August 15, 2019

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-2019-0185**

Re: Comments on the Draft Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations for Pesticides

Dear Ms. Perry,

CropLife America ("CLA")[1] appreciates the opportunity to comment on EPA's Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides, 84 Fed. Reg. 22120 (EPA, May 2019) (the "Revised Method"). The Revised Method is a constructive step in EPA's ongoing process to improve how pesticide re-registrations under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") are reviewed for conformance with the Endangered Species Act ("ESA") and to be more reflective of actual exposure. It builds logically on EPA's experience applying the interim pilot process released in 2017. It is also fully consistent with EPA's legal obligations and – importantly – could be immediately implemented to allow pending reregistration decisions to proceed.[2] Finally, the Revised Method establishes a firm foundation for further process improvements going forward.

CLA's comments are organized into four sections. First on page 3, CLA provides an Executive Summary of these comments. Second, beginning on page 6, we discuss the need for broader coordination between EPA and the U.S. Fish & Wildlife Service or the National Marine Fisheries Service ("FWS" and "NMFS," collectively, "the Services"), and consideration of

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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 crop protection and biotechnology products used by American farmers.

[2] *See, e.g.*, *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013-1014 (9th Cir. 1987) ("[t]o the extent that [a] directive merely provides *guidance* to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make 'individualized determinations,' it constitutes a general statement of policy… and parties can challenge the policy determinations made by the agency only if and when the directive has been applied specifically to them.").

conservation approaches. Third, on page 6, we provide a short summary of why the Revised Method is fully consistent with applicable legal requirements. Fourth, on page 7, we present detailed comments on the four issues as requested by EPA regarding: (1) the method for incorporating usage data; (2) the interpretation that a <1% overlap of listed species' ranges with potential use sites; (3) the approach to probabilistic analyses; and (4) the weight-of-evidence framework. Finally, beginning on page 18, we provide additional comments regarding several issues, including: "no effect" determinations, aquatic exposure modelling, addressing uncertainty, and the use of surrogates for selecting effects endpoints. Within each substantive section, CLA highlights the improvements present in the Revised Method, suggestions that would further improve the final version but need not delay its publication, and areas for review in the future. We also include estimated annual agricultural pesticide use for thirteen widely used crop protection active ingredients (Appendix A, starting on page 31), and a case study using malathion (Appendix B, starting on page 39) to support the incorporation of usage data for risk assessment.

CLA appreciates the opportunity to comment and share information with EPA in response to the "Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides, 84 Fed. Reg. 22120." Thank you for engaging in a dialog with stakeholders on this important issue and please do not hesitate to reach out to us with questions.

Sincerely,

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EXECUTIVE SUMMARY

In the Revised Method document, EPA has proposed refinements to the interim method for conducting national-level biological evaluations (BEs). The Revised Method is both a sustainable and scientifically defensible risk assessment process to prepare BEs, developed using input from public comments as well as the National Research Council (NRC)[3] recommendations. The Revised Method is consistent with the requirements of the ESA and its implementing regulations, in a manner that remains aligned with the NRC recommendations, while being responsive to regulatory mandates and public input that will result in protections for endangered species. Our analysis suggests that the Revised Method is a step in the right direction to allow the Agency to meet its legal and regulatory obligations under ESA. CLA, therefore, urges EPA to finalize the Revised Method to achieve the policy goals that can be supported by the industry and the Agency, as well as consider our feedback for improving the final Revised Method in future iterations. Below are the highlights of our comments:

- **The Revised Method is consistent with EPA's statutory mandates and authority while being scientifically defensible.**

- **EPA should continue and expand its collaboration with the Services and the U.S. Department of Agriculture (USDA) to improve the ESA pesticide risk assessment process.**

- **Pesticide usage data represents the "best scientific and commercial data available," and must be incorporated into BEs to ensure they are completed accurately, efficiently, and in compliance with the ESA.**

- **A less than 1% spatial overlap does not compel a "May Affect" determination given the uncertainty inherent in the spatial data and in view of NRC's recommendations that further data should be applied.**

- **The probabilistic methods outlined in the Revised Method will improve efficiency, transparency, defensibility, and facilitate decision making in the risk assessment process.**

- **A robust weight-of-evidence approach should be implemented when conducting a BE and all uncertainties should be clearly communicated to demonstrate the credibility of the risk assessment process**

- **The Agency should expand the potential for Scoping (making early and efficient "no-effect" determinations where possible), to improve efficiency of resource use.**

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

ABBREVIATIONS

BE	Biological Evaluation
CDPR	California Department of Pesticide Regulations
CLA	CropLife America
DA	Drainage Area
ECOFRAM	Ecological Committee on FIFRA Risk Assessment Methods
EEC	Estimated Environmental Concentrations
EOF	Edge-of-Field
EPA	Environmental Protection Agency
ESA	Endangered Species Act
ESRA	Endangered Species Risk Assessment
EXAMS	Exposure Analysis Modeling System
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FWS	U.S. Fish & Wildlife Service
IWG	Interagency Working Group
LAA	Likely to Adversely Affect
MCnest	Markov Chain Nest Model
NAS	National Academy of Sciences
NC	Normal Capacity
NLAA	Not Likely to Adversely Affect
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
PCA	Percent-Cropped Area
PCT	Percent-Crop Treated
PRA	Probabilistic Risk Assessment
PRZM	Pesticide Root Zone Model
PUR	California Pesticide Use Record

PWC	Pesticide Water Calculator
REJV	Residential Exposures Joint Venture
SWAT	Soil and Water Assessment Tool
TIM	Terrestrial Investigation Model
UDLs	Use Data Layers
USDA	U.S. Department of Agriculture
VFSMOD	Vegetative Filter Strip Modeling System
VVWM	Variable Volume Water Model

SUBSTANTIVE COMMENTS

1 Coordination Between Agencies and Conservation Efforts

After publishing the final Revised Method, EPA may consider publishing a detailed process on coordination and collaboration with the Services. Providing clear guidance on the level of interaction required between scientists at EPA and the services would build greater trust between the agencies and result in an efficient and seamless consultation process. A Biological Evaluation (BE) carried out using a well-defined, coordinated and collaborative process will reflect the views of all the three agencies and will assist in the process of obtaining concurrence or development of Biological Opinions based on the outcome of the BE. This coordination along with the involvement of the USDA, was directed by the Congress in the 2018 Farm Bill. CLA strongly supports section 10115 and looks forward to continued progress of the Interagency Working Group (IWG) to drive improvements to the ESA reviews of pesticides registration decisions.

The proposed Revised Method published by EPA focuses on minimization, and avoidance without considering conservation and mitigation efforts proposed by registrants and adopted by growers. Including conservation and mitigation measures during the BE process can reduce or offset anticipated adverse effects. Conservation and mitigation approaches would further allow EPA and the Services to reduce the risk of a jeopardy or adverse modification finding by offsetting some or all of the estimated adverse effects of the pesticide action on listed species and their critical habitats.

2 The Revised Method is Consistent with EPA's Statutory Mandates and Authority

The Revised Method describes EPA's process for determining whether a pesticide review decision requires consultation with the Services. The determination of whether consultation is required clearly and solely rests with EPA, the "action agency."[4] The Services have expressly agreed that the action agency determines whether consultation is required, even if (unlike here) the action agency in question does not possess relevant subject matter expertise and experience. For example, in 2008, the Services rejected the argument that action agencies "are not equipped to make their own [may affect] determinations either because they lack the requisite expertise, lack funding, will not be able to find qualified reviewers, or do not have a mission compatible with resource protection." [5] More recently, in a 2017 guidance document on "'No Effect' Determinations," NMFS's leadership explained that "[t]he term 'may affect' is not defined in the ESA or by National Oceanic and Atmospheric Administration (NOAA) Fisheries/United States

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[4] See, e.g.,; 51 Fed. Reg 19926, 19949 (June 3, 1986) ("Federal [action] agencies have an obligation under Section 7(a)(2) to of the Act to determine whether their actions may affect listed species and whether formal consultation is required under these regulations"; the "determination of possible effects is the Federal agency's responsibility."); *Pacific Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n. 8 (9th Cir.1994), cert. denied, 514 U.S. 1082 (1995); "[I]f the [action] agency determines that a particular action will have no effect on an endangered or threatened species, the consultation requirements are not triggered."

[5] 73 Fed. Reg. 76272, 76282 (December 16, 2008).

(U.S.) Fish and Wildlife Services joint regulations." Therefore, if "the federal action agency determines that its action will not affect any ESA listed species or designated critical habitat within NOAA Fisheries" jurisdiction (i.e., it makes a 'no effect' determination), there is no need to consult with NOAA Fisheries."[6]

Moreover, an action agency's method of deciding whether to consult – i.e., the method it uses to arrive at a "no effect" decision or a "may affect" decision – is owed deference by the Courts. *See, e.g.*, *Sw. Ctr. for Biological Diversity v. Glickman*, 100 F.3d 1443 (9th Cir. 1996).

It is also appropriate that EPA use a "clarifying document," like the final Revised Method, to explain the way it intends to exercise its discretionary authority. This ensures good governance and transparency, fostering "communications between agencies and their regulated communities that are vital to the smooth operation of both government and business." *Valero Energy Corp. v. EPA*, D.C. Cir. No. 18-1028 (June 25, 2019), at 6, *citing Rhea Lana, Inc. V. Dep't of Labor*, 824 F.3d 2023, 2028 (D.C. Cir. 2016) (*quoting Independent Equip. Dealers Ass'n*, 372 F.3d at 428). In addition, it avoids judicial interference in EPA's and Services' difficult effort to work out the implementation of the separate mandates of the ESA and FIFRA. *Cf., e.g., National Mining Assn v. McCarthy*, 758 F.3d 243 (D.C. Cir. 2014); *Mada-Luna v. Fitzpatrick*, footnote 2, supra.

3 Comments on the Four Specific Areas of Interest Identified by EPA

3.1 Methodology for Incorporating Usage Data

- The Revised Method correctly recognizes that agricultural pesticide usage data represents the "best scientific and commercial data available," and must be incorporated into BEs to ensure they are completed accurately, efficiently, and in compliance with the ESA.
- More non-agricultural use data is available than EPA has recognized, and CLA will help provide it to EPA as the Revised Method is implemented.
- EPA should clarify how the Percent-Crop Treated ("PCT") concept will be applied.
- Appendix B presents a CLA-sponsored case study that demonstrates an approach to applying usage data at the state and county level. EPA should consider this approach and others going forward as it builds upon the Revised Method.

CLA strongly supports the inclusion of usage data by EPA in the Revised Method. Usage data can reliably predict how products will be applied based on usage volumes and patterns. It is well established that pesticide usage data tends to be robust and reliable years after the introduction of products containing a new active ingredient.[7] Thus, for active ingredients and related products

[6] NMFS Procedural Instruction 02-110-20 (January 13, 2017), http://www.nmfs.noaa.gov/op/pds/index.html, (Last accessed August 2, 2019). The paragraph from which the quotations in the text are excerpted concludes: "Neither the ESA nor the NOAA Fisheries/U.S. Fish and Wildlife Services' joint consultation regulations mandate consultation when federal action agencies determine their proposed actions have 'no effect' on any ESA-listed species critical habitat."

[7] Appendix A displays estimated annual agricultural pesticide use for thirteen widely used crop protection active ingredients. For all States except California, pesticide use rates were estimated for Crop Reporting Districts using two methods and proprietary surveys to ensure accuracy. For California, use estimates were obtained from annual California Department of Pesticide Regulation use reports on county-levels. See also, Pesticides Industry Sales and

undergoing registration review and ESA analysis, EPA's inclusion of usage data will assist in a better BE.

3.1.1 EPA's Proposed Approach for Incorporating Usage Data

CLA supports EPA's Revised Method incorporating pesticide usage data at both Step 1 (No Effect/May Affect), and Step 2 (Likely to Adversely Affect (LAA)/Not Likely to Adversely Affect (NLAA)). In both steps, the application of usage data will allow refinement of exposure potential and extent of the action area.

In addition, the Services standard allows for using the 'best scientific and commercial data available'; this standard should allow the Services to rely on pesticide use / usage data & recognize the limits in the available data/information (https://www.fwspubs.org/doi/pdf/10.3996/052017-JFWM-041, last accessed August 15, 2019).

3.1.2 Incorporating Usage Data at Step 1

At Step 1, EPA proposes to use national and state level data from the most recent five years to identify areas that, despite being identified as potential use sites on a Use Data Layer (UDL), have not received pesticide application. These areas would then be removed from the UDL for purposes of establishing the Action Area. For an entire state to be excluded from an agricultural UDL, all labeled uses within that UDL would have to be reported as zero usage for the past five years.

CLA notes, however, that county-level data are available in connection with several BEs EPA is currently or will soon begin working on. As explained below using malathion as a test case, CLA has developed a methodology that provides estimates of UDL-level (*i.e.*, crop group) pesticide usage at the county level. The case study using malathion is included in Appendix B and the raw data can be made available to EPA upon request. CLA believes that using county data, where available, would allow for a more refined UDL where usage at the state-level occurs. EPA may consider reviewing the attached methodology to develop an approach which will incorporate county-level information in both Step 1 and, as explained below, Step 2 where possible.

The Revised Method document states that usage data for non-agricultural purposes are less readily available than agricultural usage data, especially at the national scale. EPA notes that if data sources were to become available that provide enough evidence that usage on a UDL was not likely to occur, then the UDL for this non-agricultural use pattern could be constrained accordingly. CLA supports this approach and notes that more pertinent information is available than has been recognized by EPA in the Revised Method. For example, the Residential Exposures Joint Venture ("REJV") task force has submitted to EPA a proprietary dataset from a National Pesticide Use Survey (MRIDs 49309501 and 49405901) that provides considerable relevant information. EPA's 2016 review of the REJV survey concluded "The REJV National Pesticide Use Survey (2012-2013) represents a reliable and robust source of residential pesticide

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Usage, 2008-2012 Market Estimates. Office of Pesticide Programs, U.S. EPA (2017) https://www.epa.gov/pesticides/pesticides-industry-sales-and-usage-2008-2012-market-estimates. (Last accessed August 2, 2019).

use information." and "EPA agrees that the survey is sufficiently representative of the U.S population and of pesticide users." (US EPA, 2016).

In addition, the American Mosquito Control Association and others have submitted usage data relevant to public health uses. At the very least, EPA should add these usage data sources to those to be considered under the Revised Method.

3.1.3 Incorporating Usage Data at Step 2

The proposed approach for incorporating usage data in Step 2 is more quantitative than Step 1. The approach is conservative because all usage is assumed to occur on potential use sites within a species range before occurring anywhere outside the species range. Using this approach may result in 100% Percent Crop Treated (PCT) within a species range and 0% PCT outside of a species range. This has the potential to significantly over-predict potential exposure to species, even when the opposite is true. The treated area in a species range is then used to determine the percent of species range potentially affected by the pesticide use. Based on species population estimates, EPA's proposed approach then determines if >1 individual is exposed. If this threshold is exceeded, steps 2b/2c are possible, based on a weight-of-evidence approach, including factors such as temporal factors, uncertainties in species range data, dietary considerations, etc. Although mentioned in passing, methods for refinement of the distribution of product usage vs. the species range are not outlined. CLA thus recommends that after the final Revised Method is published, the following three specific elements are addressed in supplemental material by the EPA:

First, EPA should clarify what method(s) it will use to determine the application volume from the five years of historical data that is used to calculate the PCT. Using statewide volumes from the year with the maximum usage may be overly conservative in certain circumstances – for instance, under certain crop rotation conditions or where there was a known event that caused elevated usage in a year that is unlikely to recur. EPA could minimize these types of distortion by relying on average volumes over the five-year period, and/or by factoring in trends where the data allow such extrapolation.

Second, accounting for actual usage rather than the maximum label rates is important to make the best judgment about exposure potential. EPA, thus, should clarify whether the PCT calculation will be directly based upon acres treated, or whether the number of treated acres are inferred from usage mass estimates divided by some usage rate(s). Using maximum label application rates in this context would be extraordinarily conservative because applicators rarely use maximum rates. If this is what EPA intends to do, the process should be identified as another conservative factor.

Third, EPA should recognize that the proposed approach has the potential to significantly over-predict the likelihood of pesticide usage within a species range and take steps to either avoid or, at the least, make this fact clear. For example, assume there are 1,000,000 acres of corn in a state and that a 1,000 acre species range overlaps with 900 acres of corn. Assume also that state-level PCT data shows that only 1% of corn is treated with the pesticide being assessed, resulting in 10,000 acres of corn treated with pesticide in the state. Following EPA's proposed approach, all 900 acres within the species' range would be assumed to be treated (i.e., 90% of its in-state range), unless portions of counties within the species range could be excluded from the calculation because the pesticide under consideration is not labelled for use in those counties. But if the 1% PCT was assumed to be evenly distributed across the state, then only nine (9) acres (0.9% of the species in-state range) would be assumed to be treated. The probability of an individual being exposed to the pesticide would be very different based in these two scenarios. To overcome this problem, CLA recommends that a more realistic approach to determining acreage treated within a species range be used when possible within the Revised Method framework, and that this topic be reviewed as EPA improves on the Revised Method in the future. A uniform likelihood of treatment across all potential use sites in a state is one approach to consider. In the meantime, any analyses that apply the approach described in the Revised Method should acknowledge the conservatizing influence of the proposed assumption.

3.1.4 A Methodology for Quantifying Pesticide Usage at the County Scale

There are many possible methods to account for pesticide usage at different spatial scales (state, county, section). CLA recently completed a research project, focused on malathion usage, to develop a methodology to refine annual pesticide usage statistics at the crop group and county level (Appendix B). This study used publicly available national and state-level datasets (including USGS Annual Pesticide Use database, Baker and Stone, 2015; USDA Agricultural Chemical Use Program Survey, USDA, 2019; and California Pesticide Use Record (PUR) database, CDPR, 2019) to provide a comprehensive understanding of agricultural pesticide usage nationwide. The methodology showed excellent agreement with observed county-level, crop group malathion usage data from the California Pesticide Use Reporting (PUR) database.

The study yielded an approach for determining annual usage and a percent of potential pesticide usage by county and crop group that is functionally equivalent to PCT at maximum label rates. By examining multiple years and multiple sources of usage data, the end results of the approach are probability distributions of annual usage and percent of potential usage at the crop group and county level. These data can be incorporated directly into multiple components of an endangered species risk assessment. CLA urges EPA to permit registrants to use such a methodology for incorporation of refined usage data into the Agency's analyses rather than relying on state-wide usage data.

3.1.5 Incorporating Usage Data into Probabilistic Exposure Modeling

The 2013 National Academy of Sciences report (NRC, 2013) stated probabilistic risk assessment methods are preferred when evaluating the risks of pesticides to endangered species. After the final Revised Method is published, CLA encourages EPA to employ usage data to refine the calculation of probability distributions of estimated environmental concentration (EECs) used in probabilistic quantitative risk assessments. Usage data should play an integral role in refined exposure modeling in terms of identifying what exposure is considered reasonably certain to occur.[8] At the local scale (field or small watershed), usage data can define the probability of a given field or watershed being treated. At the broader scale, usage data can define the percentage of use sites treated within a watershed or species range. At either scale, usage data

[8] https://www.fws.gov/endangered/improving_ESA/pdf/ITS%20Final%20Rule%20FAQs%20Final%205-1-15.pdf (Last accessed August 15, 2019)

are one of the most important datasets for developing accurate exposure probability distributions for use in endangered species risk assessments.

Appendix B provides a further discussion on approaches for future inclusion of pesticide usage data in refined exposure modeling. In addition, 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.*, 2017a,b), as are case studies incorporating pesticide usage data in refined aquatic exposure modeling (Winchell *et al.*, 2018a,b). CLA members have also contributed recommendations and examples of incorporating pesticide usage data in exposure modeling and endangered species risk assessments as a part of previous public comment submissions on EPA's pilot BEs (CLA, 2016; Padilla and Winchell, 2016; Winchell *et al.*, 2016). The refined, spatially explicit and species-specific exposure modeling examples and recommendations/comments provided in these case studies remain valid and merit EPA's attention to build upon the Revised Method.

3.2 Interpretation of the <1% Spatial Overlap at Step 1

- CLA supports EPA's conclusion that <1% spatial overlap does not compel a "May Affect" determination given the uncertainty inherent in the spatial data and in view of NRC's recommendations that further data should be applied.
- CLA encourages EPA to ensure that sources of uncertainty and the directional implications of the assumptions made in the assessment, *e.g.*, AgDrift parameters and results, are identified in the assessment and clearly explained in a manner accessible to and comprehendible by general audience.
- After the Revised Method is in place, CLA recommends that EPA re-examine its use of AgDrift and Kenaga nomograms to ensure these tools do not result in estimated exposures that are hyper-conservative.
- CLA looks forward to providing recent research on chronic effects metrics, so that EPA may integrate it into future analyses.

CLA supports EPA's proposed <1% overlap rule as a positive step forward as it recognizes the limits in precision of the best available data but urges that after it begins implementing the final Revised Method, the EPA take further efforts to minimize the overestimation of exposure that persist in Step 1 of the analyses.

The final Revised Method documentation also should more clearly explain the continuing conservatism of EPA's approach. In the past, EPA has had limited success communicating the level of conservatism in its exposure estimations, particularly to general audiences who take greater interest in EPA's work at this phase. The final Revised Method should strengthen stakeholder and public understanding of this process, wherein EPA could mention some of the conservative assumptions in AgDrift modelling as documented in a submission by CLA[9] in docket EPA-HQ-OPP-2013-0676-0002. For example, the drift estimates produced by AgDrift

[9] CropLife America. 2014. Comments on Pesticides: Consideration of Spray Drift in Pesticide Risk Assessment. OPP Docket. Submitted by Michael Leggett, Ph.D., Sr. Director of Environmental Policy, CropLife America. EPA-HQ-OPP-2013-0676-0044

are upper limit values of distributions derived from empirical studies designed to assure measurable levels of drift. The estimates are not representative of typical pesticide applications under normal circumstances with current spray technology and best practices. CLA suggests that the final Revised Methodology present lower bound and median estimates of drift exposure from best available data in addition to the upper bounds currently being used.[10]

Many of the default assumptions used by EPA in modeling drift are not representative of typical practice. An abundance of studies demonstrates that the mass of chemical moving off-site due to drift of spray droplets from ground applications rapidly declines within the first 10 meters from the field edge. Within 30 meters of the field edge, there generally is greater than 90% reduction in chemical deposition from that at the field edge. The Revised Method document indicates that drift exposure will be capped at 2600 feet, but regardless of limitations of the data, at 2600 feet the probability of detecting any chemical applied in accordance with label restrictions is likely to be infinitesimal. The EPA assumptions do not reflect this reality. These issues should be acknowledged in the near term and fixed in the future.

If 1% of a species range was exposed at concentrations understood to have an adverse effect, it may have significance for the well-being of the species. However, 1% overlap of an assumed range with a greatly inflated exposure zone (drift exposure capped at 2600 feet based on the limits of the spray drift models)[11] relative to actual exposure will thus yield a much-exaggerated level of potential exposure. The result would lead to diverting resources to species that have a very low probability of being exposed and thus potentially affected. In the short term, CLA recommends that EPA acknowledge the conservatism in the proposed approach for estimating off-field exposure. In the longer term, CLA recommends that EPA develop a more realistic approach to estimating on and off-field exposure.

EPA should also consider updating its models for exposure through food sources to better approximate reality than the current use of the Kenaga nomograms allows. EPA should review CLA's prior comments on this issue in connection with the organophosphate BEs (CLA, 2016). The probabilistic approach described in CLA's prior comments and our recommended approach is to adjust the Kenaga nomograms (or empirical nomograms if available) for proximity based on the upper-bound estimates of off-site movement.

Once the Revised Method is finalized, CLA urges EPA take the additional steps described below in our comments to increase efficiency by reducing the number of "May Affect" determinations based on overly conservative exposure analyses.

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[10] The biased dataset used as a foundation for AgDrift has a distribution that should be reported in each assessment and considered in estimation of the potential for exposure to endangered species. This is especially true because it is conservatively assumed that off-site movement of pesticides from spray drift always occurs uniformly in every direction from a treated field, without interception from near field vegetation, under the worst possible conditions for application, with application methods known to promote off-site pesticide movement. The reality is that drift exposure to areas adjacent a treated field is likely to range from levels that are non-detectable – effectively zero – to the upper bound levels estimated using EPA default assumptions.

[11] EPA (Environmental Protection Agency). 2019. DRAFT EPA Proposed Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides.

3.3 CropLife America Supports Use of Probabilistic Methods in the Endangered Species Risk Assessment (ESRA) Process

- The probabilistic methods outlined in the Revised Method will improve transparency and credibility, focus data collection, and improve decision making.
- Models exist, or could be readily adapted, to address more species groups than presently contemplated in the Revised Method in the future.
- EPA's proposal to report a "yes/no" determination for impacts to individuals will hinder effective decision making and de-emphasizes more critical variables and data.
- EPA should provide a more explicit set of criteria for how the outputs of the probabilistic methods will be applied to the weight-of-evidence assessment to ensure consistent, transparent, and effective decision making.

3.3.1 Advantages of probabilistic methods

CropLife America strongly concurs with EPA's decision to make greater use of probabilistic analyses than was employed in the pilot BEs. There are numerous advantages to the use of probabilistic methods.

3.3.1.1 Probabilistic risk assessment improves transparency

Although the degree of over- or under-protection resulting from specific risk-based decisions (*e.g*., mitigations to protect listed species) is inherently uncertain, decisions that are not supported by an explicit, quantitative uncertainty analysis hide that uncertainty. As a result, groups of stakeholders may have a different perception regarding the direction of bias in the assessment. An open and explicit probabilistic risk assessment ("PRA"), including discussion of the sources of uncertainty not explicitly included in the PRA, will enhance transparency and improve the understanding of all parties involved.

3.3.1.2 Probabilistic risk assessment improves credibility

Even in the case of well-studied listed species and pesticides, there will always be numerous sources of uncertainty, including variability (which cannot be reduced but can be better understood) and lack of knowledge (which can be reduced with further empirical effort). Presentation of risk quotients with several significant digits exacerbate the failure to adequately describe uncertainty, because it implies a level of confidence that does not exist. As the NRC (1994) stated, "[q]uantitative uncertainty analysis is the only way to combat the 'false sense of security,' which is caused by a refusal to acknowledge … and quantify the uncertainty in risk predictions."

3.3.1.3 Probabilistic risk assessment identifies where additional data collection is necessary

All PRAs should include sensitivity analyses to identify the most important sources of uncertainty. If risk estimates are not certain enough to allow sound decision making, sensitivity analysis may be used to target data collection to improve the understanding of risk and, if necessary, allow EPA and other stakeholders to adopt mitigation measures that will protect listed species without adversely impacting farmers, manufacturers, and consumers.

3.3.1.4 Probabilistic risk assessment improves decision making

When risk is routinely overestimated, one cannot determine where to focus risk mitigation efforts because the high concern risk scenarios have not been separated from the no concern risk scenarios. There are many possible risk mitigation measures for pesticides (e.g., in-field buffers, droplet size restrictions, prohibitions on application in sensitive areas, restrictions on timing of application) and choosing the optimal mitigation measures, given the benefits of each pesticide, requires a detailed and unbiased understanding of risk.

The proposed Revised Method recognizes the above and the other benefits of probabilistic risk assessments. CropLife America is encouraged by EPA's decision to more fully implement the NRC's 2013 recommendation to include probabilistic analyses in future ESRAs for pesticides.

3.3.2 Recommendations to Ensure Realistic, Useful Probabilistic Risk Assessments

The Revised Method document provides some details on how EPA will conduct PRAs for aquatic and terrestrial listed species. For example, EPA indicates that a modified version of the Terrestrial Investigation Model ("TIM") will be used to assess risk to listed bird species. The major modifications include incorporating usage data to determine the proportion of a species range that could be treated, using proximity of different parts of the species range to treated areas to adjust dietary residues to which birds will be assumed to be exposed, and including variability in sensitivity between individuals to the pesticide. For aquatic exposure assessments, the document indicates that variability in application date and hydrologic soil group, two critical factors affecting pesticide concentrations in water bodies, will be incorporated in future PRAs. These modifications will lead to significant improvements in future PRAs for listed bird and aquatic species.

CropLife America also believes that more can be done to fully realize the value of probabilistic exposure assessments in pesticide ESRAs. We urge that the following additional issues concerning probabilistic risk assessments for terrestrial and aquatic species receive attention from EPA after the finalization of the Revised Method.

3.3.2.1 Terrestrial Species

The Revised Method section on probabilistic exposure analysis for terrestrial habitats addresses acute risks from flowable pesticides to listed bird species that forage primarily on surface and crop-dwelling invertebrates and plant parts (*i.e.*, seeds, fruit, foliage). That is the current scope of TIM. But TIM is not applicable to listed carnivorous, piscivorous or scavenger bird species, nor can it be used to estimate risk to bird species arising from use of granular, seed treatment or bait formulations. There is no mention in the Revised Method document of the probabilistic methods that will be used to estimate chronic risk to listed bird species (*e.g.*, Markov Chain nest model (MCnest)) for flowable pesticides. Nor is there any mention of the probabilistic models that would be used to estimate direct risks to listed terrestrial mammals, herptiles, plants, or invertebrate species, or indirect risks to any listed terrestrial species.

There are probabilistic models that could be adopted or adapted to fill some of these needs. For example, a probabilistic version of EPA's KABAM[12] could be used to estimate pesticide concentrations in aquatic prey. EPA's T-HERPs[13] includes a component that estimates residues in small mammals. The outputs from these models could be linked to TIM. This would enable risk to be estimated for listed bird species that primarily forage on aquatic invertebrates, fish and/or small mammals. Similarly, EPA's probabilistic MCnest was used previously to estimate chronic risk to listed bird species (Etterson *et al.*, 2017) and needs only be linked to the modified TIM to produce more realistic estimates of exposure. The modified TIM could be expanded to address acute risk to listed mammal and herptile species from flowable pesticides by adding in the required diet, body weight, and ingestion rate input data from the Services species status information and related equations.

For risks to birds from granular pesticides, the probabilistic GranPARAM model developed by Moore *et al.* (2010, 2014) could be expanded to include listed bird species that forage for grit on treated fields.

Finally, EPA should incorporate life history and ecological information and scrutinize range maps for listed birds. Often habitats clearly not used by the species, but contained in the range maps, are included in determining the potential for exposure.

3.3.2.2 Aquatic Species

As with terrestrial exposure modeling, there are additional steps that EPA could take after finalization of the Revised Method to produce more realistic and useful probabilistic aquatic exposure assessments. For example, Whitfield-Aslund *et al.* (2017a) used a probabilistic version of EPA's standard aquatic exposure model (Surface Water Concentration Calculator, version 1.106), as well as a specialized vegetative filter strip model (VFSMOD) to estimate concentrations of imidacloprid in a 1 ha pond that drains a 10 ha field for various agricultural use patterns. Rather than relying on standard scenarios representative of high runoff and erosion potential to define model input values, Latin Hypercube sampling of the probability distributions of key characteristics (*i.e.*, application date, proximity, soil profile and land surface slope, pond-integrated spray drift fraction and percent cropped area) was used to develop 1000 unique sets of the required model input parameters for each use scenario. The results indicated that use of probabilistic input distributions for the variables cited by EPA in its revised guidance (*i.e.*, application date, hydrological soil group) produced much more realistic exposure predictions than did the standard screening-level exposure assessment. However, several other probabilistic input variables (*e.g.*, percent cropped area, filter strip efficiency) were found to have larger effects on the predicted exposures, by approximately an order of magnitude each for median predictions (see Figure 1, below). Thus, EPA could further improve its probabilistic modeling tool for aquatic exposure assessment by incorporating distributions for a larger number of important input variables beyond the two cited in the final Revised Method.

[12] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/kabam-version-10-users-guide-and-technical (Last accessed August 15, 2019)

[13] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-herps-version-10-users-guide-risk-amphibians-and (Last accessed August 15, 2019)

An even more advanced modeling system was used by Clemow *et al.* (2018) to estimate the risks of malathion to the listed California red-legged frog, delta smelt and California tiger salamander. Five probabilistic exposure models were linked and used to estimate exposure in worst-case scenarios for each species in California: Pesticide Root Zone Model (PRZM), Vegetative Filter Strip Modeling System (VFSMOD), Exposure Analysis Modeling System (EXAMS), Soil and Water Assessment Tool (SWAT), and Variable Volume Water Model (VVWM). Rather than relying on a hypothetical standard farm pond, the modeling system was specific to the agricultural setting and habitats of each of the three listed species. The results indicated negligible risks to the 3 listed species for both direct and indirect effects. These two case studies show the breadth of factors that can affect aquatic exposure and demonstrate that more rigorous exposure simulation methods are readily available. Utilization of these methods could greatly increase the robustness of EPA analyses under the Revised Method, as well as allow greater understanding of the uncertainties inherent in the exposure analysis. CLA recommends that EPA consider the deployment of such methods in further iterations of the final Revised Method.

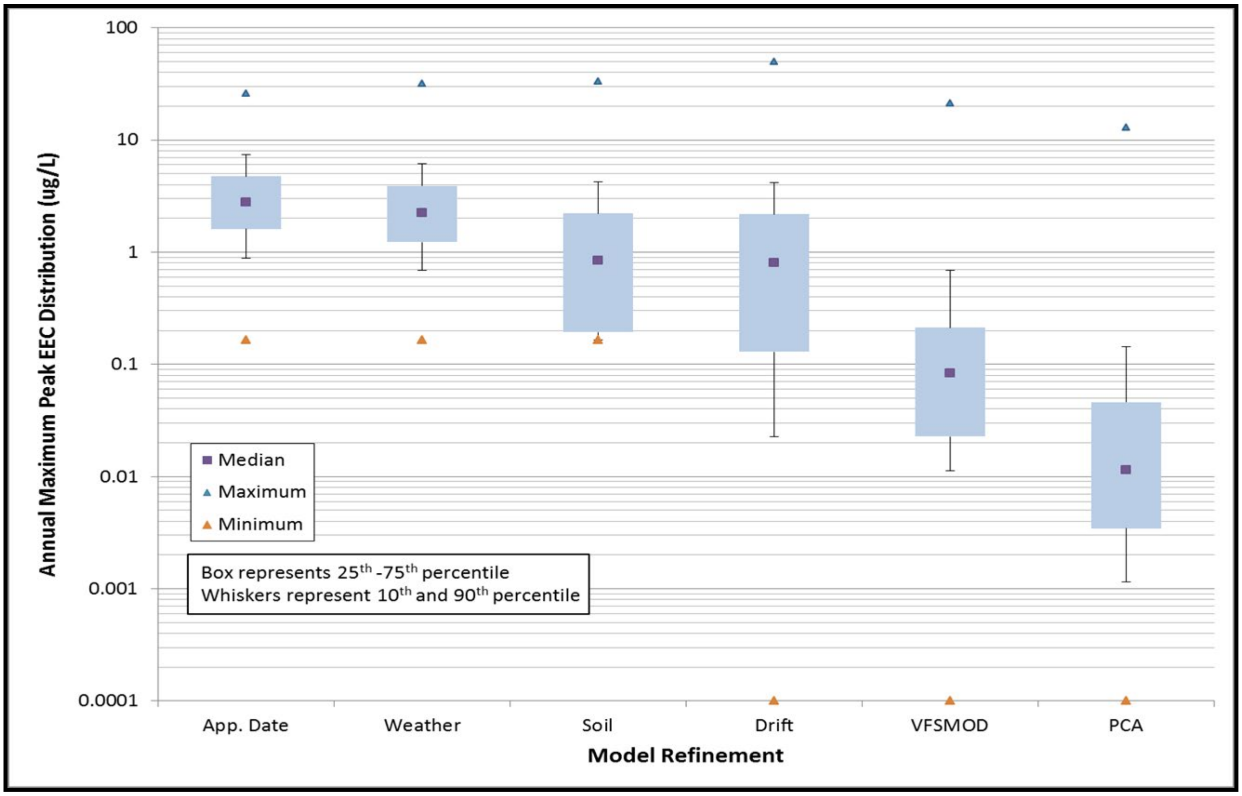

Figure 1. Predicted distributions of imidacloprid in a farm pond for Florida citrus use pattern (see Whitfield-Aslund et al., 2017(b) for method details). The figure illustrates how the predicted exposure distributions changed as successive model refinements were added to the analysis.

3.3.3 Interpretation of Probabilistic Outputs

The Revised Method indicates that probabilistic risk analyses will be used to determine the likelihood that one or more individuals are being adversely impacted as well as "the most likely number of impacted individuals" (page 36 of the Revised Method document, 2019). CropLife America strongly supports EPA providing additional information on probability, magnitude, and consequences of adverse effects across entire populations or sub-populations of listed species. This information will better inform the Biological Opinions (if necessary) and is required for population modelling. It can also be used to prioritize the need for mitigation actions (*e.g.*, identify which listed species are at greatest risk) and to determine how much risk reduction can be achieved with different mitigation options.

Although CLA generally supports the Revised Method's approach to making effects determinations, EPA needs to provide more information – either in the final version of the Revised Method or in supplemental or subsequent documents – to indicate exactly how probabilistic outputs will be used in weight of evidence determinations.[14] EPA should provide or reference a more explicit set of criteria to ensure that the outputs from a probabilistic risk assessment are used in a way that ensures consistent, transparent, and effective decision making. Criteria for categorizing risk as negligible, low, intermediate or high have been proposed in previous probabilistic risk assessments (*e.g.*, Moore *et al.*, 2010, 2014; Whitfield-Aslund *et al.*, 2017; Clemow *et al.*, 2018) and could be a starting point for EPA's development of decision criteria for listed species over time, after the Revised Method document is finalized.

3.3.4 Guiding Principles for Conducting Probabilistic Risk Assessments

In conducting their probabilistic assessments, EPA should follow the principles developed by Burmaster and Anderson (1994), the U.S. EPA (1997), and others. Fairbrother *et al.* (2016) adapted those principles for use in pesticide assessments for listed species. If adhered to, the principles identified in Fairbrother *et al.* (2016) will make EPA's future PRAs easier to understand and more transparent.

3.4 Weight-of-Evidence Framework

- CropLife America agrees that a robust weight-of-evidence approach should be implemented when preparing a BE.
- EPA should explain more clearly how it will weigh lines of evidence, but the development of this explanation should not delay implementation.
- Looking ahead, options exist for both qualitative and quantitative expression of the results of the weight-of-evidence assessment.

CLA applauds EPA for greater use of weight-of-evidence (WoE) principles in Step 2 and Step 3.[15] The list of lines of evidence EPA mentioned in the proposed revised method could be refined and expanded, but it is a good start at cataloging the many sources of information that should be considered in a NLAA/LAA or a jeopardy decision.

Unfortunately, however, the Revised Method says nothing about how the weight of evidence process will work in practice. CLA does not believe EPA's development of such an explanation

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[14] For example, would a 1% probability of affecting the most at-risk individual in a listed species population be used as support for, or to refute, a "Not Likely to Adversely Affect determination"? If the probability of affecting one or more individuals is non-negligible but other important lines of evidence (*e.g.*, field and mesocosm studies, population trends) indicate negligible risk, how will EPA make its effects determination?

[15] EPA also has identified many of the critical factors that could be included in the analysis, but also notes that "the list of factors considered in this WoE approach is not exhaustive." Revised Method at p. 23.

should delay adoption of the Revised Method but urges EPA to turn to doing so after the final Revised Method is published. At some point, a system must be implemented to objectively weigh each piece of evidence, evaluate the overall relevance and reliability of each line of evidence, and combine the weighted lines of evidence into a useful conclusion. Particularly as the Services make it clear that this approach (e.g., professional judgement) is appropriate for endangered species decisions. Therefore, the Services should acknowledge that EPA has expertise in the assessment of pesticides including such things as selection of endpoints, potential for exposure, and the use of a WoE approach. (https://www.fws.gov/policy/E1620fw1.html, last accessed August 15, 2019).

Ideally, the final information from all lines of evidence on exposure and response would be available in the form of probability distributions. Strategies for integrating exposure probabilities with sensitivity distributions have been proposed (and implemented) since before ECOFRAM (Ecological Committee on FIFRA Risk Assessment Methods) (ECOFRAM, 1999). The outcome can be expressed categorically (*e.g.* low, medium, and high risk) or quantitatively (*e.g.*, area under the risk curve). A categorical result may be helpful for No Effect/May Affect decisions. A quantitative result is useful for ranking the relative risk to species, or prioritizing species for further analysis, mitigation, or conservation. A quantitative result is especially useful if the results indicate a clear gradient among species from low risk to high risk, rather than simply concluding that "risk is excessive for 97% of listed species."[16]

4 Further Comments on Step 1 and Step 2 Methods

CLA has identified and provides the comments below on four additional aspects of the EPA revised guidance – "scoping," the approach to estimating aquatic exposures, dealing with uncertainty, and the use of surrogate species in ecological risk assessment. These topics are important to the scientific defensibility and transparency of the re-envisioned methods.

4.1 Scoping as an Important Tool Early in a Biological Evaluation

- Scoping (making early and efficient "no-effect" determinations) is critical to conserving limited Agency resources and properly focusing efforts.
- The Revised Method could include additional avenues for determining that an exposure pathway is incomplete.
- Lack of sensitivity to the chemical is another logical basis on which to include/exclude a species/group.

Part of the considerable challenge of conducting endangered species risk assessments for hundreds of pesticides and over 1600 listed species and their critical habitats is finding scientifically defensible approaches to assign "no effect" determinations to those species that will not be affected. This is in part due to the need to balance efforts and scientifically defensible decision making using available resources.

[16] EPA (US Environmental Protection Agency). 2016a. Biological Evaluation Chapters for Malathion ESA Assessment. https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment. (Last accessed August 15, 2019).

CLA refers to the process of concluding that no further attention needs to be directed to effects on a species or its critical habitat as "off-ramping." In the Revised Method, EPA describes two criteria early in the assessment that will distinguish between listed species that would clearly be assigned a no effect determination and those that would not: whether an exposure pathway is incomplete, or whether a species is most likely extinct or extirpated (steps 1a and 1b on p. 7).

The Revised Method indicates that an incomplete exposure pathway may be determined by examining the species characteristics such as where they are located (*e.g*., an island with no pesticide use). Exposure may also be unlikely if a pesticide is contained in a bait station or other device used indoors that would eliminate the potential for exposure to listed species (or the species on which they may depend).

However, there are other ways to conclude that the exposure pathway is incomplete, and EPA should recognize them in future iterations of its methodology. For example, use of a pesticide product may not be restricted by the federal label, but there may be state or county level restrictions. New York State may not allow the use of a pesticide in Nassau and Suffolk counties, because these two counties are found on Long Island, which is underlain by sensitive groundwater aquifers. California is similarly attentive to local conditions in granting registrations. Listed species found only in counties with county-level bans are not at risk of exposure.

Determinations to off-ramp species also can be based on label, chemical, or biological information. For example, if a pesticide is labelled for use on minor crops found well away from the coast, and the fate and behavior characteristics of the pesticide indicate it is unlikely to move off-field (*e.g.*, tightly binds to soil and is not water soluble) then, estuarine and marine species could be assigned a no effect determination early in the problem formulation. There are other possible exclusions for lack of sensitivity. Existing FIFRA analyses routinely determine that one or more species groups are not sensitive to a compound being evaluated. In these cases, this lack of sensitivity should be considered at the onset of the risk assessment for listed species of that group.

4.2 Aquatic Exposure

CLA urges EPA to move forward with elements of the Revised Methods that relate to aquatic exposure, because they include improvements to the aquatic exposure modeling approach that allow for an efficient tiered process, opportunities for reasonable off-ramping of species, and more appropriate use of previously vetted and accepted tools. However, the description of the Revised Method regarding aquatic exposure leaves some important details unstated, so our comments below are necessarily limited in scope.

4.2.1 Qualitative Evaluation of Downstream Dilution Off-site Transport Zone for Aquatic Species in Medium and High Flow Habitats

- CLA agrees with EPA that the tool used for this analysis previously should be discarded.
- After publication of the final Revised Method, EPA should clarify how the replacement approach will address hydrologic connectivity, and how the presence of possible effects from "upstream" usage will be determined.

- CLA refers EPA to its prior comments for available tools to analyze medium and larger high-flow habitats.

CLA supports the EPA proposal of discarding the previously implemented downstream dilution tool for future BEs. As EPA notes, the methodology and tool have not been fully validated and vetted. In addition, the tool was overly conservative and did not consider many important fate and transport processes, including dissipation and dispersion.

In place of the previous downstream dilution methodology, the Revised Method (page 12) proposes to "qualitatively evaluate the potential for downstream impacts to aquatic species in the medium and high-flowing bins located in areas that have been removed from consideration during Steps 1 and 2 based solely on usage data, as pesticide may be transported from upstream states where usage occurs to states where there is no usage." CLA has interpreted this statement to mean that EPA will look at state-level usage data for the watershed, and if there is usage in a state "upstream" of an area (assumed to be a watershed), then aquatic species found in medium and high flow habitats located in it could be not be assigned a "no effect" at Step 1 or a NLAA at Step 2. If our interpretation is correct, we request EPA to provide additional details about how the method will be applied after the final Revised Method has been published. Issues that should be addressed are:

1. How upstream/downstream relationships are to be determined. The hydrologic connectivity of watersheds can be complex, with flowing waterbodies both following state boundaries and flowing into and out of adjacent states. EPA should provide details concerning the methods and datasets it believes should be used to determine downstream locations from states where usage is occurring, and how to relate this back to species ranges.
2. How the upstream usage thresholds for "No Effect" / "May Affect" determinations at Step 1 or LAA/NLAA determinations at Step 2 will be documented. CLA is concerned that the proposed approach will be difficult to apply consistently and in an unbiased and scientifically defensible manner across assessments for different products if analyses do not clearly indicate underlying assumptions and applicable thresholds. EPA has already proposed adopting a 1% direct usage overlap threshold for co-occurrence analysis. CLA recommends a similar, 1% quantitative threshold for upstream usage when making "No Effect" / "May Affect" and NLAA/LAA determinations at Steps 1 and 2, respectively. At the very least, however, a report on the application of the methodology should specify the threshold employed.

In previous comments, CLA has provided extensive options for modeling methods appropriate for medium and larger flowing water bodies that can consider land use characteristics and habitat relevant assumptions. For Step 3 analysis, EPA is currently not using tools available for modelling potential exposure in larger waterbodies flowing away from treatment sites and analyzing the time-dependent nature of pesticide concentrations. As outlined in our previous comments (CLA, 2016; Breton *et al.*, 2016 a,b), these tools are available to the EPA for use . CLA urges that EPA apply these tools in future iterations of its methodology to more accurately represent aquatic exposure potential.

4.2.2 Simulation of Aquatic Habitat Exposure with Modified Receiving Water Bodies and Modeling Approaches

EPA's Revised Method includes some improvements for simulating exposure in aquatic habitats. These changes are consistent with previously submitted CLA comments and constitute a positive step forward. Notably, several approaches applied in the pilot BEs that resulted in highly variable watershed/receiving water body characteristics across geographic regions (most importantly, drainage area to water body normal capacity ratio [DA/NC]) have been discarded. In addition, the updated methodology is greatly simplified, particularly regarding receiving water bodies that will be simulated.

4.2.3 Step 1 Aquatic Exposure Modeling

CLA understands that EPA intends to retain the pilot BE aquatic "bin" concept but will be using a smaller number of water bodies in exposure modeling to represent those same aquatic bins. This should be explicitly stated in the final Revised Method. In addition, it would be helpful for the final Revised Method document to clarify what aquatic exposure tools will be used to estimate conservative concentrations for the Step 1 analysis. It currently is not clear if the intent is a single conservative exposure or, if regional, crop-specific variations on exposure potential will be used.

For example, from the presentation at the June 10th public meeting, it appears the analysis will include a drift-only analysis using the pilot BE aquatic habitats along with Pesticide Water Calculator (PWC) modeling for edge-of-field (EOF), standard pond, and index reservoir concentrations for use areas adjacent to waterbodies. But it is not clear from the Revised Method whether species-relevant crop/soil scenarios, assignments of relevant aquatic bins, and relevant labeled use assumptions based on species location will be utilized at this step and, if so, to what extent. If not included in this iteration of the final Revised Method, these matters should be addressed in future updates.

4.2.4 Step 2 Aquatic Exposure Modeling; Receiving Water Bodies and Scenarios

- The Revised Method approach is an improvement but continues to include conservative assumptions that should be clearly communicated.
- CLA proposes specific revisions for modelling within individual Bins that should be incorporated into the next iteration of the Revised Method.

The revised aquatic exposure modeling approach proposed by EPA relies largely upon existing regulatory exposure models (PRZM and VVWM) and scenarios (associated with PWC) in Step 2. Again, CLA agrees that this is an improvement over the interim methodology but believes that the method will continue to be overly conservative. EPA should acknowledge the inherent conservatism in future versions of the final Revised Method. As discussed in previous CLA comments[9], the surrogate waterbodies are useful for screening but continue to employ conservative assumptions such as: worst case drift exposure; high runoff soils; high slopes and erosion; 100% Percent Cropped Area (PCA); 100% PCT (Percent Crop Treated); and concurrent pesticide application timing throughout an entire watershed.[17]

Furthermore, CLA has several concerns with the explanations in the Revised Method, particularly regarding how flowing habitats and small static water habitats are modelled. Additional details should be provided prior to publication of the Revised Method, or soon after it is published.

4.2.4.1 Exposure in medium and large static water bodies (Bins 6 and 7)

EPA has proposed that the standard Farm Pond and associated landscape scenarios be used to represent exposure in these aquatic habitats. The Farm Pond scenarios have been used successfully for several decades to represent conservative aquatic exposure concentrations for ecological risk assessments required for pesticide registrations under FIFRA. CropLife America agrees that this approach is generally appropriate.

4.2.4.2 Exposure in medium and high flow water bodies (Bins 3 and 4)

EPA has proposed that the Index Reservoir and associated landscape scenarios be used to represent exposure in these flowing water aquatic habitats.[11] On a short-term basis this would be an improvement over current methodologies but is ultimately not appropriate for medium and high flow habitats. A reservoir hydrological system is very different from medium to high flow rivers and streams. For products with moderately broad use patterns, an Index Reservoir scenario would result in a PCA of 100%, and for many chemicals, the exposure concentrations in the Index Reservoir exceed concentrations in a static Farm Pond. This is due to a combination of the Index Reservoir's higher DA/NC, 100% PCA, and sluggish water flow-through. An aquatic exposure methodology that results in EECs in medium/large flowing systems exceeding EECs in high vulnerability medium/large static water bodies is inconsistent with scientific consensus.

CLA thus recommends that, after the final Revised Method is published, EPA reconsider its approach for modeling Bin 3 and Bin 4 exposure. This can be kept very simple for Step 2 yet made much more physically realistic. Our suggestions include:

1. Maintain well-tested characteristics of the Farm Pond scenario, including a DA / NC ratio of 5.
2. Allow flow through to occur on a 1-day timestep (flow-averaging period), which follows the real-word hydrologic dynamics stream/river systems.
3. Include baseflow at the design flow rate for the habitat bin, another real-world process that differentiates exposure in flowing water bodies compared to static water bodies.

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[17] As a species moves to more refined Step 3 analysis (if not off-ramped in Step 1 or 2), species-specific habitat characteristics should be evaluated in comparison to the assumption of this framework with modifications to represent the variable and specific hydrology and conditions related to potential use sites. Furthermore, more appropriate watershed scale models such as SWAT (*see* previous CLA comments (CLA, 2016)] will be required to more accurately reflect exposures in flowing water habitat.

4. Include the original bin depth and width characteristics so that drift exposure can be accurately simulated for the intended habitat.

4.2.4.3 Exposure in small static and low flow water bodies (Bins 5 and 2)

EPA has proposed that exposure in these water bodies be represented by EOF concentrations from PRZM. This approach would not incorporate the VVWM receiving water body. While PRZM EOF concentrations have been used by EPA historically to represent EECs for terrestrial species, and may be appropriate in the terrestrial context, CLA does not believe this is an appropriate approach for aquatic species in Bins 5 and 2. CLA is concerned that the proposed approach: (1) results in unrealistically high concentration predictions associated with very low runoff events; (2) is unable to determine chronic EECs based on multi-day averages in the absence of a receiving water body; and (3) is unable to calculate exposure for benthic organisms when no pore water of sediment calculations can be determined.

Thus, CLA recommends that in the next iteration of the methodology EPA reconsider how exposure is calculated for the species in bin 2 and bin 5 aquatic habitats. Our specific suggestions are:

1. Bin 2 (low flowing): Adopt an approach like CLA's recommendations for Bin 3 and Bin 4 species in Section 4.2.4.2, above.
2. Bin 5 (small static): A receiving water body needs to be simulated for calculating chronic EECs and benthic concentrations. A small water body can be simulated to approximate the inflow of EOF runoff concentrations by establishing a relatively large drainage area providing inflows, while allowing outflows from the receiving water at a daily timestep.

Finally, EPA's Revised Method does not discuss how water quality monitoring data will be evaluated. For registered pesticides and aquatic systems with extensive monitoring datasets (*e.g.* USGS NAWQA[18]; Heidelberg datasets[19]), measured concentrations in the environment can be used to both validate exposure model predictions and, in some situations, used in place of modeled concentrations. This issue should be addressed in future iterations.

4.2.5 Aquatic Exposure Modeling Conducted at Step 2, Monte Carlo Analysis

The addition of a Monte Carlo analysis to combine variability in effects and exposure is a welcome addition to Step 2. The details and implementation are not fully documented in the Revised Method, but as summarized and presented by EPA staff on June 10th, having a method to account for variable exposures in the aquatic environment based on variable conditions that occur in a species range/habitat will be useful in the final Revised Method. Moreover, CLA agrees that application timing and hydrologic soil group are key factors and important to include in a Monte Carlo analysis, and would suggest considering additional factors based on sensitivity analysis, such as slope, soil organic carbon, and environmental fate properties. In addition, the

[18] https://www.usgs.gov/mission-areas/water-resources/science/national-water-quality-assessment-nawqa?qt-science_center_objects=0#qt-science_center_objects (Last accessed August 15, 2019)

[19] https://www.heidelberg.edu/academics/research-and-centers/national-center-for-water-quality-research (Last accessed August 15, 2019)

assignment of appropriate scenario-specific weather stations will capture habitat-relevant weather conditions near listed species.

CLA is concerned about the use of "scaling factors" to reflect an adjustment to a baseline EEC relative to simulations where two inputs have been modified, the application date and the hydrologic soil group. EPA has suggested that this "scaling factor" strategy will be simpler and more efficient than a traditional Monte Carlo analysis where comprehensive permutations of model inputs are sampled for each exposure scenario; however, given modern computer resources and technology, we are unclear whether any efficiencies gained with this simplification are meaningful. We suggest that EPA should, at a minimum, better explain its reasoning in the final Revised Method and provide examples that demonstrate that the simplified "scaling factor" approach results in exposure distributions that are comparable to those from a full Monte Carlo analysis. Preferably, EPA should run a complete ensemble of exposure scenarios where the most sensitive inputs are varied across a defined range. These multiple exposure scenario simulation results can be combined to generate a probability distribution. The distribution can then be used to predict the probability of exceedance of an appropriate effect metric or combined with an effects distribution (e.g. concentration-response, species sensitivity distribution) to generate risk curves. If EPA does not make this revision in the Revised Methodology in the short term, it should be considered as a goal for the immediate future.

4.3 Uncertainty

- General audiences do not appreciate the distinction between risk and uncertainty, which is understandable as uncertainty is often incorrectly characterized as risk.
- EPA should take steps to properly delineate the two, both in its substantive analysis and in the explanations that it provides for general audiences in BEs and elsewhere.
- EPA should explicitly report the sources, direction, and magnitude of uncertainty.

Failure to adequately communicate the directional implications of risk assessment assumptions can result in the misperception that the Agency is not adequately addressing the needs of endangered species. Without systematic description and characterization of assumptions made in risk assessment, the conservatism intended to eliminate potential Type II errors (false negative) becomes normative at the expense of highly increased Type I error (false positive). As a result, uncertainty is communicated as risk; the public is confused; government and industry resources are wasted; and the use of needed crop protection tools is drawn into question.

Even with the proposed revisions, it is clear the Revised Method will produce very conservative effects determinations. However, the sources of this conservatism are not adequately described or characterized. This information should be more clearly presented, so that the public is better informed by reported findings. CLA urges EPA to include language recognizing this conservatism in the final Revised Method (and in future BEs). EPA should also compile the supporting evidence available from the long history of EPA documentation that contains the underlying uncertainties, including FIFRA Scientific Advisory Panel reports,[20] and explain the directional implications of each source of uncertainty.

Consistent with EPA's Information Quality Guidelines,[21] ultimately EPA should identify and report the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; each appropriate upper-bound or lower-bound estimate of risk; and each significant source of uncertainty identified in the process of the assessment of risk.

Table 1 contains a partial list of assumptions excerpted from a recent Agency risk assessment (EPA, 2015). The assumptions were identified in the text of the assessment, but there was no indication of the directional implication of individual assumptions or the probability of their occurrence. Table 1 could serve as a model for identifying and communicating assumptions and directional implications either in the body of a risk assessment or in a standard-form Appendix.

Table 1. Examples of Step 1 assumptions and directional implications (EPA, 2015)

Assumption	***Directional Implications***
100% efficiency of applications	Assumption that 100% of applications reach soil and are subject to runoff and partially drifts away from field, inflates the assumed level of off-site exposure.
Most sensitive species endpoint used	Likely to over-estimate the potential for effect because there is no evidence that listed species are generally more sensitive than tested species.
Run-off and drift are uniform dispersing from the target area	Assumption over-estimates the actual level and significance of potential exposure to chemical since dispersion is understood to occur in a gradient from treated area and will decline at greater distances.
Adsorption desorption and degradation kinetics	The assumed soil or water DT_{50} and soil absorption coefficient used in modeling off-site movement of chemical is a conservative value obtained from laboratory studies. The potential for leaching, or off-site movement of chemical may be over-estimated. The range in measured values was x, the value used in modeling was y, if the least conservative measured values were used the estimate would be z. There is uncertainty because not all soils are tested.

[20] The National Academies of Sciences (NAS) has recommended in multiple reports that "risk assessments should provide a quantitative, or at least qualitative, description of uncertainty and variability consistent with available data" (NRC, 2013). The NAS has further suggested that "EPA should develop guidelines that define key terms of reference used in the presentation of uncertainty and variability, such as central tendency, average, expected, upper bound, and plausible upper bound."

[21] https://www.epa.gov/quality/epa-information-quality-guidelines (Last accessed August 15, 2019)

4.4 Use of Surrogates

- The Agency should reconsider the narrow view of surrogacy taken in the Revised Method document for selecting appropriate effects metrics once the revised method is published.

In the Revised Methodology, the Agency states its intention to use the most sensitive species within each broad taxonomic group of each listed species for deriving effects metrics. Although this approach may be justified in the case of a screening-level FIFRA risk assessment intended to protect all species including unknown species, we believe that more specific effects data would be preferable for refined risk assessment of individual listed species.

There is a significant opportunity to decrease the uncertainty of risk assessments when toxicological data are available for other species that are both reliable and relevant to the species, or species group, being evaluated. It is not uncommon for the EPA to consider toxicity information in FIFRA risk assessments from species other than those typically required by guidelines (https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances, last accessed August 15, 2019). For ecological risk assessments of pesticides under ESA, the opportunity to apply additional, best available, toxicity data on a much wider range of representative species exists for some chemicals with robust databases.

5 Conclusion

CLA appreciates the work done by EPA to publish the Revised Method and supports the proposed draft published by the Agency. As reflected in our comments, we would request that EPA acknowledge the conservatism in the Revised Method, make uncertainties clear throughout the documentation, and consider the following improvements after the agency publishes the final Revised Method:

- A detailed process on coordination and collaboration with the Services and USDA pursuant to the 2018 Farm Bill.

- A mechanism to include conservation and mitigation measures during the BE process to offset anticipated adverse effects.

- A realistic approach be used to determining acreage treated within a species range, when possible.

- Provide guidance permitting registrants to use an approach for determining annual usage and a percent of potential pesticide usage by county and crop group that is functionally equivalent to PCT at maximum label rates.

- Provide guidance on modeling of usage data like case study submitted by CLA.

- Provide explicit set of criteria for how the outputs of the probabilistic methods will be applied to the weight-of-evidence assessment to ensure consistent, transparent, and effective decision making.

- The Agency should expand the potential for Scoping (making early and efficient "no-effect" determinations), to facilitate cost savings and improve efficiency in resource use.

- EPA applies appropriate modeling tools in future iterations of its methodology to more accurately represent aquatic exposure potential.

- Discuss how water quality monitoring data will be evaluated.

We once again thank the Agency for the developing he Revised Method and for the opportunity to submit comments.

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7 Appendix A

Estimated Annual Agricultural Pesticide Use

(https://water.usgs.gov/nawqa/pnsp/usage/maps/index.php)

Estimates of Pesticide Use EPest-low and EPest-high methods

For all States except California, two different methods, EPest-low and EPest- high, are used to estimate a range of pesticide use. Both EPest-low and EPest-high methods incorporate proprietary surveyed rates for Crop Reporting Districts (CRDs), but EPest-low and EPest-high estimates differ in how they treat situations when a CRD was surveyed and pesticide use was not reported for a particular crop present in the CRD. In these situations, EPest-low assumes zero use in the CRD for that pesticide-by- crop combination. EPest--high, however, treats the unreported use for that pesticide-by- crop combination in the CRD as missing data. In this case, pesticide -by- crop use rates from neighboring CRDs or CRDs within the same region are used to estimate the pesticide-by- crop EPest-high rate for the CRD.

State-based restrictions on pesticide use were not incorporated into EPest- high or EPest-low estimates. However, EPest-low estimates are more likely to reflect these restrictions than EPest-high estimates. Users of the maps and data should consult the methods presented in Thelin and Stone (2013) and Baker and Stone (2015) to understand the details of how both estimates were determined. Maps are provided for both EPest-low and EPest-high estimates.

Use estimates for California are obtained from annual California Department of Pesticide Regulation pesticide use reports. Because these reports provide county-level use estimates, they are incorporated into the data without further processing and low and high rates are the same for counties in California. California county data are appended after the estimation process is completed for the rest of the Nation.

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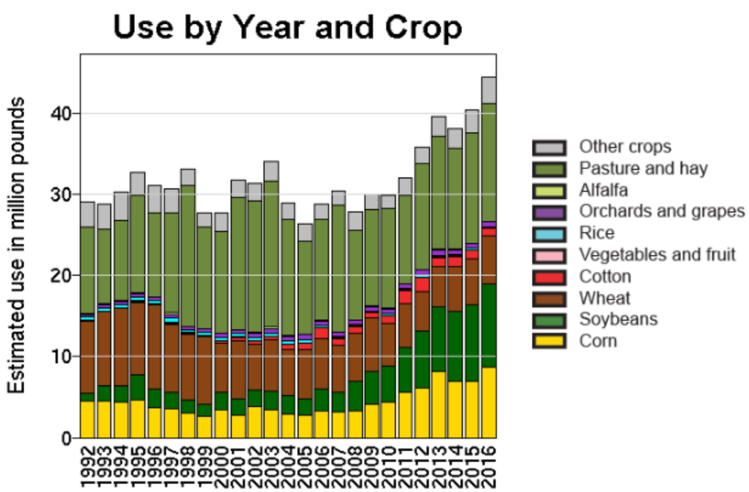
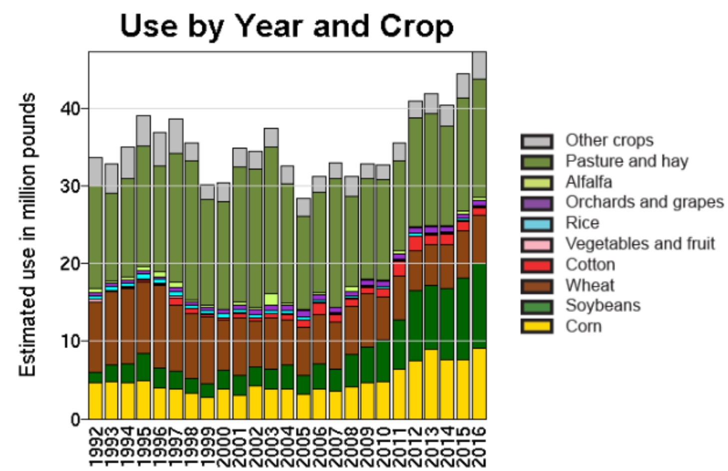
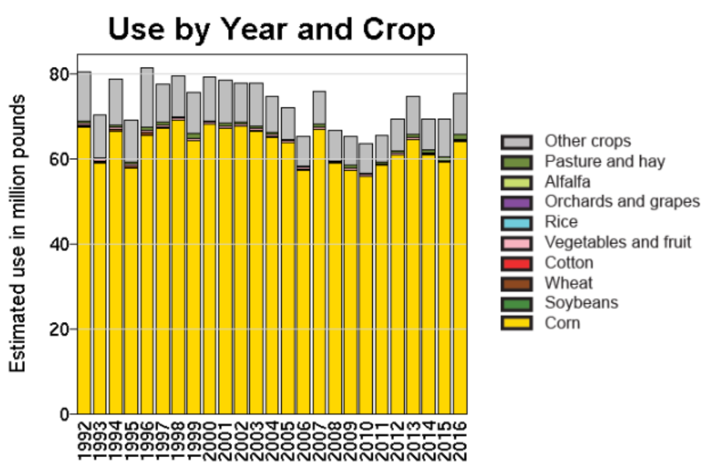
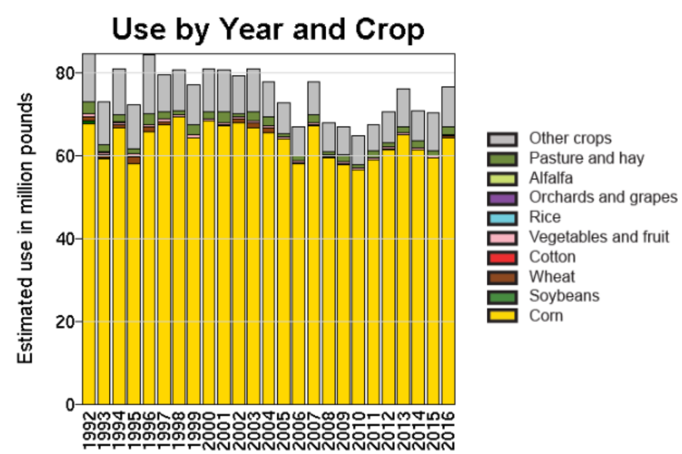
2,4-D		
Atrazine		

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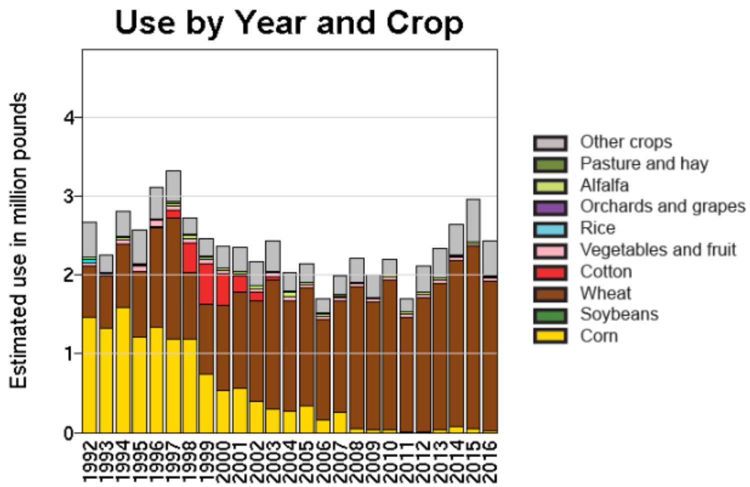

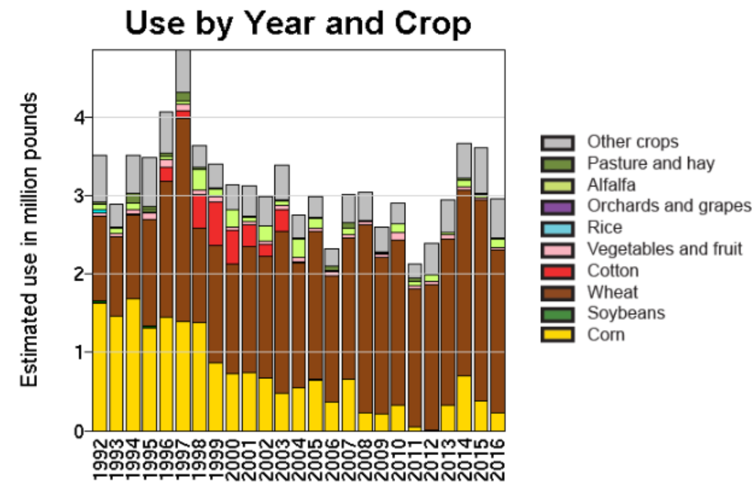

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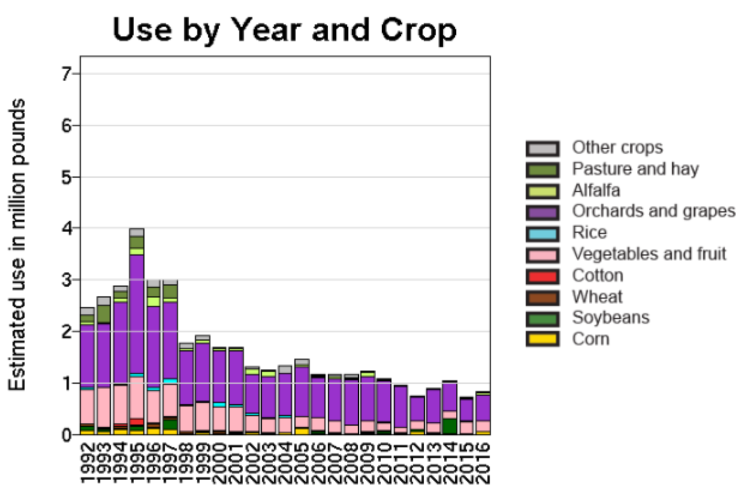

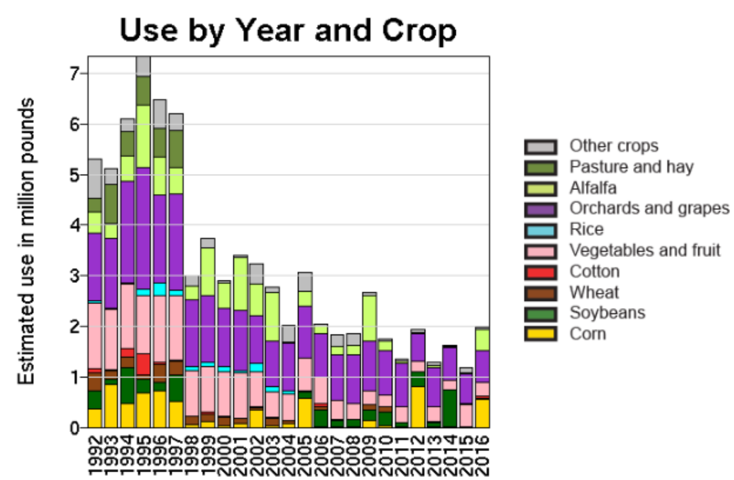

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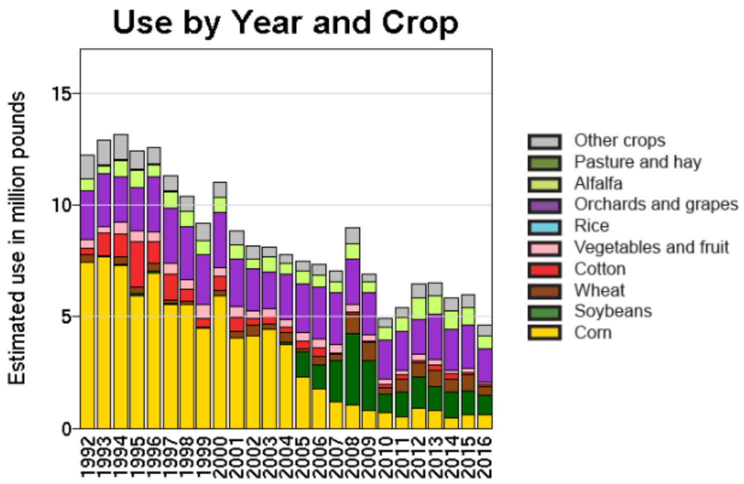
<td>
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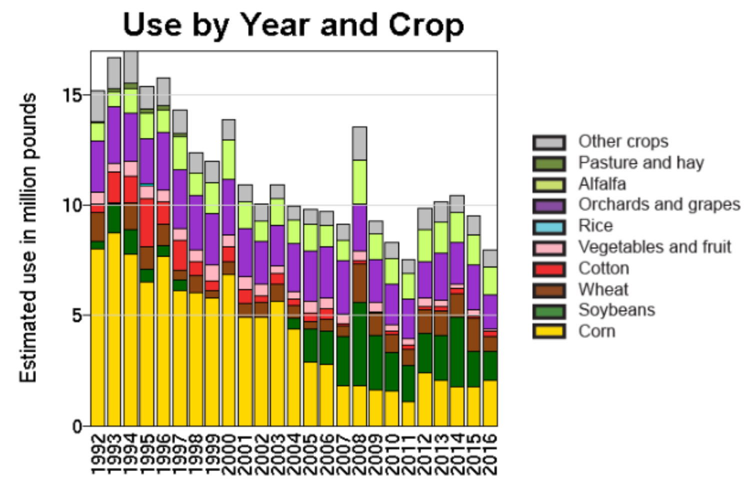
<td>
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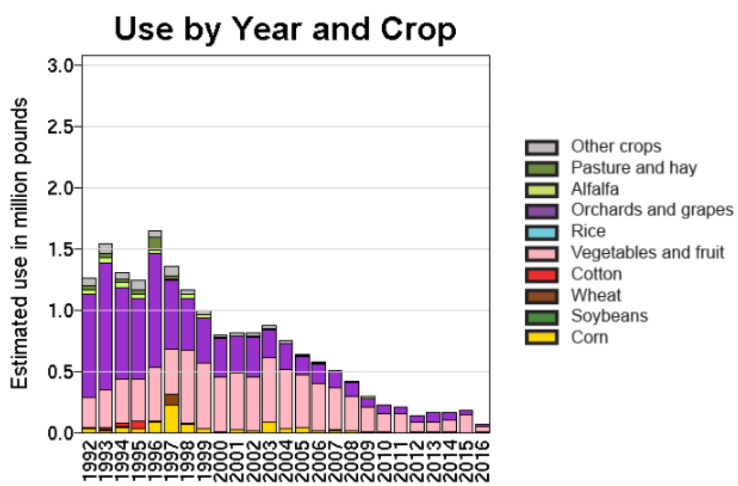
<td>
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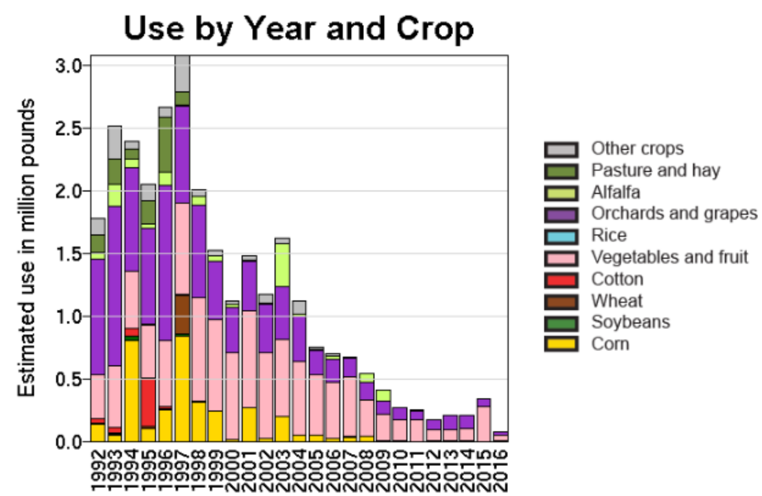
<td>
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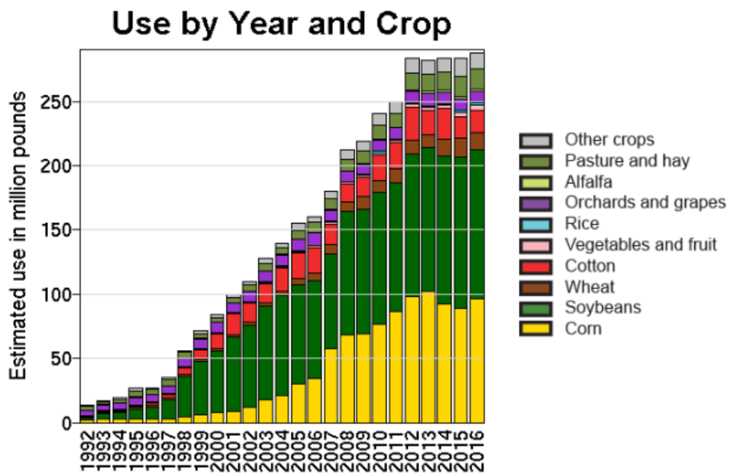

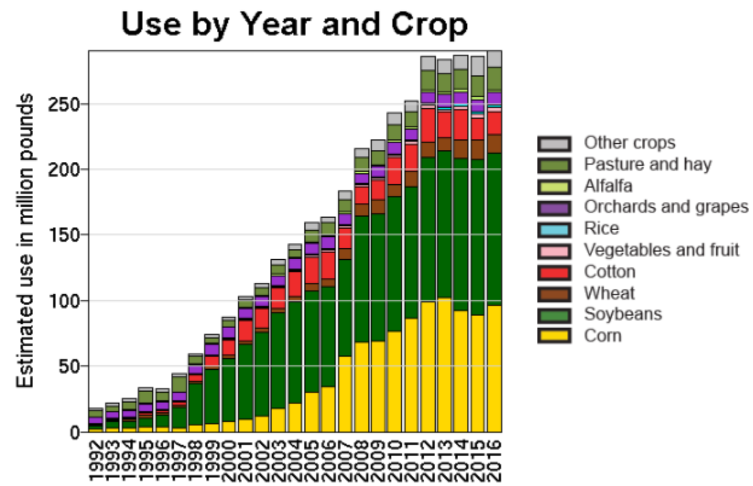

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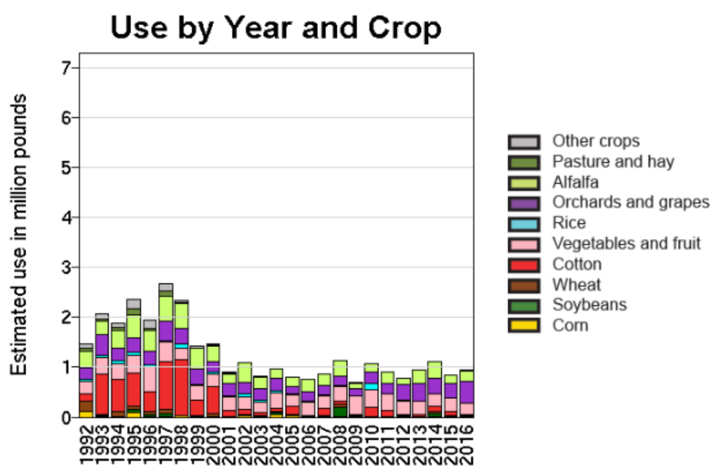

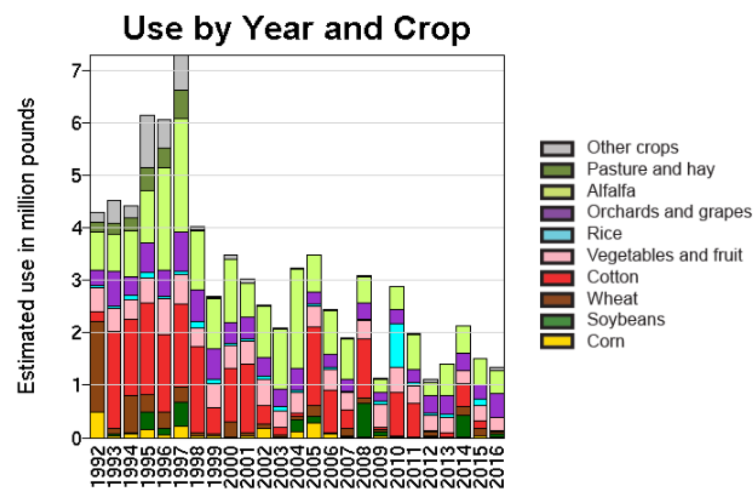

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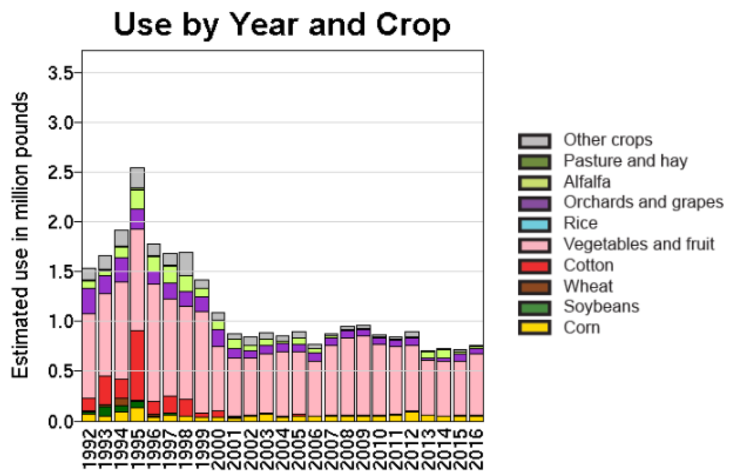
<td>
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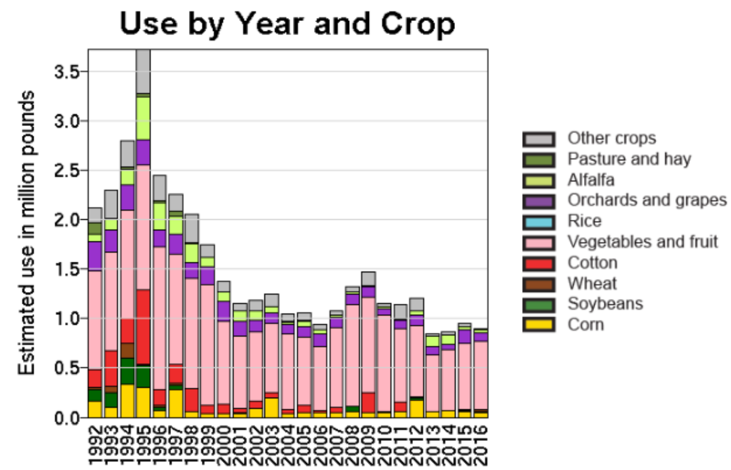
<td>
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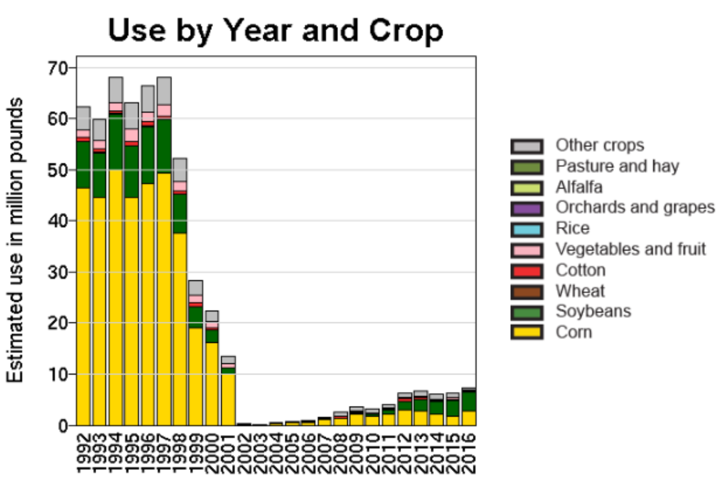
<td>
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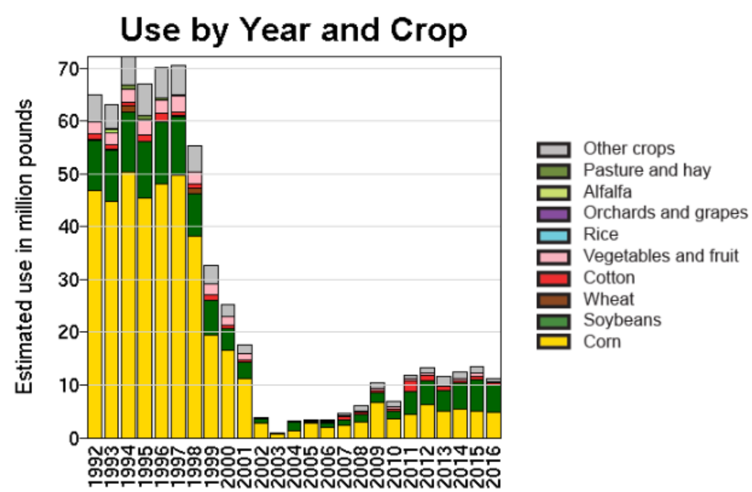
<td>
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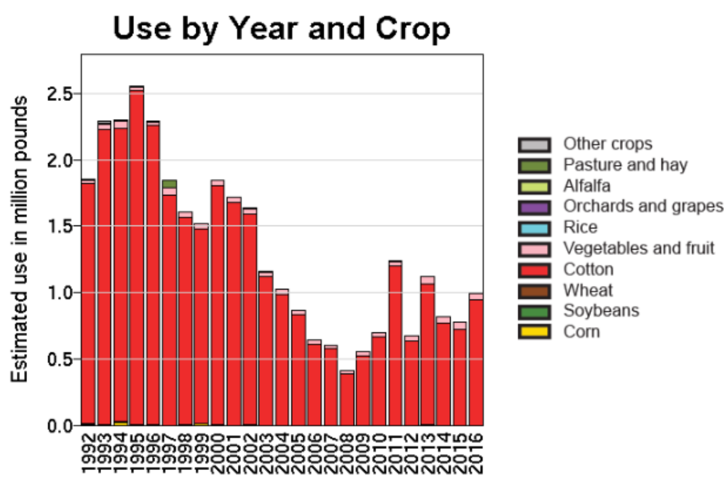
<td>
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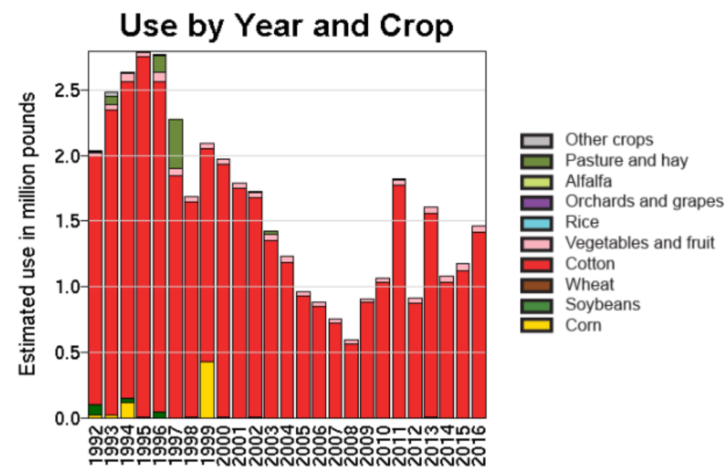
<td>
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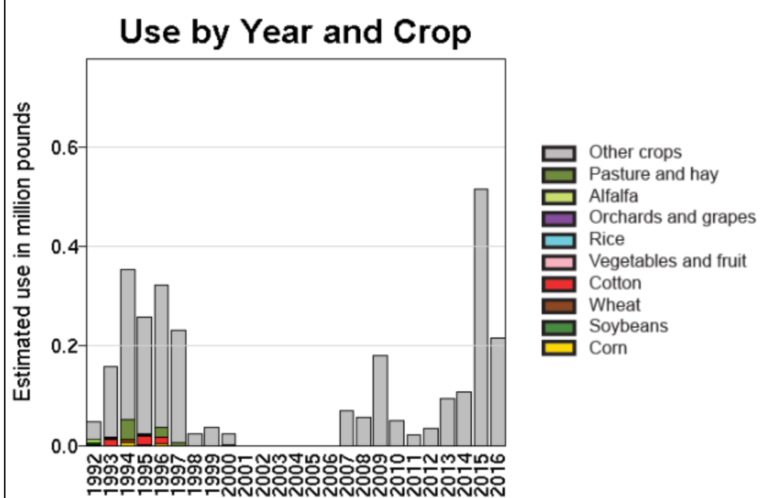
<td>
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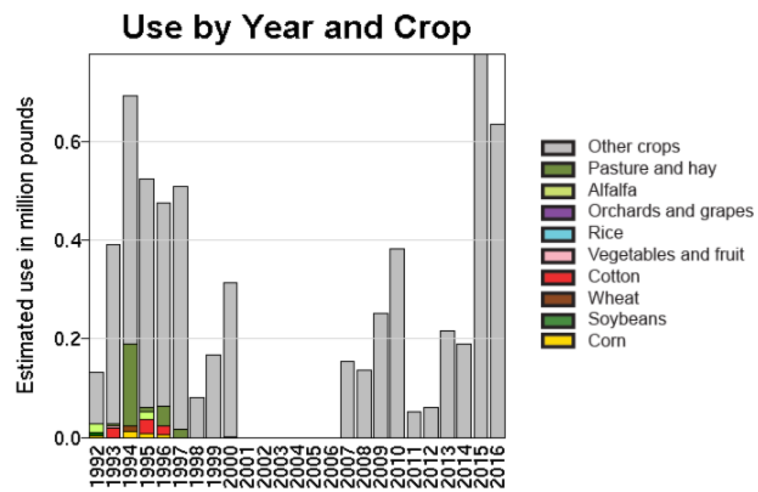
<td>
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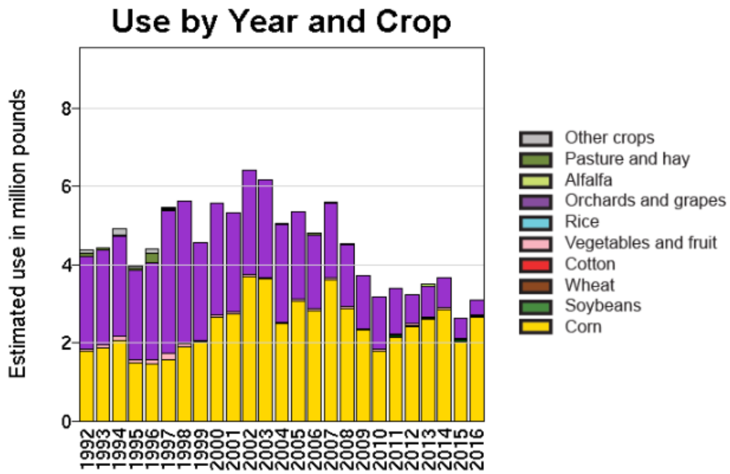

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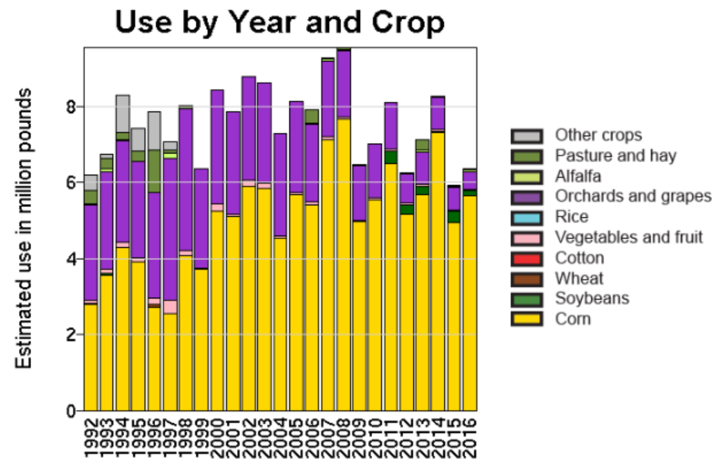

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8 Appendix B

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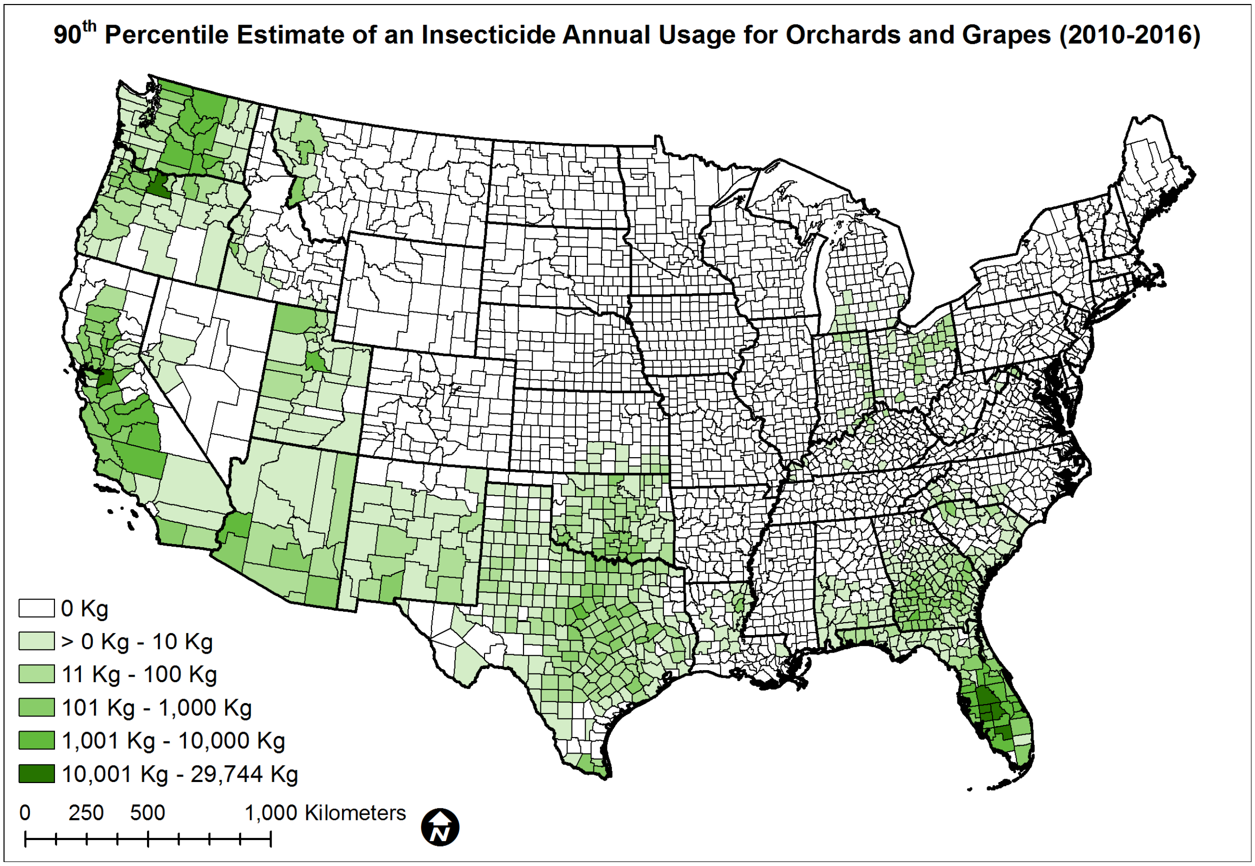
Development and Application of a Methodology for Quantifying National Pesticide Usage at the County Scale

STONE ENVIRONMENTAL



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19-033

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Acknowledgements

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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 0.7974 for county-level estimates and 0.8417 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:

$$\begin{aligned} &Crop\ Group\ Potential\ Usage - Survey\ Adjusted_{cg,i,j} \\ &\qquad = Crop\ Group\ Potential\ Usage - CDL_{cg,i,j} * \text{BiasFactor}_{cg,s} \end{aligned}$$

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 Table 1, 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.

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

County	TotalUse	Crop1Pot.Use	Crop2Pot.Use	Crop3Pot.Use	TotalPot.Use
1	100	0	1000	0	1000
2	500	1000	0	1000	2000
3	1000	2000	1000	1000	4000
4	400	0	1000	1000	2000
State		**Crop1Act.Use**	**Crop3Act.Use**	**Crop3Act.Use**	**Total Use**
1		800	800	400	2000

Method 2 Estimate				
County	**Crop1Use**	**Crop2Use**	**Crop3Use**	**Total Use**
1	0	100	0	100
2	250	0	250	500
3	500	250	250	1000
4	0	200	200	400
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 0.0308 and linear regression slope of 0.5628. The estimates based on Method 2 were considerably improved, with an R^2 statistic of 0.44662 and linear regression slope of 1.1948. The usage estimates were further improved following Method 3, with an R^2 statistic of 0.7974 and linear regression slope of 1.1083. Overall, Method 3 resulted in a very strong agreement with the observed county-level crop group annual malathion usage. The linear regression slope of 1.1083 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 0.7974 to 0.8417 and the linear regression slope decreased from 1.1083 to 1.0468. 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.

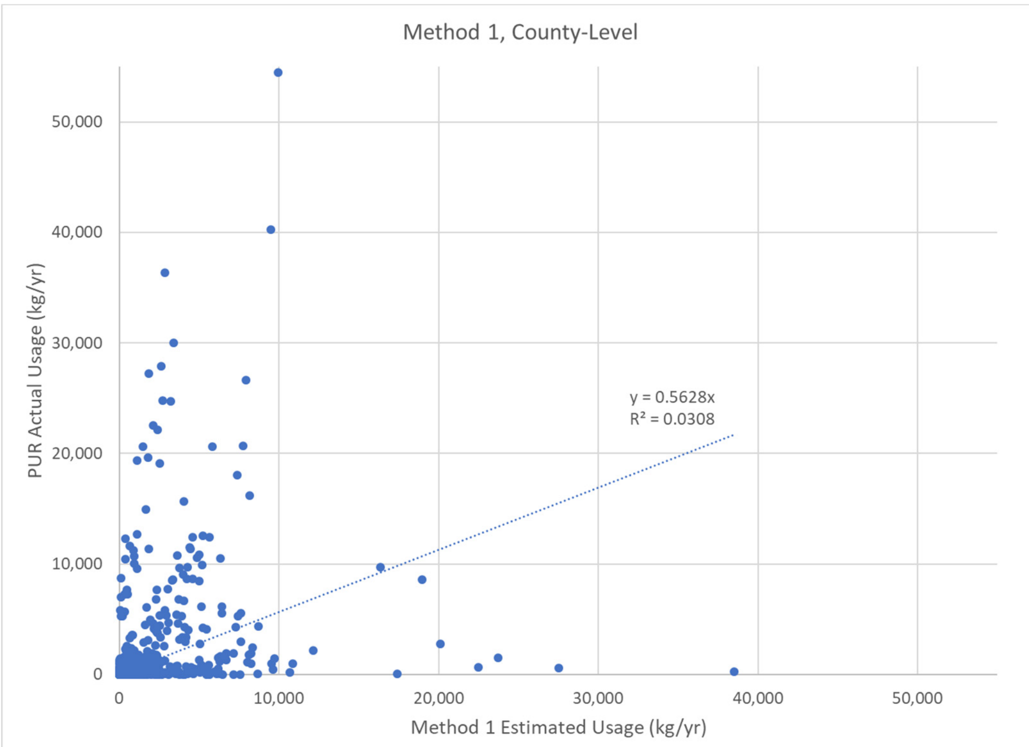

Figure 1. Linear Regression of Method 1 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

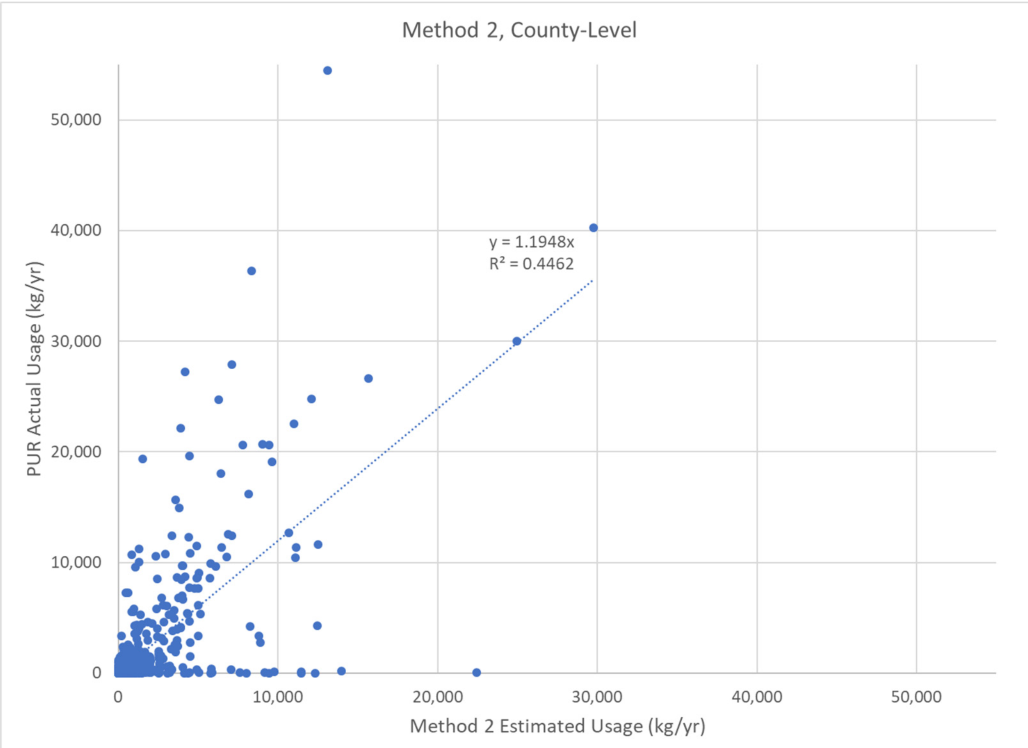

Figure 2. Linear Regression of Method 2 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

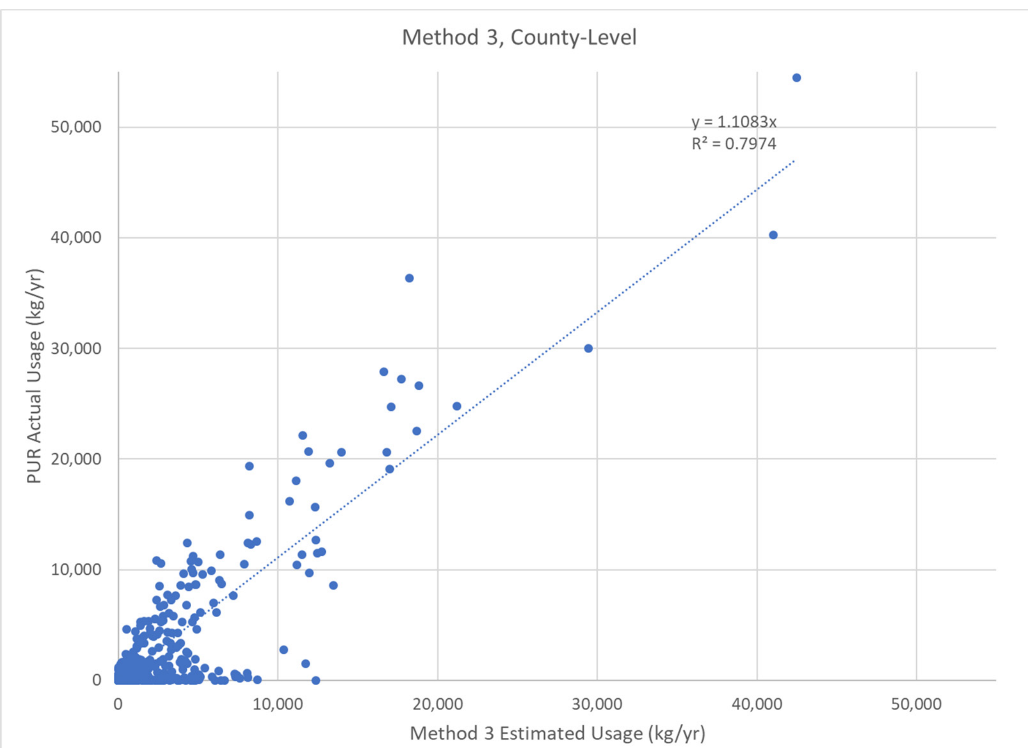

Figure 3. Linear Regression of Method 3 County-Level Crop Group Annual Malathion Usage Estimates and PUR Observed County-Level Crop Group Malathion Usage.

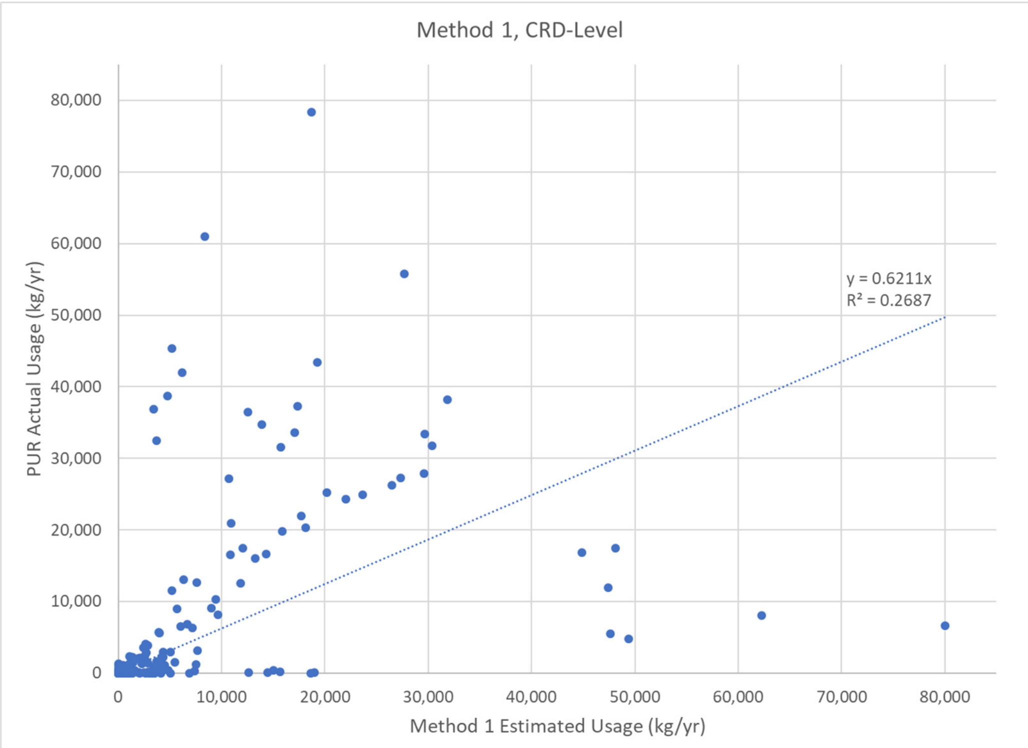

Figure 4. Linear Regression of Method 1 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

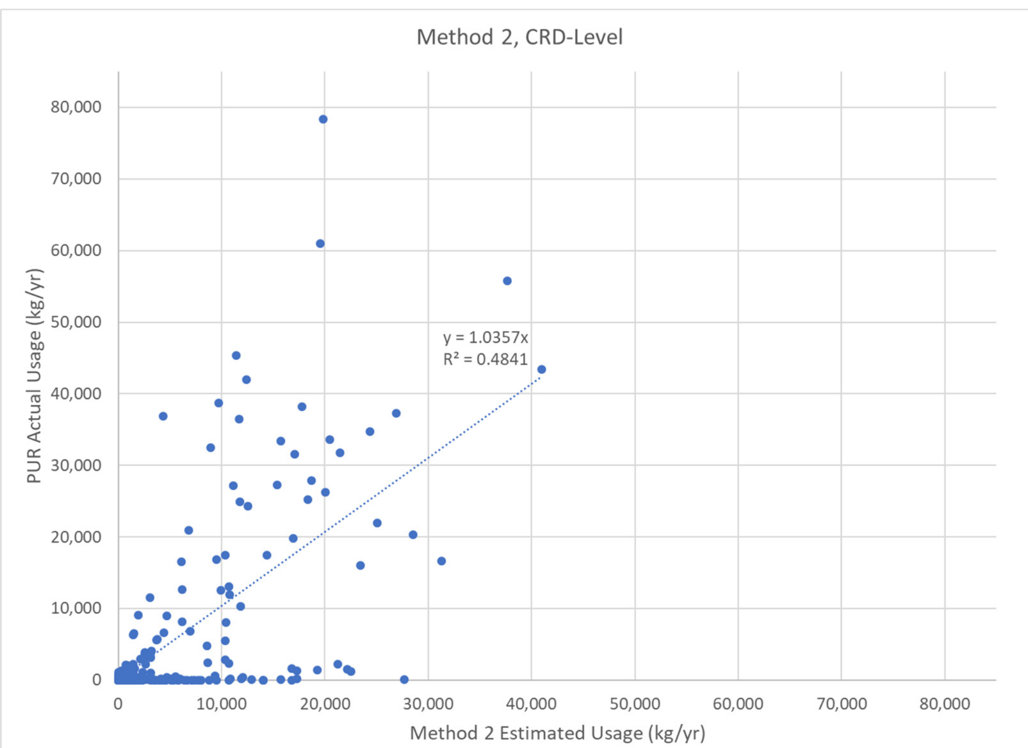

Figure 5. Linear Regression of Method 2 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

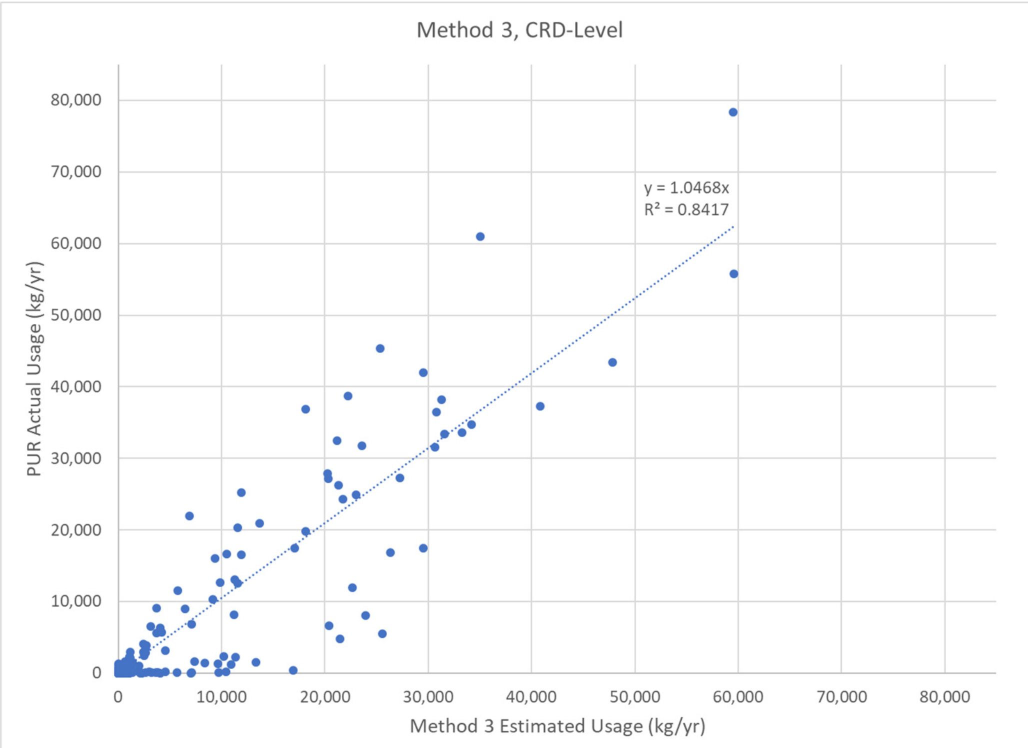

Figure 6. Linear Regression of Method 3 CRD-Level Crop Group Annual Malathion Usage Estimates and PUR Observed CRD-Level Crop Group Malathion Usage.

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.

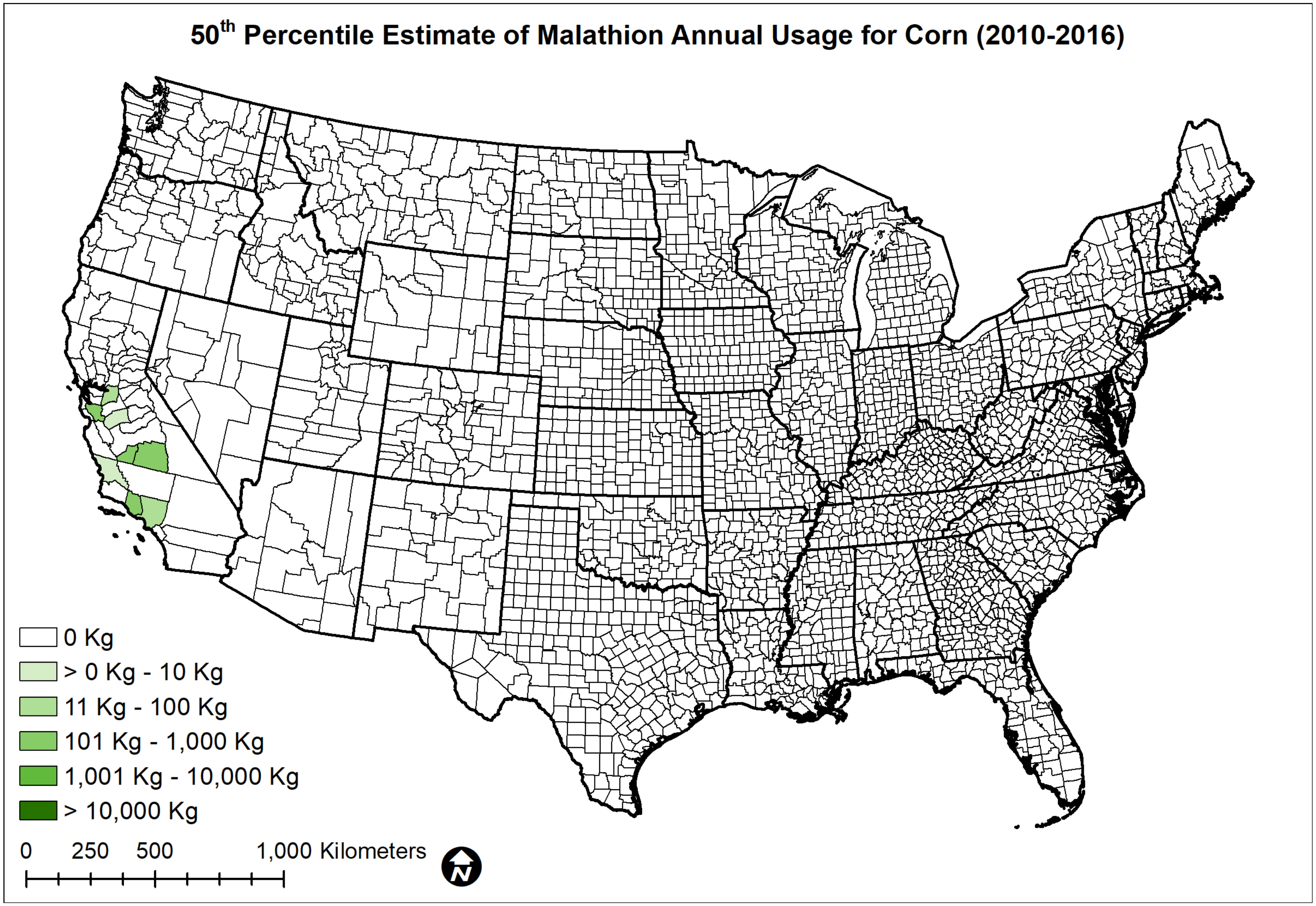

Figure 7. 50th Percentile Estimate of Malathion Annual Usage for Corn (2010-2016).

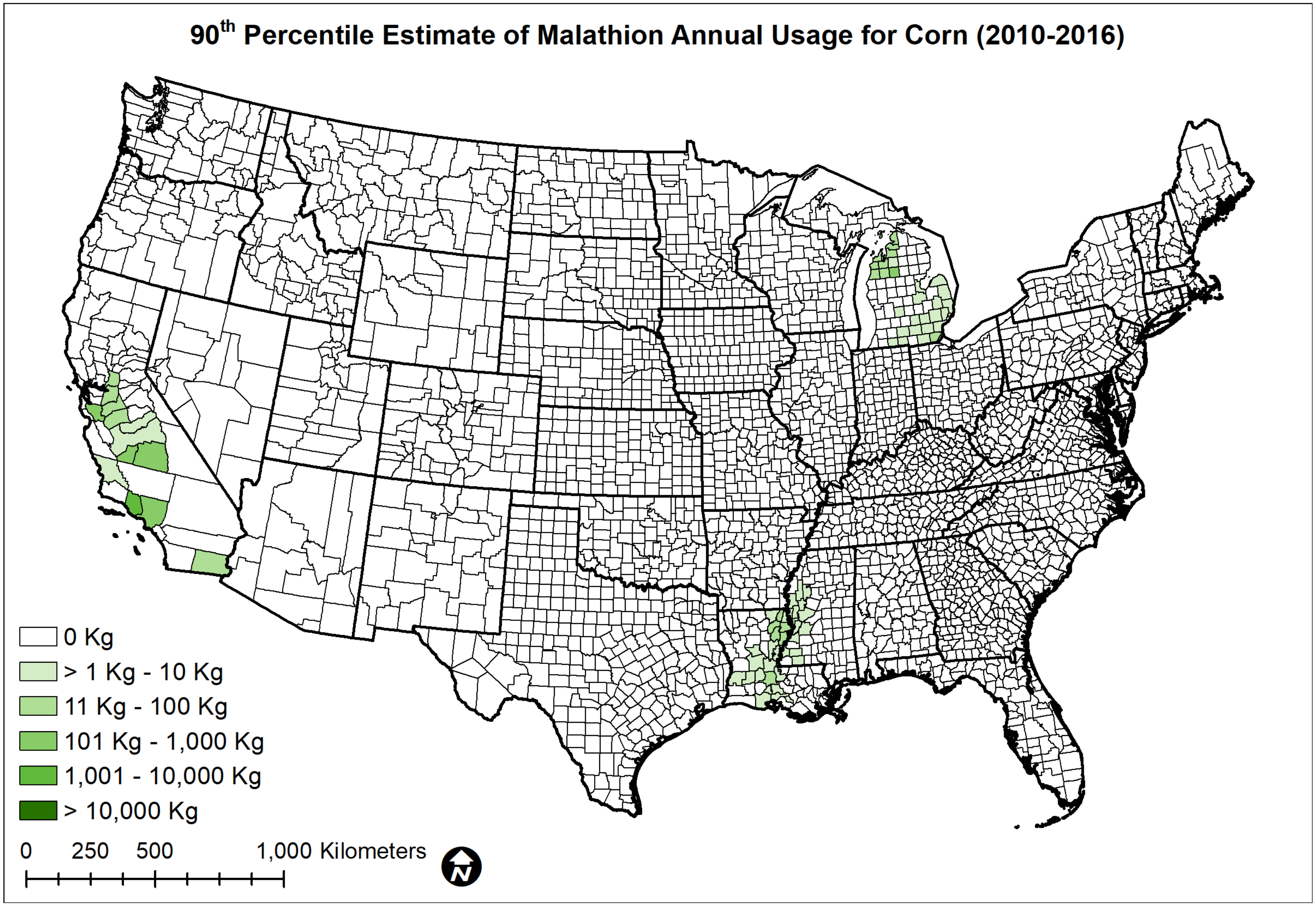

Figure 8. 90thPercentile Estimate of Malathion Annual Usage for Corn (2010-2016).

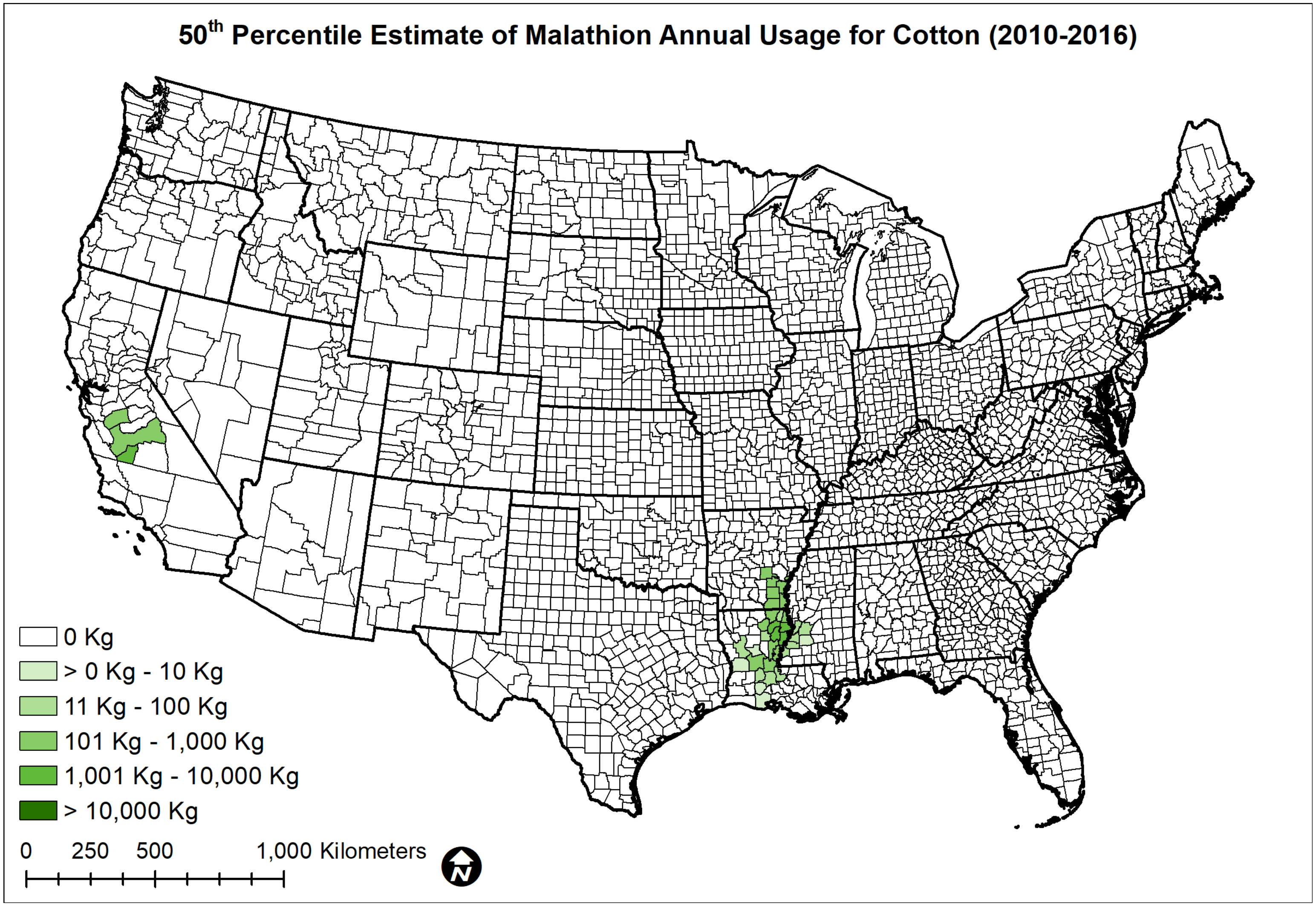

Figure 9. 50th Percentile Estimate of Malathion Annual Usage for Cotton (2010-2016).

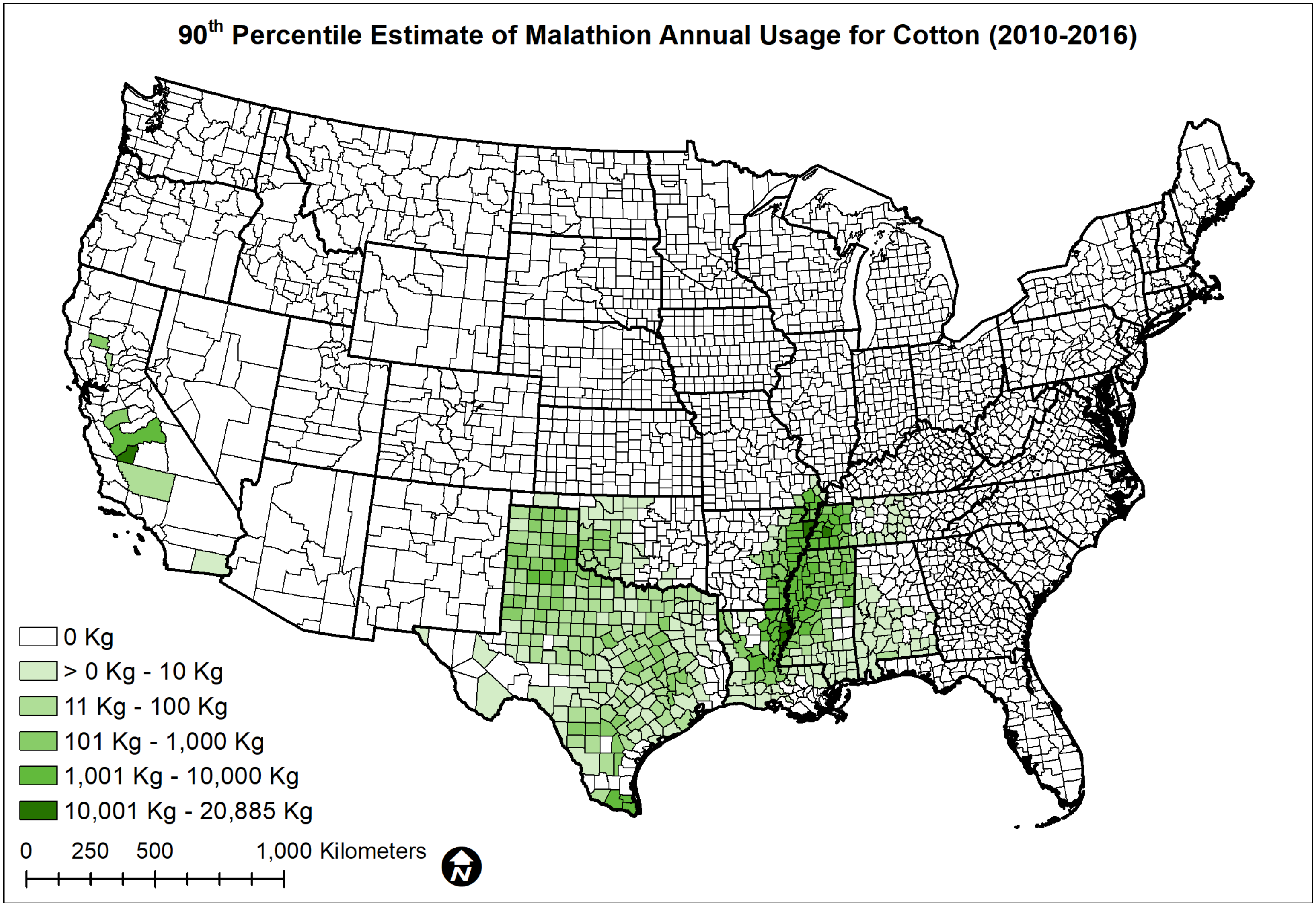

Figure 10. 90th Percentile Estimate of Malathion Annual Usage for Cotton (2010-2016).

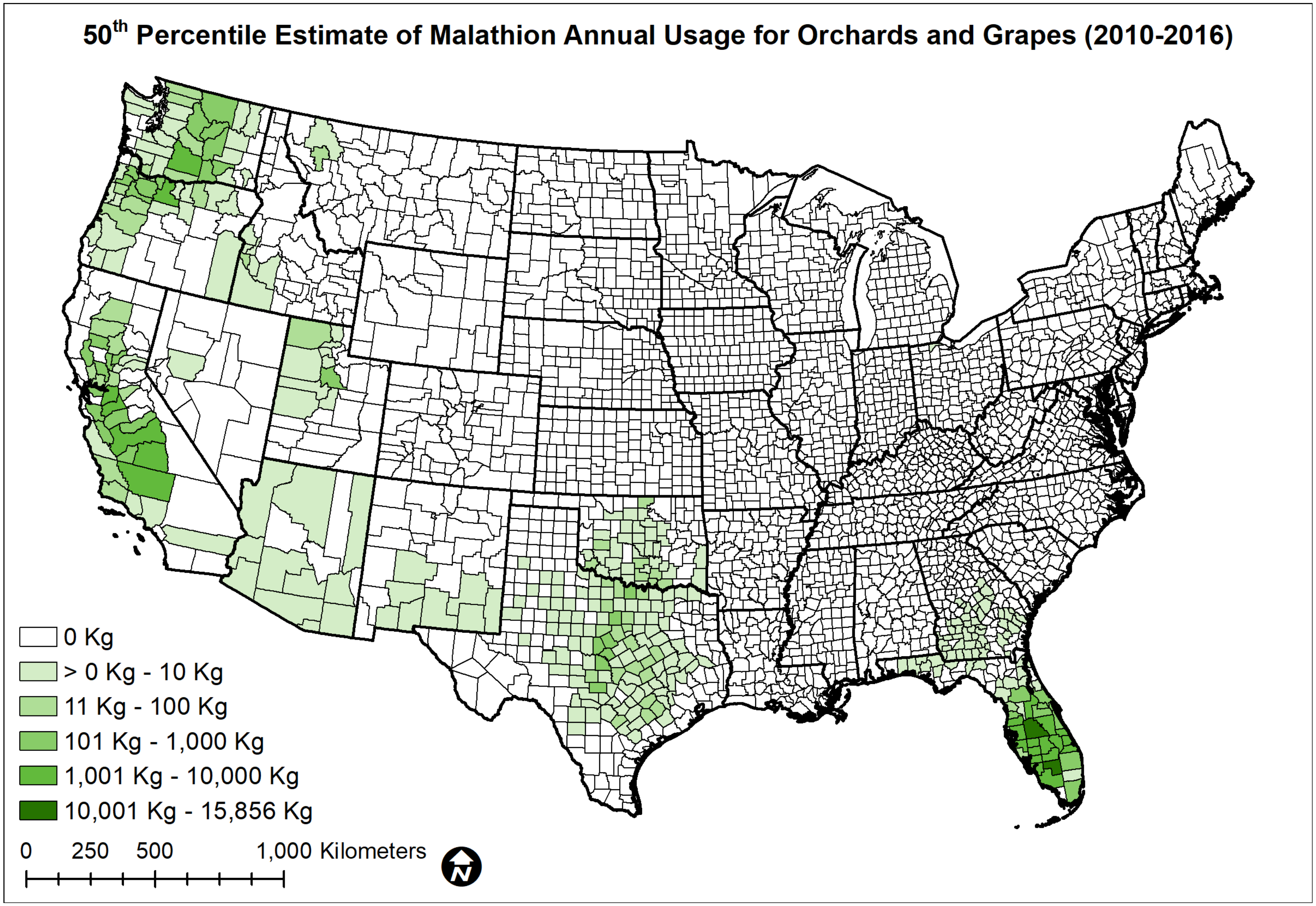

Figure 11. 50th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes (2010-2016).

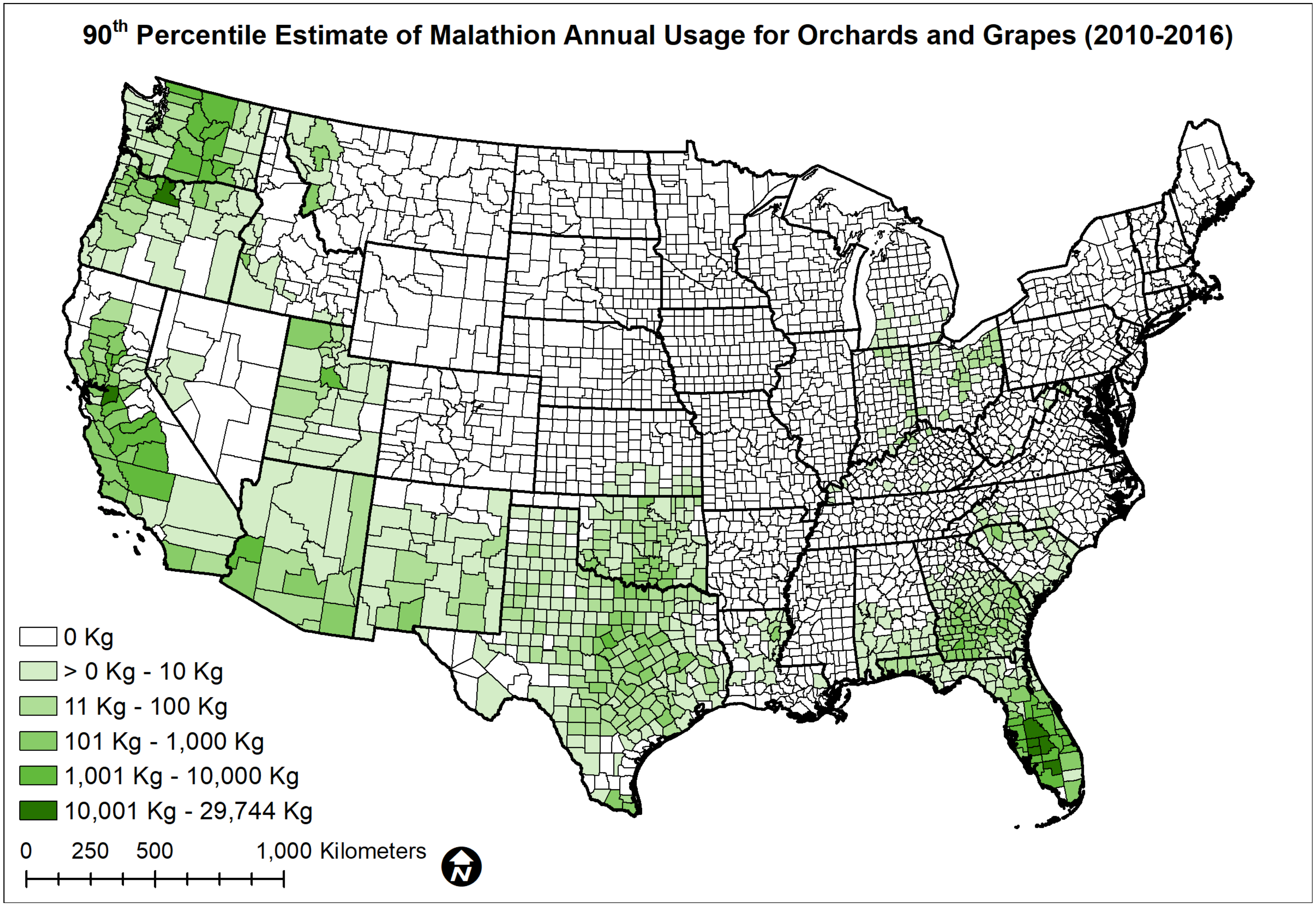

Figure 12. 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes (2010-2016).

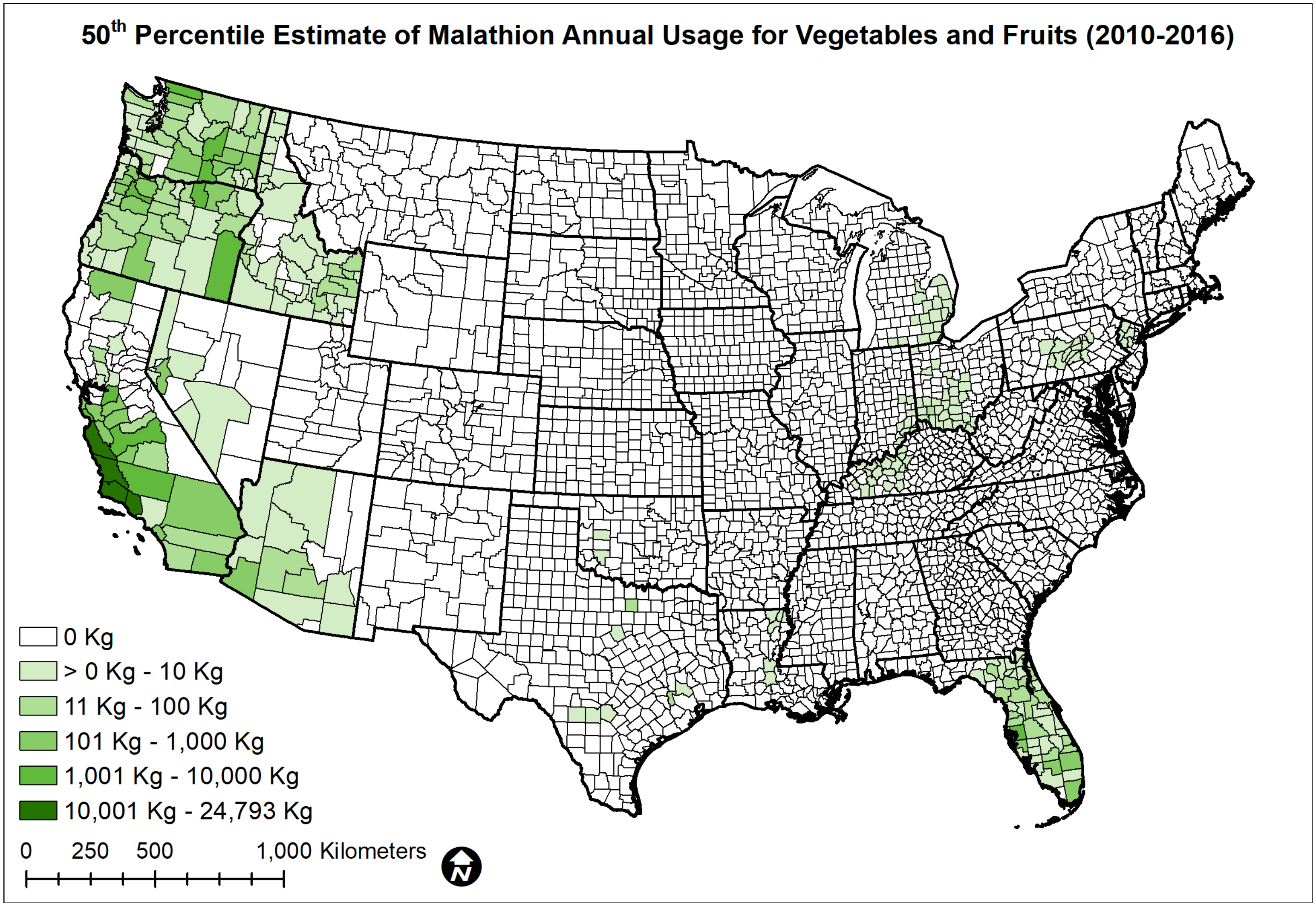

Figure 13. 50th Percentile Estimate of Malathion Annual Usage for Vegetables and Fruits (2010-2016).

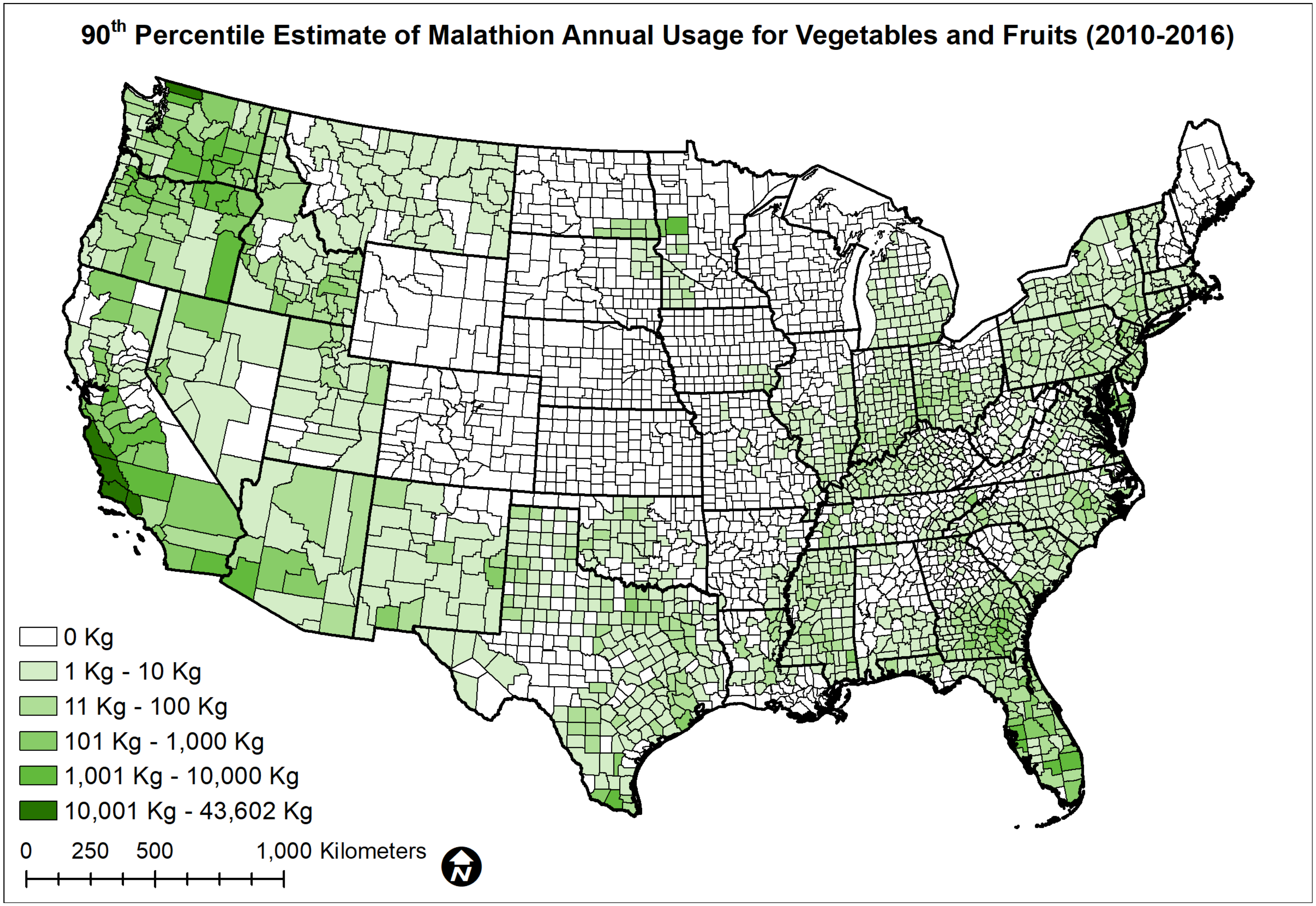

Figure 14. 90th Percentile Estimate of Malathion Annual Usage for Vegetables and Fruits (2010-2016).

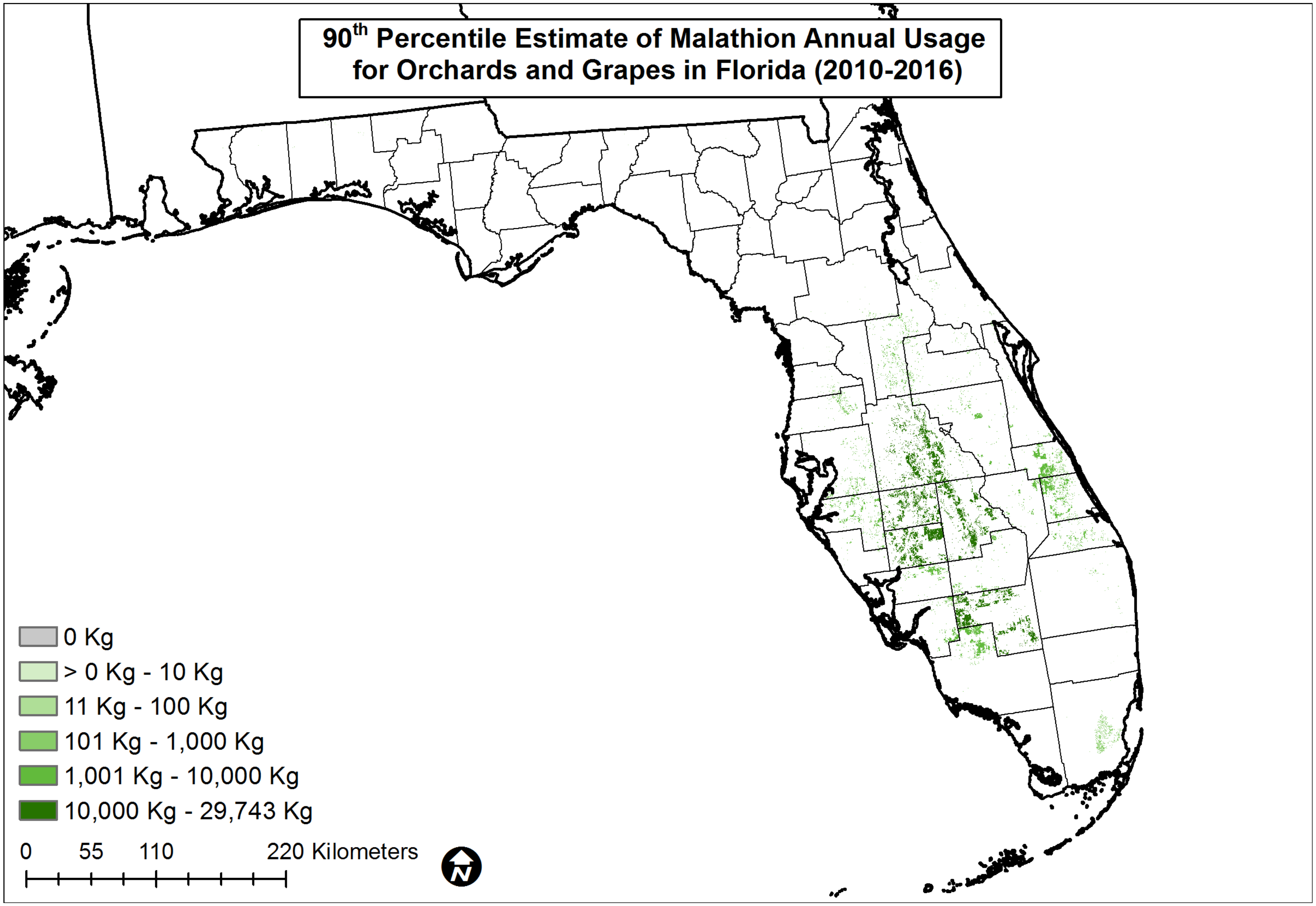

Figure 15. Florida 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes, Mapped to CDL Crop Footprint.

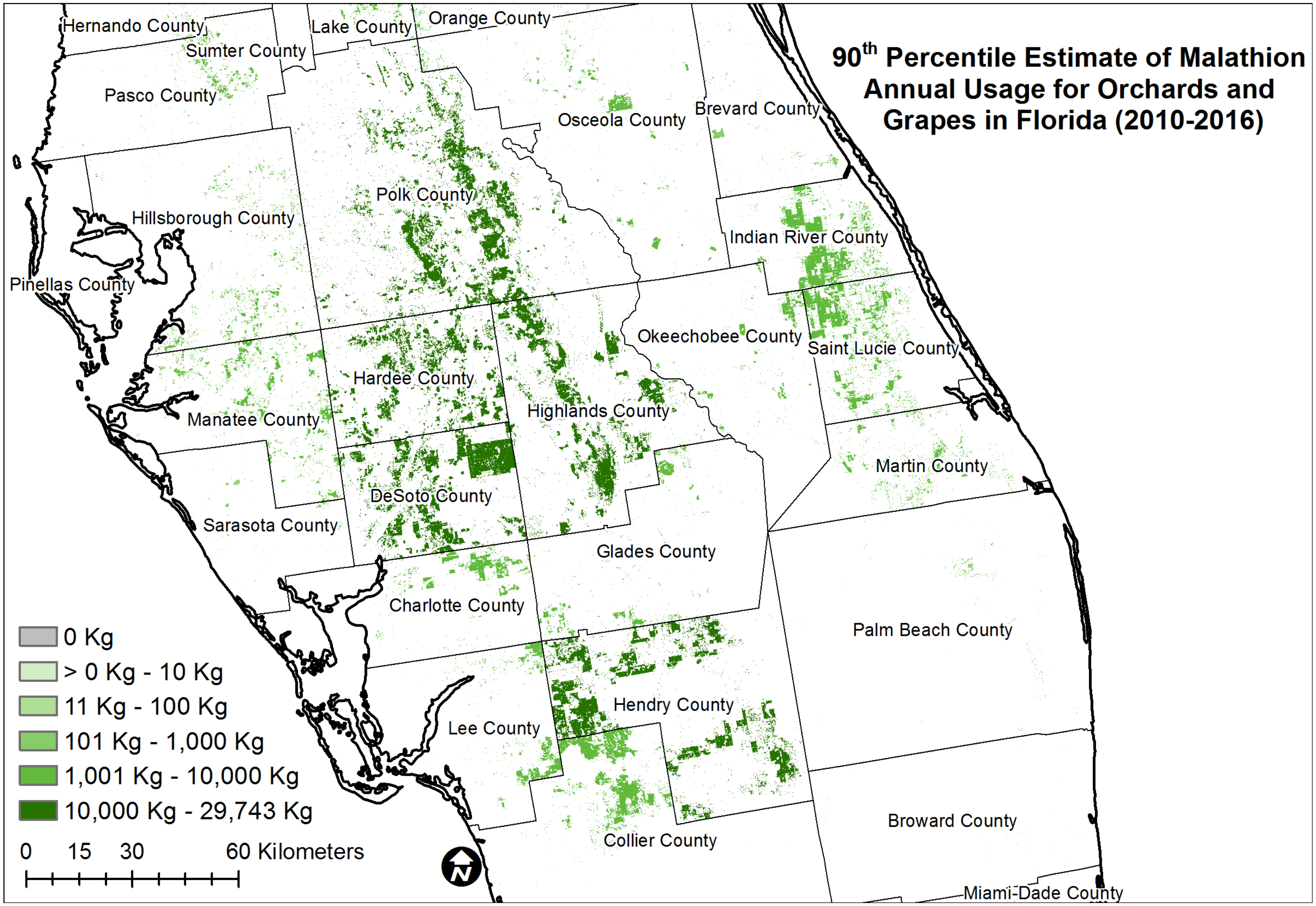

Figure 16. Central Florida Focus, 90th Percentile Estimate of Malathion Annual Usage for Orchards and Grapes, Mapped to CDL Crop Footprint.

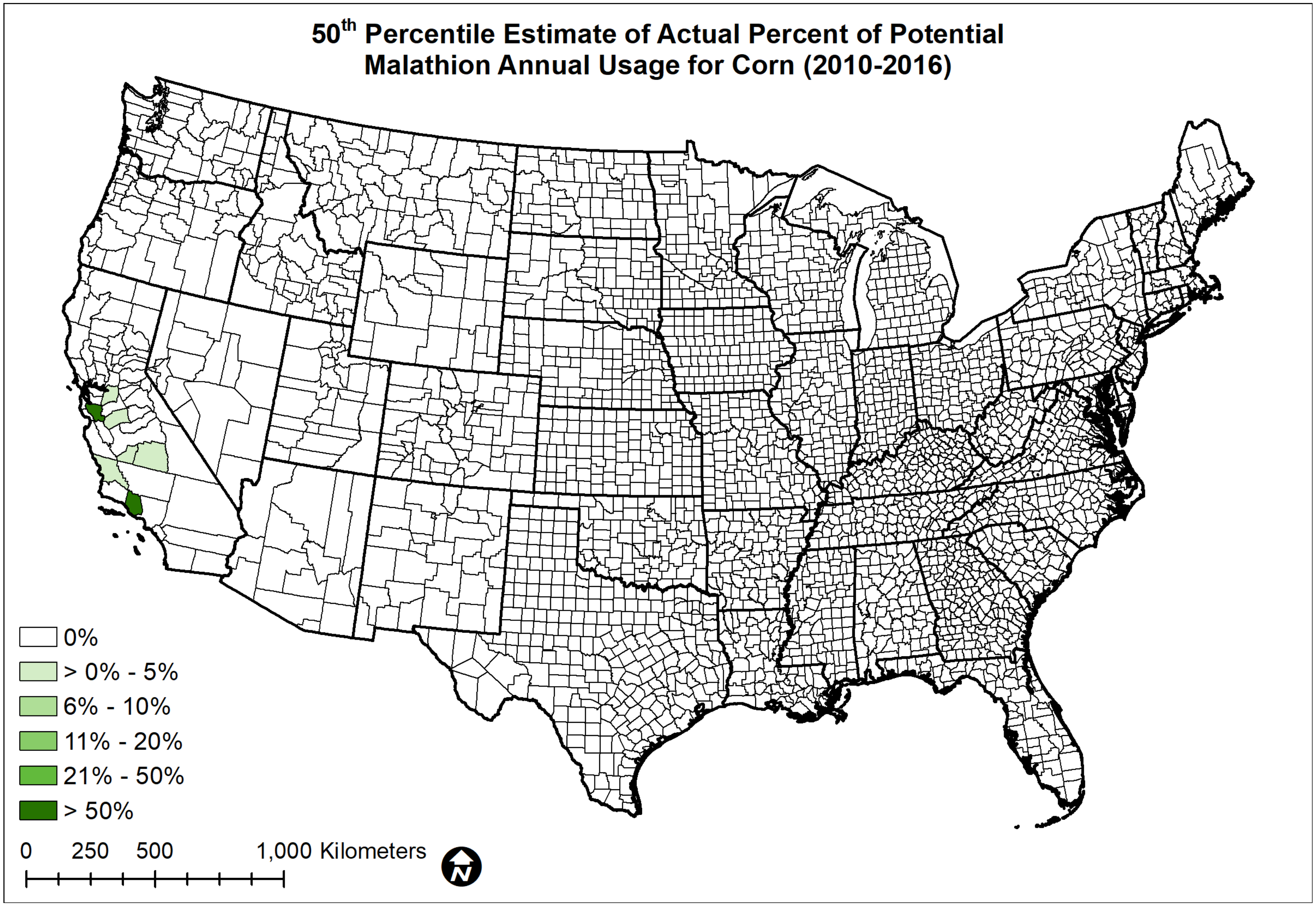

Figure 17. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Corn (2010-2016).

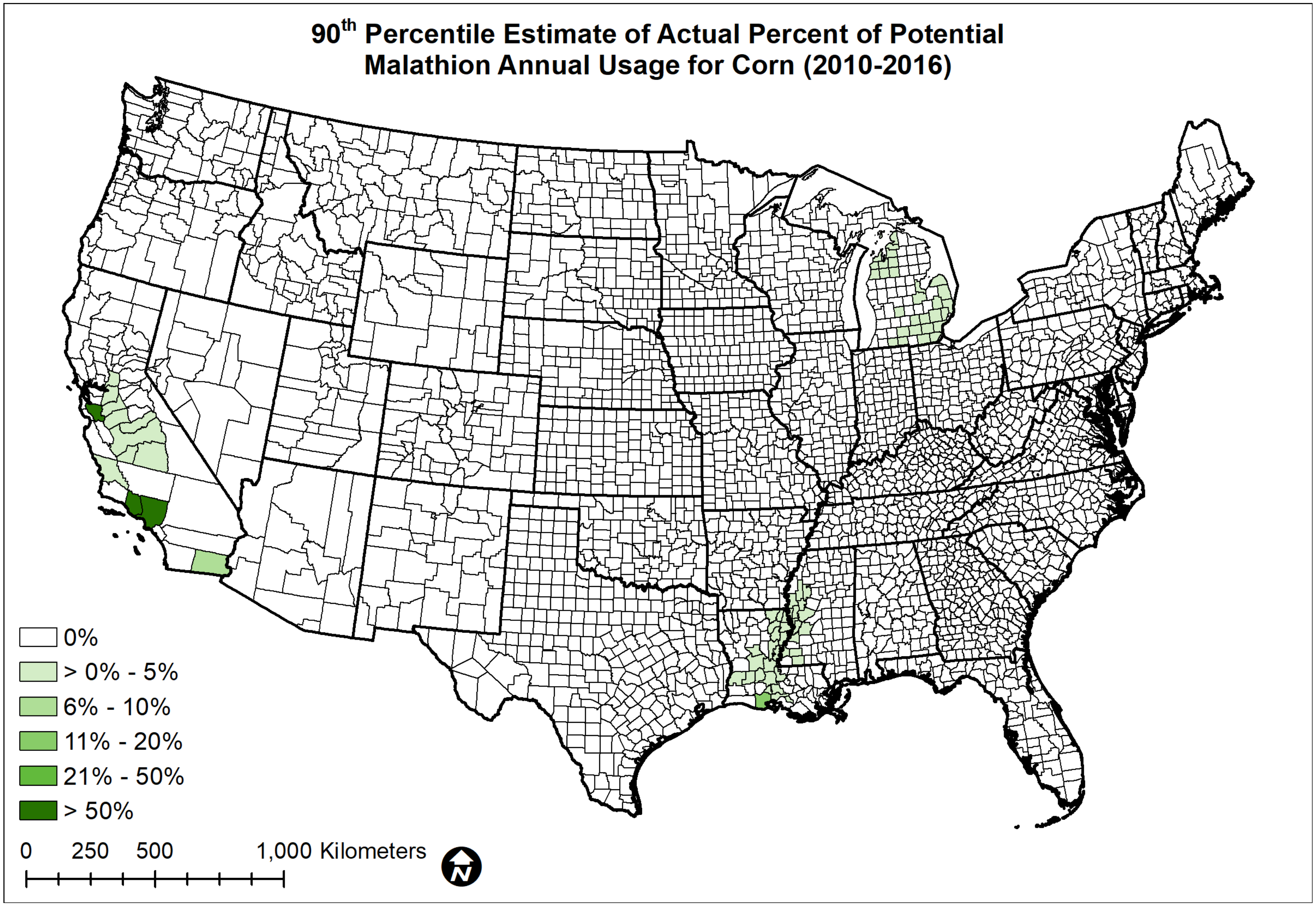

Figure 18. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Corn (2010-2016).

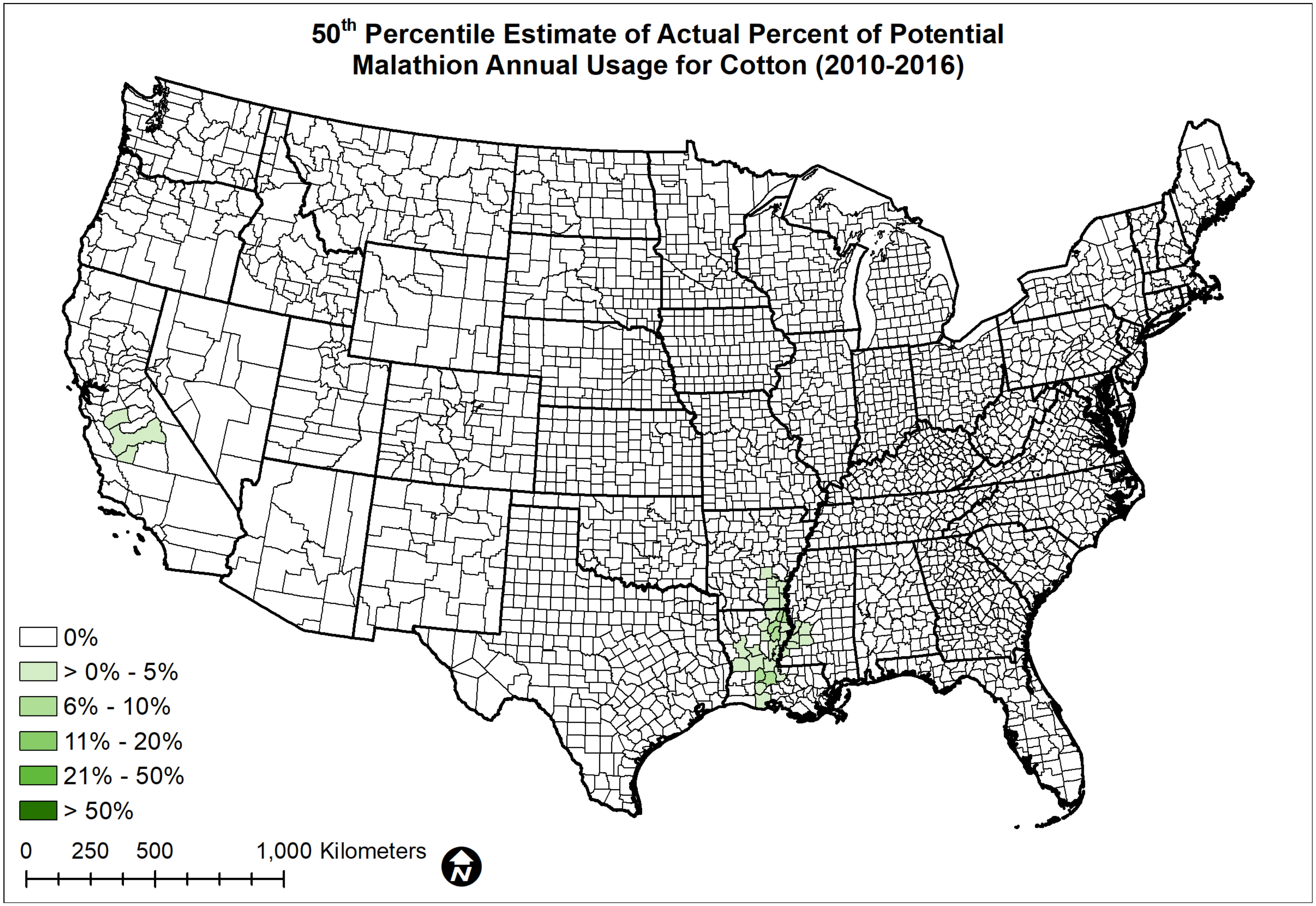

Figure 19. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Cotton (2010-2016).

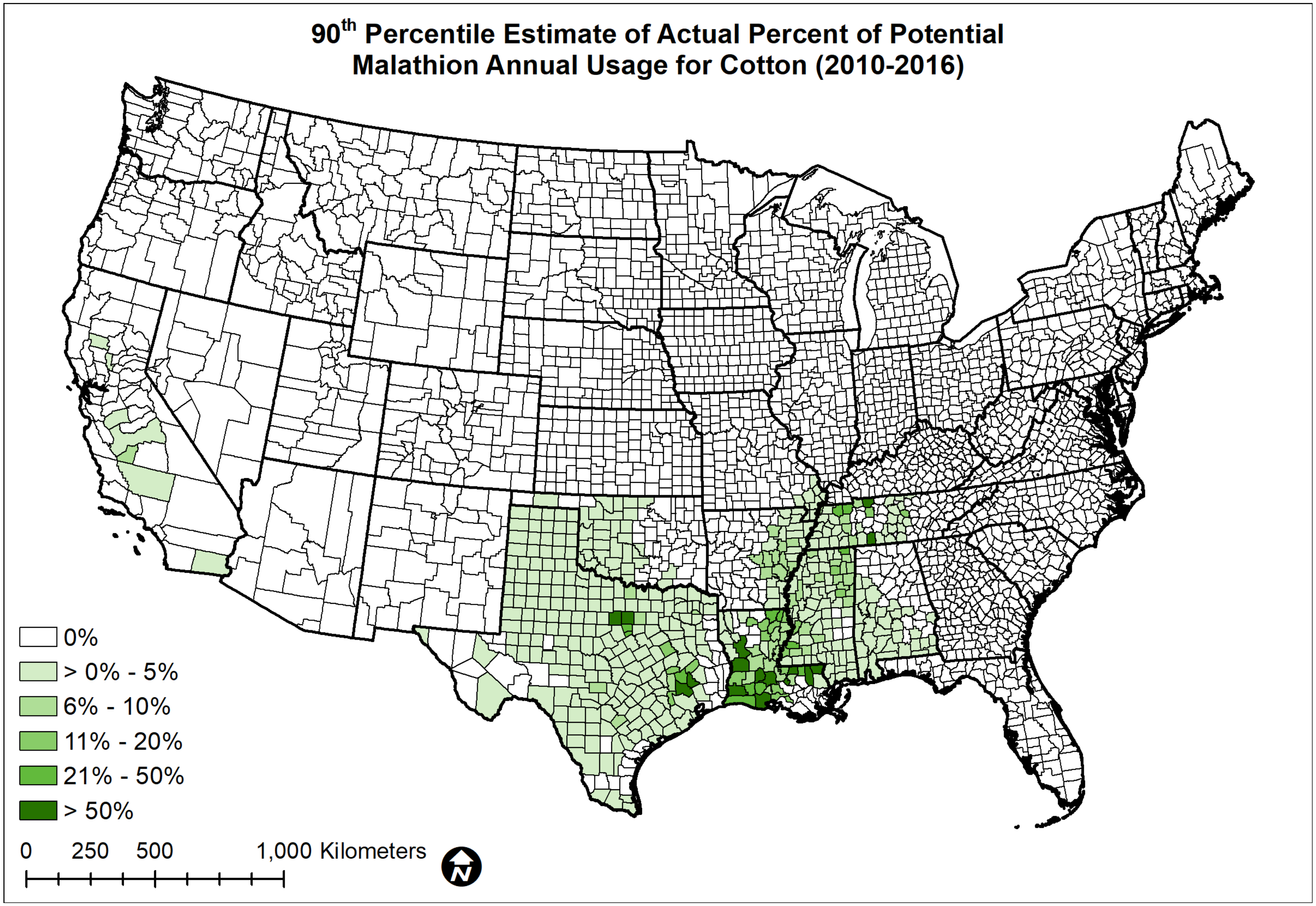

Figure 20. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Cotton (2010-2016).

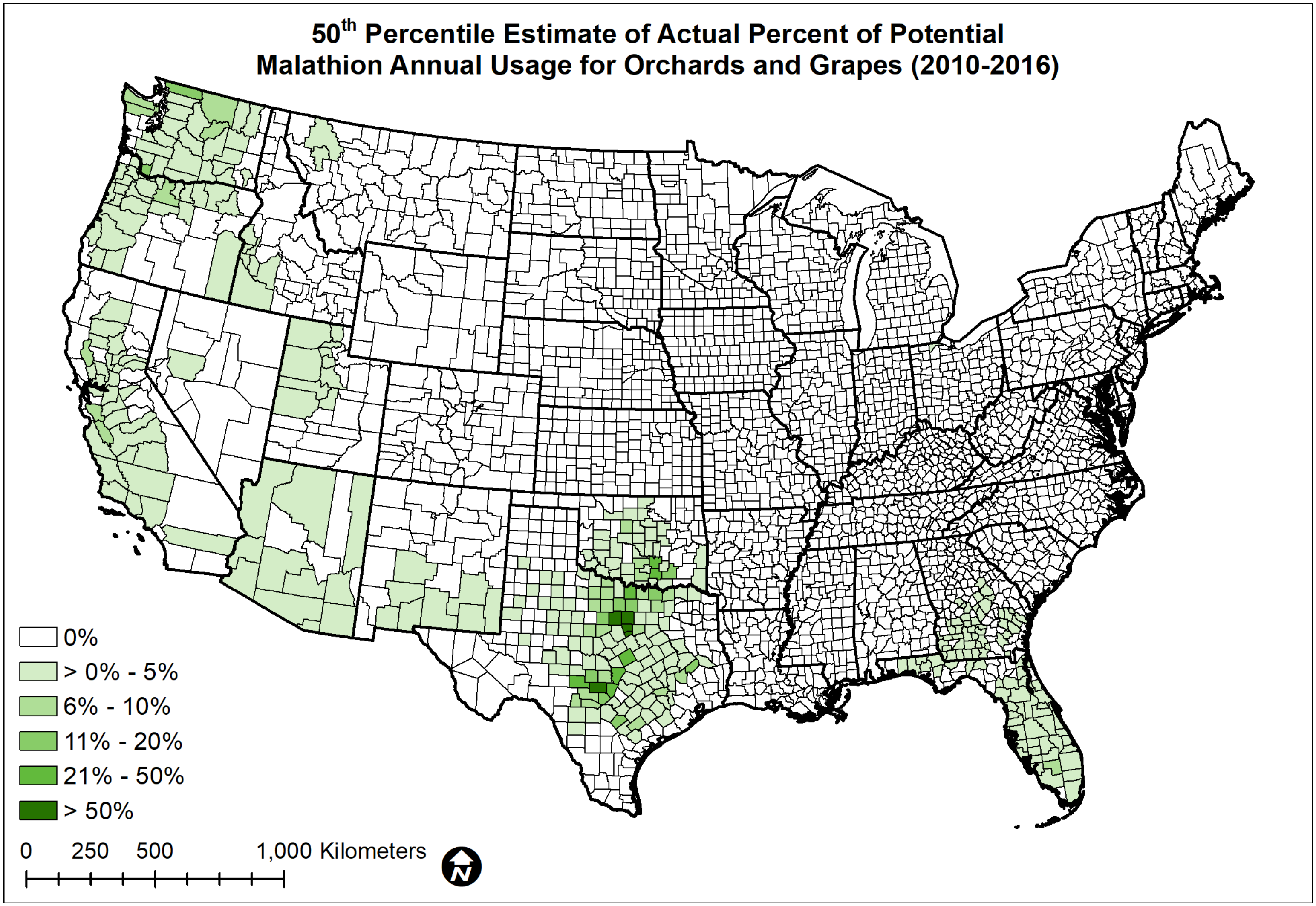

Figure 21. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Orchards and Grapes (2010-2016).

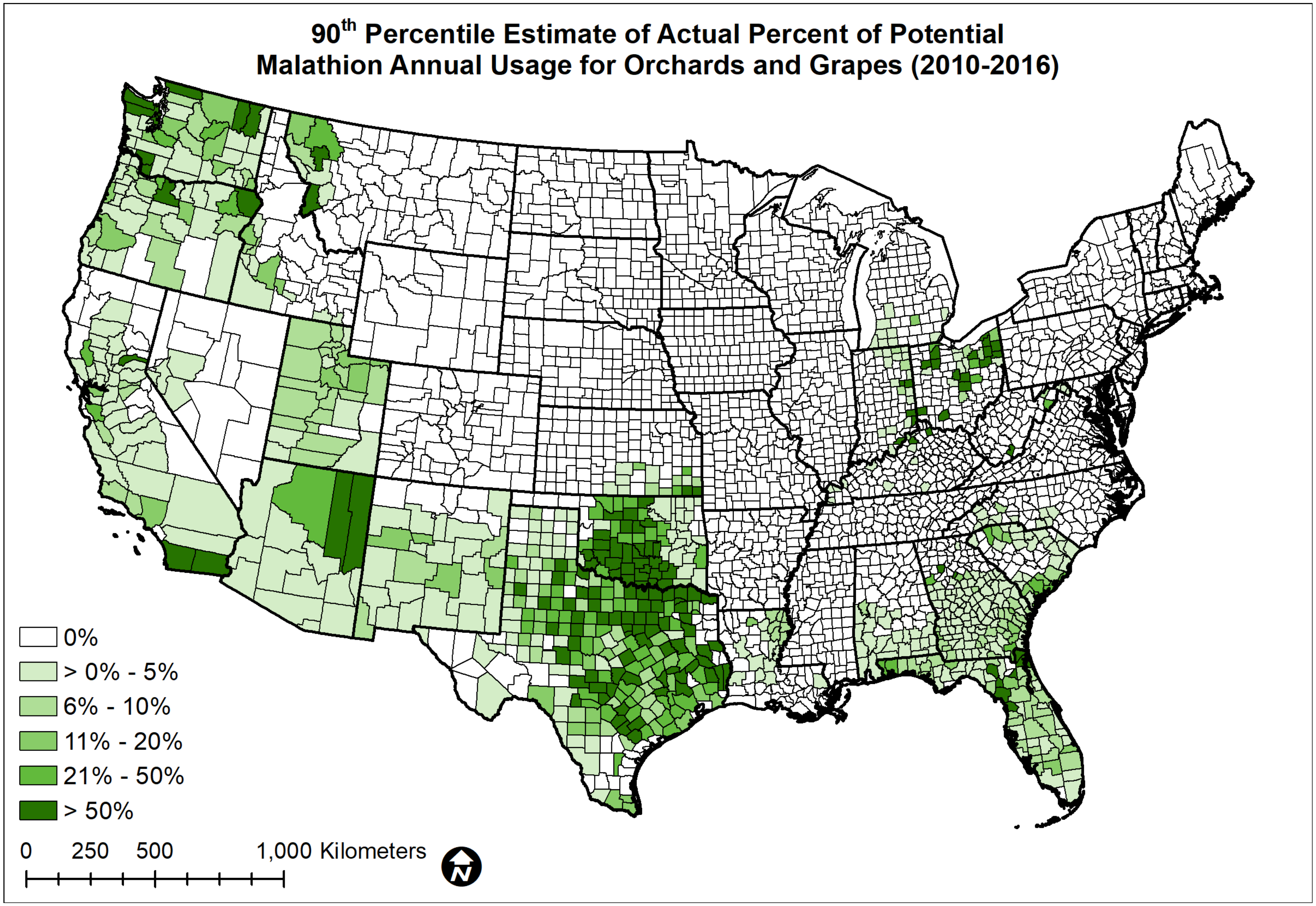

Figure 22. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Orchards and Grapes (2010-2016).

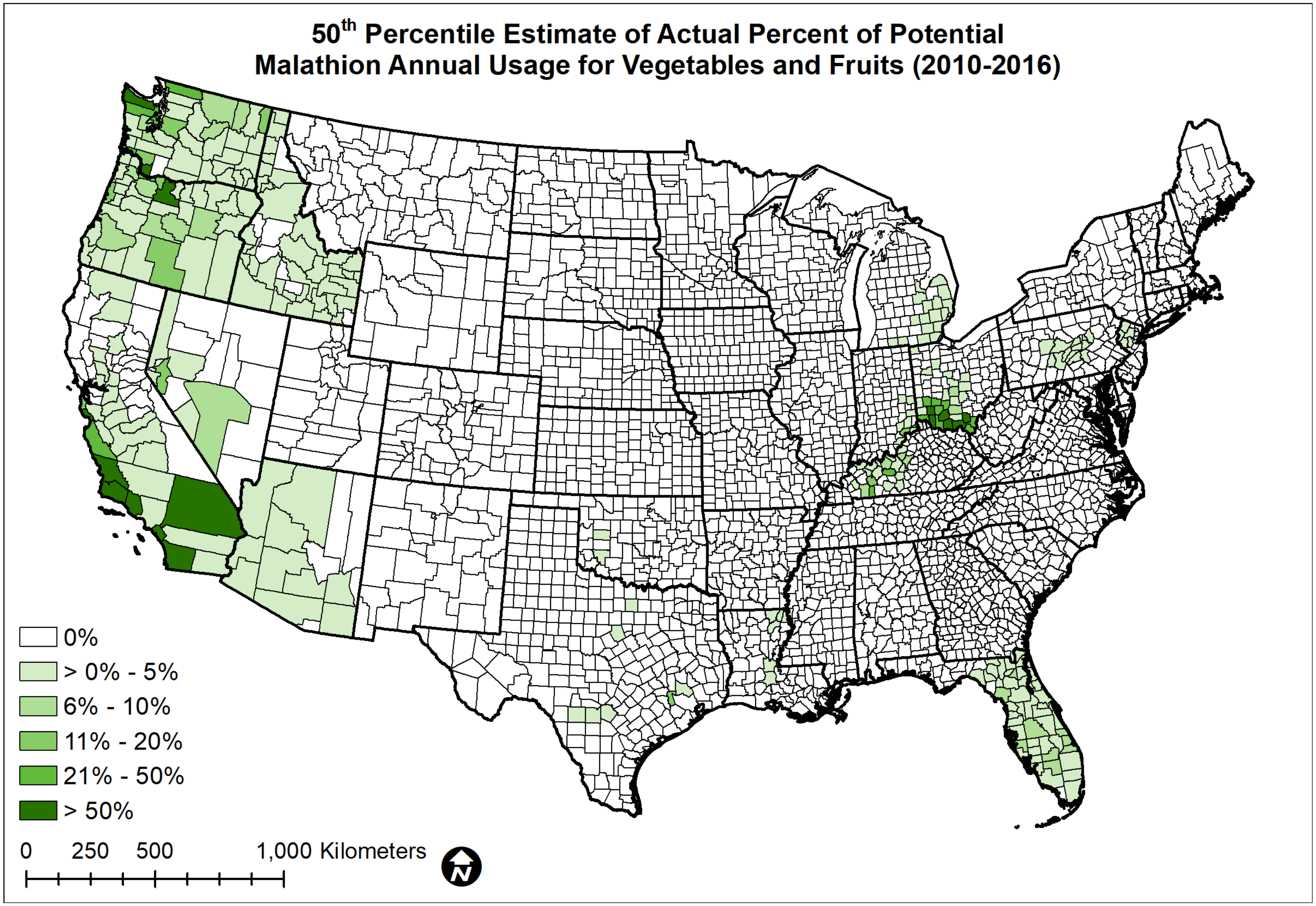

Figure 23. 50th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Vegetables and Fruits (2010-2016).

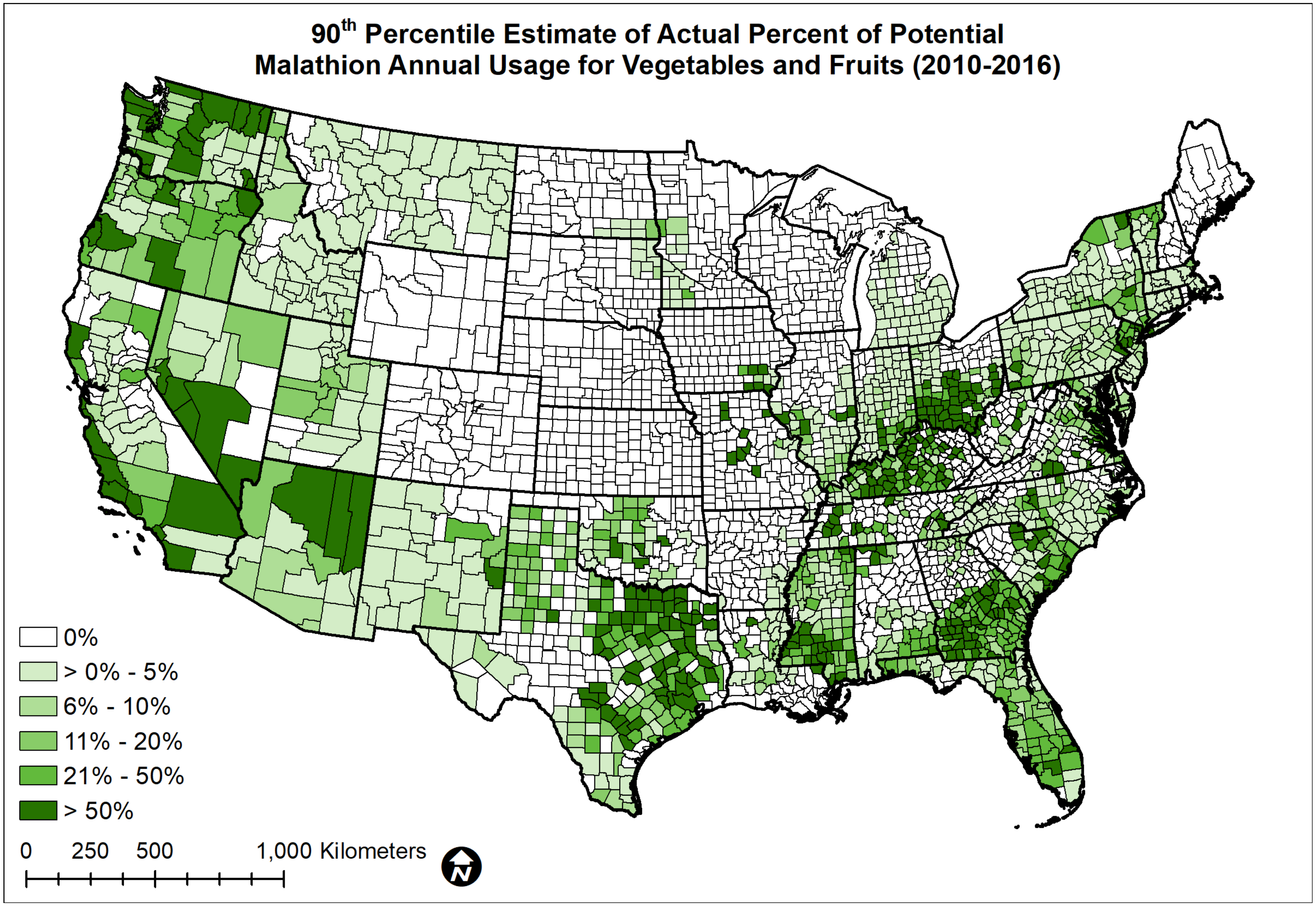

Figure 24. 90th Percentile Estimate of Actual Percent of Potential Malathion Annual Usage for Vegetables and Fruits (2010-2016).

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 0.7974 for county-level estimates and 0.8417 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
horseradish	Misc Vegs & Fruits	47	vegetables and fruits	3.75

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)
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
oats	Dbl Crop Soybeans/Oats	240	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)
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
salsify	Misc Vegs & Fruits	47	vegetables and fruits	3.75

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Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
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
wheat (spring and winter)	Dbl Crop WinWht/Sorghum	236	wheat	2
wheat (spring and winter)	Dbl Crop WinWht/Soybeans	26	wheat	2

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Malathion Label Crop	CDL Class Name	CDL Class Code	USGS Crop Group	Potential Use Rate (lbs ai/ac)
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