

Response to Public Comments Received on
Draft Biological Evaluations for
Carbaryl and Methomyl

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1. Introduction

In March 2020, EPA released the Revised Method for National Level Listed Species Biological Evaluations (BEs) of Conventional Pesticides. EPA used the Revised Method to conduct the draft BEs for carbaryl and methomyl. On March 12, 2020, EPA released the draft BEs for carbaryl and methomyl for public comment. EPA requested comments on three specific aspects of the draft BEs for carbaryl and methomyl, including: 1) evaluation of the likelihood of effects to an individual of a listed species from the use of carbaryl on non-agricultural use areas (considering data limitations and uncertainties); 2) strength-of-evidence criteria used for Likely to Adversely Affect (LAA) determinations; and 3) properties of methomyl and carbaryl or particular characteristics of listed species or their habitats that affect the confidence in the link between thresholds used to evaluate prey, pollination, habitat, or dispersal (PPHD) effects and resulting potential effects to an individual of a listed species. 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 draft carbaryl and methomyl BEs, comments received that were not specific to the BEs (*e.g.*, on the Revised Method, on Biological Opinions, programmatic consultation) are outside the scope and not addressed here. Some of the comments submitted on the draft carbaryl and methomyl BEs focused on the Revised Method; however, EPA previously responded to comments on the draft Revised Method¹.

A total of 35 comments were submitted². Seven of those were requests for extensions of the public comment period. Twenty-eight comments that pertained to the draft biological evaluations for carbaryl and methomyl were submitted by varying stakeholders, including: US Department of Agriculture (USDA), Washington State Department of Agriculture, wastewater treatment and stormwater agencies, pesticide applicators, pesticide registrants or registrant groups/affiliates, grower groups or affiliates, environmental non-governmental organizations and unaffiliated individuals (**Appendix A**). EPA appreciates the input provided during the public comment period. The sections below summarize comments received and the EPA responses. Comments are organized by the three topic areas on which EPA requested comment, general comments on the draft biological evaluations, and comments specific to the carbaryl and methomyl BEs.

When updating the BEs for carbaryl and methomyl, EPA carefully considered these comments. Based on the input from the public, EPA notes the following major differences between the draft and the final BEs for carbaryl and methomyl and the supporting tools:

- The MAGtool³ was updated to include a streamlined batch function to include the option of deterministic vs probabilistic effects determinations and other modifications and improvements to increase transparency as detailed in the updated documentation for the model (*i.e.*, user's guide);
- The spatial footprints for alfalfa, pasture and rangeland were revised;
- Stormwater discharges of carbaryl residential uses were considered;
- The methodology was modified for estimating aquatic exposures from residential uses; and
- Additional monitoring data were incorporated.

¹ Available at: <https://www3.epa.gov/pesticides/nas/revised/response-to-public-comments.pdf>

² See EPA-HQ-OPP-2020-0090 at www.regulations.gov; [an additional submission was made by TKI in February 2021 that was not reviewed by EPA by the time the final BEs were conducted in March 2021.](#)

³ The MAGtool is the tool used to make effects determinations, utilizing toxicological information, exposure analysis and results of the spatial analysis in one tool.

A common theme throughout the comments was that EPA should do more to evaluate risks to listed species based on what is commonly occurring on the landscape (e.g., the use of typical application rates, common agricultural practices, and updated spray drift technologies) and consider risks associated with individual uses. EPA has considered some of these common practices in its weight of evidence analysis. EPA's objective is to evaluate, according to the labels, whether an individual of a listed species may be affected. As such, EPA evaluates all uses on the labels for carbaryl or methomyl, maximum label rates and method of application that are specified on the label even if the majority of the applications may be made using scenarios (e.g., application rate, technology) that could result in lower exposures. The action area represents the full spatial footprint of the labeled uses. When determining the likelihood of adverse effects to an individual and the strength of the evidence supporting risk conclusions, EPA considers labels in the context of available usage data and common practices.

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

2.1. Non-Agricultural Uses of Carbaryl

In the Federal Register Notice announcing the availability of the draft BEs for carbaryl and methomyl, EPA stated that it was seeking comment on the following:

there are uncertainties in the spatial footprint associated with the non-agricultural uses (e.g., residential, forestry, rangeland) of carbaryl and there are limited data available to inform the extent of usage in any given area for these types of uses. EPA has previously requested input on availability of spatial data to define use sites and on usage data for non-agricultural uses, including seeking public comment on: The registration review plan for carbaryl in 2010; the NMFS biological opinion on chlorpyrifos, diazinon, and malathion in 2018; and the draft Revised Method for conducting national level endangered species risk assessments for pesticides in 2019. In light of these data limitations and associated uncertainties, EPA is seeking input on the evaluation of the likelihood of effects to an individual of a listed species from the use of carbaryl on non-agricultural use areas.

The summarized comments below are relevant to this topic.

Comment 1: Bayer commented on the residential aquatic modeling for carbaryl: "The residential scenario incorporated in the carbaryl BE followed a conceptual model of a residential house lot and neighborhood that has been used in multiple recent EPA assessments, including the pyrethroids registration review assessment and the organophosphate BEs. The conceptual model breaks up a residential lot into groups of use sites, each with different runoff potential modeled with three different PRZM scenarios (Residential, ROW, and Impervious)..... There are several aspects of the residential conceptual model as implemented in the carbaryl BE that are unrealistic and should be revisited in the final BE. These include:

- Incorrect parameterization of "Residential" scenarios for turf and garden areas
- Unrealistic parameterization of "Right of Way" contributions to off-site runoff transport
- House lot application rate assumptions inconsistent with best available data."

Bayer also commented: "The areas of a house lot that represent the garden and the remainder of the yard (colored in white) are simulated with a PRZM model "Residential" scenario. In the PRZM residential scenarios (e.g., ResidentialBSS and CAResidentialIRLF), the runoff potential is moderately high (curve number of 83). The house lot areas that include the area around the foundation perimeter and

foundation wall (pervious areas), the area of a fence-line over pervious areas, and miscellaneous patios, garbage cans shrubs, etc. are simulated with the PRZM “Right of Way”(ROW) scenario. Although the Right of Way scenario is meant to represent pervious areas, it is a very high runoff scenario (curve number of 92). The PRZM “Impervious” scenario is only used to simulate fence areas over an impervious surface (carbaryl applications do not occur on any portion of the driveway). Summing the percent areas for the ROW, Residential, and Impervious scenarios, results in 90% of the lot being treated. The assumption for carbaryl exposure simulations was that all treated use sites receive the maximum annual application rate found on any current labels (8.36 lbs/ac) at four applications per year for a total of 33.44 (lbs/ac-yr).”

EPA Response: *Table 1 shows the areas and allocation of area for a quarter acre lot and is copied from Draft Chapter 3 of the Biological Evaluation. Bayer is correct that the assumption is that 90% of the lot may be treated, as the house footprint only accounts for 9.2% of the area in a quarter acre lot. Additionally, it is assumed that there is some overspray on the vertical surfaces of the house in a perimeter treatment. While the 90% applies to an individual quarter acre lot, it is assumed that only 58.7% of the watershed is taken up by quarter acre lots, resulting in a final assumption that 53% of the residential area may be treated, based on use patterns allowed on the label. The assumptions made in the parameterization are based on the maximum allowed use patterns on labels. Below are some statements on the labels that support these assumptions for use of carbaryl on lawns, ornamentals, vegetables, shrubs, or in general around the outside of your home.*

- *“Treat entire lawn and perimeter wooded areas and property boundaries where exposure to ticks may occur.”*
- *“Using a spreader, apply granules uniformly in an 8-foot band around the outside perimeter of home. Apply granules....to shrub, flower beds, foundations, ornamental plantings and lawn and soil areas immediately adjacent to the home.”*

If the labels were amended to limit the portion of the lot that could be treated or for reduced application rates, then alternate assumptions could be utilized in the Biological Evaluation. The main uncertainty in the assumption is whether all of these areas may be treated on multiple lots on the same day. This would depend on many factors including the watershed size, breadth and intensity of pest pressure throughout a neighborhood, diversity of homeowners’ lawncare maintenance practices, etc. This may be more likely when a homeowner’s association or another organization may be making pesticide application decisions for a community. Bayer has indicated that the Residential Exposure Joint Venture (REJV) estimated that annual carbaryl application rates over an entire house lot ranged from 0.001 to 3.944 lbs/acre/year. It should be noted that the usage information reported in the REJV were for a one-year period (2012-2013) and may not be reflective of other periods when usage could be higher. Additionally, the database does not provide direct application rates, but rather the rates reflect assumptions made by Bayer based on the uses reported in the database. The analysis does support that essentially an entire house lot may be treated with carbaryl as users reported applying carbaryl to the entire residential lot. In the Biological Evaluation, the maximum rates allowed on labels are evaluated (33.4 lbs/acre/year). EPA did not include 3.9 lbs/acre in the analysis due to uncertainties in the REJV data.

Table 1. Application information for modeled homeowner scenario based on maximum labeled application rates.

Scenario	Areas contributing	Total Area (ft ²)	Percent of Total Area	Total Percentage Applying to Scenario
Rights of Way	Fence Pervious	608	5.6	19
	Patio, etc	1000	9.2	
	Perimeter Pervious	461.6	4.2	
Residential	Garden	1200	11	69.4
	Turf	6366	58	
Impervious Treated	Fence Impervious	178	1.6	1.6
Driveway	Not treated	375	2.8	2.8
House	Not treated	999	9.2	9.2

¹ The total area includes the house perimeter treatment as well as the treatment of the vertical walls, which is not a part of the horizontal area of the lot. As such, the sum of percent of the total area is slightly greater than 100% (102%).

Comment 2: Bayer commented: “The EPA modeled the pervious garden and turf area of a house lot with a Residential scenario. The curve number (CN) of 83 for the EPA California residential scenario (CAResidentialRLF) comes from the National Resource Conservation Service (NRCS) standard curve number tables (NRCS, 1986) and represents a ¼ acre lot with 38% impervious surfaces for a hydrologic group C soil. This is explicitly noted in EPA’s metadata for the scenario (CAResidentialRLF) regarding the CN value selection. Thus, applying the residential scenario to the turf and pervious portion of a house lot is incorrect, as the curve number for the residential scenario was intended to represent an entire house lot, including impervious surfaces. The correct scenarios and curve numbers to use for this portion of the house lot would be the “Turf” PRZM scenarios.”

Bayer also commented: “A portion of the residential lot (19% of the area) was modeled by EPA using the California Right of Way scenario (CArightofwayRLF_v2). This scenario was designed by EPA to represent rights-of-way areas including roads, power lines, and railroads. The CN value is 92 throughout the year, making it the highest EPA standard scenario in terms of runoff vulnerability, other than the impervious scenarios. The EPA metadata for the scenario describes the land cover characteristics for the CN values selected as “CN for paved; open ditches (including rights-of-way)”. In the residential simulations for carbaryl, the CArightofwayRLF_V2 scenario was used to simulate runoff from a broad collection of patios, under porches, garbage cans, wood piles, shrubbery, and ornamentals.”

EPA Response: EPA agrees that the curve number in the Endangered Species Residential PWC scenarios were developed based on the CAresidentialRLF scenario. The scenarios have a curve number of 83 (see Attachment 3-1 of the BEs), which represents a ¼ acre lot with a hydrologic soil group (HSG) C soil⁴ and

⁴ USDA, & NRCS. 2004. Chapter 9 - Hydrologic Soil-cover Complexes. In *Part 630 Hydrology National Engineering Handbook* U.S. Department of Agriculture. National Resources Conservation Service. Available at <https://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/water/manage/hydrology/?cid=stelprdb1043063>

38% impervious surfaces. **Table 2** below is an excerpt from Appendix D: Determining the Runoff Curve Number in guidance for developing Pesticide in Water Calculator (PWC) scenarios⁵.

Table 2. Curve Number Guidance based on NRCS TR-55 Methodology

Cover Type	Treatment of practice	Hydrologic Condition (HC) or Percent Impervious surface	Hydrologic Soil Group			
			A	B	C	D
Developed Open Space	<50% grass cover	Poor HC	68	79	86	89
	50 – 75% grass cover	Fair HC	49	69	79	84
	>75% grass cover	Good HC	39	61	74	80
Residential	1/8 ac lots or less	65% impervious	77	85	90	92
	¼ acre lots	38% impervious	61	75	83	87
	1/3 acre lots	30% impervious	57	72	81	86
	½ acre lots	25% impervious	54	70	80	85
	1 acre lots	20% impervious	51	68	79	84
	2 acre lots	12% impervious	46	65	77	82

Table produced from page 42 Appendix D on instructions for determining curve number for developing PWC scenarios (see footnote 3). The bold value is the value chosen to parameterize the curve number for the CAresidentialRLF scenario.

EPA agrees that the residential curve number reflects a combination of impervious and pervious areas and when it is utilized there is an assumption that some of the treated area is to impervious surfaces. EPA also agrees that there are other appropriate methods for modeling residential areas than applying this residential curve number to a portion of a lot that is assumed to be pervious surface. The residential modeling approach utilized in the draft carbaryl BE was developed in order to be able to quantify the contribution of pesticide runoff from different surfaces. Use of the developed open space curve numbers from **Table 2**, reflecting various percentages of grass cover, may be more appropriate to represent the pervious surface around a house that may be treated with a pesticide. However, as can be seen from **Table 2**, the curve number of 83 falls between Class C and D soils with a 50-75% grass cover, so it is considered a representative value.

In regard to the use of the impervious surface scenario, for the carbaryl BE, the impervious surfaces scenario is representative of a small percentage of overspray on impervious surfaces when carbaryl was sprayed to a fence line. This scenario is applied to only 1.6% of the lot and it was assumed that a fence was only treated along one side of the lot. With carbaryl being allowed for perimeter treatments and in and around homes, it is a reasonable assumption that a user may have some overlap of granules or dust to sidewalks, adjacent roads, and driveways. As such, some impervious surfaces would be treated. The range of landcover types across the United States for residential areas will cover the range of curve numbers reflected in **Table 2** above and an analysis needs to be completed evaluating the HSG soil groups, grass coverage, and percent impervious surfaces in different HUC2⁶ regions across the United States to determine which would be the most appropriate curve number to be protective of different areas. Rather than modeling the various treated areas of the residence separately and combining them

⁵ USEPA. 2019. Estimating Field and Watershed Parameters Used in USEPA's Office of Pesticide Programs Aquatic Exposure Models - The Pesticide Water Calculator/Pesticide Root Zone Mode (PRZM) and Spatial Aquatic Model (SAM). December 31, 2019. Office of Pesticide Programs. U.S. Environmental Protection Agency.

⁶ HUC stands for Hydrologic Unit Code. There are 21 HUC2 areas in the US (<https://waterdata.usgs.gov/hydrological-unit/>)

proportionally afterwards, EPA modeled the entire residence using the Residential ESA scenarios, with the curve number of 83, as these scenarios were readily available, carbaryl is expected to be mainly applied to pervious surfaces, the curve number is in the range of curve numbers reflected for developed open spaces, and this approach simplifies the modeling for residential uses. EPA will continue to explore alternative ways to model residential uses and revisions to the curve numbers in the ROW and turf scenarios.

Comment 3: Bayer commented: “An error in the PRZM scenario parameterization used to represent the pervious turf and garden areas of a residential house lot resulted in over-prediction of pesticide runoff from these areas by up to at least a factor of 4.3x.” Bayer also commented on the “unrealistic parameterization of house lot use sites parameterized with “Right of Way” scenarios resulted in over-prediction of pesticide runoff from these areas by up to at least a factor of 3.7x.” Lastly, Bayer commented that “unrealistic residential use pattern assumptions implied residential carbaryl usage is 639x higher than EPA’s conservative carbaryl residential usage estimate.”

EPA Response: *Based on previous comments, EPA has revised its approach to modeling residential applications, such that the first two comments are no longer pertinent. With regards to the usage, the 639x is based on comparing the product of EPA’s annual application rate (33.4 lb ai/A/yr) and the total acreage of residential lots potentially receiving applications (25,301,291 A) to the annual usage estimate provided in the BE (1.3 million lbs ai/yr). EPA agrees that not every residence uses carbaryl at the maximum rate, that is why percent crop treated is taken into consideration. EPA also takes into account the typical application rate in the MAGtool weight of evidence analysis. The application rate used in the modeling should not be used with the potential acreage to evaluate the overall usage rate. The application rate is used in the modeling to estimate an upper-bound EEC to which an individual of a species may be exposed. The application rate is used for regional modeling of what could potentially be used and should not be used to estimate the amount of carbaryl being used on a national basis.*

Comment 4: NovaSource/Tessenderlo Kerley, Inc. commented: “The methods and approach utilized for residential and non-agricultural assessments was evaluated by industry groups related to the pyrethroid registration review noted in this summary. A formal guidance and review process for the new tools and posting of these methods with other tool sets (*i.e.*, <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>) would be a more transparent and easier method for potential users rather than having specific assessments provide the development and review process.”

EPA Response: *Because the usage data for carbaryl suggests that the majority of carbaryl applied occurs in residential areas, and the spatial footprint of residential uses was an uncertainty, EPA determined it was important to seek public comment on this use. Based on the comments received, EPA will continue to review its approach for residential use assessments and make any changes to these tools available to the public. It should be noted that EPA has conducted a formal review and quality control check of the tools used in the BE process.*

Comment 5: Bayer commented: “More recent usage data shows that carbaryl usage has declined significantly since 2016, indicating that the BE analysis is based on usage that is three times higher than usage since 2018. This leads to inflated PCTs and spatial extents of Usage Data Layers (UDLs).

EPA Response: *EPA agrees that the most recent carbaryl usage reported was lower than usage observed just several years ago. However, short term trends are often not sustained. Because usage can fluctuate*

in the short-term, EPA usage estimates for ESA assessments are based on the most recent 5-years of data. Notwithstanding changes in the market or the regulatory status of the chemical that would result in more permanent changes in usage, EPA does not agree that the reduced time period proposed by Bayer is appropriate to estimate usage.

Comment 6: Bayer commented: “Higher resolution, best available usage data for California (PUR database) was not used in the usage analysis. Bayer’s evaluation of the PUR data showed:

- CA PCT for professional usage on Developed (residential) areas of 0.005%
- CA PCT for professional usage on Developed, Open (turf) areas of 0.0003%”

EPA Response: *California PUR data were used to estimate usage for appropriate uses. The CA PUR data for Developed (residential) areas account for professional usage only. Consumer usage of carbaryl on the residential areas, in particular, is not captured by the CA pesticide usage reporting requirements and is likely to be important. Also, usage on Developed, Open (turf) is likely to exclude a fair amount of usage, as per California DPR, “The primary exceptions to the use reporting requirements are consumer home-and-garden uses and most industrial and institutional uses, including schools and childcare facilities.” Thus, while turf farms, which are agricultural sites, would report under agricultural reporting requirements, turf in developed areas may not be reported, unless treated by professional applicators that are subject to CA pesticide use reporting requirements.*

Comment 7: Bayer commented: “The carbaryl SUUM for residential and turf uses relied upon surveys conducted by Kline in 2013 and 2016 (specific references not provided in the BE). Additional data sources exist that can provide a more current and more accurate indication of the amount of carbaryl usage across the US and for different usage segments.” These other sources included registrant production and sales, CA PUR and REJV.

EPA Response: *EPA has used the best data available, at this time, to refine residential and turf uses in the carbaryl BE. Market data provides usage estimates based on national-level studies. The data sources identified by Bayer have been considered and were not used for the reasons identified below.*

- *Production and sales data cannot be tied to usage in specific locations or for specific use sites.*
- *California PUR data are relevant to CA only and do not include consumer pesticide usage. Carbaryl has well established products that are intended for consumer use, which makes those data incomplete for the purposes of estimation of usage on residential sites.*
- *The REJV data were collected in 2012-2013. While the REJV study was designed to capture consumer pesticide use and usage trends, the statistical validity of those data for the purposes of estimating consumer usage of carbaryl individually has not been established.*

Comment 8: Bayer provided a summary of the amount of technical carbaryl sold on an annual basis from 2014-2020.

EPA Response: *The amount of technical material sold on an annual basis cannot be tied to specific uses, application locations, or even years, necessarily. Therefore, sales are not a reliable estimator of usage for carbaryl in this biological assessment.*

Comment 9: Bayer commented: “Carbaryl homeowner application rate data was not considered. Data from the Residential Exposure Joint Venture (REJV) showed that house lot averaged annual application rates ranged from 0.001 to 3.9 (lbs/ac-yr), whereas the BE exposure modeling assumed an annual application rate of 33.44 (lbs/ac-yr) over 90% of every house lot.”

EPA Response: While the REJV data was designed and may have utility in terms of understanding general consumer pesticide use patterns, the robustness of those data for determining usage of individual AIs has not been fully evaluated. In particular, the carbaryl usage data within the REJV dataset have not been determined to be statistically robust for the purposes of estimating carbaryl usage at the national, regional, or state levels.

Comment 10: Bayer commented: “The methodology for calculating PCTs and generating UDLs used carbaryl application rates that were inconsistent with exposure modeling assumptions. The BE approach used maximum, average, and minimum **single** application rates to determine areas treated, yet all exposure modeling scenarios considered only **annual maximum** rates to calculate exposure magnitude. This disconnect resulted in UDLs that are inflated in size and that do not reflect the accompanying exposure modeling results. The resulting overestimates in PCT due to this application rate assumption inconsistency were:

- Developed (residential) Use Sites: Two to 18 times overestimation of PCT based on EPA’s usage values and five to 49 times overestimation based on more recent Bayer usage values
- Developed, Open (turf) Use Sites: Two to 39 times overestimation of PCT based on EPA’s usage values and five to 108 times overestimation based on more recent Bayer usage values”

EPA Response: Pesticide usage data available are based on surveys of growers and/or other user groups and is not an exhaustive of all usage. For this reason, an update made for the final BE set the lowest possible PCTs at 2.5%. PCTs below this value are rounded up to 2.5% to buffer against uncertainty associated with these surveys and low usage estimates. The surveys utilized by EPA are designed to be statistically robust, but by definition sample the target populations rather than provide a complete accounting of all pesticide usage. Therefore, PCT estimates resulting in values below 2.5% are generally a good indicator of limited usage of an active ingredient but by using 2.5% the PCT accounts for possible usage not captured by the survey data. Following the update, the PCTs for the residential area at this lowest possible value of 2.5%.

EPA used maximum application rates to derive initial exposure estimates in order to be protective of listed species. In Step 2, the MAGtool uses typical rates, along with scaling factors to look at other application dates and hydrologic conditions, to evaluate risks at other than maximum application rates. If risks are still occurring, then EPA is more confident in a Likely to Adversely Affect determination.

Comment 11: Bayer commented: “The disconnect between usage analysis and exposure scenarios leads to exposure modeling results that are roughly 1000 times too high for a typical aquatic habitat in a residential watershed. This overestimate does account for the additional issues identified with regard to the residential scenario parameterization.

EPA Response: Pesticide usage data available are based on surveys of growers and/or other user groups and is not an exhaustive accounting of all usage. As discussed in **Comment 10**, EPA sets the lowest possible PCTs at 2.5%. PCTs below this value are rounded up to 2.5% to buffer against uncertainty associate with these surveys and low usage estimates.

The statement that exposure estimates are “1000 times too high for a typical aquatic habitat” reflects a comparison of the various usage estimates derived by Bayer and EPA to that derived using the maximum annual application rate (33.44 lbs/A/yr) and the national residential acreage. As discussed above, it not

valid to estimate a national annual usage estimate using the maximum label application rate, as the label rate is used to derive an EEC that is appropriate for use to estimate potential risk on a local scale.

Comment 12: FIFRA Endangered Species Task Force (FESTF) commented: “In 2015, FESTF obtained a data license to a spatial dataset from American Digital Cartography, Inc. (ADCi) containing various land use categories. FESTF has renewed this data license agreement on an annual basis and each dataset has been submitted to the EPA for use in pesticide evaluations (see MRIDs 49643403, 49974902, 50436802, 51011102). The licensed dataset can also be downloaded from, and viewed, along with species location data and other land cover/land use, in Gopher, to which EPA has access. FESTF conducted a data validation exercise on some of the feature classes in this dataset (see MRID 49643403). FESTF’s licensed dataset from ADCi contains additional feature classes representing the spatial location of various non-agricultural land uses categories that are directly related to pesticide labels” and included several specific use sites. They added: “FESTF asserts that this information meets the “best available” ESA standard and recommends that the licensed dataset from ADCi should be used to represent golf courses and other non-agricultural use sites represented by these features, when evaluating potential pesticide use areas.”

EPA Response: *For the purpose of transparency, EPA uses publicly available datasets, when available, to account for uses found on the pesticide label with the spatial Use Data Layers. Use of these national and publicly available datasets are part of the built-in conservatism when assessing the impacts to an individual in the Step 1 and Step 2 analysis completed in the BE. In circumstances where additional refinement is warranted, for example if a species is only impacted by a single UDL, or as part of the Step 3 analysis, incorporation of other data, such as the ADCi, may allow for greater precision and refinement of the analysis.*

2.2. Application of Strength of Evidence Criteria for LAA Determinations for Carbaryl and Methomyl

In the FRN for the draft BEs for carbaryl and methomyl, EPA stated that it was seeking comment on the following:

EPA has developed a systematic process, using the best available data, to determine if a pesticide is likely to adversely affect an individual of a listed species and, if so, then characterizes the strength of evidence associated with likely to be adversely affected (LAA) determinations. The criteria used to characterize the strength of evidence are described in Attachment 4-1 of the BEs. EPA is seeking input on these strength-of-evidence criteria.

The summarized comments below are relevant to this topic.

Comment 13: Creekbank Associates commented: “While we generally applaud EPA’s effort to provide the Services with information regarding your opinion of the strength of the evidence used to develop the BE conclusions, we believe it would be helpful to have more information regarding the standards used for this approach. Was this process developed jointly with the Services or at least with their coordination and input? Has this approach been applied in the past? Has it been peer reviewed? If so, perhaps the results of peer review can be shared. In general, it is good to provide indications regarding the strength of evidence used in an evaluation, however, particularly when using broad and perhaps fairly nebulous and subjective categories such as “weakest,” “moderate,” and “strongest,” it is important that the reader understand and accept the significance of the categorical separations.”

EPA Response: *The EPA developed the weight of evidence criteria based on a review of all factors that were included in the revised methods that were determined to impact the confidence in a LAA determination. This was based on consideration of the certainties and uncertainties associated with the Revised Method, consideration of other weight of evidence methods, as well as discussions with the Services. The final criteria utilized in the BEs incorporated input from the Services and the USDA.*

Comment 14: Corteva commented: “A robust weight-of-evidence approach should be implemented, and all uncertainties should be clearly documented and communicated to demonstrate the transparency and scientific defensibility of the risk assessment. In methomyl BE attachment 4-1, the criteria for strength of evidence in LAA determination is vague and confusing.”

“Essentially it appears that if at least 1 individual is potentially impacted under the worst-case scenario (maximum_upper acres distribution) an LAA determination is made. Then 10 additional lines of evidence (3 quantitative and 7 qualitative) are evaluated as increased, decreased, or no impact. No information is given as to the degree to which the quantitative criteria are increased or decreased; thus, one is left to assume that whether the increase is by 1 individual or 1000 individuals it receives the same weight. Furthermore, none of the strength descriptions list what number of factors, nor the degree to which confidence is decreased for quantitative or qualitative factors, is needed to move from a LAA to NLAA determination. Clearly identifying the number of LAA determinations that were changed based on the confidence calls would be prudent.”

EPA Response: *Attachment 4-1 outlines the factors that go into each part of the weight of evidence and how these criteria are used in weighting each line of evidence. As the effects determinations are based on the impact to one individual, the strength of evidence attempts to give an indication of the confidence in impacts to one individual, rather than focusing on the absolute number of individuals predicted to be potentially impacted. The magnitude of the number of individuals impacted is meant to provide additional information to the Services to assist in the Step 3 analysis.*

The “worst-case” scenario in the WoE, as referred to in comment, utilizing the maximum PCT and upper distribution of acres, includes many factors that move off of a screening level approach, such as:

- *Basing the EECs on a variety of dietary items or a preferred dietary item in the terrestrial environment,*
- *Applying on/off field assumptions about the species,*
- *Using application methods that are associated with the most likely type of application (ground vs aerial) instead of the most conservative*
- *In the probabilistic analysis, basing EECs on a distribution of values*
 - *For terrestrial exposure, based on the mean Kenaga and standard deviation*
 - *For aquatic exposure, based on consideration of a range of daily EECs from multiple scenarios, varying curve numbers and varying applications dates*

Based on these refinements, EPA does not consider the WoE a “worst-case” scenario.

Comment 15: Corteva commented: “Attachment 4-1 mentions that these automated NLAA/LAA and confidence calls are reviewed by an assessor. Providing documentation and statistics on where and how often the reviewer disagreed with the automated determination and confidence calls would be appropriate to discern if the tool is working appropriately.”

EPA Response: *The manual review of the calls was most often in agreement with the automated calls. However, EPA could consider recording and documenting the analysis in the future to determine when*

calls were changed. Differences noted in the call were reevaluated to improve the automation of the initial call.

Comment 16: Corteva commented: “As with organophosphate BEs (2017a-c), the Revised Methods (2020b) WoE analysis as applied in the draft methomyl BE (2020a) is a missed opportunity to use additional lines of evidence to screen out species/critical habitats. Analysis of lines of evidence to form a WoE analysis was implemented in the draft methomyl BE in a rudimentary fashion and did not appear to affect the effects determination in any substantive way. In fact, the only part of the determination that appeared to be affected by using WoE analyses was the Agency's confidence in their LAA determinations. No specifics are provided on conducting a quantitative WoE assessment, and what lines of evidence can be used or how they should be used. Indeed, one line of evidence, upstream monitoring data, was used only to revise potential NLAA calls to LAA. It is unclear why such a line of evidence (along with others) could not also be used to revise a LAA to a NLAA call. A mechanism to do this would be a positive improvement to the process. Better yet, consideration of these other lines of evidence should occur before the effect determination call is made”

Corteva also comments: Other lines of evidence (e.g., field studies, field surveys, comparing monitoring data to toxicity test results, comparing exposure data to mesocosm endpoints, species trends vs pesticide use trends, in situ bioassays, incident reports) are not mentioned in the revised guidance, let alone how such information would be used in a WoE assessment.”

EPA Response: *EPA reviewed the list of species that did not meet the criteria to perform a quantitative analysis and instead analyzed them qualitatively. This was to some extent the equivalent of an early weight of evidence evaluation, with species evaluated differently when criteria such as incomplete exposure pathways or exposure models that are unreliable for the species habitat were identified. Any species that are determined to be suitable for a quantitative analysis indicates that there is some degree of confidence that the overlap analysis conducted will reasonably represent the potential for the species range or critical habitat to intersect with the application site or off site transport zone. Additional factors applied in the process serve to step through assumptions that decrease conservatism with each step, therefore increasing the confidence that an effect may occur, ultimately ending with the weight of evidence and a strength of evidence associated with each call.*

The weight of evidence method was developed by EPA and further revised based on input from the Services. Additional data for analysis is provided to the Services through ECOTOX reports and discussed in the effects and exposure chapters (2 and 3) in the BE. Monitoring data and incidents are included in the lines of evidence.

Comment 17: Rotam commented: “For each LAA determination, the BE uses a rating of “strongest, moderate and weakest” to characterize the strength of the determination. LAA determinations are made if at least one individual could be exposed for any use pattern using the assumption that maximum use rates, maximum PCT, and upper use distributions (use will first be applied directly to critical habitat and range, and most sensitive species thresholds as described above). Using this set of unrealistic assumptions and not weighting all lines of evidence does not allow for a WoE framework to be applied, nor does it allow for the strength of the LAA to be assessed. The fact that LAA determinations were made for 1114 species and 335 critical habitats for Methomyl indicates the inadequacy (from not applying necessary chemical, use, and species information) of the assessment. Since the importance of many of these items is mentioned in the BE, it is assumed that resource limitations impacted the completeness and reasonableness of the BE effects determinations. The BE

indicates that “for approximately 62% of all species and 42% of critical habitats, an LAA determination was made” and that “of those LAA determinations, 29% were considered to have strongest evidence of LAA, 44% were considered to have moderate evidence of LAA, and 27% were considered to have weakest evidence of LAA”. These statements point to the uncertainty that needs to be addressed in the assessment. Additionally, the BE states that “the pasture use data layer (which represents use on alfalfa for Methomyl) was cited as the top use site associated with impacts to species or critical habitats with LAA determinations”. This plainly highlights the different exposure potential from each individual use pattern and the need to include additional detail in the assessment to address screening level risk concerns.”

Rotam also commented: “The inclusion of a WoE approach in the draft BE is a positive indication of the importance of a WoE framework. The application of a robust WoE is critical, and a WoE is made robust by including all relevant lines of evidence that are reliable and relevant to the assessment. However, all lines of evidence were not adequately considered at the level needed to be effective. The relevance, strength, reliability and overall weight of each line of evidence should be considered.”

EPA Response: *Effects determinations are based on all labeled uses for an assessed pesticide active ingredient. As part of the weight of evidence output, the UDLs that were associated with impacts to a species are listed, providing some context to what use drivers are associated with each effects determination. The strength of evidence assigned to each determination is meant to provide some additional characterization to the Services when a number of LAA determinations are made. For the final carbamate BEs, updates to the MAGtool summarized output and discussion and tables in Chapter 4 have been improved to help better capture use drivers that may be impacting effects determinations. The number of LAA determinations is not an indicator of the adequacy of the analysis. Methomyl has a large number of use sites and associated spatial footprint that overlaps with a large number of species ranges. Given that EPA evaluates the potential for a pesticide to impact a single individual of a species, it is not surprising to have a large number of LAA determinations.*

EPA included lines of evidence in the WoE that were determined to be factors that could have the most impact on the confidence and reliability in the determination and did weight these factors as provided in the description in Attachment 4-1. These included the manner of potential effects to an individual (mortality, sublethal or PPHD impacts), range data quality, reliability of usage data, species surrogacy of toxicity data, usage data reliability, incidents reported, habitat and exposure model, drift contribution to impact and monitoring data. Additional factors such as incomplete exposure pathways or inadequate exposure models are essentially captured in the review EPA performs to determine if a species can be analyzed using a quantitative method. EPA will continue to work with the Services on how additional lines of evidence and other information is most useful to provide and can best inform the Biological Opinion.

Comment 18: Rotam commented: “Sources of uncertainty and assumptions contained in the draft need to be adequately addressed with modifications included in the lines of evidence within a robust WoE framework. They include:

1. Uncertainties in the spatial footprint associated with the non-agricultural uses (e.g., residential, forestry, rangeland) of Methomyl.
2. All agricultural uses are captured in one spatial footprint in the non-contiguous United States and territories.

3. Available range data for some listed species are at the sub-county level, with boundaries that are biological in nature, while others follow geopolitical boundaries, such as county or state lines.
4. Species with overly broad ranges that include habitats the species would not utilize lead to uncertainties in effects determinations.
5. Assumptions with respect to where pesticide-treated acres could occur relative to a species habitat (e.g., all treated acres occur within the habitat, evenly dispersed throughout the state, or primarily outside of a species habitat). It should be noted that in the BE all effects determinations were made with the assumption that all treated acres occur within the species habitat. This significantly overestimates risk potential.
6. There are uncertainties associated with the magnitude of impact to a particular species prey base or habitat for a given pesticide that could result in a discernible effect to that listed species.
7. Application of local agronomic practices (rates, methods, application timing) in relation to species locations.
8. A synthesis of available detail regarding species known locations and key habitat characteristics that will support listed species populations available from the Services.
9. The use of probabilistic exposure methods using realistic (use specific) application methods and exposure assumptions.
10. An overlay of spatial and temporal patterns of species and local use sites to evaluate co-occurrence at the time of applications.
11. Including natural history information that might impact exposure potential (e.g., species use of treated areas, suitable habitat near treated areas, habitat preferences, species elevations, subterranean or forest associations, dietary proportions, metabolic and food consumption rates).
12. The analysis plan should outline how all, or a portion of a species habitat, being on federal, state or lands with conservation management occurring will be used and weighted in the assessment.
13. Adding a line of evidence for locations of remaining or known populations and exposure potential.
14. Weighting the fact of pesticides being, or not being, identified as a likely driver in the decline and status of listed species. This is especially important in the prioritization of resources for species protection.”

EPA Response: *Many of these factors are already considered in the assessment and weight of evidence. When conservative assumptions are made, the EPA recognizes this and specifically outlined this in the Revised Methods documentation. EPA will continue to evaluate improvements to the weight of evidence process, such as those listed above, as part of our efforts to improve our assessments in this iterative process. This includes working with the Services to determine information that is most useful and impactful in the full consultation process.*

Comment 19: FIFRA Endangered Species Task Force (FESTF) commented: “While not explicitly stated in the Final Revised Method, the Weight of Evidence (WoE) is characterized and generated in Step 2 of the Final Revised Method. EPA states that as they assess “a species through parts h and i of Step 2, uncertainties and conservative assumptions are revisited, and EPA makes determinations based on the weight of the available evidence (EPA, 2020).” While EPA specifically asked for comments on the strength-of-evidence criteria, there is some confusion regarding how the WoE fits into the overall process, including the strength-of-evidence criteria. In Figure 4 of the Final Revised Method (p. 29), the same statement is made as quoted above but with slightly different language highlighting that parts h

and I will characterize the weight of evidence as strongest, moderate, or weakest (EPA, 2020). This distinction is important because it appears the lines of evidence for the WoE are incompletely developed during Step 2. Only parts h and I are used to characterize the strength-of-evidence. Related to the strength of evidence are the following:

- o The methodology behind selecting species that would need further evaluation “for potential adjustment of the species determination, such as unique habitat or species traits” in the criteria for strength-of-evidence is unclear.
- o Habitat and exposure level (Factor 8) should be included among the heavier-weighted lines of evidence (Factors 1-3). If habitat is a mismatch to exposure models, this is quite relevant.
- o In Table 1 of Attachment 4-1, a report of incidents related to either direct or indirect (PPHD) taxa of concern increases the confidence in Factor 7: Incidents Reported; however, if there are not any incidents reported, there is no impact on confidence. For a product, like methomyl, which has numerous labeled uses and has been on the market for years, if there are no incidents reported then that fact should decrease the confidence in Factor 7: Incidents Reported.”

EPA Response: *EPA screens all species to determine whether a qualitative or quantitative analysis is warranted, which considers a factor such as if the exposure model is clearly inadequate for the habitat of the species. EPA continues to evaluate and improve the clarity of the assumptions in the weight of evidence methodology. Regarding incidents, the absence of empirical data or incident reports associated with effects to an individual or groups of individuals of listed species does not mean that they have not occurred, but rather that they were not observed. Therefore, the lack of reported incidents is not a reliable indicator of lack of occurrence of environmental effects. For this reason, incidents may be used to increase the confidence in a call but are not used to decrease the confidence in a call.*

Comment 20: Crop Life America commented: “The Draft Carbamate BEs provide the first opportunity to evaluate how EPA applied weight-of-evidence approaches to effect determinations made for individual listed species and/or their critical habitat. In the Draft Carbamate BEs, as well as in the organophosphate BEs, no line of evidence had any impact on an effect determination call once it was made. EPA appears to apply its weight of evidence approach only to determine confidence (Steps 2h and 2i). Unfortunately, the confidence determination appears immaterial to the effect determination and seems intended to provide information to the Services on whether EPA believes the effect determinations made for each species were well supported or not. It does not appear to provide the Services with meaningful direction regarding a Likely to Adversely Affect/Not Likely to Adversely Affect (LAA/NLAA) determination.”

Crop Life America commented: “In the Draft Carbamate BEs, EPA makes highly conservative assumptions to account for uncertainties in the data, model inputs, and the models themselves. This leads to compounding conservatism throughout the BE and generates risk estimates that do not reflect the reality of the listed species being evaluated. Therefore, it is critical that other lines of evidence are considered in Step 1 and 2 to provide appropriate context to the effect determination and proposed LAA/NLAA calls prior to them being made.”

Crop Life America (CLA) commented: “CLA has provided an alternate case study for the West Indian manatee that applies semi-quantitative and qualitative approaches and incorporates available lines of evidence to support the effect determination. This approach reflects a more realistic assessment of carbaryl’s effect on this species more likely to meet the ESA regulations’ “reasonable certainty” standard (see Attachment III: West Indian Manatee Case Study).”

Crop Life America provided a refined risk assessment, including integration of lines of evidence.

NovaSource/Tessenderlo Kerley, Inc. commented: “The draft BE provides the first opportunity to evaluate EPA’s revised application of a weight-of-evidence (“WoE”) approach as applied to the effect determinations for individual listed species and/or their critical habitat. Appropriately, EPA describes the value of a WoE approach in their Revised Methods. EPA’s implementation, however, was not consistent with a WoE robust analysis. WoE analyses, by definition, apply all lines of evidence available (e.g., incident report, mesocosm studies, field studies, monitoring data, species ecology, etc.) and include those lines of evidence in the risk characterization to draw a final risk conclusion (in this case an effect determination). In the draft carbaryl BE, the lines of evidence that were applied (e.g., monitoring data) were used only for adjustment of the effect determination to a more conservative result (e.g., NE or NLAA to LAA). Thus, if a single individual was predicted to be adversely affected prior to the WoE analysis, no other line of evidence had any impact on an effect determination. Instead, EPA applied more lines of evidence in its WoE approach only when making confidence determinations (Steps 2h and 2i in the Revised Method), resulting in confidence predictions ranging from low to high confidence.”

NovaSource/Tessenderlo Kerley, Inc. commented: “By not implementing a quantitative or fully qualitative WoE approach in the draft carbaryl BE, the single modeling line of evidence with its compounded conservatism effectively drove the effect determinations for every species evaluated. The BE model (i.e., MAGtool) used species-specific information including body weight, diet, and other factors to develop a risk characterization for each listed species. Due to the automated, linear approach, however, the model did not account for specific life history information or other lines of evidence that may influence the probability of exposure and effect. To develop and complete a risk characterization that leads to a scientifically defensible LAA/NLAA effect determination, these important lines of evidence must be applied from the start in the refined assessment. In addition, to support the scientific defensibility of the BE, EPA must clearly and completely document the assumptions and sources of uncertainty in its WoE analysis and indicate if they are reasonably certain to occur.”

“NCC urges EPA to expand guidance in the development of weight-of-evidence to ensure continuity as well as avoiding being overly conservative based on a few studies suggesting an impact that others do not support. The studies should not be ignored. Their influence should not significantly bias any weight-of-evidence study without careful documentation increasing the validity of the findings (new scientific technique, new and appropriate methodology).”

EPA Response: *EPA applied factors to the weight of evidence that were deemed to impact the confidence in an effects determination. Criteria that was used and how it was applied to result in an LAA or NLAA determination were based on discussions and agreements with the Services. These agreements included what would constitute the difference between an NLAA and LAA decision, and based on the conservatism that comes with the risk to impacting one individual, as laid out in the statute, EPA still needs to maintain this level of conservatism, even when considering the application of additional lines of evidence. EPA included lines of evidence in the WoE that were determined to be factors that could have the most impact on the confidence and reliability in the determination and did weight these factors as provided in the description in Attachment 4-1. Although the LAA/NLAA determination is weighted heavily on if impacts are predicted to greater than or less than one individual based on the maximum PCT and upper acres distribution in the WoE, other factors such as a species being an interior forest species or a cliff dwelling species can also impact a species effects determination to change an LAA call to an NLAA call. Additional factors such as incomplete exposure pathways or inadequate exposure models are essentially*

captured in the review EPA performs to determine if a species can be analyzed using a quantitative method. EPA will continue to work with the Services on how additional lines of evidence and other information is most useful to provide and can best inform the Biological Opinion.

Regarding the case study with the manatee, although elements in the general methodology in the case study have merit, there are many assumptions made with respect to generalizing the manatee's habitat, location, and diet. Even the RQs presented in the case study for direct acute effects of 0.8 would likely result in an LAA determination. The case study also discussed uncertainties that could result in overestimate of potential risks, such as applying toxicity reference values derived from a rat to a manatee. However, it is possible that a manatee is more sensitive or has similar sensitivity to carbaryl toxicity than a rat. Therefore, some uncertainties can result in either an over- or under-estimation of risks. Many of these factors are considered in the biological evaluation when EPA assesses the impacts of lower exposures, lower usage, and lower toxicity on the effects determinations. EPA continues to improve its assessment methodology, and these approaches will continue to be further considered as we move forward.

As described in the Revised Method document, EPA considers whether an effect is "reasonably certain to occur" in Step 2. Since the Revised Method document was reviewed by and incorporates comments from the Services, EPA believes that the approach described in the Revised Method is consistent with the current "reasonably certain to occur" standard.

2.3. Links Between PPHD and Potential Effects of Carbaryl and Methomyl on Listed Species

In the FRN for the draft BEs for carbaryl and methomyl, EPA stated that it was seeking comment on the following:

a number of draft LAA determinations were made for methomyl and carbaryl based on potential impacts on prey, pollination, habitat, or dispersal (PPHD) of a listed species using endpoints identified in Table 3 of the Revised Method document and chapter 2 of the BEs. There are uncertainties associated with the magnitude of impact to a particular species' prey base or habitat for a given pesticide that could result in a discernible effect to that listed species. EPA requests public input regarding properties of methomyl and carbaryl or particular characteristics of listed species or their habitats that affect the confidence in the link between thresholds used to evaluate PPHD effects and resulting potential effects to an individual of a listed species.

The summarized comments below are relevant to this topic.

Comment 21: Creekbank Associates commented: "Indirect Effects – There exists a need to evaluate indirect effects to prey species; However, we question the selection of the ">10% mortality to prey base" category." Also: " EPA should provide a clear explanation of the thought process used to support the selection of the 10%-level."

EPA Response: *EPA assumes that >10% mortality to animal prey could potentially impact an individual of a listed species. This assumption is consistent with EPA's levels of concern for FIFRA risk assessments, where RQs that would generate potential effects of 10% or more would indicate risk concerns for mortality to animals. This effect level is comparable to the detectable amount of mortality of a standard acute toxicity study, where 10% background (i.e., control) mortality or less is considered acceptable. Therefore, there is a potential for indirect effects when there are levels of mortality in prey that exceed background. There is uncertainty in the approach, as information is not available to quantitatively link the magnitude of decrease in available prey to an effect to an individual of a listed species.*

Comment 22: Creekbank Associates recommended the following: “Effect categories more meaningful than simply 0% to 10% and 10% to 100% should be presented. EPA should provide a clear explanation of how you believe the Services should use this information. For example, given the broad nature of the categories, should they assume that the individuals experiencing these effects will have their prey base reduced by either 10% or 90%, or something in-between? A more refined presentation of this information is needed.”

EPA Response: *The magnitude of impact on prey of a listed individual is relevant to the services’ consideration of population level effects. The services may consider the range or distribution of effects to prey as they may impact different individuals of a listed species population.*

Comment 23: Rotam commented: “Several assumptions are made in the BE regarding exposure and impacts to listed species from impacts to PPHD. The use of endpoints from the lowest end of the sensitivity spectrum is considered representative for all PPHD in each taxon. There is an assumption that suitable habitat, individuals of a listed species and PPHD are proximate methomyl use sites. There is an assumption that they will be proximate during product application. Therefore, there is the assumption that 100% of the PPHD will be exposed. Finally, there is an assumption that these exposures will lead to a measurable and meaningful impact to individuals of a listed species. These additive assumptions represent a highly unlikely scenario. For general relationships with PPHD, it is more likely that a wide range of species is utilized by a listed species. This PPHC species will represent a wide range of sensitivities and not be proximate to use sites such that full populations are exposed and impacted. Many of the PPHD invertebrate community are R strategist meaning that they reproduce rapidly, and numbers would likely recovery from an exposure if impacts were to occur on or near treated areas. Without the direct application of a wide range of population models, the most practical approach for the WoE analysis would be to consider a threshold closer to the midpoint of the entire distribution (e.g., HC50), the application of refined ranges discussed above, and a weighting of exposure on and off treated areas. The highly conservative assumptions contained in the assessment using the lines of evidence mentioned above, and a midpoint effects endpoint from the relevant taxonomic effects distribution for PPHD, represents a reasonable assumption if habitat suitability is taken into account on and off treated areas.” They added: ““using the most sensitive endpoints for listed species is highly conservative and that effects metrics for PPHD should be represented by a wider response.”

EPA Response: *EPA agrees that several conservative assumptions are made related to exposure of PPHD to carbaryl or methomyl and that an effect to PPHD will lead to an impact to an individual of a listed species. Rotam stated that “these additive assumptions represent a highly unlikely scenario.” There is uncertainty in the approach, as information is not available to quantitatively link the magnitude of decrease in available prey to an effect to an individual of a listed species. EPA utilizes a conservative endpoint (e.g., HC05 or most sensitive tested species) to represent potential impacts on an individual of a listed species due to declines in PPHD. EPA agrees that it is relevant to consider endpoints that represent a mid-point of sensitivities among tested species within a taxon. Since the relationship is unknown between the most sensitive tested species responses and those of species representing PPHD of listed species, EPA chose a conservative approach. It is unknown if the most sensitive tested species are really conservative when considering the relative number of untested species. To evaluate the influence of EPA’s assumptions regarding use of the most sensitive endpoint, EPA considered other endpoints in an alternative analysis with the MAGtool. The purpose of this analysis was to evaluate whether EPA’s conservative assumptions influenced the effects determination for a given species. In cases where the use of less conservative endpoints would result in a conclusion that there were no impacts to PPHD,*

additional species-specific information would be helpful to suggest whether a PPHD species would be better represented by a less conservative endpoint.

Comment 24: Rotam commented: “it is excessively unrealistic to assume that PPHD will be exposed (present at the time of application), that populations of PPHD will be fully exposed (i.e., all populations of PPHD supporting a listed species), that low end thresholds used for PPHD represent population impacts, and that a total impact on PPHD will result in impacts to individuals of a listed species. These assumptions need to be addressed and adjusted as they do not provide appropriate bounds or likelihood of the effects occurring. Proximity between suitable habitat should be the starting point and exposure based on realistic use patterns and methods should then be considered. Effects endpoints from the distribution of thresholds for PPHD should then be considered to evaluate the possibility of individual PPHD effects (before assuming community responses that lead to individual impact). Next, natural history characteristics of the species should be considered to determine if it is likely that PPHD populations are isolated and would collapse based on applications of Methomyl. The probability all these assumptions being true is very low and this uncertainty should be addressed in the BE. This line of evidence is currently very weak in making effects determinations. Direct effects metrics should be held to a higher weighting level with more realistic assumptions applied. The fact that plants are not sensitive to Methomyl above maximum use rates, yet 541 LAA determinations were made for plants, illustrates the lack of realism in these assumptions.”

EPA Response: *EPA utilized the range information provided by the services to determine proximity of a listed species and its PPHD to a pesticide exposure site. In some cases, life history and habitat information were considered (e.g., to determine if a listed species may visit a use site directly or only stay “off-site”). In cases where only impacts to PPHD (and not direct effects to the listed species) were identified, a LAA determination was made but the strength of evidence reflected uncertainty in the determination. In regard to the LAA determinations for listed plants, these were not based on potential impacts to listed plants themselves, but rather to animals that represent the PPHD of those listed plants. Additional discussion of the effects threshold is provided in the response to **Comment 23** (above).*

Comment 25: FIFRA Endangered Species Task Force (FESTF) commented: “SOS profiles provide PPHD information sourced from FWS documents and in much more detail than EPA included in the materials on the draft BE website. EPA should use the attribute information from the SOSs housed in FESTF’s Gopher to better inform each effects determination.”

EPA Response: *EPA is currently using listed species information from documentation developed by the Services and that has gone through their vetting process. In the future, EPA may consider using other sources of data or databases, with input from the Services.*

Comment 26: NovaSource/Tessenderlo Kerley, Inc. commented: “The assumed community level impacts to PPHD are not reasonably linked to impacts to individuals of a listed species.” *Also:* “Community level measures for PPHD would be expected to be well above an HC05 estimate from an SSD (the BE does note this uncertainty in Chapter 4).”

Also: “Use of the species sensitivity distribution (SSD) approach is a valuable advancement in the BE, particularly with the application of the new SSD tool developed by EPA ORD where multiple models are evaluated. However, the selection of an HC05 in all cases (both direct effects and PPHD) is inappropriate given the wide range of species sensitivity.”

EPA Response: Conceptually, for a non-obligate relationship between a listed species and other species representing PPHD, a loss of organisms from sensitive species (representing PPHD) do not necessarily result in an impact to an individual of a listed species. This is as long as there are other organisms available to address a listed species' PPHD. Since there is no quantitative link between the magnitude of decline in an element of a listed species' PPHD and an impact to the listed species itself, EPA chose to use conservative magnitudes of effect (e.g., HC05). If species-specific information is available to help quantify a different link between impacts to PPHD and a listed species (either individual or population) this quantitative link could be considered.

3. Summary of General Comments Applying to Draft BEs for Both Carbaryl and Methomyl

Comment 27: An individual commented: "CONCEPTUAL EXPOSURE MODELS UTILIZED IN MODELING DIFFER SUBSTANTIALLY FROM SPECIES HABITAT. If the models do not match actual conditions, how can the studies be used?"

EPA Response: EPA's models are simplified representations of aquatic and terrestrial habitats where non-target organisms may be exposed to pesticides. In general, the models are intended to generate conservative estimates of exposure. To accomplish this, conservative assumptions are generally made and simulated habitats represent surrogates for other habitats (e.g., farm pond is also used to represent flowing water bodies). In cases where the available models are not considered representative of a species' habitat, exposure and potential for effects are characterized qualitatively.

Comment 28: An individual commented: "While I appreciate the intent to use real data in evaluating effects of pesticides on wildlife, you have even stated there is limited data to determine effects. How are you planning on addressing this?"

EPA Response: EPA employs a taxa-based approach, where tested species within the same taxon as a listed species (or its PPHD) are used as surrogates to represent the listed species (or PPHD) responses to the assessed pesticide. Since it is not possible to test all species being assessed, toxicity data with species that are taxonomically related represent the best available information to represent effects of a pesticide on a listed species and its PPHD.

Comment 29: Minor Crop Farmer Alliance expressed that the BEs do not reflect how the pesticides are actually used. They indicated that effects to listed species are not being observed at the scale reflected in the BEs. The BEs reflect a "worst-case" scenario that is not consistent with the "reasonably likely to affect" standard of ESA.

EPA Response: The Biological Evaluations incorporate usage data that describe documented applications of a pesticide, including percent crop treated (PCT) and typical application rates. EPA conservatively used maximum PCT and maximum label rates to evaluate the likelihood of impacts to an individual. In the BEs, EPA also evaluated the impact of using average PCT and typical application rates on the likelihood of individual effects.

Comment 30: Minor Crop Farmer Alliance expressed concerns about how the use patterns were grouped. This made it difficult to differentiate the risks between individual uses.

EPA Response: *The USDA NASS (2013-2019) 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 31: “NCC urges EPA to refine drift estimates to reflect the latest technology and use. Extensive research and technology have advanced application technology to minimize potential for drift.”

EPA Response: *EPA employed spray drift estimates that reflect the conditions specified on the product labels. If the registrants wish to revise the labels to reflect the latest technology and advances, EPA could apply these to the estimation of spray drift values.*

Comment 32: Minor Crop Farmer Alliance commented: “The Agency’s analysis of spray drift potential is similarly flawed. The model used creates deposition levels higher than what is observed with the Ag-Drift model. Certainly the technologies for drift such as nozzle sizes, wind speed, etc., need to be refined. It appears that the assumptions relied on by the Agency in its evaluations of drift potential are not based on available data and it is not clear what their basis is. The source the Agency is using for these assumptions is not presented. These assumptions are unreasonable on their face. For example, the Agency essentially uses a “cone zone” for drift, with the idea that there is equal opportunity for drift to occur in all directions throughout the zone. That simply fails to consider things such as wind speed or direction at the time of application.”

EPA Response: *EPA used the deposition values reported in AgDRIFT to derive equations for use in the modeling. EPA acknowledges that, at times, the deposition estimates may over or underestimate the deposition, but EPA does not believe that this happens at such a level as to impact the effects determination. The deposition values were derived from field studies, in the case of ground applications, or were confirmed by field studies, in the case of aerial applications, which accounted for wind speed conditions. While it is true that wind direction plays a role in the drift estimates, EPA cannot predict which way the wind is blowing during an application and so, to protect the species, assumes the drift is blowing towards the species. At Step 2, EPA applies a wind direction scaling factor based on the number of applications made, as described in Appendix 1-7. With multiple applications, the odds increase that an application will occur in the direction of the species. As discussed in the previous comment, if the registrants wish to revise their labels to account for updated technologies, EPA could consider them in refining the spray drift estimates.*

Comment 33: The National Agricultural Aviation Association disagreed with the use of the Tier I AgDRIFT model to assess spray drift transport for aerial applications of carbaryl and methomyl. They criticized the

use of fine-medium droplets as the default assumption, indicating that larger droplets are often applied. They recommended use of a medium droplet size when utilizing AgDRIFT. They expressed concerns that the model does not account for best management practices (e.g., lowered spray booms) employed by applicators to reduce drift. A survey of applicators was provided along with the comments. They criticized some of the model assumptions related to swath displacement, atmospheric stability and surface roughness.

EPA Response: *EPA employed spray drift estimates that reflect the conditions specified on the product labels. If the registrants wish to revise the labels to reflect the latest technology and best management practices, EPA could apply these to the estimation of spray drift values.*

Comment 34: The Generic Endangered Species Task Force (GESTF) derived a new meta model of AgDRIFT data. Their submissions were intended to be relevant to carbaryl, but may also be considered applicable for methomyl. In regard to EPA's equations representing AgDRIFT deposition that are used in the MAGtool, GESTF commented: "GESTF's examination of the properties of this equation found that in all cases the meta-model fit deviated from the direct AgDRIFT calculated values and, in the worst case Orchard - Airblast (Sparse) scenario, effectively increased the estimated Dt by as much as 15% (144') over the actual AgDRIFT values. Within the context of the BE, this is significant to multiple aspects of the evaluation. For example, the error leads to a corresponding increase in the distance that UDLs are buffered to represent the Action Area, which in turn affects the estimation of the number of acres within a species' range or critical habitat that is potentially exposed due to spray drift. This effectively increases the estimated number of individuals of a species potentially impacted in an ESA effects determination." GESTF developed a new equation that was intended to address this concern. They commented that "the new meta-model developed by the GESTF matches the target AgDRIFT results with a high degree of correlation and accuracy."

EPA Response: *EPA used the modified Morgan-Mercer-Floden function as it was simple to develop parameters from the deposition values exported from AgDRIFT, allowed for deposition at the edge of the field to match that in AgDRIFT, and could be rearranged to estimate the distance from the edge of the field where exposure exceeded thresholds. The new GESTF meta-model is complex, employing two power law functions combined with two exponential functions to estimate the distance to a threshold based on the fraction of the applied rate that deposited. It does not allow EPA the flexibility to rearrange the equation to estimate deposition at a specified distance from the field.*

For orchard airblast, sparse applications, EPA cannot replicate the errors discussed by GESTF. The "EPA values" provided in Figure 1 of the report do not match those derived using the EPA values. For instance, at a fraction of the applied rate of 0.0001, the AgDRIFT value is 761 ft, the EPA value is 761 ft, and the GESTF value is 762 ft. However, Figure 1 indicates a distance of over 800 ft for the EPA values. It should also be noted that the overestimation that is cited occurs for a deposition fraction that exceeds 1000 ft. EPA cuts off its distance values at 1000 ft, so this distance error would not occur. Lastly, based on the figures provided for other ground and aerial applications, the EPA model for the most part matches those for AgDRIFT and the GESTF model, and when it doesn't, is within the 30 m spatial intervals used to estimate exposure due to drift.

Comment 35: Minor Crop Farmer Alliance indicated that the assumption that individuals of a species are uniformly distributed throughout their range is "not the case in the real world."

EPA Response: *At this time, EPA does not have species specific information describing the distributions of species throughout their ranges. Without that information, 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 36: Minor Crop Farmer Alliance commented “Given the substantial, more than 40 years of use of these products, a “likely to adversely affect a species” determination does not comport with any observation or reliable data. As a result, such a determination is not reflective of actual conditions.”

EPA Response: *EPA’s BEs are intended to assess potential exposures and effects to a single individual of a listed species. The absence of empirical data or incident reports associated with effects to an individual or groups of individuals of listed species does not mean that they have not occurred, but rather that they were not observed. The BEs do not consider population level impacts. In the Biological Opinions, the services will consider potential impacts of carbaryl and methomyl on the populations of listed species. These assessments may consider observational data, such as population trends over the time when the pesticides have been registered.*

Comment 37: “The NCC urges EPA and the Agencies to “report the number of species identified as Likely to Adversely Affect (LAA) that are believed to be extinct. Species believed to be extinct represent great uncertainty in the consultation process. NCC urges the Agencies and EPA to collectively address species believed to be extinct and remove such listings. The impact of false LAA (such as LAA for a species already extinct) identifies a major economic risk.”

EPA Response: *EPA worked with the Services to identify which species are likely extinct. All of the species currently considered extinct are under the authority of FWS. The list of likely extinct species has been reviewed by FWS. Likely extinct species received a NLAA determination and EPA will informally consult on these species allowing the Service to provide additional information if it becomes available.*

Comment 38: NW Horticultural Council: “The data is far too reliant on pesticide usage permitted by labels and is not representative of actual usage data that considers pesticide application locations in relation to endangered species habitat. Method of pesticide application overrepresents aerial application. Typical pesticide rates applied are eschewed for maximum rates. Timing of pesticide application in relation to endangered species presence is under considered, and maximum number of label-allowed applications are selected over frequencies of application that are reasonably certain to occur on an annual, recurring basis. Simply put, the theoretical pesticide usage scenarios used to develop the BEs so tremendously overestimate actual use as to have little bearing on likely exposure to endangered species under consideration.”

EPA Response: *EPA has refined exposure estimates based on the best available usage data. In many cases, adequately reliable data are not available to further refine potential exposure of listed species. Typical application rates, maximum number of applications, and aerial application rates are reported and used, when available and reliable. Data on the application timing, both the time between applications and the timing of applications during the year, are typically more linked to weather and subject to greater variability both temporally and geographically, which makes characterizing usage for these statistics more challenging.*

Comment 39: Washington State Potato Commission: “All potatoes in WA are irrigated, the vast majority with center-pivot irrigation systems that have the capacity for chemigation, a technique that allows agrichemicals, including fertilizers and pesticides, to be applied with irrigation water. Center-pivot systems use low water pressure (20 psi) and nozzles, not far above the canopy, that are designed to create large droplets that inhibit drift. The Columbia Basin where most of these potatoes are grown is an intensive desert agricultural area with little potential for off-target impacts. This area receives ca 9 inches of rain annually, and there is little surface water. These factors reduce the risks of agrichemicals impacting human health, off-target sites, and endangered species.”

EPA Response: *Historical, geographically specific meteorological data are incorporated into the exposure assessment for each scenario.*

Comment 40: The Washington State Department of Agriculture provided data collected by the state. These data included crop mapping, usage of carbaryl and methomyl and surface water monitoring.

EPA Response: *The Washington State surface water monitoring data was added to the monitoring summaries in Chapter 3 and was included in the MAGtool and downstream analysis. Unfortunately, the chemical usage data provided by WSDA were not collected in a manner that allowed for their incorporation into the BE in a quantitative manner. At this stage in the consultation process, the priority is to leverage national, and publicly available spatial dataset. In circumstances where additional refinement is warranted, incorporation of other data, such as the state crop data, may allow for greater precision and refinement of assessments later in the process, such as during step 3 (i.e., the Biological Opinions).*

Comment 41: “USDA is concerned that conservative usage and exposure assumptions in the BEs and subsequent Biological Opinions may result in mitigations that contribute to crop losses by weakening farmers’ ability to protect crops from insect damage. Removing some uses of carbamates could lead to increased dependence on and increased insect resistance to the remaining tools available. In addition, we are concerned that limitations of certain uses of carbaryl and methomyl could reduce the ability of federal and state agencies to control invasive and quarantine pests.”

EPA Response: *EPA recognizes the important role that pesticides have in controlling invasive and quarantine pests and thanks USDA for its comments. The next step in the ESA review process is for EPA to initiate formal consultation by transmitting the final BEs for carbaryl and methomyl to the Services for their consideration in developing draft biological opinions. As explained in the 2013 enhanced stakeholder process for ESA consultations⁷, USDA plays a critical role in evaluating any proposed risk reduction measures given its expertise on crop distribution, farming/pest management practices, and the feasibility of potential risk reduction strategies. Accordingly, EPA plans to include USDA in meetings with the Services and pesticide registrants on any needed preliminary reasonable and prudent alternatives and measures (RPAs/RPMs).*

Comment 42: “USDA continues to be concerned that pesticide usage information currently used by EPA is not detailed enough to demonstrate overlap between species ranges and critical habitat with areas where pesticides are applied. In addition, there are significant differences in agricultural application rates across regions and states due to variation in pest pressure, crop varieties, and agronomic practices. Accordingly, USDA encourages EPA to consider state-level usage data, such as from the National

⁷ See Section 4 (pp. 9-11); <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0442-0038>

Agricultural Statistics Service (NASS), Agricultural Market Research Data (AMRD), the California Pesticide Information Portal Pesticide Use Reporting (CalPUR) database, and other data from individual states whenever possible to more accurately determine exposure to listed species and critical habitat. Note that a statistical sampling of application sites in each state or region may be appropriate for determining the range of application methods and rates without the need for surveying all possible application sites.”

EPA Response: *EPA agrees with USDA and is currently adopting the proposed approach by using state-level pesticide usage data from USDA NASS, Kynetec (previously cited as AMRD), and California PUR. In cases where appropriate individual state data or data from commodity groups are available and of an acceptable quality, those data will be incorporated into the usage analysis.*

Comment 43: The USDA expressed concerns that EPA conservatively assumed that all applications were aerial, when aerial applications were allowed for a given use. They indicated that usage data indicate that not all applications are made via aerial methods and encouraged EPA to utilize available data on the proportion of applications made via aerial applications.

EPA Response: *For future BEs, EPA will consider whether usage data for typical application practices may also be incorporated into the analyses.*

Comment 44: USDA suggested that EPA utilize typical or 90th percentile application rates (not just maximum registered application rates) and characterize the risks of the typical rates to listed species. Average and 90th percentile application rates of carbaryl and methomyl for specific crops were provided in the comments.

EPA Response: *The Biological Evaluations incorporate typical application rates. EPA conservatively used maximum label rates to evaluate the likelihood of impacts to an individual. In the BEs, EPA also evaluated the impact of using typical application rates on the likelihood of individual effects.*

Comment 45: The USDA also provided comments from the Animal and Plant Health Inspection Service (APHIS) on their pest management programs that use carbaryl and methomyl. These programs include the Grasshopper and Mormon Cricket Area-Wide Suppression Program that uses carbaryl and the Glassy Winged Sharpshooter Area-Wide Management Program that uses methomyl. They commented that “pesticide applications that are made as part of USDA pest management programs, including APHIS’s Grasshopper and Mormon Cricket Area-Wide Suppression Program and the Glassy Winged Sharpshooter Area-Wide Management Program, as well as U.S. Forest Service programs, have undergone environmental analysis under both ESA and NEPA⁸.” “APHIS requests that EPA, FWS, and NMFS consider existing NEPA and ESA compliance processes and locally tailored mitigations already put into place to protect listed species and critical habitats”

EPA Response: *EPA appreciates the additional information provided on the existing APHIS programs that involve carbaryl or methomyl. Since EPA’s assessment considers the sum of all uses and their potential impact on individuals of listed species, these programs were included in the national level BEs for carbaryl and methomyl. EPA believes that information on other consultations is relevant for the Services to consider as part of the species level analysis of a biological opinion.*

⁸ National Environmental Policy Act

Comment 46: Crop Life America commented: “In the case of the Mormon cricket, consultations occurred between APHIS, and FWS under Section 7. The consultation impacted large amounts of pasture/rangeland, one of the key drivers for LAA determinations in the draft carbaryl BE. These types of consultations should be considered, and listed species and their critical habitat that have been addressed can be removed from consideration in the BE *a priori* under applicable circumstances.”

EPA Response: see EPA response to **Comment 45**

Comment 47: Beyond Pesticides commented “When assessing carbaryl and methomyl, EPA fails to assess use in conjunction with other pesticides and synergists like methylenedioxyphenyl compounds, the aryloxyalkylamines, the thiocyanates, the propynyl aryl ethers, and the 1,2,3-benzothiadiazoles. Due to the predictable development of resistance, pesticides need more and more support to kill pests or regulate plant growth. Additions of other pesticides and synergists pose an issue as they heighten effects of the chemical activity. There is also a lack of information on impacts of “inert” ingredient mixtures, as the tests do not look at chronic effects of formulations.”

EPA Response: EPA’s BEs focus on assessing potential effects of the assessed pesticide active ingredient. EPA’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. EPA would consider formulated products that demonstrate greater toxicity than the technical material if reliable data are available to allow for such a comparison.

Comment 48: Beyond Pesticides asked “Does EPA consider the geology and topography of regions and how it might impact the movement of pesticides in the environment? Additionally, how does EPA plan to mitigate groundwater contamination for highly mobile and moderately persistent chemicals in environment?”

EPA Response: In modeling exposure to aquatic organisms, EPA’s Pesticide in Water (PWC) scenarios attempt to account for the slope of a field and soil geology (soil layer thickness, bulk soil density, water holding capacity) conducive to runoff on a regional basis. The same scenarios are also used to evaluate plant exposure using the Plant Assessment Tool (PAT). Spray drift is evaluated using deposition values derived from the AgDRIFT model, which assumes flat terrain, which generates protective exposure estimates. Topography is not considered in the exposure modeling. EPA has a groundwater model in PWC that can be used to evaluate groundwater exposure; however, it is uncertain for which listed species groundwater is a complete exposure pathway.

Comment 49: Beyond Pesticides commented: “Lima *et al.* state, “[T]emperature may increase the deleterious effects of carbaryl to non-target organisms, which is important considering both seasonal and latitude related differences, as well as the global climate change context.” In another article, they show that, “climate variations may cause changes on [carbaryl] toxicity or bioavailability. Earthworms and plants are exposed simultaneously to carbaryl and flood and drought conditions. Synergism was observed for earthworms exposed to carbaryl and drought conditions. Antagonistic interactions were observed for plants, in flood conditions and carbaryl.” Based on these findings, how does EPA plan to tackle the challenge of heightened toxicity and chemical volatility—and hence off-target movement of pesticides—with climate change? ” They also asked “how can EPA prevent risks to endangered species

far from application sites, due to the combination of pesticide transport and pesticides' contribution to climate change?"

EPA Response: *EPA's BEs focus on the risks of the assessed pesticide to an individual of a listed species using the best available toxicity information. EPA has models (AERMOD, PERFUM) that can be used to evaluate offsite exposure resulting from volatility if appropriate. However, methomyl and carbaryl's properties do not warrant such an analysis.*

Comment 50: Beyond Pesticides asked: "how will EPA more accurately assess pesticide impacts on coastal, intercoastal, pelagic, anadromous, and migratory species? (E.g., corals, marine mammals, salmon, and seabirds.)"

EPA Response: *EPA's aquatic models used in the BEs represent a pond and a larger flowing water body. EPA currently lacks tools to model concentrations in tidal and marine environments. For species in marine and estuarine habitats, EPA uses aquatic environments it can model, such as static and flowing freshwater waterbodies, as surrogates to estimate exposure in intertidal coastal environments. For species that exclusively inhabit deep-water marine environments, EPA qualitatively assessed the potential for exposure.*

Comment 51: Beyond Pesticides asked: "Since studies find that some pesticide metabolites are highly toxic to marine species, include pelagic or migratory oceanic species, how can EPA ensure pesticide metabolites and degradants do not cause harm to endangered species?"

EPA Response: *During the problem formulation stage of a BE, EPA considers the environmental degradates of the assessed pesticide and determines if they are of toxicological concern to non-target organisms. This analysis considers available toxicity data for the assessed pesticide and for its metabolites. If any degradates are of concern, they included in the exposure estimates and risk analysis for listed species.*

Comment 52: Beyond Pesticides asked: "How can EPA ensure that new products with same active or other ingredients—used in a similar way as cancelled or suspended products—do not pose threat to endangered species? Are there any pesticide products containing these or similar ingredients that are cancelled or suspended?"

EPA Response: *EPA's BEs consider all uses registered for carbaryl and methomyl.*

Comment 53: Beyond Pesticides asked: "Given their use as plant growth regulators, EPA must assess and mitigate the impacts of carbaryl and methomyl application on nontarget endangered plants?"

EPA Response: *In BEs, EPA assesses potential effects to all listed species, regardless of their intended mode of action. EPA considered available plant exposure and toxicity data when determining whether carbaryl and methomyl may have impacts on listed plants.*

Comment 54: The Center for Biological Diversity commented: "the EPA did make some incorrect "not likely to adversely affect" ("NLAA") findings for numerous species" for methomyl. They provided several comments on specific species.

EPA Response: EPA reviewed the information provided on individual species and incorporated this into the weight of evidence. Most of the comments centered around the application of habitat specific to the beach and areas where this may not have been relevant. EPA reviewed these species and updated the habitat layers relevant to these species using the GAP/Landfire layer. This map layer defines specific habitats as defined by the U.S National Vegetation Classification and NatureServe Ecological System classification. For species identified in the draft BE as coastal beach, a review of all habitat layer was completed. The updated information was utilized in the effects determinations for these species.

Comment 55: The Center for Biological Diversity commented: “The EPA has failed to provide the public with basic mapping information on pesticide use footprints and species’ range in its biological evaluations.” Adding later “Furthermore, it is simply unacceptable that the public has not been provided a single, actual map showing the overlap of pesticide footprints with listed species ranges. The non-transparent use of species’ range maps will only compound the deficits of using pesticide “usage” data.”

EPA Response: Species location data for both the range and designated critical habitats are managed by the Services and made publicly available on their websites. The date this information was downloaded by EPA is documented in the BE. The pesticide use footprints, or Use Data Layers, are developed from publicly available datasets. The source of these datasets and methods taken to develop the Use Data Layers are documented in the Use Site Footprints Appendix (1-6). Layers are updated routinely by automated tools; those tools are available for download from the BE models and tools website. With the available materials provided with the BE, the spatial data used in the BE can be recreated. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration.

Comment 56: The Center for Biological Diversity expressed concerns about inaccuracies and the source of the map for the Florida Bonneted Bat as presented at the April 2020 webinar.

EPA Response: The map shown in the webinar on April 2020 represented the range provide by the U.S Fish and Wildlife Service for the draft methomyl and carbaryl BEs. As the species experts, EPA uses species location files provided by The Services.

Comment 57: The Center for Biological Diversity commented “EPA must act conservatively when the range maps provided by the Services do not 100% match up with habitat descriptions in ESA recovery planning documents that were never intended for this type of use and are, in many instances, woefully out of date. In multiple cases we have found in EPA’s Weight of evidence (“WOE”) approach that the following statement is made “Parts of range data do not fit with Services document descriptions.” This really goes to the heart of the problem with relying on a qualitative description of habitat to make a complex decision. The EPA can’t simply take a two-sentence description in a Recovery document and somehow try to accurately reconstruct the complex range of a species.”

EPA Response: The Services have indicated for the purposes of the BE analysis the best available species location information is available on ECOS for U.S. Fish and Wildlife species and on the NOAA’s National Marine Fisheries website for National Marine Fisheries Service species. As the species experts, EPA relies on the Services’ expertise when identifying the species location data. As part of Weight of Evidence, EPA notes if there is available documentation about the species location not captured in the spatial location, such as areas currently missing from the location information, as well as areas unoccupied by the species. Although the information may be briefly summarized in the Weight of Evidence, this is not based on a “two-sentence description in a Recovery document”. If the review of the Services documentation

indicates a discrepancy between these documents and range data that is used in the quantitative analysis, this is considered in the Weight of Evidence and species are captured separately to inform the Services of the discrepancy.

Comment 58: The Center for Biological Diversity commented: “If EPA is faced with a discrepancy between a range map and a habitat description, it must act conservatively to ensure the protection of the species.”

EPA Response: See response to **Comment 57**

Comment 59: The Center for Biological Diversity commented: “The information contained in the carbaryl and methomyl draft BEs is less clear, less understandable, and more arbitrary in its quality than was the case in the first pilot BEs for chlorpyrifos, diazinon and malathion. The use of proprietary data is extremely problematic, especially given how much EPA appears to rely on it - especially when the data collected are both incomplete and provide absolutely no useful information regarding future uses of carbaryl or methomyl. *The fact that nearly 2 million pounds of carbaryl are used in non-agriculture settings each year* and that EPA knows virtually nothing about where and how that use occurs illustrates two simple facts (1) EPA’s Office of Pesticide Programs has not assembled sufficiently useful data to support its analysis; and (2) the agency is in no position to ask the public or stakeholders to simply trust that its analysis is protective of listed species or is accurate and robust.”

EPA Response: *The BEs for carbaryl and methomyl provide summaries (within chapters 1-4) of the data used in the determinations. The BE appendices and attachments also provide detailed information on the fate data, exposure estimates, toxicity data, species life history, and other lines of evidence that were made in species-specific determinations. In regard to the usage data, 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. EPA also uses this data in a conservative manner that is consistent with its applicability, strengths, and limitations. EPA cannot allocate usage within a state or region of the US for the largest segment of non-agricultural usage, residential, outdoor premise treatments; however, knowing that 1.3 million of approximately 1.6 million pounds of non-agricultural usage are applied to residential premises is informative with respect to associating carbaryl usage with spatial footprints (i.e., developed areas). While the available data may not allow EPA to make refinements in terms of the amount applied per state, the placement of the acres that are potentially being treated relative to the species locations are informative.*

Comment 60: The Center for Biological Diversity commented: “the EPA using <1% overlap to discount harm to species that have indirect effects. When indirect effects are substantial, using this arbitrary cutoff to make a NLAA finding is even more harmful and unwarranted.” Examples were provided for the methomyl determinations for Etonia Rosemary and Furbish Lousewort. They later added: “EPA should entirely scrap this ridiculous proposal to discount range/pesticide use overlap that is less than 1% at Step 2. However, if the agency decides to retain it, then it must make an exception for species that have a high potential for *indirect* harms. When indirect harms are implicated, the species’ range and pesticide use overlap is **irrelevant**, it is the overlap with pesticide use and the food source or insect pollinator that that can result in the indirect harm.”

EPA Response: *When there is <1% overlap, EPA believes that the probability of an exposure to individuals of a listed species as well as their PPHD is negligible 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%.*

Comment 61: Crop Life America commented: “Application of the 1% threshold in Step 2e of the Draft Carbamate BEs did not impact effect determinations for most listed species and critical habitats evaluated primarily due to the compounding conservative assumptions used. For most of the listed species analyses, the largest of the direct and indirect effects buffer distances is added to the aggregate UDL footprints to define the action area extent for selected uses. This approach is highly conservative and expands the action area beyond what is reasonable for most species. The action area is then intersected with the coarse listed species range data (generally county-level) to produce the percent overlap. It does not account for usage (e.g., PCT, application rates), species effects, or other considerations. Thus, the value of the application of a 1% threshold to account for spatial resolution for individual listed species is questionable. However, considering other lines of evidence, the <1% threshold would be far more likely to demonstrate a more realistic understanding of the extent of overlap for many species and critical habitats.”

EPA Response: *The 1% threshold is meant to be conservative and applied prior to the application of usage. 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%. The purpose of this step is to account for species where the probability of an exposure is negligible. In the step following 2f, usage is incorporated and the likelihood of less than 1 individual being exposed determined. Steps 2e and 2f both result in an NLAA determination, 2e is meant to be more conservative because usage information has not been incorporated. The conservative assumptions are further refined in a later step via the MAGtool.*

Comment 62: Creekbank Associates commented: “We believe it would be helpful for the registrants to have an opportunity to work directly with the Services to explore the potential value of incorporating measures such as off-labeling certain geographic areas (avoidance), implementing enhanced use restrictions such as limiting application under certain wind conditions in proximity to certain species (minimization), and implementing offsetting “mitigative measures” such as habitat protection programs (mitigation) in helping to reduce estimated undesired changes to listed species’ populations.”

Crop Life America (CLA) commented: “CLA members recognize the importance of collaboration on listed species issues among EPA, USDA, and the Services and strongly encourages increased collaboration with the individual registrants in the future. Registrants know their products, where the best available data are located, and can potentially provide expertise and knowledge on product use, sales, and other information that may be important to EPA’s evaluations. It is critical to all interested parties that there be a manageable, efficient, and defensible process to share information to address listed species issues in the future.”

EPA Response: *As registrants require approval from EPA to register their pesticides, they are considered applicants under the ESA. Per ESA regulations, applicants have a role in the consultation process and will be provided an opportunity to submit information for consideration and work with EPA, as the action*

agency, and the Services to identify reasonable and prudent alternatives when needed to address any jeopardy or adverse modification of designated critical habitat determinations.

Comment 63: NovaSource/Tessenderlo Kerley, Inc. commented: “EPA needs to engage with TKI as an applicant and work together to complete the BE.”

EPA Response: At a November 30, 2020 meeting with EPA, TKI and the Generic Endangered Species Task Force (GESTF) gave an overview of possible lines of evidence that they believe would be useful to the Services in developing their draft biological opinion for carbaryl. The next step in the ESA review process is for EPA to initiate formal consultation with the Services by transmitting the final BE for carbaryl and a list of applicants, including TKI, to the Services. Per ESA regulations, applicants have a role in the consultation process and will be provided an opportunity to submit information for consideration and work with EPA and the Services to identify reasonable and prudent alternatives when needed to address any jeopardy or adverse modification of designated critical habitat determinations.

Comment 64: Creekbank Associates recommended that EPA include a discussion of how single endpoint values for individuals may be extrapolated to populations.

EPA Response: EPA’s BEs focus on impacts of the assessed pesticide on an individual of a listed species. Information was also provided in the MAGtool outputs on the number of individuals of a given species that may be impacted. This information may be considered by the services when considering potential impacts of the assessed pesticide on listed species populations.

Comment 65: Creekbank Associates commented: “While the MAGtool output files contain significant amounts of useful information, the appropriate use of this information is not always clear.” They provided the following recommendations:

“RECOMMENDATION: Before finalizing the BE, EPA should work with the Services to develop a clearer explanation of the meaning and appropriate use of the MAGtool output in furthering the NAS recommendation of implementing population modeling techniques.

RECOMMENDATION: We recommend that exposure estimates within the MAGtool be adjusted to represent an annual, yet relatively conservative expected condition for each age-class-specific species endpoint. Because endpoint data can be linked to species life stage (age-class), for each species, the MAGtool should be run separately for each life-stage endpoint for the purposes of developing a reduction rate (i.e., combined rates of mortality and reduced reproduction) that can be used in population (i.e., demographic) modeling. Next, for each species, all runs of the MAGtool representing each life stage sensitivity should be evaluated at the population-level using a conservative version of exposure estimates. Additionally, we do not agree that the currently-used exposure estimates from standard EPA modeling should be used to represent a lifetime or even annual exposure; rather, for population modeling purposes, the reduction rates linked to various species age classes derived from the MAGtool should be reflective of a conservative, yet realistic annual estimate. For this reason, we suggest that exposure estimates within the MAGtool be reflective of a percentile closer to the mean, but still conservative. Then the MAGtool could be used to estimate the number of individuals at risk, and this information converted to a reduction rate for use in a population model where all age-class linked MAGtool output would be integrated to evaluate effects at a population-level.”

EPA Response: As the consultation process progresses, EPA will continue to work with the Services to explore the utility of the MAGtool outputs to best inform the Biological Opinions.

Comment 66: Creekbank Associates recommended:

“EPA should provide information describing why the agency believes exposure will or will not occur for each species to inform the consultation. While we acknowledge that assembling this information will require significant effort, it is an effort required by the ESA to initiate Section 7 consultation (50 CFR 402.14(c)). We further recommend that EPA and the Services work together, perhaps with the registrants, to conduct these assessments.”

EPA Response: *EPA considers all labeled uses as part of the BE and determines if a species overlaps with potential use sites, using the species location information provided by the Services, and the Use Data Layers. If an overlap occurs, exposure is assumed to be possible, and the potential of risk evaluated under several scenarios in the MAGtool. When conducting the spatial overlap, species life history information can be taken into consideration, for example - is the species expected to occur on site? These on/off site determinations were developed in consultation with the Services. Following additional consultation with the Services, additional life history may be incorporated in the future.*

Comment 67: Creekbank Associates recommended: “EPA should identify the geographic location within each species’ range that different effects should be anticipated, and the magnitude of the effects. This is information the Services will need to assess these effects in terms of the viability of each population.”

EPA Response: *The overlap of use sites (combined as UDL layers) with a species range or critical habitat are provided based on both direct overlap with the UDLs or overlap in the off-site transport zone at 30 m increments. Impacts to the species are assessed for both effects predicted due to direct overlap as well as those predicted in the off-site transport zone. The number of individuals impacted based on mortality or sublethal effects or due to effects to PPHD, is provided based on all UDLs with direct overlap with the range or critical habitat and for the off-site transport zone under different PCT scenarios and are reported in the Weight of Evidence output of the MAGtool. For a subset of species, output after applying habitat preferences for the species is also provided in the MAGtool GAP WoE analysis output. This information will be provided to the Services for consideration in Step 3, and the population level analysis. For the BE, the consideration is an impact to a single individual of a listed species (including impacts to the PPHD of an individual).*

Comment 68: Creekbank Associates recommended: “EPA should account for aspects of each species’ life history when completing the exposure and effects analyses. For example, though a species’ prey base may be affected by an active ingredient, might these effects occur at a time that the species is not dependent on these prey?”

EPA Response: *EPA has considered temporal impacts as part of the analysis and continues to discuss the utility of these analyses with the Services. As part of the weight of evidence, information is gathered on whether a species migrates or potentially enters a dormant phase. For many pesticides, there are few label restrictions on timing of application or they are applied during times of the year (e.g., spring, summer) when species, and their prey base, are active and present. However, EPA will continue to explore the utility of timing implications as appropriate.*

Comment 69: Responsible Industry for a Sound Environment commented: “We are concerned the use data layers (UDL) EPA includes in the BEs overestimate exposure to listed species and critical habitat. All use patterns are considered within one spatial footprint, and when combined with overly conservative coarse species range information, the analysis provides an overestimate of the overlap between the action area and where species are found. As a result, EPA is unable to successfully identify species and

habitats with greater risk of exposure from pesticides, making the Step 1 screening tool ineffective. Separating out different labels and use patterns within a UDL would give EPA greater ability to realistically assess potential risks.”

EPA Response: *Step 1 of the BE defines the action area for the proposed action, which includes areas where the pesticide can be applied and areas subject to offsite transport. For this reason, individual UDLs are combined into a single layer that defines the full spatial extent of the action. The individual UDLs that define the spatial extent for specific use patterns are considered as part of Step 2 when making the LAA or NLAA determination. Considering individual UDLs as part of Step 1 does not meet the responsibilities of the action agency as outlined in Section 7 of the Endangered Species Act. EPA relies on the Services (who are the species experts) when identifying the species location data. Species location data for both the range and designated critical habitats are managed by the Services and made publicly available on their websites. As this species location information is updated and/or refined it will be incorporated into the BE process.*

Comment 70: Corteva commented: “The Agency did perform some alternative analysis steps, defined as being based upon "alternate population, alternate toxicity endpoint, typical rates" [factor #3 taken from the weight-of-evidence (WoE) output spreadsheets]. It appears that these alternative analyses were only used as one of the nine factors influencing the confidence level assigned to the LAA determination (an example is shown below in Section 2.4), whereas if considered independently and/or earlier in the process they may have resulted in a NLAA determination. This is a missed opportunity to utilize these existing tools and data to, at the very least, define some boundaries upon the effects determination, which could have significant utility as lines of evidence in a more robust WoE analysis.”

EPA Response: *The alternative analyses conducted in the weight of evidence allows for an assessment of the confidence and uncertainty in the effects determination where less conservative assumptions are made and the impact of changing those assumptions is assessed. The characterization provided in the alternative analysis is useful for understanding the impact of some of the analysis assumptions and may be utilized more fully in the Biological Opinion.*

Comment 71: Corteva commented: “methomyl has 3 active registrants and 34 active product registrations with different labels, resulting in a wide range of possible use scenarios. Generating aggregated UDLs based on all the uses across multiple registrants and products does not allow for an evaluation of risk from an individual label or an individual use pattern. This renders it virtually impossible to evaluate potential reasonable and prudent measures (RPMs) or reasonable and prudent actions (RPAs) for an individual labelled use pattern, much less quantify the net benefit of the RPMs to the listed species of concern.”

EPA Response: *The BEs present output for all species on which impacts to the species occur. Updates have been made to the MAGtool and to Chapter 4 to better summarize the UDLs that are most often of concern. This allows mitigation to be focused in this manner. Where a UDL may be associated with a number of crops, it is possible to explore which crops within the group may be associated with the most usage or be present in distinct geographical areas. EPA intends to work with the Services to determine the best path forward to find reasonable mitigation informed by the available data.*

Comment 72: NovaSource/Tessenderlo Kerley, Inc. commented: “EPA did not base the analysis and conclusions in the draft BE on clear and substantial information, and the Agency did not use the best scientific and commercial data available to develop realistic conclusions about whether an individual of

a species is likely to be adversely affected. If it had done so, EPA necessarily would have concluded TKI's uses of carbaryl (as distinguished from other uses authorized on other companies' labels) are not likely to adversely affect an individual for a substantial number of listed species. EPA also should have provided the Services with realistic usage data on the limited uses authorized by TKI's labels, as opposed to others' labels. But it did not." They also commented: "EPA is required by the ESA and FIFRA to evaluate whether TKI's labels would adversely affect an individual of an endangered species. TKI believes that such an evaluation, if it uses the best scientific and commercial data available, would conclude that TKI's labels are not likely to adversely affect an individual for a substantial number of listed species. *EPA must present a use pattern/species specific evaluation in the final BE and should include a summary of it to assist the Services in developing any required biological opinions. It is critical for the Services to understand initial potential risk to individual labels, so that an evaluation of potential impacts to species populations can be made more effectively and efficiently.*"

EPA Response: *EPA's draft BE for carbaryl considered the potential exposure and risk of the sum of all uses of carbaryl on each listed species and designated critical habitat. This includes the uses from all formulated products containing carbaryl, for which there are multiple registrants. The MAGtool output characterizes the relative contributions of each UDL to the risk of carbaryl to each species. This information can be used to identify those uses that are relevant to TKI's labels. Additional summary tables have been integrated into the MAGtool output and Chapter 4 to capture uses that are most often associated with impacts to species.*

Comment 73: Corteva commented: "To improve transparency and reproducibility, EPA should provide a user's guide for the MagTool and the underlying assumptions should be well-documented."

EPA Response: *A Users guide for the MAGtool was provided with the draft BEs. Additional updates and improvements have been made to the tool and updated users' information has also been provided.*

Comment 74: Corteva commented: "The Revised Method recognizes usage data (actual application rates and timing) for refinement of the risk assessment in Step 2h. The USDA Census of Agriculture, California PUR, and Kynetec AgroTrak usage data constitute the best available scientific and commercial data. A cursory examination of these data show that EPA's conservative assumptions—applications occur at the maximum label rate on 100% of the crop footprint—are not realistic and therefore do not meet the 'reasonably certain to occur' standard. Thus, it is unclear why incorporation of usage data in a quantitative risk assessment is merely considered an alternate assumption and only given consideration in the context of a best professional judgement LAA confidence call."

EPA Response: *While EPA starts with the conservative assumption that the maximum label rate is used on 100% of the crop footprint, the PCT and other factors (i.e., typical use rates, alternative application methods, average percent crop treated and uniform distribution of the acres treated) are considered in the weight of evidence approach used in the MAGtool.*

Comment 75: Rotam commented: "The draft BE was conducted for "listed species", broadly referred to as federally listed, threatened, and endangered species, but also includes the evaluation of experimental population and proposed candidate species for federal listing. While proposed candidate species are not federally protected under the ESA, it is assumed that those species were included for future reference should they become formally listed. At the same time, some listed species were not included in the analysis but will be included in the final BE. For clarity, it is recommended that effects determinations for non-listed species be identified separately from those currently listed under the ESA. Additionally,

those listed species not included in the draft BE should be identified with an opportunity for public comment on the effects determinations for those species.”

EPA Response: *EPA has made separate effects determinations for each listed species, which is defined as federally listed endangered and threatened species, those species that are proposed for listing or candidates and experimental populations. Proposed and candidate species and experimental populations are included in case they are formally listed between the time when the BE is completed and the biological opinion is developed. EPA clearly makes separate calls for each of the listed species, so, it is possible to distinguish determinations for endangered threatened species from those that are proposed and candidates and experimental populations. Because the specific species that are considered listed changes over time, EPA identifies a “cutoff date” for the list of species that are considered in the BE. that list will be updated for the final BE.*

Comment 76: USDA commented that the relatively small number of incidents reported for carbaryl and methomyl over the decades of their use speak to their “relative safety.”

EPA Response: *One source of uncertainty associated with incident data is the nature of reporting. Many more incidents may have occurred due to pesticide exposures but may not have been reported due to various factors, such as a lack of reporting, or a lack of witnessing of effects. Therefore, the lack of an incident report does not necessarily indicate a lack of an incident. In addition, “relative safety” is not the focus of the BEs, but rather on determining if the assessed pesticide chemical might impact listed an individual of a listed species.*

Comment 77: Rotam commented: “The BE states “The federal action of registration review for Methomyl encompasses the review of all the registered uses, and the approved product labels for all pesticide products containing Methomyl.” However, this does not mean that product use specific information should be excluded from the assessment. Unfortunately, the draft BE effects determinations were presented using a composite view of all uses rather than evaluating use and use patterns independently in adequate detail. Not utilizing use pattern specific detail (e.g., typical agronomic practices) also limits the reasonable application of species-specific detail (e.g., is the species likely to be near treated areas based on habitat suitability) necessary to effectively characterize risk to a species.”

EPA Response: *Currently, the information on each WoE species page provides a list of Use Data Layer that show impact to the species in addition to the drift impacts for the species, and if available impacts to suitable habitat location. Likelihood of a species being on an individual use site is also captured through the application of the On/Off field review in the weight of evidence. Additionally, although the effects determination is based on all uses, any relevant information for particular use sites, such as typical rates, typical application methods, etc. are applied to each UDL.*

Comment 78: Rotam commented: “it is requested that the final BE clarifies initial risk concerns by use pattern, application, and species with typical uses and species-specific information applied. This detail would provide a much-improved effects determination for each species. This effort will also be critical for the Services so they have a manageable starting point for the presumed BO that will be conducted.”

EPA Response: *The information on each WoE species page provides a list of Use Data Layer that show impact to the species. EPA agrees that there may be additional ways to summarize the information, including regional patterns for the UDLs, summarizing the dependencies between UDLs for a species,*

looking at additional species life history information and additional information related to the application method. These types of considerations may be revisited in the future, especially if they support the needs of Biological Opinions.

Comment 79: Rotam commented: “The final BE should be performed for each use pattern and listed species interaction using realistic assumptions (e.g., typical use rate and usage) and be done in a probabilistic way to assess the “reasonable” likelihood of these events occurring to an individual of a species.”

EPA Response: *The draft and final BEs include the use of the MAGtool which evaluates each use pattern and listed species interaction. The typical use rates and usage are applied through the Weight of Evidence can be done in a probabilistic way, which uses a distribution of potential exposures, to assess the likelihood of these events occurring to an individual of a species. In addition, the assessment includes actual usage data. Therefore, the analysis and its underlying assumptions and data are reasonable.*

Comment 80: Rotam commented: “An alternative analysis and probabilistic analysis were conducted based on BE output files. Typical use rates, average PCT, and average use distributions as well as alternative threshold assumptions appear to have been included. It also appears that assumed species population numbers are adjusted in the analysis. While the use of alternative/more realistic assumptions are warranted, it does not appear this analysis was used directly in the effects determination. This analysis was also conducted on a composite of all combined use patterns. It appears that this analysis was used in a confirmatory way if any overlap between use sites, drift area, and species range or critical habitat could occur for any use. The analysis plan does not specifically lay out the steps of the alternative analysis and the specific use of that output. The output was found in a series of files, but not referenced in detail in the BE conclusions. It is recommended that the alternative output be provided in more detail and included in the conclusions based on the probability of those conditions occurring for each methomyl use pattern and method. Additionally, species specific information (e.g., suitable habitat) relative to use sites should be included in the analysis to improve the effects determinations.”

EPA Response: *The alternative analysis is used as a line of evidence in the WoE approach and the details of the analysis are provided in the MAGtool WoE output. Species specific information, and how it is used, is discussed in greater detail in the Revised Methods document. Additional summary tables have been added to Chapter 4 of the final carbaryl and methomyl BEs, including the number of species not predicted to be impacted using the alternative analysis assumptions (Specific listings of which species are in that category are found in Appendix 4-1). Additional summary data provided include how many species were impacted by drift only and which species were impacted based on overlap with only one use site, which may help provide further characterization of effects determinations. Likelihood of a species being on an individual use site is also captured through the application of the On/Off field review completed and applied in the weight of evidence.*

Comment 81: Rotam commented: “the combined use of unrealistic use and usage assumptions and the composite use area footprint for each species results in an unrealistically high number of LAA effects determination for methomyl. Further, the approach taken does not allow for a weight-of-evidence (WoE) analysis using available lines of evidence. The assumptions used in the BE analysis almost guarantees an LAA effects determination for most listed species. All available lines of evidence should be applied to a WoE framework in the final BE that includes:

- Exposure, effects, and risk characterization (Effects Determinations) for each species and specific use pattern.
- The use of tiered direct and indirect thresholds as outlined in the revised methods (USEPA 2020).
- The use of average or a probabilistic determination of PCT.
- The use of an average or probabilistic use distribution.
- Applications at a typical use rate for each use pattern.
- Exposure estimates for each labeled use pattern based on labeled applications methods (e.g., ground, aerial, airblast).
- Potential exposure and risk broken down by treated areas, offsite transport with emphasis potential exposures to range, critical habitat and suitable species habitat.
- Species specific information regarding habitat affinity, temporal patterns, likelihood of exposures based on habitat preferences (e.g., underground, cave dwelling, high elevation species, forest species, species dissociation from treated areas based on habitat).
- Proportion of habitat within protected areas (e.g., government lands or conservation areas).
- If pesticides are considered a major stressor, or not, in species-specific conservation and recovery plans documented by the Services. These plans often point to stressors impacting the status of the species and those that are responsible for altering, or potentially improving, the baseline of the listed species.”

EPA Response: *EPA’s responsibility in the endangered species process as the action agency is to evaluate if an individual of a species may be affected. As a result, the process must be protective and evaluate circumstances where the maximum potential exposure could occur. EPA has considered the majority of these lines of evidence (probabilistic use distribution, typical rates and application methods, exposure for treated areas versus offsite transport, species-specific information, etc.) in its lines of evidence and modeling in the MAGtool. EPA is required as the action agency to consider whether its action, which is the registration of the assessed pesticide, could impact an individual of a listed species. EPA may consider cases where recovery plans identify pesticides as stressors.*

Comment 82: Rotam commented: “The analysis plan did not clearly lay out analysis steps, assumptions outputs, and how each line of evidence would be evaluated. All lines of evidence included in parts of the analysis (e.g., typical use rates) were not listed in the WoE framework, nor was the rationale for their exclusion.”

EPA Response: *Both the User’s guide for the MAGtool as well as the Revised Method provided with the draft BEs include discussions about the assumptions that were made and how the lines of evidence are applied in the BEs. For the final BEs, the documentation accompanying the MAGtool has been updated to provide more transparency.*

Comment 83: Rotam commented: “The models used include MAGtool (aquatic and terrestrial versions) and Crystal Ball. The user guides provided for both tools lacked adequate descriptions of how to use the models. While physically running the models was possible, there was a lack of transparency in how assumptions were applied to the specific processing steps occurring within the analysis. It was also noted in the BE that there are several parts of the MAGtool no longer functional or used. These areas should be clarified or removed. Some data in the tools were copied and pasted without a clear indication of the source or origin. Much of the information in the tool is not referenced. The usability and transparency of the MAGtool requires additional documentation, a much more detailed user guide, and a removal of obsolete portions of the tool. Additionally, an improved user interface and a training file are needed to validate and verify functionality.”

EPA Response: *The MAGtool was developed in Excel and uses visual basic to provide transparency in how assumptions were applied. The MAGtool will continue to evolve as will the associated documentation and BE methodology. In order to keep the tool at a manageable size, some data are copied and pasted without the links to where they were derived. However, as the code is developed using visual basic, a user can evaluate where the data are coming from by stepping through the code. Like all tools, the MAGtool was initially built for functionality, for use in BEs. As methods are revised and updated, tools will be refined and upgraded as necessary.*

Comment 84: Rotam commented: “Treated areas should only be considered in the BE if the specific use site is reasonably likely to be used as habitat for a listed species.” They also commented: “Offsite transport areas (those areas with range or critical habitat overlap) should only be considered in the BE if those areas are reasonably likely to be used as habitat for a listed species.”

EPA Response: *If species specific data are available to indicate that a species will not utilize a treatment site, EPA assumes that individuals of the species will not be exposed on the treated site. Those individuals may still be exposed if areas they do inhabit receive spray drift or runoff. If information is not available to confidently conclude that a species will not use the treated site or areas receiving spray drift or runoff, EPA assumes that individuals of the species may be exposed on the treated site.*

Comment 85: Rotam commented: “The BE should effectively narrow the specific-species and uses where potential impact can occur in an effective and efficient manner with the output being the identification of spatially explicit areas where additional risk assessment or risk management may be needed.”

EPA Response: *EPA’s BEs are intended to narrow the list of species to those with potential impacts to one or more individuals. Once the Biological Opinions are developed and reasonable and prudent measures and alternatives are identified, risk management can be considered. This may involve identification of spatially explicit areas where mitigations may be needed. EPA agrees that there may be additional ways to summarize the information, including regional patterns for the UDLs, summarizing the dependencies between UDLs for a species, looking at additional species life history information and additional information related to the application method. These types of considerations may be considered in the future, especially if they support the needs of Biological Opinions.*

Comment 86: Rotam commented: “The wide variety of methomyl uses (terrestrial food and feed crops, terrestrial non-food crops, greenhouse food/non-food, and non-agricultural indoor and outdoor sites) on 34 active product labels (16 Section 3s, 18 Special Local Needs) is mentioned. The diversity of application methods is also mentioned (aerial and ground application methods, including broadcast, soil incorporation, orchard airblast, and chemigation). The broad labels and diversity of application methods and technologies require an assessment of these combinations so that those that clearly result in negligible risk to a species and those that may require additional analysis can be prioritized. The BE appears to make effects determination as a composite of all these variables. This approach does not allow for the ability to determine if exposures and effects are “reasonably likely to occur” for an individual use pattern or species combination. Moreover, localized use conditions and practices relative to a specific species of interest were not brought into the assessment as important lines of evidence for the determination for a species. This approach makes it difficult for individual registrants to make label changes as the risk characterization was not specific enough to take such focused action.”

Crop Life America commented: “Labels for a given active ingredient from different registrants often have unique combinations of labelled uses, but the aggregated UDLs are based on all the labeled uses combined. This does not allow for an evaluation of risk from: 1) an individual label (the federal action), 2) or an individual use pattern, nor does it allow for a, or 3) subsequent evaluation of whether reasonable and prudent measures or actions, specific to an individual labelled use pattern, are required in a biological opinion (BiOp). Providing more nuance and refinement in UDLs within the BE will save resources later in the review process.”

EPA Response: *EPA’s draft BE for methomyl considered the potential exposure and risk of the sum of all uses of methomyl on each listed species and designated critical habitats. The MAGtool output characterizes the relative contributions of each UDL to the risk of methomyl to each species. This information can be used to identify those uses that pose the greatest risk to a given species. For those species with LAA determinations, local use conditions and practices may be relevant when determining the potential impacts to populations or designated critical habitats. EPA intends to work with the Services to determine the best path forward to find reasonable mitigation if needed informed by the available data.*

Comment 87: Rotam commented: “The BE only considered a subset of application practices for Methomyl. Generally, those selected produced the highest exposure estimates without considering both the full range of application methods and local methods that can have a high degree of influence on actual exposure concentrations. The exposure modeling done in the BE should take a stepwise approach and first evaluate the full range of application practices for each use. Second, typical or expected practices should be evaluated. Finally, localized species-centric assumptions should be employed in the exposure analysis. This approach not only utilizes relevant and available data but allows for a screening approach to be performed. The screening approach would separate application practices that may require additional analysis from those where risk is not expected.”

EPA Response: *EPA conservatively used maximum label rates and practices to evaluate the likelihood of impacts to an individual. In cases where multiple uses with different application practices were relevant to a given UDL, the application practices resulting in the maximum potential for exposure was simulated. In the BEs, EPA also evaluated the impact of using more typical application rates and practices representing a UDL on the likelihood of individual effects.*

Comment 88: Rotam commented: “Conducting the BE at the local use site- and species-specific habitat affords the opportunity to incorporate the influence of application timing on likelihood of species exposures. Many species have spatial and temporal patterns, as well as life stage variations, that can influence their proximity to potential use sites during typical application windows. Adding this level of information to the assessment for species that require further evaluation is necessary to reduce the uncertainty in the BE.”

EPA Response: *EPA agrees that listed species may have temporal patterns that influence their potential for exposure; however, effects to a species’ prey, pollination, habitat and/or dispersal (PPHD) should be considered, even if a species is not present. Additional information on local use, application timing and species-specific life history (related to temporal patterns that may influence potential exposure) may be relevant to consider at the population level.*

Comment 89: Rotam commented: “The results at the HUC level for surrogate habitat scenarios (bins) represents a reasonable starting point in the assessment prior to adding localized relevant refinements.

The 1-in-15-year maximum daily average values presented here, and used in the BE effects determinations, are taken from a 30-year simulation with values extracted near the highest observed values from these theoretical simulations. Peak exposures using these generic assumptions do not represent what is reasonably likely to occur or localized conditions. The use of these simulations for screening is appropriate but full distributions available in the BE modeling that considered potential duration of exposures relative to duration of exposure used to generate effects metrics should be considered. Use and site-specific information and proximity to habitat should then be applied as a refinement to relate the probabilistic frequency, magnitude, and duration of exposures to effect metrics taken from continuous exposures over time.”

EPA Response: *While the 1-in-15 year estimates are used as a starting point in estimating exposure, various scaling factors are used to adjust the estimates to account for varied meteorological and hydrological conditions. Additionally, probabilistic methods are used to vary EECs within a particular crop group. For instance, if a listed species is exposed to EECs from a use on vegetables, the range of EECs for various uses on vegetables are used to assess exposure to the species. Lastly, all 30 years worth of maximum daily EECs are used. For most effects studies, it is uncertain at which point the exposure resulted in the effect. For instance, while a typical fish study is conducted over a 96-hour period, it is unclear whether the potential toxicity evaluated occurred in the first day or the last day. As such, EPA uses daily exposure values when evaluating risk. Given the spatial resolution of the use data and the species ranges/critical habitats, proximity refinements are not possible.*

Comment 90: Rotam commented: “The BE acknowledges that the modeling used for the effects determinations is an upper bound exposure estimate. This does not represent what is likely to occur in the environment and therefore should not be used for making LAA determinations. Exposure values should be expressed probabilistically and compared to effects distributions spatially across areas of overlap for range, critical habitat, and suitable habitat for use patterns that indicate a potential exposure concern from a screening level assessment. This requires the use of watershed scale modeling to estimate inputs and dilution potential across these areas. The most practical approach would be to fully utilize habitat information and information on species locations and then refine areas of interest for exposure analysis within the watershed.”

EPA Response: *EPA is developing the ability to conduct watershed-scale modeling (the Spatial Aquatic Model), but the development of this model is still ongoing and cannot be effectively done in the time required to conduct the BEs at this time. As discussed above, EPA is using scaling factors, the distribution of 30-year maximum daily values, and other methods to evaluate exposure that is more realistic and not necessarily upper bound.*

Comment 91: FIFRA Endangered Species Task Force (FESTF) provided USDA-NRCS definitions of spatial layers representing pastureland and rangeland. They commented: “Due to the distinct management differences, combining the various land covers to represent potential use in pastureland does not provide an accurate portrayal of distribution and overestimates potential impact from management practices involving pesticides.” They added: “To create a more accurate depiction of rangeland and pasture in the continental US, using methodology identified in Levi and Bestelmeyer (2018), a spatial data layer for rangeland from the 2016 USGS NLCD (Yang et al., 2018) can be created by combining all pixels classified as shrubland and herbaceous (classes 51, 52, 71, 72, 73, and 74 (including dwarf scrub, shrub/scrub; grassland/herbaceous; sedge/herbaceous; lichens; and moss)). A separate spatial data layer can be created for pasture by combining all pixels classified as pasture/hay (class 81) in the 2016 USGS NLCD (Yang et al, 2018) and, to account for some of the agricultural classes that can be used for

pastureland and grazing, adding classes for alfalfa (36), clover/wildflowers (58), and switchgrass (60) from the 2016 CDL (USDA-NASS, 2019a).”

EPA Response: *The final BEs include updates to the pasture and rangeland UDLs. Cultivated grasses and grass crops, as identified in USDA Cultivated Layers are included in the new Alfalfa UDL. These crops included Alfalfa (36), Switchgrass (60), and Vetch (224). Non-cultivated pasture/grass areas typically used for grazing are included in the new Pasture/Rangeland UDL. This Pasture/Rangeland UDL includes CDL land cover categories, Other Hay/Non- Alfalfa (37), Pasture/Grass (62), Pasture/Hay (176 and 181), in addition to other grazing/rangeland sources outlined in Appendix 1-6. The Bermuda grass UDL has been updated to reflect areas where cultivated grasses grow as defined in USDA’s Cropland Data Layer (CDL) and limited to latitudes where warm season grasses occur. Additional information on these updates will be available in the final BE in Appendices 1-5 and 1-6.*

Comment 92: FIFRA Endangered Species Task Force (FESTF) commented: “According the USDA-NRCS (2017), alley cropping is defined as “trees or shrubs planted in sets of single or multiple rows with agronomic, horticultural crops, or forages produced in the alleys between the sets of woody plants that produce additional products.” In the draft BE for methomyl, it is unclear how the alley cropping UDL is assessed differently from the other orchards UDL, and why acres in alley cropping would not be covered under the other orchards UDL or the UDL for the crop being grown between the sets of woody plants.”

EPA Response: *The creation of the alley crop UDL was specific to a methomyl use on soybean/beans grown between orchard rows. As the dominant agricultural practice, the Other Orchards UDL was used to identify the locations, then refined to California counties that reported alley cropping practices based on the Census of Agriculture.*

Comment 93: FIFRA Endangered Species Task Force (FESTF) commented: “due to on-going research and technology development in non-crop production systems, FESTF recommends that for non-crop uses, such as bermudagrass, pasture, and alley cropping, EPA contact crop, forage, and agricultural production experts located in states and/or territories to verify acreage and distribution of use assumptions.”

EPA Response: *Refining the non-crop location is extremely difficult but it is a task EPA plans to continue to move forward in the future. Collection of available data for refinement, including the possibility of requesting information from production experts, will continue to be explored in the future.*

Comment 94: FIFRA Endangered Species Task Force (FESTF) commented: “FESTF notices that the sources of data that EPA used in the draft BEs for certain spatial and species attributes are not consistently the most recent and best available data. It is almost impossible to keep up with such information without a methodical and regularly scheduled process to maintain data sources as “current.” FESTF aggregates and keeps up to date the best available information on species locations and species attribute data, compiled from authoritative sources such as USFWS listing rules. Over the 20 years that FESTF has been active in aggregating and managing data, we have been able to establish predictable update methods and practical update intervals so that the data contained in Gopher maintains its “best available” status.”

EPA Response: *EPA is currently using listed species information from documentation developed by the Services. EPA is also using spatial data (i.e., ranges and designated critical habitats) provided by the Services. In the future, EPA may consider using other sources of data or databases, with input from the Services. The data sources are routinely reviewed and updates and are incorporated when they become*

Available when feasible. But due to evolving nature of the data, once a specific assessment is started new data is not incorporated into the BE. However, this information can be included by the Services in their BiOp.

Comment 95: FIFRA Endangered Species Task Force (FESTF) commented: “FESTF acknowledges that species ranges change overtime as new survey data are collected and conditions change and that USFWS is currently working to refine range maps. EPA stated in the draft BEs that USFWS and NMFS provided the range maps used in the draft BE but it is unknown if these are the same maps available to the public on the USFWS Environmental Conservation Online System (ECOS). The species range files used in EPA’s draft BEs should be made available with the other BE materials so that results can be replicated.”

EPA Response: *The species spatial location data from USFWS and NMFS are available for download from their respective websites, which are available to the public. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration.*

Comment 96: FIFRA Endangered Species Task Force (FESTF) commented: “the date that species range files are obtained can play a major factor in the overlap and resulting determination for a given species.”

EPA Response: *The download date for the species location dataset are provided with the discussion of the spatial overlap analysis in Appendices 1-7 and 1-8.*

Comment 97: FIFRA Endangered Species Task Force (FESTF) commented: “While a date-stamped dataset is helpful, it still does not allow tracking or re-creation of information downloaded from it on any given date. Consequently, the job of tracing why a conclusion made “now” does not match a conclusion from data applied previously - or of defending conclusions - becomes tedious or even impossible. It is important, for these reasons, to have a stable dataset with known intervals for updates. Gopher provides this stability and consistency, as well as historical data archiving, which allows tracking of changes between datasets. FESTF is exploring Gopher enhancements to notify users when changes to species range files may require changes to decisions and to aid in staying current with this ever-changing dataset. FESTF welcomes the opportunity to discuss these enhancements with EPA.”

FESTF also commented: “FESTF’s aggregated species location data in Gopher should be used to inform if exposure to known populations of a species is likely.”

EPA Response: *The species spatial location data are managed by the USFWS and NMFS (together, the Services) and available for download from their respective websites. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration. In the future, EPA may consider using other sources of data or databases, with input from the Services.*

Comment 98: FIFRA Endangered Species Task Force (FESTF) commented: “information from FESTF’s Gopher indicates that there are 23 additional species that are only known to occur on uninhabited islands. The definition of ‘Uninhabited Island’ used is based on the qualifications for a Minor Outlying Island which are uninhabited or have no permanent residents (these islands may have temporary scientific and/or military personnel).” Specific species were provided in Table 2 of the submitted comments.

EPA Response: *The species identified as occurring on uninhabited islands, are species occurring exclusively on uninhabited islands. There are additional species occurring on unhabituated islands or Minor Outlying Island, however, they also occur on populated islands or areas it is assumed the analysis based on these populated areas is protective of the uninhabited areas.*

Comment 99: FIFRA Endangered Species Task Force (FESTF) commented: “FESTF is very familiar with the inconsistencies between species range information and what is available in USFWS and NMFS documentation and appreciates EPA’s efforts of starting to identify these. Using species ranges that are mapped at the state or county level does not realistically inform where a species is or could be located and leads to an exaggeration of the species range and in turn, overlap with pesticide use sites. Data in FESTF’s Gopher can identify additional species with uncertain ranges.” Species specific examples were provided.

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 100: FIFRA Endangered Species Task Force (FESTF) commented: “Species’ population sizes are used by EPA in various parts of the draft BEs including in the MagTool and in the Weight of Evidence. When species-specific quantitative population estimates are not available, EPA uses taxon-level estimates, provided in Table 2 of the Final Revised Method. Population estimates for many species that EPA used taxon-level estimates are available in the SOSs in FESTF’s Gopher and these should be used instead of the taxon-level estimates. Population estimates in FESTF’s Gopher represent the best available information.”

EPA Response: *EPA obtained population level estimates from the most current services documentation available. For those species that rely upon defaults for their taxa, EPA is interested in refining the population size estimates to be species specific. If the population size estimates that have been collected by FESTF are from FWS or NMFS documentation, EPA will consider incorporating those estimates into future BEs.*

Comment 101: FIFRA Endangered Species Task Force (FESTF) commented: “In the materials posted on the draft BEs (including Chapter 4 and Appendix 4-1), EPA indicates that a “No Effect” (NE), “Not Likely to Adversely Affect” (NLAA), or a “Likely to Adversely Affect” (LAA) determination is made for each species and designated critical habitat. However, the determination for potential impact to designated critical habitat should be described to better fit the newly adopted ESA rule changes that address, among other things, minimal or predictable adverse effects from those reasonably expected to cause destruction or adverse modification of critical habitat (84 FR 44976). If EPA adopts parallel terminology there may be better opportunities to take advantage of newly adopted ESA Section 402.14 for expedited consultations. Additionally, as USFWS (2000) explains, only the areas within the spatially delineated critical habitat that contain Primary Constituent Elements (PCEs) or physical and biological features (PBFs), which are features that are essential to the survival and conservation of the species, are considered critical habitat. Therefore, EPA’s analysis of potential impacts to critical habitat needs to be limited to where PCEs/PBFs occur and not simply an overlap and exposure analysis using spatial data as EPA has completed in the draft BEs. As part of FESTF’s effort of compiling SOSs under the supervision of USFWS, FESTF compiled information related to designated critical habitat including legal unit definitions and PCEs/PBFs as USFWS defines them in the document designating critical habitat. This information is housed in FESTF’s Gopher and should be used by EPA to assess potential impacts to critical habitat.”

EPA Response: EPA's method and determinations are consistent with the ESA rule changes. In regard to the determinations made for designated critical habitat, the considerations for effects to an individual of a listed species and its PPHD are assumed to apply to both the listed species determination and its critical habitat.

Comment 102: FIFRA Endangered Species Task Force (FESTF) commented: "EPA's process of representing labeled uses by grouping CDL classes, exaggerates the potential extent of any given labeled use. While grouping certain CDL layers together may be appropriate due to the uncertainty in various classes in the CDL and rotation practices, grouping other CDL layers together only overestimates potential extent."

EPA Response: The USDA NASS (2013-2019) 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 103: FIFRA Endangered Species Task Force (FESTF) commented: "it is not clear why "Federal Lands" are treated as a separate UDL instead of as line of evidence"

EPA Response: EPA reports the species overlap with Federal Lands in the weight of evidence output for additional consideration when a species is evaluated. As described in the March 2020 response to comments on the Revised Method, the existence of a species on Federal Lands by itself is not a factor used to make an NLAA determination. The EPA will continue to work with the Services on how to refine the consultation process for species largely on Federal Lands.

Comment 104: FIFRA Endangered Species Task Force (FESTF) commented: "FESTF suggests that EPA revise the UDLs by excluding crops not labeled for use or at a minimum, account for over-estimation by adjusting the footprint to better match the Census of Agriculture."

EPA Response: As described in the Revised Method, the Census of Agriculture is used to identify counties where no registered crops occur for a given UDL. To do this, all crops found in the each UDL are linked to the Census Agriculture and the number of registered crops found in each county identified. As part of the spatial analysis, the overlap is removed for the counties with no registered crops prior to the use as an input for the MAGtool. If a single registered crop occurs in the county the overlap remains unaltered.

Comment 105: FIFRA Endangered Species Task Force (FESTF) commented: "For the non-crop UDLs, no scripts are provided in the Spatial Analysis Tools and it is therefore difficult to replicate these datasets. FESTF suggests that all the UDLs developed for the BEs be made available. EPA does not explain how

updates in datasets will be handled such as newly released CDL. Additionally, the Spatial Analysis Tools that EPA posted use outdated datasets all of which impact spatial extent and or overlap determinations and need to be updated to be compatible with the most recent versions of Python and ArcGIS (the scripts are not Python3 compatible, the raster catalog tools are no longer supported in ArcGIS pro, and the 2013 County boundary layer used is out of date (discrepancies with counties that have changed names and GEOID). FESTF recommends that EPA use an updated County boundary layer, update tools to be compatible with the most recent versions available and explain how data updates will be handled.”

EPA Response: *Scripts were not initially developed for the non-crop UDLs. Instead, the landcover data sources and the classes used to develop each of the non-crop UDL are identified in Appendix 1-6. If scripts are developed as part of the updates to non-crop UDL they will be incorporated into the spatial analysis tools. The data sources are routinely reviewed and updates incorporated when they become available. Specifically, the Cropland Data Layer (CDL) used to generate the Use Data Layers (UDLs) is updated once a year following the release of the new CDL. Other land use and landcover data sources are not updated as frequently but they are routinely checked. Species location data is also routinely reviewed and updated. But once a specific assessment is started new data is not incorporated. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration. EPA plans to update the Python tools to Python 3 in the future.*

Comment 106: FIFRA Endangered Species Task Force (FESTF) commented: “EPA’s application of usage data to determine percent crop treated (PCT) is highly conservative when usage data are not available for uses such as bermudagrass, alley cropping, and other crops, and leads to many more LAAs than necessary. In Appendix 1-7 of the draft methomyl BE, EPA outlines how they applied surrogate usage data (p. 5) for a UDL (like bermudagrass pasture) that does not have usage data for any state: “the highest available PCT from all state-crop combinations will be used. This last scenario applies to three UDLs, including alley crop, bermudagrass pasture, and other crops.” For example, since there are no usage data for methomyl on bermudagrass pasture, EPA assumed 100% crop treated, which is the highest available PCT from all state-crop combinations. The following crops have at least one state with a maximum annual PCT of 100%: onions, succulent beans, squash, peaches, and sweet corn (Appendix 1-4; EPA, 2020). The management of these crops is not representative of the management of bermudagrass pasture. It does not appear that this assumption is backed by literature, recommendations from agronomic experts, Cooperative Extension Service personnel, or guidance from USDA. FESTF recommends that for UDLs without available usage data EPA contact crop, forage, and/or use experts located in states and/or territories to verify usage assumptions. Contacting experts meets the “best available” standard set as outlined in the Services’ ESA Section 7 Consultation Handbook (USFWS and NMFS, 1998).”

EPA Response: *The selection of a surrogate usage value when no usage is available nationwide is a conservative assumption of the Revised Method. Without available usage data, EPA chooses to make conservative assumptions. EPA agrees that the 100% usage of methomyl on vegetables may not directly translate to the usage on pasture, Bermuda grass or other crop, but it does show the possibility of this occurring. This assumption may be refined in the future as more information becomes available.*

Comment 107: In regard to Step 1, FIFRA Endangered Species Task Force (FESTF) commented: “this leads to many more species than needed with MA determinations because it does not consider important factors related to exposure and effects. Pesticide toxicity, species attributes (such as habitat in relation to the use site, diet, physical barriers, and distribution) and other conditions related to the pesticide and use sites under evaluation that preclude any possibility of exposure even if overlap does

occur, need to be considered sooner in the process. Step 1 is a lengthy process that does not result in the identification of which species are potentially at risk. This places the unnecessary burden on the USFWS and NMFS to consult on incorrect MA determinations.”

EPA Response: *In Step 1, EPA intentionally established a conservative method for distinguishing between those species where the assessed pesticide has no effect or is not likely to adversely affect an individual. The Step 1 method incorporates input from USFWS and NMFS.*

Comment 108: FIFRA Endangered Species Task Force (FESTF) commented: “MagTool output and input files provided were not transparent enough to follow the steps through the MagTool as outlined in the Final Revised Method. While the output files were organized by species range and critical habitat and by general taxon groupings, it is still necessary to move between numerous different files and locations to obtain the full information for a given species and following various data points through the process is not transparent, and often impossible.”

EPA Response: *EPA has updated the MAGtool to provide additional summary data on all species to allow easier review of data, the uses most often associated with impacts and other overall factors regarding effects determinations. These are included in Appendix 4-1 as well as Chapter 4.*

Comment 109: FIFRA Endangered Species Task Force (FESTF) commented: “Supporting tables and final outputs from the Spatial Analysis Tools are needed, including UDLs, action area, species range, and critical habitat files. Without these, it is not possible to confirm or replicate results.”

EPA Response: *Due to the complexity of sharing the large spatial dataset used in the BE, EPA provides the tools and documentation used to generate the spatial data. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration.*

Comment 110: Crop Life America commented: “The Revised Method released in March 2020 and the Draft Biological Evaluations for Carbaryl and Methomyl are the first two Biological Evaluations (“BEs”) developed under the revision. The Draft BEs for Carbaryl and Methomyl show evidence of some incremental improvements to the Environmental Protection Agency’s (“the Agency’s”) process for conducting national level threatened and endangered (listed) species biological evaluations (“BEs”) for conventional pesticides, but the improvements are uneven and the Revised Method’s practical application in the Draft Carbamate BEs demonstrates that the Agency has not yet reached a workable, legally defensible, or sustainable approach to listed species risk assessments.”

EPA Response: *EPA is using an iterative process for developing methods and conducting national-level BEs. The methods used to develop BEs will continue to evolve as EPA gains experience and as scientific methods and data improve. EPA will continue to evaluate approaches for improving the efficiency of developing national-level BEs. EPA application of the Revised Method, which was developed through a transparent process (including working with the Services), is scientifically based and robust, and legally defensible*

Comment 111: Crop Life America commented: “The Agency should make a significant effort in the final carbamate BEs to (a) reduce the level of compounding conservatism in the assessment; (b) adjust the approach to more accurately incorporate use and usage information; and (c) strive to better establish whether or not pesticide exposure at a concentration causing adverse effects is reasonably likely to occur as described in the Service’s recently amended Endangered Species Act regulations (Sec 50 CFR §

402.02).” They later commented: “Based in large measure on the Agency’s concern over uncertainties in applying usage data only at the state level, the exposures it predicts are highly overestimated. The resulting compounding conservatism in the Draft Carbamate BEs is one of the severe weaknesses in the Agency’s application of the Revised Method. For example, the use data layers (“UDLs”) generated by the Agency overstate actual use due to lumping use patterns from all registered labels together (from multiple registrants including both agricultural and non-agricultural uses). Similarly, the listed species range maps are imprecise and highly conservative (county-level in most cases). The exposure modeling approaches use this unrealistically portrayed data and compound the error, by themselves being highly conservative in design. Furthermore, for most of the listed species analyses, the largest buffer distances resulting from the application of the most sensitive direct and indirect effects thresholds are added to the aggregate UDL footprints to define the action area for selected uses. Adding all these measures of conservatism across the Revised Method results in Draft Carbamate BEs that do not meaningfully distinguish species that are reasonably certain to be exposed to and affected by the assessed pesticides from those that are not likely and for the most part do not appropriately distinguish between “no effect” and “may affect”. These approaches are highly conservative and expand the action area beyond what is reasonable for most species, making the “1% overlap” meaningless.”

They also added: “The Draft Carbamate BEs provide the first opportunity to evaluate how EPA applied weight-of-evidence approaches to support the effect determinations made for individual listed species and/or their critical habitat. Again, the results are disappointing. In the Draft Carbamate BEs (as in the organophosphate BEs), no line of evidence was able to reverse a determination call from Likely to Adversely Affect (LAA) to Not Likely to Adversely Affect (NLAA) or to No Effect (NA). This creates the perception that there is no point in the review process at which more realistic exposure estimates will be incorporated into the review. The Agency’s failure to explain how “mitigating” lines of evidence will be incorporated puts a greater burden on the Services to undertake this incorporation during the Biological Opinion (BiOp) process and unnecessarily confuses the public.”

Crop Life America also commented: “EPA should expand upon the notice provided in Section 4 (pg. 4-5 in the draft carbaryl BE): *“Throughout this analysis, the BE maintains conservative assumptions and may overstate the number of species exposed to and impacted by a pesticide.”* The Draft Carbamate BEs should better identify the considerable uncertainties in the data (e.g., effects surrogacy, spatial, exposure estimates) on which they are based, and the resulting compounding conservative assumptions EPA makes to give deference to the listed species.” They also commented: “In Section 4 (draft carbaryl BE), EPA provides a summary of some of the major uncertainties in the spatial data, usage data, and effect thresholds, and indicates that addressing these uncertainties will increase confidence in the effect determinations. However, there is ample opportunity to reduce uncertainty for many of these variables by incorporating lines of evidence that can support and/or refute models (e.g., applying knowledge of the species habitats, probabilistic usage data methods, appropriate aquatic exposure modeling specific to species habitat, and others). We encourage the Agency to incorporate these lines of evidence into the BE methods, communicate the results with the Services and the public clearly, and address these uncertainties.”

EPA Response: *When making determinations, EPA made conservative assumptions to address uncertainty and to be protective of the assessed species. The influences of those conservative assumptions are considered in the MAGtool, where alternative parameter values are selected and estimates of the likelihood of individual effects are calculated. If both the conservative and alternative assumptions both arrive at the conclusion that one or more individuals of a listed species may be impacted, there is a greater degree of confidence in the LAA determination. If there is a difference in*

conclusions when using conservative and less conservative assumptions, EPA has less evidence to support the LAA determination; however, there is still the potential for impacts to an individual under some circumstances. The alternative analysis considered more typical usage data, including typical application methods and practices. EPA believes that this approach is consistent with the current “reasonably certain to occur” standard.

Comment 112: NovaSource/Tessenderlo Kerley, Inc. commented: “EPA included a wide range of effects thresholds across each taxonomic group in the draft BE data. EPA also calculated multiple threshold values (e.g., HC05, HC50, HC90) that are available for use to demonstrate bounds around the full range of species sensitivities. EPA thus could have readily incorporated information on typical use rates and more relevant, realistic usage assumptions found in the alternative analysis (e.g., percent crop area and treated acre distributions), and the significant amount of information available on species dependencies, habitats, and population estimates to present a more refined assessment using individual use patterns and methods of application. This would have permitted a more robust analysis of effects reasonably certain to occur as illustrated in the Case Studies in the Appendix of this document. EPA’s failure to do so violates the Services’ consultation regulations and represents a significant flaw in the draft BE.”

They also commented: “As currently implemented, the draft BE is a series of compounded worst-case assumptions. While employing multiple worst-case assumptions might be considered appropriate for a Step 1 screening-level assessment, it is inconsistent with EPA’s stated intent of Step 2 of the BE—to determine “whether an individual of a listed species is **reasonably expected** to be exposed to a pesticide at a level that results in a discernable effect, and, if so, distinguishes effects that are likely to adversely affect an individual of a species from those that are not likely to adversely affect an individual”—much less whether those effects are reasonably certain to occur, as required by the applicable regulations and EPA policy. The final BE must correct inaccuracies in the draft BE, reassess the highly unlikely and compounded worst-case assumptions at Step 2, and present the additional information and scenarios that have been generated to provide context and appropriately evaluate what may be reasonably certain to occur.”

EPA Response: See response to **Comment 111**

Comment 113: Crop Life America (CLA) commented: “CLA believes in Step 1, a May Affect (MA) determination should reflect whether an effect is “reasonably certain to occur.” However, Step 1a in the Revised Method simply examines whether exposure *can* occur based on an evaluation of species range data overlapped with action area. In Steps 1b-c, effects analyses are made using sensitive surrogate effect thresholds.”

EPA Response: As described in the Revised Method document, EPA considers whether an effect is “reasonably certain to occur” in its analysis.

Comment 114: Crop Life America commented: “For the Draft Carbamate BEs, the Agency relied upon studies used for effect thresholds that do not appear to follow EPA’s own study quality criteria.”

EPA Response: When evaluating unpublished studies submitted by registrants, EPA utilized the standard test guidelines that were most representative of the studies (e.g., OCSPP 850 test guidelines, OECD test

guidelines). For studies available in the scientific literature (identified using the ECOTOX database), EPA used its open literature guidance⁹.

Comment 115: Crop Life America (CLA) commented: “The Draft Carbamate BEs outline several new models, including a MAGTool, that is highly complex and incorporates spatial data, effects thresholds, exposure models, and the probabilistic tools in the alternative analyses that the Agency hopes to use to evaluate risk to listed species. Within the time limit of the Public Comment period, this tool is far too complex to be able to evaluate fully. Furthermore, there is currently a lack of transparency and insufficient documentation on how the model functions and inputs required to the MAGTool. This is especially worrisome because the Agency claims that eight new models were used in the Draft Carbamate BEs. However, to CLA’s knowledge, none of the models have been previously available for public review and comment. For example, UDL generation takes a considerable amount of time and effort to reconstruct and evaluate. In this case, the fact that the UDLs were not available with the Draft Carbamate BEs makes it very difficult to review and comment on this critically important component. The use site generation tool was presumably used to generate the UDLs for carbaryl and methomyl, but this is not clearly stated.”

EPA Response: *As described in Comment 109, due to the complexity of sharing the large spatial datasets used in the BE, EPA has provide the tools and documentation used to generate the spatial data. EPA will continue to explore ways to efficiently make the spatial data and analysis available. Additional documentation has been provided with the final BEs and the updated version of the MAGtool.*

Comment 116: Crop Life America commented: “Given the lines of evidence available (e.g., import certificates, sales data, usage data, pesticide products supplied to USDA’s Animal and Plant Health Inspection Service (“APHIS”) programs and other sources of information) demonstrating actual usage at a significantly lower application rates, an assumption of full label rate application on 100% of the crop footprint, 100% of the time, is simply not relevant for a meaningful effect analysis on any listed species or its critical habitat.”

EPA Response: *EPA agrees that the full label rate is a protective assumption; however, growers apply products at a range of rates and some growers may indeed apply at the maximum application rate. Because the Agency cannot anticipate that a reduced application rate will be used on specific parcels of land, the maximum label rate is used to be protective. Typical rates are also incorporated into the BEs to inform the likelihood of potential risk.*

Comment 117: Crop Life America commented: “EPA’s application of usage data at the state-level in Step 2 does not provide an appropriate level of detail to effectively allow for realistic exposure estimations for individual listed species.” They provided a method for quantifying pesticide usage at the county scale (Attachment 1).

Crop Life America also commented: “Situations where high quality usage data are readily available at refined spatial resolutions (e.g., California Pesticide Use Reporting data – “PUR”) present best available data, but the Agency appears to ignore these data and default to the gross California state-level view.”

⁹ Available online at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open>

EPA Response: *To the extent possible, probabilistic methods that utilize the available usage data in a scientifically defensible way are being applied. For example, the usage on a crop is mapped to the UDL, which is where the crops within the UDL were grown within the state based on geospatial data; this is a probabilistic method. EPA agrees that the distribution of pesticide usage within a state, and within a crop within a state, is likely uneven. In addition to pest pressures noted by Crop Life America, this occurs simply as a result of the pest management decisions made by different growers/applicators, including selection of alternative pesticide(s) or other pest management decisions, that are based on factors beyond pest pressure.*

Crop Life America provided a document entitled, “Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale: May 2020 Revision.” This attachment was “restricted to show metadata only because it contains copyrighted data.” While the contents of the document are protected, it generally provides a comparison of several methods for using available usage data to estimate sub-state usage with validation against known county-level usage. Additionally, approaches for expressing estimated usage statistics and incorporation into the BE were provided. EPA acknowledges receipt of the proposed methodology and preliminary review suggests that the methods may have some utility for estimating historical usage below the state level.

Refining Biological Evaluations to incorporate the location of pesticide usage for a crop within a state at the “sub-state level,” is more complicated than simply understanding the location and number of acres of crops grown within a state and the fraction of those acres that are treated with an active ingredient and overlaying historical pest pressure, as proposed by Crop Life America. The availability of reliable and spatially refined historical pesticide usage estimates (whether those usage data were collected and reported by a data source (e.g., the California PUR data) or derived through a methodology (e.g., imputation of county-level usage from state-level data) is but only one of two primary requirements for implementation of a more refined probabilistic methodology for allocation of pesticide usage at the sub-state level. The other requirement is the ability of historical usage data to adequately estimate future usage at the sub-state level. One major concern with county-level usage estimates is the impact that individual growers’ decisions in the future will have on the usage for that county. Data from the USDA NASS 2017 Census of Agriculture indicate that for the crops surveyed by Kynetec and NASS, if a crop is reported as grown in a county, the number of operations growing the commodity within a county is heavily skewed toward a small number of growers.

While a small number of operations does not affect usage statistics for mandatory reporting programs and can be accounted for in the statistical design of surveys of grower usage to ensure reliable estimates of historical usage, the utility of those data for predicting future applications is limited because the choice of a single individual to use or not use a pesticide in the future has a large impact on the accuracy of the predicted usage. Therefore, while data and or methods may be available to estimate usage at the county-level, the reliability of those data for estimating future usage require further validation before they can be incorporated into assessments. If they are deemed reliable for estimating historical usage. EPA will need to evaluate the ability of those sub-state estimates of historical usage to estimate future usage and the extent to which they could potentially replace models relying on the existing state-level usage estimates.

Comment 118: *Crop Life America commented: “Application of usage data at Step 2 at the state level within the species ranges is also highly conservative. EPA assumes the percent crop treated (“PCT”) would be applied within the area where use patterns and species ranges (or critical habitat area) overlap. This ignores the fact that a pesticide could be applied anywhere within a state and not just*

within the species range or critical habitat area, making this assumption unrealistic. The justification for this assumption is that it is conservative and intended to address the inherent uncertainty. Given that foliar applied insecticides are used only where pest pressure reaches the potential for crop damage thresholds, application is certain to occur unevenly throughout a state. How usage data is distributed within a state should therefore be estimated using probabilistic methods. Step 2, as applied, does little to address compounding conservatism, as a refined step in a hierarchical Ecological Risk Assessment (ERA) process should do.”

EPA Response: *The BEs considered alternative assumptions related to how usage data are applied and their influence on whether one individual or more may be impacted by the assessed pesticide. Including the merits of the methodology presented by Crop Life America and incorporate appropriate information and methods into future BEs as part of our efforts to improve our assessments in this iterative process. Proposals were submitted on probabilistic methods for applying usage data, including one by Crop Life America. In that submission, a probabilistic methodology incorporating the location of pesticide usage for a crop within a state was recommended based on historical usage data and pest pressures; however this is more complicated than simply understanding the location and number of acres of crops grown within a state and the fraction of those acres that are treated with an active ingredient and underlying historical pest pressure. The availability of reliable and spatially refined historical pesticide usage estimates (whether those usage data were collected and reported by a data source (e.g., the California PUR data) or derived through a methodology (e.g., imputation of county-level usage from state-level data) is but one of the primary requirements for implementation of a more refined probabilistic methodology for allocation of pesticide usage at the sub-state level. Another requirement is the ability of historical usage data to adequately estimate future usage at the sub-state level. One major concern with county-level usage estimates is the impact that individual growers’ decisions in the future will have on the usage for that county. In the future, EPA may incorporate refinements to its current probabilistic approach as part of our efforts to improve our assessments in this iterative process.*

Comment 119: Crop Life America (CLA) commented: “CLA recommends that EPA’s analysis incorporate existing conservation areas within the agricultural landscape. For example, USDA conservation programs are being supported by an estimated \$6B expenditure in FY 2020. Recognition of existing protections and conservation efforts in the EPA assessment process, and alignment with the Services on how these existing protections can inform the pesticide assessment process, could allow the Agency to work with IWG partners to leverage ongoing conservation efforts and maximize benefits to listed species.”

EPA Response: *EPA agrees that existing conservation programs are relevant to consider. In the Biological Opinions, the Services will consider impacts of carbaryl and methomyl on the populations of listed species. For those species with LAA and Jeopardy determinations (or adverse modification of critical habitat), reasonable and prudent alternatives will be identified. Existing conservation measures may be relevant when identifying RPAs.*

Comment 120: Crop Life America commented: “From the perspective of potential exposure, combining agricultural and non-agricultural uses into a single spatial footprint over-estimates use (i.e., the action area) in Step 1. Combining this with highly conservative species range information (e.g., often county level or multiple HUC12s) and ignoring areas that cannot be used by the species (e.g., urban areas, open water for terrestrial species etc.) significantly overestimates overlap between the action area and species locations.”

EPA Response: Step 1 of the BE defines the action area for the proposed action, which includes anywhere the pesticide can be applied plus offsite transport. For this reason, all individual UDLs both agricultural and non-agricultural, are combined into a single layer that defines the full spatial extent of the action. The individual UDLs that define the spatial extent for a specific use pattern, and some species life history information, are considered as part of Step 2 when making the LAA or NLAA determination. Considering individual UDLs as part of Step 1 does not meet the responsibilities of the action agency as outlined in Section 7 of the Endangered Species Act. Species location data for both the range and designated critical habitats are managed by the Services and made publicly available on their website. As this location information is updated and/or refined it will be incorporated into the process.

Comment 121: Crop Life America commented: “Probabilistic assessments can be used to develop risk statements such as “there is a 20% probability of a 25% or more reduction in the population growth rate as a result of this action.” This probabilistic approach has been used in many ecological risk assessments and in listed species risk assessments for a variety of species. In the final carbamate and future BEs, this sort of probabilistic risk statement would better describe the potential for adverse effects to one or more individual organisms and communicate the confidence the Agency has in the modeling line of evidence.”

EPA Response: EPA agrees that determining the probability associated with a given magnitude of effect may be useful information, in particular for determining the most likely number of individuals impacted. This type of information may be considered by EPA in future BEs, especially if it is useful to the Services when evaluating potential population level effects.

Comment 122: The Generic Endangered Species Task Force commented: “As part of its review of the draft BE, the Generic Endangered Species Task Force (GESTF) attempted to generate the UDLs using the information provided in the draft BE. Through its investigation, it was estimated that it will take 30+ days to generate the UDLs using the current processing methodology. This led the GESTF to attempt to address this issue by enhancing the UDL algorithm with an emphasis on efficiency and performance. This report describes improvements to the existing algorithm that yield an approximately 90% reduction in overall UDL processing time.” GESTF added: “An analysis of the EPA algorithm identified opportunities to improve performance in a number of processing steps, and these steps are highlighted in the orange portion of the flowchart in Figure 1. Specific areas of potential improvement include:

- 1) All counties are spatially extracted and reintegrated regardless of whether they require expansion. The process of extracting (or “clipping”) and reintegrating (or “mosaicking”) each county is computationally expensive, and in the EPA algorithm this is done to both the UDL and the Cultivated Layer even when not required for any given county.
- 2) The process of iteratively expanding the UDL one pixel per cycle is computationally expensive.
- 3) The county boundaries used to extract each county do not perfectly coincide with the pixel boundaries, necessitating an extra step to fix “gaps” in the reconstituted (mosaiced) UDL.”

EPA Response: EPA appreciates the feedback and suggestions for optimizing the UDL generation. The processing is computationally intensive taking several weeks each time the Cropland Data Layer is updated. During a future update of the Cropland Data Layer, EPA will consider the feedback on optimizing the tool crop UDLs and make updates to the tools. Specifically, the feedback related to processing each county regardless of whether it requires expansion could provide significant optimization of the tool.

Comment 123: The Generic Endangered Species Task Force submitted “methods for utilizing existing sources of pesticide usage data” in a framework that addresses the variability of pesticide usage and the uncertainty of which use sites are treated and to what degree. This work is premised by the belief that available usage data can improve exposure predictions and ultimately lead to improved risk assessments. Therefore, the overarching question is “How can we utilize pesticide usage data to help inform our understanding of potential exposure within listed species ranges or habitats?”. The goal of this work is to account for variability in pesticide usage practices in an attempt to identify what is “reasonably certain to occur”, and present this information in a format suitable for use in both deterministic and probabilistic modeling of pesticide usage information.” They illustrated the approach with usage data available for carbaryl.

EPA Response: *The refinements in the submission “Proposed Methods for Characterizing Agricultural Pesticide Usage Information to Support Listed Species Exposure Estimates” are included in the Biological Evaluations in some cases (e.g., application rates, number of applications per year, and PCTs), albeit possibly in slightly different ways than proposed. EPA is still considering how and to what extent it can incorporate additional refinements included in the proposal such as the Percent Field Treated analysis, which could help the Agency better understand the way in which a pesticide is typically used on a crop.*

Comment 124: GESTF provided a probabilistic method for incorporating usage data. They provided a case study involving the Fresno Kangaroo Rat and usage of carbaryl on apples. The proposed framework includes the following four phases:

“Phase 1: Define applicable pesticide usage variables as input, both as distributions and as a scalar value (e.g., total pounds applied), from data sources.

Phase 2: Conduct probabilistic assessment utilizing the pesticide usage information from Phase 1, combined with information on potential use sites and species range/habitat.

Phase 3: Evaluate model processing and output to determine that the model used the inputs as expected and outputs are within the expected range based on other metrics or sources of data.

Phase 4: Summarize multi-dimensional probabilistic output into usable information to support end user needs. “

EPA Response: *EPA is incorporating usage data and probabilistic analyses in a manner that we believe is consistent with the strengths and limitations of the data. EPA will further consider GESTF’s proposal as part of our efforts to improve our assessments in this iterative process.*

Comment 125: NovaSource/Tessenderlo Kerley, Inc. commented: “As a threshold matter, EPA applied the wrong legal standard when conducting its draft BE. That document fails to reflect the revisions to the regulations for interagency cooperation that the U.S. Fish and Wildlife Service (“FWS”) and the National Marine Fisheries Service (“NMFS”) (collectively, the “Services”) issued last year. Those revisions modified the definition of “effects of the action” in ways fundamental to the analysis EPA is required to undertake and present in a BE.”

EPA Response: *EPA is aware of the changes to the implementing regulations. EPA discussed these changes with the Services and the BEs were conducted in a manner that is consistent with these regulations.*

4. Summary of Comments Specific to the Draft Carbaryl BE

Comment 126: USDA commented: “For pesticides such as carbaryl that have very diverse uses, including residential and agricultural, combining uses into one analysis can make it difficult to determine which uses contribute most to species calls, as shown in the Weight of Evidence Analysis files (Appendix 4-9).”

EPA Response: *Currently, the information on each WoE species page provides a list of Use Data Layers that show impact to the species. EPA agrees that there may be additional ways to summarize the information, including regional patterns for the UDLs, summarizing the dependencies between UDLs for a species, looking at additional species life history information and additional information related to the application method. These types of considerations may be considered in the future, especially if they support the needs of Biological Opinions.*

Comment 127: USDA commented: that usage data for the APHIS Grasshopper and Mormon Cricket Area-Wide Suppression Program “was rounded up to < 1% PCT, which gives an overestimate of rangeland acres treated and an overestimate of the risk to listed species and critical habitat.” They later added “further characterization of risk findings (number of LAA calls) is warranted given that the actual PCT for APHIS-assisted treatments (rangeland treated by APHIS divided by the entire potential rangeland ‘crop’) in all 17 western program states is about 1000 times smaller than 1%”

EPA Response: *EPA appreciates this input and recognizes that rounding up from very small acreage to even 1 PCT in the case of very large acreage use sites, such as rangeland, may dramatically overestimate usage when the acreage is relatively minimal. Alternative approaches for such situations will be considered for incorporation into future BEs as part of our efforts to improve our assessments in this iterative process.*

Comment 128: USDA provided a list of species for which APHIS has consulted with FWS for the Grasshopper and Mormon Cricket Area Wide Suppression program. No LAA determinations were made for any listed species (all determinations were either NE or NLAA). For some species with NLAA determinations, mitigations are in place.

EPA Response: *EPA’s BE considers all registered uses of carbaryl. For those species with potential exposure to carbaryl due to use to control grasshoppers and mormon crickets, there was also potential exposure to carbaryl from other uses. Information on existing consultations and associated mitigations may be considered by the Services in the Biological Opinion for carbaryl.*

Comment 129: USDA commented: “Use of carbaryl for the Grasshopper and Mormon Cricket Area-Wide Suppression Program should be exempt from potential cancellation or further mitigation resulting from the ESA-FIFRA compliance process between EPA, FWS, and NMFS. If rangeland use of carbaryl remains a risk driver, APHIS wants to be a part of discussions on any proposed carbaryl label changes. Pending agreement from carbaryl registrants, APHIS is willing to discuss potential restrictions on labels, for example, to allow only state and federal programs and ‘authorized users’ (i.e., private landowners) who are controlling grasshoppers as part of quarantines in their state (i.e., ‘official control’) to apply carbaryl for grasshopper and Mormon cricket suppression on rangeland. Additionally, APHIS wants to be involved, along with our stakeholders, with any proposed label language development.”

EPA Response: EPA anticipates a robust discussion between the Services and the applicants, to include USDA, when developing reasonable and prudent alternatives (RPAs) and reasonable and prudent measures (RPMs), and prior to EPA's implementation of any risk reduction measures. Per the 2013 enhanced stakeholder process for ESA consultations¹⁰, USDA plays a critical role in evaluating any proposed risk reduction measures given its expertise on crop distribution, farming/pest management practices, and the feasibility of potential risk reduction strategies.

Comment 130: Bay Area Clean Water Agencies (BACWA) and National Association of Clean Water Agencies (NACWA) expressed concerns that the carbaryl BE does not address exposures to aquatic organisms from publicly-owned treatment works (POTW) effluents. They provided literature sources that contain carbaryl monitoring data. The Agencies indicated that the monitoring data exceed the BE toxicity endpoints and EPA's benchmarks for chronic exposures to aquatic invertebrates. The agencies request that EPA evaluate POTW effluent in the carbaryl BE.

EPA Response: EPA re-evaluated carbaryl labels and confirms that there are no registered indoor uses of carbaryl. It is possible that some of the outdoor residential uses reach a sewer that enters into a POTW.

Comment 131: "USDA encourages EPA to work with registrants toward improving consistency and clarity of product labels, particularly for older products. Some labels for carbaryl have not been revised to include standard improvements that have been made to pesticide labels, which may result in confusion, including about application rates. Such lack of clarity can lead to unrealistic assumptions about usage and potential exposure, due to literal interpretations of 'lowest-common denominator' labels rather than practical understanding of how products are being used in agriculture."

EPA Response: EPA routinely works with registrants to clarify and standardize products labels as part of its registration review process. The Agency plans to engage carbaryl and methomyl registrants in these types of discussions in the early stages of the formal consultation process with the Services.

Comment 132: "USDA examined the 9 active labels for formulated carbaryl products used in agriculture that were updated in or after 2013 for statements that reduce environmental impacts. Such existing mitigations may be protective of listed species and habitat" and were summarized in USDA's comments.

EPA Response: The label statements summarized were hazard statements and non enforceable recommendations to reduce offsite movement of pesticides. The exposure modeling utilized in the BE reflects assumptions that are consistent with current labels. All currently registered products are considered in the BE, not a selected subset of labels.

Comment 133: USDA commented: "When estimating exposure to listed species and critical habitat in California, USDA requests that EPA consider that all carbaryl products used within the state of California will be designated as 'restricted materials' as of August 2020, with the exception of baits labeled only for agricultural use. In California, "restricted materials can only be possessed or used by, or under the direct supervision of, a certified private applicator or a certified commercial applicator... Generally, the purchase, possession, and use of a restricted material are allowed only under a permit issued by a local county agricultural commissioner"¹³. This change of carbaryl's regulatory status in California will eliminate of homeowner use of carbaryl and may reduce other uses of carbaryl within the state as well."

¹⁰ See Section 4 (pp. 9-11); <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0442-0038>

EPA Response: *While the changes in California’s regulations on use of carbaryl may change, the current labels registered with the USEPA allow for applications by homeowners. Therefore, potential applications in residential areas by homeowners was evaluated. While California may restrict application of carbaryl to certified applicators, certified pesticide applicators may make pesticide applications around homes. Therefore, EPA evaluated the potential risk to endangered species from applications of carbaryl to residential areas in California. If labels prohibited applications of carbaryl to residential areas, then those use sites would not be considered in the BE.*

Comment 134: USDA provided information on the benefits of carbaryl use to agriculture, including information on the importance of the chemical for specific crops and pests. Responsible Industry for a Sound Environment also discussed the benefits of carbaryl for non-agricultural uses.

EPA Response: *EPA appreciates the information on the benefits of carbaryl identified by Responsible Industry for a Sound Environment. While ESA is not a risk-benefit statute, this information may be useful for regulatory decisions under FIFRA and may also inform how RPAs are implemented, if necessary.*

Comment 135: The National Cotton Council commented: “The diminishing number of alternate MOAs forces over-reliance on the few MOAs available and intensifies selection for pests resistant to those MOAs. The carbamates Carbaryl and Methomyl represent a unique MOA of great importance for MOA rotation to comply with resistance management practices. As noted in the BE, the use of Methomyl and Carbaryl are relatively low, especially when considering the acreage of agriculture. However, they provide a unique MOA for resistance management rotation, and effectively address situations of multiple pests that other MOAs cannot address alone.”

EPA Response: *The benefits of carbaryl and methomyl as rotational partners for other MOAs in resistance management programs, especially in particular circumstances, are notable benefits. While ESA is not a risk benefit statute, this information may be useful for regulatory decisions under FIFRA and may also inform how RPAs are implemented, if necessary.*

Comment 136: During the April 16 webinar discussing the carbaryl and methomyl draft BEs, EPA indicated that exposures to aquatic organisms would be greater for aquatic uses compared to indoor uses. Therefore, it was not necessary to model indoor uses since the agricultural uses would be protective. BACWA and the San Francisco Bay Regional Water Quality Board (SFBRWQB) expressed concerns about this approach and indicated that it would be helpful to assess agricultural and indoor uses separately so that mitigations specific to indoor uses could be identified.

EPA Response: *As discussed above, EPA has re-evaluated the labels and did not identify any registered indoor use of carbaryl. It is possible that some of the outdoor residential uses reach a sewer that enters into a POTW. Methomyl is not registered for use indoors or in residential setting, so it is not expected to be discharged to POTWs.*

Comment 137: BACWA, SFBRWQB and NAWCA all indicated that EPA has previously assessed risks from indoor uses of pesticides, including the pyrethroids. They indicated that EPA has previously used the Exposure and Fate Assessment Screening Tool (E-FAST). They indicated that this modeling approach may be useful for understanding ecological risks, especially when combined with available monitoring data.

EPA Response: *While EPA appreciates these comments, they are not relevant for methomyl or carbaryl because there are no registered indoor uses for carbaryl or methomyl.*

Comment 138: BACWA provided several recommendations for improving the modeling approach for estimating exposure after indoor pesticide uses (and discharges from POTWs), including: “1) Adjust consumer product discharge estimates to reflect geographic and seasonal use; 2) Update per capita water use to reflect today’s conditions and account for conservation; 3) Assume zero dilution; 4) Improve POTW removal estimates and 5) For pesticides likely to partition to sediment, include a biosolids analysis.”

EPA Response: *While EPA appreciates these recommendations, they are not relevant for methomyl or carbaryl because there are no registered indoor uses for carbaryl or methomyl. EPA will consider these recommendations for use in future BEs where modeling down-the-drain exposures is relevant.*

Comment 139: California Citrus Quality Council commented: “ We believe that EPA’s use of worst-case scenarios throughout the assessment and the use of overly conservative assumptions accumulate in the analysis in a way that greatly exaggerates the effect of carbaryl on listed and threatened species. One example of EPA’s conservative approach is the construction of its model, which assumes that a vulnerable water body is adjacent to the application site. This scenario would also incorporate a highly conservative estimate of spray drift that would then cause exposure to species in the theoretical vulnerable water body. However, bodies of water are rarely found in citrus production areas where carbaryl is used.”

EPA Response: *The PWC EECs are used to evaluate exposure to listed species that have ranges or critical habitat that are within 30 meters of a use. This is consistent with EPA’s understanding of runoff and that spray drift could occur in a nearby waterbody. If a species range/critical habitat occurs beyond the 30 meters, only spray drift is considered. If bodies of water are rarely found in citrus production areas, then the species range/critical habitat would not overlap with the actual use area and the PWC EECs would not be used in the exposure estimates.*

Comment 140: California Citrus Quality Council commented: “ EPA’s analysis also misrepresents the scope and range of species and habitat to include areas as large as whole states. California is a geographically diverse state that has several mountain ranges, coastline, deserts, rivers, wetlands, estuaries, grasslands and forests. If the habitat of each species is estimated to be the size of the entire state, then the methodology would assume that carbaryl applications on citrus would affect all the species in each of these habitats. This scenario is highly unlikely, if not impossible.”

EPA Response: *EPA relies on the Services, who are the species experts, when identifying the species location/range data. Species location data for both the range and designated critical habitats are managed by the Services and made publicly available on their website. The species location information provided by the Services define the extent of the species range and all habitats within the range are considered. The habitat analysis completed for the some of the species provides information related to the extent of overlap observed for specific habitats within the species ranges. This information is considered in the Weight of Evidence to make effects determinations and is also provided to the Services for consideration in Step 3.*

Comment 141: California Citrus Quality Council commented: “EPA could significantly improve its analysis by defining the species that are present in areas where applications occur. This could be achieved by overlaying accurate county level species maps with counties where carbaryl applications occur.”

EPA Response: EPA relies on the Services, who are the species experts, when identifying the species location data. When completing the spatial overlap analysis these locations are considered in conjunction with where potential use sites occur and usage as defined in EPA's SUUM. The species locations are not specifically refined based on known applications but this does inform the result of the spatial analysis.

Comment 142: California Citrus Quality Council commented: "Another factor that undermines the accuracy of the carbaryl evaluation is the uncertainty of EPA's estimates. The uncertainty around EPA's estimates is measured by the strength of evidence assigned to its classification of likely to adversely affect estimates. Ninety percent of the Agency's likely to adversely affect estimates for species and critical habitat are based on weak or moderate evidence. These classifications strongly suggest that EPA does not have a clear picture of carbaryl's effect on endangered species or habitat. EPA could improve the confidence of its estimates by refining the analysis to include more realistic inputs regarding use rates, spray drift and more accurately matching use sites to species overlay maps."

EPA Response: The Services indicate for the purpose of the BE analysis the best available species location information is the publicly available data on ECOS for U.S. Fish and Wildlife species and on the NOAA's National Marine Fisheries website for National Marine Fisheries Service species. EPA relies on the Services when identifying the species location data. As new BEs are conducted, they will incorporate the best available information, including updated ranges developed by the Services. For Step 1 and 2 of the BE, EPA leveraged publicly available national level datasets for the UDLs. In circumstances where additional refinement is warranted, incorporation of other data may allow for greater precision and refinement of assessments later in the process. In the future, EPA may consider using other sources of data or databases, with input from the Services. The classification of determinations as weak or moderate often helps to characterize the uncertainty in some effects. EPA integrated typical use rates and spray drift label instructions into the analysis.

Comment 143: California Citrus Quality Council commented: "EPA's estimates are also structured to determine carbaryl's effect on an *individual* in a species population. The Agency evaluates the impact on individuals using factors such as mortality and sublethal effects; the impact of percent crop treated; population rates; pesticide toxicity; species range data; pesticide use data; incident reports; habitat exposure and spray drift. Using such a broad scope of factors to assess the impact of carbaryl is much more likely to affect an individual than many individuals in a given population. We believe the decision to focus on individuals is an overly conservative standard, since the vast majority of endangered species populations are not substantively harmed by the loss of a single individual."

EPA Response: As discussed in the Revised Method document, EPA's BEs consider the potential for impacts to an individual of a listed species, while the Services' Biological Opinions consider the impact of the pesticide on listed species populations (and designated critical habitats). As described in the consultation handbook,¹¹ "may affect" is "the appropriate conclusion when a proposed action may pose any effects on listed species or designated critical habitat." The handbook later states: "An effect exists even if only one individual or habitat segment may be affected."

Comment 144: Northwest Horticultural Council commented "Carbaryl usage patterns vary between crops and geographic regions where crops are grown. Usage variations are found within the same crop depending on pest complex being managed, weather, soil conditions and other variables. The NHC urges

¹¹ Available online at: https://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf

EPA to consider incorporating state-level usage data. The Washington State Department of Agriculture regularly surveys typical pesticide usage in tree fruit crops in Washington state. Actual and potential exposure of species of concern, both spatially and temporally, would also be better represented by working with state partners.”

EPA Response: *EPA has quantitatively estimated pesticide usage and refined exposure estimates based on the best available usage data at the state-level, if available, using those data that meet EPA quality standards. Washington State Department of Agriculture usage surveys are conducted in a way that provides characterization that may have qualitative value for some crops, but EPA is not able to use these data in a quantitative way.*

Comment 145: The Strategic Solutions Team commented:

“The consequences of sequentially consulting on registration actions that are evaluated individually and in isolation is a main concern related to the current pesticide registration Section 7 consultation process. This can result in a lack of coordination regarding both the environmental consequences of registration actions and the benefits of associated conservation actions. When considering the draft carbaryl BE (March 2020), 1,745 listed species are identified as having ranges within the action area. In the effects determination, step one eliminates 4 species from further evaluation via “no-effect” determinations, while step two identifies another 199 species that EPA determines are not likely to be adversely affected, resulting in a total of 1,542 species (86%) advancing for consultation. EPA thus passes the baton by handing off the bulk of the species to the Services with no guidance for equating the EPA-identified outcomes to an assessment of biologically relevant population-level change estimates for those species, or for relating them to other pesticide consultations involving the same species and action area.”

EPA Response: *EPA’s BEs are intended to narrow the list of species to those with potential impacts to one or more individuals. In the Biological Opinion, the Services consider effects of the assessed pesticide on listed species populations, in addition to other factors influencing those populations (e.g., registration of other pesticides, existence of conservation measures).*

Comment 146: Responsible Industry for a Sound Environment commented: “The Agency has made efforts to incorporate some usage data for specialty use patterns in the carbaryl BE (methomyl’s non-agricultural uses are extremely limited, so we do not address them here). However, EPA still makes several assumptions about specialty usage for carbaryl in lieu of incorporating real usage data into the BE. For example, EPA estimates the average number of treated acres for developed land, open space developed land, right-of-way, and nursery use by “taking the number of lbs [sic] applied and dividing by ½ [sic] of the maximum application plus the minimum application rate,” as stated in the BE. The Agency says it chose to use one-half of the maximum application rate because most average applications reported in the SUUM are half of the maximum application rate, but the data it used to determine this are not readily available for review.”

EPA Response: *The usage data from the SUUM indicating most average applications are half of the maximum is available in Appendix 1-4. The appendix citation has been added to the statement for clarification in the final BE. The non-crop PCT estimates were also updated for the final BE. Available pesticide usage data are based on surveys of growers and/or other user groups and is not exhaustive of all usage. For this reason, an update made for the final BE set the lowest possible PCTs at 2.5%. PCTs below this value are rounded up to 2.5% to buffer against uncertainty associated with these surveys and low usage estimates. The surveys utilized by EPA are designed to be statistically robust, but by definition*

sample the target populations rather than provide a complete accounting of all pesticide usage. Therefore, PCT estimates resulting in values below 2.5% are generally a good indicator of limited usage of an active ingredient but by using 2.5% the PCT accounts for possible usage not captured by the survey data. Following the update, the PCTs for the residential area are set at this lowest possible value of 2.5%.

Comment 147: Responsible Industry for a Sound Environment commented: “The equation EPA uses to identify the average number of treated acres for these uses of carbaryl is not grounded in data about how the products are typically applied, and it appears to be arbitrarily chosen to ensure an overestimate of how much product is applied. The Agency does not appear to consider certain scenarios common to non-agricultural applications; for example, many non-agricultural uses of carbaryl are spot treatments and do not pose the same risk of exposure to listed species, nor would they normally be applied at high rates across wide areas. Likewise, though some developed areas may be within listed species’ historical ranges, this does not mean the species are likely to live in the locations where spot treatments are commonly made (e.g. residential areas).”

EPA Response: *EPA considers all labeled uses as part of the BE and determines if a species overlaps with the potential use sites, based on the species location information provided by the Services, and the Use Data Layer. If a use is a spot treatment, this is taken into consideration when developing the UDL, and developing the exposure area for the use. When conducting the overlap, certain species life history information is taken into consideration, such as if the species is expected to occur on non-crop sites like residential, right of way and forested areas. These on/off site determinations were developed in consultation with the Services.*

Comment 148: FIFRA Endangered Species Task Force (FESTF) commented: “Also, there are inconsistencies in the assignment of labeled uses to CDL and UDLs, such as Grapes assigned to both the “Vineyards” and the “Other Orchards” UDL in the draft BE for carbaryl (see Appendix 1-6)”

EPA Response: *These errors have been corrected for the final BE.*

Comment 149: NovaSource/Tessenderlo Kerley, Inc. commented: “The executive summary needs a complete discussion of the uncertainties and assumptions presented in the BE.” They later added: “The analysis should include a detailed “assumptions and uncertainties” section that allows the reviewer to better understand the cumulative effects of additive conservatism (increased lack of realism) used throughout the assessment.”

EPA Response: *The draft BEs follow the Revised Method. The document describing the Revised Method includes the method’s major assumptions and uncertainties and conservatism of the approach. The MAGtool characterizes species-specific influences of uncertainty and conservative assumptions using strength of evidence.*

Comment 150: NovaSource/Tessenderlo Kerley, Inc. commented: “While carbaryl may have some structural similarity to plant auxins, effects data clearly show that plant sensitivity to carbaryl is very low at or near maximum and typical use rates.”

EPA Response: *The Effects Determination is based on the measured toxicity endpoints for plants and the toxicity data for aquatic and terrestrial plants are clearly described in the BE.*

Comment 151: NovaSource/Tessenderlo Kerley, Inc. commented: “The risk characterization for many species and use patterns was effectively lost in the analysis because the risk characterization was ultimately made across all use patterns combined into a single spatial footprint. If a potential exposure to a single individual of a single species was estimated for any single use pattern, an LAA for that species was concluded and analysis for that species did not continue.”

Also: “The BE evaluates combined potential risks of all pesticide products containing carbaryl into a single assessment. This makes it impossible to assess the potential risk contribution of an individual label or use pattern to a species and as such an Applicant’s ability to address potential risks identified in the BE. Additionally, the final BE is designed to be the starting point for the United States Fish and Wildlife Service and National Marine Fisheries Service (the Services) to develop Biological Opinions (BOs) for carbaryl. Presenting a use pattern/species specific evaluation summary in the BE is critical for the Services to understand initial potential risk to individual labels and uses so that an evaluation of potential impacts to species populations can be made more effectively and efficiently.”

EPA Response: *EPA’s draft BE for carbaryl considered the potential exposure and risk of the sum of all uses of carbaryl on each listed species and designated critical habitat. This includes the uses from all formulated products containing carbaryl. The impact of each UDL on the effects determination is carried through the entire analysis. For species that are determined to be LAA through the weight of evidence analysis, the relative contribution of each UDL to the effects determination is presented, based on the potential number of individuals predicted to be impacted. The impact of any UDL on a determination includes the consideration of the overlap of the UDL with the species range, the application of usage data specific to the chemical and UDL, application rates and methods associated with the UDL as well as the potential for a species to use the UDL for habitat or foraging. This information is provided to the Services where it can help inform the predominant risk drivers overall (e.g., non-agricultural vs agricultural use sites) or for any particular use site. Summary tables of the UDL risk drivers are included in Chapter 4, as well as Appendix 4-1 in greater detail, and finally in the individual species weight of evidence output sheets (Appendix 4-9).*

Comment 152: NovaSource/Tessenderlo Kerley, Inc. commented: “Spray drift estimates do not account for interception in potential exposure scenarios where the listed species habitat is located; for example, a plant that is found only in forested areas that may be in proximity to an action area.”

EPA Response: *EPA agrees that interception is not quantitatively accounted for in the spray drift estimates. For those species with habitats that are only in forests and for those chemicals where forestry applications are not allowed, EPA assumed that there would be a limited exposure due to interception of spray drift.*

Comment 153: NovaSource/Tessenderlo Kerley, Inc. commented: “It is excessively conservative and not realistic to assume that a 100% of a species prey base will be proximate to a carbaryl use site.”

EPA Response: *If additional information is available to refine this assumption, EPA may consider alternative approaches. EPA notes that this assumption is more realistic for species with small home ranges.*

Comment 154: NovaSource/Tessenderlo Kerley, Inc. commented: “It is not realistic to assume a listed species’ prey items will be exposed to maximum exposure values resulting at maximum residues such that the entire prey community will be impacted.” They added: “There is an assumption that a wildlife

species might consume a food item at maximum residue levels (*i.e.*, directly after application) - this is not realistic at an individual nor at a species population level given the time dependency of exposure concentration and wildlife consumption rates.” They also commented: “Dietary residue values applied in the BE are excessively conservative and generated using assumptions that are not scientifically defensible and do not reflect listed species movement in the environment (*i.e.*, spatial averaging).”

EPA Response: *For terrestrial organisms, EPA assessed risks associated with maximum exposures, presumably associated with high end concentrations at a given location at Step 1. In Step 2, the BE also considered exposures to residue values representing a central estimate of exposure (i.e., Mean Kenaga) and these exposure estimated were considered in the weight of evidence. Average estimates of exposure may represent exposures from different locations where exposure may occur.*

Comment 155: NovaSource/Tessenderlo Kerley, Inc. commented: “Spray drift assumptions used in the BE are highly conservative and do not reflect actual application methods, logistics (*e.g.*, wind direction, canopy, topography), timing of mobile species presence, and many other factors.”

EPA Response: *The spray drift assumptions reflect the application methods and spray drift requirements specified on the labels.*

Comment 156: NovaSource/Tessenderlo Kerley, Inc. commented: “Data quality and relevance appears to be an issue for key threshold studies.” Specifically, “Based on the lack of information and analytical confirmation in the Toumi *et al.* (2016) study, is it impossible to determine the actual exposures that occurred in the study, or reproduce the study design. Therefore, it is impossible to extract reliable effects endpoints from the study. The inconsistency in results compared to other *Daphnia* chronic studies further call into question the validity of that study. **These issues represent major study deficiencies that would, and should, invalidate the study for use in regulatory pesticide risk assessment.**”

EPA Response: *Toumi et al. (2016) found a 48-hr EC50 of 7.47 µg/L while, as TKI points out, another study using the same clone found a 48 hr EC50 of 12.47 µg/L – these endpoints are similar and this kind of variation in lab studies is expected. Furthermore, Toumi et al. (2016) also references a study conducted with 99.5% technical grade active ingredient carbaryl which resulted in an even lower 5.6 µg/L 48 hr EC50 in *Daphnia* (see Table 3). Variation is expected in toxicity studies and is not indicative of issues with the culture or test system.*

*Toumi et al. (2016) cites OECD 211 as its guideline for the chronic test. EPA has reviewed this study and found that the chronic study meets the validity requirements for this test guideline. Those guidelines state that for the test to be valid the mortality of the parent animals in the control(s) (female *Daphnia*) cannot exceed 20% and the mean number of living offspring produced per parent animal surviving in the control(s) at the end of the test is >60.*

As noted by TKI, the article by Toumi et al. (2016) does not describe analytical verification of carbaryl in the test. The lack of analytical verification does not impact our confidence in the study due to the use of technical grade active ingredient carbaryl that was >98% pure, as well as the fact that renewals of solutions occurred every 2 to 3 days (3 times per week). There is an expectation that carbaryl will be sufficiently persistent over a 2 to 3 day period because carbaryl’s hydrolysis half-life at pH 7 is 12 days, and its aerobic aquatic metabolism half-life is 4.9 days.

Furthermore, in researching endpoints to use as thresholds for the biological evaluations, EPA has sought the most protective endpoints. Other evidence to support this endpoint includes the fact that in carbaryl's 2010 problem formulation, a chronic aquatic invertebrate endpoint was estimated using an acute to chronic ratio and the resulting endpoint was 0.5 µg/L, a value in the same range as the endpoint found by Toumi et al., (2016). Other endpoints available for evaluation of the effects of carbaryl on aquatic invertebrates include a NOAEC of 1.5 µg a.i./L (with an associated LOAEC of 3.3 µg a.i./L) based on a significant reduction in the number of offspring (MRID 150901). However, this study does not represent the most sensitive, reliable endpoint for assessing the risk of carbaryl to aquatic invertebrates because of the endpoint found by the Toumi et al., (2016) study.

Comment 157: NovaSource/Tessenderlo Kerley, Inc. commented: "The effects thresholds selected in the BE are by nature extremely conservative. Laboratory studies do not compare well with the exposure that occurs in the environment given species mobility, the spatial and temporal variability in actual carbaryl applications, and the variability in tolerance of species being evaluated."

EPA Response: *EPA agrees that the thresholds are conservative representations of the available data. EPA also considers other available toxicity data. For acute toxicity data, EPA uses the LC/LD50 data and associated slope to account for variability in tolerances among individuals. EPA also accounts for variability in exposure and typical application rates as part of the weight of evidence. The comment noted some factors that could overstate exposure or toxicity; however, there are also environmental factors and stressors that increase the vulnerability and sensitivity of species to toxic effects to these pesticides in natural environments.*

Comment 158: NovaSource/Tessenderlo Kerley, Inc. commented: "As EPA notes in the BE, bivalve mollusks are tolerant of carbaryl. The diversity of non-mollusk aquatic invertebrates tested clearly indicates that these species vary considerably in carbaryl tolerance. This variability indicates that the BE is highly conservative in its selection of effects thresholds for most aquatic invertebrate species."

EPA Response: *Values selected as thresholds represent the most sensitive available chronic toxicity, or "the endpoint that results in the farthest distance from the treated field where any direct or indirect effect may occur relative to a specific species will be used to determine the Action Area for the species". Therefore, the threshold is expected to be more conservative than the broader range of toxicity within a taxa – it is meant to be a protective value. Also, HC₀₅ values determined from species sensitivity distributions (SSDs) were used to determine acute thresholds. SSDs are composed of all available usable acute toxicity data for a given taxa, and thus reflect a wide range of toxicity. Furthermore, separate SSDs were assembled (and HC₀₅ values determined) for mollusks and non-mollusks to best reflect the diversity in the toxicity ranges between these two groups.*

Comment 159: In regard to chapter 3 of the draft carbaryl BE, NovaSource/Tessenderlo Kerley, Inc. commented: "TKI would like to highlight that improvements/corrections need to be made prior to finalization:

- Update the aerobic aquatic degradation input value;
- Utilize the airblast application method drift assumptions for orchard crops whenever they are identified as "ground" in the assessment application method; and,
- Consider modeling other low drift methods when typical practice may employ those methods to provide the assessor a full range of exposure options to select based on local conditions. Reference Appendix 1-4 Table 1 for percent applied by air for each use pattern / state combination."

EPA Response: EPA updated the calculated degradation kinetics using the most up to date methodology¹² and also considering MRID 46580701/ 46580702. The updated aerobic aquatic metabolism input is documented in the updated Chapter 3 and is 18. Hydrolysis varies from stable to 3.2 hours at pH 9. Measured aerobic aquatic metabolism half-life values vary from 2 to 18 days, with higher stability at lower pH. It is reasonable that the aerobic aquatic metabolism half-life may vary within the range of measured values of hydrolysis and aerobic aquatic metabolism studies. This updated model input would have a relatively small impact on estimated environmental concentrations (EECs) that were calculated in the previous BE. Aquatic modeling was updated to reflect the updated aerobic aquatic metabolism input value.

EPA agrees that carbaryl will most likely be applied via airblast to orchards. Therefore, orchard modeling was updated to reflect airblast applications for citrus, orchards, and grapes.

EPA agrees that it would be informative to understand the potential risk with alternative spray drift assumptions; however, the number of items varying creates confusion in understanding results. In the risk mitigation phase, additional modeling may be completed to support decision making as needed.

Comment 160: NovaSource/Tessenderlo Kerley, Inc. commented: The following language should be included in chapter 3.

“The aquatic modeling conservatively assumes that the waterbody abuts the treated area. As such, any reduction in loading from runoff that could occur as the result of managed vegetative filter strips or unmanaged naturally-occurring interfaces between treated areas and waterbodies are not taken into account.”

- “Regional differences in exposure are assessed using regionally-specific PWC scenarios (*e.g.*, information on crop growth and soil conditions) and meteorological conditions at the HUC 2 level (Section 3.3. Scenario Selection). The information used in these scenarios is designed to reflect conditions conducive to runoff. In instances where PWC scenarios do not exist in a HUC 2, surrogate scenarios from other HUCs are used. For fields where agricultural practices that result in less conservative scenario parameters are employed (*i.e.*, conditions less conducive to runoff and pesticide loading of waterbodies), the potential for lower EECs would be expected.”

- “It is acknowledged that a watershed/basin-scale model capable of evaluating the impact of pesticide and water transport at the field-scale and aggregating these loadings to waterbodies at the larger watershed-scale is needed to evaluate these flowing aquatic systems.”

EPA response: The first quote is already included in the uncertainties section of Chapter 3. The current uncertainty language in Chapter 3 already covers the other two recommended discussion items.

Comment 161: NovaSource/Tessenderlo Kerley, Inc. commented: The use of the edge of field concentration for small waterbody environments introduces a new approach that leads to high concentrations that assume a proximity of field to focused habitat which are only relevant when those

¹² USEPA. 2015. *Standard Operating Procedure for Using the NAFTA Guidance to Calculate Representative Half-life Values and Characterizing Pesticide Degradation. Version 2.* March 23, 2015. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://www.epa.gov/sites/production/files/2015-08/documents/ftt_sop_using_nafta_guidance_version2.pdf.

conditions are met. The analysis and use of species habitat data do not support the application of this approach to all species simply because a bin 2 or bin 5 assignment has been made generally.

EPA Response: *Species have been assigned to bin 2 or 5 by the Services using analysis of the species habitat. If the species range or critical habitat is within 30 meters of a use, then the edge of field EECs are applicable, as these waterbodies are very small and can be easily overwhelmed by runoff from a field. If a species range/critical habitat occurs beyond the 30 meters, only spray drift is considered. It should be noted that the MAGtool uses all of the aquatic bins a species is in, along with other scaling factors, to probabilistically estimate to what a species may be exposed.*

Comment 162: NovaSource/Tessenderlo Kerley, Inc. commented: The noted reference for tools for aquatic modeling does not include all that is required to verify the modeling work. TKI was able to verify results after some level of investigation. The general tool reference provides part of the material an expert user needs to conduct this type of modeling, but it would add clarity to also reference the new tools used for this assessment found at <https://www.epa.gov/endangered-species/models-and-tools-national-level-listed-species-biological-evaluations-carbaryl#Aquatic>. Once comments are addressed and processes upgraded, the tools should be made available in a user-friendly and transparent way as users may want to evaluate impacts of their new uses or evaluate the impact of conservative assumptions or potential label language modifications.

EPA Response: *EPA assumes that the “noted reference” cited in the comment refers to Attachment 3-1, Background Document Aquatic Exposure Estimation for Endangered Species. EPA developed this reference to provide a background on how the aquatic bins, PWC scenarios, and the conceptual model for aquatic exposure were developed, not as a means for an expert user to do the actual modeling. The tools themselves have Read Me worksheets that explain the function of the tool and how to use them. The tools are currently in Excel, such that the visual basic or Python code is accessible.*

Comment 163: NovaSource/Tessenderlo Kerley, Inc. commented: Aquatic modeling in a HUC2 regions should be limited to areas where species or habitat are located.

EPA Response: *EPA agrees that ideally, aquatic modeling specific to species location and habitat would allow for a more refined understanding of whether effects are likely to occur. However, the tools needed to conduct this high-level assessment are not developed and available for this analysis.*

Comment 164: NovaSource/Tessenderlo Kerley, Inc. commented: Section 3.3 indicates that PWC scenarios were developed for each landcover class and HUC2, but Attachment 3-1 (Table 3) clarifies that standard scenarios were assigned, not developed, for this important work. In many cases, a scenario is applied to multiple HUC areas.

EPA Response: *Attachment 3-1 discusses how PWC ESA scenarios were developed and while one standard PWC scenario may have been utilized as the basis for multiple HUC2 regions, weather files specific to each HUC2 regions were utilized in combination with the previously developed PWC scenarios. Thus, HUC2 specific PWC ESA scenarios were developed and utilized in modeling.*

Comment 165: NovaSource/Tessenderlo Kerley, Inc. commented: It was recommended that EPA utilize the newly EPA released methodologies for generating PWC ESA scenarios titled "Creating New Scenarios for Use in Pesticide Surface Water Exposure Assessments" and "Estimating Field and Watershed Parameters Used in USEPA's Office of Pesticide Programs Aquatic Exposure Models – The Pesticide Water

Calculator (PWC)/Pesticide Root Zone Model (PRZM) and Spatial Aquatic Model (SAM)". When scenarios are developed, weather files specific to the location of the species habitat should be utilized in the assessment.

EPA response: *EPA is in the process of creating PWC scenarios for use in ecological risk assessments, utilizing the methods recommended by TKI, and will utilize those for ESA modeling when they become available and the tools for the ESA methods have been updated to utilize the updated PWC results.*

Comment 166: NovaSource/Tessenderlo Kerley, Inc. commented: The relevance of the paddy/in bog concentration can only be evaluated by determining the actual likelihood that the listed species under evaluation is likely to visit that type of environment. The tools provide concentrations in-paddy but also produce EECs for outflow to receiving water and the species biology should inform the source of concentration and relevance.

EPA Response: *EPA agrees with TKI and utilizes the aquatic bins to determine which waterbodies are relevant to different species. While water may be released from cranberry bogs and rice paddies into adjacent waters, a conceptual model for simulating this has not been developed. Thus, the in-paddy or in-bog concentrations are utilized as a surrogate. The PFAM results were calculated and found to be within the range of EECs calculated using the PWC for the aquatic bins. Therefore, the PFAM results for cranberries are only utilized for characterization purposes. The PFAM results for rice were incorporated into the MAGtool.*

Comment 167: NovaSource/Tessenderlo Kerley, Inc. commented: The full distribution of EECs should be utilized in the exposure assessment. While the appendices and result files provide daily values, the peak exposures do not represent the full time-distribution of exposure available, the length of time of potential exposure, and a chronic exposure. With flow and degradation, concentrations are predicted to be significantly reduced over time as the peaks represented in this summary are short lived.

EPA response: *While the full distribution of EECs can provide characterization of the level of potential exposure in a waterbody, it is dependent on a number of factors (application date and method, meteorological data, etc) such that concentrations in the waterbody at times much later than when the application was made may not reflect that which a species is exposed. To be protective of the listed species, the 1-in-15 year daily exposures are used to quantify potential exposure in risk assessments, with other values provided as characterization in appendices and used in the MAGtool and weight of evidence analysis. With the amount of data and complexity of the assessment it is not possible to go into in depth descriptions of all data and distributions in the body of the document.*

Comment 168: NovaSource/Tessenderlo Kerley, Inc. commented: Monitoring data collected between 1973 to 2018 are summarized in the document. TKI believes measured exposure concentrations can be utilized in the assessment as a supporting line of evidence to provide context for the modeled EECs. TKI asserts that with the historical high level of usage and monitoring during the similar time frame, that the low level of detections suggests that this demonstrates low level of detections. Monitoring data obtained prior to the registration eligibility decision (RED) should not be utilized in the assessment. Thus, only data collected after 2007 should be utilized in the upstream exposure analysis.

EPA response: *Monitoring data is used as a line of evidence in the MAGtool and are characterized in Chapter 3 of the assessment. However, as already stated in Chapter 3, the measured exposure may not be utilized to estimate potential upper bound of exposure for many reasons. EPA corrected the 400 µg/L*

highest reported detection value to 335 µg/L as it was a typo. EPA agrees with TKIs recommendation to only utilize monitoring data collected after the RED and implemented this for the updated BE. Some important regulatory changes occurred from 2005 to 2008 with implementation of the re-registration mitigations. Applications to wheat were cancelled, aerial applications of some formulations were no longer allowed, broadcast applications of liquid formulations were cancelled in residential settings, and dust applications in agricultural settings were cancelled^{13,14}. Because these registration changes have the potential to impact concentrations that may be observed in monitoring, only monitoring data collected after 2006 were considered in the downstream analysis and the weight of evidence analysis in the MAGtool (discussed in Chapter 4).

Comment 169: NovaSource/Tessenderlo Kerley, Inc. commented: “TKI does not agree that the TED tool is now capable of predicting the magnitude of effect at a population scale. Although a population size estimate is used and the MAGtool is run to evaluate the potential effects to one or more individuals in this population, estimating how many individuals may be affected (exposure vs. effect) out of an assumed population size in the TED/MAGtool is not a population level analysis. The approach used in the BE is far too conservative and does not provide the information necessary to say anything about the magnitude of impact or viability of the listed species population”

EPA Response: *As part of the output of the MAGtool, EPA provides an estimate of the number of individuals potentially impacted based on the use of the pesticide under varying assumptions including different usage estimates, toxicity assumptions and estimated exposure concentrations, including assumptions that move off of the most conservative assumptions. This information is provided to the Services to assist in their own assessment of potential impacts to the population due to the use of the pesticide. The EPA will continue to work with the Services to determine what information is most useful in the BE to assist in a population analysis.*

Comment 170: NovaSource/Tessenderlo Kerley, Inc. commented: “The risk characterization for all species and use patterns was lost in the analysis as the exposure characterization was made using general habitat and use assumptions. The regional approach to aquatic modeling should be viewed as a screening level assessment and tools exist to improve the selection of soils, weather, and agronomic practices that would better represent the species being evaluated.”

EPA Response: *As discussed above, EPA is in the process of developing new scenarios that is intended to make use of more regional soils, weather, and agronomic practices. Once these scenarios have been evaluated and are appropriate for use, EPA will use them for ESA purposes.*

Comment 171: NovaSource/Tessenderlo Kerley, Inc. commented: “The EPA states that “BE methods will continue to evolve and be improved over time,” and lists uncertainties that, if addressed, would improve the assessment. While TKI supports EPA’s continued improvement and refinement of the BE methods, *it is today impermissible to negatively impact the registration of a pesticide due to an immediate lack of*

¹³ USEPA. 2007. *Reregistration Eligibility Decision (RED) for Carbaryl*. EPA-738R07-018. September 2007. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:::1,3,31,7,12,25:P3_XCHEMICAL_ID:1736

¹⁴ USEPA. 2008. *Amended Reregistration Eligibility Decision (RED) for Carbaryl*. EPA-738-R-08-010. August 2008. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:::1,3,31,7,12,25:P3_XCHEMICAL_ID:1736.

analysis methods, an incomplete analysis, or unrealistic findings based on methods that are underdeveloped. A gap in analysis techniques or excessive uncertainty should not result in a default assumption between pesticide use and species impact.”

EPA Response: *EPA believes that the analysis included in the BEs are complete. The BEs rely upon the best available data and make conservative assumptions when needed to address uncertainties in the available data.*

Comment 172: NovaSource/Tessenderlo Kerley, Inc. commented: “Given the ongoing development of the methods and the underlining assumptions used in the BE, it is critical that the following qualifiers found in Chapter 4 of the BE are included at the beginning of the Executive Summary of the Final BE so that stakeholders understand the nature of the conclusions.

- “It is important to note that the output generated is the potential number of individuals that could be impacted (based on the assumptions of the simulation), not a prediction that they will be impacted”.
- “Throughout this analysis, the BE maintains conservative assumptions and may overstate the number of species exposed to and impacted by a pesticide”.

EPA Response: *See response to Comment 149*

Comment 173: NovaSource/Tessenderlo Kerley, Inc. commented: “For any risk assessment to be valuable, screening techniques should allow for species at greatest risk to be highlighted for additional evaluation. Given that the BE concluded a “May Affect” determination for 97% of listed species after Step 1, it is clear that how the final EPA BE methods were applied did not result in an effective screen based on what is reasonably certain to occur, thus the identification and prioritization of listed species and critical habitat potentially at risk failed.”

EPA Response: *This comment presumes that additional species should have been screened out, but does not provide a basis for why 97% of species should not receive May Affect determinations. Since the focus of the BE is on an individual of a listed species and carbaryl has a wide variety of uses, a great deal of usage data, and poses a risk to many taxa, it is possible that this chemical may affect an individual of many listed species. Whether this actually rises to the level of jeopardy for the same number of species has not yet been assessed.*

Comment 174: NovaSource/Tessenderlo Kerley, Inc. commented: “The evaluation of potential risk to a species and the value of potential mitigations measures are not possible for each use pattern given the cumulative nature of the results based on all use patterns.”

EPA Response: *See response to Comment 86*

Comment 175: NovaSource/Tessenderlo Kerley, Inc. commented: “Many assumptions used in the effect determinations are unlikely to occur under realistic field conditions, and do not provide an adequate screen for any future consultation to be conducted with the Services.” They also commented: “While alternative assumptions appear to have been used in parts of appendices (e.g., typical use rates, more realistic use distributions, application methods, and alternate effects metrics), it does not appear they were included in the final analysis.”

EPA Response: *When making determinations, EPA made conservative assumptions to address uncertainty and to be protective of the assessed species. The influences of those conservative assumptions are considered in the MAGtool, where alternative parameter values are selected and estimates of the likelihood of individual effects are calculated. If both the conservative and alternative assumptions arrive at the conclusion that one or more individuals of a listed species may be impacted, there is a greater degree of confidence in the LAA determination. If there is a difference in conclusions when using conservative and less conservative assumptions, EPA has less evidence to support the LAA determination; however, there is still the potential for impacts to an individual under some circumstances.*

Comment 176: NovaSource/Tessenderlo Kerley, Inc. commented: “A “most likely” result for number of individuals impacted from the probabilistic approach was reported in output files. The actual metric this refers to is not described in the BE and was only clarified as being the statistical mode during the April 2020 public meeting when asked directly. The interpretation of mode as a descriptor for a continuous distribution (like number of individuals) is unclear (*e.g.*, there is no way to know if the mode is greater or less than the mean or median), and even potentially misleading. Additional descriptors of the distribution, including median and 5th percentile, should be added to help describe the resulting distribution.”

EPA Response: *EPA has made changes to model to provide additional outputs and more clarification of the output in the documentation. The inclusion of additional outputs will be considered as future method updates are considered and as the EPA works with the Services to determine what information is most useful in the completion of the BiOp.*

Comment 177: NovaSource/Tessenderlo Kerley, Inc. commented: “The significant value of species-specific natural history and habitat information is not realized in this BE Effects Determinations given the gross assumption and lack of a species/use pattern specific analysis (*e.g.*, the likelihood a species would be on or near a use site at the time of applications was not considered). Use of this type of information to support an effect determination is demonstrated in the Case Studies in the Appendix of this document.”

EPA Response: *The case studies presented by TKI provided alternative interpretations of the analysis in the BEs as well as the available species range and habitat information for two species. At this time, EPA doesn't believe that these metrics would change our conclusions on the two species that were the subject of the case studies. EPA will continue to consider this proposal, along with other proposals submitted as public comments, as we continue to improve the consultation methodology in this iterative process.*

Comment 178: NovaSource/Tessenderlo Kerley, Inc. commented: “Risk bounds should be provided in the final BE for each species/use pattern combination by applying typical use rates, average use distributions, average PCT, and a range of PPHD thresholds (*e.g.*, community level HC25).

Effects determinations should be made separately for range, critical habitat, and suitable habitat to have an appropriate view of potential exposures and potential risk to individuals of a species. A “strength of habitat” designation could be employed to better consider the spatial use footprint relative to species habitat suitability to improve and focus conservations efforts.”

EPA Response: EPA already considers many of the factors suggested in this comment, and EPA already makes determinations for a species and its critical habitat and has considered suitable habitat for a subset of species. EPA will continue to consider suggestions as part of our efforts to improve our assessments in this iterative process and in consultation with the Services as the consultation process evolves.

Comment 179: NovaSource/Tessenderlo Kerley, Inc. commented: “There appear to be several hundred species/use pattern combinations in which data in MAGtool WoE output tables indicate what could be theoretical “No Effect” or “Not Likely to Adversely Affect” determinations at the species-use pattern level (Chapter 4, Appendix 4-9). This should be highlighted in the final BE for clarity and prioritization.”

EPA Response: EPA does not make effects determinations on a use-specific basis, rather on the registration of the active ingredient for all labeled uses. However, as noted, output generated from the analysis can allow EPA and the Services to focus on use sites that appear to be more significant risk drivers for listed species.

Comment 180: NovaSource/Tessenderlo Kerley, Inc. commented: “The species ranges used in the assessment are often dated, with species locations based on historical ranges that are no longer relevant to the species. Refined ranges and a weighting towards critical habitat or suitable habitat are needed in the WoE analysis.”

EPA Response: The Services have indicated that, for the purposes of the BE analysis, the best available species location information is the publicly available data on ECOS for U.S. Fish and Wildlife species and on the NOAA’s National Marine Fisheries website for National Marine Fisheries Service species. As the species experts, EPA relies on the Service when identifying the species location data.

Comment 181: NovaSource/Tessenderlo Kerley, Inc. commented: “The BE appears to quantify the proportion of the species range on Federal lands; however, this does not appear to have been used in the WoE or in any conclusions.”

EPA Response: EPA reports the species overlap with Federal Lands in the weight of evidence output to be used if needed when a species is evaluated. As described in the March 2020 response to comments on the Revised Method, the existence of a species on Federal Lands by itself is not a factor used to make an NLA determination. The EPA will continue to work with the Services on how to refine the consultation process for species largely on Federal Lands.

Comment 182: NovaSource/Tessenderlo Kerley, Inc. commented: “The WoE approach was not effective as the analysis was not conducted at the species/use pattern level (i.e., the cumulative nature of the assessment discounts the utility of any WoE approach).”

EPA Response: EPA reports output in the weight of evidence on a species-specific basis, along with the impacts due to each UDL, impacts due to drift, and if effects are predicted based on mortality, sublethal effects or effects to the species PPHD.

Comment 183: NovaSource/Tessenderlo Kerley, Inc. commented: “Risk reduction or qualifying factors for lines of evidence indicating likely reduced risk should be included in the WoE approach (see examples of this approach in the Case Studies at the end of this document):

- A risk reduction factor for species that clearly spend little or no time in habitats associated with a treatment site type.
- A risk reduction factor for species where life history (*e.g.*, migration, burrowing, elevation) mitigates exposure potential.
- A risk reduction factor for species in which the principal stressor (*e.g.*, habitat loss) driving their listing status is clearly not a pesticide.
- A risk reduction factor for ranges that likely overestimate current species range.
- A risk reduction factor for uncertainties that significantly reduce the likelihood of species exposures (*e.g.*, wind not always blowing during application, wind not always blowing towards habitat during application, drift reduction potential via canopy or topographic intercept).
- A risk reduction factor for drift-reducing technologies and methods employed for each use.
- A risk reduction factor for species with all or part of its range on Federal lands or other highly protected state or private lands.”

EPA Response: *Many of these factors are more appropriate to be considered during the biological opinion or RPA development. Other factors do not lend themselves to derivation of risk reduction factors or are not appropriate to serve as the basis for effects determinations. EPA believes that the factors considered currently in its weight of evidence are appropriate; however, EPA will continue to consider these suggestions as part of our efforts to improve our assessments in this iterative process and in consultation with the Services.*

Comment 184: NovaSource/Tessenderlo Kerley, Inc. commented on MAGtool: “Most of the analysis was conducted using the MAGtool and Crystal Ball software. The input, processing, and output data are buried within layers of spreadsheets with some data apparently not used (see EPA comments in Methods document). This makes the understanding and review of the overall analysis impossible for even the most experienced ecological risk assessor. This is exacerbated by the limited time available to review documents, models, and outputs. The MAGtool v2.1 user guide is more of an overview document and does not provide adequate information to successfully understand, review, and run the model. The user guide needs to be significantly expanded for this to occur. This is also true for the Crystal Ball tool and analysis. Units are not included in multiple modeling spreadsheets and summaries making it difficult to understand inputs, the analysis, and outputs. Data used in the assessment tools are not well-referenced which does not allow the reviewer to track and understand source data.”

EPA Response: *The MAGtool has continued to undergo revisions as the method has evolved and updates have been made including stakeholder feedback. For the final carbamate BEs, substantial changes were made to streamline the tool. Additional documentation has also been provided. Improvements will continue to be made based on method revisions and user feedback.*

Comment 185: NovaSource/Tessenderlo Kerley, Inc. provided three case studies involving species specific determinations for carbaryl.

EPA Response: *The case studies presented by TKI provided alternative interpretations of the analysis in the BEs as well as the available species range and habitat information for two species. At this time, EPA doesn't believe that these metrics would change our conclusions on the two species that were the subject of the case studies. EPA will continue to consider this proposal, along with other proposals submitted as public comments, as we continue to improve the consultation methodology in this iterative process.*

5. Summary of Comments Specific to the Draft Methomyl BE

Comment 186: “USDA examined active Section 3 labels for formulated methomyl products for statements that reduce environmental impacts. Such existing mitigations may be protective of listed species and critical habitat and are summarized here to assist in development of further mitigations”

EPA Response: *EPA appreciates the summarization of label information to assist in the development of mitigations. While spray drift advisory language is not enforceable and therefore cannot be used in modeling, the PWC exposure modeling does account for the inclusion of spray drift ground and aerial buffers.*

Comment 187: USDA provided methomyl usage data for the Glassy Winged Sharp Shooter program in Kern County, California.

EPA Response: *EPA thanks USDA for the additional usage data for methomyl used against Glassy Winged Sharpshooter.*

Comment 188: California Fresh Fruit Association requested “that methomyl continues to be a registered chemical available for agricultural application, particularly for pomegranates. Pomegranates have an especially narrow spectrum of integrated pest management (IPM) tools available for use.”

EPA Response: *If there is no overlap of the use on pomegranates and species ranges/critical habitats, then EPA and the Services should be able to minimize the impact to growers. If there is, then the Services and EPA can work with the growers to reduce the impact of this overlap as appropriate. While Section 7 of ESA does not allow for consideration of the benefits of a pesticide, EPA will consider this comment when making a FIFRA decision and to help inform appropriate mitigations.*

Comment 189: The Washington State Potato Commission commented: “Methomyl is an insecticide with a broad-spectrum activity that is judiciously used by Washington potato growers, particularly to treat their crop when several insect pests impact it simultaneously. It has good to excellent activity against 7 of the 10 major insect pests of potato in Washington. It is also important should Colorado potato beetle (CPB) develop resistance to insecticides with other modes of action, a property that is extensively documented for this insect. CPB has the potential of destroying entire fields early in the season. It is important that our growers have access to a wide selection of products with different modes of action to manage insect pests that develop resistance to one or more insecticide modes of action.”

EPA Response: *While Section 7 of ESA does not allow for consideration of the benefits of a pesticide, EPA will consider this comment for FIFRA decisions.*

Comment 190: Corteva commented: “In the draft methomyl BE the pasture/hay/forage UDL was often identified as the driver for potential risk in Step 2. This is primarily a result of the use on alfalfa being aggregated in the pasture/hay/forage UDL. In the SUMM (Appendix 1-4), use on alfalfa for methomyl was listed for only five states (AZ, CA, KS, OK, and PA), with 24 other states reporting no use. Yet listed species such as the Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*, species #85 in WoE range animal bird spreadsheet) or Garber's spurge (*Chamaesyce garberi*, species #663 in WoE range terrestrial plant CONUS 2 spreadsheet) with ranges entirely in Florida, were given LAA determinations resulting from the pasture/hay/forage UDL, even though there was no use reporting for Florida in the SUMM. Indeed, an examination of NASS statistics indicated there were no acres of alfalfa grown in Florida. From even these simple lines of evidence, which utilize the best available data, the possibility of methomyl exposure is likely *de minimus*.”

EPA Response: EPA agrees that usage was reported in the SUUM on alfalfa for 5 states with 24 reporting no usage. Florida was not one of the states reporting no usage, meaning this state was not surveyed for usage on alfalfa. When a crop was not surveyed, a surrogate usage value was applied. The Revised Method describes the process for selecting the surrogate usage value. The final BEs include updates to the pasture UDLs, used for alfalfa. Cultivated grasses and grasses crops, as identified in USDA Cultivated Layers are included in the new Alfalfa UDL made up of crops like alfalfa, switchgrass, and Vetch. This update provides greater refinement to where alfalfa and other harvested grass/hay crops are grown. Additional information on these updates will be available in the final BE in Appendices 1-5 and 1-6.

Comment 191: Corteva commented: “There is also a very minor use on Bermuda grass pasture for which the Agency defines a UDL stretching across the southern latitudes of the US (Figure 2). The Bermuda grass UDL was not identified as one of the major sources of overall risk, but was associated with potential impact on a few species. A simple inquiry about this use pattern could have served as a convincing line of evidence to indicate low risk from this use pattern.”

EPA Response: For the final BE, the Bermuda grass UDL has been updated to reflect areas where cultivated grasses grow as defined in USDA's Cropland Data Layer (CDL) and limited to latitudes where warm season grasses occur. This update more clearly defines where Bermuda grass is likely to grow. Due to the fact that UDLs are not independent from each other, species impacted by Bermuda grass are likely also impacted by other uses. Low overlap with a single UDL may not indicate low risk to the species. Species impact by the Bermuda grass UDL will also be impacted by the new alfalfa UDL.

Comment 192: Rotam commented that usage “data should be used as a key line of evidence in the BE for Methomyl. The data provide a baseline of likelihood of use that should be expressed probabilistically for use in the BE.”

EPA Response: EPA agrees that usage data are important to determine the likelihood that an individual of a listed species may be exposed and has incorporated these data into the Step 2 analysis for methomyl. Several probabilistic methods have been proposed (e.g., see Crop Life America case study). At this time, EPA has not established a probabilistic method for applying usage data, but evaluates several possible scenarios regarding the extent that usage occurs within a species' range. EPA believes that this analysis provides appropriate bounding with respect to the influence of usage data on the effects determination. Nonetheless, we will continue to consider these suggestions as the consultation process evolves.

Comment 193: Rotam commented: “Some toxicity endpoints for freshwater and saltwater fish were taken from studies with maintained exposures lasting 35 to 36 days. Under these conditions non-lethal effects were noted at 145 and 490 ppb for fresh and saltwater fish, respectively. A primary toxicity endpoint for amphibians comes from a study with 21 days of continuous exposure non-lethal effects noted at 186 ppb. It is highly unlikely that exposures at these concentrations over this period would occur in the environment. Therefore, it is highly unlikely that individuals of a listed species or full populations of fish and amphibians serving as PPHD for other listed species would be exposed at these concentrations for equivalent durations. This should be considered in the WoE for likelihood of effect to occur.”

EPA Response: *EPA estimates exposure using the PWC. This model accounts for the persistence of pesticides. These EECs account for dissipation of the assessed pesticide, as well as additional inputs of the chemical into the model water body (e.g., through runoff events or spray drift from additional applications).*

Comment 194: Rotam commented: “According to the BE, mammals have a wide range of acute sensitivity to Methomyl with a mortality effect range from 7.14 to 5367 mg/kg-bw. However, the BE uses the lowest value (7.14 mg/kg-bw) as representative for all listed mammals. The BE should include a wider range of effects responses as multiple lines of evidence to consider the potential range of exposures and effects. The distribution for mortality effects was also normalized assuming an exposure to 15-gram mammals. This assumption does not cover mammals with higher body weights and varying metabolic and consumption rates. These parameters should be closely linked to the specific attributes of the listed species being evaluated.”

EPA Response: *In the BEs, EPA utilized the most sensitive scientifically valid and reliable endpoints. As part of the weight of evidence, EPA considers alternative endpoints. This alternative analysis was used to evaluate the influence of using the most sensitive endpoints in the risk analysis. Dose-based toxicity values for mammals are converted to be representative of the assessed species using the adjustment approach described in the T-REX user’s guide and Attachment 1-1 of the BEs.*

Comment 195: Rotam commented on the legality of the reported incidents and associations with other pesticides. They also commented on uncertainty in linking legal applications of methomyl to the reported incidents.

EPA Response: *EPA excluded incidents known to be associated with misuses from the lines of evidence used in the Step 2 analysis. When information was not available on the legality of a use, that incident was included. In those cases, EPA acknowledges that there is uncertainty in whether the incident was associated with a legal or an illegal (misuse) use; however, EPA assumes that the incident is relevant to currently registered uses of methomyl unless there is evidence reported to indicate otherwise.*

Comment 196: FIFRA Endangered Species Task Force (FESTF) commented: “In the draft BE for methomyl, EPA used USGS National Land Cover Database (NLCD; Yang et al, 2018) class 81 (pasture/hay), masked to Figure 1 in Appendix 1-6, to represent the spatial extent of potential methomyl use in bermudagrass pasture. The pasture/hay Use Data Layer (UDL), represented by seven different Cropland Data Layer (CDL) classes (alfalfa, other hay/non-alfalfa, switchgrass, pasture/grass, pasture/hay [176 and 181], and vetch) was used by EPA to represent methomyl use in alfalfa. Both the bermudagrass pasture UDL and the pasture/hay UDL overestimate the potential extent of these use

sites because 1) these UDLs do not adequately account for the difference between pastureland and rangeland, and 2) the UDLs include use site areas not labeled for use.”

EPA Response: *The final BEs include updates to the pasture and rangeland UDLs. Cultivated grasses and grasses crops, as identified in USDA Cultivated Layers are included in the new Alfalfa UDL. Some crops found in the new UDL include Alfalfa (36), Switchgrass (60), and Vetch (224). Non-cultivated pasture/grasses areas are included in the new Pasture/Rangeland UDL. This Pasture/Rangeland UDL includes CDL land cover categories, Other Hay/Non- Alfalfa (37), Pasture/Grass (62), Pasture/Hay (176 and 181), in addition to other rangeland of grazing sources outlined in Appendix 1-6. The Bermuda grass UDL has been updated to reflect areas where cultivated grasses grow as defined in USDA’s Cropland Data Layer (CDL) and limited to latitudes where warm season grasses occur. Additional information on these updates will be available in the final BE in Appendices 1-5 and 1-6.*

Comment 197: FIFRA Endangered Species Task Force (FESTF) commented: “The pasture/hay UDL used by EPA in the draft methomyl BE includes CDL classes for alfalfa, other hay/non-alfalfa, switchgrass, pasture/grass, pasture/hay (176 and 181), and vetch. Of these, alfalfa is the only labeled methomyl crop. The use of the pasture/hay UDL overstates the extent of alfalfa acres by including use sites not labeled for use, including rangelands, and potentially double counts bermudagrass and pasture/hay acres. EPA provided spatial data tools for the standard UDLs but not for the bermudagrass UDL. Without the spatial data file outputs for the UDLs, it is not possible to replicate this process nor conduct comparison analysis to fully understand the extent of each UDL. As emphasized later in our comments (see Comment 4), it is essential that EPA provide all spatial data files and all other tools utilized in these and future draft BEs to allow stakeholders to review, and to provide suggested improvements; it is particularly important to do this given the complexity of the risk assessment underlying draft BEs.” They added: “To represent the spatial extent of methomyl use in alfalfa, FESTF recommends that the pasture/hay UDL is limited to the CDL class for alfalfa.”

EPA Response: *In the final BE there is a new Alfalfa UDL, which includes cultivated grasses and grass crops as defined in USDA’s Cultivated Layer, see **Comment 196** for additional details. The information related to the Bermuda grass extent is provided in Appendix 1-6. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration*

Comment 198: FIFRA Endangered Species Task Force (FESTF) commented: “Bermudagrass is a perennial, warm-season grass which can be used for forage for livestock, both as grazed forage and hay. As detailed in the draft BE for methomyl, it is limited to the southern US (see Figure 1 in Appendix 1-6). However, not all permanent pasture and hay acres in the identified states are bermudagrass.” They later added: “FESTF recognizes the difficulty in spatially delineating bermudagrass using the available spatial data, but recommends that the extent could be adjusted based on input from crop, forage, and agricultural production experts located in states and/or territories to better represent potential extent. Considering the overestimation of the extent and assumed usage in the pasture/hay and bermudagrass pasture UDLs, LAA determinations based on these UDLs need to be re-evaluated after corrections are made to spatial extent and usage assumptions.”

EPA Response: *For the final BE the Bermuda grass UDL has been updated to reflect areas where cultivated grasses grow as defined in USDA’s Cropland Data Layer (CDL) and limited to latitudes where warm season grasses occur. This update refines where Bermuda grass is likely to grow. However, due to the fact that the UDLs are not independent from each other, species impacted by Bermuda grass are*

likely also impacted by other uses. Low overlap with a single UDL, like Bermuda Grass, may not indicate low risk to the species.

Comment 199: FIFRA Endangered Species Task Force (FESTF) commented: “Using the spatial data tools and process outlined in the methomyl draft BE, the other grains UDL includes 16 CDL classes including barley, sugarcane, canola, oats, and rye, which covers an area of 53,097,951 acres (using 2014-2018 CDL). The only labeled methomyl crops in this UDL are sorghum (CDL class 4, and double-crop classes with sorghum 234, 235, and 236) and anise (represented by CDL class 25 “other small grains”). When the UDL is limited to the labeled crops, the total extent of this UDL is 25,573,588, less than half of the acres in the other grains UDL used by EPA, realistically portraying the potential footprint in the part of the US where the labeled crops are grown”

EPA Response: *As described in the Revised Method, the Census of Agriculture is used to identify counties where no registered crops occur for a given UDL. To do this, all crops found in the each UDL are linked to the Census Agriculture and the number of registered crops found in each county identified. As part of the spatial analysis, the overlap is removed for counties with no registered crops prior to the use as an input for the MAGtool. If a single registered crop occurs in the county the overlap remains unaltered. When conducting the Step 2 spatial analysis for methomyl, the other grains UDL is limited to just those counties where registered crops occurs.*

6. Conclusion

EPA received many public comments on the draft BEs for carbaryl and methomyl. Comments were requested on three subject areas, including: non-agricultural uses of carbaryl, application of strength of evidence criteria for LAA determinations for carbaryl and methomyl and links between PPHD and potential effects of carbaryl and methomyl on listed species. Additional comments were also provided on the carbaryl and methomyl draft BEs. Submitted comments from different stakeholders expressed various, often conflicting, perspectives. EPA has carefully considered all comments and modified the BEs for carbaryl and methomyl, where appropriate and feasible, taking into account the comments received.

Appendix A. Submitters of public comments

This appendix lists the submitters of public comments on the draft BEs for carbaryl and methomyl. This list excludes the submissions that requested extensions of the public comment period.

Individual citizens

County, State, and Federal Governments:

- (1) United States Department of Agriculture
- (2) Washington State Department of Agriculture

Wastewater Treatment and Stormwater Agencies:

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

Environmental and other Non-Governmental Organizations:

- (1) Beyond Pesticides
- (2) Center for Biological Diversity
- (3) Center for Biological Diversity, Beyond Pesticides, Council for Hawaii, Environmental Protection Information Center, Grand Canyon Trust, Great Old Broads for Wilderness, Greater Hells Canyon Council, Howling for Wolves, International Marine Mammal Project of Earth Island Institute, Klamath Forest Alliance, New Hampshire Audubon, Northcoast Environmental Center, Northwest Center for Alternatives to Pesticides, NY4WHALES, The United Methodist Church-Peninsula-Delaware Conference, Resource Renewal Institute, Save Wolves Now Network, Toxic Free NC, Turtle Island Restoration Network, Western Nebraska Resources Council

Pesticide Registrants or Registrant Groups, Affiliates and Consultants:

- (1) Bayer Crop Science
- (2) Creekbank Associates
- (3) Crop Life America
- (4) E.I. du Pont de Nemours and Company (Corteva Agriscience)
- (5) FIFRA Endangered Species Task Force
- (6) Generic Endangered Species Task Force
- (7) NovaSource/Tessenderlo Kerley, Inc¹⁵
- (8) Responsible Industry for a Sound Environment
- (9) Rotam Agrochemical Co.
- (10) Strategic Solutions Team

Grower Groups, Pesticide Applicators or Affiliates

- (1) California Citrus Quality Council
- (2) California Fresh Fruit Association
- (3) Minor Crop Farmer Alliance
- (4) National Agricultural Aviation Association
- (5) National Cotton Council
- (6) Northwest Horticultural Council
- (7) Washington State Potato Commission

¹⁵ Comments submitted in February 2021 were not included in this document.