occurs within a county is not appropriate.** [emphasis added]*

EPA has discussed the reliability of the pesticide usage data at various scales with the primary data source for both USGS and EPA, Kynetec USA, Inc. The availability of reliable pesticide usage statistics below the state level are not available, with a few exceptions. Some usage statistics may be reliable for an individual crop at the crop reporting district scale, but the reliability varies by year for each crop and crop reporting district combination. This results in inconsistent reliability below the state level over multiple years of historical data. Therefore, the EPA is not using the the AgroTrak® Study by Kynetec USA, Inc data at a scale below the state level at this time.

EPA has made a decision not to use available sub-state level usage data after careful deliberation. While the data do exist and others may find the data suitable for their purposes, EPA has determined that the data lack sufficient statistical rigor below state level for incorporation in the BEs.

Comment 23: Florida Department of Agriculture and Consumer Services asked for information on the source of usage data for urban uses.

EPA response: *EPA acquires non-agricultural usage information from a commercial, proprietary data source, stakeholders, federal, state, and local government agencies, and some public sources. These data will vary for specific active ingredients. Data sources will be disclosed in the SUUM for each AI that will be placed into the docket with the draft and final BEs.*

Comment 24: Crop Life America indicated that additional non-agricultural data are available and that CLA will help provide it to EPA.

EPA response: *As stated in the previous comment response, EPA also utilizes a proprietary data source.*

Comment 25: Responsible Industry for a Sound Environment and Crop Life America indicated that usage data may be available through the Residential Exposures Joint Venture task force.

EPA response: *EPA is in the process of considering the utility of the Residential Exposures Joint Venture data for ESA assessments.*

Comment 26: BASF indicated that SUUMs should be made publicly available. They stated that “it is very important that more information is provided on how the data are collected, filtered, organized, and analyzed for use in the ESA process.”

EPA response: *When a BE is developed for a pesticide, EPA intends to release the pesticide-specific SUUMs with the draft BE during the public comment period. The SUUM will include the data sources used in the use and usage analysis, as well as characterization of the data and usage statistics.*

Comment 27: FIFRA Endangered Species Task Force commented that it would be helpful if EPA establish a transparent procedure describing which usage data are accessed.

EPA response: *As mentioned previously, EPA intends to release the SUUMs with the draft BEs during the public comment period. The SUUMs provide citations of the sources of data used to generate the document.*

Comment 28: Northwest Indian Fisheries Commission, Northwest Center for Alternatives to Pesticides (and 8 other groups), Trout Unlimited (OR) and Individuals expressed concerns that monitoring data

included detections in areas where no usage was reported. They cited a presentation by the National Marine Fisheries Service that included a comparison of states where there was no diazinon usage data reported (from 2010-2014) to detections of diazinon in monitoring data (sampling dates not reported).

EPA response: *Ambient monitoring data involve collection of available water and sediment samples, most often without information on pesticide usage within the watershed where the samples were collected. When comparing monitoring data to usage data, it is important to consider whether the times when the data were collected match so that the usage data are representative of the uses registered at the time the monitoring samples were collected. During the re-registration of diazinon, substantial changes were made to the registered labels, including alteration of many uses (e.g., cancellation of residential uses, rate reductions, prohibition of aerial applications)³. There is uncertainty in the comparisons of the usage data to the monitoring detections because the dates of the monitoring data were not provided. The usage data reflect current registrations of diazinon. If the monitoring samples were collected prior to 2010-2014 (when the usage data were collected) and prior to the implementation of the label changes, the monitoring data may represent detections relevant to uses that are no longer registered, including usage of existing stocks. Another consideration is that if usage of a pesticide is rare, it may not be detected in a survey or even by required reporting, but use may be detected in monitoring data. For this reason, the Agency intentionally differentiates between “No usage reported” and “no usage” and EPA considers monitoring prior to the final determination for the species. Additionally, EPA is including the consideration of water quality monitoring data in the Revised Method as a specific line of evidence for each effects determination and to qualitatively evaluate downstream transport.*

Comment 29: Wastewater and Stormwater Treatment Agencies commented that EPA must evaluate all pesticide uses that are being approved, not just those uses with historic usage.

EPA response: *EPA will consider all uses allowed on product labels for the assessed pesticide that are registered under Sections 3, 24(c), and 18 of the Federal Insecticide Fungicide Rodenticide Act (FIFRA) when developing BEs. As stated above, the proposed Revised Method included usage data in the derivation of the Action Area. EPA has changed the Revised Method so that usage data are no longer incorporated into Step 1. Therefore, all registered uses, even those without demonstrated usage are included in Step 1, definition of the Action Area.*

EPA incorporates usage data into Step 2 of the Revised Method. When usage data (i.e., PCT, average rate, application timings, etc...) are incorporated into the risk assessment, the best available, scientifically valid data are used. EPA believes that data on pesticide usage represent critical information for determining whether an individual of a listed species is likely to be exposed and adversely impacted, which is the goal of Step 2.

Comment 30: Several commenters, including Crop Life America, Generic Endangered Species Task Force, Pesticide Policy Coalition and Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau, expressed concerns that the calculation of percent crop treated values was unclear. Also, they expressed concerns about the proposed approach where all treated acres are assumed to occur within the range of the species and expressed that a uniform treated acre approach (throughout the state) or probabilistic approach should be considered.

³ https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-057801_31-Jul-06.pdf

EPA response: Additional details on how PCT is calculated and applied have been added to the Revised Method. Also, the Weight of Evidence analysis considers the influence of the assumption that all treated acres are located within a species' range or critical habitat. In the Weight of Evidence, EPA will assume that treated acres are uniformly located throughout a given state (to which the usage data apply) and also concentrated within the species range and use both results in making its final conclusions.

Comment 31: Xerces Society expressed concerns about defining the action area using usage data and using state-level aggregated PCT values when not all crops within a state are assessed. They expressed concerns that the PCT values may not account for variability and may not be conservative.

EPA response: As stated above, the proposed Revised Method included usage data in the derivation of the Action Area. EPA has changed the Revised Method so that usage data are no longer incorporated into Step 1. EPA has incorporated usage data into Step 2 of the Revised Method. When usage data (i.e., PCT, average rate, application timings, etc...) are incorporated into the risk assessment, the best available, scientifically valid data are used. EPA believes that data on pesticide usage represent critical information for determining whether an individual of a listed species is likely to be exposed and adversely impacted, which is the goal of Step 2.

The use of state-level aggregated PCT values, as outlined in the Revised Method, make very conservative assumptions about the PCT for unsurveyed crops. The aggregated PCTs are a combination of estimated PCTs for crops surveyed in the state weighted by the acreage of the crop within the state, upper-bound estimated PCTs for crops that are not surveyed within the state, but for which usage data exist, and unsurveyed crops without suitable surrogates, which are included as 100 PCT. (Estimates of usage for unsurveyed uses through the use of surrogate, surveyed crops must be done on a case by case basis and will be detailed in each BE. When identifying a surrogacy method, the EPA takes a conservative approach intended to refine the usage estimate, but avoid underestimation. In very few cases is the alternative – a default assumption of 100 PCT – a reasonable approximation of the likely usage of a pesticide.)

Comment 32: Crop Life America indicated that EPA should clarify if the PCT calculation is based on treated acres or if treated acres is estimated from the amount of pesticide mass applied divided by a maximum label application rate.

EPA response: For our primary agricultural data sources, the PCT is the base acres treated (BAT) (i.e., the number of unique acres treated at least once in given survey year for a use site) divided by the crop acres grown (CAG) (i.e., the acres of a given use site that occur within a given survey year). BAT is directly reported in the agricultural usage data, not calculated based on label rates.

For some non-agricultural usage sources, the treated acres may be back-calculated using a maximum label rate and the average annual pounds AI applied per year, which are provided in the SUUM. The mass of pesticide applied divided by the maximum label rate for each site provides an estimate of the minimum number of acres treated. If applications were made at less than the maximum label rate, then this calculation could underestimate the number of acres treated. However, for non-agricultural uses, these may be best available data at this time. EPA considers the methodology used to derive usage statistics and would consider this to method a potential underestimate of the number of acres treated and treat it accordingly.

Comment 33: In regard to the use of USDA's census data for all insecticides to represent usage of a single pesticide active ingredient (when no chemical specific data are available), Responsible Industry for

a Sound Environment indicated that this would be an overestimate of the pesticide usage of that single assessed pesticide.

EPA response: *EPA agrees that this will over-estimate the usage for the single assessed pesticide; however, in the absence of other available data, this substantively improves the accuracy of the estimate relative to a default assumption of 100% crop treated.*

Comment 34: Crop Life America provided usage data for 13 pesticides and pointed out several case studies published in the scientific literature that involve application of usage data for endangered species assessments. Crop Life America summarize their submission as “suggestions that would further improve the final version but need not delay its publication, and areas for review in the future.”

EPA response: *EPA is considering the additional information provided by Crop Life America. As requested by Crop Life America, EPA expects to fully evaluate the information, including the merits of the methodology used in the malathion case study, and incorporate appropriate information and methods into future BEs as part of our efforts to improve our assessments in this iterative process.*

Comment 35: The Skokomish Tribe comment that they do not support incorporation of usage data because it does not have checks and balances. They questioned what will be done if “usage is illegal and/or undocumented or misrepresented”? They also questioned how we know that data from industry sources are reliable and how objective guidelines are established for the application of usage data. They commented that the method does not predict future use.

EPA response: *As mentioned above, EPA uses a combination of proprietary and publicly available usage data. The primary publicly available usage data sources include: USDA NASS, California Pesticide Use Reporting, USDA APHIS, and the USDA Forest Service. Proprietary agricultural usage data are obtained from an agricultural market research company, Kynetec USA, Inc, which is an independent company that is not affiliated with pesticide registrants or government agencies. Similarly, non-agricultural data are obtained from Kline and company, a private, commercial source, as well as other private, commercial sources, governmental agencies, and public sources. EPA has evaluated the data and determined that they meet the EPA Quality System Policy (CIO 2106.0) and contracted proprietary sources are required to provide EPA with documented quality assurance procedures.*

While proprietary survey methodology and sampling strategy are trade secret, EPA provides transparency by providing a general description of the survey methodology and sampling strategy and the pesticide usage estimate data that are used in the BEs are summarized (i.e., averaged and rounded) in the SUUMs that are released publicly with the draft BEs in the docket, consistent with our contractual agreements.

EPA has evaluated the use of historical usage data to forecast future usage and currently uses this method for dietary assessment. In specific circumstances, EPA agrees that historical data alone are likely to be inadequate indicators of future pesticide usage. Introduction of a novel key pest (e.g., Asian Citrus Psyllid and huanglongbing in citrus in Florida is one example), market shifts due to the introduction of a pesticide tolerant crop, new uses, and certain other events have the potential to increase (or decrease) usage relative to historical observations, making forecasts for some active ingredients in those crops more complex. EPA considers the agricultural systems being evaluated to reduce the likelihood of incorporation of forecasts of pesticide usage reasonably anticipated to perform below expectations. In addition, EPA is evaluating ways to present information about pesticide usage data and usage

forecasting, while still fulfilling our obligations to protect the individual commercial, proprietary data points.

Comment 36: The Northwest Indian Fisheries Commission indicated that usage data are unreliable because they are proprietary and not open to scrutiny. They also commented that because the data have not been peer reviewed, they likely do not meet EPA’s standard for “best available science”.

EPA response: *As mentioned above, EPA uses a combination of proprietary and publicly available usage data. The primary publicly available usage data sources include: USDA NASS, California Pesticide Use Reporting, USDA APHIS, and the USDA Forest Service. Proprietary agricultural usage data are obtained from an agricultural market research company, Kynetec USA, Inc, which is an independent company that is not affiliated with pesticide registrants or government agencies. Similarly, non-agricultural data are obtained for private, commercial and public sources. EPA has evaluated the data and determined that they meet the EPA Quality System Policy (CIO 2106.0) and contracted proprietary sources are required to provide EPA with documented quality assurance procedures.*

Comment 37: The Northwest Indian Fisheries Commission commented “As a snapshot in time, past market reports are a poor predictor of future pesticide usage in a context of crop rotations, climate variability, shifting crop patterns, and regulatory and other changes in relation to competing pesticides. Market reports are insufficient to inform pesticide application registrations for a 15-year period. EPA should retain reliance on labeled use to determine action areas.”

EPA response: *As stated in response to **Comment 35**, EPA has evaluated the use of historical usage data to forecast future usage and currently uses this method for dietary assessment. In specific circumstances, EPA agrees that historical data alone are likely to be inadequate indicators of future pesticide usage. Introduction of a novel key pest (e.g., Asian Citrus Psyllid and huanglongbing in citrus in Florida is one example), market shifts due to the introduction of a pesticide tolerant crop, new uses, and certain other events have the potential to increase (or decrease) usage relative to historical observations, making forecasts for some active ingredients in those crops more complex. EPA considers the factors above to determining if there is a reasonable potential that the historical usage data may not adequately forecast future usage for the agricultural systems being evaluated. Other, more conservative methods for refining PCT could be considered if the described forecasting method was deemed inappropriate for a specific use. In addition, EPA is evaluating ways to present information about pesticide usage data and usage forecasting, while still fulfilling our obligations to protect the individual commercial, proprietary data points.*

The EPA agrees that the labeled uses should determine the action area for the consultation. The incorporation of usage data into the Revised Method has been moved from Step 1 to Step 2.

Comment : Washington State Department of Fish and Wildlife commented that EPA should use labeled use to determine action areas.

EPA response: *The EPA agrees that the labeled uses should determine the action area for the consultation. The incorporation of usage data into the Revised Method has been moved from Step 1 to Step 2.*

Comment 38: Responsible Industry for a Sound Environment commented that pesticide usage in forestry and rangeland areas is “likely to be limited and infrequent.”

EPA response: EPA has evaluated forestry and rangeland data for a limited number of pesticides. For those pesticides, EPA has found that usage in rangeland and forestry areas is limited to a small PCT. EPA will evaluate this on a case-by-case basis and consider how to best incorporate this into the assessments.

Comment 39: The Center for Biological Diversity criticized the proposal to use surrogate usage data when crop-state usage data are not available.

EPA response: In the absence of sufficient data of an acceptable quality for the use site in the state of interest, EPA may develop a usage estimate based on surrogate data (i.e., similar crops in the same state, the same crop in a nearby location with similar agronomic conditions, use of the national maximum in lieu of state data, etc...). When identifying a surrogacy method, the EPA takes a conservative approach intended to refine the usage estimate, but avoid underestimation. In very few cases is the alternative – a default assumption of 100 PCT – a reasonable approximation of the likely usage of a pesticide.

2.2. Probabilistic analysis

Comment 40: Several commenters expressed support for inclusion of probabilistic methods in the Revised Method. FIFRA Endangered Species Task Force, Crop Life America, Generic Endangered Species Task Force, the Pesticide Policy Coalition, the National Council for Air and Stream Improvement, Inc., Oregonians for Food & Shelter, Oregon Seed Council and Oregon Farm Bureau supported inclusion of probabilistic methods in the Revised Method. They indicated that probabilistic methods are more consistent with recommendations provided by the National Academy of Sciences and represent an advancement in the scientific methods used to assess risks to listed species. The American Mosquito Control Association expressed support for use of probabilistic methods, indicating that they represent a “more accurate measure of actual exposures requiring mitigation than deterministic methods.” The National Cotton Council expressed appreciation for the use of probabilistic methods rather than deterministic approaches, the latter of which do not represent environmental variation. The Minor Crop Farmer Alliance and California Rice Commission also expressed support for the use of probabilistic methods. The Washington State Department of Agriculture commented that the probabilistic analyses included in the proposed Revised Method “are reasonable and represents an important advancement in the methodology for assessing risk to listed species.” They encouraged EPA to expand the probabilistic methods. Responsible Industry for a Sound Environment commented “using probabilistic methods can also improve risk assessments’ credibility and avoid overconfidence in uncertainty-containing assessments by acknowledging and addressing this uncertainty up front. It also allows for better identification of pesticide applications that may actually pose risks to listed species, thus freeing up resources absorbed when models inaccurately find that species may be affected by pesticides, when in fact risks have been overestimated.” BASF supported the change from deterministic (in the interim method) to a probabilistic approach. They expressed support for the approach to account for variability in aquatic EECs using sensitive model parameters (application date and curve number).

EPA response: EPA agrees that probabilistic methods are consistent with the current state of the science and provides a more robust analysis, which is why we have incorporated those approaches in the Revised Method.

Comment 41: Responsible Industry for a Sound Environment commented that probabilistic analyses and discussion of uncertainties "can focus data collection activities by identifying points of uncertainty that could affect the Agency's ability to make quality, science-based decisions and that may require the collection of additional data."

EPA response: *EPA agrees that probabilistic analyses and incorporation of uncertainties can help identify areas where specific data could result in improvements to risk assessments, including BEs.*

Comment 42: Defenders of Wildlife supported the use of probabilistic analyses and at the same time encouraged the "agency to guard against any temptation to place probabilities above species protections." They also suggested that EPA provide more detail on the method and how analyses will proceed with "insufficient data."

EPA response: *Additional detail on the probabilistic method has been added to the Revised Method, including a discussion of the exposure estimates, as well as explanation of assumptions and uncertainties when data may be limited. Specific details on how the probabilistic method will be applied to effects determinations will be incorporated into pesticide-specific BEs. As discussed in the Revised Method document, NLAA and LAA determinations (where the probabilistic method is applied) are still conservative in nature (based on conservative assumptions made to address uncertainties).*

Comment 43: The Pesticide Policy Council recommended that EPA include a sensitivity analysis to allow for identification of the most influential uncertainties on the risk conclusions. This can inform future data collection efforts and risk mitigations. Crop Life America also suggested that EPA conduct a sensitivity analysis.

EPA response: *Additional details on major uncertainties, directional implications for assumptions have been added to the Revised Method (see Tables 5 and 6). 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. Sensitivity analyses are available for many of EPA's exposure models. In the future, EPA will consider conducting additional sensitivity analysis.*

Comment 44: The Pesticide Policy Coalition and Crop Life America indicated that EPA should explain the directional implications and magnitude of uncertainty in BEs.

EPA response: *EPA has added discussions and summary tables to the Revised Method to describe uncertainties and assumptions, including characterization of the conservativeness of the assumptions (Table 5 and Table 6).*

Comment 45: Crop Life America, Pesticide Policy Coalition and Responsible Industry for a Sound Environment indicated that EPA should make it clear that uncertainty does not equate to risk.

EPA response: *EPA agrees that risk and uncertainty are not the same. In the context of a BE, risk describes the likelihood that use of a pesticide will adversely affect an individual of a listed species. Uncertainty represents a lack of information. In cases where there is uncertainty, the Revised Method is designed to explore the influence of assumptions made to represent a range of possibilities given a specific uncertainty in the analysis.*

Comment 46: BASF indicated that the description of how the effects determination is made is described as a probabilistic analysis, but it seems that a screening analysis is conducted first.

EPA response: *In Step 1, the determination of “May Affect” vs. “No Effect,” includes a conservative analysis that is similar to EPA’s screening risk assessments conducted under FIFRA. However, Step 2, the determination of “Likely to Adversely Affect” vs. “Not Likely to Adversely Affect” is based on screening criteria, probabilistic analyses, and the weight of the evidence in consideration of variability and uncertainty (see description of Step 2 in Revised Method).*

Comment 47: The Center for Biological Diversity indicated that the Monte Carlo analysis method is substantially different from the Terrestrial Investigation Model (TIM) and is not vetted or tested.

EPA response: *The probabilistic method is different from TIM; however, it utilizes components of TIM and established probabilistic risk assessment methods (e.g., Monte Carlo analysis). These approaches have been vetted and discussed at FIFRA SAP meetings.^{4, 5}*

Comment 48: The Center for Biological Diversity commented that EPA does not discuss how the Revised Method addresses limitations previously identified with Monte Carlo analyses. Specifically, how variability and uncertainty are distinguished.

EPA response: *Additional details have been added to the Revised Method to describe how variability and uncertainty are addressed. In cases where distributions of model parameters are known and believed to influence exposure estimates (e.g., curve number), that variability is considered by incorporating distributions that capture the variability. Uncertainty is assessed by conducting multiple probabilistic analyses using conservative and median/average and lower bound assumptions. For example, in the case of how treated acres within a state are allocated relative to a species range, acres are assumed to be located within a species range. Treated acres are also assumed to be uniformly located throughout a state (average) and concentrated outside of the species range (lower bound).*

Comment 49: Crop Life America indicated that when risk is consistently overestimated, high and low risk situations cannot be separated, preventing identification of cases where risk mitigation should be focused.

EPA response: *The assessment process in the Revised Method distinguishes between those species where the pesticide will have no effect and may affect but is not likely to adversely affect and may affect but is likely to adversely affect an individual. For those species where a pesticide determination is LAA, EPA will describe the strength of the evidence. This process is intended to distinguish between cases where there is strongest, moderate or weakest evidence supporting the risk finding. Where there is risk to an individual, the EPA will characterize the evidence and confidence associated with the risk conclusion. This*

⁴ USEPA. 2001. A Probabilistic Model and Process to Assess Acute Lethal Risks to Birds. Prepared for the March 13 – 16, 2001 Scientific Advisory Panel Meeting. February 16, 2001. Prepared by Edward Fite, M.S., EFED/OPP; Ed Odenkirchen, Ph.D., EFED/OPP; and Timothy Barry, Sc.D., Office of the Administrator/Office of Policy, Economics and Innovation, US EPA.

⁵ USEPA. 2004. A Discussion with the FIFRA Scientific Advisory Panel Regarding the Terrestrial and Aquatic Level II Refined Risk Assessment Models (Version 2.0). USEPA/OPP/EFED. March 4, 2004.
http://www.epa.gov/scipoly/sap/meetings/2004/033004_mtg.htm#materials

allows risk managers to focus mitigation on specific species and use patterns and is also intended to better inform the biological opinions.

Comment 50: Crop Life America commented that the Revised Method does not discuss probabilistic analyses for acute and chronic exposures and risks to all assessed terrestrial organisms (e.g., mammals, reptiles, plants) and relevant exposure routes.

EPA response: *Detailed descriptions of the application of specific probabilistic methods will be included in the BE in which they are applied. This includes both acute and chronic exposures to terrestrial vertebrates, invertebrates and plants.*

Comment 51: Generic Endangered Species Task Force and Crop Life America suggested that EPA consider additional factors in the probabilistic analysis, including parameters related to drift and usage. For aquatic assessments, Crop Life America suggested that EPA consider using distributions for additional PWC parameters, including: slope, soil organic carbon and pesticide fate properties. Crop Life America also expressed concerns about the use of scaling factors in the probabilistic analysis of aquatic exposure, questioning whether the approach is more efficient. They requested that EPA provide additional discussion of the rationale for this approach. They indicated that it would be preferable that a Monte Carlo analysis would include variation of the most sensitive input parameters.

EPA response: *EPA agrees that additional factors could be considered for the probabilistic analysis. 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. In the future, EPA will consider adding other parameters to the probabilistic method.*

At this time, EPA intends to adjust the most important parameters with respect to runoff in the conduct of the PWC simulations and developing a distribution of EECs based on these simulations would be a good first attempt at applying a probabilistic approach to evaluating exposure to listed species. In the late 1990's the FIFRA Environmental Modeling Validation Task Force (FEMVTF) compared edge-of-field outputs from PRZM against measured data and conducted a sensitivity analysis of input parameters^{6,7}. FEMVTF found that two parameters, rainfall during the key period when the pesticide is on the field/crop and runoff curve number, were more important when considering runoff outputs than any other parameters. Rainfall during the key period when the pesticide is on the field/crop can be accounted for by adjusting the application date. Curve number can be accounted for by adjusting the hydrologic soil group based on the PWC scenario metadata and USDA's National Engineering Handbook⁸. EPA adjusted these two parameters in separate PWC simulations and, using the distribution of EECs, estimated scaling factors for use in the probabilistic assessment. In order to do a Monte Carlo analysis, as suggested by Crop Life America, EPA would have had to do thousands of runs for each initial PWC simulation. Using the scaling factor approach, EPA redid each of its initial PWC simulations 367 times, 365 times for the application dates and two additional times to adjust the curve numbers. The process proposed by EPA is

⁶ Jones, R.L., and M.H. Russell (ed.). 2001. FIFRA Model Validation Task Force Final Report. The FIFRA Environmental Model Validation Task Force.

⁷ Jones, R.L., and G. Mangels. 2002. Review of the validation of models used in federal insecticide, fungicide, and rodenticide act environmental exposure assessments. Environ. Tox. Chem. 21:1535-1544.

⁸ USDA. 2004. Chapter 9. Hydrologic Soil-Cover Complexes. Part 630 Hydrology National Engineering Handbook. USDA Natural Resources Conservation Service. 210-VI-NEH, July 2004

more efficient and still provides the best available information. Additional details have been added to the Revised Method document to describe the probabilistic approach.

Comment 52: Crop Life America suggested that EPA follow principles for conducting probabilistic risk assessments that have been previously published.

EPA response: EPA considered guiding principles for Monte Carlo analysis⁹. The probabilistic analysis in the Revised Method follows established scientific principles, as discussed at past FIFRA SAP meetings.^{10,11}

Comment 53: King County (Washington State) expressed support for the use of probabilistic methods. They disagreed with using it as part of a screening tool or during informal consultation with the services. They recommended that the probabilistic analysis include input from the Services about species life history (as part of formal consultation).

EPA response: EPA believes that probabilistic methods are consistent with the current state of the science and provide a more robust analysis than deterministic methods. Since the goal of Step 2 is to determine if a pesticide is likely or not likely to adversely affect an individual of a listed species, EPA believes that probabilistic approaches are appropriate to make a NLAA or LAA determination. After a determination is made, EPA would consult (either informally or formally) with the appropriate Service.

Comment 54: The Northwest Indian Fisheries Commission commented: “EPA acknowledges that its probabilistic analysis is inadequate by failing to integrate relevant data including chemical properties, aquatic species distribution, and field-scale application rates.”

EPA response: EPA believes that probabilistic methods are consistent with the current state of the science and provide a more robust analysis than deterministic approaches. The development of nation wide BEs continues to be an iterative process and will evolve as EPA gains experience. Additional discussion in response to **Comment 51**.

2.3. Weight of Evidence Methodology

Comment 55: Americal Mosquito Control Association, Minor Crop Farmer Alliance, Responsible Industry for a Sound Environment, Crop Life America, FIFRA Endangered Species Task Force, Pesticide Policy Coalition, Washington state Department of Agriculture: expressed support for the proposed Weight of Evidence methodology. Several indicated that use of a Weight of Evidence approach is an improvement to the method for assessing risks to listed species.

⁹ EPA (Environmental Protection Agency). 1997. Guiding Principles for Monte Carlo Analysis. Risk Assessment Forum, United States Environmental Protection Agency, Washington, D.C. EPA/630/R-97/001.

¹⁰ USEPA. 2001. A Probabilistic Model and Process to Assess Acute Lethal Risks to Birds. Prepared for the March 13 – 16, 2001 Scientific Advisory Panel Meeting. February 16, 2001. Prepared by Edward Fite, M.S., EFED/OPP; Ed Odenkirchen, Ph.D., EFED/OPP; and Timothy Barry, Sc.D., Office of the Administrator/Office of Policy, Economics and Innovation, US EPA.

¹¹ USEPA. 2004. A Discussion with the FIFRA Scientific Advisory Panel Regarding the Terrestrial and Aquatic Level II Refined Risk Assessment Models (Version 2.0). USEPA/OPP/EFED. March 4, 2004. http://www.epa.gov/scipoly/sap/meetings/2004/033004_mtg.htm#materials

EPA response: EPA agrees that Weight of Evidence methods provides a more robust analysis, which is why we have incorporated those approaches in the Revised Method.

Comment 56: Crop Life America, Pesticide Policy Coalition, Responsible Industry for a Sound Environment and BASF indicated that the Weight of Evidence method and qualitative method are unclear and additional details should be provided.

EPA response: EPA has updated the Revised Method to include additional description of the Weight of Evidence approach (see sections describing Step 2 parts h and i and section titled: “Confidence associated with LAA determinations”).

Comment 57: Several commenters objected to inclusion of dormancy and migration of species in the Weight of Evidence considerations. The Xerces Society and the Center for Biological Diversity (and 37 other groups) commented that this approach does not consider that dormant individuals may still be exposed, that persistence of a chemical may lead to a later exposure. Defenders of Wildlife indicated that indirect effects should be considered even when individuals of a species are not present, as they may impact the species when individuals are again present.

EPA response: EPA agrees that effects to a species’ prey, pollination, habitat and/or dispersal (PPHD)¹² should be considered, even if a species is not present. EPA also agrees that a pesticide’s persistence should be considered in determining if an individual of a listed species may be exposed after an application. On a limited basis, EPA intends to consider dormancy and migration of listed species. For example, if a pesticide does not impact PPHD of a listed species and it is not persistent, exposure may be limited for a listed species that is not present in the area of application (e.g., due to migration).

Comment 58: King County (in Washington State) commented that “EPA’s proposed assessment of dormancy, migration patterns, species range, and diet has numerous off-ramps to avoid analysis of the impacts of a pesticide.”

EPA response: Consideration of species life history characteristics are not intended to avoid analysis of a pesticide’s impacts, but rather to consider factors that may influence the likelihood that an individual will be exposed to the pesticide.

Comment 59: The National Cotton Council suggested that EPA incorporate some of the Weight of Evidence factors included in Step 2 (e.g., Dormancy State and Migration Pattern) into Step 1.

EPA response: EPA believes that these factors represent refinements to conservative assumptions related to species location that are relevant to the Step 1 analysis. These refinements are more appropriate to be considered in the Step 2 analysis, where the purpose is to determine the likelihood that an individual will be exposed and affected.

Comment 60: BASF indicated that EPA should provide additional information on how assessors determine whether a species will be dormant during pesticide applications.

¹² As discussed in response to **Comment 99**, EPA has replaced the term “indirect effects” with PPHD effects.

EPA response: EPA reviews the Services' documentation for listed species (e.g., recovery plans, 5 year reviews) and obtains information on the dormancy periods of specific species (if available). Species specific examples will be available in pesticide-specific BEs.

Comment 61: Xerces Society and Center for Biological Diversity (and 37 other groups) objected to focusing on a species' preferred diet, as other dietary items may still lead to relevant exposures.

EPA response: In Step 1, EPA will use the dietary item that results in the most conservative exposure. Since the objective of Step 2 is to determine whether a pesticide is likely or not to adversely affect an individual, the Step 2 analysis focuses on the dietary item that is most likely to lead to exposure.

Comment 62: Crop Life America indicated that the Weight of Evidence method should involve objectively weighing each piece of evidence, evaluating the relevance and reliability of each line of evidence and combining all lines of evidence to draw a conclusion.

EPA response: As described in the updated Revised Method, EPA has developed a process to consistently and objectively weigh evidence for each pesticide and species (see sections describing Step 2 parts h and i and section titled: "Confidence associated with LAA determinations"). Additional details will also be provided in pesticide-specific BEs.

Comment 63: Crop Life America indicated that it would be ideal if each line of evidence representing exposure and response is expressed as a probability distribution.

EPA response: EPA has incorporated distributions of several variables. Some variables are qualitative in nature and do not lend themselves to a probabilistic distribution (e.g., incident reports, monitoring detections). As the Revised Method is implemented, EPA will continue to develop the probabilistic approaches.

Comment 64: The Center for Biological Diversity commented that Step 2 does not include a Weight of Evidence approach, but rather a "triage approach." They described a Weight of Evidence approach as one that "takes into account multiple lines of evidence to come to a single conclusion" and a triage approach as one "whereby the EPA looks at a single line of evidence and decides if a NLAA or NE call can be made."

EPA response: Modifications were made to the decision frameworks and to the Weight of Evidence approach to make the method more transparent. Additional description was added to the Revised Method to clarify how multiple lines of evidence are considered in Step 2 to draw a conclusion, i.e., to make a LAA or NLAA determination. The decision frameworks are intended to clearly describe a process for making effects determinations in a consistent and efficient manner among species and pesticides. The frameworks are consistent with EPA's tiered risk assessment framework, where the analysis starts with simple, conservative analyses. If no effects are expected or if they are not likely, EPA can confidently make NE or NLAA determinations (respectively) based on the conservativeness of the assumptions. If not, the species proceeds to a refined risk analysis is conducted. This refined analysis takes more time and information to complete. The decision frameworks are designed to allow the EPA to focus its time and efforts on species that need additional consideration.

Comment 65: The Center for Biological Diversity commented that the final determination in Step 2 is subjective. They commented: "If the EPA finds the most conservative assumptions predict less than 1

individual being harmed, then the call will be NLAA. Conversely, if the least conservative assumptions predict greater than 1 individual being harmed, then the call will be LAA. However, if the prediction lies somewhere in the middle then EPA gives itself blanket authority to simply consider “other factors” to determine what call to make.” Northwest Center for Alternatives to Pesticides (and 8 other groups) commented “the EPA should be using consistent, scientifically valid methods to undertake the analysis. Conclusions should be based on the results of the consistent method and should not be suspected of bias by allowing too much case-by-case judgment.”

EPA response: *The Revised Method includes a process to allow assessors to consistently and objectively weigh evidence for each pesticide and species. EPA has updated the decision frameworks for Steps 1 and 2 and added a description of the weight of evidence method (see sections describing Step 2 parts h and i and section titled: “Confidence associated with LAA determinations”). The Revised Method description identifies the factors related to the assessed species and pesticide that may be considered. These revisions are intended to clearly articulate the decision logic for making LAA and NLAA determinations.*

2.4.1% overlap threshold for No Effect determinations

Comment 66: EPA proposed the 1% overlap threshold for NE determinations based on the co-occurrence of the species with the pesticide action area. This analysis would consider all potential use sites for the pesticide and the associated drift. This 1% threshold is based on the resolution of the data use in the spatial analysis. Several commenters, including Crop Life America, California Rice Commission, BASF, and Responsible Industry for a Sound Environment indicated that a cutoff is needed and appropriate given the conservativeness of the analyses.

EPA response: *EPA agrees with these commenters but has decided to move the 1% threshold to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations, EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.*

Comment 67: BASF commented that “the 1% cutoff is a reasonable cutoff threshold.” They indicated that “larger cutoff thresholds (than 1%) should be considered when, for example, county/state boundaries are used to define the extent of species range as there is inherently higher inaccuracy.”

EPA response: *EPA agrees that a larger cutoff value may be appropriate in some cases; however, since accuracy analyses are not available for species range data, alternative cutoff values cannot be quantified at this time.*

Comment 68: The National Cotton Council expressed support for the use of the 1% overlap threshold based on the explanation provided in the proposed Revised Method document. They indicated that this approach is highly conservative, “given the conservative nature of AgDRIFT.”

EPA response: *EPA agrees with these commenters but has decided to move the 1% threshold to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species*

specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.

Comment 69: Washington State Department of Agriculture expressed concerns about underestimating risk when using a 1% threshold, stating: “Species density may vary significantly throughout the species range and in the absence of refined datasets it is not advisable given the high level of uncertainty inherent in the species range data, pesticide use data, and pesticide usage geospatial datasets.” They agreed to the establishment of “protocols for overlap analysis” but commented that “an arbitrary censoring level or overlap of an area that is too small or doesn’t incorporate the correct zones of overlap would result in an unacceptable censoring level.”

EPA response: *EPA believes that the probability of an exposure is negligible under these conditions given the conservative assumptions included in the analysis. In addition to the very low likelihood of actual exposures occurring, the accuracy of the spatial data is not sufficient to put any meaning into results of 1% or less. The data accuracy and resolution simply do not support a level of specificity that is <1%. EPA may not have been clear in how this threshold would work and have clarified this analysis in the Revised Method and BEs. EPA has decided to move this to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.*

Comment 70: Xerces Society commented that “A one-percent overlap threshold for a may affect is ill-advised for all species but especially so for small, obscure, or difficult to identify invertebrates. Such species do not necessarily have range maps that can be considered reliable.” They added that the 1% threshold “ignores important considerations such as proximity of the application to the species’ habitats and whether the individuals of the species are evenly distributed across the mapped range.”

Similarly, the Northwest Center for Alternatives to Pesticides (and 8 groups) commented “A one-percent overlap threshold for a may-effect is ill-advised.” They expressed concerns with the approach because “Listed species ranges are often very poorly defined or broadly drawn.” Also, the approach does not account for “proximity of the application to the species’ habitats and whether the individuals of the species are evenly distributed across the mapped range.”

EPA response: *EPA has decided to move this to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.*

Comment 71: Washington State Department of Fish and Wildlife, Florida Department of Agriculture and Consumer Services, Attorneys General from ten states and Washington DC, the US House of Representatives Committee on Natural Resources, Environmental Policy Innovation Center, Defenders of Wildlife, Center for Biological Diversity (and 37 other organizations), Trout Unlimited, OR, and individuals indicated that a 1% cutoff is not consistent with the ESA. They expressed concerns that a 1% area could represent a large area for species with large ranges, potentially resulting in take. They were

also concerned that overlap of pesticide exposure sites (representing <1% total overlap) could occur in areas where species density is greater and does not account for species migration. Commenters suggested that EPA do not use a cutoff and that NE only be applied when there is no overlap.

EPA response: *EPA believes that the probability of an exposure is negligible under these conditions given the conservative assumptions included in the analysis. In addition to the very low likelihood of actual exposures occurring, the accuracy of the spatial data is not sufficient to put any meaning into results of 1% or less. The data accuracy and resolution simply do not support a level of specificity that is <1%. EPA may not have been clear in how this threshold would work and therefore clarified this analysis in the Revised Method and BEs. EPA believes this method is consistent with the ESA. It is important to note that based on the application of the method, 1% of the species range does not equal 1% of use area. This is because the 1% threshold includes all potential use sites in addition to drift from those use sites in all directions. EPA has decided to move this to step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.*

Comment 72: FIFRA Endangered Species Task Force suggested that EPA assess whether there is <1% overlap of species range and each separate use.

EPA response: *EPA has chosen to employ a conservative approach and will apply the 1% threshold to the action area, not each individual use. The decision to use the 1% threshold for the action area was made to err on the side of the species and keep effect determinations made using this threshold conservative. Additional consideration of the overlap is made during the Weight of Evidence when it is used as a surrogate for population exposed. EPA agrees these thresholds may be appropriate for the individual UDLs in some cases; however, to keep the application of this threshold conservative EPA has decided to only apply it to the action area at this time.*

Comment 73: King County (in Washington State) expressed concern that the 1% threshold “does not account for the downstream interconnected nature of watersheds, nor for sensitive life history stages.”

EPA response: *EPA will qualitatively evaluate the potential for downstream impacts to listed species associated with the medium and high-flowing bins, located in areas that have been removed from consideration during Step 1 or 2, as pesticides may be transported from upstream locations where usage occurs to locations where there is no usage. For listed species initially classified as NE or NLAA, EPA will consider the persistence of the pesticide and identify monitoring sites with detections that are upstream of the species range/critical habitat prior to making a final determination. Additional details are provided in the Exposure, Aquatic Habitats, Downstream transport section of the Revised Method.*

Comment 74: The Skokomish Tribe does not agree with the use of the <1% threshold of overlap to make NE determinations. They indicated that this approach is “ill advised when considering salmonids,” which are migratory and have large ranges.

EPA response: *EPA has decided to move this to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the*

distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.

Comment 75: The Northwest Indian Fisheries Commission commented that the use of a 1% threshold “undermines the purposes of the ESA.” They presented estimates of how much area is represented by 1% for salmonid species.

EPA response: *EPA has decided to move this to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations. It is important to note that based on the application of the method, 1% of the species range does not equal 1% use area. This is because the 1% threshold includes all potential use sites in addition to drift from those use sites in all directions.*

Comment 76: The Center for Biological Diversity commented: “An overlap of <1% could just as easily mean that the overlap is actually greater than 1% due to the 60 meter uncertainty in the CDL data points.”

EPA response: *EPA believes that the probability of an exposure is negligible under these conditions given the conservative assumptions included in the analysis. In addition to the very low likelihood of actual exposures occurring, the accuracy of the spatial data is not sufficient to interpret meaning from results of 1% or less. The data accuracy and resolution simply do not support a level of specificity that is <1%. EPA may not have been clear in how this threshold would work and therefore clarified this analysis in the Revised Method and BEs. It is important to note that based on the application of the method, 1% of the species range does not equal 1% of use area. This is because the 1% threshold includes all potential use sites in addition to drift from those use sites in all directions. The threshold is proposed only for the action area, which includes drift in all directions from the potential use site. This errs on the side of the species and retains conservatism in the effect determinations made with this threshold. EPA has decided to move this to Step 2 out of an abundance of caution following additional dialogue with the Services. By making NLAA determinations EPA will enter informal consultation with the Services for these national level listed species BEs. The informal consultation process will provide the Services an opportunity to share species specific information related to the distribution of individuals or more refined locations with EPA. This information may influence the effect determinations.*

3. Summary of General Comments on Proposed Revised Method and EPA Responses

Comment 77: Several groups, including Crop Life America, BASF, Generic Endangered Species Task Force, the National Council for Air and Stream Improvement, Inc. and Responsible Industry for a Sound Environment, expressed support for the Revised Method. Commenters indicated that the Revised Method is more scientifically robust, incorporating several National Research Council recommendations and represents an improvement to the method for assessing risks to listed species.

EPA response: EPA agrees that the Revised Method represents an improvement to the risk assessment method for BEs, is more robust and incorporates recommendations from NRC.

Comment 78: Responsible Industry for a Sound Environment and Crop Life America encouraged EPA to simplify the method through “scoping,” which would involve making no effect determinations earlier in the process to removing species or critical habitat from deeper analysis earlier in the risk assessment process, which would improve efficiency and save resources.

EPA response: The decision frameworks are intended to clearly describe a process for making effects determinations in a consistent and efficient manner among species and pesticides. The frameworks are consistent with EPA’s tiered risk assessment framework, where the analysis starts with simple, conservative analyses. If no effects are expected or if they are not likely, EPA can confidently make NE or NLAA determinations (respectively) based on the conservativeness of the assumptions. If not, the species proceeds to a refined risk analysis is conducted. This refined analysis takes more time and information to complete. The decision frameworks are designed to allow the EPA to focus its time and efforts on species that need additional consideration.

Comment 79: BASF and Generic Endangered Species Task Force indicated that, in order to fully understand the Revised Method, additional detail is needed.

EPA response: The Revised Method has been updated with additional details describing the method. In addition, details on how the Revised Method is implemented will be provided in pesticide-specific BEs.

Comment 80: Wastewater and Stormwater Treatment Agencies agreed that the pilot BEs, including the BE for malathion, was “unnecessarily complex,” “difficult to peer review” and “relatively inaccessible”. Responsible Industry for a Sound Environment commented that the BEs published so far were “extremely resource intensive but did not produce a meaningful assessment of potential risks from pesticides to endangered species.” They commented that the assessments relied upon overly conservative assumptions, resulting in conclusions that “were not grounded in the best available science.”

EPA response: Consistent with stakeholder input on the pilot BEs for chlorpyrifos, diazinon and malathion, EPA believes that the pilot method had the following major limitations: (1) The method did not meaningfully distinguish species that are likely to be exposed to and affected by the assessed pesticides from those that are not likely; (2) The level of effort was too high for EPA to sustain for all pesticides; and (3) The amount of documentation produced was too great for the public to review and comment upon in a reasonable timeframe. Therefore, EPA determined it was appropriate to refine the methodology. As discussed previously, the process for developing the national level BE methodology is iterative. The Revised Method builds upon lessons learned and comments from the Interim Method.

Comment 81: Center for Biological Diversity and the Skokomish Tribe commenters objected to the proposed Revised Method, expressing support for EPA to use the interim method.

EPA response: The process for developing the national level pesticide risk assessment method for listed species is an iterative process. EPA believes that the Revised Method represents an improvement to the interim method and includes a process for using the best available scientific information.

Comment 82: The Skokomish Tribe and an individual commented that it is necessary to conduct thorough BEs for pesticides. They expressed concerns with prioritizing efficiency over a thorough review.

EPA response: *EPA agrees that it is important to thoroughly assess the risks of pesticides to individual species. Given that there are approximately 2600 effects determinations (including listed species and critical habitats) to make for each pesticide and the number of pesticides to be assessed, EPA believes that it is necessary to improve efficiency in the BE process, where possible.*

Comment 83: Several commenters criticized the Revised Method, indicating that the method appears to be designed to reduce the number of species needing review. Washington State Department of Fish and Wildlife commented “Although not specifically stated, it appears the intent of the revision is to decrease the number of pesticide/species interactions to be sent for the full three-step evaluation, by increasing the number of No Effects determinations by EPA in Steps 1 and 2 of the BE.” Center for Biological Diversity (and 37 other groups) indicated that the Revised Method is designed to exclude species for consultation. The Attorneys General of 10 states and Washington DC commented “the Draft Method appears designed at each step to minimize the likelihood that further review of impacts to species will be required.” The Skokomish Tribe commented that, with this approach, species may be removed from further consideration before they reach Step 3. The Northwest Indian Fisheries Commission stated: “EPA should not utilize shortcuts that abort this complete review of pesticide registration impacts on the survival of species at both the individual and population scales.” The Garden Club of America commented “The adjustment of the language used in the modifications when describing the likelihood of ‘adverse effects’ weakens the guidelines and is intended to decrease the number of requests requiring full and formal evaluations.” The Northwest Center for Alternatives to Pesticides commented “It is very clear that the new methods are designed to produce fewer Likely to Adversely Affect calls (LAA), which must be forwarded for consultation to the Services.”

EPA response: *The objective of the Revised Method is to produce both a sustainable and scientifically sound risk assessment process to prepare BEs for pesticides. Consistent with EPA’s Tiered risk assessment framework, EPA has designed the Revised Method so that NE or NLAA determinations can be made with confidence, using conservative assumptions. This allows for more time and resources to be spent on species that the pesticide is LAA or for species that require more detailed analyses to distinguish between LAA and NLAA. Given the number of species and of pesticides, it is necessary for EPA to prioritize resources.*

Comment 84: Defenders of Wildlife recommended that EPA review the dichotomous keys in the Revised Method so that each question should result in “yes” or “no” answers.

EPA response: *EPA has revised the decision frameworks with “yes” and “no” answers.*

Comment 85: The Attorneys General of 10 states and Washington DC commented “the Draft Method should, but fails to, resolve data ambiguities in favor of species protection.” Adding: “the Draft Method uses the term ‘conservative’ in an inconsistent and contradictory fashion, but should instead hew to a species-protective approach consistent with the ESA’s precautionary approach.”

EPA response: *Step 1 has been revised to rely only on potential use sites and does not consider usage data. This approach is designed to be conservative and is precautionary in nature. EPA has a high degree of confidence in No Effect determinations given the highly conservative nature of the revised Step 1 approach. Since the goal of Step 2 is to determine whether the use of the pesticide is Likely or not to*

impact an individual, a probabilistic approach is warranted. Even in Step 2, however, LAA determinations are based on conservative approaches. The Revised Method is based on a Weight of Evidence approach. When uncertainties are identified, the Weight of Evidence considers the impact of assumptions on the risk conclusions. EPA believes that the conservative assumptions in the Revised Method are appropriate for assessing risks to listed species.

Comment 86: The Environmental Policy Innovation Center indicated that Step 1e is vague, lacking clarity and objective standards. FIFRA Endangered Species Task Force indicated that Step 1e is logical and can be based on the FIFRA screening risk assessment. Crop Life America suggested that, for taxa that are not expected to be impacted based on the FIFRA risk assessment, that lack of effect be considered for listed species within those taxa.

EPA response: *EPA has updated the Revised Method document to clarify that NE determinations may be made in Step 1 if no effects are expected to a listed species or taxa upon which it depends (i.e., for prey, pollination, habitat and/or dispersal). This approach is similar to the one employed in the FIFRA screening risk assessment.*

Comment 87: The Skokomish Tribe indicated that Step 3 is not discussed in the proposed Revised Method. They questioned: “If the BO determines that a listed species is in “jeopardy” or its designated critical habitat becomes “adversely modified”, is the EPA free to register the pesticide regardless of this consultation?”

EPA response: *The Revised Method describes the method to be used in BEs, which included Steps 1 and 2. Step 3 involves the development of a BO (when appropriate) by the Service(s). If a BO determines jeopardy or adverse modification, EPA will consider any Reasonable and Prudent Alternatives as well as any Reasonable and Prudent Measures in determining next steps under FIFRA.*

Comment 88: FIFRA Endangered Species Task Force suggested that EPA meet with pesticide registrants during Step 1 to discuss label changes that may result in “no effect” determinations.

EPA response: *EPA welcomes conversations with registrants to discuss their proposed changes to existing labels.*

Comment 89: Responsible Industry for a Sound Environment recommended that EPA also consider the beneficial uses of pesticides (e.g., invasive species control) in making its effect determinations for listed species.

EPA response: *Uses of a pesticide that are completely beneficial will be considered in making an NLAA or LAA effects determination for a species.*

Comment 90: The attorneys general of ten states and Washington DC indicated that climate change should be considered in the method.

EPA response: *The Revised Method is focused on potential discernible effects of an assessed pesticide active ingredient on a listed species. In a Step 3 analysis, the Services may consider other stressors on a listed species.*

Comment 91: Several commenters including Northwest Center for Alternatives to Pesticides (and 8 other groups) and BASF indicated that the proposed Revised Method document was unclear, lacked sufficient details and was difficult to understand. They indicated that it would be helpful to have examples of how the method is applied.

EPA response: *EPA has updated the Revised Method document to include more details to describe the method. Pesticide-specific BEs will provide specific applications of the Revised Method.*

Comment 92: Defenders of Wildlife, Center for Biological Diversity (and 37 other groups) and the Garden Club of America commented that EPA should consider off-label pesticide uses in BEs.

EPA response: *Since the action is based on labels registered under FIFRA, BEs focus on registered uses of pesticides. Because off-label uses are not legal, they are not part of the action, and are not included in the BEs. There are enforcement mechanisms to address off-label uses.*

Comment 93: Xerces Society and Northwest Center for Alternatives to Pesticides (and 8 other groups) commenters indicated that the assessment should be applicable to the 15-year time period of the registration review of a pesticide. They expressed concerns about language in the Revised Method that suggested that the assessment would be based on “any given year.”

EPA response: *EPA has clarified in the Revised Method that the assessment is applicable to the 15-year time period of registration review.*

Comment 94: Defenders of Wildlife recommended that EPA update the Revised Method document to cite the scientific literature that is the basis for the method.

EPA response: *EPA has added relevant citations throughout the Revised Method.*

Comment 95: Defenders of Wildlife recommended that EPA update the Revised Method by adding a discussion of how unoccupied habitat will be assessed.

EPA response: *EPA has updated the Revised Method to clarify that it will assume that unoccupied habitat is or could be occupied.*

Comment 96: Crop Life America suggested that EPA describe the sources and associated direction and magnitude of uncertainty in the Revised Method.

EPA response: *EPA has provided additional details in the Revised Method on major uncertainties, directional implications for assumptions (see Tables 5 and 6).*

Comment 97: Defenders of Wildlife, Xerces Society, Northwest Center for Alternatives to Pesticides and individuals objected to definitions of direct and indirect effects because they do not represent consultation handbook.

EPA response: *In the proposed Revised Method for public comments, EPA used the terms direct and indirect effects to represent toxicological effects of the pesticide on the assessed species or taxa upon which it depends (respectively). The commenter is correct that these definitions are different than those included in the consultation handbook, and EPA has updated the Revised Method to no longer use the*

terms “direct” and “indirect” effects to represent toxicological effects. Instead of indirect effects, in the updated Revised Method, EPA refers to effects to taxa for prey, pollination, habitat and/or dispersal (PPHD).

Comment 98: Xerces Society commented: “EPA must consider other dependencies in addition to prey, plant food, and pollination.” As an example, they pointed out that listed mussels require host fish to complete their reproductive cycles. US House of Representatives Committee on Natural Resources commented that the proposed Revised Method does not consider ecological relationships between listed plants and their pollinators.

EPA response: *The Revised Method considers effects to the Prey, Pollination, Habitat and Dispersal of a listed species. Potential effects to listed plants are assessed by considering effects to their pollinators. Effects to listed mussels will be assessed by considering potential impacts to their host fish (which is relevant to dispersal).*

Comment 99: Xerces Society commented: “It is unclear what taxon would be considered for indirect effects analysis to the many listed invertebrate filter feeders who consume bacteria, detritus, assimilated organic material, diatoms, phytoplankton, zooplankton, phagotrophic protozoans, and other microorganisms.”

EPA response: *In these specific examples, toxicity endpoints for algae and aquatic invertebrates would be used to assess potential dietary effects to listed aquatic species that are filter feeders.*

Comment 100: The Attorneys General from ten states and Washington DC, Environmental Policy Innovation Center, Center for Biological Diversity (and 37 other groups), Northwest Center for Alternatives to Pesticides objected to the use of the “reasonably certain to occur” standard, indicating that EPA is redefining the term “may affect.” The US House of Representatives Committee on Natural Resources commented “This proposal of a reasonable certainty threshold is unclear, and we are greatly concerned that its adoption would allow the EPA and other agencies to falsely claim that there is insufficient certainty about the effect of the pesticide and to therefore not take necessary actions to protect endangered and threatened species.”

EPA response: *Recently, the Services revised the implementing regulations for ESA. The following clarification was included:*

Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused 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. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. (Sec 50 CFR § 402.02).

Based on this language, a may affect determination considers whether an effect is reasonably certain to occur.

Comment 101: FIFRA Endangered Species Task Force and Crop Life America indicated that additional discussion of the conservativeness of the method should be included. Other commenters expressed concern that the Revised Method is not conservative.

EPA response: Additional discussion was added to the Revised Method to explain specific assumptions and uncertainties throughout the method, as well as the conservativeness of the assumptions (see Tables 5 and 6).

Comment 102: The National Cotton Council indicated that they believe that the proposed Revised Method is “overly conservative,” likely resulting in an overestimation of the number of May Affect and LAA determinations.

EPA response: The Revised Method is designed to be conservative. When NE and NLAA determinations are made, EPA is confident in the basis for these determinations. When uncertainty influences the whether or not it is likely that an individual will be adversely impacted, EPA will err on the side of the species and make a conservative determination. If an LAA determination is made, EPA will characterize the strength of the evidence supporting that determination, including consideration of uncertainties.

Comment 103: The Garden Club of America commented “The modifications [captured in the Revised Method] do not rely on impartial sources for data, skewing favorably towards industry.”

EPA response: EPA conducts independent reviews of available data prior to use in BEs. Data are reviewed for their quality, reliability and relevance. EPA uses the best available data when conducting risk assessments, including BEs.

4. Summary of Additional Comments on Specific Topics Related to the Proposed Revised Method and EPA Responses

4.1. Determination of off-site transport distances for pesticide exposure

Comment 104: Xerces Society, Northwest Center for Alternatives to Pesticides (and 8 other groups) and individual citizens expressed concerns that the method for accounting for off-site transport and exposure from spray drift (with a 2600 foot cutoff) does not account for downstream transport of pesticide runoff, volatilization, wind and rain transport, leaching to groundwater that is connected to surface water or long range transport.

EPA response: EPA’s Revised Method includes a process to evaluate downstream transport by using available monitoring data and the proximity of the measurements to the endangered species ranges/critical habitats (see discussion below). Volatilization and deposition are not considered significant routes of exposure for the pesticides currently slated for listed species analysis, based on their vapor pressures and Henry’s Law Constants; however, if EPA determines that these routes of exposure are significant and appropriate for the chemical under consideration, it will ensure that these exposure routes are considered in those assessments. Currently, EPA does not have a process for evaluating the impacts of groundwater connections to surface water and how pesticide concentrations in groundwater can influence surface water concentrations or downstream transport. However, given that EPA’s surface water aquatic modeling uses scenarios that are more vulnerable to runoff and less vulnerable to leaching to groundwater, the estimated exposure concentrations should be protective of groundwater intrusion into surface water. Additionally, EPA’s method for evaluating downstream transport, by looking at monitoring data that occurs upstream of a listed species range or critical habitat, should capture this connection between groundwater and surface water. EPA acknowledges that, under certain conditions,

long-range transport of certain pesticides with specific characteristics via wind and precipitation can occur. Evaluation of this type of transport is regional and chemical specific and time intensive. EPA believes that, for most pesticides, it should focus its efforts on evaluating near transport exposure routes, as they are the most likely to result in exposure at levels that can cause adverse effects to species. EPA will continue to evaluate how these issues can be addressed and is willing to discuss these issues with stakeholders.

Comment 105: Several commenters from Pesticide registrants or Registrant Groups/Affiliates or Grower Groups or Affiliates expressed concerns that the spray drift model (AgDRIFT) is out of date and overly conservative, resulting in overestimation of the off-site transport estimates for drift. The model does not include data from studies with drift reducing nozzles that are commonly used at this time. BASF suggested that EPA use REGDISP, which contains newer spray drift deposition data.

EPA response: *AgDRIFT is EPA's current tool for evaluating impacts due to spray drift. While the underlying data used to develop the algorithms used in AgDRIFT were conducted in the 1990s, the data and model estimates are still appropriate and valid for use in EPA's ecological risk assessments, including the BEs. EPA has not completed its evaluation of the underlying data from the Canadian trials used to develop the REGDISP model and thus cannot use the tool for the BEs. While the REGDISP tool allows for the use of newer spray drift deposition data, particularly coarse and ultra-coarse nozzles, there are no label restrictions for the pesticides currently slated for listed species analysis (i.e., only apply with coarse nozzles) that would necessitate the use of such data.*

Comment 106: Responsible Industry for a Sound Environment commented that AgDRIFT may not accurately estimate exposure for non-crop applications (e.g., ultra-low volume applications of mosquito adulticides) because it is based on agricultural application data.

EPA response: *EPA uses the AGDISP model, not AgDRIFT, when evaluating the potential deposition from non-agricultural applications, such as adulticide applications. Please refer to the 2017 malathion and chlorpyrifos BEs for details on how EPA evaluates spray drift from adulticide applications.*

Comment 107: Several commenters, including Attorneys General from ten states and Washington DC, the US House of Representatives Committee on Natural Resources and Environmental Non-governmental Organizations expressed concerns that the 2600-foot spray drift cutoff distance for the action area is arbitrary and insufficient.

EPA response: *EPA has limited the spray drift distance to 2600 feet based on the limits of the underlying data used to evaluate aerial applications in the Tier 3 module of AgDRIFT tool. 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. EPA believes that spray drift deposition estimates and the limits of the AgDRIFT model are protective of listed species in considering downwind deposition. 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 theoretically could occur under extreme circumstances, estimation of deposition should be limited to the extent of the model.

Comment 108: The California Department of Pesticide Regulation commented that “it is unclear if the EPA’s Pesticide in Water Calculator (PWC) is also used to set the boundaries of the off-site transport zone.” They also indicated that the off-site transport zone should include other pesticide transport mechanisms, including runoff, wastewater effluent and sediment transport (in addition to spray drift). They noted that these routes may transport pesticides further than 2600 feet.

EPA response: *EPA is not using the PWC to evaluate the off-site transport zone. Rather, AgDRIFT, along with the highest application rate and minimum toxicity threshold, are used to estimate an aquatic exposure concentration in order to define the extent of the action area. For listed species initially classified as NE or NLAA, EPA will consider the persistence of the pesticide and identify monitoring sites with detections that are upstream of the species range/critical habitat prior to making a final determination. Using ARCGIS and NHDPlus, EPA will evaluate the potential for any detected concentrations to reach the species range/critical habitat.*

Comment 109: The Washington State Department of Agriculture commented that the 2600 foot off site transport maximum distance is unlikely to characterize off site transport of pesticides due to down stream transport. They suggested that EPA “include a qualitative discussion of reliable monitoring data that shows detections above EPA’s estimated environmental concentrations.”

EPA response: *For listed species initially classified as NE or NLAA, EPA will consider the persistence of the pesticide and identify monitoring sites with detections that are upstream of the species range/critical habitat prior to making a final determination. Using ARCGIS and NHDPlus, EPA will evaluate the potential for any detected concentrations to reach the species range/critical habitat. This information will be used in the weight-of-evidence analysis before a final determination is made for the species.*

Comment 110: The Skokomish Tribe commented that the use of the 2600 maximum off site transport zone is a “dramatic ‘in a vacuum’ oversimplification of what happens in the landscape, where heavy weather, wind and rain can carry pollutants for miles.”

EPA response: *EPA acknowledges that, under certain conditions, long-range transport of pesticides via wind and precipitation can occur. Evaluation of this type of transport is regional and chemical specific and time intensive. EPA believes that, for most pesticides, it should focus its efforts on evaluating near transport exposure routes, as they are the most likely to result in exposure at levels that can cause adverse effects to species. EPA believes the use of the 2600-foot distance is protective of listed species, as it is based on validated spray drift modeling using a bare ground landscape and no interception.*

Comment 111: Wastewater and Stormwater Treatment Agencies commented that the 2600 foot geographic limitation on pesticide transport from use sites is insufficient because sources of pesticides reaching a water treatment facility may extend miles upstream from the facility.

EPA response: *It should be noted that the Revised Method is designed to evaluate the impacts of pesticides on listed species and is not designed for the evaluation of pesticide impacts at water and wastewater facilities. That being said, the 2600-foot distance is based on aerial agricultural applications of validated spray drift modeling using a bare ground landscape and no interception. The sources of pesticides reaching wastewater treatment facilities are typically those that are classified as down-the-*

*drain, or non-agricultural applications that are transported to the facility via sewer drains. In these cases, EPA includes a Developed use data layer that encompasses residences, rights-of-way, commercial areas, etc. This use layer is very large, expanding the action area and encompassing sources that may occur miles upstream of a wastewater treatment facility. For listed species that may be impacted by surface water transport beyond their range or critical habitat, similar to water treatment facilities that may use surface water as a source of drinking water, EPA is evaluating downstream transport using monitoring data (see EPA response **Comment 112**).*

Comment 112: Several commenters, including Crop Life America, the National Cotton Council and Responsible Industry for a Sound Environment expressed support for exclusion of the downstream dilution tool from the proposed Revised Method. Crop Life America and BASF indicated that EPA should provide more details on the qualitative analysis of downstream exposure. They requested information on how the method will incorporate hydrologic connectivity and how effects from upstream uses will be assessed.

EPA response: *Using the Revised Method, EPA will qualitatively evaluate the potential for downstream impacts to listed species associated with the medium and high-flowing bins, located in areas that have been removed from consideration during Step 1 or 2, as pesticides may be transported from upstream locations where usage occurs to locations where there is no usage. For listed species initially classified as NE or NLAA, EPA will consider the persistence of the pesticide and identify monitoring sites with detections that are upstream of the species range/critical habitat prior to making a final determination. Using ARCGIS and NHDPlus, EPA will evaluate the potential for any detected concentrations to reach the species range. This information will be used in the weight-of-evidence analysis before a final determination is made for the species. EPA will continue to research modelling options to address downstream transport in a more quantitative way.*

Comment 113: The Northwest Center for Alternatives to Pesticides (and 8 other groups) recommended that EPA reinstate the use of the downstream dilution tool or another model that can be used to estimate downstream transport of pesticides. Crop Life America suggested that EPA consider other models that are available to model downstream transport.

EPA response: *EPA/OPP has consulted with representatives at the USGS and EPA's Office of Water to determine if government-approved models were available to evaluate downstream transport. Based on these discussions, EPA could not identify an approved model that could be used to evaluate the downstream transport of pesticides. EPA has developed a transparent qualitative approach to evaluating downstream transport (see EPA response to **Comment 112**).*

Comment 114: The Washington State Department of Agriculture commented: "EPA should request additional resources and seek the expert advice required to develop and validate appropriate offsite transport models."

EPA response: *EPA/OPP has consulted with representatives at the USGS and EPA's Office of Water to determine if government approved models were available to evaluate downstream transport. Based on these discussions, EPA could not identify an approved model that could be used to evaluate the downstream transport of pesticides. EPA has developed a transparent qualitative approach to evaluating downstream transport (see EPA response to **Comment 112**).*

Comment 115: BASF commented that label language intended to reduce spray drift (e.g., boom height, droplet size) should be considered when establishing the off-site transport zone.

EPA response: *When evaluating the off-site transport zone, EPA will include parameters such as boom height and droplet size, when those restrictions are on all of the relevant labels.*

Comment 116: The Oregon Council of Trout Unlimited indicated that pesticides are known to move beyond the 30 m limit (from the application site) of runoff modeled using PWC.

EPA response: *EPA will consider downstream transport movement of pesticides using the method described above (see response to **Comment 112**). EPA derives its aquatic exposure estimates as if the waterbody environment for the listed species is located next to the treated field.*

Comment 117: The Center for Biological Diversity objected to the establishment of the off-site transport area by using endpoints for taxa relevant to specific species. They indicated that the EPA does not have the expertise to establish prey, habitat and obligate relationships without consulting with the Services.

EPA response: *EPA has consulted the Services' documentation to identify the taxa relevant to the prey, pollination, habitat and/or dispersal (PPHD) of listed species, including obligate relationships (where applicable). EPA is using toxicity endpoints representative of the taxa relevant to the PPHD of a listed species.*

Comment 118: FIFRA Endangered Species Task Force commented that the approach utilizes species specific spray drift distances to establish the action area. They suggested that the approach could be simplified by using the most conservative off-site transport distance based on consideration of all species. This approach could possibly be refined later.

EPA response: *EPA believes utilizing species-specific spray drift distances provides a scientifically defensible method for determining whether a species is a No Effect or May Affect. While using the most conservative off-site transport distance based on all species would be simpler, it could improperly result in a May Affect determination for a species that should be No Effect.*

4.2. Overlap calculation

Comment 119: As part of the Revised Method, usage data in the form of a PCT is applied to estimate the treated acres for a given use. However, since the actual location of these treated acres are unknown it is not possible to calculate the drift area for these treated acres. In order to account for the reduction in the drift area after the application of usage several factors are applied to the composite drift overlap. The composite drift overlap is represented by drift in all directions from all potential use sites. Several commenters from Pesticide Registrants or Registrant Groups/Affiliates and Environmental Non-Governmental Organizations indicated that EPA needs to provide more information and an example of how the composite factor (for adjusting spray drift overlap) is calculated and applied.

EPA response: *Examples of the factors applied to adjust drift area in addition to the equations used are provided in the pesticide-specific BEs. Usage information is applied in Step 2 to estimate treated acres for a given use by state. But the actual location of these treated acres within a state is unknown. For this reason, specific treated areas cannot be buffered for drift. In order to account for the reduction in the*

drift area associated with the acres treated compared to all acres of a use several factors are applied to the composite drift area. The composite drift area is represented by drift in all directions from all potential use sites. The first factor applied is based on a state aggregated PCT for all of the uses combined. The aggregated PCT is developed using the method described below. For the upper bound scenario, no additional factor is applied to the aggregated PCT, but for the uniform and lower scenarios, additional factors are applied. This secondary factor for the uniform and lower bound scenarios is the ratio of the number of treated acres calculated for the uniform or lower bound scenario to the upper bound scenario. After applying these factors, the adjusted aggregated PCT value is rounded up to the nearest ten place value (e.g., factor of 0.056 is rounded to 0.1). This final adjusted aggregated PCT is referred to as the composite factor.

The final factor used to scale the area impacted by drift considers the impact of wind direction on off-site transport based on the number of applications that can occur for the use patterns that are relevant to a species. For the composite factor determined above, a wind direction scaling factor is applied where the factor is scaled to 25% for each application allowed, to represent movement of a chemical off-site in only one direction, or essentially $\frac{1}{4}$ of a circle when one application is made. More specifically, if only one yearly application is allowed for the relevant use sites, a factor of 0.25 is applied, if 2 applications are allowed, a factor of 0.5, if 3 applications are allowed, a factor of 0.75 and if 4 or more applications are allowed, a factor of 1 (or no additional scaling is applied). Additional details related to the calculation of these factors and the equations are provided in the BEs.

Comment 120: Defenders of Wildlife recommended that EPA clearly describe how non-overlapping use and range areas will be removed from future consideration in Step 2.

EPA response: *In Step 2 the overlap of the species and the potential use site is used as a surrogate for estimating the population exposed. The different overlap scenarios described in the BEs are considered as part of the Weight of Evidence to provide a range for the estimated population exposed. Five different overlap scenarios are generated for consideration in the Weight of Evidence. The first is chemical independent and provides results for the species with no adjustment to the overlap. This is followed by incorporating the usage data, scaling for redundancy of the UDLs, and then adding species life history information to the overlap results. Additional details on these different scenarios can be found in the BEs.*

Comment 121: Generic Endangered Species Task Force suggested “that the Step 2 overlap analysis be performed individually for each applicable UDL followed by a spatial union of the buffers, and not once using a single drift distance from the composite UDL.”

EPA response: *The decision to use the single drift composite layer, that include all UDLs for the pesticide, was made due to the fact that when buffering the individual UDLs for drift, the drift areas from one UDL will often overlap with other UDL. By using the composite drift layer there is no redundancy in the drift area. If the individual UDLs were used, over 100% of species range would be found in the drift area and therefore over 100% of the population would be exposed. The individual UDL are buffered for drift and this information is provided for consideration but it is not incorporated into the calculations for the number of individuals exposed.*

Comment 122: Several commenters disagreed with consideration of federal lands in the Step 1 decision framework. Xerces Society and Northwest Center for Alternatives to Pesticides (and 8 other groups) indicated that EPA should assess potential uses on federal lands because it is part of the action associated with the national level registration of pesticide labels. Attorneys General from ten states and

Washington DC commented that the proposed Revised Method “would unlawfully curtail evaluation of effects on species whose range overlaps fully with federal lands without assessing whether the species would actually be sufficiently protected by other means.” Defenders of Wildlife, Xerces Society, Northwest Center for Alternatives to Pesticides (and 8 other groups) and the States Attorneys General pointed out that other federal agencies may lack the expertise or data to assess pesticide risks to listed species.

EPA response: *Based on the feedback from stakeholders the consideration of federal lands will not be included in Step 1 due to the possibility that some federal land management agencies may not consult with the Services when they decide to apply pesticides on their land. EPA will continue to consider if the species occurs on federal lands as part of the Weight of Evidence. Additional details related to this Step 2 consideration is provided in the Weight of Evidence section of the Revised Method.*

4.3. Incomplete exposure pathway

Comment 123: The proposed Revised Method document included indoor uses as an example of those with incomplete exposure pathways for listed species. Wastewater and Stormwater Treatment Agencies commented that this assumption is not “scientifically supported.” They provided several references to scientific literature involving pesticide discharges in the effluent and biosolids of POTWs, where the sources of the pesticides were from indoor uses. They also indicated that EPA assesses exposures from indoor uses using the Exposure and Fate Assessment Screening Tool (E-FAST). Similarly, the California Department of Pesticide Regulation objected to the assumption that indoor pesticide uses represent incomplete exposure pathways. They provided citations to demonstrate that indoor uses may result in environmental exposures of pesticides. Xerces Society, Northwest Center for Alternatives to Pesticides (and 8 other groups) and Center for Biological Diversity also objected to the assumption that indoor uses result in an incomplete exposure pathway, referring to EPA assessments that assessed pyrethroid exposures from indoor uses.

EPA response: *EPA will consider potential exposures of listed species to pesticides applied via indoor uses if the use is reasonably expected to result in exposures to listed species. The specific determination of an incomplete exposure pathway for a given pesticide and species will be documented in the BEs.*

Comment 124: Defenders of Wildlife, Environmental Policy Innovation Center and FIFRA Endangered Species Task Force indicated that it would be helpful if EPA clearly define the term “incomplete exposure pathway.” The Center for Biocide Chemistries commented that it would be helpful if there were a “more exhaustive list (or criteria for the decision)” of when the incomplete exposure pathway would be applicable.

EPA response: *EPA has added a definition of this term and more explanation of its meaning and application for its ESA analysis in the Revised Method (Step 2, part a).*

Comment 125: FIFRA Endangered Species Task Force indicated that it would be helpful if EPA identify species that will always have an incomplete exposure pathway or other reason for exclusion from assessment.

EPA response: *EPA will identify specific species that have incomplete exposure pathways in pesticide specific BEs. These species will be reevaluated with each BE.*

Comment 126: The Northwest Indian Fisheries Commission commented: “EPA analysis of exposure pathway completion, as with all other determinations under its methodology, must give the benefit of the doubt to listed species.”

EPA response: *EPA will conservatively assess whether an exposure pathway is complete for each species.*

Comment 127: Crop Life America suggested that EPA consider state or county restrictions when determining if an exposure pathway is incomplete.

EPA response: *When deriving the action area, EPA will consider if the federal label prohibits use within a state or county.*

4.4. Exposure modeling

Comment 128: The California Stormwater Quality Association and California Department of Pesticide Regulation indicated that it is incorrect to assume that pesticides are not applied to impervious surfaces and that this assumption could underpredict exposure. Citations were provided to demonstrate that impervious surface applications lead to insecticide detections in urban runoff.

Defenders of Wildlife recommended that EPA carefully consider how much impervious surface to exclude for specific pesticides (some pesticides may be applied to impervious surfaces). They indicate the NLCD impervious surface landcover may be helpful.

Xerces Society and Northwest Center for Alternatives to Pesticides (and 8 other groups) commented that “structural pest control companies routinely spray impervious surfaces for exterior ant treatments.”

EPA response: *EPA has corrected its discussion of applications to impervious surfaces in the Revised Method. The discussion was not meant to indicate that EPA would not evaluate applications to impervious surfaces. Rather, it was intended to generate a footprint for developed areas that was more realistic. In the Revised Method, 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. For applications designed for impervious surfaces, EPA will model the application using the impervious PWC scenario, along with appropriate adjustments to account for the area treated.*

Comment 129: Responsible Industry for a Sound Environment supported an approach to remove impervious surfaces from treatment sites. They suggested that EPA consider other sites within the developed class that are non-impervious but not expected to be treated.

EPA response: *With regards to applications to impervious and pervious applications in developed areas, please consult the previous comment and response (Comment 128). EPA agrees that just using the developed footprint can overestimate the amount of area treated and that incorporating usage data will help refine these exposure routes. In cases where usage data are available, EPA will use the data as described in the Revised Method to refine the developed footprint.*

Comment 130: The California Rice Commission questioned whether irrigation water will be considered as a drinking water source for birds and mammals.

EPA response: *Given that birds and mammals can access open waterbodies, such as irrigation ditches, for drinking water, EPA considers them as a potential drinking water sources for birds and mammals.*

Comment 131: Several commenters (see **Comment 3** and **Comment 4**) indicated that EPA should estimate exposures based on maximum labeled rates.

EPA response: *EPA uses the maximum label rates when estimating exposure to listed species. EPA only uses alternative application rates in its determination of the strength of the evidence when conducting its Weight of Evidence analysis.*

Comment 132: BASF commented that concentrated flow and a flowing water body were discussed at the June 10 (2019) public meeting; however, the Revised Method does not clearly describe how these concepts are incorporated. They request that EPA provide information on how concentrated flow will be simulated, which bin will be applied, the off-field distance where concentrated flow will transport pesticides, how dissipation will be considered and whether concentrated flow affects vegetated filter strips. They also suggested consideration of the influence of best management practices on concentrated flow.

EPA response: *In the pilot BEs for chlorpyrifos, diazinon, and malathion and the current draft BEs for carbaryl and methomyl, EPA evaluated EECs from runoff in nearby waterbodies by assuming that the waterbody was receiving sheet flow and that flowing waterbodies, particularly the small flowing waterbody (Bin 2), would capture exposure concentrations that would be indicative of concentrated flow. In the Revised Method, concentrated flow concentrations will be simulated using edge-of-field estimates derived from the pesticide and water flux estimates generated from the PRZM model runs conducted in support of the PWC runs. Distance and dissipation are not being considered in the concentrated flow estimates, nor the impact of vegetative filter strips. If best management practices have been adopted by growers in regions, EPA is open to considering their impact in its aquatic modeling. Attachment 3-1 to the draft BEs for carbaryl and methomyl, the Background Document: Aquatic Exposure Estimation for Endangered Species, includes a discussion of these concepts.*

Comment 133: BASF supported consideration of whether exposure modeling is realistic considering species habitat. They also suggested that EPA consider cases where a species' habitat is not compatible with agriculture (e.g., species inhabits high elevations where agriculture does not occur).

EPA response: *For listed species where the conceptual model for the exposure models used by EPA does not match that of the listed species, EPA will be conducting a qualitative risk assessment. For instance, EPA's models are not applicable for use in estimating aquatic exposure to listed species in offshore marine environments. As such, certain species (e.g., the orca) will be evaluated qualitatively. EPA will consider the listed species' habitat, particularly those that may not be compatible with agriculture (i.e., habitats with high elevations) qualitatively in the weight of evidence analysis.*

Comment 134: BASF indicated that the Revised Method should explain how aquatic EECs will be aggregated at the HUC-2 level and its impact on the exposure assessment. They also indicated that the Revised Method document does not state which percentile of aquatic EECs will be used.

EPA response: EPA is using the PWC to develop EECs as measures of exposure for listed species. PWC simulations are conducted for uses identified in the HUC 2, using scenarios developed for each HUC 2. The 1-in-15 year EEC from each simulation is identified and used in the analysis. EPA will consider EECs for any use in the action area that overlaps with the species range in its effects determination for the species.

Comment 135: BASF indicated that the aquatic bins are “flawed,” particularly for flowing aquatic systems with large watersheds.

EPA response: EPA understands the concern regarding the flaws with the aquatic bins, particularly the flowing bins. The dimensions of the flowing bins were provided to EPA by the Services, with EPA trying to determine the relevant watershed acreage contributing to the bin. This analysis resulted in very large watersheds, which, when coupled with the waterbody, resulted in very large concentrations that were not considered reliable. As a result, EPA has decided to use the index reservoir and its associated watershed to model the mid-size and large flowing bins and the edge-of-field concentrations used for the small flowing bin.

Comment 136: BASF indicated that it is unclear how application date and soil runoff factors will be distributed in the probabilistic analysis.

EPA response: EPA reran the PWC model using alternative application dates (i.e., every application date within the application window) and, using the EECs, developing a distribution of scaling factors that represents the ratios of the EECs at different application dates relative to the EEC developed for the original application date. Additionally, EPA reran the PWC model runs using different curve numbers derived from the hydrologic soil conditions that are less prone to runoff than the original PWC scenario and derived scaling factors using the EECs. Using the metadata for each PWC scenario, EPA estimated new curve numbers by going down one and two levels in the hydrologic soil group (i.e., going from D to C). The scaling factors are then randomly selected and used to adjust the EEC to which the listed species is exposed.

Comment 137: The California Department of Pesticide Regulation suggested that EPA use available monitoring data to validate, calibrate and refine available models. They indicated that they have a Surface Water database with a “significant amount of water and sediment pesticide data” that could be useful.

EPA response: EPA routinely uses monitoring data in its assessments as a way to evaluate its exposure estimates and to evaluate its aquatic models. However, it is important to also understand pesticide usage in the watershed and how it relates to the observed monitoring. Application date, application method, and the relationship of the application site to the monitoring site also factor into the use of monitoring data to evaluate models. While California Pesticide Use Report provides this information, the spatial resolution (1 square mile) can make it difficult to use in model evaluation. Likewise, California’s water management strategies (i.e., restrictions on water use and discharge) make it difficult to interpret how to evaluate modeling results in comparison to the observed monitoring data. It should be noted that

a recent article by Xie et al¹³ confirmed that the farm pond concentrations well captured the worst-case monitoring data and that VVWM with the standard farm pond scenario is appropriate for the screening-level regulatory exposure assessment in California's agricultural settings. It should be noted that care should be exercised when using monitoring data to evaluate models. While models tend to do an adequate job of predicting the longer-term (i.e., monthly, annual) concentrations observed in the environment, adequate prediction of daily estimates tends to be more complicated. For instance, the SWAT model (Soil and Water Assessment Tool), proposed by many as a means to model concentrations in watershed systems, was found to do well when replicating pollutant loads on an annual or monthly basis, but was found to be inadequate in some studies when comparisons of the predicted output were made with measured daily pollutant loss data.¹⁴

Comment 138: The Garden Club of America indicated the exposure through contaminated prey is not considered.

EPA response: The Revised Method accounts for exposure through consumption of contaminated prey (e.g., invertebrates, mammals). As discussed in the exposure subsection of the section of the revised method describing data to be used in Biological Evaluations, KABAM will be used. According to KABAM guidance, for pesticides with the potential to bioaccumulate in aquatic food webs, the assessment will also consider exposure through contaminated aquatic plants, invertebrates and fish.

Comment 139: The Center for Biological Diversity commented that the Pesticide in Water Calculator is not validated and cannot be used to assess risks to species that are downstream.

EPA response: EPA is not using PWC to assess concentrations downstream from a pesticide release, but rather is using it to assess exposure next to a treated area. However, the PWC and its underlying models the Pesticide Root Zone Model (PRZM) and the Variable Volume Water Model (VVWM) have undergone extensive peer-review through FIFRA Scientific Advisory Panels, the regulated community, and within scientific literature. Most recently, Xie et al¹⁵ confirmed that the farm pond concentrations well captured the worst-case monitoring data and that VVWM with the standard farm pond scenario is appropriate for the screening-level regulatory exposure assessment in California's agricultural settings.

Comment 140: In addition to the upper bounds on drift estimates included in the proposed Revised Method, Crop Life America (CLA) suggested that EPA consider lower bounds and median estimates.

EPA response: EPA believes its approach is scientifically defensible and protective of listed species. While EPA could use the various spray drift curves in its probabilistic analyses to evaluate lower and median deposition estimate, doing so could result in the use of a deposition curve that isn't correct. For example, a low boom application to corn after corn has reached its maturity (boom height would be too low), or an aerial application of an insecticide using Coarse to Very Coarse droplets (droplet spectra may not be efficacious). As more data become available, EPA will evaluate and update its approach to spray drift.

¹³ Xie, Yina & Luo, Yuzhou & Singhasemanon, Nan & Goh, Kean. (2018). Regulatory Modeling of Pesticide Aquatic Exposures in California's Agricultural Receiving Waters. Journal of Environment Quality. 47. 10.2134/jeq2018.05.0198.

¹⁴ Gassman, P.W., Reyes, M.R., Green, C.H., and Arnold, J.G. 2007. The Soil and Water Assessment Tool: Historical Development, Applications, and Future Research Direction. American Society of Agricultural and Biological Engineers. 50(4):1211-1250. May 2007

¹⁵ Xie et al, op. cit., p. 41

Comment 141: Crop Life America suggested that EPA update its dietary exposure model (currently based on the Kenaga nomogram).

EPA response: *EPA believes that the data supporting the T-REX model are sufficiently robust to estimate exposure to terrestrial organisms that consume arthropods, leaves, grasses, fruit and seeds. At this time, EPA will continue to rely upon the methods incorporated in the current version of the T-REX model.*

Comment 142: The proposed Revised Method discussed the TIM model, which estimates exposures to terrestrial animals through diet, drinking water, inhalation and dermal exposure routes. Crop Life America suggested that EPA utilize other models that are available to estimate exposure to other terrestrial animals, including T-HERPS and KABAM.

EPA response: *The MAGtool incorporates exposure estimates based on other models, including T-HERPS and KABAM. Additional details have been provided in the Revised Method (section titled "Data to be Used in Biological Evaluations").*

Comment 143: Crop Life America suggested that EPA use additional models, such as VFSSMOD.

EPA response: *EPA is still in the process of evaluating VFSSMOD to determine if it can be applied in ecological assessments. EPA is also considering how to employ this tool if determined to be applicable.*

Comment 144: Crop Life America suggested that EPA clearly state that the bin concept used in the pilot BEs will also be applied in the Revised Method. They also indicated that it would be helpful if the Revised Method document state what tools will be used to estimate exposure in Step 1. It is not clear if the estimate will be a single conservative exposure or if the step 1 exposure will be based on regions or crops.

EPA response: *The Revised Method now discusses how the bins used in the pilot BEs will be used and adjusted for aquatic modeling. For Step 1, the maximum EEC identified for a specific listed species, specific to the region and crop associated with the species, along with drift only estimates based on the smallest aquatic bin a species may inhabit, will be used to identify whether a species is No Effect or May Affect.*

Comment 145: Crop Life America indicated that use of the index reservoir is not appropriate for medium and high flowing water bodies. Crop Life America suggested that EPA revise the modeling approach for bins 3 and 4 considering a DA/NC ratio of 5, allowing flow through with a 1 d flow averaging period, include baseflow and include the original bin depth and width.

EPA response: *EPA acknowledges that the use of the index reservoir is a conservative approach for the Bins 3 and 4. EPA is open to ways to appropriately model these waterbodies and validate the approach. If Crop Life America can provide support for the development of their approach, EPA is willing to have further discussions about its applicability to this process.*

Comment 146: Crop Life America does not agree with edge of field estimates of exposure to represent bins 5 (small static) and 2 (low flow). They expressed concerns that the estimates would be unreasonably high, would not appropriately represent chronic exposures and would not generate

benthic EECs. They indicated that, for bin 2, EPA consider modifications suggested for bins 3 and 4. For bin 5, they suggested simulating a small water body.

EPA response: *EPA does not believe that the EECs would be unreasonably high. On the contrary, the EECs would reflect concentrations at headwater streams that do not have other sources of water contributing them and stream edges, that may be reflective of a Bin 2 or 5.*

Comment 147: Crop Life America commented that the Revised Method did not describe how water quality monitoring data will be evaluated.

EPA response: *EPA will use water quality monitoring data as it did in the pilot BEs for chlorpyrifos, diazinon, and malathion, as a qualitative line of evidence when considering exposure to listed species. EPA will also use monitoring data in the evaluation of the potential for downstream transport, as described above (response to **Comment 112**). Further discussion of the use of monitoring data is provided in Attachment 3-1 to the draft BEs for carbaryl and methomyl, the Background Document: Aquatic Exposure Estimation for Endangered Species.*

Comment 148: In estimating exposures, Mosquito Control Organizations expressed the need to model application parameters representative of how mosquito adulticides are actually applied.

EPA response: *EPA concurs and has consulted experts on adulticide applications from the American Mosquito Control Association to refine its modeling approach and exposure estimates.*

Comment 149: In regard to the off-site transport zone that is part of the action area, Generic Endangered Species Task Force commented that the most conservative drift buffer may be applied to all uses within a UDL, regardless of how likely that application method and use site method occurs in a given area. They indicated that this is “highly conservative” in nature. They suggested that the fraction of crop acres associated with the most conservative application method be quantified as a fraction of the total crop acres treated.

EPA response: *When a UDL includes multiple crops with different application methods that may influence the off-site transport zone, EPA uses the most conservative off site transport buffer in Step 1. This approach is refined in Step 2, when usage data are considered by applying the composite factor. EPA may also consider altering the off site transport zone to represent the application methods used on crops that are treated within the UDL in Step 2. In the future, as EPA gains more experience, the approach used to calculate the off-site transport zone may be updated for Step 1 and Step 2.*

Comment 150: Responsible Industry for a Sound Environment commented the Revised Method was “unclear what aquatic exposure tools EPA will use to estimate conservative pesticide concentrations within the Step 1 analysis.”

EPA response: *In Step 1, the maximum 1-in-15 year aquatic exposure concentration, derived using PWC for uses that overlap with the species range, for a HUC 2 region and aquatic waterbody in which the listed species resides, will be used, along with the minimum toxicity threshold, as a screening approach to determine if the pesticide may affect the listed species. AgDRIFT, along with the highest application rate and minimum toxicity threshold, are used to estimate an aquatic exposure concentration in order to define the extent of the action area.*

Comment 151: Responsible Industry for a Sound Environment noted that “applications of specialty products differ from applications of agricultural products” and if they are treated the same, exposure potential can be significantly overestimated for specialty uses.

EPA response: EPA agrees that the applications of specialty products may differ from agricultural products. However, the exposure potential may be higher or lower depending on the pesticidal product under consideration. EPA evaluates the exposure potential for each use in accordance with that use pattern.

4.5. Toxicity endpoints

Comment 152: In regard to Step 1, the National Cotton Council indicated that considering growth endpoints is a conservative approach. “The NCC urges EPA to exercise caution in any additional sublethal effects without quantitatively linking the effects to survival.”

EPA response: EPA believes that growth is an important relevant sublethal endpoint to consider under this framework because of well-understood general links between the effects of decreased growth on reproduction and survival. 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, 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.

Comment 153: Environmental Policy Innovation Center, Northwest Center for Alternatives to Pesticides and Center for Biological Diversity expressed concerns that lack of consideration of other sublethal endpoints is not sufficiently conservative or consistent with the ESA definitions of “take” or “harm.” Commenters objected to the proposed Revised Method’s reliance on a quantitative link between sublethal endpoints and apical endpoints.

EPA response: As discussed in the Revised Method, EPA makes a may affect determination when there are discernable effects. The most scientifically valid manner to evaluate whether a pesticide has a discernible effect on listed species is to determine whether use of the pesticide may affect an individuals' survival, growth or reproduction. As cited in the Revised Method, this approach is consistent with the National Research Council recommendations. Additional sublethal effects will also be considered for use in the Step 1 and 2 analyses if they are strongly linked to survival, growth or reproduction. 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. One way to apply this approach is through the use of a quantitative adverse outcome pathway, where effects at lower levels of organization (e.g., biochemical) are linked to effects on survival, growth or reproduction. EPA will include information on other sublethal endpoints that are not strongly linked to apical 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 for consideration in the consultation process.

Comment 154: Xerces Society and Northwest Center for Alternatives to Pesticides indicated that use of apical endpoints in Steps 1 and 2 is not consistent with National Research Council recommendations (p. 93):

“Therefore, the committee recommends that EPA in Step 2 (see Figure 2-1) cast a wide net and identify information about sublethal effects of a chemical. If possible, EPA’s assessment should include information about responses at various chemical concentrations (a concentration/response curve) and, at a minimum, include a qualitative assessment of the relationship between sublethal effects and survival and reproduction. In Step 3 (see Figure 2-1), the Services should show how such effects change demographic measures (survival or reproduction) of a listed species and incorporate such information into the population viability analyses or should state that such relationships are unknown but possible and include a qualitative discussion in the uncertainty section of the biological opinion (BiOp).”

EPA response: *As described in the Revised Method, in addition to apical endpoints (i.e., survival, growth or reproduction) and those quantitatively linked to apical endpoints, EPA will consider other relevant sublethal endpoints 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.*

EPA believes that 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) in its BEs for consideration by the Services in the consultation process. 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 in the consultation process.

Comment 155: Washington State Department of Fish and Wildlife commented that the need to quantitatively link sublethal endpoints to apical endpoints “shifts the burden of proof unfairly in situations where effects may be difficult to demonstrate but can otherwise be qualitatively linked to fitness.” They indicated that sublethal effects, including reduced olfaction, altered behavior and performance (e.g., swimming speed) are “critically important” to consider in the BE. Similarly, Trout Unlimited, OR disagreed “with the proposal to exclude sublethal effects that cannot be quantitatively linked to apical endpoints from biological evaluations,” noting that effects to olfaction, behavior or physical strength “can result in failure of reproduction and reduced survival.”

EPA response: *As described in the Revised Method, in addition to apical endpoints (i.e., survival, growth or reproduction) and those quantitatively linked to apical endpoints, EPA will consider other relevant sublethal endpoints 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. EPA will include information on other sublethal endpoints (e.g., changes to behavior or enzyme levels) for consideration by the Services in the consultation process. 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 in the consultation process.*

Comment 156: The Attorneys General of ten states and Washington DC commented “EPA should not limit its toxicity evaluations at Step 1 to those effects linked with apical endpoints.” They commented that Step 1 should consider whether the action has any effect on a listed species or designated critical habitat. They commented that “Apical effects are more appropriately considered at Step 2.”

EPA response: EPA makes a may affect determination when there are discernable effects. The most scientifically valid manner to evaluate whether a pesticide has a discernible effect on listed species is to determine whether use of the pesticide may affect an individual's survival, growth or reproduction. As cited in the Revised Method, this approach is consistent with the National Research Council recommendations. Additional sublethal effects will also be considered for use in the Step 1 and 2 analyses if they are strongly linked to survival, growth or reproduction. 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. EPA will include information on other sublethal endpoints that are not strongly linked to apical 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 for consideration in the consultation process.

Comment 157: The Center for Biological Diversity and 37 other organizations commented “The ESA requires the EPA to look at the full range of effects and there is no basis in the science, law, or common sense that allows the EPA to look only at whether individuals will be killed or experience growth effects.”

EPA response: Consistent with the recommendations of National Research Council, 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, growth is also an important relevant sublethal endpoint to consider under this framework. 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. In the proposed method that went out for public comment, in order for a sublethal effect to be used in the Step 1 and 2 analyses it needed to have a quantitative link to an apical endpoint (i.e., survival, growth or reproduction). In the final Revised Method, in addition to apical endpoints and those sublethal effects quantitatively linked to apical endpoints, EPA will consider other relevant sublethal effects that are strongly linked to apical endpoints for use in the Step 1 and 2 analyses. 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.

Comment 158: The Center for Biological Diversity expressed concern that the ECOTOX database will be used to identify toxicity endpoints, indicating that the database is not comprehensive and does not identify the best available data.

EPA response: The ECOTOXicology knowledgebase (ECOTOX) is a comprehensive, publicly available knowledgebase providing single chemical environmental toxicity data on aquatic life, terrestrial plants and wildlife. The ECOTOX database includes toxicity data from the scientific literature, including published and unpublished studies and is updated regularly (more details on the ECOTOX database can be found online at: <https://cfpub.epa.gov/ecotox/>). Prior to conducting a BE, EPA updates the ECOTOX

database with the current published studies relevant to the assessed pesticides. EPA considers ECOTOX to be comprehensive of the best available toxicity data for an assessed pesticide.

Comment 159: Defenders of Wildlife indicated that the most sensitive species in a taxon should be used to derive endpoints for that taxon.

Responsible Industry for a Sound Environment and Crop Life America commented that when effects data more relevant to listed species are available, they should be used instead of more sensitive data for the taxon. This would reduce uncertainty.

EPA response: *The most sensitive test species within a taxon will be used to derive endpoints to represent effects to listed species and other species upon which listed species depend that are within that taxon. If there is a test species available that is more representative of the assessed species, but has a less sensitive endpoint, the less sensitive endpoint may be used because uncertainty due to surrogacy would be lower.*

Comment 160: Wastewater Treatment and Stormwater Agencies recommended that EPA integrate Clean Water Act compliance into BEs.

EPA response: Office of Pesticide Programs and Office of Water work together on water issues to address issues under each of their statutes.

Comment 161: Wastewater and Stormwater Treatment Agencies commented that chronic invertebrate toxicity data must be used in BEs. They indicated that the proposal to only use mortality toxicity data for aquatic invertebrates “deviates from the CWA regulation of aquatic ecosystems to protect food supplies for endangered species.”

EPA response: *EPA will consider effects to mortality, growth or reproduction and other sublethal endpoints linked to survival or reproduction of taxa relevant to a listed species’ prey, pollination, habitat and/or dispersal.*

Comment 162: Xerces society and Northwest Center for Alternatives to Pesticides (and 8 other groups) expressed concerns about the reliance on mortality endpoints for assessing indirect effects. They commented: “Since sublethal effects can ultimately suppress populations of any taxa, it is a mistake to base the biological evaluation analysis only on mortality endpoints.”

EPA response: *As described in the Revised Method, effects to a listed species that relies on animals (i.e., for prey, pollination, habitat and/or dispersal) 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).*

Comment 163: Xerces Society and Northwest Center for Alternatives to Pesticides (and 8 other groups) expressed concern that the toxicity endpoints do not include the following exposure routes: diet (for fish and amphibians) and consumption of sediment (for aquatic invertebrates).

EPA response: *If a pesticide is expected to bioaccumulate in aquatic food webs, these exposure routes will be assessed. This will be evaluated on a case-by-case basis.*

Comment 164: Xerces society indicated that community structure effects should be assessed through consideration of available mesocosm studies.

EPA response: *At this time, toxicity thresholds for Steps 1 and 2 will be based on laboratory toxicity studies. Available mesocosm studies may be used as lines of evidence as part of the Weight of Evidence framework and characterization of the strength of the evidence.*

Comment 165: The Environmental Policy Innovation Center indicated that it is unclear how the threshold is calculated for mortality to an individual of a listed species. They suggested that EPA clarify this calculation.

EPA response: *The Revised Method has been updated to clarify the threshold calculation for mortality to an individual (see page 14 of the Revised Method for details).*

Comment 166: The Center for Biological Diversity indicated that the EPA should consider additivity, synergy and cumulative effects of other stressors, including chemicals and non-chemicals. This includes chemicals in formulations, tank mixtures and the environment and water quality. The Garden Club of America commented that the Revised Method “does not consider the adjuvant effect of multiple pesticides.”

EPA response: *EPA’s BEs will focus on assessing potential effects of the assessed pesticide active ingredient. EFED’s historical process for evaluating pesticide ecological risks has relied on toxicity information from studies conducted with single active ingredients based on the lack of information on pesticide interactions and the expectation that they are rare. When considering the impacts of a pesticide active ingredient on assessed species, the Services consider other stressors on the species.*

Comment 167: The Northwest Indian Fisheries Commission expressed concerns with the focus of toxicity endpoints on survival and fecundity because other sublethal effects (e.g., reductions in feeding and growth) are included in the ESA definition of a prohibited take.

EPA response: *As described in the Revised Method, 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 National Research Council, 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 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. EPA will include information on other sublethal endpoints (e.g., changes to behavior or enzyme levels) for consideration by the Services in the consultation process. 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 for consideration in the consultation process.*

Comment 168: Florida Department of Agriculture and Consumer Services commented that excluding sublethal effects that are not quantitatively linked to apical endpoints is “shortsighted.” They

commented that “Sublethal effects to mobility, olfaction, behavior, etc. can be as impactful in the long term as the more easily quantifiable sublethal effects.”

EPA response: *As described in the Revised Method, 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. EPA will include information on other sublethal endpoints (e.g., changes to behavior or enzyme levels) for consideration by the Services in the consultation process. 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 for consideration in the consultation process.*

Comment 169: Defenders of Wildlife recommended that EPA provided the scientific basis for the habitat effects endpoints (i.e., 50% and 25% growth declines in aquatic and terrestrial plants, respectively).

EPA response: *As discussed in the Revised Method, 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^{16,17}. 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 prey, pollination, habitat and/or dispersal.*

4.6. Spatial data

Comment 170: National Center for Alternatives to Pesticides (and 8 other groups) commented that a state level scale is “inappropriate” for ESA assessments.

EPA response: *EPA uses the best available species location data as provide by the Services, the most refined landcover and land use available at the national level for the Use Data Layers (UDLs), and usage information at the recommended resolution by the data owner. As more refined national level data becomes available it can be incorporated in the process. If state level is the best available information, that is used.*

Comment 171: FIFRA Endangered Species Task Force indicated that more current data sets are available for the Crop Data Layer and the National Land cover Dataset. They questioned how updates to data will be integrated into the method.

EPA response: *The data sources are routinely reviewed and updates are incorporated when they become available. But once a specific assessment is started new data is not incorporated. Specifically, the Cropland Data Layer (CDL) used to generate the Use Data Layers (UDLs) is updated once a year following*

¹⁶ Hazard Evaluation Division, Standard Evaluation Procedure, Non-Target Plants. USEPA. Office of Pesticide Programs. June 1986

¹⁷ Hazard Evaluation Division, Standard Evaluation Procedure, Non-Target Plants: Growth and Reproduction of Aquatic Plants...”, OPP, June 1986

the release of the new CDL. Other land use and landcover datasets are not updated as frequently but they are routinely checked. The new version of the National Land Cover Database has not been incorporated as it was released after finalizing the data sources for these next assessments. It will be considered for future BEs.

Comment 172: BASF disagreed with the grouping of CDLs into UDLs, because they do not believe this improves the accuracy of the spatial layers. They commented that this approach will overestimate the amount of crop area, especially for minor crops. BASF suggested that EPA consider a qualitative approach for assessing minor crops rather than grouping them into UDLs.

EPA response: *The USDA NASS (2013-2017) accuracy assessments show that, on a state-by-state basis, the Cropland Data layer (CDL) is relatively accurate (90% or greater) for states that are major producers of major commodity crops. These crops such as corn, soybeans, wheat, and cotton are grown over extensive contiguous areas, and USDA has independent data for training and quality assurance analysis. However, as indicated on the USDA error matrices for the CDL, the high frequency of error for other crops suggests that CDL may not be suitable for representing non-commodity minor crops. To address this, EPA aggregates minor crops into broader crop groupings to reduce the level of uncertainty in the spatial footprints for individual crops. In order to have certainty in the footprints, it is more critical to distinguish between vegetables or orchards than between apple and peach orchards or between tomatoes and peppers. While this may overestimate the area for a given crop such as peaches, the available data does not provide enough certainty to consider crops at that scale and the aggregations increases the certainty of the orchard footprint. Additional grouping could be considered as the accuracy of the CDL for the individual crops increase.*

Comment 173: FIFRA Endangered Species Task Force questioned the grouping of CDLs into UDLs, noting that agronomic factors need to be considered in the groups. They also questioned whether the groups were intended to account for crop rotation.

EPA response: *EPA evaluated the more general crop groupings used for the UDLs based on those used by the U.S. Geological Survey (Baker and Capel, 2011¹⁸) and the Generic Endangered Species Task Force (Amos et al, 2010¹⁹). This information considers environmental factors that influence the location of crops in addition to the error matrices provided by USDA with the original CDL data. By considering these agronomic factors in addition to the error matrices it is possible to improve the accuracy and year-to-year matches for these UDLs. The spatial aggregation into the UDL crop groups does not account for crop rotation but the temporal aggregation across years helps identify changes in agricultural practices such as crop rotations.*

Comment 174: FIFRA Endangered Species Task Force suggested that CDL metadata be used to “develop a spatially explicit probability distribution of landcover and changes.”

EPA response: *EPA is not currently considering a spatially explicit probability distribution of landcover and landcover changes. While this type of information is not being used for the current method it could*

¹⁸ Baker, N.T., and Capel, P.D., 2011, Environmental factors that influence the location of crop agriculture in the conterminous United States: U.S. Geological Survey Scientific Investigations Report 2011–5108, 72 p.

¹⁹ Amos, J.J., C.M. Holmes, C.G. Hoogeweg, and S.A. Kay. 2010. Development of Datasets to Meet USEPA Threatened and Endangered Species Proximity to Potential Use Sites Data Requirements. Report Number: 437.01-Overview. Prepared by Waterborne Environmental, Inc. for the Generic Endangered Species Task Force.

be considered in future. USDA releases a number of landcover change products and confidence layers with the release of the CDL.

Comment 175: Generic Endangered Species Task Force suggested that crops aggregated from CDL into a UDL be re-evaluated as confidence in the CDL improves.

EPA response: *The crop aggregation used to generate the UDLs from the CDLs will be re-evaluated as the accuracy and confidence in the CDL improves. Most recently the orchard and vineyards UDL was split into 3 individual UDLs, citrus, other orchards, and vineyards based on the increased accuracy of the CDL.*

Comment 176: Generic Endangered Species Task Force commented that the time scale of the aggregation process for UDLs is not specified and “The number of years of CDL data for aggregation should be based on the CDL confidence for each UDL.” They suggested that EPA and USDA (NASS) coordinate on the accuracy assessment.

EPA response: *Currently, the time scale for the temporal aggregation of the UDLs is 5 years, additional details about the time scale are provided in the methomyl and carbaryl BEs. The selection of 5 years is consistent with the most recent 5 years of data used by USDA when generating the Cultivated Layer released with the CDL. EPA will continue to coordinate with USDA (NASS) on the best way to use the accuracy assessments, confidence layers and other materials provided with the CDL.*

Comment 177: Defenders of Wildlife and California Department of Pesticide Regulation indicated that EPA should use the best available species range data. Several of those data may be from sources other than the Services. California’s Department of Fish and Wildlife has a database (Natural Diversity Data Base) with detailed location information for listed species.

EPA response: *As the species experts, EPA relies on the Services and their expertise to provide the best available species location data for the purposes of Section 7 consultation under the Endangered Species Act. Additional sources of species location information should be provided to the Services for incorporation into their species files. In the future, EPA may consider using other sources of data or databases with agreement from the Services. Element occurrence data similar to the California Natural Diversity Database does not provide the full range of the species. This information could be beneficial to the FWS for consideration when creating the species range files.*

Comment 178: The Center for Biological Diversity expressed concerns about the proposed approach to consider the precision of the species range. They indicated that this is subjective and outside of the expertise of EPA.

EPA response: *The proposed approach considers the precision of the spatial analysis based on the available information for the UDLs. Information related to the precision of the species ranges is currently unavailable and EPA assumes the species range information meet or exceeds the precision of the UDLs. See **Comment 69** for a discussion on how the accuracy of the UDLs is incorporated into the spatial analysis.*

Comment 179: California Department of Pesticide Regulation suggested that EPA better define what landcovers will not be evaluated due to "limited spatial extent" and expressed concern that nurseries should not be included in that group. Nurseries should not be considered with 1% not being representative of real exposure potential that is unreliable.

EPA response: Landcovers with limited spatial extents do not have available and reliable spatial use footprints. All mappable landcovers, including nurseries, will be evaluated; however, use sites that are not mappable due to the limited spatial extent (e.g., dumpsters) may not be mapped. These use sites will either be assessed qualitatively or conservatively incorporated into other mappable layers to be assessed quantitatively. Assumptions related to conservatism and the resolution of the landcover data layers may be revisited if appropriate in the Weight of Evidence analysis. This consideration is important for layers with limited spatial extents because the resolution may be conflicting with other data used in the analysis. The concern related to the 1% does not apply to layers with limited spatial extent, the 1% was proposed for and is applied to the action area.

Comment 180: Responsible Industry for a Sound Environment expressed support for the proposed approach to only revisit the 100% treated area for nursery uses when there is >1% overlap with this use. they commented that these uses are small and do not frequently overlap with listed species habitats.

EPA response: See response to **Comment 179 above**.

Comment 181: The Attorneys General from 10 states and Washington DC commented that the CDL data may be inaccurate, resulting in false negatives.

EPA response: To address concerns of false negative, or error of omissions, the CDL data is aggregated into the Use Data Layers (UDLs) in a three-step process. First the CDL data is categorically aggregated into the 13 crop groups, then temporally aggregated to include the 5 most recent years of the CDL. The categorical aggregation increases the certainty of the crop footprint and the temporal aggregation accounts for changes in agricultural practices such as crop rotations. Finally, the UDL layers are expanded using the region grow process to meet or exceed the reported area from the Census of Agriculture. The region growing process compares the area of the categorically and temporally aggregated UDLs to the reported area grown in the Census of Agriculture. The expansion occurs by adding one pixel at a time along the complete edge of the UDL. The process ensures the UDLs used for the analysis will never be less than the reported area grown from the Census of Agriculture and often exceeds the reported area grown, minimizing false negatives, or missing cropped areas in the UDLs.

Comment 182: Several commenters expressed concerns that the proposed spatial data overestimates acreage of minor crops.

EPA response: As indicated on the USDA error matrices for the CDL, high frequency of error for minor crops suggests that CDL may not be suitable for representing non-commodity minor crops. To address this, EPA aggregated minor crops into broader crop groupings to reduce the level of uncertainty in spatial footprints in individual crops. In order to have certainty in the footprints, it is more critical to distinguish between vegetables or orchards than between apple and peach orchards or between tomatoes and peppers. While this may overestimate the area for a given crop such as peaches, the available data does not provide enough certainty to consider crops at that scale.

EPA evaluated whether some of the broader general crop groups (vegetables, orchards, grains, ground fruit) could be divided into smaller UDL crop groupings. In most cases, the smaller label crop groupings are less accurate than the broader UDL classes. In that analysis, only the original orchard and vineyards layer could be broken down into citrus, other orchards, and vineyards. Additional grouping could be considered as the accuracy of the individual crops in the CDL increase. Minor crops will be represented

by the UDL crop group and not individual crops as there is more confidence in the footprint for those layers, but this will be re-assessed as the accuracy of the CDL increases for these minor crops.

Comment 183: BASF indicated that the Revised Method does not clearly describe the region growing approach. If the approach is the same as the one used in the pilot BEs, they are concerned that using the CDL cultivated layer as a mask will include pixels that were incorrectly identified as agriculture. BASF requested additional information on why the region growing adjustment is necessary and when it would be applied.

EPA response: *The region growing approach is the same as the pilot BEs and additional details will be provided in the pesticide-specific BEs. As indicated by USDA, the "Cultivated Layer" or "Crop Mask Layer" is based on Cropland Data Layers from the most recent five years of data and is updated annually. This is the same time step as the UDLs used in the ESA assessment. Pixels are assigned to this cultivated layer if it is identified as a crop in at least two out of the last five years of CDL data. The exception is that all pixels identified as cultivated in the most recent year are assigned to the 'Cultivated' category regardless of whether or not they were cultivated in the previous four years of CDL data. This is the best available footprint information and limits the region growing to areas identified as cultivated based on the USDA method. The purpose of this masking is to minimize the possibility of growing a layer into a non-cultivated site.*

Comment 184: BASF indicated that EPA should clarify the meaning "many habitat types" when considering the precision of state or county level range data.

EPA response: *The species range data does not impact the consideration of habitat. If species life history indicates preferential use of specific habitat types, this information can be considered as part of the Weight of Evidence. If it is more likely the species will be found in these specific habitat types an additional step 2 analysis is conducted with the overlap limited to the portion of the range represented by the suitable habitats. The results of the analysis can be considered with the results of the full range as part of the Weight of Evidence.*

Comment 185: FIFRA Endangered Species Task Force indicated that it is not clear how EPA will obtain species range data from the Services. They suggested that EPA utilize utility range data that were developed for pesticide consultation (which is stable and transparent), rather than going to ECOS (which is constantly changing).

EPA response: *As the species experts EPA relies on the Services' expertise to provide species location data. Files are routinely updated from ECOS with the download date documented. Once an assessment is started the species location information is not updated. In the future, EPA may consider using other sources of data or databases with agreement from the Services.*

Comment 186: FIFRA Endangered Species Task Force indicated that EPA does not describe how data sets will be updated. FIFRA Endangered Species Task Force pointed out that newer NLCD and CDL data are available than were cited in the proposed Revised Method.

EPA response: *Data sources are routinely updated, but once an assessment has started the data sources are not updated. Specifically, for the Cropland Data Layer the Use Data Layers are updated once a year following the release of the new CDL. The current years of the CDLs used in BEs include 2013-2017, additional years will be considered in future BEs. The 2017 data was the most recent available CDL*

dataset available when the methomyl and carbaryl analysis was conducted. Other land use and landcover datasets used to generate the UDLs are not updated as frequently but they are routinely checked. The new version of the National Land Cover Database has not been incorporated as it was released after 'locking' the data sources for these next assessments. It will be incorporated in future BEs after updating the UDLs.

Comment 187: Crop Life America commented: "EPA should incorporate life history and ecological information and scrutinize range maps for listed birds. Often habitats clearly not used by the species, but contained in the range maps, are included in determining the potential for exposure." FIFRA Endangered Species Task Force indicated that it is not clear how GAP landcovers will be applied. They asked for additional information on how supplemental species ranges may be developed.

EPA response: *If species life history indicates preferential use of specific habitats this information can be considered as part of the Weight of Evidence. If it is more likely the species will be found in the specific habitat types an additional Step 2 analysis will be conducted with the overlap limited to the portion of the range represented by those habitats, based on the GAP landcover. The results of the analysis can be considered with the results of the full range as part of the Weight of Evidence Additional details will be available in the methomyl and carbaryl draft BEs.*

Comment 188: Responsible Industry for a Sound Environment expressed support for the use of a qualitative analysis of uses where reliable spatial use footprints are not available.

EPA response: *Use sites that are not mappable due to the limited spatial extent (e.g., dumpsters) are not mapped. These use sites will either be assessed qualitatively or be conservatively incorporated into other mappable layers to be assessed quantitatively.*

4.7. Species considered and their Life History and Assumptions

Comment 189: FIFRA Endangered Species Task Force indicated that they do not agree with inclusion of species that are not currently listed as endangered or threatened (*i.e.*, candidate species). Xerces society indicated that proposed and candidate species should be included in BEs.

EPA response: *Because proposed and candidate species may be formally listed as endangered or threatened over the course of the 15-year period of the action (registration review), EPA decided to include effects determinations for proposed and candidate species based on the recommendation from the Services.*

Comment 190: The Northwest Indian Fisheries Commission indicated that EPA lacks expertise and/or authority to determine if listed species are extinct or extirpated. The Center for Biological Diversity commented that EPA lacked expertise to determine the status of listed species, noting that the ESA does not include a "presumed extinct" category. Northwest Center for Alternatives to Pesticides (and 8 other groups) also commented that EPA does not have authority to determine if species are extinct. They also commented that by not considering these species, EPA runs the risk of further harming species that are "still extant but so diminished that it may not have been detected for some years." Environmental Policy Innovation Center supported exclusion of species that the services recommend delisting and suggested that EPA obtain a list of extinct and extirpated species from the Services. The Attorneys General from ten states and Washington DC commented that the exclusion of species near extinction is

“in direct contravention of the ESA’s fundamental purpose to prevent species from going extinct.” Xerces Society and Northwest Center for Alternatives to Pesticides (and 8 other groups) commented that EPA should conduct BEs for all species listed by the Services.

EPA response: *EPA worked with the Services to identify which species are likely extinct or extirpated. All of the species currently considered extinct are under the authority of FWS. The list of likely extinct species has been reviewed by FWS. Additional information on how species are identified as extinct will be provided in the BEs. Likely extinct species will receive an NLAA determination and EPA will informally consult on these species allowing the Service to provide additional information if it becomes available.*

Comment 191: Defenders of Wildlife recommended, when considering species that are extirpated from the US, that EPA consider the likelihood that a species is extirpated and the likelihood that it will be introduced to its US range.

EPA response: *Following additional dialogue with the Services, the Revised Method has been updated so that NE determinations are no longer made for species that are assumed to be extirpated. Species thought to be extirpated will receive an NLAA determination and EPA will informally consult with the Services on these species. If the Services have additional information related to extirpated including the likelihood it will be re-introduced into the US range it can be provided during the informal consultation process.*

Comment 192: FIFRA Endangered Species Task Force and BASF suggested that EPA use the GOPHER database to obtain life history and spatial data on listed species. To obtain additional information on listed species, FIFRA Endangered Species Task Force suggested that EPA utilize additional research provided by registrants and the open literature.

EPA response: *EPA is currently using listed species information from documentation developed by the Services. In the future, EPA may consider using other sources of data or databases, with input from the Services.*

Comment 193: Environmental Policy Innovation Center requested clarification on how population size will be factored into estimation of number of individuals exposed and impacted.

EPA response: *The Revised Method has been updated to include more details on how population size is included in Steps 1 and 2; see the Data to be used in Biological Evaluations section. The draft BEs for carbaryl and methomyl also provide applications of these data for specific pesticides and species.*

Comment 194: Defenders of Wildlife expressed concerns about the lack of precision in available population size data. They recommended that EPA use an upper bound to account for uncertainty and to be protective.

EPA response: *The Revised Method utilizes an upper bound on the estimated population size. Conservative estimates for population are made for both species with and without available estimates. When population estimates are available, these estimates are rounded up to the next digit (e.g., if the population size is 90, the value is represented as 100). If the 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. Additionally, the low and high end range of the population are used as part of the Weight of Evidence in Step 2 to understand the range of impacted individuals. Additional considerations, beyond the low and*

high end estimates are also given to species ≤ 100 individuals. The result of these conservative assumptions is population size is likely overestimated, increasing the number of the individuals predicted to be exposed. In addition, to account for the uncertainty in the population size probabilistic analyses are conducted in Step 2, part g and h using the conservative estimates. Lower bound estimated of the population are also considered to understand the range of individuals predicted to be exposed.

Comment 195: Xerces Society commented “If we were confident of population sizes and actual distributions for all listed, proposed, and candidate invertebrates, the use of the deterministic procedure outlined might be reasonable.” Since reliable ranges and population estimates are not available for all species and many have small population sizes, they commented that the use of population size data is “risky.”

EPA response: *The availability and quality of information on population size varies greatly among species for this reason conservative assumptions are made related to population estimates. As indicated by commenters, the greater a population size, the lower the threshold (i.e., a larger population number yields a more conservative approach). Conservative estimates for population are made for both species with and without available estimates. When population estimates are available, these estimates are rounded up to the next digit (e.g., if the population size is 90, the value is represented as 100). If the 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. Additionally, the low and high end range of the population are us as part of the Weight of Evidence in Step 2 to understand the range of impacted individuals. Additional considerations, beyond the low and high end estimates are also given to species ≤ 100 individuals. Additional information on population size can be found in “Data to be used in Biological Evaluations” section of the Revised Method.*

Comment 196: BASF commented that the calculation of the number of individuals exposed, where the % overlap in Step 2 is multiplied by the population size “seems to contradict the protection goals that should be afforded very small populations as opposed to large ones” because the determination may be different for a species with a smaller population size compared to a larger one.

EPA response: *See the response to Comment 195 above.*

Comment 197: The Center for Biological Diversity indicated that the uniform distribution assumption of individuals in their ranges is not scientifically based. Defenders of wildlife recommended that EPA look for data on the distribution of individuals of a species before assuming the uniform distribution.

EPA response: *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.*

Comment 198: The Center for Biological Diversity objected to exclusion of overlap areas when a species habitat does not include the pesticide use site. They also objected to the assumption that taxa upon which a species is dependent are not present on those areas because mobile animals (e.g., insect pollinators) would not be considered.

EPA response: EPA believes that potential overlap of pesticide exposure areas and species location are overestimated when considering habitats that a species is not expected to use. Therefore, if information is available to indicate that a listed species does not utilize a use site, that use site is removed before calculating the overlap. Given the uniform distribution of individuals throughout the range, this approach is conservative (concentrating individuals into a smaller area within the range). This approach also includes animals relevant to the prey, pollination, habitat and/or dispersal of the listed species that are at the site where individuals of the listed species are expected to be located.

4.8. Conservation measures, stewardship and mitigation

Comment 199: The FIFRA Endangered Species Task Force indicated that conservation measures and mitigations already in place should be considered. California Rice Commission commented that management practices, stewardship and mitigation do not appear to be incorporated into the Revised Method. The California Rice Commission commented that “Almost all pesticide labels use 200-foot buffers as the most conservative distance for pesticide applications to non-target crops.” They suggested that the CDL could be revised to reflect these buffers.

EPA response: If all labels for the same use include mitigations, EPA will consider them for exposure modeling; however, if only some labels include mitigations, the most conservative scenario will be evaluated. EPA is willing to consider conservation measures in place for a given species in the future. However, at this time, EPA cannot implement this on a consistent basis, as EPA does not currently have a database of existing conservation measures.

Comment 200: FIFRA Endangered Species Task Force indicated that the Revised Method does not clarify how RPAs and RPMs will be implemented.

EPA response: The Revised Method is focused on the BE (Steps 1 and 2). RPAs and RPMs are included in biological opinions (Step 3). Since the Revised Method does not include the Step 3 method, it does not include implementation of the RPAs and RPMs.

Comment 201: BASF indicated that EPA should consider instructions and restrictions that are on labels that may reduce exposure and risk (including: soil type restrictions, geographic restrictions, spray drift mitigations, no-spray buffers and vegetative filter strips). Crop Life America suggested that EPA consider state or county restrictions of pesticide labels.

EPA response: If a given pesticide use includes use restrictions on all registered labels, EPA can consider label instructions and restrictions. If only some labels include restrictions, but others do not (for the same use), EPA will consider the more conservative (i.e., less restrictive) label.

5. Comments Related to Additional Review of Revised Method and EPA Responses

Comment 202: Commenters from State and Federal Governments, Federally Recognized Tribes, Environmental non-governmental organizations, Pesticide registrants or Registrant Groups/Affiliates and Grower Groups or Affiliates indicated that the extent to which EPA collaborated with the Services on the

proposed Revised Method was unclear. Many expressed concerns about a lack of collaboration between EPA and the Services. They suggested that the EPA collaborate with the Services in the future development of the Revised Method.

EPA response: *Before the proposed Revised Method was released for public comment, EPA incorporated input from the Services and USDA. Between the release of the proposed Revised Method and the final Revised Method, EPA incorporated additional input from the Services and USDA. In addition, several interagency meetings were held where FWS, NMFS, and USDA provided input on the Revised Method.*

Comment 203: US House of Representatives Committee on Natural Resources, Attorneys general from ten states and Washington DC, King County (Washington), and Center for Biological Diversity (and 37 other groups) recommended that EPA withdraw the proposed Revised Method.

EPA response: *The methods applied to BEs will continue to evolve as EPA gains experience and as scientific methods and data improve. EPA will continue to solicit input from the public and it's federal partners in the advancement of the method. The basis for the request to withdraw the Revised Methods have been addressed in this response to comments document. EPA believes that the Revised Methods are an important advancement and will result in an improved ESA consultation process.*

Comment 204: The Skokomish Tribe requested more information on whether there is active consultation between EPA and the Services during Steps 1 and 2.

EPA response: *Once a pesticide-specific BE is finalized, if there are NLAA or LAA determinations, EPA initiates consultation with the services. At that point, Steps 1 and 2 are complete.*

Comment 205: The Skokomish Tribe indicated that there was no formal outreach to Tribes about the proposed Revised Method. They commented that the public notice (posted on May 16, 2019) and public meeting held on June 10, 2019 in Washington D.C. do not represent “timely or meaningful communication or consultation.” The Northwest Indian Fisheries Commission commented that the EPA must consult with interested tribes on the proposed Revised Method and must extend the public comment period for that consultation.

EPA response: *EPA conducted tribal consultation and coordination in accordance with EPA’s Policy on Consultation and Coordination with Indian Tribes. EPA conducted tribal outreach, during the public comment period, followed by formal tribal consultation. This engagement period took place from July – October 2019 with four scheduled webinars for tribes interested on the proposed Revised Method.*

Comment 206: The Skokomish Tribe commented that EPA made a minimal effort in regard to public outreach to obtain public comments on the proposed Revised Method.

EPA response: *In order to obtain public comment on the Revised Method, EPA published a federal register notice and held a public meeting on June 10, 2019. EPA also conducted formal tribal consultation. EPA also held an Exposure Modeling Public Meeting focused on application of usage data for risk assessment in October 2019.*

Comment 207: Commenters from Pesticide registrants or Registrant Groups/Affiliates and Grower Groups or Affiliates suggested that EPA hold additional meetings or workshops so that more details of the Revised Method can be discussed between the EPA and stakeholders. BASF commented that “there

are many areas where the proposals are either too vague to allow for proper understanding or describe a series of calculations for which it is very difficult (if not impossible) to follow to their logical conclusion (i.e., how they would result in meaningful refinements to the risk assessment) without looking at an actual assessment.”

EPA response: *EPA held an Exposure Modeling Public Meeting focused on application of usage data for risk assessment in October 2019. EPA plans to have a public webinar after the draft BEs are released. Pesticide-specific BEs will be issued as drafts and subject to a 60 day public comment period. EPA will also continue to participate in workshops hosted by stakeholders.*

Comment 208: BASF suggested that EPA have another public comment period on the Revised Method after additional details on the method are available.

EPA response: *EPA will continue to consider comments on risk assessment methods as they apply to specific biological evaluations. The first draft biological evaluations that will incorporate the Revised Methods will be methomyl and carbaryl. The public will be able to consider the methods in the context of these draft biological evaluations and provide comments with each application.*

Comment 209: The Center for Regulatory Effectiveness commented that EPA should submit the proposed method to OMB to determine if the procedures are major rules.

EPA response: *EPA does not believe that the trigger for consulting with OMB has been met because this is not a significant regulatory action under EO 12866. In fact, the methods themselves are not regulatory actions. Final action under section 7 occurs when action agencies make no effect determinations or when the Services complete informal or formal consultation with action agencies. Proposed flexible science policies that address how agencies will generally approach the development of assessments that go into completing those final agency actions are not themselves reviewable final agency actions as they do not in fact represent the consummation of the decision-making process.*

Comment 210: The Center for Regulatory Effectiveness commented that EPA has to provide increased access to data.

EPA response: *Risk assessments will use data and tools that are accessible and readily available to the public.*

Comment 211: The Center for Regulatory Effectiveness commented risk assessment procedures should be peer reviewed.

EPA response: *The development of the interim methods included an extensive peer review process that included numerous presentations at professional society meetings such as SETAC, ACS, and WSSA in addition to public input and interagency collaboration. The Revised Method include updates to the interim methods, and they have also undergone public vetting, interagency review, and tribal consultation. In addition, application of the methods in biological evaluations will continue to receive public input as every draft BE that utilizes the Revised Method will be subject to public comments.*

Comment 212: The Center for Biocide Chemistries commented: “The Revised Method applies to all pesticides registered or undergoing Registration Review, including antimicrobial pesticides.” Wastewater and Stormwater Treatment Agencies acknowledged that the Revised Method applies to

conventional pesticides. They commented that when a method is developed for reviewing antimicrobial pesticides, they would “appreciate the opportunity to provide input.”

EPA response: *At this time, EPA intends to apply the Revised Method to conventional pesticides. When EPA expands its methods to other types of pesticides (e.g., antimicrobial), the public will have the opportunity to comment on specific BEs.*

6. Conclusion

EPA received many public comments on the proposed Revised Method for conducting national level listed species assessments for pesticides. Comments were requested on several subject areas, including: incorporation of usage data, probabilistic analyses, Weight of Evidence method, and application of a 1% overlap threshold for NE determinations. Additional comments were also provided on other areas of the revised method (e.g., use of apical endpoints, determination of off-site transport distances for exposure). Submitted comments from different stakeholders expressed various, often conflicting, perspectives. EPA has carefully considered all comments and modified the Revised Method, where appropriate and feasible, taking into account the comments received. 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.

Appendix A. Submitters of public comments

County, State, and Federal Governments:

- (1) King County Executive (Washington State)
- (2) California Department of Pesticide Regulation
- (3) Florida Department of Agriculture and Consumer Services
- (4) North Carolina Department of Agriculture and Consumer Services
- (5) Washington State Department of Agriculture
- (6) Washington State Dept. of Fish and Wildlife
- (7) Attorneys General of New Mexico, California, Maryland, Massachusetts, New Jersey, New York, Oregon, Pennsylvania, Washington, Vermont, and the District of Columbia
- (8) US House of Representatives Committee on Natural Resources

Federally recognized tribes:

- (1) Skokomish Tribe
- (2) Northwest Indian Fisheries Commission (includes 20 member Tribes)

Wastewater Treatment and Stormwater Agencies:

- (1) San Francisco Bay Regional Water Quality Board
- (2) Bay Area Clean Water Agencies
- (3) California Stormwater Quality Association
- (4) National Association of Clean Water Agencies

Environmental and other Non-Governmental Organizations:

- (1) Center for Biological Diversity and Center for Food Safety
- (2) Center for Biological Diversity, Beyond Pesticides, Beyond Toxics, California Rural Legal Assistance Foundation, Center for Food Safety, Central Maryland Beekeepers Association, Delaware Ecumenical Council on Children and Families, Endangered Habitats League, Endangered Species Coalition, Environmental Protection Information Center (EPIC), Friends of the Earth, Heartwood, Howling for Wolves, Indiana Forest Alliance, International Marine Mammal Project of Earth Island Institute, Klamath Forest Alliance, Last Chance Audubon Society, Maryland Pesticide Network, Mass Audubon, National Native Plant Society for the United States, Native Plant Conservation Campaign, New Hampshire Audubon, Northcoast Environmental Center, Northern Jaguar Project, Northwest Center for Alternatives to Pesticides, Northeast Organic Farming Association/Massachusetts Chapter, NY4WHALES, Ohio Valley Environmental Coalition, Organic Consumers Association, People and Pollinators Action Network, Pollinate Minnesota, Predator Defense, Rocky Mountain Wild, Save the Manatee Club, Toxic Free North Carolina, Turtle Island Restoration Network, Unexpected Wildlife Refuge and WildEarth Guardians
- (3) Defenders of Wildlife
- (4) Environmental Policy Innovation Center
- (5) Combined comment from Northwest Center for Alternatives to Pesticides, Northern California Council of International Federation of Fly Fishers, Wisdom of the Elders, Inc., Endangered Species Coalition, Northwest Environmental Advocates, Oregon Environmental Council, Pacific Coast Federation of Fishermen's Associations, Wild Farm Alliance, Institute for Fisheries Resources
- (6) Trout Unlimited, OR
- (7) Xerces Society
- (8) Garden Club of America
- (9) Center for Regulatory Effectiveness

Pesticide Registrants or Registrant Groups/Affiliates:

- (1) BASF
- (2) Center for Biocide Chemistries
- (3) Crop Life America
- (4) FIFRA Endangered Species Task Force
- (5) Generic Endangered Species Task Force
- (6) Responsible Industry for a Sound Environment

Grower Groups or Affiliates:

- (1) California Rice Commission
- (2) Minor Crop Farmer Alliance
- (3) National Cotton Council
- (4) National Council for Air and Stream Improvement
- (5) Oregonians for Food & Shelter, Oregon Seed Council, and Oregon Farm Bureau
- (6) Pesticide Policy Coalition

Mosquito Control Organizations:

- (1) American Mosquito Control Association
- (2) Lee County Mosquito Control District

Individual citizens