EPA-HQ-OPP-2020-0090

July 2, 2020

Ms. Tracy Perry
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Via Regulations.gov: EPA-HQ-OPP-2020-0090

Re: Comments on the Draft Biological Evaluations for Carbaryl and Methomyl
EPA-HQ-OPP-2020-0090-0001; 85 Fed. Reg. 15168 (March 17th, 2020)

Dear Ms. Perry:

CropLife America ("CLA")[1] appreciates the opportunity to comment on the Draft National Level Listed Species Biological Evaluation for Carbaryl[2] and Draft National Level Listed Species Biological Evaluation for Methomyl[3]produced by the Environmental Protection Agency's ("EPA" or "the Agency") (the documents collectively, the "Draft Carbamate BEs"). These Draft Carbamate BEs provide the first opportunity to see the Agency's current approach to application of the Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides ("Revised Method"). As such, these comments are focused not only on the Draft Carbamate BEs but also on the Revised Method.

CLA comments are organized into three sections. First, at page 1, we provide an Executive Summary of our comments. Second, beginning on page 6, we provide a discussion of major points on the Draft Carbamate BEs, how the Revised Method was applied in practice, and suggestions to improve the Draft Carbamate BEs as they are finalized and the Revised Method as it is applied over time. The framework for this discussion is the previously submitted CLA

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[1] Established in 1933, CropLife America represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

[2] EPA (Environmental Protection Agency). 2020. Draft National Level Listed Species Biological Evaluation for Carbaryl. March 2020.

[3] EPA (Environmental Protection Agency). 2020. Draft National Level Listed Species Biological Evaluation for Methomyl. March 2020.

comments[4] on the proposed Revised Method[5]. Third, Conclusions are drawn on page 24. Finally, we provide an updated report: Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale (Attachment I); Malathion: Aquatic Endangered Species Risk Assessment – Synopsis (Attachment II); and West Indian Manatee Case Study (Attachment III).

We would like to thank you for engaging in a dialog with stakeholders on this important issue, including continuing the stakeholder engagement within the Interagency Work Group called for in the 2018 Farm Bill. We look forward to being able to work with the Agency and other interested stakeholders on opportunities to share information on pesticide product issues that may help inform future regulatory decisions. Please do not hesitate to reach out to us with questions on these comments.

Sincerely,

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[4] CLA (CropLife America). 2019. Comments on the Draft Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations for Pesticides. August 15th, 2019. Via Regulations.gov: EPA-HQ-OPP-2019-0185

[5] EPA (Environmental Protection Agency). 2019. Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides. Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington DC.

CLA Comments on the Draft Biological Evaluations for Carbaryl and Methomyl

(EPA-HQ-OPP-2020-0090)

1 EXECUTIVE SUMMARY

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.

In the response to Public Comments Received on Proposed Revised Method for National Level Endangered Species Risk Assessments for Biological Evaluations of Conventional Pesticides ("Response to Comments"),[1] the Agency told the public that the "...pilot method[2] had the following major limitations: (1) the method did not meaningfully distinguish species that are likely to be exposed to and affected by the assessed pesticides from those that are not likely; (2) the level of effort was too high for EPA to sustain for all pesticides; and (3) the amount of documentation produced was too great for the public to review and comment upon in a reasonable timeframe." Based on CLA's careful review, the major limitations cited as rationale for revising the interim methods are largely uncorrected and, in some ways, compounded.

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):

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[1] EPA (Environmental Protection Agency). 2020. Response to Public Comments Received on Proposed Revised Method for National Level Endangered Species Risk Assessments for Biological Evaluations of Conventional Pesticides. Environmental Fate and Effects Division, Office of Pesticide Programs. Washington D.C.

[2] "Interim Measures," https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report. (Last accessed: July 2, 2020)

> *Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is* ***reasonably certain to occur****. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. [****emphasis added****]*

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.[3] These approaches are highly conservative and expand the action area beyond what is reasonable for most species, making the "1% overlap" meaningless. 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".

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. This has similarly been noted in comments submitted on the draft and final organophosphate BEs.[4] The use of public literature in

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

[4] Priest et al. (2016). Response to the Biological Evaluation for Malathion. Prepared for Cheminova A/S by Intrinsik Corp and Stone Environmental Inc. Submitted to Docket EPA-HQ-OPP-2009-0317.

BEs without data curation impacts the quality of the Agency's BEs and underscores the limitations on the public's opportunity to review and comment in a reasonable timeframe.

CLA continues to advocate for probabilistic methods in the development of BEs. Within the Revised Method, screening-level, deterministic methods are used in Step 1 to identify listed species that are potentially at risk (*i.e.*, May Affect or No Effect) from exposure to a pesticide. The methods are deliberately and overly conservative to reduce the likelihood of Type II errors (failure to reject a false null hypothesis of *de minimis* risk), but correspondingly increase Type I errors (falsely reject a null hypothesis of *de minimis* risk). As the Agency and the Services (Fish and Wildlife Service ("FWS"), and National Marine Fisheries Service ("NMFS")) gain experience with the Endangered Species Act ("ESA") risk assessment process, refinements that better reflect the reasonable certainty of realistic effects of pesticides on listed species should be incorporated earlier in the review process.

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.

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[5] was presumably used to generate the UDLs for carbaryl and methomyl, but this is not clearly stated.

Finally, CLA recognizes that the Revised Methods alone cannot address all the flaws in the current process of ESA review of pesticides. CLA urges the Agency and its federal partners within the Interagency Working Group ("IWG") to, as soon as practicable, follow the direction of Congress regarding regular consultation with interested stakeholders, taking into account their differing viewpoints, to develop a nationwide evaluation of pesticide risks to listed species that is efficient, scientifically defensible, and that relies on the best available scientific and commercial data. For example, the Agency could convene its stakeholder meetings before the deadline for progress reports required by Sec. 10115 of Agriculture Improvement Act of 2018 (P. L.115–334) so that the IWG has enough time to consider stakeholder comments as it drafts reports to Congress and further improves the ESA review process for pesticides.

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5 https://www.epa.gov/endangered-species/models-and-tools-national-level-listed-species-biological-evaluations-carbaryl#spatial (Last Accessed: July 2, 2020)

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Attachment I	Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale
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2 SUBSTANTIVE COMMENTS

The Agency released the Revised Method[6] and the two Draft Carbamate BEs concurrently in March 2020.[7,8] In response to the proposed Revised Method,[9] CLA submitted comments to the Agency in August 2019.[10] The Draft Carbamate BEs represent the first application of the Revised Method and thus the first opportunity to evaluate how EPA implemented it after considering public comments. Because CLA had some major concerns with the proposed Revised Method,[10] the current opportunity to comment allows us to examine the Agency's response to public comments,[11] and note how actions not taken to improve the Revised Methods have impacted the Draft Carbamate BEs.

2.1 Reasonably Certain to Occur

EPA 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) better establish whether pesticide exposure at a concentration causing adverse effects is reasonably certain to occur as described in the new ESA implementation regulations (Sec 50 CFR § 402.02):

> *Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are*

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[6] EPA (Environmental Protection Agency). 2020. Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides. Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington DC.

[7] EPA (Environmental Protection Agency). 2020. Draft National Level Listed Species Biological Evaluation for Carbaryl. March 2020.

[8] EPA (Environmental Protection Agency). 2020. Draft National Level Listed Species Biological Evaluation for Methomyl. March 2020.

[9] EPA (Environmental Protection Agency). 2019. Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides. Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington DC.

[10] CLA (CropLife America). 2019. Comments on the Draft Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations for Pesticides. August 15th, 2019. Via Regulations.gov: EPA-HQ-OPP-2019-0185

[11] EPA (Environmental Protection Agency). 2020. Response to Public Comments Received on Proposed Revised Method for National Level Endangered Species Risk Assessments for Biological Evaluations of Conventional Pesticides. Environmental Fate and Effects Division, Office of Pesticide Programs. Washington D.C.

> *caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and* ***it is reasonably certain to occur****. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. [****emphasis added****]*

Based on this language, 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. These analyses are compared to the highest estimated exposure concentration (EEC) predicted for the species in the terrestrial and/or aquatic environment. Ultimately, if the EECs exceed the sensitive effect thresholds, then a MA determination is made. Insufficient species-specific information is applied to inform the Step 1 risk characterization beyond use of the coarse and uncertain range data, often at the county-level (location and exposure); assignment of an aquatic or semi-aquatic listed species to a surrogate aquatic BIN (or BINs); and an approximation of diet (to estimate dietary residues). Given the vast differences in landscape (and associated pesticide needs) across the area that may be captured in these estimations, this approach does not appear to establish that a given pesticide is "reasonably certain" to affect a specific listed species.

Broader consideration of specific individual exposure scenarios for each listed species (e.g., watershed level modeling); species life histories; factors that may mitigate exposure (e.g., landscape, behavior); and the probability of exposure actually occurring given appropriate historical use and usage data, are needed to establish whether the effects of the registration action would be reasonably certain to affect a listed species. It is not appropriate to shift this level of complex risk assessment to the Services without additional direction from EPA. The discussion in the sections below addresses the need for EPA to more carefully define "may affect" and then thoroughly apply listed species information, refined exposure predictions, and lines of evidence to make defensible and realistic predictions of what is reasonably certain to occur to lessen the burden on the Services at later stages of review.

2.2 Pesticide usage data

CLA is encouraged that EPA has considered usage data in the Draft Carbamate BEs. As noted in our previous comments[4] on the proposed Revised Method, usage data allow for a more accurate reflection of pesticide use. CLA has updated its proposed methodology to demonstrate how usage data can be applied (see Attachment I: "Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale"). 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'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. Further, conservative assumptions must be made regarding how to address the actual percent crop treated area ("PCT") within a species range using best available data; thereby considerably increasing the uncertainty and conservatism of the risk characterization. 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.

EPA's acknowledgement of the uncertainties in the adoption of usage data at the state level (see draft carbaryl BE Section 4 – Page 4-13) supports the argument that the exposures predicted are highly overestimated. Step 1 results in most species (97% for carbaryl; 85% for methomyl) receiving a May Affect (MA) determination essentially automatically with little consideration for whether the determinations are reasonably certain to occur for each species. Thus, Step 1 is highly conservative, inefficient, and does not reflect the reality of pesticide exposure potential for listed species.

Compounding conservatism in the Draft Carbamate BEs reveal one of its severe weaknesses. In Step 1, a determination of NE or MA is partially based on species range/action area overlap, with the assumptions that use at full label rates on 100% of crop and non-crop area will occur. The UDLs generated by EPA are overestimates of actual use due to lumping together of use patterns, both agricultural and non-agricultural, from all registered labels from multiple registrants. The listed species ranges are imprecise and highly conservative (county-level in most cases).

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.[12] 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.[13] Step 2, as applied, does little to address compounding conservatism, as a refined step in a hierarchical Ecological Risk Assessment (ERA) process should do. (See the following references for examples).[13,14,15,16,17,]

How usage data are applied also leads to unrealistic conservatism within the exposure modeling approaches themselves. For example, the UDLs and usage data inform pesticide inputs into the exposure models. The aquatic exposure modeling in the Revised Methods is then very conservative itself. For example, using variable field sizes (depending on whether standard pond, index reservoir, or edge-of-field was used as species aquatic habitat (bin) surrogates). The results are highly generic and represent unrealistic and highly conservative exposure scenarios

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[12] See EPA response to Comment 21

[13] Richardson L, Bang J, Budreski K, et al. A Probabilistic Co-Occurrence Approach for Estimating Likelihood of Spatial Overlap Between Listed Species Distribution and Pesticide Use Patterns. Integr Environ Assess Manag. 2019;15(6):936-947. doi:10.1002/ieam.4191

[14] EPA (US Environmental Protection Agency). 1992. Framework for Ecological Risk Assessment. EPA/630/R-92/001

[15] EPA (US Environmental Protection Agency). 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F

[16] NAS (National Academies of Science). 2013. Assessing risks from endangered and threatened species from pesticides. Washington, DC: The National Academies Press. https://doi.org/10.17226/18344 (Last accessed: July 2, 2020). ISBN 978-0-309-28583-4

[17] See EPA response to Public Comment (Citation 11). Comment#21

for any individual listed species. For terrestrial listed species, the usage data and UDLs inform the exposure concentrations/residues predicted at a distance for off-field drift, but the off-field drift component does not account for the habitat that a species may be found in. This is an important line of evidence, especially since edge of field habitats may indeed already be managed for agricultural production. An additional example of this is spray drift interception by trees. Not accounting for this likelihood causes an overestimate of pesticide exposure for listed species found only in old growth forests. As another example, pray drift interception and direction comprised one line of evidence used qualitatively by EPA to evaluate the potential for risk for beach species (discussed in Carbaryl BE Appendix 4 through 8 and in more detail below).

Given Step 1 already identifies the vast majority of species as MA based on the compounding of conservative assumptions laid out above, the usage data as applied in Steps 2f and 2g then makes it extremely likely that a listed species will receive a LAA determination, whether or not a listed species (or critical habitat) has the potential to be actually exposed to, or adversely affected by, a pesticide. The application of the usage data to predict listed species exposure should be conducted at the sub-state level and account for the fact that usage can occur unevenly throughout the state because certain areas will experience greater pest pressures than others. Probabilistic methods applied to spatially distribute the pesticide at finer spatial resolutions using all available knowledge would provide more accurate and realistic assessments. EPA should consider how usage data should be applied in the Revised Method and within the Draft Carbamate BEs to provide a more realistic assessment of the effects of pesticides on listed species and critical habitat, relieve the Services of more of the analytical burden of these reviews, and focus mitigation resources where potential risk may be appropriately identified.

Further, 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.

Overall, CLA believes that a thorough review of the compounding conservatism of the BE within the context of the usage data application and impacts on the likelihood of exposure is warranted.

2.3 Data Quality

CLA recognizes that a significant effort is required to evaluate all open literature studies for quality, reliability, and relevance. However, this review is necessary to provide a scientifically defensible assessment of risk and is regularly undertaken during the FIFRA registration process where data evaluation records are produced.[18] EPA has stringent data quality requirements for conducting guideline studies,[19] usually conducted under Good Laboratory Practice ("GLP"), and for peer-reviewed studies available in the public literature. Much of the data used in the Draft Carbamate BEs came from electronic sources such as the ECOTOXicology knowledge-base (ECOTOX) and the Office of Pesticide Products Information Network ("OPPIN"), both of which include registrant submitted studies as well as studies from other sources. While these databases are represented as curated, meaning data placed in the databases are assumed to have been reviewed for quality, that representation does not hold when certain studies referenced there are fully evaluated. In the Draft Carbamate BEs, Appendices 2-2 (All Accepted Reports – ECOTOX), 2-3 (Open Literature Review Summaries), and 2-4 (Studies Submitted to EPA) contain information on the studies collected for use in the BEs. Appendix 2-3 specifically contains reviews by EFED staff of the ECOTOX studies collected. However, there are studies used for effect thresholds that do not appear to follow EPA's own study quality criteria. This situation has similarly been noted in comments submitted on the draft and final organophosphate BEs.[20]

[18] https://www.epa.gov/pesticide-registration/oecd-data-evaluation-record-templates

[19] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines (Last accessed: July 2, 2020)

[20] Priest et al. (2016). Response to the Biological Evaluation for Malathion. Prepared for Cheminova A/S by Intrinsik Corp and Stone Environmental Inc. Submitted to Docket EPA-HQ-OPP-2009-0317.

The Pellston Workshop on Improving the Usability of Ecotoxicology in Regulatory Decision-Making,[21] in which the Agency took part, highlighted a multitude of limitations of using open-literature data to support risk assessment decisions. These limitations focused on the need to evaluate quality, reliability, and relevance, to ensure that minimum requirements and standards for the application of ecotoxicity studies are applied to regulatory decision making. A template such as those developed for EPA's study data evaluation records ("DER")[18] needs to be designed to present complete review information on which studies follow EPA guidance, while also commenting on the quality (adherence to protocols and GLP standards), reliability (fitness for use as a representative endpoint through the surrogate species comparison), and relevance of the study (comparison to GLP guideline or peer-reviewed published study results for the same species. Developing this template would ensure that only studies of sufficient quality, relevance and reliability were applied to the risk assessment, thus increasing confidence in the outcomes.

2.4 Spatial data, and a less than 1% spatial overlap

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.[22] 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. This approach was

[21] Ågerstrand, M. and J. Staveley. 2015. Improving the usability of ecotoxicology in regulatory decision-making. A SETAC Pellston Workshop. https://cdn.ymaws.com/www.setac.org/resource/resmgr/publications_and_resources/Usability_Workshop_Executive.pdf

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

applied in the beach species analysis in Appendix 4-8 of the draft carbaryl BE. Overlap of very specific species habitats with use patterns in proximity were used to identify where overlap was <1%. The beach species are further discussed in the weight-of-evidence discussion below.

2.4.1 Spatial Data, Usage and Resolution

EPAs' UDLs combine use patterns from all registered labels (from multiple registrants) together (including both agricultural and non-agricultural uses), and this can be problematic for the BE exposure assessment as well as from the perspective of each of the individual label registration actions. 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. This is one reason why, so few NE determinations were made at Step 1. From the results of Step 2, EPA discusses the UDL risk drivers for LAA determinations, which for methomyl most often include the pasture UDL (see Chapter 4, p 4-12), in part because pasture is used as a surrogate for alfalfa. However, according the BEAD analyses (see methomyl BE Appendix 1-4) methomyl is only used on alfalfa in five states (AZ, CA, KS, OK, PA). Thus, generalization of the pasture UDL can result in incorrect and unreasonable predictions of exposure, and therefore, effect determinations. Use of the pasture UDL in this example clearly does not meet the "reasonably likely to occur" standard.

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.

2.5 Probabilistic methods

CLA continues to advocate for probabilistic methods in the development of BEs. Within the Revised Method, screening-level, deterministic methods are used in Step 1 to identify listed species that may be affected by exposure to an active ingredient. The methods are deliberately and overly conservative to reduce the likelihood of Type II errors (accept a false null hypothesis of *de minimis* risk), but correspondingly increase Type I errors (reject a true null hypothesis of *de minimis* risk). As demonstrated in the Draft Carbamate BEs, this approach places the resource and administrative burden on the Services, which have fewer resources and less expertise on pesticide issues than the Agency.

Probabilistic methods provide a robust means to evaluate risk, including variability and uncertainty, particularly at the landscape scale which is most relevant to listed species and their critical habitat. Probabilistic methods are ideal for use in a BE, given that most modeling inputs (e.g., usage data, exposure models, spatial data) are variable and have associated uncertainty. The National Academies of Science[16] suggested that at Step 2 risk managers would be best informed using probabilistic methods to capture variability and uncertainty of parameters. 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[23,24,25,] and in

[23] Moore, D.R.J., R.S. Teed, S.I. Rodney, R.P. Thompson and D.L. Fischer. 2010. Refined avian risk assessment for aldicarb in the United States. Integrated Environmental Assessment and Management 6(1):83-101.

[24] Giddings, J.M., T.A. Anderson, L.W. Hall, A.J. Hosmer, R.J. Kendall, R.P. Richards, K.R. Solomon and W.M. Williams. 2005. Atrazine in North American surface waters: a probabilistic aquatic ecological risk assessment. Society of Environmental Toxicology and Chemistry, Pensacola, FL.

[25] Moore, D.R.J., R.P. Thompson, S.I. Rodney, D.L. Fischer, T. Ramanaryanan and T. Hall. 2010. Refined aquatic risk assessment for aldicarb in the United States. Integrated Environmental Assessment and Management 6(1):102-118.

listed species risk assessments for a variety of species. [26,27,32] 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. Once EPA and the Services gain experience with the process, they would benefit from operational guidelines by which assumptions could be made on NE and MA decisions that could streamline the need for repetitive analysis on pesticides with similar exposure patterns and/or toxicity profiles.

2.6 A robust weight-of-evidence approach

EPA has long considered how to evaluate ecological risks and in 1992, the Agency published the Framework for ERA[14] incorporating the concept of a tiered approach. The 1998 revision of the ERA[15] maintained the iterative, tiered process. This tiered strategy has thus served as the general basis of environmental risk assessment at EPA for the past 28 years. The revised 1998 ERA guidance is cited in the National Research Council (NRC) Panel report[16] as an appropriate basis for the endangered species risk assessment process. In all cases the early tiers serve as screening-levels or coarse filters, while in later refined tiers, additional information, data, refined methods, and more realistic assumptions are used to characterize risk, and finally, draw risk assessment conclusions. In the Draft Carbamate BEs, this process is short circuited by making effect determination 'calls' (NE/MA) early and not later in the process considering evidence that can provide considerably more context and realism to the effect determination. This is particularly important given the level of detail and information required in listed species assessments to evaluate effectively each individual listed species (and its critical habitat) in a scientifically defensible manner. This missing refined evaluation and context ultimately

[26] Clemow, Y, G.E. Manning, R.L. Breton, M.F. Winchell, L. Padilla, S.I. Rodney, J.P. Hanzas, T. E. Estes, K. Budreski, B.N. Toth, K.L. Hill, C. D. Priest, R.S. Teed, L.D. Knopper, D.R.J. Moore, C.T. Stone and P. Whatling. 2018. A refined ecological risk assessment for California Red-Legged frog, Delta Smelt, and California Tiger Salamander exposed to malathion. Integrated Environmental Assessment and Management 14(2):224-239

[27] Breton, R., Y. Clemow, G. Manning, S. Rodney, D. Moore, and C. Greer. 2016. Refined Effects Determination for California Tiger Salamander Potentially Exposed to Malathion. Unpublished study performed by Intrinsik Environmental Sciences Inc., Ottawa, ON, Project No. 60455, for Cheminova, Inc., Arlington, VA. final report dated June 10, 2016. [MRID 49949505].

increases the burden on the limited resources of the Services to evaluate far more listed species than can reasonably be considered to have adverse effects that are "reasonably certain to occur." EPA should take responsibility for undertaking the initial review of this refined data, for later concurrence by the Services.

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.

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.

Considerable documentation is available on conducting qualitative and quantitative weight-of-evidence (WoE) analyses for regulatory decision making.[28,29,30,31] Risk assessments on listed species have also been conducted with a WoE component[28,32] and illustrate how lines of evidence, including those for modeling, are incorporated into the risk characterization to inform the risk conclusion (in this case, effect and proposed LAA/NLAA determinations). As an example of how this can be done, a synopsis of the Refined Aquatic Endangered Species Risk Assessment for Malathion[32] is provided as Attachment II.

In its practical application of the Revised Method in the Draft Carbamate BEs, EPA takes a highly linear approach. At each step, an effect determination (Step 1 – NE or MA and Step 2 - NLAA or LAA) can be made which does not appear to be influenced by any further evidence collected and evaluated at subsequent steps. The one exception to this is a re-visitation of the potential for pesticide exposure for aquatic species assigned NE or NLAA. If carbaryl was detected in water monitoring data found upstream of or in the species range, an effect determination can be changed to LAA. This process is documented in Attachment 4-1 of both draft BEs. In the draft carbaryl BE, the effect determination was changed for the Rio Grande Silvery Minnows (see draft carbaryl BE Appendix 4-6). There does not appear to be a mechanism to use the same line of evidence (monitoring data) to review and change an LAA determination to NLAA. This illustrates propagation of compounding conservatism throughout the BE process. A final BE should provide clear context and analysis on how EPA reached its conclusions, how further refinement could provide a more realistic understanding of the

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[28] SETAC (Society of Environmental Toxicology and Chemistry). 2018. Weight-of-Evidence in Environmental Risk Assessment – Virtual Issue. Integrated Environmental Assessment and Management https://tinyurl.com/y78osxef

[29] Hall, T.A., S. E. Belanger, P.D. Guiney, M. Galay-Burgos, G. Maack, W. Stubblefield, and O. Martin. New approach to Weight-of-evidence Assessment of Ecotoxicological Effects in Regulatory Decision-Making. Integrated Environmental Assessment and Management 13(4):573 – 579.

[30] Lutter R, L. Abbott, R. Becker, et al. 2015. Improving weight of evidence approaches to chemical evaluations. Risk Anal. 2015;35(2):186-192. doi:10.1111/risa.12277

[31] Linkov I, D. Loney, S. Cormier, F.K. Satterstrom, T. Bridges. 2009. Weight-of-evidence evaluation in environmental assessment: review of qualitative and quantitative approaches. Sci Total Environ. 2009;407(19):5199-5205. doi:10.1016/j.scitotenv.05.004

[32] Teed, R.S., M. Winchell, L. Padilla et al. 2019. Refined Aquatic Endangered Species Risk Assessment for Malathion. Unpublished Study Prepared by Stone Environmental, Inc. 719p. [MRID 51064201]

interaction between the pesticide and listed species, and a well-supported recommendation on an LAA/NLAA determination for the Services.

The risk assessment models (*e.g.*, TED, a form of AgDrift) found within the BE MAGTool are generic in their approach and deterministic in their implementation. Although the MAGTool does have some probabilistic analyses using Crystal Ball™, these analyses are by and large limited to the alternative analyses, which does not appear in the Draft Carbamate BEs to have influenced the effect determinations for each listed species or their critical habitat. These models use species-specific information on body weight, diet, and other factors (*e.g.*, species range, proximity to use patterns) to develop a risk characterization for each listed species. However, they do not account for specific life history information or other lines of evidence that may influence the probability of exposure and effect. Given that EPA had access to an updated national FWS validated species status dataset, but built its own dataset for species information in these draft BEs makes this approach even more problematic. These lines of evidence must also be applied to develop and complete the refined risk characterization leading to a scientifically defensible effect determination.

Although this comment applies to the listed species for which quantitative risk characterization was conducted, it is particularly true for those species where a qualitative risk assessment was conducted due to a lack of quantitative information (BE Chapter 4 Steps 2a - i and Appendix 4-8 in the carbaryl BE). For example, in the Agency's qualitative treatment of listed species associated with beach environments, EPA applied a finer spatial lens to a group of beach species in Step 2d (draft carbamates BE Appendix 4-8). It did so by incorporating information on habitat preference and refining the spatial extent of range information to focus on beach habitats where the species are known to be found. This approach uses lines of evidence (i.e., FWS information on habitat preference, location, and additional data in the form of the GAP/Landfire spatial datasets) to inform the modeling effort. *CLA strongly agrees supports this general approach.*

CLA recognizes that the generic spatial data used in the Draft Carbamate BEs does not necessarily represent where a listed species may be located. When conservative assumptions are made to account for this uncertainty, the results are conservative. When the same uncertainty strategy is applied multiple times, such as applying county-level or HUC12 range data without consideration of habitat; applying an aggregated use footprint to maximize a potential action area; and applying the most sensitive of the indirect or direct effect thresholds to generate maximum off-field movement buffers, the conservatism of the assessment is significantly compounded and no longer reflects the listed species' reality.

Another example of this is in the qualitative analysis of the West Indian manatee (*Trichechus manatus*) (Draft Carbaryl BE Appendix 4-8, Step 2d), which led to an LAA effect determination for carbaryl's effect on this species. 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).

2.7 Making efficient and scientifically defensible "no-effect" determinations

As set forth above and in CLA's comments on the draft Revised Method, the Agency can make the BE process more efficient by addressing the potential for harm to listed species much earlier in the process. The following highlights why the issue was identified by CLA in the proposed revised method CLA continues to advocate for this approach, based on the carbaryl and methomyl BEs as well as results from the organophosphate BEs.[33,34,35]

Appendix 4-8 (additional qualitative species analysis), in both the Draft Carbamate BEs, provides evidence regarding listed species that are unlikely to be exposed due to incomplete exposure pathways. EPA also qualitatively determines whether the exposure modeling applied in the BE is appropriate for the listed species being evaluated. This section adds limited but needed

[33] EPA (US Environmental Protection Agency). 2017a. Biological Evaluation Chapters for Malathion ESA Assessment. https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment. Accessed May 5th, 2020

[34] EPA (US Environmental Protection Agency). 2017b. Biological Evaluation Chapters for Chlorpyrifos ESA Assessment.https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment. Accessed May 5th, 2020

[35] EPA (US Environmental Protection Agency). 2017b. Biological Evaluation Chapters for Diazinon ESA Assessment. https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon-esa-assessment Accessed May 5th, 2020

realism to the assessment that should be applied much earlier in the assessment process. For example, for most pesticides, application of a pesticide to the open ocean is very unlikely as stated in the BE in the statement below:

"Exposures to species that predominantly occur in the open ocean (*e.g.,* whales) or rely on ocean species (*e.g.,* seabirds) are reasonably expected to be *de minimis*. This is because carbaryl is not applied directly to the ocean and does not bioaccumulate."

The same justification was used in the organophosphate ("OP") BEs, and the subsequent OP BiOp and NMFS concurred.[36]

This logic holds for most of the other species that are unlikely to be impacted (pinnipeds, sea birds, and the other species mentioned). Thus, it should be straightforward for the EPA to have an *a priori* informal consultation with the Services to establish an agreed upon list of species, including extirpated and extinct species that do not have to be independently investigated in future BEs.

These specific determinations could be reviewed regularly. If new information arises that might suggest the potential for impact to a listed species has changed, a justification can be recorded in the problem formulation to include a more detailed analysis. Otherwise, no further assessment is needed. This would make the BE process more efficient, saving effort and resources moving forward. Looking for these opportunities fits with the Agency's recognition that:

"*The methods applied to BEs will continue to evolve as EPA gains experience and as scientific methods and data improve.*" (Page 8 of Revised Method)[6]

These types of opportunities abound in endangered species assessments and should be addressed where possible in the preparatory stages of BE development. CLA has documented

[36] NMFS (National Marine Fisheries Service). 2017. Endangered Species Act Section 7 – BO. Environmental Protection Agency's Reregistration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion. Endangered Species Act Interagency Cooperation Division, Office of Protected Resources. Consultation Tracking Number FPR-2017-9241.

some of these opportunities in a recent white paper.[37] Other areas where efficiencies can be secured include (but are not limited to): geographic and label restriction mitigations, existing federal consultations,[38,39,40] and state restrictions, and a realistic application of usage data.

2.7.1 Consideration of Previous Programmatic Consultations

The Services often conduct programmatic consultations with various federal agencies (*e.g.*, APHIS, US Forest Service, Bureau of Land Management, Army Corps of Engineers, National Parks Service) to address the potential effects of an action on listed species, such as consultations on the Mormon cricket[41] and Boll Weevil Eradication Program.[42] In these cases, consultation occurs between the USDA APHIS and appropriate Services under Section 7 of the ESA to evaluate whether listed species in the area covering the spatial extent of the program would be at risk considering the measures proposed (in this case insecticide applications). 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

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[37] CLA (CropLife America). 2020. A CropLife America White Paper Report: Thinking about Step Zero. Washington D.C.

[38] U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) Grasshopper and Mormon Cricket, Final Environmental Impact Statement, January 31, 2020, https://www.aphis.usda.gov, (last visited 04/07/2020).

[39] The Boll Weevil Eradication Program is a cooperative effort between the U.S. Department of Agriculture (USDA) and State officials, who work with cotton growers to eradicate the boll weevil, in incremental stages, from the United States. To date, the boll weevil has been eradicated from more than 98 percent of the U.S. cotton acreage in 15 Southeastern and Southwestern States, as well as significant portions of 3 others.

[40] A Finding of No Significant Impact (FONSI) is the penultimate and concluding step in an environmental impact analysis pursuant to the National Environmental Policy Act, 42, U.S.C. §4321, *et. seq.* If no significant effects on the environment (including T&E species, are found after investigation and the drafting of an EA, the agency must produce a Finding of No Significant Impact (FONSI). This document explains why an action will not have a significant effect on the human environment and includes the EA or a summary of the EA that supports the FONSI determination.

[41] U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) Grasshopper and Mormon Cricket, Final Environmental Impact Statement, January 31, 2020, https://www.aphis.usda.gov, (last visited 04/07/2020).

[42] The Boll Weevil Eradication Program is a cooperative effort between the U.S. Department of Agriculture (USDA) and State officials, who work with cotton growers to eradicate the boll weevil, in incremental stages, from the United States. To date, the boll weevil has been eradicated from more than 98 percent of the U.S. cotton acreage in 15 Southeastern and Southwestern States, as well as significant portions of 3 others. https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/sa_environmental_assessments/ct_boll_weevil

listed species and their critical habitat that have been addressed can be removed from consideration in the BE *a priori* under applicable circumstances. Communication with the registrant is also important to understand how the products may be used in any of these programs. For example, a percentage of the annual volume of a pesticide imported / manufactured may be dedicated to these programs. This information can provide an additional line of evidence that usage data are the appropriate data to apply to estimate exposure in the BE and further the Agency's and Services understanding of how a pesticide is used.

2.8 Collaboration

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.

2.9 Communication

Communication with registrants, the Services, other sister agencies within the IWG and with interested stakeholders will be a critical component of developing a durable, well-accepted ESA review process for pesticide registration decisions. Several areas where communication can be strengthened are discussed below.

2.9.1 Modeling

The MAGTool is a highly complex model that incorporates spatial data, effects thresholds, exposure models, and the probabilistic tools in the alternative analyses that EPA uses is using to evaluate risk to listed species. Within the time limit of the Public Comment period (and extension) this tool is far too complex for a full evaluation during the comment period to be able to evaluate fully. There is currently a lack of transparency and insufficient documentation on how the model functions and what the inputs to the MAGTool are; this is especially true when eight (8) new models were used in the Draft Carbamate BEs that to our knowledge have not been previously open for public review and comment. For example, UDL generation takes a considerable amount of time and effort to reconstruct and/or 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 of them. The use site generation tool[43] was presumably used to generate the use data layers UDLs for carbaryl and methomyl. However, this does not appear to be clearly stated in the Draft Carbaryl BEs.

CLA encourages EPA to simplify the MAGTool (and associated tools) if EPA intends to continue to use it for the final carbamate BEs and future BEs. This includes clear user documentation and case studies/examples of how to parameterize the model. CLA also strongly recommends that a workshop or course be offered to allow interested parties to better understand exactly how the model works and how it will be employed in future BEs. Finally, given the importance of these tools in the assessment process, each of them should be subjected to thorough review and public comment by stakeholders after these workshops are held to allow for improvements.

2.9.2 Notice of the Limitations of the Biological Evaluation

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. In future, EPA should also use the species status information that has been validated by FWS, in lieu of constructing its own dataset as was done in these Draft Carbamate BEs. To the extent that future BEs overstate potential risk to listed species (as CLA strongly believes they do in the Draft Carbamate BEs), the documents would benefit by sufficient context to allow for more meaningful understanding by both the

[43] https://www.epa.gov/endangered-species/models-and-tools-national-level-listed-species-biological-evaluations-carbaryl#spatial

Services and the public to understand where, and if, potential risks need to be mitigated to protect listed species and their habitat.

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 pubic clearly, and address these uncertainties.

2.9.3 Working Relationship with Stakeholders

CLA continues to advocate for a close working relationship with EPA on topics associated with pesticide products. CLA represents the registrants of these products and can bring significant knowledge to the table on pesticide usage, integrated pest management, and many other issues, as can other interested stakeholders. CLA and other stakeholders can work with EPA by providing scientific expertise, agricultural knowledge, and information relevant to the scientific foundation for pesticide regulatory decisions.

3 Conclusion

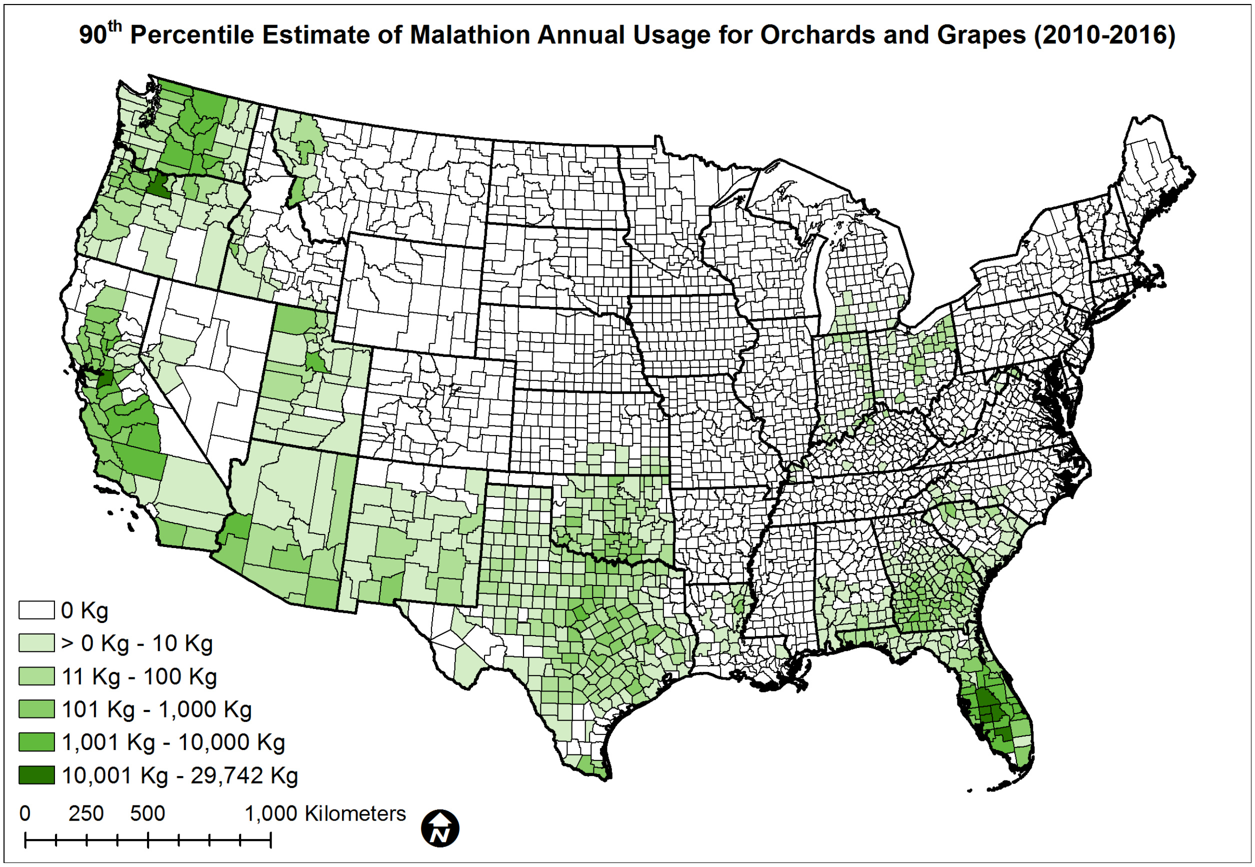
As applied in the Draft Carbamate BEs, the Revised Method appears to require an extraordinary amount of data and resources without providing meaningful analysis that will allow the Services to perform their obligations under the ESA – making a determination as to whether EPA’s registration action will jeopardize the listed species or adversely affect a critical habitat. There continues to be a need to identify methods that will reduce the effort required to generate scientifically defensible effect determinations while providing realistic information to the Services on which they can make their required determinations in an accurate and timely manner. The Draft Carbamate BEs fail to provide that analysis in an efficient and informative way. Rather, compounding conservatism, coarse exposure modeling, and incomplete weight-of-evidence analyses that do not progress significantly beyond the FIFRA-based screening level assessment do not currently allow for this type of evaluation. We look forward to continued improvements as all involved gain experience with the process.

ATTACHMENT I

EPA-HQ-OPP-2020-0090

Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale: May 2020 Revision

STONE ENVIRONMENTAL



PROJECT NO.

19-033

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Acknowledgements

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May 2020 Revision Notes

The original version of this report and accompanying datasets, released in August 2019, have been revised to correct a deficiency identified in the county-scale crop group usage estimation method that occurred in uncommon circumstances involving inconsistences of reported pesticide usage and independent estimates of labeled crop group use site acreage. The methodology described in this report was slightly modified to better handle these situations and the resulting malathion usages estimates were also updated to reflect this. The updates to this report and accompanying malathion usage datasets can be summarized as follows:

- New text added to page 16, end of last paragraph, "We found two situations where using Method 3 to iteratively adjust potential and actual usage calculations that were initially widely diverged resulted in state crop use total estimates that varied widely from the original estimates. If the only crop group with reported usage in the state data has no potential usage in the state, after Iteration 2 the state crop group total would be set to 0 for all crops, so Method 2 is applied instead. If a crop group with state reported usage only has potential usage in counties that reported no usage, usage data would get dropped out for the crop group and state total usage would be reduced after Iteration 2, so Method 1 is applied instead."
- Regression statistics comparing Method 1, Method 2, and Method 3 estimates to CA PUR data changed slightly, so those numbers were updated in the text.
- Regression figures comparing Method 1, Method 2, and Method 3 estimates to CA PUR changed slightly, so were updated.
- Maps of usage statistics changes slightly, so all were updated.
- The accompanying Excel spreadsheet usage results stats for several states and crop groups changed (slightly in most cases, modestly in a few cases) so those were updated.

Executive Summary

This study develops a methodology for estimating pesticide usage and actual percent of potential usage estimates at the highest spatial resolution practical using publicly available data sources. The study focuses on agricultural uses of pesticides. An important objective of the study was the estimation of usage for individual crops or crop groups at the sub-state-level, namely county-level or Crop Reporting District (CRD) level. The final usage estimates generated in this assessment are expressed probabilistically as annual usage percentiles, which reflects both the temporal variability in usage and the uncertainty in the source data and estimation methods.

Pesticide usage data represent the actual historical usage of a registered pesticide. At a minimum, the data describe the amount of pesticide applied over a specified geographic region over a given period of time. Pesticide usage data can often include the specific crop or group of crops (e.g., orchards and grapes) that the pesticide was applied to. Pesticide use information represents where and how a registered pesticide can be legally applied in accordance with its approved label. While pesticide use information describes how a pesticide could be potentially used, pesticide usage data describe how a pesticide is used in practice. Pesticide usage data is important to human health and ecological risk assessments, and in particular, endangered species risk assessments. Pesticide usage data provides the information necessary to refine the assumption that labeled pesticide use reflects pesticide usage on all potential use sites.

Pesticide usage by crop group at the county-level can be estimated from best available, publicly available nationwide data sources. Several methods to generate these estimates were developed. These methods were evaluated against observed crop group county-level annual malathion usage from the Pesticide Use Reporting (PUR) database in California using malathion as a case study. The best performing method considered county-level total usage, state-level crop group usage, and potential usage based on CDL crop acreage and label use rates. This method resulted in strong agreement with the PUR across all counties and crop groups, with an R^2 of 0.7978 for county-level estimates and 0.8419 for CRD-level estimates. The method was applied nationally using seven years of malathion usage data (2010-2016) resulting in probability distributions of annual usage and percent of potential usage. The percent of potential usage was based on crop acreage estimates from both CDL and USDA AgCensus and annual surveys. These usage statistics were generated for malathion at the county, CRD, and state-levels for nine crop groups (alfalfa corn, cotton, orchards and grapes, other crops, pasture and hay, rice, vegetables and fruit, and wheat) and are provided as Excel spreadsheets that accompany this report. Example maps of county level actual usage and percent of potential usage were provided to demonstrate how the data generated can be used to visualize the spatial distribution and magnitude of usage. Maps depicting usage associated with the specific locations of crops showed how locations of pesticide usage can be reconciled at the sub-county scale.

The pesticide usage statistics generated in this study represent probability distributions of usage that can be incorporated into multiple phases of an endangered species risk assessment. The more conservative 90th percentile or maximum usage rates and percent of potential usage data would be appropriate at screening-level steps or initial refinements of exposure, while the 50th percentile estimates represent the most likely usage scenarios for more refined exposure and ecological modeling. Several examples of incorporating usage data into endangered species risk assessments include refined crop footprint and co-occurrence analysis, refined exposure modeling, and weight-of-evidence analysis.

The pesticide usage data sources and the estimation and analysis methodologies presented in this report represent an unbiased and reproducible approach to maximizing the utility of publicly available pesticide usage data in human health and ecological risk assessments, including endangered species assessments. This report demonstrates that a tremendous amount of valuable information on the spatial distribution and magnitude of pesticide usage nationwide can be garnered with the currently available datasets. Thoughtful application of this data will enable more defensible and scientifically accurate assessments concerning the potential risks of pesticide use to humans and the environment.

Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale

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1. Background

Pesticide usage data represent the actual historical usage of a registered pesticide. At a minimum, usage data describe the amount of pesticide applied over a specified geographic region over a given period of time. Pesticide usage data can often include the specific crop or group of crops (e.g., orchards and grapes) that the pesticide was applied to. The spatial scale of the reporting units of pesticide usage data can vary from the sub-county scale to the national scale, with finer spatial scales more desirable when available. In addition to the amount of pesticide usage (i.e., pounds or kilograms), the area treated with the pesticide can also be reported. Some pesticide usage databases will also include other information, such as the specific timing of applications, the method of application, and the specific product used.

Pesticide use information represents where and how a registered pesticide can be legally applied in accordance with its approved label. Critical elements of pesticide use information include the potential use sites where the pesticide may be applied, the maximum single and annual application rates, the number of applications per year or crop cycle, the minimum interval between applications, and the permissible application methods. While pesticide use information describes how a pesticide could be potentially used, pesticide usage data describe how a pesticide is used in practice and accounts for market share relative to competitive products, climatic factors, integrated pest management practices, and the variability in annual pest pressures.

Pesticide usage data is important to human health and ecological risk assessments, and in particular, endangered species risk assessments. The goal of an endangered species risk assessment is to understand whether the registration of a pesticide is likely to adversely affect a species or its critical habitat. The EPA's guidance on conducting ecological risk assessments for pesticides (EPA, 1998; EPA, 2004), including endangered species risk assessments, follows a tiered approach, starting with a conservative screening level risk assessment (SLERA) and moving on to incorporating more data and more sophisticated models and methods in a refined risk assessment. Screening-level environmental exposure modeling, and subsequent risk assessment methods, typically assume that the pesticide use described on a pesticide label reflects the actual pesticide usage. This implicitly assumes that all potential use sites for a pesticide receive applications at the maximum annual rate and for every year, often 30 consecutive years. In reality, actual pesticide usage is far different from this conservative assumption. Pesticide usage data provides us the information necessary to refine the assumption that the labeled pesticide use reflects pesticide usage on all potential use sites.

The utility of actual pesticide usage data is increased when the potential pesticide usage is also well-understood. When both of these quantities are known, we can determine the actual usage as a percent of potential usage. The percent of potential usage is very similar to the Percent of Crop Treated (PCT) for a given pesticide. When the PCT reflects the area of crop treated at maximum label rates, the percent of potential usage is equivalent to the PCT. If the PCT reflects the area of crop treated at less than maximum label rates, the percent of potential usage will be lower than the PCT. In the case where the PCT and the percent of potential pesticide usage are different, the percent of potential usage is a better indicator of the likely spatial extent and magnitude of pesticide exposure.

Pesticide usage data in the United States is available from both publicly-available and proprietary sources. Publicly available sources are published by federal government agencies (US Geological Survey [USGS], US Department of Agriculture [USDA]) and state government agencies (California Department of Pesticide Regulation Pesticide Use Reporting [PUR]). The ways in which these public datasets can be applied in scientific research and assessments are unrestricted. Proprietary pesticide usage data sources, such as the AgroTrak® database of agricultural pesticide usage (Kynetec, 2019), come with associated costs and restrictions in how the raw data can be used and published. The analyses in this study will focus on publicly available usage data sources, in large part because the most comprehensive proprietary dataset available (Kynetec, 2019) serves as the source data for the most comprehensive public dataset developed by the USGS (Baker and Stone, 2015).

The goal of this study was to develop of a methodology for estimating pesticide usage and actual percent of potential usage estimates at the highest spatial resolution practical using publicly available data sources for agricultural pesticide uses. . An important objective of the study was the estimation of usage for individual crops or crop groups at the sub-state-level, namely county-level or Crop Reporting District (CRD) level. The final usage estimates generated in this assessment are expressed probabilistically as annual usage percentiles, which reflects both the temporal variability in usage and the uncertainty in the source data and estimation methods. This report begins with a review of publicly available datasets that can be used to estimate pesticide usage and potential pesticide usage at the scales of interest. The sections that follow present an evaluation of the potential methods for estimating crop group pesticide usage at the county-scale, using the organophosphate insecticide malathion as an example. The results of applying the usage estimation method to malathion at the national-level are then presented and discussed for both actual pesticide usage and percent of potential usage. The discussion concludes with recommendations for how the pesticide usage estimates derived from the methodology developed here can be applied in the context of refined environmental exposure modeling and endangered species risk assessments.

2. Materials and Methods

2.1. Datasets

This first step of this study was to evaluate publicly available datasets that can be used to derive pesticide usage statistics at the crop group and county-scale. The pesticide usage statistics of interest included the annual usage (i.e., kg/year) and the percent of potential usage, where potential usage is defined by maximum label rates. Both national level and state-level datasets were considered. In order to ensure a robust analysis, the datasets included in the study were limited to those that provide quantitative estimates of usage for all crops within a crop group. In addition, to usage datasets, crop acreage datasets were also reviewed for estimating potential pesticide usage by crop group, both at the state- and county-scales. As with the usage estimates, crop acreage estimates needed to be quantitative and complete for a crop group at either the state- or county-scale for inclusion in this study

2.1.1. Pesticide Usage

The review of datasets found that the following pesticide usage datasets were sufficiently robust to include in this analysis:

1. USGS Annual Pesticide Use database(Baker and Stone, 2015): State-level crop group annual usage and county-level total annual usage;
2. USDA Agricultural Chemical Use Program Survey (USDA, 2019a): State-level crop/crop group annual usage; and the
3. California Pesticide Use Record (PUR) database (CDPR, 2019): Subcounty-level crop/crop group annual usage.

Other potential state-level datasets reviewed (e.g., Arizona (APMC, 2014), Massachusetts (MDAR, 2019), Minnesota (MDA, 2019), New York (NYSDEC, 2016), New Hampshire (NHDA, 1997), Oregon (ODA, 2000), and Washington (ODA, personal communication, 2019)) did not prove to be robust enough to provide meaningful usage estimates at the state and/or county-levels.

The USGS usage datasets (Baker and Stone, 2015) include both a county-level total annual usage estimate and a state-level annual usage estimate by crop group. For each of these estimates, the USGS provides a low estimate of usage (referred to as EPest-low) and a high estimate of usage (referred to as EPest-high). These two estimates can be thought of as providing upper and lower bounds on the usage estimates. These USGS datasets are derived from more detailed proprietary market surveys (Kynetec, 2019) and aggregated to a level that preserves the required confidentiality of the survey respondents. Details concerning the EPest-low and EPest-high usage estimates are provided in Baker and Stone (2015). As a result of their spatial and temporal completeness, both the USGS county-level total usage and the state-level crop group usage represented the most important datasets used in this assessment.

The USDA provides state-level estimates of pesticide usage as part of their annual Agricultural Chemical Use Program survey (USDA, 2019a). The survey is conducted for a selection of commodities on a rotating schedule (i.e., each commodity is surveyed only once every few years). The surveyed crops available for this analysis included: 1.) vegetables, corn & potatoes (2016), 2.) fruits, cotton, oats, soybeans, and wheat (2015), 3.) vegetables, corn & potatoes (2014), 4.) peanuts & rice (2013), 5.) soybeans and wheat (2012), 6.) fruits, barely & sorghum (2011), and 7.) vegetables, corn, cotton and potatoes (2010). The USDA surveys are targeted at the top-producing states for each commodity. As is typical of USDA survey data, the estimates of pesticide usage are sometimes undisclosed due to limited sample size and confidentiality requirements. While this information provides an indication of the presence of pesticide usage, there is no way quantify the amount of usage. This data source was often incomplete for a given year, state, and crop group, and was incorporated into the assessment only when the data provided a usage estimate that reasonably covered the entire crop group.

The California Pesticide Use Record (PUR) database (CDPR, 2019) is maintained by CDPR and has been comprehensively recording agricultural usage of pesticides since 1990. The source data provides actual usage records at the one square mile section level and reports the crop, acreage, rate, and the date of application. The PUR database is broadly viewed as the "gold standard" when it comes to pesticide usage data. Thus, for the purposes of this study, the PUR will be the single pesticide usage dataset considered in California.

2.1.2. Crop Acreage

Crop acreage estimates at both the county- and state-levels are needed to estimate the potential pesticide usage based on the pesticide label. Three sources of crop acreage data were evaluated in this assessment, all of which are managed by the USDA. These include:

1. Cropland Data Layer (Boryan et al., 2011; USDA, 2019b): a nationwide 30 m resolution spatial dataset of crop class, produced annually;
2. Census of Agriculture (USDA, 2019c): county- and state-level census of crop acreage by county and state; and
3. National Agricultural Statistics Service Annual Survey (USDA, 2019d): county- and state-level survey of crop acreage by county and state.

The USDA Cropland Data Layer (CDL) provides a seamless, national data layer depicting crop classes at a 30-meter (m) resolution from remote sensing data (Boryan et al., 2011; USDA, 2019b). This dataset is used extensively in pesticide exposure risk assessments to define the spatial extent of potential pesticide use sites. In this assessment, the CDL estimates of crop acreage were used to calculate county-level crop group pesticide usage estimates from source datasets, as well as the potential malathion usage by year, crop group, and county.

In addition to the CDL, the USDA also produces crop acreage estimates based on producer surveys, including the Census of Agriculture (AgCensus) conducted once every five years (e.g., 2012, 2017), and annual commodity surveys. The AgCensus (USDA, 2019c) seeks to compile county-level acreage (harvested acres are reported) for nearly all agricultural crops grown in the US. The annual commodity surveys (USDA, 2019d) are less comprehensive than the AgCensus, but can provide useful information for the more dominant crops and production regions. They also provide estimates of planted acreage, which can be a better indicator or potential pesticide usage than the harvested acres reported in AgCensus. The biggest challenge with the use of the AgCensus and

National Agricultural Statistics Service (NASS) survey data is missing or undisclosed data. Missing data is most common for the years of NASS survey data (years when the full AgCensus does not occur), and typically arises for lower acreage crops and counties where acreage is low for the major crops. Undisclosed data occurs when USDA determines that the number of samples in their survey/census is small enough that confidentiality concerns would arise in reporting actual values (e.g., acres planted or harvested) for a particular commodity and county or state. In these cases, USDA only reports that a commodity occurred in the county/state, but the actual values (e.g., acreages) are not disclosed. The methods developed in this study for estimating county and crop group level pesticide usage, as well as potential usage, are heavily dependent on a complete picture of the crop acreage at both the state- and county-levels. For this reason, the application of the USDA survey estimates of crop acreage were used in a more limited way than the USDA CDL estimates of crop acreage. The details of how each dataset was incorporated into the analysis are provided in the methodology discussions that follow.

2.2. Methods

The potential pesticide usage by county and crop group is critical to understanding the context of actual pesticide usage. For example, usage of 500 kilograms could represent nearly 100% of potential use sites being treated at the maximum label rate, or it could represent less than 1% of potential use sites being treated. Understanding this percent of potential usage is essential to interpreting screening level exposure and risk assessments, as well as parameterizing models applied in refined exposure modeling and analyses. In this assessment, potential pesticide usage estimates were derived using both CDL-based crop acreages and crop acreages adjusted using AgCensus and NASS Survey data (USDA "Survey-Adjusted"). Given the uncertainty in both the CDL and AgCensus/NASS Survey data, both acreage estimates were treated with equal likelihood when calculating potential pesticide usage. These two calculation methods are described in the sections that follow.

Estimating actual pesticide usage statistics at the county and crop group level is a primary goal of this assessment and method development. The USGS pesticide usage data at the state/crop group level and the county/total level, along with crop group acreage estimates from CDL, provides several options for making county/crop group estimates. The USDA chemical use survey data, which provides only state-level crop group use for a subset of crop groups each year, is more limited in how county/crop group level use can be estimated. Several different methods were evaluated for developing these county/crop group estimates using the USGS usage data. These estimates were evaluated in the State of California and compared with measured county/crop group level malathion usage from the PUR to assess the robustness of each estimation methodology. In these evaluations, the PUR data was aggregated to be analogous to the USGS EPest-Low/EPest-High data, resulting in total pesticide usage by year at the county-level and crop group usage by year at the state-level (note that EPest-Low and EPEst-High are the same in California). This "surrogate" USGS data was then used as the basis to apply and evaluate three different disaggregation methods to estimate pesticide crop group usage at the county-level. California is the only state where these methods could be evaluated against ground truth data, i.e., the PUR. The results of these comparisons informed the choice of a methodology applied to the entire US. These methods and the comparisons with PUR are discussed following the potential pesticide usage estimate sections.

2.2.1. Potential Pesticide Usage by Crop Group and County, CDL-Based

The labels of two products containing malathion as the sole active ingredient were used to identify the crops to which this pesticide can be used, namely*: Fyfanon® 57EC (EPA Reg. No. 279-3607; formerly EPA Reg. No. 67760-40)*and *Fyfanon® ULV AG (EPA Reg. No. 279-3450; formerly 67760-35)*. Annual maximum application rates (in a.i. lbs/acre) for each of the crops were also obtained from these labels. In cases where the labels listed different application rates for the same crop, the highest value of the set was selected to represent the use pattern. The CDL was then used to estimate county- and state-level crop group acreage for malathion-labeled crops between 2010–2016. As a first step, each malathion-approved crop was matched to one or more of the crop classes in the CDL datasets. Most of the crops in the malathion labels were matched to specific crop classes in the CDL dataset. The "Grassland/Pasture" (code 176) CDL crop class was excluded from this analysis; this crop class includes both managed and naturally occurring grasslands and would require additional analysis to differentiate these potential use sites. Next, all CDL classifications representing malathion labeled crops were assigned to one of the USGS crop groups used in their pesticide usage estimates. These malathion-labeled crops, CDL crop classes, USGS crop groups, and annual use rates are summarized in Appendix A, Table A- 1.

Using ArcGIS 10.5 and ArcPy, spatial analysis was conducted to determine the crop acreages, and ultimately the potential annual malathion usage for each USGS crop group, county, and year combination. First, a spatially explicit malathion crop footprint was produced from each year of CDL by extracting and reclassifying those classes to one of the crops potentially treated with malathion into a new raster dataset. Each crop footprint raster plus a feature class depicting the county boundaries were added as inputs to the tabulate area tool in ArcGIS. This tool was then used to determine the crop group acreage for each county in the contiguous United States across all seven years evaluated (2010–2016). Using these crop acreage estimates and the following equation, malathion annual potential usage was estimated for each USGS crop group, county, and year combination:

$$Crop\ Group\ Potential\ Usage - CDL_{i,j} = \sum_{c=1}^{n} crop\ acreage_{i,j,c} \times \max annual\ use\ rate_c$$

where,

c = individual CDL crop class
i = county
j = year
n = number of individual crop classes in crop group

2.2.2. Potential Pesticide Usage by Crop Group and County, USDA Survey-Adjusted

The USDA AgCensus and NASS Surveys provide valuable estimates of crop acreage at the county- and state-levels. As discussed previously, the shortcoming of these datasets for this assessment is that acreages can often be undisclosed due to confidentiality requirements, making estimates of crop group total acreage and potential pesticide use incomplete. Nevertheless, we recognize the CDL estimates of crop group acreage are imperfect, thus incorporating survey-based crop group acreage estimates into this assessment will help in accounting for uncertainty the CDL data.

The USDA AgCensus and NASS Survey data were used to calculate state-level crop-group acreage bias factors that were then used to adjust the CDL-based crop group acreage values at the county-level. State-level bias factors were chosen instead of county-level bias factors because the frequency of undisclosed data at the state-level was much less than undisclosed data at the county-level. In addition, two years of AgCensus/NASS survey data were considered, 2012 and 2017. Only these years were selected because they correspond with the AgCensus, which contains much more complete data than years with only NASS Survey data.

For each year, state, and crop group, the total crop group acreage was calculated. Information from the AgCensus served as the primary data in this calculation. The acreage of each crop was represented by the "Area Harvested" (field crops, vegetables, other crops), "Area Grown" (berries), or "Area Bearing & Non-Bearing" (orchards). In cases where a crop had disclosed data in the NASS Survey dataset, then the NASS Survey "Area Planted" data was used in place of the AgCensus "Area Harvested" data. The choice to use "Area Planted" in place of "Area Harvested" was based on comparison with CDL, which showed better agreement with "Area Planted", and to be more conservative in estimating the area of potential pesticide use. In cases where AgCensus was NASS Survey was undisclosed, a nominal area of 160 acres was assigned.

Bias factors for USDA Survey (BiasFactor) crop group acreage compared to CDL-based crop acreage were calculated at the state and crop group level by averaging the ratios of USDA Survey acreage to CDL acreage based on 2012 and 2017 estimates. We then used these bias factors to calculate additional estimates of potential pesticide use at the county and crop group level following the equation below:

$$Crop\ Group\ Potential\ Usage - Survey\ Adjusted_{cg,i,j} = Crop\ Group\ Potential\ Usage - CDL_{cg,i,j} * \mathrm{BiasFactor}_{cg,s}$$

where,

cg = individual CDL crop class

i = county

j = year

s = state

2.2.3. Actual Pesticide Usage by Crop Group and County

State and county-level malathion usage data from multiple sources were used to derive the county-level usage estimates for each crop group. Three different county-level crop group usage estimation methods were applied and evaluated in California . The starting point of usage estimates for each method was state-level crop group usage by year and county-level total usage by year derived by aggregating PUR data. This starting point is analogous to the USGS EPest-Low/EPest-High data and was used in place of the USGS data to allow for a more direct comparison with PUR data and a more accurate performance evaluation of each estimation method. All three methods incorporated crop group acreage estimated from CDL. Crop group acreage from AgCensus/NASS Survey data were not used in these actual usage estimates due to the missing/undisclosed data limitations of these datasets at the county-level. The best performing method of the three was then applied to all the lower 48 states.

2.2.3.1. Actual Pesticide Usage Methods 1 Calculation

For the first method, the county-level crop group usage was calculated as a fraction of the state-level crop group usage, which was assumed to be proportional to the fraction of crop group acreage in the county relative to the state-level crop group acreage. This method maintains the source data's state-level crop group usage estimate but is not necessarily consistent with the source data's county-level total usage estimate. The Method 1 estimate was calculated according to the following equation:

$$County\ Crop\ Group\ Usage - M1_{i,j} = \frac{County\ Crop\ Group\ Acreage_{i,j}}{State\ Crop\ Group\ Acreage_j} \times State\ Crop\ Group\ Usage_j$$

where,
- i = county
- j = year

2.2.3.2. Actual Pesticide Usage Methods 2 Calculation

For the second method, the county-level crop group usage was calculated as a fraction of the total county-level usage which was assumed to be proportional to the fraction of potential crop group usage in the county relative to the total (all crop groups) potential usage in the county. This method maintains the source data's county-level total usage estimate but is not necessarily consistent with the source data's state-level crop group usage estimate. The Method 2 estimate was calculated according to the following equation:

$$County\ Crop\ Group\ Usage - M2_{i,j} = \left(\frac{Crop\ Group\ Potential\ Usage_{i,j}}{Total\ Potential\ Usagei_{i,j}} \times Total\ Actual\ Usage_{i,j} \right)$$

where,
- i = county
- j = year

2.2.3.3. Actual Pesticide Usage Methods 3 Calculation

The Method 1 and Method 2 calculations each have their shortcomings. Neither of the two consider both the state-level crop group usage information and the county-level total usage data together. To improve upon these two methods, a third approach was developed to incorporate both the state-level and county-level data. This approach, Method 3, begins with the Method 2 estimate and then iteratively adjusts those county-level crop group usage estimates to conform to the state-level crop group usage estimates. The mechanics of this approach are best demonstrated though the example shown in Table 1 below. In this example, the source data is highlighted in red. The table includes the county-level total usage estimates for four counties, as provided by the USGS pesticide usage datasets. It also includes the state-level usage estimates by crop group for three crop groups, which was also provided from USGS pesticide use datasets. In examining this portion of , we see that summing the county-level total usage results in 2,000 (kg) of usage, and that summing the state-level crop group usage also results in 2,000 (kg) of usage. The third piece of source data, as presented, is the county-level crop group potential usage estimates, derived from the county-level crop acreages determined from CDL and the labeled maximum annual application rates for the pesticide.

The first derived portion of the calculation is the Method 2 estimates shown at the top right of Table 1 in blue. These county-level crop group estimates maintain the county-level total usage estimates from the source data; however, the resulting state-level crop group usage deviates from the source data, sometimes significantly. For example, the Method 2 calculations result in an estimated 700 (kg) of usage on Crop3; however, the source data reported 400 (kg) of usage on Crop3. Method 3 addresses this inconsistency by rescaling the county-level crop group estimates back towards the state-level crop group estimates.

In Iteration 1, the county-level crop group usage estimates from Method 2 are multiplied by the ratio of the source data state-level crop group usage to the state-level crop group usage estimated from Method 2. For example, for Crop1 in County 2, the Method 2 estimate of 250 (kg) is multiplied by (800/750) to get an adjusted estimate of 267 (kg). Similarly, for Crop 3 in County 2, the Method 2 estimate of 250 (kg) is multiplied by (400/700) to get an adjusted estimate of 143 (kg). In making this adjustment, as presented in the table, the estimated state-level crop group usage is now equal to the source data, with a bias of 1.0 (no bias) for all crop groups. However, our county-level total usage estimate at Iteration 1 is now not equivalent to our source data, with bias ranging from 0.82 (County 2) to 1.45 (County 1).

Iteration 2 adjusts the estimates from Iteration 1 back toward the source data county-level total usage estimates. Here, the county-level crop group usage estimates from Iteration 1 are multiplied by the ratio of the source data county-level total usage to the county-level total usage estimated at Iteration 1. For example, for Crop1 in County 2, the Iteration 1 estimate of 267 (kg) is multiplied by (500/410) to get an adjusted estimate of 326 (kg). Similarly, for Crop 3 in County 2, the Iteration 1 estimate of 143 (kg) is multiplied by (500/410) to get an adjusted estimate of 174 (kg). In making this Iteration 2 adjustment, the estimated county-level total usage is now equal to the source data, with a bias of 1.0 (no bias) for all crop groups, as shows in Table 1. However, our state-level crop group usage estimate at Iteration 2 is now not equivalent to our source data, with bias ranging from 0.92 (Crop2) to 1.06 (Crop3).

Subsequent iterations were performed, alternating between adjusting to the state-level crop group usage and the county-level total usage, until the bias in both quantities stabilized near 1.0. In this example in Table 1, both sets of bias values converge near 1.00 after 9 iterations. Notice that the usage estimates at Iteration 9 look quite different than they did after only Method 2 was applied. Although not shown here, a purely Method 1 estimate would have resulted in very different county-level crop group estimates as well. It should be noted that while Method 3 results in a balance between honoring both scales of source data (county-level total and state-level crop group), it is not guaranteed to achieve a “perfect” estimate. Rather, it represents a way in which these readily available source datasets can be combined to make a well-informed estimate of crop group specific usage at a higher spatial resolution than is publicly available. We found two situations where using Method 3 to iteratively adjust potential and actual usage calculations that were initially widely diverged resulted in state crop use total estimates that varied widely from the original estimates. If the only crop group with reported usage in the state data has no potential usage in the state, after Iteration 2 the state crop group total would be set to 0 for all crops, so Method 2 is applied instead. If a crop group with state reported usage only has potential usage in counties that reported no usage, usage data would get dropped out for the crop group and state total usage would be reduced after Iteration 2, so Method 1 is applied instead.

Table 1. Method 3 County and Crop Group Level Actual Pesticide Usage Calculation Example.

County	TotalUse	Crop1Pot.Use	Crop2Pot.Use	Crop3Pot.Use	TotalPot.Use	Method 2 Estimate				
1	100	0	1000	0	1000	**County**	**Crop1Use**	**Crop2Use**	**Crop3Use**	**Total Use**
2	500	1000	0	1000	2000	1	0	100	0	100
3	1000	2000	1000	1000	4000	2	250	0	250	500
4	400	0	1000	1000	2000	3	500	250	250	1000
State		**Crop1Act.Use**	**Crop3Act.Use**	**Crop3Act.Use**	**Total Use**	4	0	200	200	400
1		800	800	400	2000	**Total**	**750**	**550**	**700**	**2000**
			Iteration 1		**Cnty Bias**	**Iteration 1**				
					1.45	1	0	145	0	145
					0.82	2	267	0	143	410
					1.04	3	533	364	143	1040
			State Crop Grp. Bias		1.01	4	0	291	114	405
		1.00	1.00	1.00		**Total**	800	800	400	2000
			Iteration 2		**Cnty Bias**	**Iteration 2**				
					1.00	1	0	100	0	100
					1.00	2	326	0	174	500
					1.00	3	513	350	137	1000
			State Crop Grp. Bias		1.00	4	0	287	113	400
		1.05	0.92	1.06		**Total**	**838**	**737**	**425**	**2000**
			Iteration 3		**Cnty Bias**	**Iteration 3**				
					1.09	1	0	109	0	109
					0.95	2	311	0	164	475
					1.00	3	489	380	129	998
			State Crop Grp. Bias		1.05	4	0	312	106	418
		1.00	1.00	1.00		**Total**	800	800	400	2000
			Iteration 4		**Cnty Bias**	**Iteration 4**				
					1.00	1	0	100	0	100
					1.00	2	327	0	173	500
					1.00	3	490	380	130	1000
			State Crop Grp. Bias		1.00	4	0	298	102	400
		1.02	0.97	1.01		**Total**	817	779	404	2000
			Iteration 5		**Cnty Bias**	**Iteration 5**				
					1.03	1	0	103	0	103
					0.98	2	320	0	171	491
					1.00	3	480	391	128	999
			State Crop Grp. Bias		1.02	4	0	307	101	407
		1.00	1.00	1.00		**Total**	800	800	400	2000
			Iteration 6		**Cnty Bias**	**Iteration 6**				
					1.00	1	0	100	0	100
					1.00	2	326	0	174	500
					1.00	3	480	391	128	1000
			State Crop Grp. Bias		1.00	4	0	301	99	400
		1.01	0.99	1.00		**Total**	806	792	401	2000
			Iteration 7		**Cnty Bias**	**Iteration 7**				
					1.01	1	0	101	0	101
					0.99	2	323	0	174	497
					1.00	3	477	395	128	1000
			State Crop Grp. Bias		1.01	4	0	304	98	403
		1.00	1.00	1.00		**Total**	800	800	400	2000
			Iteration 8		**Cnty Bias**	**Iteration 8**				
					1.00	1	0	100	0	100
					1.00	2	325	0	175	500
					1.00	3	477	395	128	1000
			State Crop Grp. Bias		1.00	4	0	302	98	400
		1.00	1.00	1.00		**Total**	802	797	401	2000
			Iteration 9		**Cnty Bias**	**Iteration 9**				
					1.00	1	0	100	0	100
					1.00	2	324	0	174	499
					1.00	3	476	396	128	1000
			State Crop Grp. Bias		1.00	4	0	303	98	401
		1.00	1.00	1.00		**Total**	800	800	400	2000

2.2.3.4. Evaluation of Actual Usage Estimates Against Known Actual Usage, California PUR

The methods described in the previous three sections (Method 1, Methods 2, and Method 3) were applied in California and compared against the PUR data. This analysis required the following steps to prepare the data for comparison.

1. The PUR data for malathion labeled crops were assigned to the USGS crop groups and aggregated to the state-level. This data was then analogous to the USGS state-level crop group usage estimates.
2. The PUR data for malathion labeled crops were aggregated to the county-level for all of the USGS crop groups combined. This data was then analogous to the USGS county-level total usage estimates.
3. The PUR data for malathion labeled crops were assigned to the USGS crop groups and aggregated to the county-level. This data the represents the "true" actual usage at the county and crop group level and is therefore the data that our usage estimates will be compared to.

The estimates from each of the three county-level crop group estimation methods were compared to the "true" PUR estimates by pairing each county crop group usage estimate for every county and year (2010–2016) and performing a linear regression. The county-level estimates and actual PUR usage were then aggregated to the CRD level, and the pairs of usage for every CRD and year were also compared in a linear regression. The coefficient of determination (R^2) and the slope of the linear regression (b) for the different estimation methods were calculated to assess the goodness of fit of each method.

Figure 1, Figure 2, and Figure 3 show the linear regression of the estimated county-level crop group malathion usage versus the observed PUR malathion usage for Method 1, Method 2, and Method 3 respectively. The poorest estimates were based on Method 1, with an R^2 statistic of 0.1293 and linear regression slope of 0.55. The estimates based on Method 2 were considerably improved, with an R^2 statistic of 0.4122 and linear regression slope of 0.9952. The usage estimates were further improved following Method 3, with an R^2 statistic of 0.7978 and linear regression slope of 1.1103. Overall, Method 3 resulted in a very strong agreement with the observed county-level crop group annual malathion usage. The linear regression slope of 1.1103 indicates that Method 3 slightly underestimated the observed usage from PUR; however, this is largely driven by the highest usage values. As seen in Figure 3, Method 3 often resulted in county-level usage estimates when the PUR reported zero usage. It was much less common for Method 3 to predict zero usage and the PUR to show non-zero usage.

Figure 4, Figure 5, and Figure 6 show the linear regression of the estimated county-level crop group malathion usage versus the observed PUR malathion usage for Method 1, Method 2, and Method 3 respectively. The ranking of the three estimation methods for the CRD-level estimates are the same as for the county-level estimates, with Method 3 far outperforming the other two methods. In addition, R^2 statistics and linear regression slope improve for all three methods for the CRD estimates compared to the county-level estimates. The R^2 for Method 3 increased from 0.7978 to 0.8419 and the linear regression slope decreased from 1.1083 to 1.0475. This improvement is expected, and is a result of, the lower variability in usage estimates when aggregating to larger spatial units.

Method 3 was determined to be the best estimation method and was applied for all subsequent county-level crop group actual usage estimates in this assessment for malathion using the USGS EPest-low and EPest-high source datasets. Method 1 was applied for the county-level crop group usage estimates using the USDA Chemical Use Survey data, because the USDA data did not include the needed county-level total usage data required by Method 3. The USDA data represented a much smaller number of source usage estimates compared to the USGS dataset (only 27 state-level crop group USDA usage estimates in total from 2010 - 2016). In California, the PUR data was used for all the county-level actual usage estimates by crop group.

This demonstration of the county-level and CRD-level crop group usage estimations in California represents one of the most complex agricultural and pesticide usage landscape in the United States, where cropping patterns and pest pressure are spatially highly variable. Yet, the estimation method presented performed extremely well. In more homogeneous states, in terms of climate, agronomy, and biology, the pesticide usage estimation method presented is expected to perform even better.

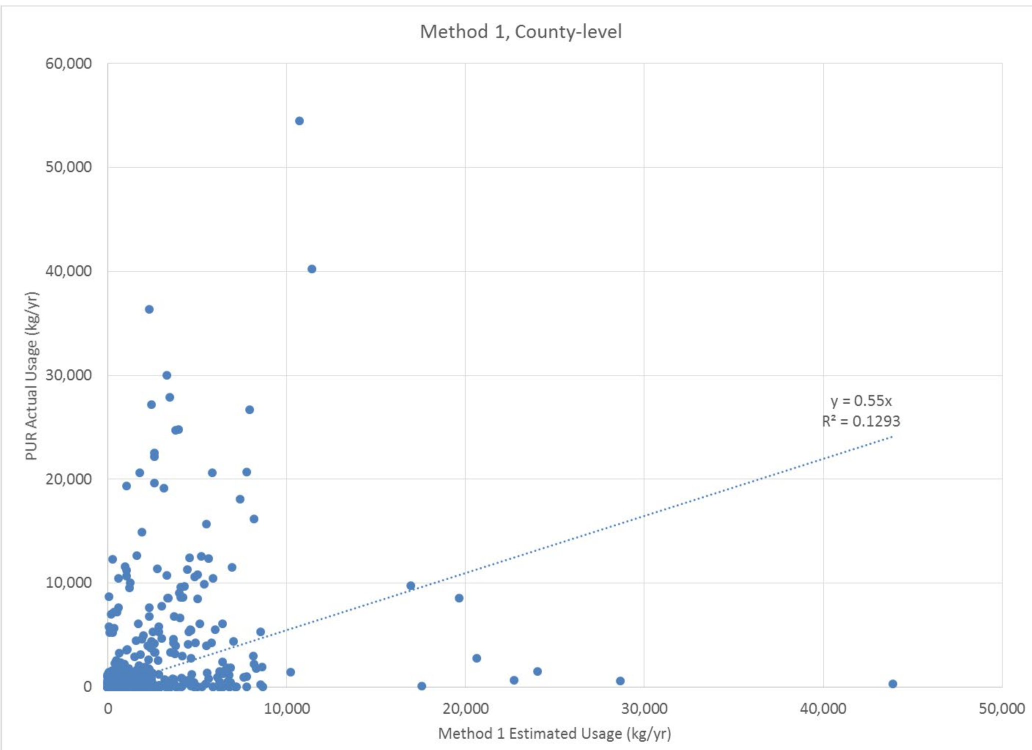

Figure 1. Linear Regression of Method 1 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

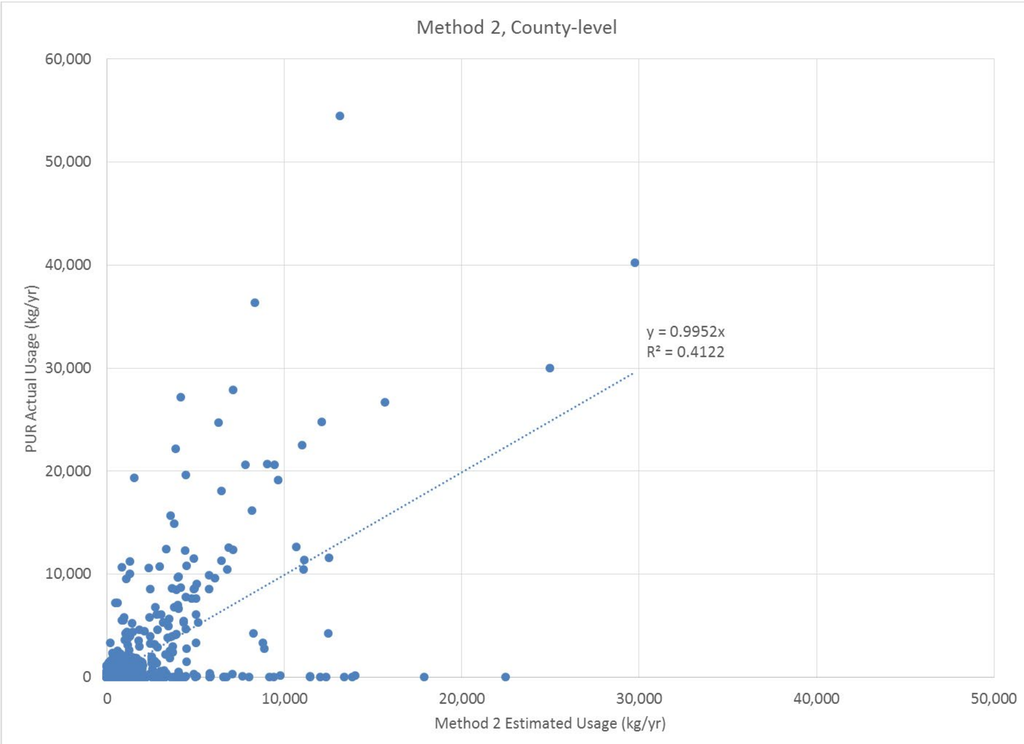

Figure 2. Linear Regression of Method 2 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

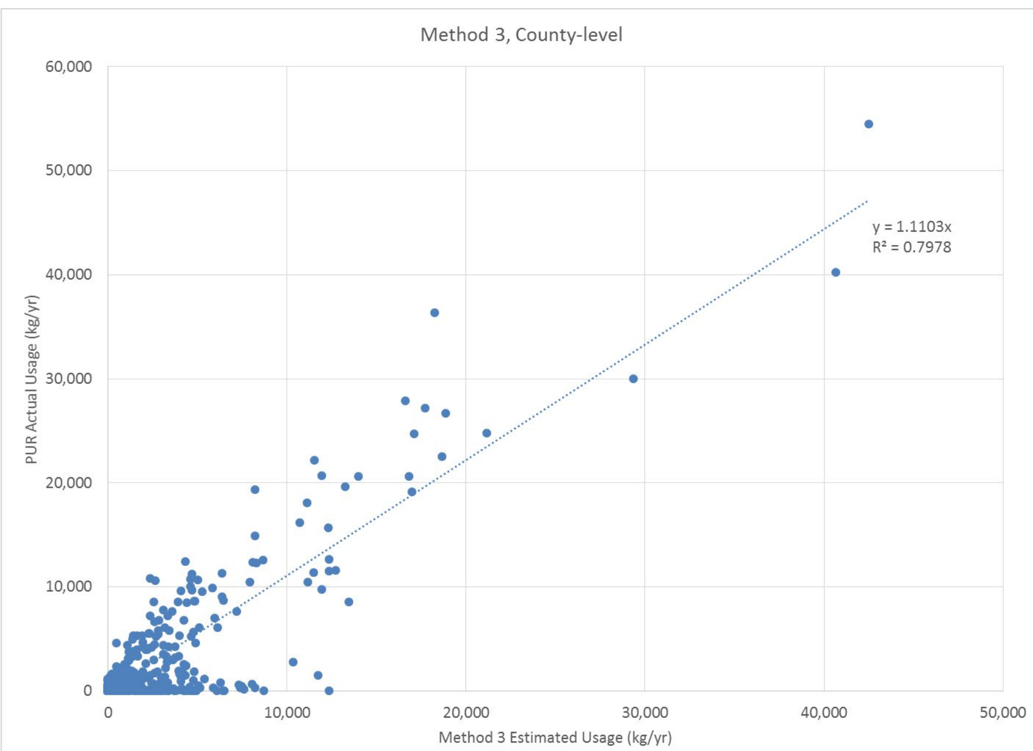

Figure 3. Linear Regression of Method 3 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

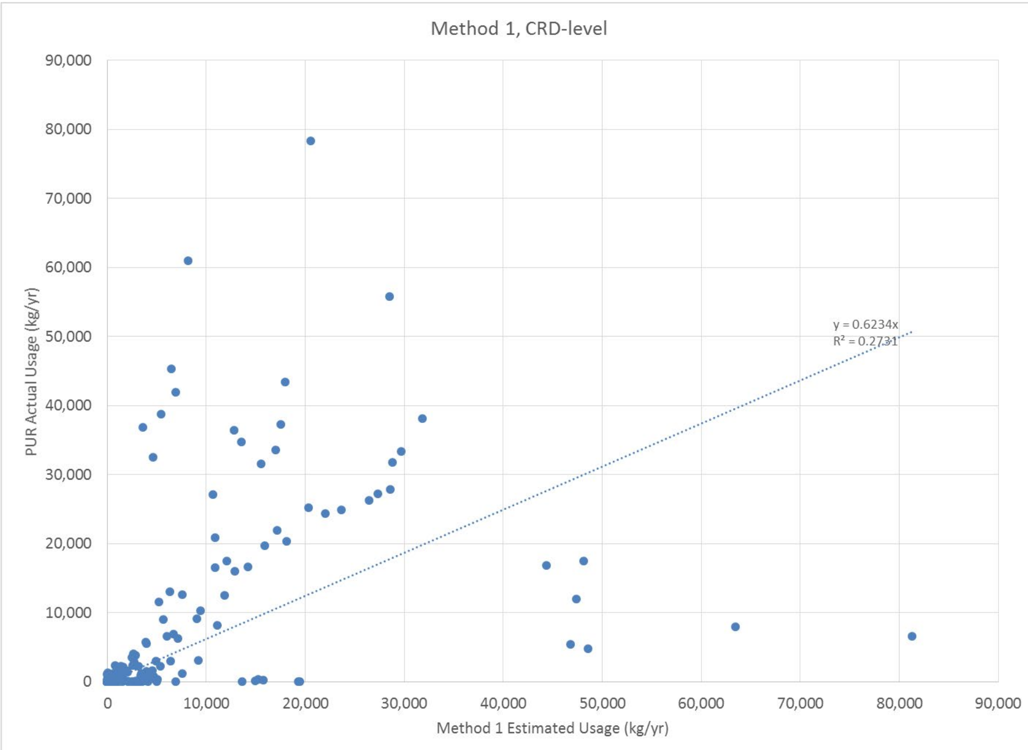

Figure 4. Linear Regression of Method 1 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

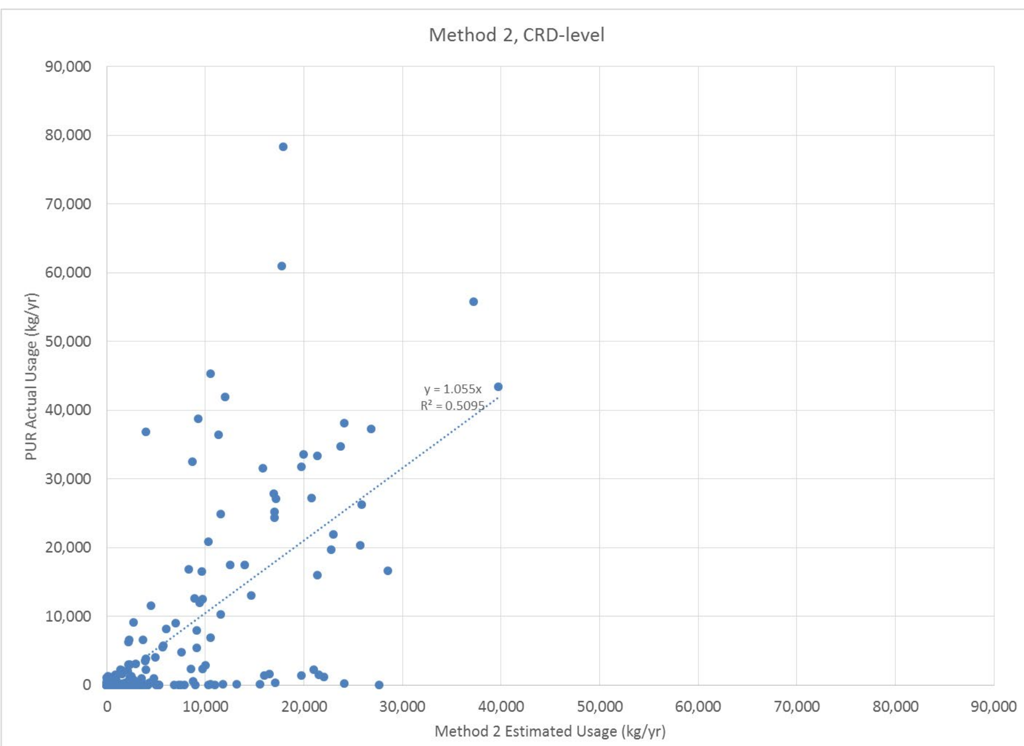

Figure 5. Linear Regression of Method 2 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

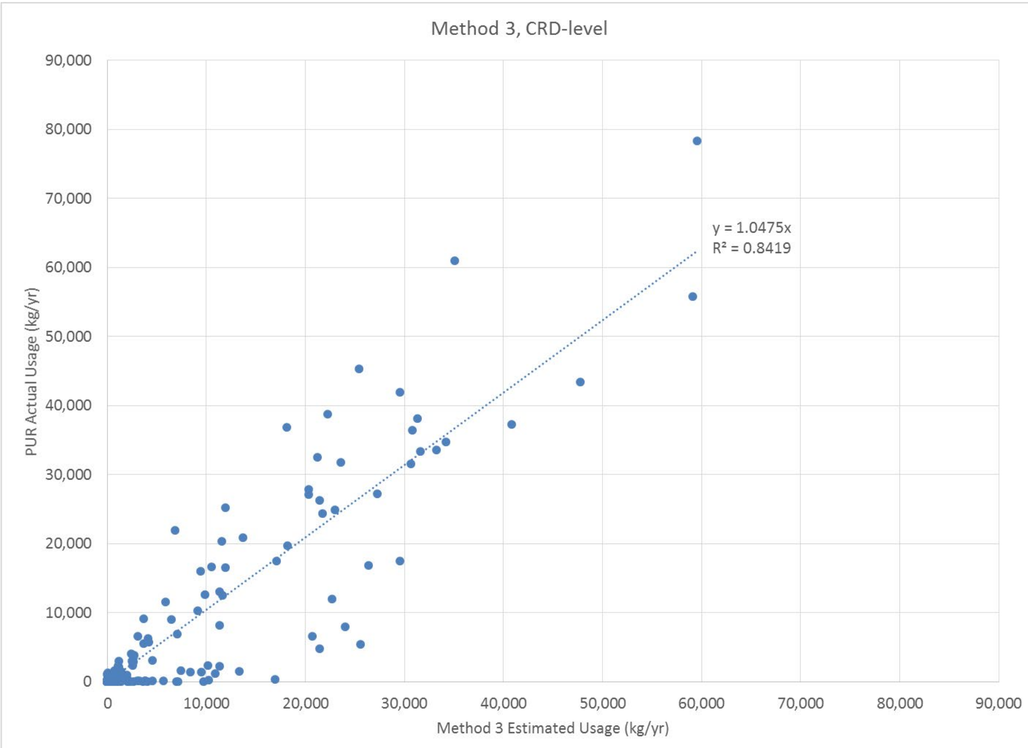

Figure 6. Linear Regression of Method 3 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

2.2.4. Actual Percent of Potential Pesticide Usage

The actual percent usage calculation is the primary indicator of how much pesticide usage is occurring relative to the potential annual usage allowed by the pesticide label. This quantification is critical in a refined ecological (endangered species) or human health risk assessment, whereas screening level exposure and risk analyses assume 100% of potential use sites are treated at the maximum annual pesticide application rates. The actual percent usage estimates can be used quantitatively in a probabilistic exposure assessment or qualitatively to put into context screening level exposure estimates or risk assessment results. These actual percent usage estimates can also be used as a component of a formal weight-of-evidence analysis.

Actual percent of potential usage calculations were developed by county, crop group, and year based on actual crop group usage estimates from:

1. USGS EPest-low (Method 3),
2. USGS EPest-high (Method 3), and
3. USDA Chemical Use Survey (Method 1).

and based on potential crop group usage estimates from:

1. CDL-based potential pesticide usage, and
2. USDA survey adjusted potential pesticide usage.

The actual crop group usage estimates by crop group were capped at the higher of the potential crop usage from the CDL-based and USDA survey adjusted estimates. This reduced the occurrence of anomalous percent of potential usage calculations which was occasionally occurring for low usage counties and crop groups. These actual percent usage calculations by county, crop group, and year for multiple estimates of actual malathion use estimates using the following equation:

$$County\ Crop\ Grop\ Actual\ Percent\ Usage_{i,j} = \left(\frac{Actual\ Crop\ Group\ Usage\ Estimate_{i,j}}{Potential\ Crop\ Group\ Usage_{i,j}}\right) * 100$$

where,

i = year
j = county

CRD-level and state-level actual percent of potential usage estimates were calculated by first aggregating the actual and potential usage at the county-level up to the CRD or state-levels. The calculations were then made according to the following equations:

$$CRD\ Crop\ Grop\ Actual\ Percent\ Usage_{i,j} = \left(\frac{Actual\ Crop\ Group\ Usage\ Estimate_{i,j}}{Potential\ Crop\ Group\ Usage_{i,j}}\right) * 100$$

where,

i = year
j = CRD

$$State\ Crop\ Grop\ Actual\ Percent\ Usage_{i,j} = \left(\frac{Actual\ Crop\ Group\ Usage\ Estimate_{i,j}}{Potential\ Crop\ Group\ Usage_{i,j}}\right) * 100$$

where,

i = year
j = state

2.2.5. Crop Group Usage Statistics by and County, CRD, and State

For each county (or CRD or state) and crop group combination, up to three usage estimates were calculated, dependent on the availability of USDA survey data, for seven years, resulting in up to 21 estimates. The usage statistics in California were based solely on the PUR; therefore, seven annual usage estimates were derived for each county/CRD/state and crop group. All annual estimates for a given crop group and county were combined into a population of estimates to calculate the minimum, 10^{th} percentile, 25^{th} percentile, 50^{th} percentile, 75^{th} percentile, 90^{th} percentile, and maximum annual usage estimate in (kg/yr).

Statistics on the percent of potential usage estimates were based on twice as many estimates as the actual usage statistics because two different potential crop group usage estimates were used (CDL-based and USDA Survey adjusted). This resulted in up to 42 estimates for each county/CRD/state and crop group. In California, where only the PUR was used for actual usage estimates, the inclusion of two different potential usage estimates resulted in 14 different percent of potential usage estimate per county/CRD/state.

3. Results and Discussion

One of the primary deliverables from this study is the methodology for estimating crop group actual usage and crop group percent of potential usage at the county and CRD scales described in the methodology section of this report. Another primary deliverable is the application of this methodology to malathion and the resulting usage statistics. These results, applied nationwide, are provided as electronic data deliverables that accompany this report as Excel spreadsheet tables, as the volume of data makes it impractical to provide these results as tables within this report. Map examples and a discussion of the resulting malathion usage estimates are provided in the sections that follow.

3.1. Usage by County and Crop Group

Figure 7–Figure 14 show the 50th and 90th percentile estimates of malathion annual usage for corn, cotton, orchards and grapes, and vegetables and fruits for the years 2010–2016 (note that additional malathion crop groups are reported in accompanying Excel spreadsheet tables). For all crop groups mapped, the distributions of both 50th and 90th percentile estimates are strongly right-skewed, with the majority of counties having no or low (< 10 kg) total use. Counties with high use (> 1,000 kg) tend to be clustered in regions within a small number of states. Of the crop groups shown, the highest usage occurs on orchards and grapes and vegetables and fruits. Figure 15 and Figure 16 show the 90th percentile annual total usage of orchards and grapes mapped on to the CDL orchards and grapes footprint in Florida. In Figure 16, a zoom-in on central Florida, we can see the spatial detail at which the locations of malathion applications can be realized.

3.2. Percent of Potential Usage by County and Crop Group

Figure 17–Figure 24 show the 50th and 90th percentile estimates of actual percent of potential malathion annual usage for corn, cotton, orchards and grapes, and vegetables and fruits for the years 2010–2016 (note that additional malathion crop groups are reported in accompanying Excel spreadsheet tables). For all crop groups mapped, the distributions of 50th percentile estimates are strongly right-skewed, with most counties having no or low (< 5%) percent of potential usage. For the 90th percentile estimates, we see a broader number of counties where percent of potential usage is 20% or greater, particularly for the orchards and grapes and the vegetables and fruits (Figure 22 and Figure 24). It is important to consider the percent of potential usage in conjunction with the actual usage, as many counties with higher percent of potential usage (> 20%) have very low actual usage (in kg/yr). For example, the 90th percentile usage on vegetables and fruits in Texas and Oklahoma (see Figure 14) rarely exceeds 100 kg/yr per county, yet the 90th percentile percent of potential usage commonly exceeds 20% (see Figure 24). This is a result of the low acreage of the vegetable and fruit crops in those counties and the estimated malathion usage on those crops from the source usage datasets.

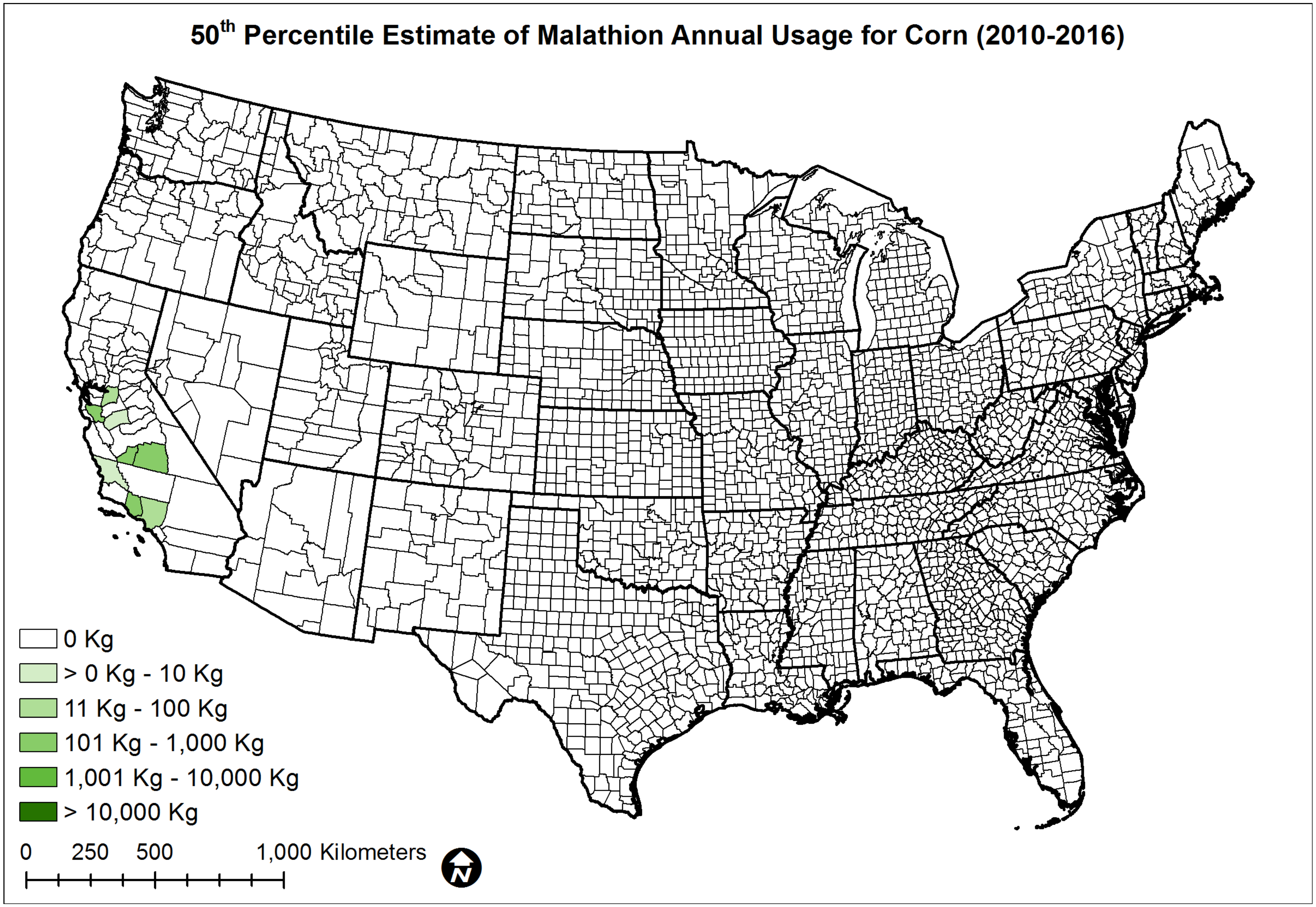

Figure 7. 50th Percentile Estimate of Malathion Annual Usage for Corn (2010-2016).

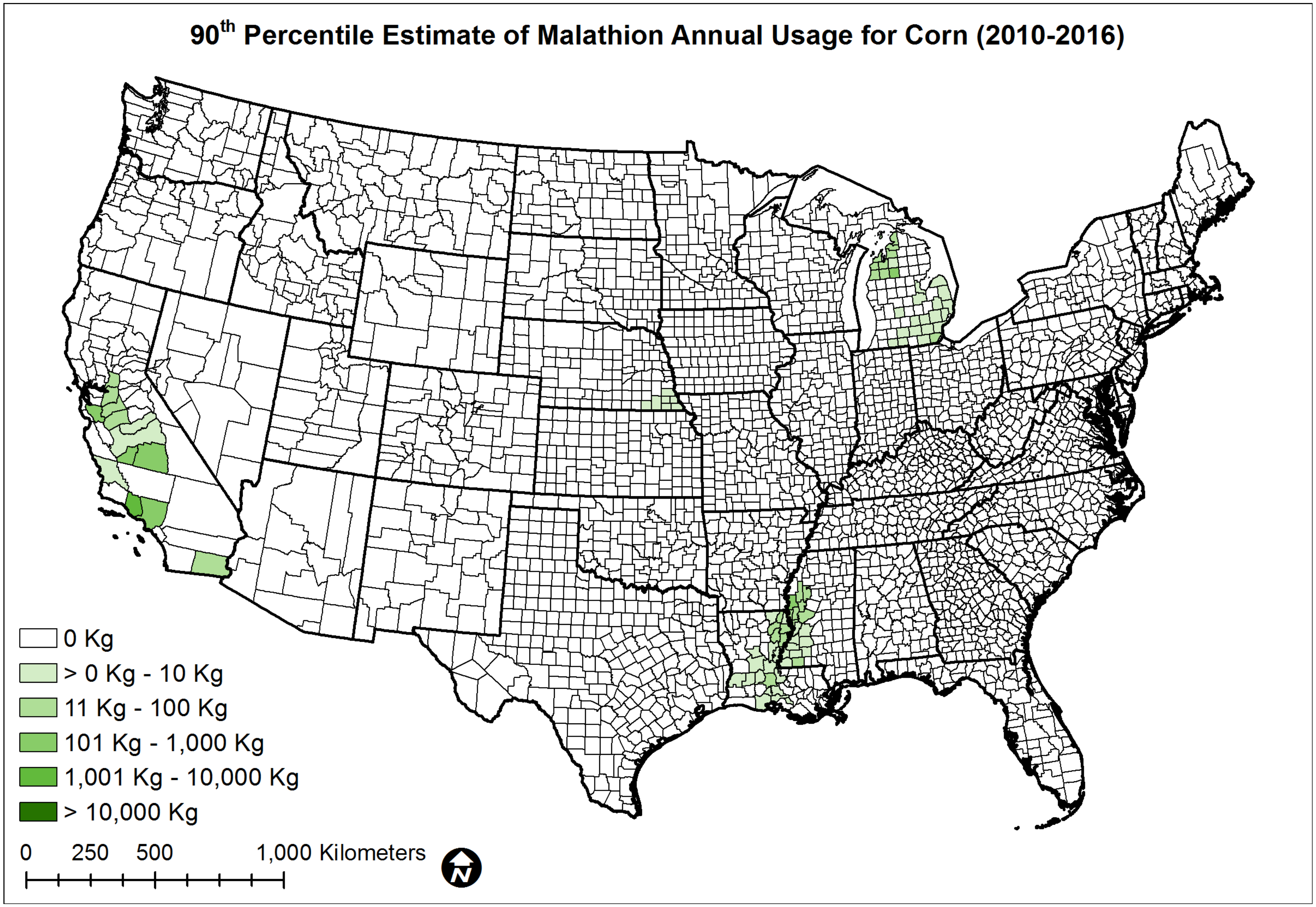

Figure 8. 90thPercentile Estimate of Malathion Annual Usage for Corn (2010-2016).

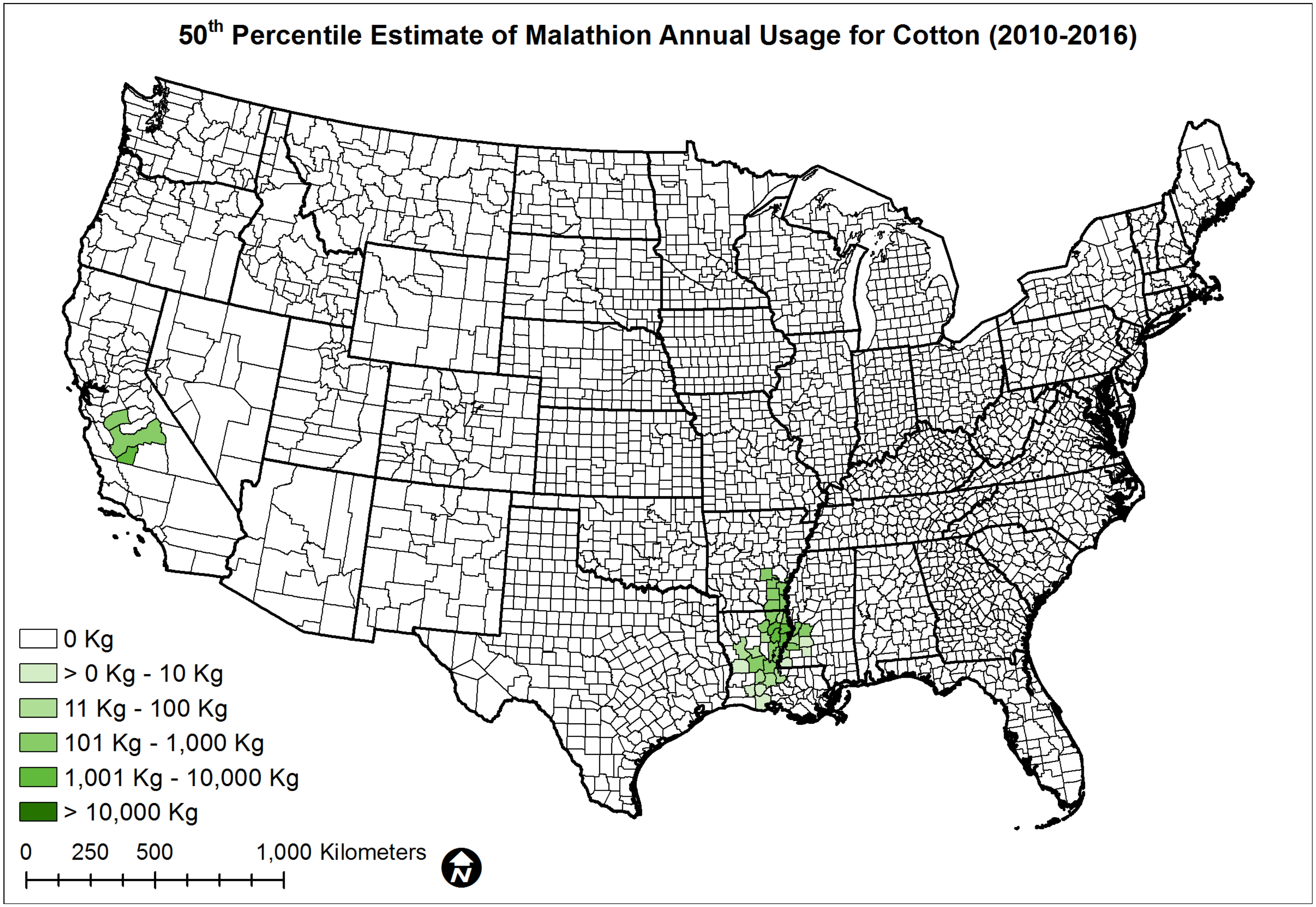

Figure 9. 50th Percentile Estimate of Malathion Annual Usage for Cotton (2010-2016).

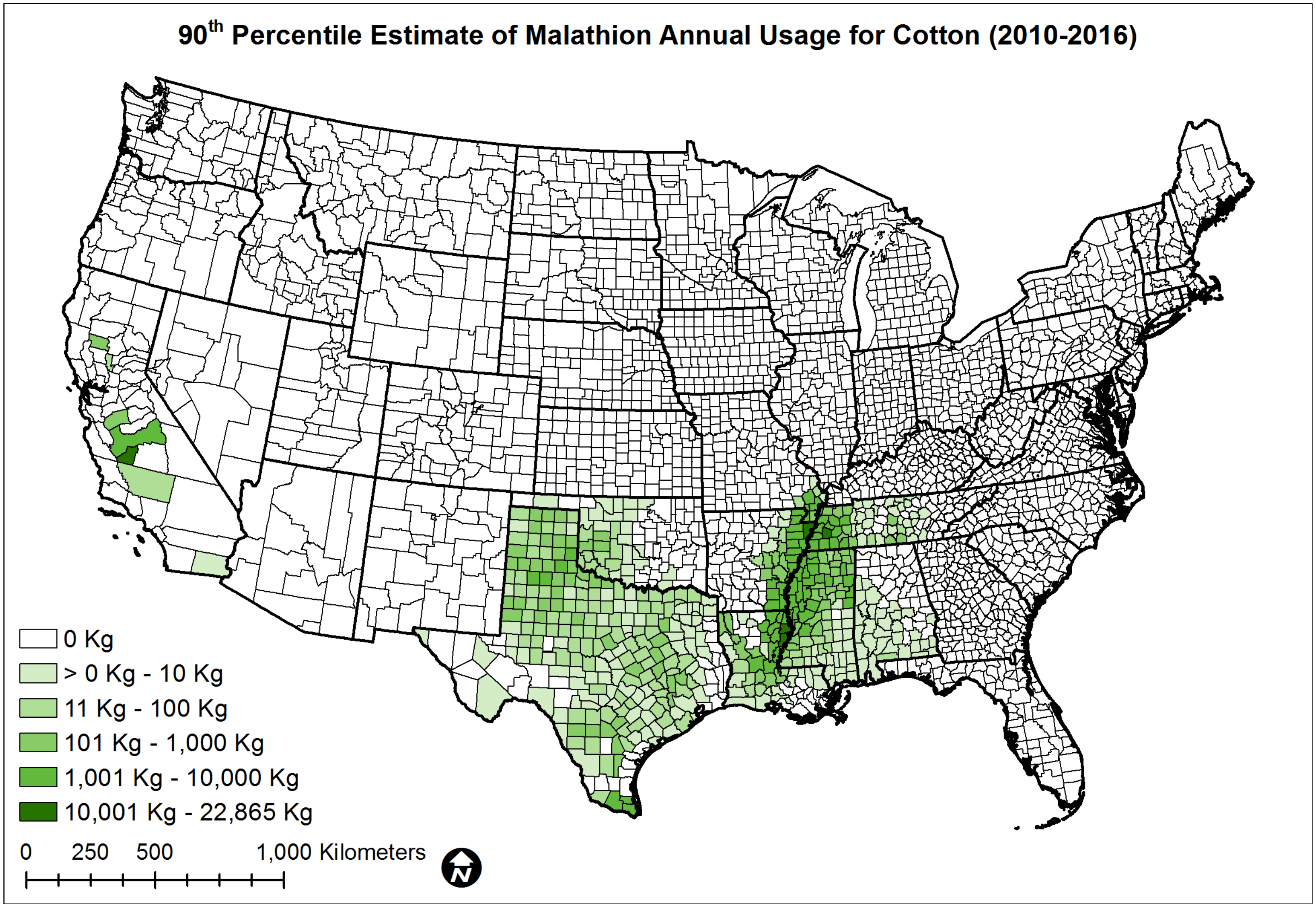

Figure 10. 90th Percentile Estimate of Malathion Annual Usage for Cotton (2010-2016).

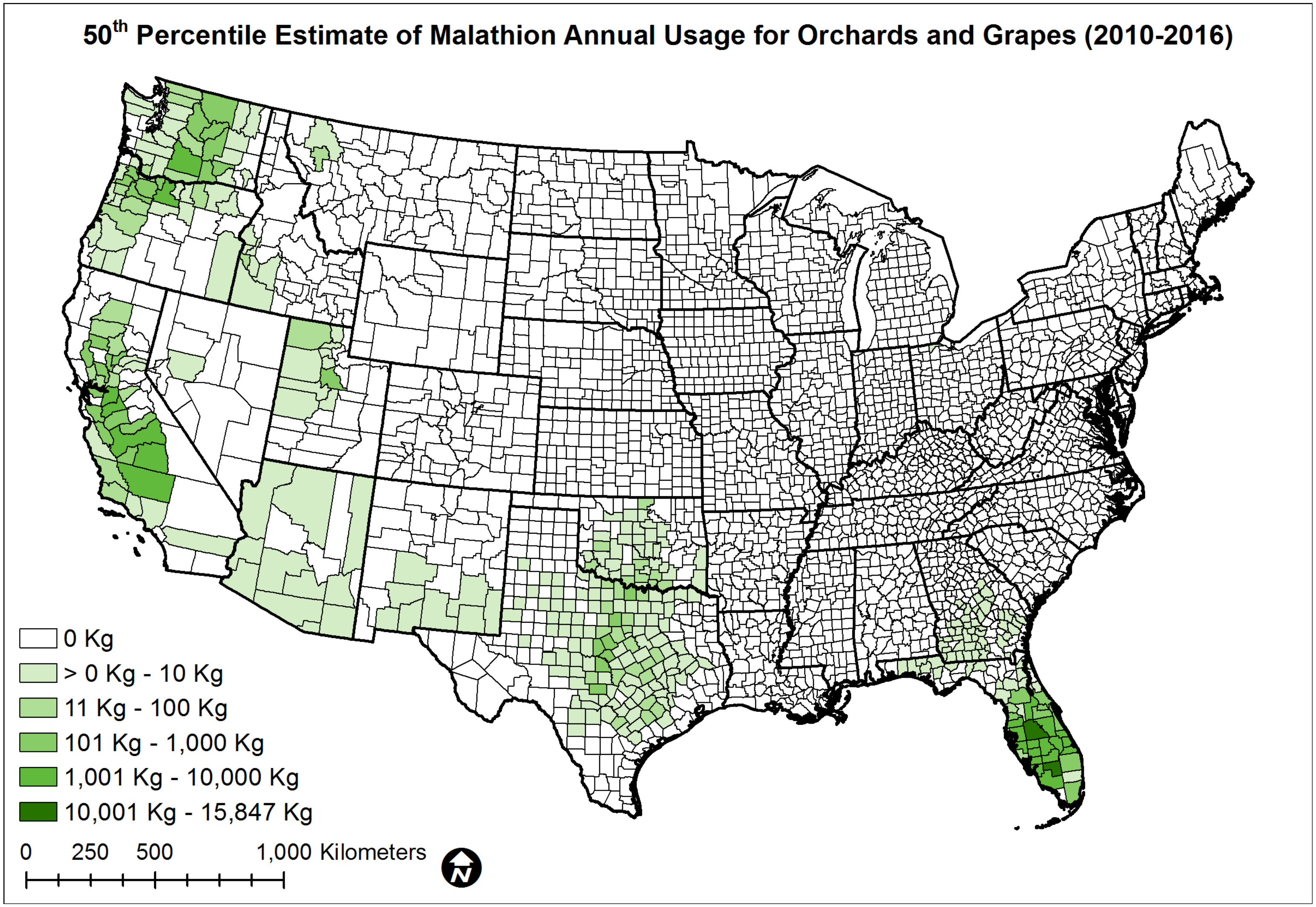

Figure 11. 50th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes (2010-2016).

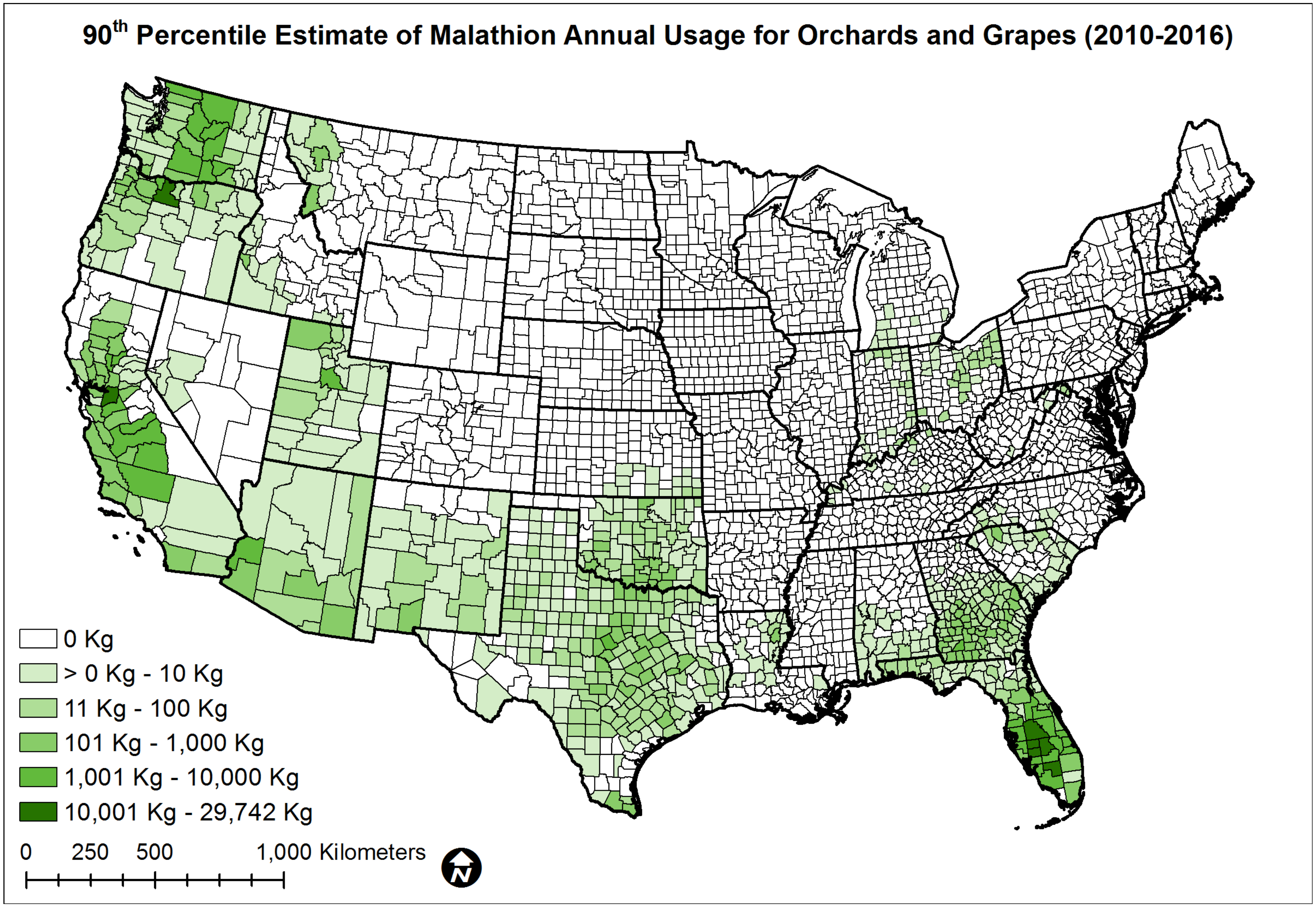

Figure 12. 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes (2010-2016).

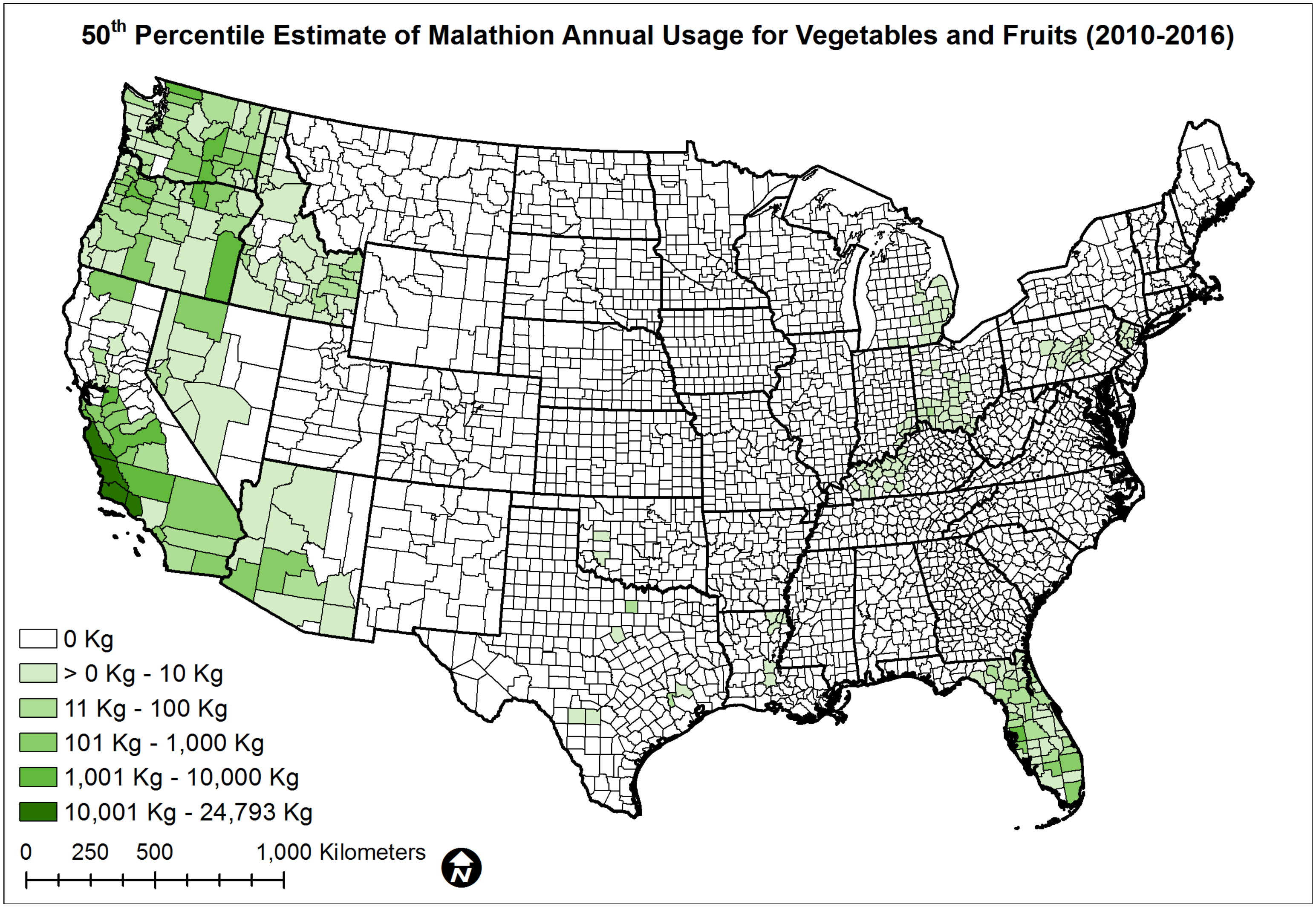

Figure 13. 50th Percentile Estimate of Malathion Annual Usage for Vegetables and Fruits (2010-2016).

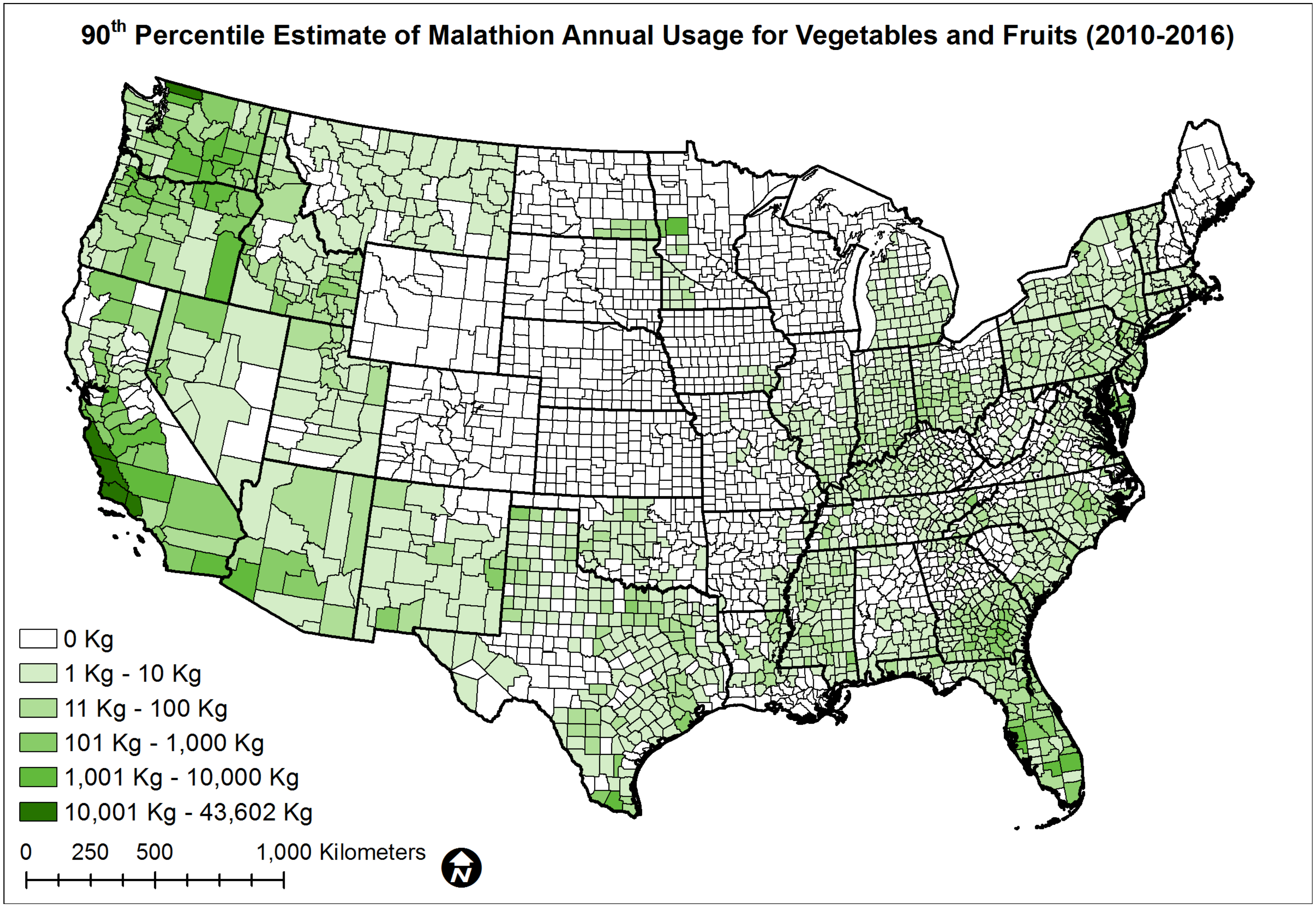

Figure 14. 90th Percentile Estimate of Malathion Annual Usage for Vegetables and Fruits (2010-2016).

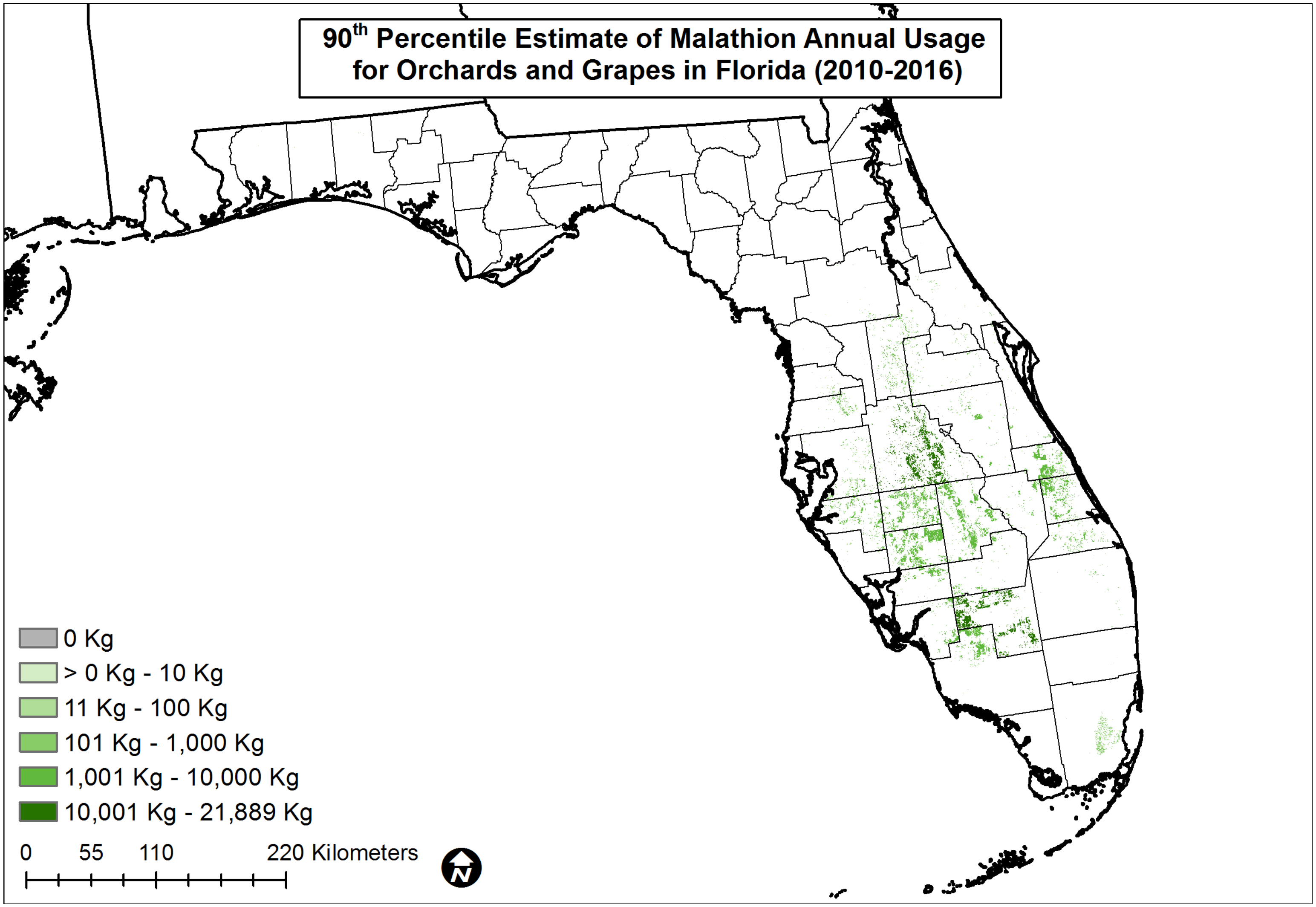

Figure 15. Florida 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes, Mapped to CDL Crop Footprint.

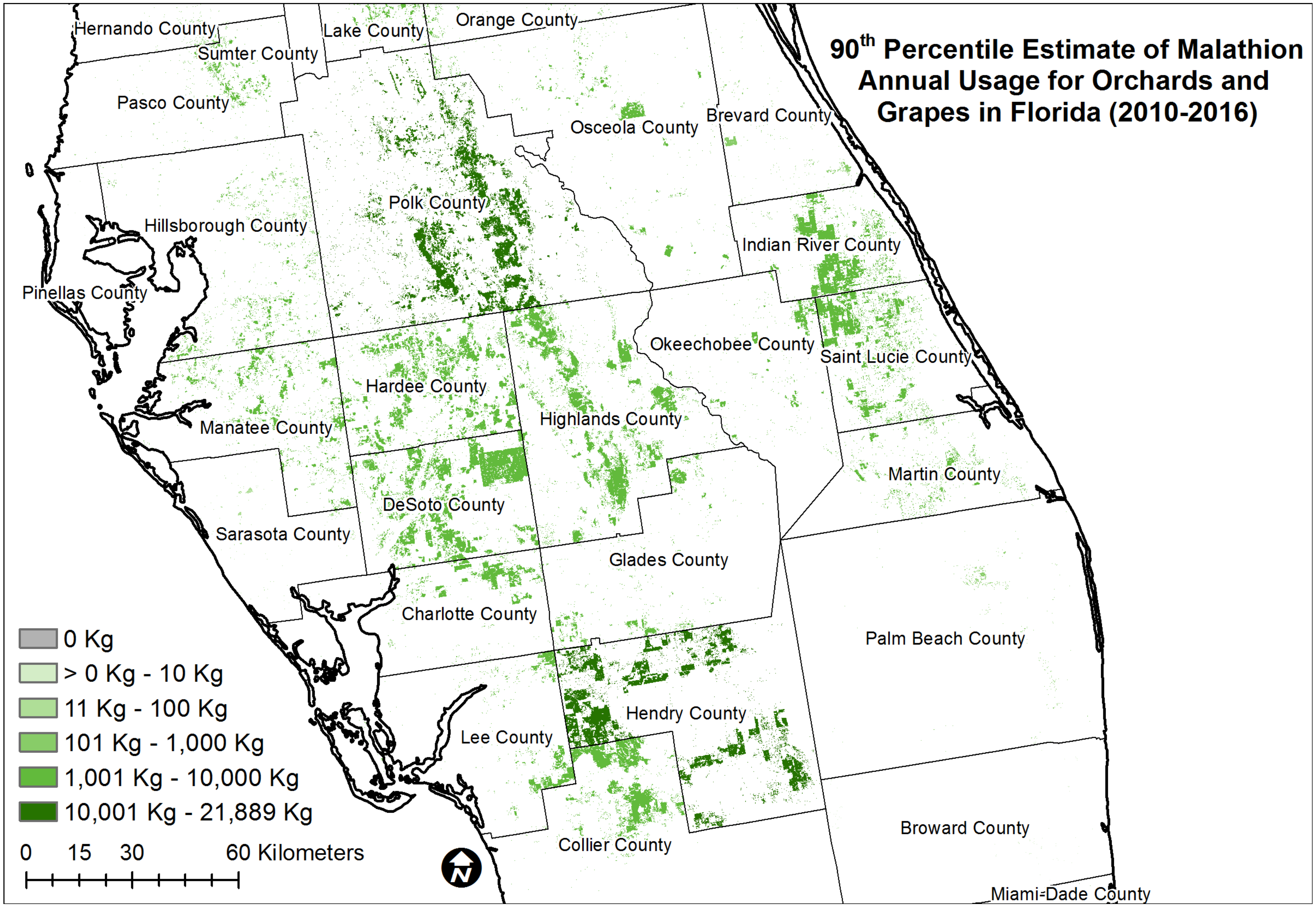

Figure 16. Central Florida Focus, 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes, Mapped to CDL Crop Footprint.

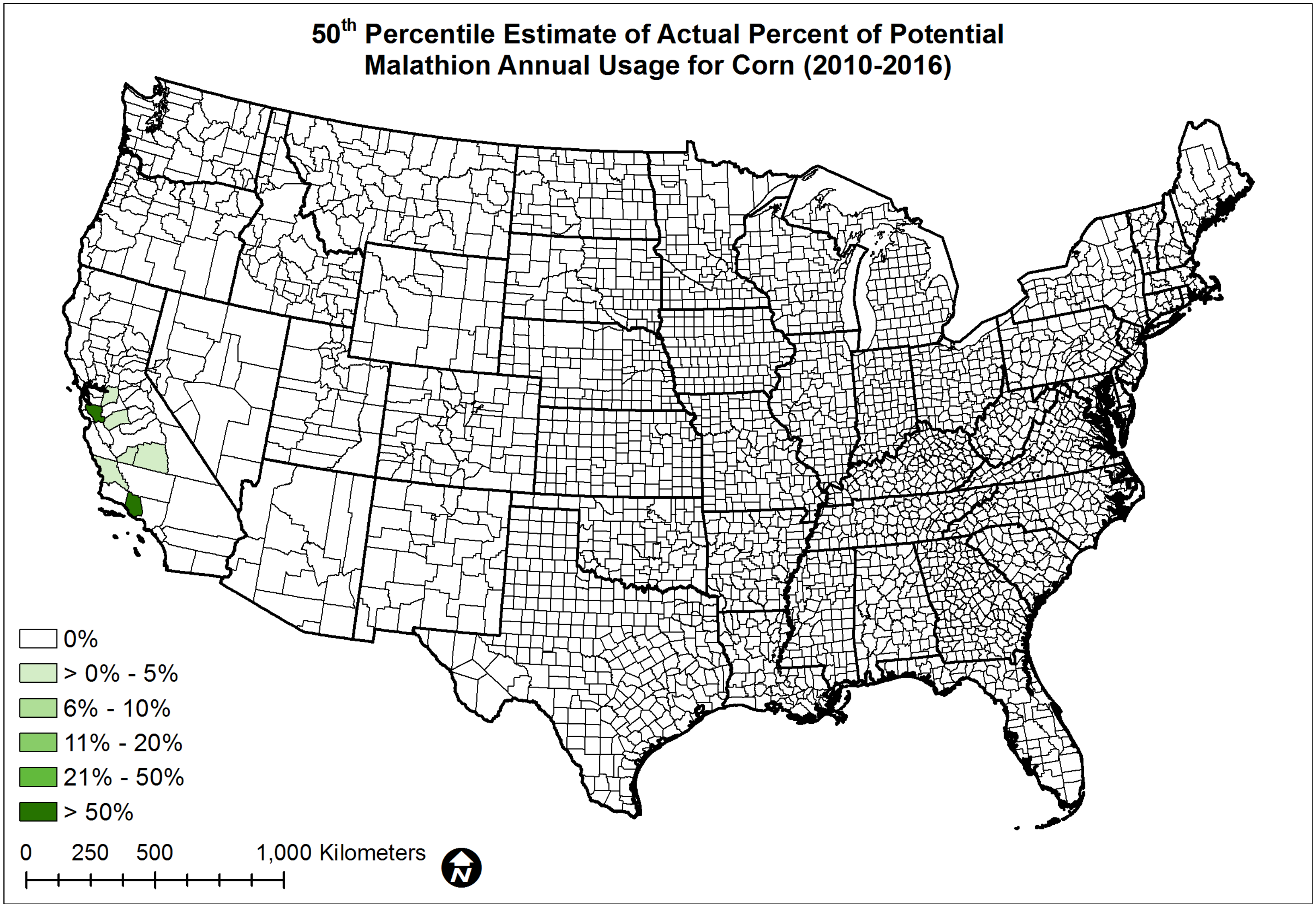

Figure 17. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Corn (2010-2016).

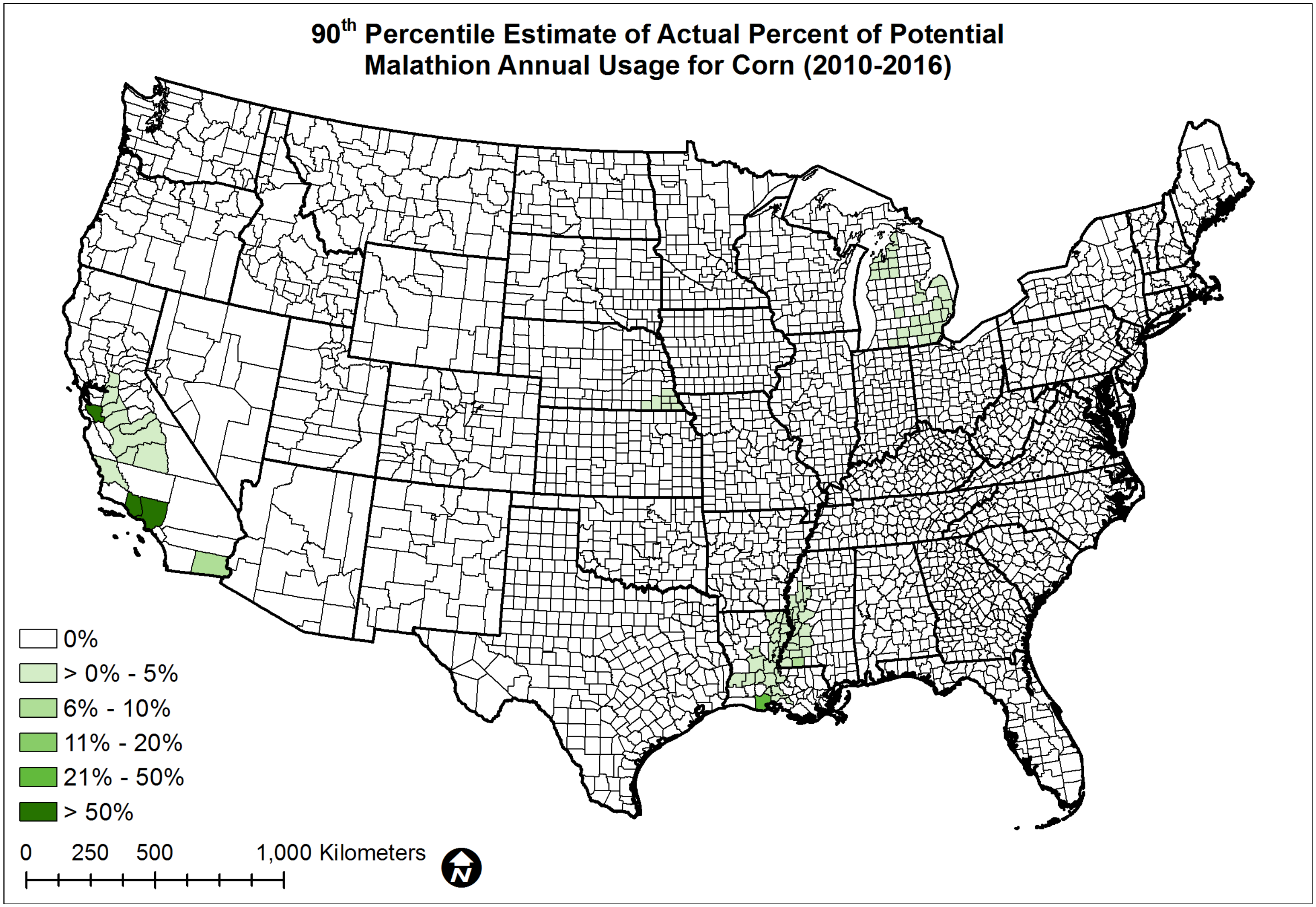

Figure 18. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Corn (2010-2016).

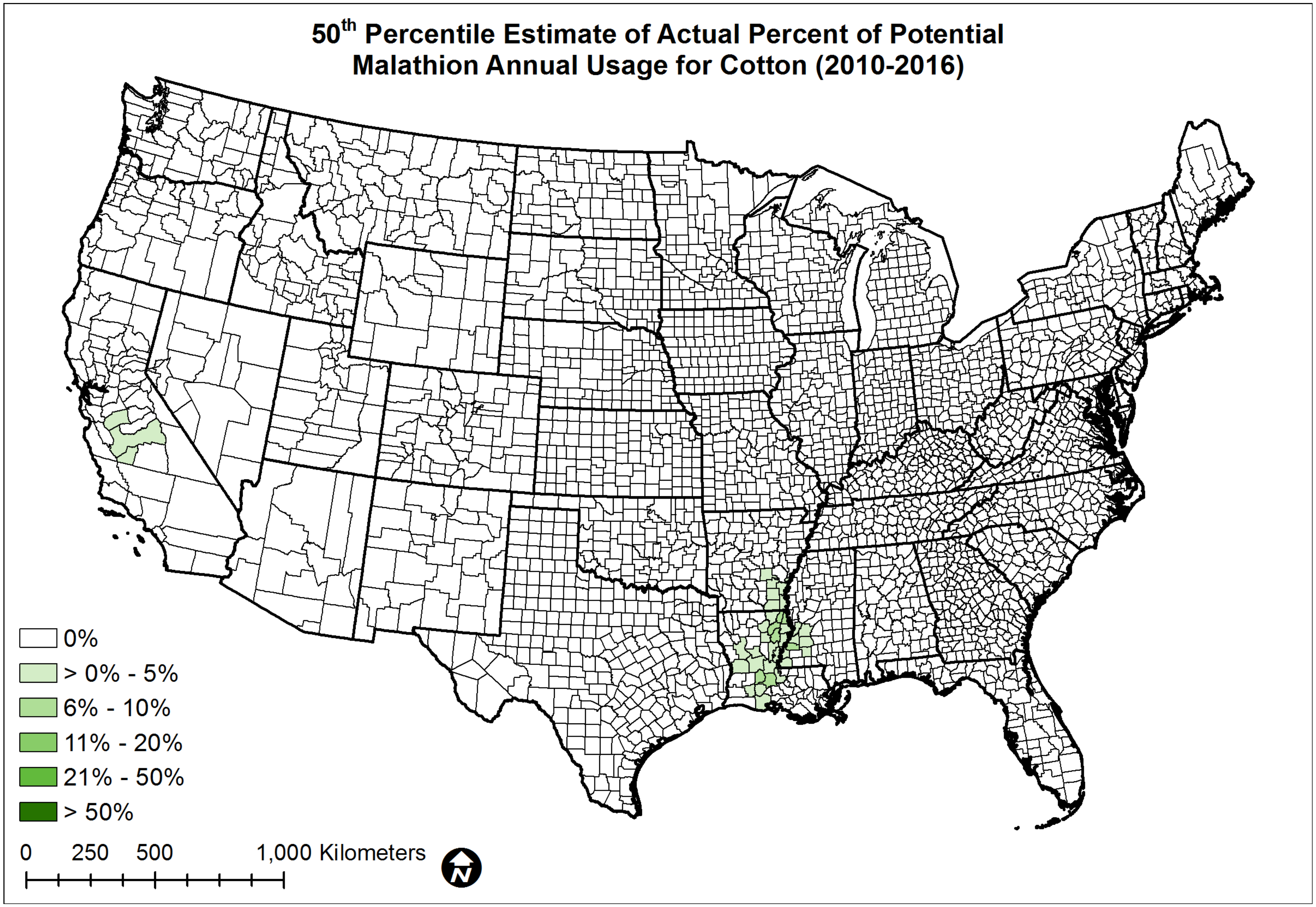

Figure 19. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Cotton (2010-2016).

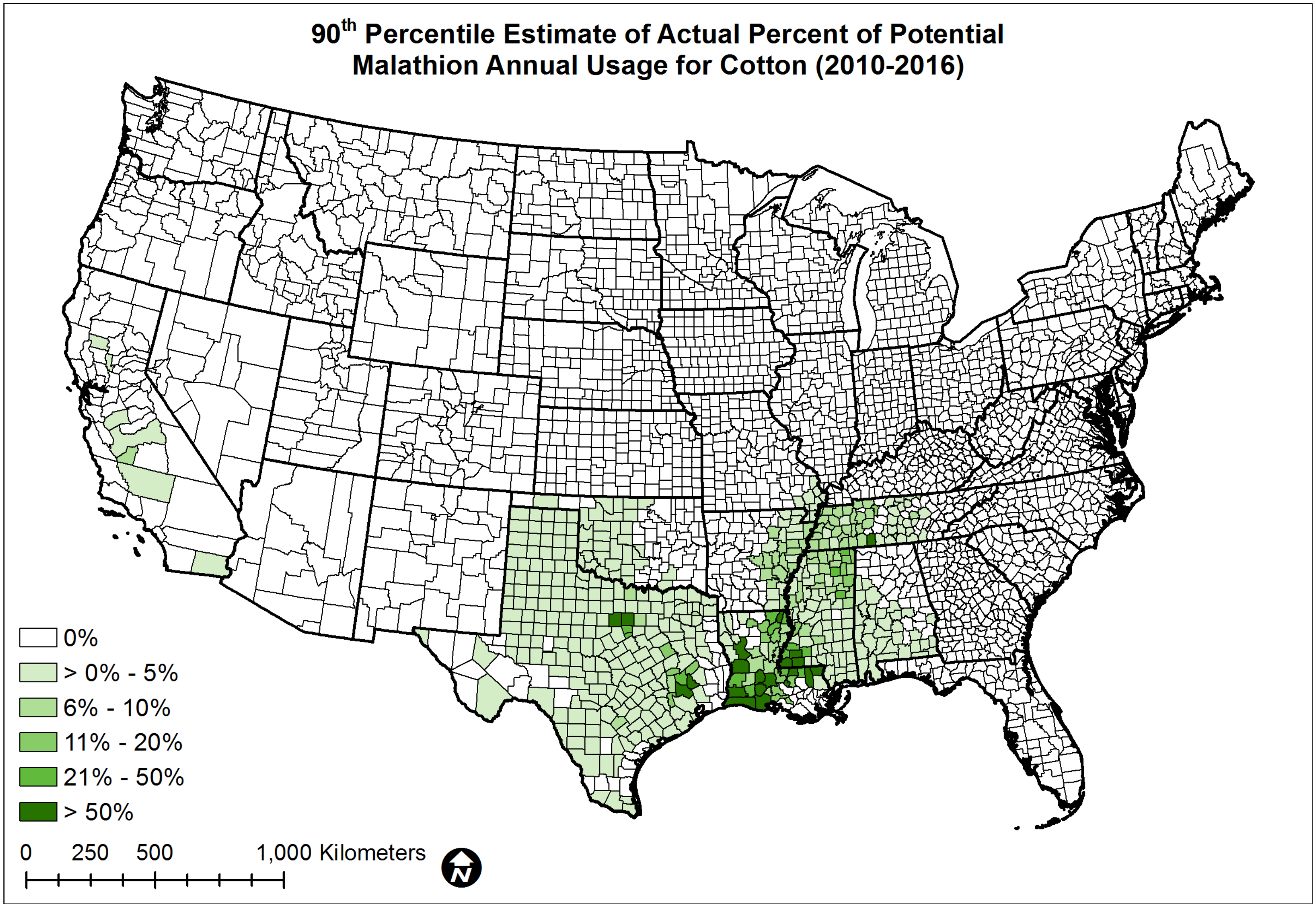

Figure 20. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Cotton (2010-2016).

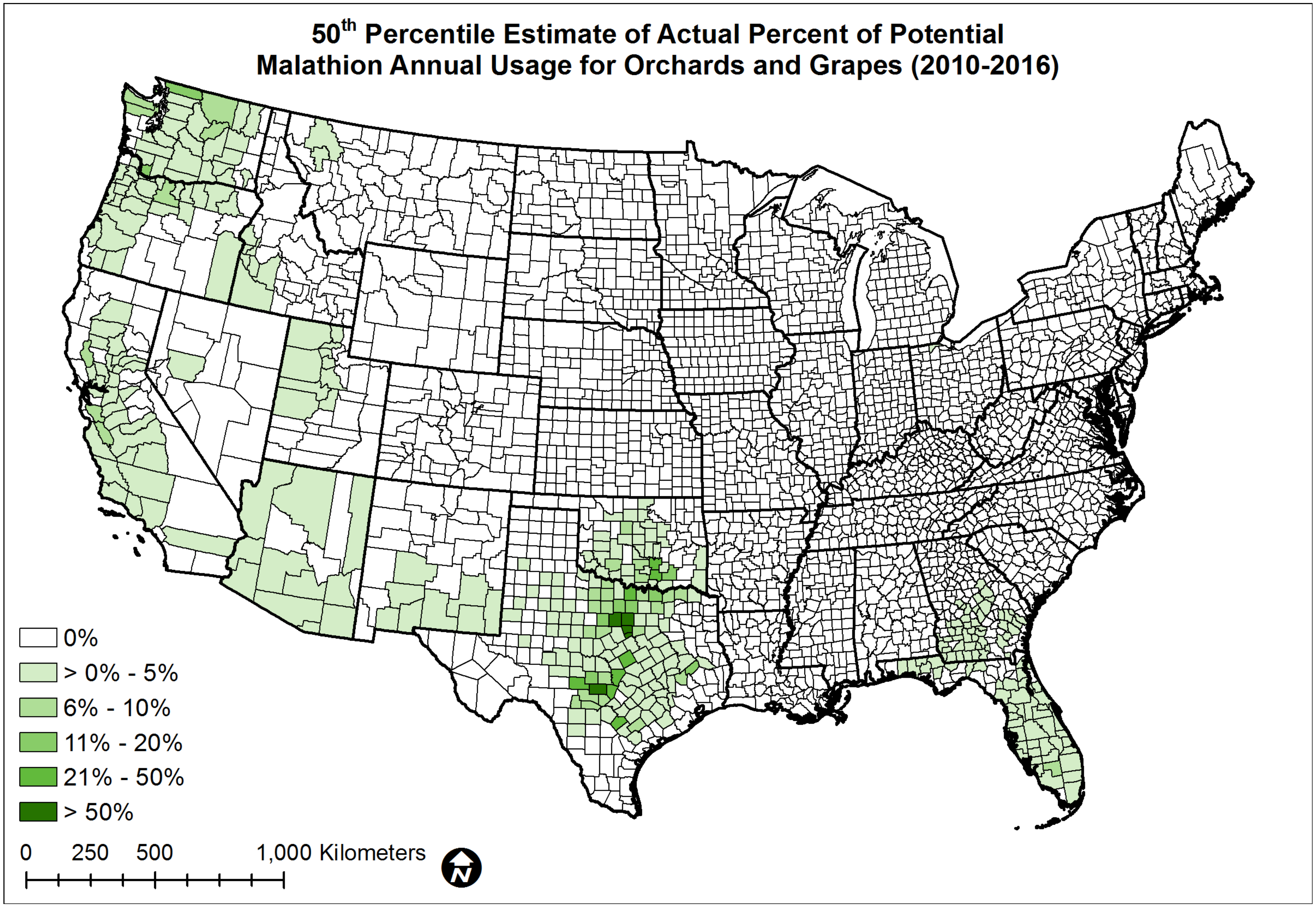

Figure 21. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Orchards and Grapes (2010-2016).

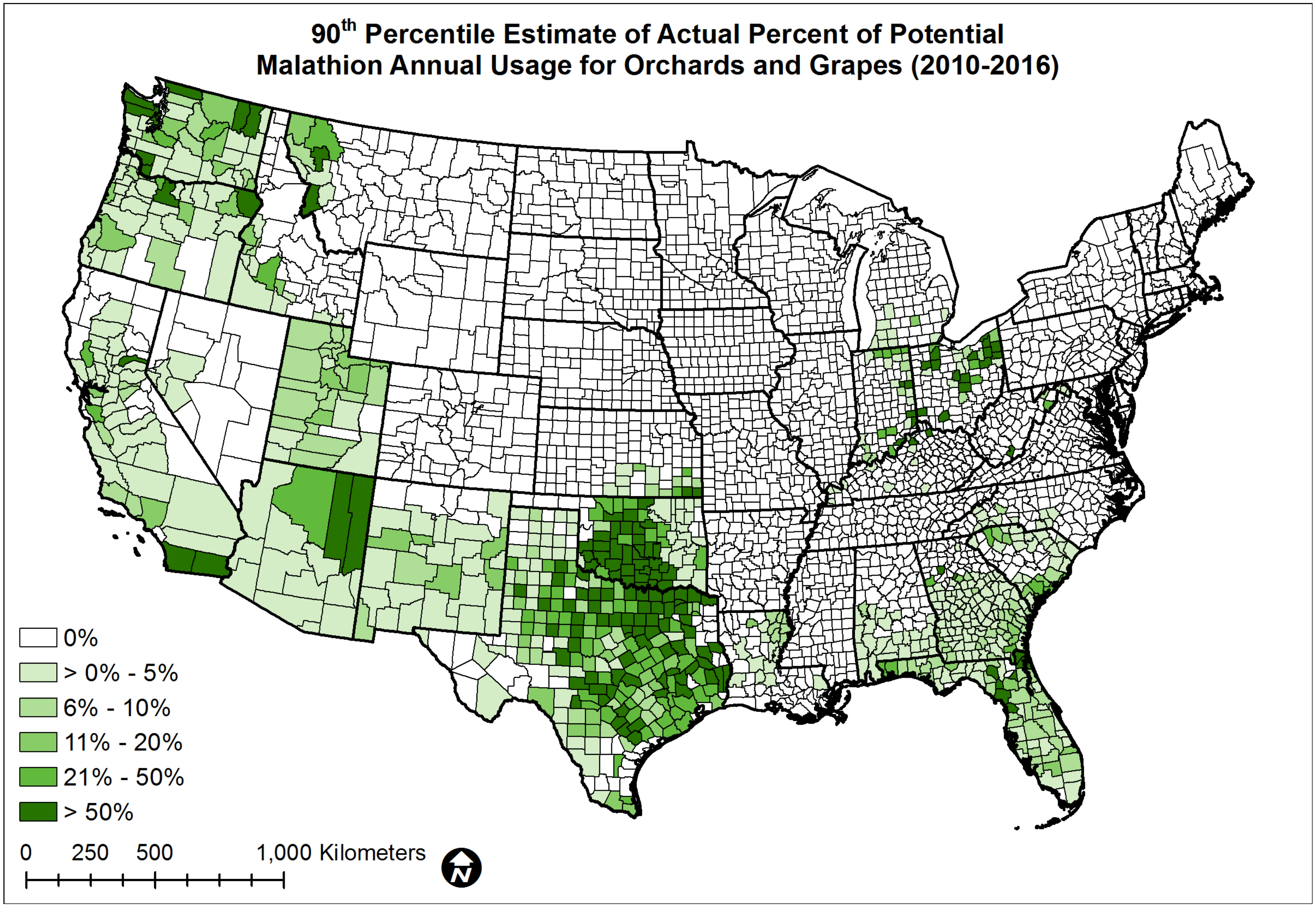

Figure 22. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Orchards and Grapes (2010-2016).

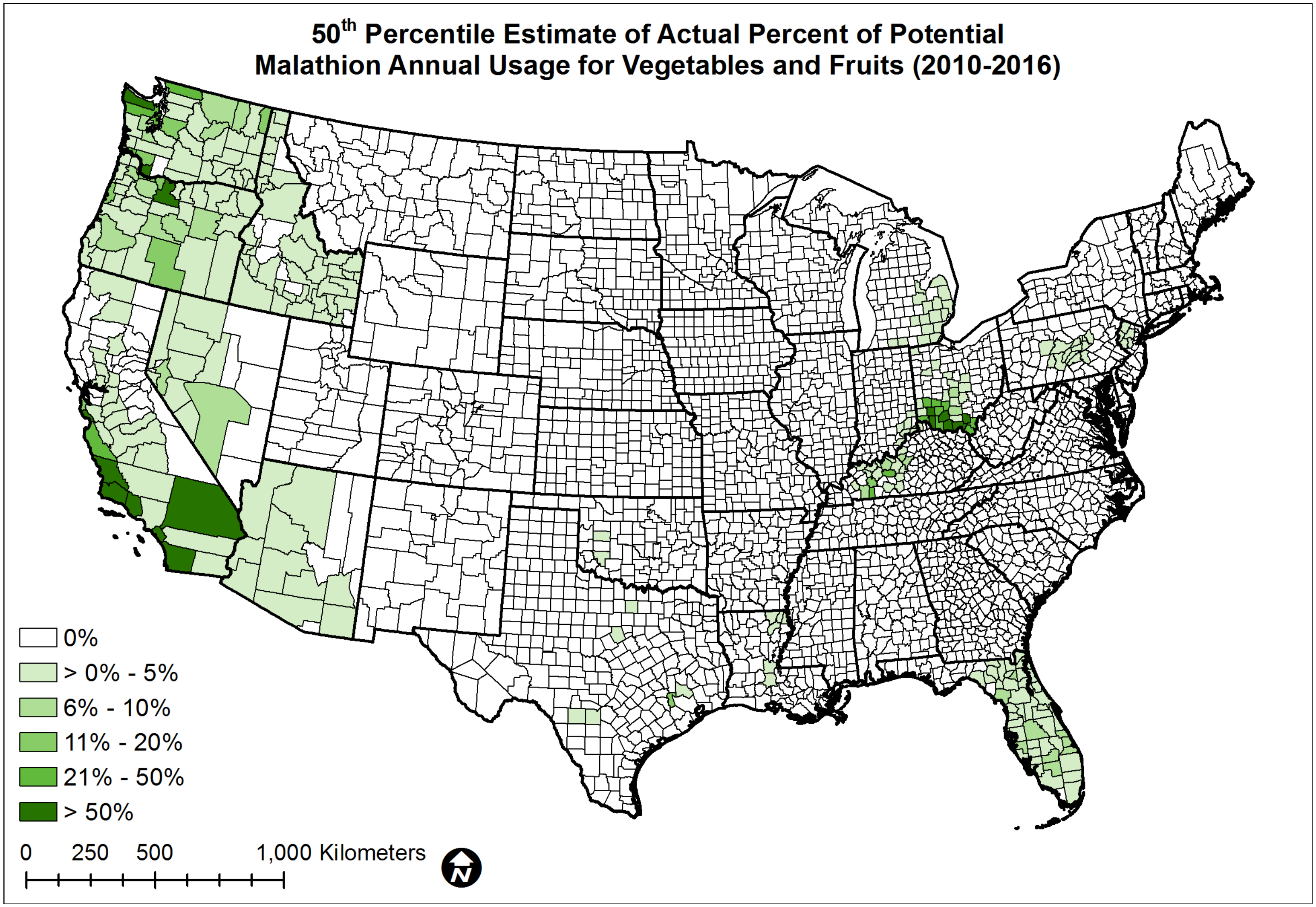

Figure 23. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Vegetables and Fruits (2010-2016).

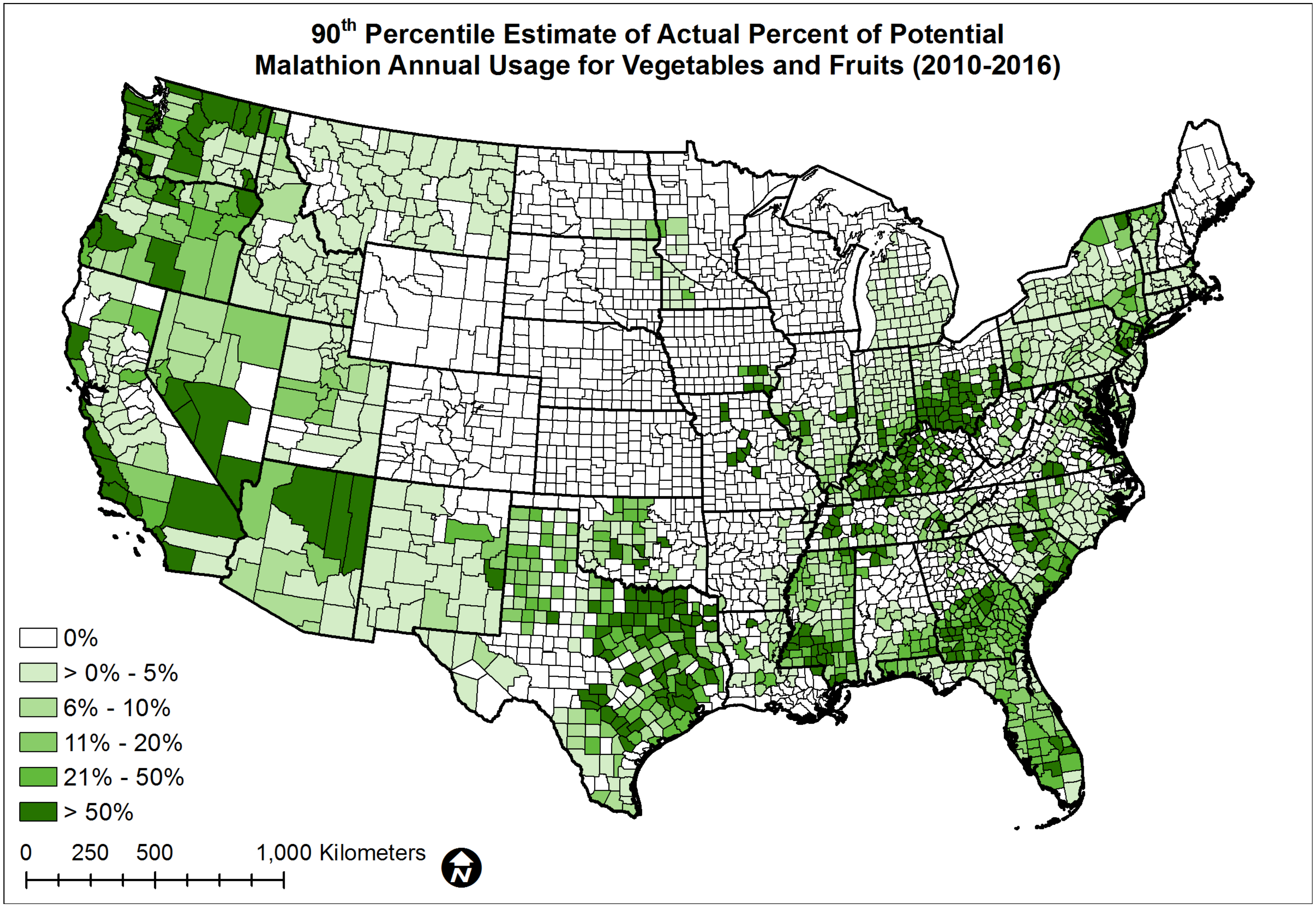

Figure 24. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Vegetables and Fruits (2010-2016).

3.3. Application of Usage Data in Endangered Species Risk Assessments

The county-level crop group pesticide usage statistics resulting from the data analysis approach presented in this report can be applied to refine endangered species risk assessments in multiple ways. This includes both quantitative and qualitative analysis methods that can be considered at multiple point during the risk assessment process. Several example applications and approaches are discussed here.

3.3.1. Refinement of Pesticide Use Footprints

The pesticide usage data can be applied directly in refinement of pesticide use footprints by crop group at the county-level. This can be done deterministically or probabilistically. A deterministic approach would first require determination of an appropriate exceedance probability. The most conservative approach would be to choose the maximum, while a slightly less conservative approach would be to choose the 90th percentile. The pesticide usage associated with, for example, the 90th percentile would then describe which counties the pesticide is expected to be used in for each crop group. For counties with no expected usage for a given crop group, those potential pesticide use sites would be removed from the pesticide use footprint. The resulting refined pesticide use site footprints would then be incorporated directly into a co-occurrence analysis with species ranges and critical habitats. This deterministic type of approach would be appropriate at a later stage in the screening level risk assessment or as an early refinement step.

A probabilistic approach to refining pesticide use footprints by crop group would result in footprints comprised of a range of use likelihoods. The approach would again begin by determination of an appropriate pesticide usage exceedance probability, such as the 90th percentile, or 50th percentile if the most likely pesticide use is desired. The associated percent of potential pesticide usage data by county ad crop group can then be used as an overlay to the use footprint to assign use probabilities at the county level. Use probabilities can also be considered as being analogous to Percent Crop Treated for each county and crop group. The resulting refined pesticide use footprints, which include a likelihood of usage, can be applied in a co-occurrence analysis with species ranges and critical habitats, providing a much more comprehensive understanding of probability of pesticide usage impacting a species.

3.3.2. Refinement of Pesticide Exposure Distributions

Refined phases of endangered species risk assessments require spatially explicit and species-specific predictions of exposure. These exposure predictions must also be represented probabilistically to account for the variability in climate, landscape conditions, agronomics, habitat conditions, and pesticide usage within a species range and critical habitat. The pesticide usage statistics resulting from the methods developed in this study can be used directly to parameterize exposure models used in refined risk assessment methods. This applies to both terrestrial and aquatic species and for species found in static and flowing water bodies.

Refinement of terrestrial species exposure modeling can be achieved by quantifying the fraction of a species range receiving pesticide applications on different potential use sites. The percent of potential pesticide usage statistics developed in this assessment describe the fraction of potential pesticide use sites treated at the maximum label rate. A target percentile of usage, such as the 90th percentile which is equivalent to a 10% exceedance probability, can be selected to achieve the desired level of usage conservatism and applied quantitatively to terrestrial species exposure scenarios. This quantification can directly translate to the fraction of use sites treated within the species range or the likelihood of a pesticide treatment at a given location within the range.

Endangered species exposure modeling scenarios for aquatic species in static water habitat are represented by water bodies ranging from 1 m^2 to 1 ha in area with relatively small watersheds of less than 10 ha. Incorporation of usage data to refine these exposure scenarios can be achieved following an approach similar to what was described for terrestrial species. The fraction of static water habitats impacted by pesticide usage within a species range or critical habitat can be quantified directly from the percent of potential usage statistics and probability distributions of exposure generated that account for water bodies within the species range where no use or limited use occurs.

Species that inhabit flowing water bodies are potentially impacted by pesticide use occurring over large watershed areas. Predicting the potential exposure at the watershed scale requires that the likelihood of pesticide usage and/or the fraction of use sites treated across many different potential use sites and over broad regions be quantified. The percent of potential pesticide usage data at the county and crop group level can be used to assign fractions of pesticide use sites receiving applications at maximum label rates. The areas of potential use sites treated within a county can be randomly selected to achieve the target faction of use sites treated. The random selection of potential use sites treated within a watershed can be realized multiple times to achieve an ensemble of potential use scenarios for a given watershed that honors the percent of potential usage data covering multiple crop groups. This approach to incorporating usage data into parameterization of exposure models at the watershed scale accounts for the probability of use on different crop groups and the uncertainty in the specific locations of pesticide use within a watershed, resulting in a probability distribution of potential exposure that is constrained by actual usage data.

3.3.3. Formal Weight-of-Evidence Analysis

Pesticide usage data can be incorporated directly into a formal weight-of-evidence analysis. The results of a refined co-occurrence analysis, as described in Section 3.3.1, can provide a quantitative measure of the likelihood of pesticide use within a species range or critical habitat. Given data and assumptions regarding the distribution of a species across its range, these co-occurrence results can also be used to estimate the percentage of individuals affected by pesticide use. A weight-of-evidence analysis that incorporates usage data may be conducted in place of refined exposure modeling for some species, which may result in more efficient use of analysis resources.

4. Conclusions

Pesticide usage by crop group at the county-level can be estimated from best available, publicly available nationwide data sources. These data sources include the USGS Annual Pesticide Use database (Baker and Stone, 2015), USDA Agricultural Chemical Use Program Survey (USDA, 2019a), California Pesticide Use Record (PUR) database (CDPR, 2019), the USDA Cropland Data Layer (Boryan et al., 2011; USDA, 2019b), the USDA Census of Agriculture (USDA, 2019c), and the USDA National Agricultural Statistics Service Annual Survey (USDA, 2019d). Several methods to generate these estimates were developed and evaluated against observed crop group county-level annual malathion usage from the PUR database in California. The best performing method considered county-level total usage, state-level crop group usage, and potential usage based on CDL crop acreage and label use rates. This method (Method 3) resulted in strong agreement with the PUR across all counties and crop groups, with an R^2 of 0.7978 for county-level estimates and 0.8419 for CRD-level estimates. Method 3 was applied nationally using seven years of malathion usage data (2010-2016) resulting in probability distributions of annual usage and percent of potential usage. The percent of potential usage was based on both CDL and USDA AgCensus and annual survey crop group acreages. Incorporating both these two data sources resulted in potential usage estimates that accounted for the uncertainty in county-level crop acreage estimates.

Analysis of multiple years of usage data, multiple sources of data, and multiple estimates from some sources (EPest-low and Epest-high from USGS) allowed for the generation of usage statistics which were presented as percentiles and tabulated for minimum, 10th, 25th, 50th, 75th, 90th percentiles and the maximum. These usage statistics were generated for malathion at the county, CRD, and state-levels for nine crop groups (alfalfa corn, cotton, orchards and grapes, other crops, pasture and hay, rice, vegetables and fruit, and wheat) and are provided as Excel spreadsheets that accompany this report. Example maps of county level actual usage and percent of potential usage were provided to demonstrate how the data generated can be used to visualize the spatial distribution and magnitude of usage. Maps depicting usage associated with the specific locations of crops from CDL showed how locations of pesticide usage can be reconciled at the sub-county scale.

The pesticide usage statistics generated in this study represent probability distributions of usage that can be incorporated into multiple phases of an endangered species risk assessment. The more conservative 90th percentile or maximum usage rates and percent of potential usage would be appropriate at screening-level steps or initial refinements of exposure, while the 50th percentile estimates represent the most likely usage scenarios for more refined exposure and ecological modeling. Several examples of incorporating usage data into endangered species risk assessments were discussed, including refined crop footprint and co-occurrence analysis, refined exposure modeling, and weight-of-evidence analysis. Several case studies of endangered species assessments where usage data played an important role are also available in the peer reviewed literature (Clemow et al., 2018; Whitfield Aslund et al., 2017) as well as case studies of pesticide usage data in refined aquatic exposure modeling (Winchell et al., 2018a; Winchell et al., 2018b). These case studies demonstrate the importance of carefully considering quantitative pesticide usage data in accurately predicting environmental exposure and deriving risk assessment conclusions.

The pesticide usage data sources and the estimation and analysis methodologies presented in this report represent an unbiased and reproduceable approach to maximizing the utility of publicly available pesticide usage data in human health and ecological risk assessments, including endangered species assessments. Additional source data, such as proprietary or higher resolution state-level data sources, could be incorporated into the generation of usage statistics in conjunction with the data sources presented here. While usage data at the spatial and temporal resolution of the California PUR database would be ideal to have in all US states and internationally, this report has demonstrated that we are still able to garner a tremendous amount of valuable information on the spatial distribution and magnitude of pesticide usage nationwide with the currently available datasets. Thoughtful application of this data will enable more defensible and scientifically accurate assessments of the risks of pesticide use to humans and the environment.

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Appendix A

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
alfalfa	Alfalfa	36	alfalfa	7.50
apricots	Apricots	223	orchards and grapes	3
asparagus	Asparagus	207	vegetables and fruits	2.5
avocado	Other Tree Crops	71	orchards and grapes	9.4
barley	Barley	21	other crops	2.5
barley	Dbl Crop Barley/Corn	237	other crops	2.5
barley	Dbl Crop Barley/Sorghum	235	other crops	2.5
barley	Dbl Crop Barley/Soybeans	254	other crops	2.5
beans (dry; snap; lima)	Dry Beans	42	vegetables and fruits	1.22
beets, garden	Misc Vegs & Fruits	47	vegetables and fruits	3.75
blueberry	Blueberries	242	vegetables and fruits	3.75
broccoli ; chinese broccoli ; broccoli rabb	Broccoli	214	vegetables and fruits	2.5
brussels sprouts	Misc Vegs & Fruits	47	vegetables and fruits	2.5
cabbage ; chines cabbage	Cabbage	243	vegetables and fruits	7.5

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
caneberries (blackberry; boysenberry; dewberry; gooseberry; loganberry; raspberry)	Caneberries	55	vegetables and fruits	6
cantaloupe	Cantaloupes	209	vegetables and fruits	2
carrots	Carrots	206	vegetables and fruits	2.5
cauliflower	Cauliflower	244	vegetables and fruits	2.5
celery	Celery	245	vegetables and fruits	3
chayote fruit	Misc Vegs & Fruits	47	vegetables and fruits	3.5
chayote root	Misc Vegs & Fruits	47	vegetables and fruits	3.12
cheeries (sweet and tart)	Cherries	66	orchards and grapes	7
chestnut	Other Tree Crops	71	orchards and grapes	7.5
citrus fruits (grapefruit; lemon; lime; orange; tangerine; tangelo)	Citrus	72	orchards and grapes	4.5
citrus fruits (grapefruit; lemon; lime; orange; tangerine; tangelo)	Oranges	212	orchards and grapes	4.5
citrus fruits (grapefruit; lemon; lime; orange; tangerine; tangelo)	Citrus	72	orchards and grapes	7.5
citrus fruits (grapefruit; lemon; lime; orange; tangerine; tangelo)	Oranges	212	orchards and grapes	7.5
clover	Clover/Wildflowers	58	other crops	7.5
collards	Greens	219	vegetables and fruits	3
corn (field)	Corn	1	corn	2

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
corn (field)	Dbl Crop Corn/Soybeans	241	corn	2
corn (field)	Pop or orn corn	13	vegetables and fruits	2
corn (sweet)	Sweet corn	12	vegetables and fruits	2
cotton	Cotton	2	cotton	7.5
cotton	Dbl Crop Soybeans/Cotton	239	cotton	7.5
cucumber	Cucumbers	50	vegetables and fruits	3.5
currant	Caneberries	55	vegetables and fruits	3.75
dandelion	Other Crops	44	other crops	2.5
eggplant	Eggplants	248	vegetables and fruits	6.24
endive (escarole)	Misc Vegs & Fruits	47	vegetables and fruits	2.5
figs	Other Tree Crops	71	orchards and grapes	4
garlic	Garlic	208	vegetables and fruits	4.68
grapes (raisin, table, wine)	Grapes	69	orchards and grapes	3.76
grass, forage, hay (Bermuda, barnyard grass, canary grass, yellow foxtail) fescue, orchardgrass, red top, timothy,	Other Hay/Non Alfalfa	37	pasture and hay	3.75
grass, forage, hay (Bermuda, barnyard grass, canary grass, yellow foxtail) fescue, orchardgrass, red top, timothy,	Other Hay/Non Alfalfa	37	pasture and hay	3.75
guava	Other Tree Crops	71	orchards and grapes	16.25
hops	Hops	56	other crops	1.89

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
horseradish	Misc Vegs & Fruits	47	vegetables and fruits	3.75
kale	Greens	219	vegetables and fruits	3
kohlrabi	Misc Vegs & Fruits	47	vegetables and fruits	2.5
leek	Misc Vegs & Fruits	47	vegetables and fruits	3.12
lespedeza	Other Hay/Non Alfalfa	37	pasture and hay	7.5
lettuce (head & leaf)	Lettuce	227	vegetables and fruits	3.76
lettuce (head & leaf)	Dbl Crop Lettuce/Barley	233	vegetables and fruits	3.76
lettuce (head & leaf)	Dbl Crop Lettuce/Cantaloupe	231	vegetables and fruits	3.76
lettuce (head & leaf)	Dbl Crop Lettuce/Cotton	232	vegetables and fruits	3.76
lettuce (head & leaf)	Dbl Crop Lettuce/Durum Wht	230	vegetables and fruits	3.76
macadamia nut	Other Tree Crops	71	orchards and grapes	5.64
mango	Other Tree Crops	71	orchards and grapes	9.4
melons (other than watermelon)	Misc Vegs & Fruits	47	vegetables and fruits	2
mint	Mint	14	vegetables and fruits	2.82
mustards (mustard greens; mustard spinach; chinese mustard mizuna)	Mustard	35	vegetables and fruits	3
nectarines	Nectarines	218	orchards and grapes	9
oats	Oats	28	other crops	2
oats	Dbl Crop Oats/Corn	226	other crops	2

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
oats	Dbl Crop Soybeans/Oats	240	other crops	2
okra	Misc Vegs & Fruits	47	vegetables and fruits	6
onion	Onions	49	vegetables and fruits	3.12
papaya	Other Tree Crops	71	orchards and grapes	10
parsley	Greens	219	vegetables and fruits	3
parsnip	Misc Vegs & Fruits	47	vegetables and fruits	3.75
passion fruit	Misc Vegs & Fruits	47	vegetables and fruits	8
pasture and rangeland	Other Hay/Non Alfalfa	37	pasture and hay	2.76
peaches	Peaches	67	orchards and grapes	9
pears	Pears	77	orchards and grapes	2.5
peas	Peas	53	vegetables and fruits	2
pecans	Pecans	74	orchards and grapes	5
peppers	Peppers	216	vegetables and fruits	3.12
pineapple	Misc Vegs & Fruits	47	vegetables and fruits	6
potatoes	Potatoes	43	vegetables and fruits	3.12
pumpkins	Pumpkins	229	vegetables and fruits	2
radish	Radishes	246	vegetables and fruits	3
rice (and wild rice)	Rice	3	rice	2.5
rutabagas	Misc Vegs & Fruits	47	vegetables and fruits	3
rye	Rye	27	other crops	3

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
salsify	Misc Vegs & Fruits	47	vegetables and fruits	3.75
shallot	Misc Vegs & Fruits	47	vegetables and fruits	3.12
sorghum	Sorghum	4	other crops	2
spinach	Greens	219	vegetables and fruits	2
squash, summer	Squash	222	vegetables and fruits	5.25
squash, winter	Squash	222	vegetables and fruits	3
strawberry	Strawberries	221	vegetables and fruits	8
sweet potatoes	Sweet Potatoes	46	vegetables and fruits	3.12
swiss chard	Greens	219	vegetables and fruits	2
tomatoes (and tomatillos)	Tomatoes	54	vegetables and fruits	6.24
trefoil (birdsfoot)	Other Hay/Non Alfalfa	37	pasture and hay	7.5
turnips	Turnips	247	vegetables and fruits	3.75
vetch	Vetch	224	pasture and hay	7.5
walnuts	Walnuts	76	orchards and grapes	7.5
watercress	Greens	219	vegetables and fruits	6.25
watermelons	Watermelons	48	vegetables and fruits	2
wheat (spring and winter)	Dbl Crop Durum Wht/Sorghum	234	wheat	2
wheat (spring and winter)	Dbl Crop WinWht/Corn	225	wheat	2
wheat (spring and winter)	Dbl Crop WinWht/Cotton	238	wheat	2

Table A- 1 CDL class name, USGS crop group and potential use rate assigned to the crops use pattern listed in the malathion product label

Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
wheat (spring and winter)	Dbl Crop WinWht/Sorghum	236	wheat	2
wheat (spring and winter)	Dbl Crop WinWht/Soybeans	26	wheat	2
wheat (spring and winter)	Durum Wheat	22	wheat	2
wheat (spring and winter)	Spring Wheat	23	wheat	2
wheat (spring and winter)	Winter Wheat	24	wheat	2
yams	Misc Vegs & Fruits	47	vegetables and fruits	3.12

Malathion

Aquatic Endangered Species Risk Assessment - Synopsis

This synopsis describes an aquatic endangered species risk assessment (ESRA) case study for malathion using 100 listed freshwater fish and aquatic invertebrate species as the starting point. The complete aquatic ESRA was prepared for FMC Corp. by Intrinsik Corp. and Stone Environmental Inc. and is comprised of three volumes[1] and 727 pages.

This case study demonstrates the necessity of developing spatially explicit and species-specific risk estimates based upon best available environmental and agronomic data, for use in the endangered species risk assessment process. Each listed species (including distinct species populations (DSP) and evolutionarily significant units (ESU)) and their designated critical habitats will have unique risk probabilities based on potential differences in exposure and effect. Numerous lines of evidence are applied to support this conclusion. To address potential risks to listed species, the Services often develop reasonable and prudent alternatives (RPAs) that may include generic spray drift buffers. However, generic spray drift buffers applied across agricultural landscapes without consideration of factors affecting specific species are arbitrary, scientifically unsupportable, and economically destructive (e.g., unnecessarily removing farm land from production).

This case study provides the basis to develop a standard operating procedure for this process, thereby making ESRAs more efficient and less resource intensive. Specific listed fish and aquatic invertebrate species are identified that may benefit from risk evaluation at the population-level or from some form of mitigation (e.g., registrant-initiated conservation mitigation) and/or potential label adjustments thereby focusing resources to protect listed species from pesticide exposure where they may be needed.

The ESRA is based largely on the CropLife America (CLA) Framework[2]. The framework describes a hierarchical approach to developing an ESRA and is based on the guidance provided by EPA[3] and the NRC National Academy of Sciences panel report[4]. Each component of the case study is briefly described in the sections that follow.

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[1] Teed, R.S., M. Winchell, L. Padilla, H. Rathjens, S. Castro-Tanzi, and R. Breton. 2019a. Refined aquatic endangered species risk assessment for malathion – ESRA - Volume 1. Prepared for FMC Corporation, Washington D.C. pp 133

... 2019b. Refined aquatic endangered species risk assessment for malathion – Exposure and Effects Appendix - Volume 2. Prepared for FMC Corporation, Washington D.C. pp 272

... 2019c. Refined Aquatic Endangered Species Risk Assessment for Malathion – Results Appendix - Volume 3. Prepared for FMC Corporation, Washington D.C. pp 322

[2] CLA (CropLife America). 2017. Endangered Species Risk Assessment Framework and Problem Formulation. CropLife America – Ecological Risk Assessment Committee (ERAC). Washington D.C. August 2017.

[3] EPA (US Environmental Protection Agency). 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs. Washington, DC. January 23, 2004 [online]. Available: http://www.epa.gov/espp/consultation/ecorisk-overview.pdf

EPA. 1992. Framework for Ecological Risk Assessment. EPA/630/R-92/001. February 1992.

EPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. April 1998.

[4] NRC (National Research Council). 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. Committee on Ecological Risk Assessment under FIFRA and ESA Board on Environmental Studies and Toxicology, Division of Earth and Life Studies, National Research Council. National Academies Press, Washington D.C.

Exposure

The aquatic exposure modeling approach was designed to move beyond the screening level by refining the landscape characteristics and malathion use characteristics relevant to specific endangered species habitat ranges. The ESRA focused on refinement of model inputs and assumptions that are known to be influential in aquatic exposure prediction for malathion. The goal of this exposure assessment was to demonstrate across a broad range of species habitat ranges, geographic regions, and water body types how the use of refined modeling approaches and data inputs can lead to significantly more realistic exposure results and conclusions than a simple screening level analysis.

Aquatic habitat found in an agricultural landscape

Exposure modeling was conducted with the US Environmental Protection Agency's (US EPA) current regulatory exposure models, including the Pesticide in Water Calculator (PWC), the Pesticides in Flooded Agriculture Model (PFAM), and the agricultural dispersion (AGDISP) and Agricultural drift (AgDRIFT) spray drift models. Exposure modeling for this assessment included a broad range of refinements designed to incorporate additional data that explicitly described landscape, climate, hydrologic, and agronomic conditions affecting aquatic habitats within each listed species range. The refinements represent a subset of possible refinements that are understood to have a meaningful impact on potential exposure and that are supported by readily available data. Examples of these refinements include those with broad impact (e.g., spatial resolution, landscape) and more specific refinements (e.g., weather, soils, and crop groups). Historical malathion usage data was used to develop the application probability for each use pattern throughout each species range. Thus, the predicted malathion applications within any species range were dependent on the use patterns found in the catchments that overlap the species range. Use data were applied to better reflect how malathion is realistically used given that annual applications at the full label rates per acre would significantly exceed the amount of malathion imported into the US each year.

In real world agricultural landscapes, watersheds for both static and flowing water bodies can contain combinations of multiple crops potentially receiving malathion applications. Therefore, multiple crops were modeled as concurrently impacting potential waterbody exposure based on actual crop area patterns from historical cropping data. Listed species distributed across the entire country were selected for modeling. Of course, not only do the individual listed species have unique habitat requirements, but across the national landscape there are a massive number of waterbodies that vary in myriad different ways (e.g. underlying geology, size, shape, depth). To simplify, surrogate habitats were used, as defined by the EPA, FWS, and NMFS[5] (Table 1) and the 100 listed aquatic species were assigned to these habitats (or multiple habitats) depending upon available information on their life history.

[5] Agencies (EPA, NMFS, FWS, USDA). 2013. Interim approaches for National-level pesticide endangered species act assessments based on the recommendations of the National Academy of Sciences April 2013 report.

Table 1	Description of surrogate freshwater habitats and habitat characteristics	
Bin Number	***Habitat Description (Depth (m), Width (m), Length (m), Flow rate (m^3/s))***	***Habitat Characteristics***
2	Low Flow (0.1, 2, variable, 0.001)	Where current is barely discernable in a low volume body of water (trickling spring, still pool within a stream, shallow areas at stream edges)
3	Moderate Flow (1, 8, variable, 1)	Intermediate current in a small to moderate-volume body of water (stream, creek, low flow areas during flooding)
4	High Flow (2, 40, variable, 100)	Fast current in a moderate to large volume body of water (river, rapids area of a creek, moderate flow areas subject to flooding)
5	Low Volume (0.1, 1, 1, NA)	Very small body of water – usually ephemeral, or the shallow edges of a moderate volume or high-volume body of water (puddle, edge of a pond)
6	Moderate Volume (1, 10, 10, NA)	Intermediate-sized body of water (pond, wetland, vernal pool)
7	High Volume (2, 100, 100, NA)	Large body of water (lake, extensive wetland, vernal pool covering many acres)

The variability in predicted environmental exposure concentrations (EECs) was a function of the type and size of the water body and to a large extent the landscape characteristics impacting those water bodies. Overall, EEC variability and the trends between habitat types within a given species range followed conceptual expectations. Exposure is generally highest for the small static water habitat and low flow habitat. The small static water habitats are more vulnerable to pesticide exposure due to their small size and relatively low volume, making them susceptible to drift-based exposure. The low flow habitats are more vulnerable to pesticide exposure due to shallow depth and narrow width leading to higher potential for drift exposure. The small watersheds associated with low flow habitats are also more likely to be heavily cropped and can receive a higher percentage of pesticide treatment.

Exposure for the moderate and high flow habitats are lower than the other types of habitat, with high flow habitat often close to a factor of 10x lower than the moderate flow habitat. These habitat types have lower exposure because watersheds draining to this size of flowing water bodies are much more likely to have a large proportion of non-cropped areas and areas that do not receive malathion use. The higher rates of flow in these types of habitat also act to dilute and transport residues downstream.

Effects

The Office of Chemistry Safety and Pollution Prevention[6] has derived standard test guidelines that meet the toxicity testing requirements for aquatic and terrestrial biota under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; registration of pesticides), the Toxic Substances Control Act (TSCA; regulation of industrial chemicals) and the Federal Food, Drug and Cosmetic Act (FFDCA; setting tolerances or tolerance exemptions for pesticide residues). For example, toxicity testing for birds is generally performed for a waterfowl (e.g., mallard duck), passerine (e.g., canary, zebra finch) and upland game bird (e.g., northern bobwhite) species. For mammals, the generic laboratory rat is typically evaluated, while both a cold water (e.g., rainbow trout) and warm water (e.g., bluegill) species is selected for fish[3]. Wild-caught organisms are often not preferred for standard toxicity testing because of extraneous variables that are difficult to control (e.g., region and waterbody-specific adaptations). Well-studied chemicals with a long regulatory history, such as malathion, have a broad array of species for which toxicity testing has been conducted. However, studies that do not follow standard testing guidelines require extensive review for relevance and quality. Study evaluation criteria were developed and applied for all malathion toxicology studies[7] only those studies that have undergone the complete data quality review and meet the evaluation criteria are used in the refined malathion assessment.

> Threatened and endangered species are identical to all other species in terms of their toxicological sensitivity or tolerance to environmental stressors such as pesticides.
>
> Just because they are listed does not mean they are toxicologically more sensitive to a chemical.

The toxicological sensitivity of most listed species to malathion is generally unknown. Therefore, methods must be used to predict what the sensitivity of each listed species may be. Given the species being evaluated is either endangered or threatened, the methods chosen to estimate sensitivity must be considered conservative while also capturing associated uncertainties. In this assessment two methods are used to predict the sensitivity of the 100 listed aquatic species examined:

1. Surrogacy
2. Species Sensitivity Distributions (SSD)

Surrogate species are used in risk assessments due to the restrictions on testing rare or imperiled species. Generally, the data generated for standard test organisms, using standard test guidelines and laboratory-reared study organisms form the basis for the selection of surrogates. However, care must be taken

[6] OCSPP (Office of Chemistry Safety and Pollution Prevention). 2016. OCSPP Harmonized Test Guidelines. US Environmental Protection Agency, Washington, DC. https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines.

[7] Breton, R., G. Manning, Y. Kara, S. Rodney and K. Wooding. 2014a. Cheminova's Ecotoxicological Study Evaluation Criteria, Study Evaluations and Proposed Screening-level Effects Metrics for the Registration Review of Malathion. Unpublished report prepared by Intrinsik Environmental Sciences, Inc., Ottawa, ON, Project No. 60320, for Cheminova, Inc., Arlington, VA. Final report dated March 4, 2014. [MRID 49333901].

to select appropriate surrogate species. When no additional knowledge is available, a general surrogate may be selected as a representative of similar species. For example, selecting the most sensitive fish species as being representative of all fish. This is typically done in a screening-level assessment and is a simple method to quickly, but with great uncertainty, establish whether there is a potential for harm. In a refined assessment, the selection of an appropriate surrogate is critical to establishing the probability of risk.

> **Risk** is a measure of the *probability of harm* from a potential **hazard** (in this case a pesticide) and thus cannot be predicted from a simple comparison of max exposure / most sensitive effect. This simple screening approach only determines whether the hazard has the *potential* to cause harm.
>
> Without evaluating species-specific exposure and effects data, there is no way to determine the *probability of harm* (risk) to individual listed species.

In this refined malathion assessment, surrogates are based on taxonomy, habitat, and/or life history features. Species may also be grouped based on a variety of commonalities, including taxonomy (genus, family, class, or order), habitats (e.g., vernal pool amphibians), shared threats (e.g., competition with invasive species), similar life-history (e.g., mollusks), body size, and others. Laboratory and listed species that had a common taxonomic family were considered surrogates for toxicological purposes. For example, a laboratory study for the Louisiana crayfish (*Procambarus clarkia*) (Taxonomic Family: *Cambriadae*) was considered an appropriate toxicological surrogate for the Nashville crayfish (*Orconectes shoupi*) (Taxonomic Family: *Cambriadae*). Both species also share commonalities based on habitat and life history features. Once a toxicological surrogate has been selected, a concentration-response distribution is developed to show the full range of response to malathion exposure. Where data do not allow for the full concentration-response distribution, a predicted no observed (NOEC) or lowest observed effect concentration (LOEC) may be used to predict sensitivity.

As previously mentioned, listed and non-listed species exist on the same full distribution of toxicological sensitivities (very sensitive to very tolerant). When toxicological data for an appropriate surrogate is not readily available, a species sensitivity distribution (SSD) can be used to predict sensitivity. An SSD takes advantage of all the available toxicological data for an appropriate sensitive endpoint (e.g., mortality, growth or reproduction) to create a full sensitivity distribution (very sensitive to very tolerant) (Figure 1).

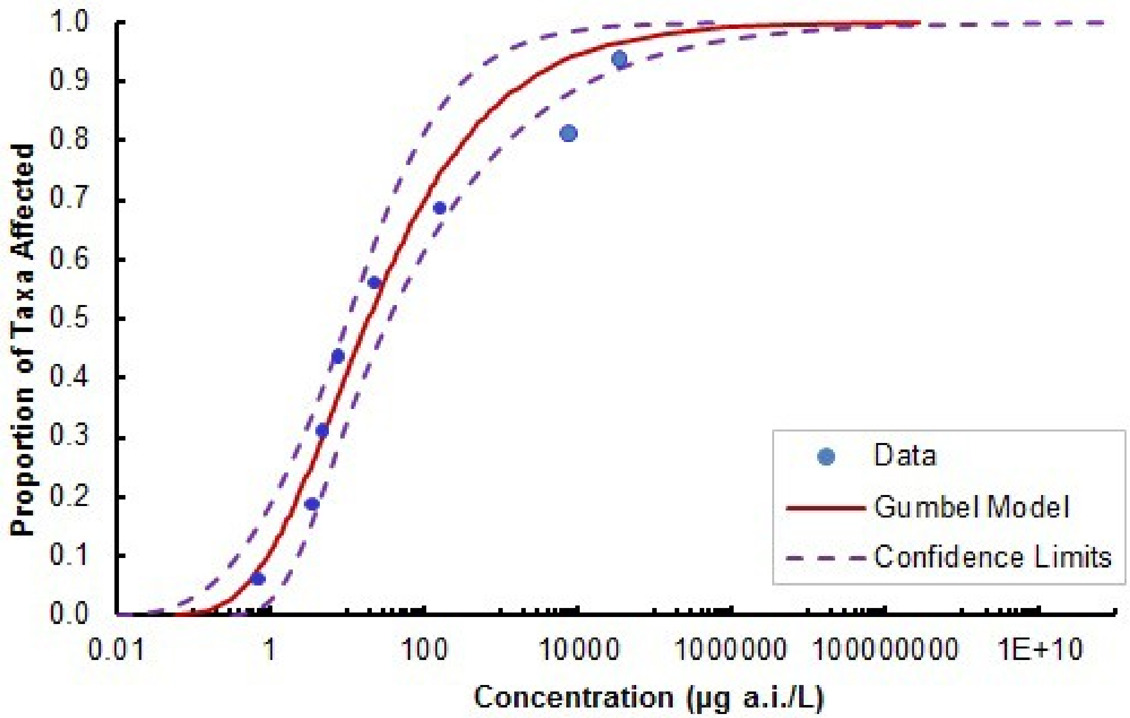

Figure 1. Species sensitivity distribution for aquatic invertebrate species exposed to malathion

The following figures (Figure 2 a,b,c,d) illustrate the pathway for measuring the potential for adverse effects in the refined risk assessment. For acute exposure in both flowing and static water and for those listed species with an appropriate surrogate, the concentration-response curve for that surrogate was used. If no surrogate was available, then the hazard quotient affecting the 5th percentile species in the SSD was used as a sensitive measure of potential effect (Figure 2a). For chronic exposure, the HC10 from the SSD was applied for species with no surrogate and a concentration-response curve for species with a surrogate (Figure 2b). For chronic exposure to fish, insufficient toxicological data were available to develop the SSD. Therefore, a NOEL for a sensitive fish species was used (Figure 2c,d).

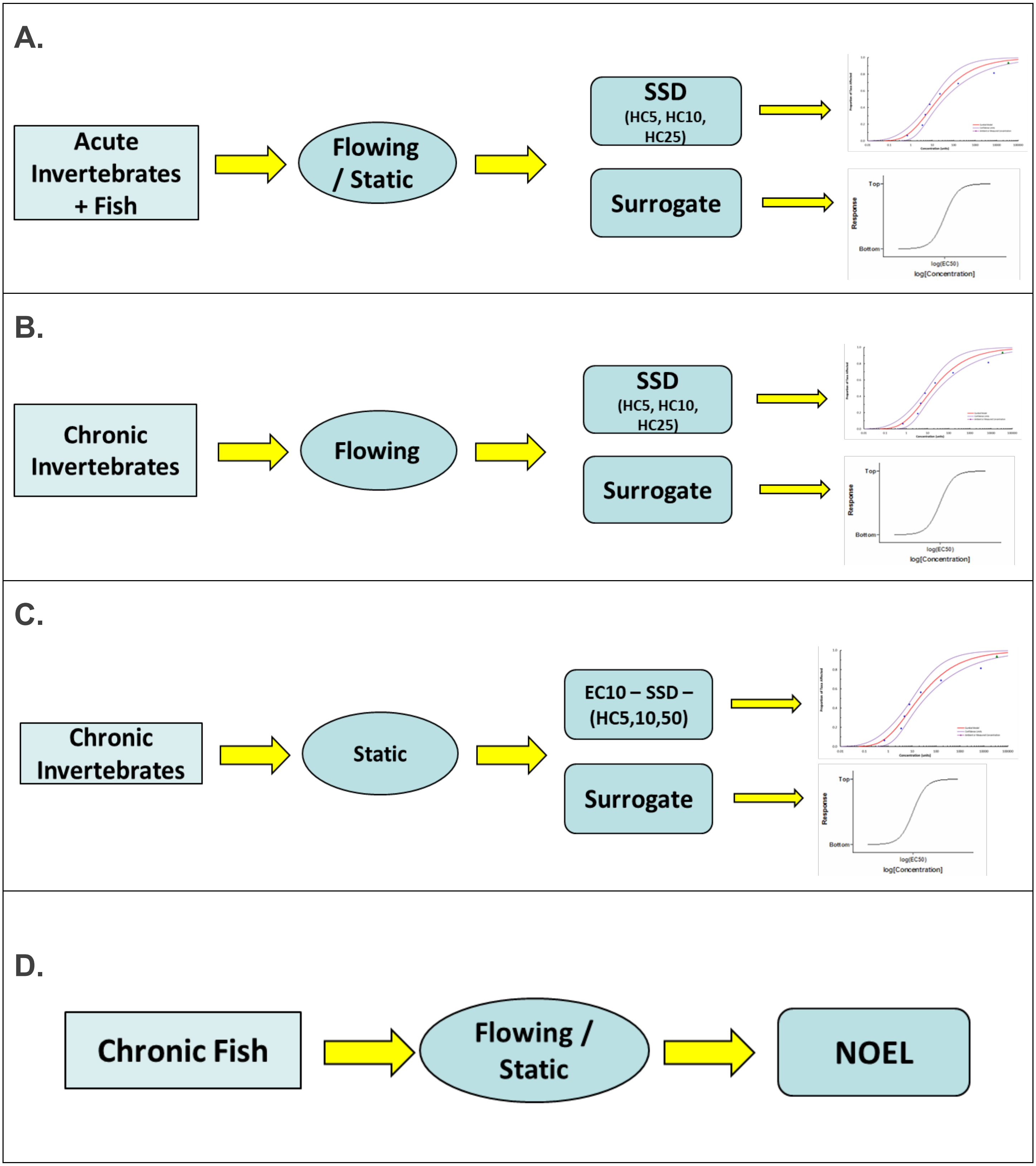

Figure 2abcd. Risk characterization pathways for acute and chronic effects to listed fish and aquatic invertebrate species

Risk Characterization

The risk characterization was supported by multiple lines of evidence including the modeling results, monitoring data, mesocosm and field studies, and incident reports. These multiple lines of evidence were integrated to provide appropriate context to the ESRA conclusions.

A risk characterization is the interpretation of the combined product of the effects and exposure analyses with consideration of all associated assumptions and uncertainties

Given the availability of exposure and effects distributions, where possible, the risk characterization was conducted using risk or joint probability curves and risk criteria were used to evaluate these risk curves. This is in keeping with the recommendations of the NRC National Academy of Sciences panel report[4] to implement a probabilistic approach in refined assessments and capture the uncertainty associated with risk estimates. In some cases (e.g., chronic fish) the probability of exceeding a sensitive NOEL was calculated.

Generic risk categories have been developed for most receptor groups. The approach involves determining the area under each risk curve (AUC) and comparing that value to criteria that specify *de minimis*, low, intermediate, or high risk. The criteria[8] are listed below:

- If the AUC is less than the AUC associated with the curve produced by risk products (risk product = exceedance probability x magnitude of effect) of 0.25% (e.g., 5% exceedance probability of 5% or greater effect = 0.25%), then the risk is categorized as ***de minimis***. The AUC for risk products of 0.25% is 1.75%;
- If the AUC is equal to or greater than 1.75%, but less than 9.82% (i.e., the AUC for risk products of 2%), then the risk is categorized as **low**;
- If the AUC is equal to or greater than 9.82%, but less than 33% (i.e., the AUC for risk products of 10%), then the risk is categorized as **intermediate**; and,
- If the AUC is equal to or greater than 33%, then the risk is categorized as **high**.

Overall, the modeling results indicate that malathion is unlikely to adversely affect listed fish species. In most of the species ranges evaluated, acute risk was either negligible or *de minimis* (a less than 5% probability of exceeding a 5% adverse effect). Chronic risk was found to be negligible when malathion use was very low within a species range. This result was due to the difficulty in sustaining malathion concentrations in aquatic systems and the fact that modeled 21-day exposure concentrations were consistently lower than the most sensitive effect metric (i.e., NOEL). For listed aquatic invertebrates, risk was predicted to be higher for some

[8] It is normally the role of the regulatory agency to provide appropriate risk criteria to use in a risk assessment. However, in this case, the agencies have not yet provided risk criteria to interpret probabilistic risk curves within the context of an ESRA, despite the NAS panel report[4] recommendations to use probabilistic methods. The risk criteria described above were originally developed on behalf of the EPA for use in a contaminated site program (CERCLA) project and are applied here to assist the reader in interpreting the risk curves. The EPA reference is provided here:

EPA (United States Environmental Protection Agency). 2004. Ecological Risk Assessment for General Electric (GE)/Housatonic River Site, Rest of River. New England Region, Boston, MA. DCN: GE-100504-ACJS.

listed invertebrate species, but within a limited portion of their range. Risk was predictable, based on proximity from the use pattern, weighted application rates, and spray drift contribution to the aquatic habitat. For many listed species, there was no, or very little exposure predicted within a species range even though at the coarse county-level there was assumed to be overlap between a species range and crop use pattern (Figure 3).

There are several lines of evidence that were used in a qualitative manner in the ESRA to provide context to the risk characterization and conclusions. These include aquatic field studies, mesocosm studies, effects of macrophytes on aquatic toxicity, water quality monitoring data, and incident reports.

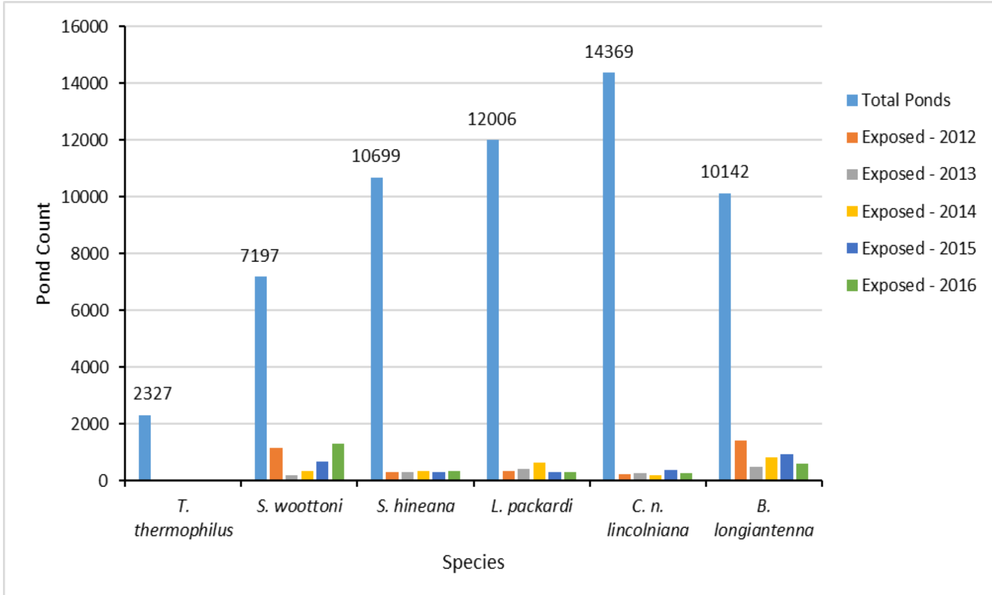

Figure 3. Number of moderate volume habitats (Bin 6) predicted to exceed the listed freshwater invertebrates EC10 for the 5th percentile species on the SSD within each listed species range

The aquatic field studies found no persistent effects of malathion on the abundance or survival of fish or aquatic invertebrate communities. Eleven mesocosm studies are available that studied the effects of malathion on aquatic communities. The studies attempted to quantify effects to fish, aquatic-phase amphibians, periphyton, phytoplankton, macrophytes, zooplankton and macro arthropods.

The mesocosm studies identified cladoceran species as being sensitive to malathion, while other aquatic invertebrate taxa (e.g., copepods, rotifers, snails, amphipods, isopods, and insects) were considerably less sensitive. This is consistent with the modeling line of evidence. Where surrogates were used, all the surrogate species identified were tolerant of malathion.

Natural aquatic systems are complex, and wildlife do not live in the inert environments used in standard toxicity tests. Factors such as variable pH and temperature, presence of organic matter and shading of water bodies, can influence the degree to which organisms are exposed to and affected by pesticides. An examination of the impact of aquatic plants in test systems on malathion toxicity demonstrated that the plants were a mitigating factor for cladoceran sensitivity. As such, the resulting effects metrics from toxicity tests may not be representative of all aquatic environments. This is particularly important given the nature of a nationwide endangered species risk assessment and examining potential risk to individual species and their critical habitat. At a minimum, the characteristics of the environment where their habitat is found should be accounted for to the extent possible and highlights one reason the use of a generic screening-level assessment is considered overly conservative for many species.

The surface water monitoring data provides a strong line of evidence for the aquatic ecological risk assessment. A variety of data sources were available from across the US with a focus on regions with heavy agricultural use with samples collected over several years. A significant number of samples have been collected over time (10's of thousands from 2001-2017) and sampling was also targeted for the timing of pesticide application and provided a reasonable estimate of peak concentrations. Overall, there was a low frequency of detection for malathion in surface water samples[1]. The surface water monitoring results for malathion support the findings of the ESRA. Comparisons of surface water monitoring data directly with sensitive effects metrics indicate that fish and aquatic invertebrates would rarely have the potential to be harmed by detected malathion levels in the environment. Furthermore, these malathion concentrations are comparable to those predicted by refined exposure modeling, indicating that the modeling conducted for the refined risk assessment is sufficiently realistic and conservative.

The incident data suggests that incidents resulting from the legal, registered uses of malathion are infrequent, particularly given the widespread use of malathion over the 37-year reporting period. Most of the reported incidents resulted from misuse of malathion or had insufficient information provided to determine whether malathion was the cause of the observed effects. Few incidents have occurred since 2000 and all aquatic incidents occurred prior to the last re-registration of malathion, which involved amendments to labeled use patterns, thereby reducing exposure. It is recognized that the incident reports are a weak line of evidence as very few, if any, incidents involving aquatic invertebrates would be reported. However, the lack of recent incidents involving fish kills suggests that the current malathion labels are protective of freshwater fish.

Conclusions

Each individual listed species and the critical habitat on which they depend, will have a different probability of exposure and effect, and therefore probability of risk. For malathion, there are many lines of evidence that support this conclusion. All the exposure modeling results conducted in this assessment were species-specific, where local weather conditions, soil types found within species ranges, and habitat presence and type (flowing or static, volume, flow rate, etc.) are known. This inherently modifies the outcomes of the exposure modeling for each of the listed species and their critical habitat. The listed species are not necessarily as sensitive as the most sensitive species identified in the fish or aquatic invertebrate datasets. Where surrogate data are available, in many cases the listed species is predicted to be more tolerant of malathion than the most sensitive species. The result of this refined aquatic ESRA is a risk determination for each of the aquatic listed species evaluated, in their assigned habitats, along with the uncertainty information that influences the risk statement. A risk manager can use this ESRA to evaluate the need for further population modeling to determine the potential for impacts at the population-level and/or the appropriateness of proposed mitigations (e.g. RPAs) on a species-specific basis.

The ESRA reports[1] serve as a valuable case study demonstrating the importance of developing both spatially explicit and species-specific exposure estimates and evaluating the appropriateness of the effects thresholds selected when deriving risk estimates for listed species. Exposure estimates should be based upon the best available environmental and agronomic data. Effects thresholds should be based on high quality data that are appropriate for each individual listed species. The ESRA can also be used as the basis for developing a standard operating procedure for this process, thereby making it more efficient and less resource intensive in future ESA risk assessments. In addition, specific listed fish and aquatic invertebrate species can be identified that may benefit from other forms of mitigation (e.g., registrant-initiated conservation mitigation) and/or adjustments to integrated pest management (IPM) activities due to a quantitative risk determination within part of their range.

West Indian Manatee
Case Study

EPA (2020) applied limited quantitative and qualitative evidence to develop an effect determination for the West Indian manatee (Draft carbaryl BE, Appendix 4-8). The conclusion of may affect, likely to adversely affect (MA/LAA) is primarily based on a qualitative evaluation of the manatee's potential exposure to drinking water containing carbaryl at overestimated concentrations. EPA calculated that for a surrogate manatee aquatic habitat (Bin 3 – moderate flow water body), the water concentration could reach a daily maximum concentration of 625 µg ai/L. EPA also assumed that the most sensitive effect metrics for mammals (i.e., LD50 = 104.3 mg ai/kg bw; LOAEL = 30 mg ai/kg bw/day; NOAEL = 4 mg ai/kg bw/day) based on decreases in fetal body weight and maternal body weight for the rat) are representative of the sensitivity of the manatee. Finally, to evaluate the potential for adverse effects to the aquatic plants on which the manatee depends, the predicted freshwater concentration (625 µg ai/L) was compared to the most sensitive adverse effects metric for non-vascular plants (IC50 = 340 µg ai/L). EPA reported that vascular plants (e.g., aquatic grasses) are tolerant of carbaryl exposure, given an IC50 of 23,900 µg ai/L for frond abundance in *Lemna gibba* (Draft carbaryl BE Appendix 4-8).

The West Indian manatee must have fresh drinking water periodically as their typical diet of sea grass found in salt and brackish waters does not contain sufficient water to maintain the manatee's daily requirements. However, drinking water is not the only source of exposure, as there can also be dietary exposure through consumption of aquatic plants.

This case study quantitatively evaluates risk to the West Indian manatee from potential exposure to carbaryl, incorporating both drinking water and dietary routes of exposure. A modified screening-level model accounts for dietary and drinking water exposure, using allometric equations. The case study analyses are described below.

Model Description

Rather than relying on a generic allometric model to estimate species-specific food intake rate and water flux rate (e.g., all birds or all mammals allometric models), such as in T-REX, two major refinements can be made. First, instead of estimating food-ingestion rate using an allometric equation, free metabolic rate was estimated. The latter, in combination with metabolizable energy of each dietary item, determines a food ingestion rate specific to the actual manatee diet. Second, we have updated the allometric model for free metabolic rate to account for data published since the Wildlife Factors Exposure Handbook was released in 1993 (the handbook upon which EPA relies for its wildlife allometric models). Food intake rate was derived using the following equation:

$$FIR = \frac{FMR}{\sum_{i=1}^{n} AE_i - GE_i}$$

where,

FMR	=	normalized free metabolic rate (kcal/kg bw/d);
AE_i	=	assimilation efficiency of i^{th} food item (unitless); and
GE_i	=	gross energy of i^{th} food item (kcal/kg ww).

The allometric relationships typically used for *FMR* from Nagy et al. (1999) are outdated. Numerous recent studies provide additional data to update *FMR* equations for different wildlife receptor groups. To update the allometric equations, data from Nagy et al. (1999) and Anderson and Jetz (2005) were obtained and analyzed.

The manatee model has a daily time step to incorporate degradation of carbaryl residues in water over time and allow for the calculation of a rolling average chronic exposure to match the exposure period of the chronic endpoint being evaluated. As per EPA's revised guidance (EPA, 2020a), the acute-effects metrics are adjusted for the estimated population size (in this case 10,000 manatees) of each listed wildlife species. The adjusted effect metric is developed by estimating the exposure level that would cause mortality to one individual in the listed species population, assuming an underlying log-probit model. There are no toxicological data for the manatee. We normally select an effects metric from the closest available taxonomic surrogate at the order level. In this case, there are no toxicity data available for species in the order Sirena to which the West Indian manatee belongs. Therefore, the most sensitive effects metrics for all mammals were used (i.e., LD50 = 104.3 mg ai/kg bw; LOAEL = 30 mg ai/kg bw/day based on decreases in fetal body weight and maternal body weight for the rat).

Indirect Effects

To estimate exposure for aquatic macrophytes, the dominant dietary item of the West Indian manatee, we relied on EPA's estimated peak daily Bin 3 concentration of 625 µg ai/L (0.625 mg ai/L). This value was used to estimate concentrations in aquatic plant using a regression-based equation from Arnot and Gobas (2006), and compared to the acute effects metric for aquatic macrophytes (IC50 = 23.9 mg ai/L), divided by the standard application factor for general dependencies, i.e., AF=1 for aquatic plants (EPA, 2020a).

Risk Characterization

Risk quotients (RQs) were calculated for: (1) direct effects to adult males and females for acute and chronic exposure durations, and (2) acute effects to aquatic plants. Maximum daily exposure estimates for the combined dietary and drinking water exposure routes were used to calculate acute direct RQs and maximum running average exposure estimates are used to calculate chronic direct RQs.

Model Inputs

Table 1 summarizes the inputs used to parameterize the model. When available, values recommended by EPA in the draft carbaryl BE were used.

Table 1. Input parameters for West Indian manatee exposure and effects model

Model Input	Value	Reference
Body weight	453.6 kg	FWS, 2020, 1000 lb assumed correct https://ecos.fws.gov/ecp0/profile/speciesProfile?sId=4469
Peak daily Bin 3 water concentration	0.625 mg ai/L	EPA, 2020
Aquatic half-life	1.8 d	EPA, 2012; aqueous photolysis
Acute effects metric	LD50 = 104.3 mg ai/kg bw	Rat mortality (EPA, 2020)
Chronic effects metric	NOAEL = 4 mg ai/kg bw/day	Decreases in fetal body weight and maternal body weight for the rat (EPA, 2020)
Effects metric for aquatic plants	IC50 = 23.9 mg ai/L	Reduced frond abundance in *Lemna gibba*. This study was conducted under 96-hour renewal conditions. (EPA, 2020)
Gross energy	667 kcal/kg ww	Aquatic vegetation data from Crocker et al., 2002
Moisture content	81.4%	
Assimilation efficiency	0.31	Average of aquatic and emergent vegetation; EPA, 1993
Log Kow	2.36	Windholz et al., 1976
Solubility	32 mg ai/L	Suntio et al., 1988
Elimination half-life	2.78 d	Mammal half-life
Proportion aquatic plants in manatee diet	1	FWS, 2020

To estimate concentrations in aquatic plants, we used the results of regression analyses conducted by Arnot and Gobas (2006). In their study, Arnot and Gobas determined the relationship between log bioconcentration factor (BCF) and log Kow following an extensive review of the literature for organic chemicals. A linear regression analysis was conducted for autotrophs (=aquatic plants).

$$Autotrophs: log\,BCF = 0.21 + 0.63 \cdot log\,Kow\ (n = 135, p < 0.0001)$$

The estimated BCF was multiplied by the conservative estimate of concentration in water (mg ai/L). For carbaryl, EPA's reported daily maximum concentration for Bin 3 was used (0.625 mg ai/L). The manatee does not depend on water bodies that resemble Bin 3. Rather, they are much more frequently found in much larger estuarine/marine habitats, bays, coves, and larger flowing waterbodies (e.g., Bin 4 and Bin 5) (FWS, 2020).

Model Results

The RQs for direct effects to the manatee consuming aquatic plants is 0.801 for acute risk and 0.39 for chronic risk. Therefore, risk from direct effects is negligible, particularly given the conservatism associated with the Bin 3 peak daily concentration of carbaryl. For effects to aquatic plants on which manatees depend, the RQ is 0.026. Thus, no indirect effects are predicted on aquatic macrophytes which are the dominant dietary item for manatees. Therefore, the risks of direct and indirect effects of carbaryl to the West Indian manatee are considered negligible.

Other Lines of Evidence

Other lines of evidence should be considered to support or refute the modeling line of evidence, such as monitoring data, incident reports, and other information. U.S. national monitoring data for 2012 to 2019 found a maximum aquatic carbaryl concentration of 2.18 µg ai/L, which is 287-fold lower than the peak daily concentration estimated by EPA for Bin 3 (Table 2).

Table 2. Summary of untreated water monitoring data for carbaryl from the Water Quality Portal (NWIS, STORET, NAWQA) (2012 to 2019).					
Year	**# Samples**	**# Detects**	**% Detects**	**Range of Detected Values (µg ai/L)**	**Range of Level of Detection (µg ai/L)**
2012	2037	223	10.9	0.003-1.67	0.006-0.06
2013	3181	241	7.6	0.003-0.724	0.006-0.06
2014	2602	375	14.4	0.003-2.18	0.006-0.06
2015	2808	194	6.9	0.004-0.361	0.006-0.06
2016	2837	246	8.7	0.006-0.307	0.006-0.06
2017	1983	150	7.6	0.003-0.466	0.0065-0.06
2018	1703	131	7.7	0.003-0.441	0.006
2019	689	32	4.6	0.006-0.033	0.006-0.0065

As a result of re-registration of carbaryl in 2007, the labels were changed to reduce many maximum application rates, cancel use on wheat, prohibit certain aerial applications, and cancel some residential uses. Thus, it is not surprising that percent carbaryl detections and maximum detected concentrations are low among 17,000+ analyzed samples (Table 2). In the draft carbaryl BE (Chapter 3), EPA reported carbaryl concentrations in surface water of up to 400 µg ai/L (surface water sample in 1973 from a creek in Pennsylvania). EPA noted that "many of the high detections were historical and reported in the late 1980s, but several more recent detections exceeded 1 µg/L." Historic monitoring data are not applicable, given the regulatory actions described above. The carbaryl ePest High predictions from the USGS (2020) indicate declining use since 1995 in the United States (Figure 1).

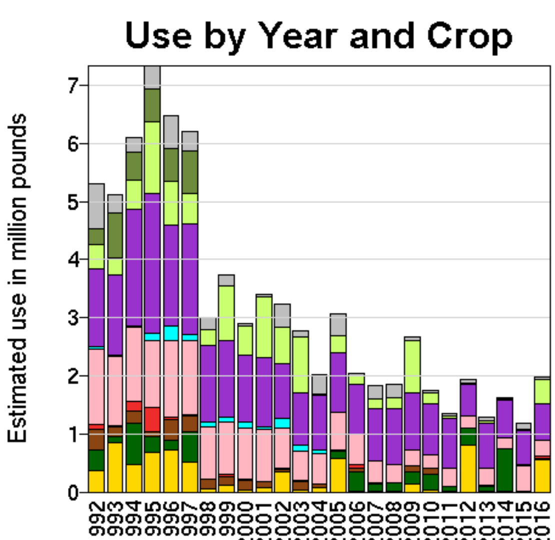

Figure 1. USGS ePest high estimated carbaryl use from 1992 to 2016 (USGS, 2020).

The EPA BEAD evaluation of carbaryl use (Draft Carbaryl BE - Appendix 1-4) also indicates a trend of diminishing carbaryl use over time. This likely reflects regulatory mitigations, label changes over time, and competition from newer pesticides. These lines of evidence (monitoring data, regulatory history, and trends in carbaryl use) provide evidence that the predicted maximum daily EEC for Bin 3 based on the modeling conducted by EPA is an overly conservative prediction of carbaryl concentrations in the surface waters where manatees reside.

For indirect effects, EPA indicated that the non-vascular-plant effect threshold (IC50 = 340 µg ai/L) was exceeded when compared to the predicted Bin 3 maximum daily EEC of 625 µg ai/L. As noted above, however, vascular plants are a far more important dietary item for manatees than are non-vascular plants. Therefore, in our analysis we relied on the IC50 of 23,900 µg ai/L for *Lemna gibba*. As indicated above, the maximum predicted water concentration is a highly conservative prediction of carbaryl exposure in water, and there is a lack of evidence to support the aquatic exposure model predictions. However, other lines of evidence are available.

As indicated in the FWS recovery plan (FWS, 2001), the West Indian manatee consumes a wide variety of submerged, floating, and emergent vegetation. The species has a clear preference for vascular sea grasses in coastal areas. Aquatic macrophytes such as manatee grass (*Syringodium filiforme*) and shoalgrass (*Halodule wrightii*) are preferred over the macroalga (*Caulerpa spp*.). In other areas, manatees are known to feed in salt marshes on smooth cordgrass (*Spartina alterniflora*) and hydrilla (*Hydrilla verticillata*). All are vascular plants except for the macroalga. Therefore, if carbaryl surface water concentrations were high enough to reduce the availability of non-vascular (algal) species, the impact on the manatee in terms of food availability would be negligible. This is due to the presence of macrophyte species that are tolerant of carbaryl and the mobility of the manatee to search for vascular plants. In addition, algal species grow exponentially when conditions are favorable, and they recover rapidly from disturbance (Havens, 1995). Thus, effects to algal communities are typically short-lived. Continuous carbaryl exposure over long durations is extremely unlikely given its typical use in the field in response to [fluctuating?] pest pressures. This line of evidence suggests that any effects to the manatee arising from adverse impacts to aquatic plants are “not reasonably likely to occur.”

Sources of Uncertainty

Effects Assessment

- Use of the rat effects endpoints as surrogate for the toxicity to the manatee is uncertain because the two species are taxonomically distant. Converting the rat LD50 with an assumed slope of 4.5 to a 1-in-a-population effect metric is highly conservative.

Exposure Assessment

- The manatee is found in marine/estuarine, brackish and freshwater environments. Applying a predicted water concentration that is a daily maximum from the most sensitive aquatic habitat that EPA modeled (Bin 3 – moderate flow) is therefore highly conservative. The simplified, generic BIN 3 habitat predicted surface water concentration significantly contributes to the conservatism of the manatee exposure modeling. This conservatism is not supported by the monitoring data and trend in carbaryl use over time.
- Generic residue unit doses are not available for aquatic plants. Therefore, we used the results of a regression-based study by Arnot and Gobas (2006) to estimate the BCF for aquatic plants and multiplied the BCF by the daily Bin 3 concentrations. Because the Bin 3 estimated water concentrations are highly conservative, the concentrations in aquatic plants are also highly conservative.

Conclusion

All lines of evidence support **No Effect** an effect determination for the West Indian manatee.

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