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Dow AgroSciences Comments on the Draft Biological Evaluations (BE) for the Registration Reviews of all Uses of Chlorpyrifos, Diazinon, and Malathion. (public comment docket specific for chlorpyrifos: EPA-HQ-OPP-2008-0850

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STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

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A. EXECUTIVE SUMMARY

Dow AgroSciences, LLC ("DAS") respectfully submits these comments on the Draft Biological Evaluations (BE) for the Registration Reviews of all Uses of Chlorpyrifos, Diazinon, and Malathion, notice of which was published in the Federal Register on April 11, 2016 (81 *Federal* Register 21,341) with the public comment docket specific for chlorpyrifos: EPA-HQ-OPP-2008-0850. DAS' views and positions on scientific issues specific to chlorpyrifos are also the subject of additional sets of comments simultaneously submitted to this docket (Clemow et al. 2016; Giddings and Winchell, 2016a, 2016b; Moore et al. 2016; Teed et al. 2016; Winchell et al. 2016a, 2016b). In addition, the registrants have submitted comments on critical policy, legal and scientific issues with respect to all three OPs at issue. These include a statement submitted jointly by all three registrants, (Weinberg and Menotti, 2016), comments by the FIFRA Endangered Species Task Force (2016), of which DAS is a member, and comments by CropLife America (2016), a trade association to which DAS belongs. DAS incorporate those comments herein.

DAS' comments are necessarily incomplete because of EPA's denial of timely and well-substantiated requests by registrants and grower organizations for extension of the comment period. DAS nonetheless has made a good faith effort to provide as constructive and substantive a set of comments as possible during the short comment period.

Chlorpyrifos is currently one of the most widely used insecticide products in agriculture in the U.S. and around the world. In the U.S., chlorpyrifos products protect a number of important agricultural crops, such as soybeans, wheat, alfalfa, citrus, tree nuts, peanuts, vegetables, and many minor crops, from losses due to insect pests. Permanent food safety tolerances have been established by EPA for the residues of chlorpyrifos in or on a variety of agricultural crops and processed commodities, as well as meat, milk, poultry and eggs. DAS has provided EPA with a detailed analysis of the importance of chlorpyrifos and its role in agriculture including discussion of regional, crop and pest-specific use information along with the multiple reasons growers need chlorpyrifos (Nelson and Schneider, 2016). DAS requests this information be considered in any evaluation of chlorpyrifos.

Major technical and policy flaws and issues with the draft BE are listed below; further details are provided in Sections B and C of this document. Additional comments and recommendations are contained in additional referenced documents submitted to this docket.

1. **The current BE for chlorpyrifos provides no sound legal or scientific basis to support regulatory decision-making or further development of Biological Opinions**.

By EPA's own admission, the interim process and methods used in the draft BEs are being invented along the way. It is experimentally applied and automated beyond the ability to produce meaningful results. Although put forth as "best available science," the weaknesses and lack of validation of the methodology, use of out-of-date and incomplete data rather than best available data, hyper-conservative assumptions, gross generalizations, and errors in the supporting data, clearly show the BE does not meet the bar for lawful ESA analysis or for regulatory decision making. And, as clearly described in these and other referenced comments, improving the science within the framework of the current approach is neither feasible nor a foundation for a replicable, sustainable and scientifically- and legally-valid process.

2. **EPA has abandoned the NAS/NRC 2013 recommendations and rather than serving as a risk-based focusing step for further analysis, the current approach is serving merely as an open conduit directing essentially all species in all locations into extensive, resource-intensive formal consultation**.

This result is exactly what the NRC/NAS committee sought to avoid in 2013 when it urged use of a common approach to eliminate many problems in assessing risk to listed species (National Academy of Sciences, 2013). The committee clearly stated that EPA's evolved methodologies for ecological risk assessment (ERA) as defined in the 1998 Guidelines for Ecological Risk Assessment is best suited to evaluating the risk from pesticides to listed species and their critical habitats. But this BE failed to follow it, most significantly with respect to the tiered framework that would have included a risk-based screening step.

Unreasonable over-estimations for both toxicity and exposure, along with a weight of evidence approach which is shown to have significant limitations and errors as described in submissions to the docket referenced in these comments, resulted in unrealistic estimates of 97% of endangered species and 99% of critical habitat receiving a classification of Likely to Adversely Effect (LAA) from the use of chlorpyrifos. These estimates are totally unrealistic, inaccurate, over-inflated and misleading. A significant number of species could have been screened out if EPA had conducted the assessment within a tiered framework that included risk-based assessment at each step, including more spatially-refined, realistic estimates of exposure along with more species-specific biological information.

3. **EPA is not following Congressional guidance**.

As detailed in the joint statement submitted to this docket by Weinberg and Menotti (2016), Congress has consistently recognized the critical need for pesticide products and has given a clear indication that ESA-related actions are neither intended or expected to materially interfere with FIFRA mandates. For example, Congress explicitly directed in 1988 that implementing agencies comply with ESA in the context of pesticide registration in a manner that “would allow persons to continue production of agricultural food and fiber commodities” and “minimize the impacts to persons engaged in agricultural food and fiber commodity production or other affected pesticide users or applicators.”[1]

The current assessment is so unrealistic and over-reaching that species, such as killer whales, sea turtles and desert pronghorn antelope, which exist only well away from agricultural areas where applications occur, are listed as likely to be adversely affected. This extreme, unnecessarily

[1] Endangered Species Act Reauthorization Act of 1998, Pub. L. No. 100-478 (Oct. 7, 1988), Section 1010(b).

protective, and scientifically flawed approach embodied in the draft chlorpyrifos BE threatens to remove this important tool from the hands of farmers, directly conflicting with the guidance from Congress.

4. **The problem formulation in the BE is conceptually incorrect which distorts the risk assessment process**.

The risk hypotheses proposed in the BE are not formulated to address key factors and questions crucial in determining actual risk to listed species. Instead there is an inherent assumption that exposure will occur, when in reality one of the first questions that should be asked is whether exposure is likely to even occur.

5. **Weight of Evidence evaluations have a prominent role in the BE, but were not conducted according to established methods. As a result, endpoints were selected that are not reliable, validated, or even relevant.**

The weight of evidence approach employed in the BE consisted of auto-generating data arrays which merely compile the range of sensitivities reported in available and often unqualified studies. The lowest value was then automatically extracted. In many cases the value selected cannot be linked to its original source, or can be shown to be from a source not validated, not relevant or not reliable.

6. **Refinements of use rates or percent cropped/treated area were not considered and would have significantly reduced the levels and extent of possible exposures**.

Maximum label use rates were used in all situations while for chlorpyrifos, extensive data exists which would have allowed further refinement and significant reduction in estimated exposure. Assumptions of 100% cropped and treated areas are unrealistic and could have been refined with best available information.

7. **Measures of data quality, data relevance and uncertainty, which are critical for assessing the reliability and validity of the data used, are not adequately addressed**.

The methods used for reviewing, analyzing and summarizing the uncertainty in the “lines of evidence” that support the risk assessment are not adequately explained to allow a objective external evaluation. One of the most egregious examples is the Agency’s evaluation of data quality and relevance. The documents do not appear to provide an explicit systematic assignment of the quality or relevance to the data sources critical to the risk characterization

8. **The analysis is incomplete and does not offer a fair appraisal of the individual crop uses**.

The Weight of Evidence summaries do not provide information on the type of use that results in each of the risk/confidence combinations. Therefore, the assumption drawn is that all uses pose the same risk. In reality some of the uses would have a “No Effect” determination in Step 1 and could be removed from further consideration; for many of the species, the only overlap with use patterns would be for the non-crop uses. To determine what uses would truly warrant further evaluation and possible mitigation, the Step 2 analysis should have been provided for each of the uses.

9. **The spatial data describing where the listed species occur and where chlorpyrifos could be used were not available for review or were not documented, but since significant errors occur in the BE in identifying the overlap between uses and species occurrences, the data cannot be considered the “best available” data.**

Even a cursory review of the species by location show obvious errors, such as the sperm and Sei whales occurring in Indiana. Such obvious errors, in combination with EPA’s hyper-conservative assumptions on product use patterns, raise serious issues about the overall validity and credibility of the spatial data and analysis.

10. **EPA should use real-world experience as a reality check of the hypothetical modelled predictions.**

Chlorpyrifos has been used by farmers for more than 50 years, yet the EPA approaches the BE as if this is a new chemical being released for the first-time and relies solely on a predictive analysis with no attempt to ground the predictions in real-world experience. If chlorpyrifos truly is likely to adversely affect 97% of species and 99% of the critical habitat, then it is reasonable to ask why significant impacts, and even mass extirpations, have not occurred?

In fact, there are examples of the opposite occurring. For example, a recently released report from the President's Council on Environmental Quality touts the recovered status of the Louisiana Black Bear, which is in apparent direct contradiction of the EPA's BE where it is classified as at high risk from the use of chlorpyrifos. Another example is the Kirkland's warbler where an ongoing recovery does not support the likely to adversely affect determination conclusion in the BE.

CONCLUSIONS AND RECOMMENDATIONS

In light of the above points, the following summary conclusions and recommendations can be made:

The draft chlorpyrifos BE demonstrates that the November 13, 2013 "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments" ("Interim Approaches") as implemented by EPA, should be set aside, and a new evaluation of chlorpyrifos uses, founded upon the 1998 Guidelines for Ecological Risk Assessment and the 2004 Overview Document should be undertaken before further consultation with the Services is even considered.

The various comments submitted and referenced by DAS present a number of reasons for these conclusions. They include the scope and conservatism of BE demanded by the Interim Approaches are extraordinarily complex and readily subject to distortion; that the BE is so badly flawed that any decisions based on it for chlorpyrifos would be scientifically unsound and unlawful, unless the BE was first substantially revised; and that the methodologies embodied in the Interim Approaches are inconsistent with FIFRA and ESA policies established by Congress.

More broadly speaking, and considering the implications of this draft BE for EPA's entire registration and registration review program, our comments demonstrate that even if the flaws in the draft chlorpyrifos BE were to be corrected, it would take far more years than Congress envisions to apply the Interim Approach methodologies in registration reviews. Moreover, it is impossible to implement the Interim Approach under the PRIA system for new product applications and to the many other actions EPA's pesticide programs take. Therefore, the sensible conclusion is that EPA and the Services should fundamentally rethink and replace the Interim Approaches employed in the draft BE.

In addition, moving forward, EPA should use its expertise and resources far more productively and efficiently. The joint statement submitted to this docket by Weinberg and Menotti (2016) explains how the implementation and expansion of the existing FIFRA Counterpart Consultation Regulations could provide a far more appropriate mechanism than the unwieldy, incomprehensible approach used in this draft BE.

B. DETAILED TECHNICAL ASSESSMENT

1. The analysis is ineffective as a demonstration of an improved assessment process

The Step 1 procedures implemented in the BEs, based solely upon a co-occurrence analysis, would have screened out more species had the analysis followed a tiered framework that included a risk-based screening step; such an approach would be consistent with the 1998 Guidelines for Ecological Risk Assessment (USEPA, 1998) . Indeed, the NAS/NRC report (pages 33-34) contains the following statement:

> *…The committee concludes that using a common approach would eliminate many problems in assessing risks to listed species that are being encountered by EPA and the Services. As noted by Suter (2007, p. 37), the "advantages of using a single standard framework include familiarity and consistency, which reduce confusion and allow comparison and quality assurance of assessments." The ERA process that has evolved over the decades is best suited to evaluating the risk to listed species and their critical habitats posed by pesticides, and, as noted by Suter (2007, p. 37), the "EPA framework is a preferred default for ecological risk assessment in the United States." …*

Is spite of this recommendation, the interim process followed in the BEs is a radical departure from the EPA process as codified in the 1998 Guidelines. Step 1 is based upon a co-occurrence analysis using a single line of evidence, a threshold of toxicity, compared to an overwhelmingly conservative estimate of exposure. Many of the deficiencies in Step 1 are carried over into Step 2. Particularly troubling are the overstated use footprints for the products, leading to systematically conservative exposure predictions. These estimates can only be considered precautionary in nature, leading to findings expressed using terms such as “could be exposed.” These findings were combined with the assumption that any level of exposure exceeding a threshold would results in ecological adversity, irrespective of the acknowledged, but unquantified, uncertainties associated with such assumptions.

The pervasive precautionary emphasis of the assessments results in unnecessarily broad scope, which in turn creates enormous programmatic challenges for EPA and the Services, both of which are mandated to complete high quality biological opinions with limited resources.

Similarly, little additional refinement was done in the iteration of Step 2, again resulting in missed opportunities to determine NE or NLAA outcomes that would simplify the overall process and conserve precious resources, particularly in the Services. Another difficulty with Step 2 is improper application of the weight of evidence process, so that any one of the lines of evidence can result in a LAA determination, regardless of the weights of the other lines. This results in species not being screened out that should be removed from further consideration.

As it stands now, the analysis frustrates rather than assists in understanding the impact of stressors to listed species. The lack of thoughtful analysis in a tiered risk assessment process puts undue burden on the Services and communicates to stakeholders an unrealistic and incomplete view of risk. EPA and the Services should reconsider their ESA methodologies to incorporate additional tools, which in turn would allow them to arrive at environmentally realistic and scientifically defensible ESA-related conclusions.

2. An environmental baseline is not considered

Temporal scale is particularly important for interpreting ecological adversity. Since the OP insecticides assessed in the BEs have been used for more than 50 years, the entire approach of the predictive analysis that assumes this agency action involves release of a new toxic chemical into the environment is conceptually unsound. If one considers a listed species to be challenged by multiple stressors limiting recovery, and a specific chemical stressor is evaluated in a predictive assessment for its marginal contribution to possible extirpation and found to greatly impact the fitness of individuals of populations for 99.9% of the species, then it is reasonable to ask why this predicted mass extirpation has not occurred after decades of potential exposure. But this question is not addressed in the BE analyses. That omission is a major flaw in the evaluation.

The entire analysis is undermined by this unrecognized conflation of causal and predictive assessment, which in turn fails to acknowledge that the environmental baseline reflects many decades of stressor presence in the environment. Consequently, there are lines of evidence such as water quality monitoring for chemical stressors vs. exposure modeling that are counter to the conclusions arrived at in the BE. . Further lines of evidence also are ignored, including, for example, population recovery surveys taking into account natural fluctuations that can be compared to predictions from effects and population models. The case of Kirtland's warbler and chlorpyrifos provides such a recovery survey, which, if included in the analysis, would not be in alignment with the LAA conclusion in the BE.

3. The Problem Formulation is conceptually incorrect

The assessment endpoints, and not the risk hypotheses, should be the first link to the protection goals (i.e., management goals) for Step 2. Then the assessment attribute part of the assessment endpoint should be linked to one or more risk hypotheses and then each hypothesis should be linked to at least one Line of Evidence (LOE) (here one based on toxicity - exposure and effect). In the BEs, however, assessment attributes are incorrectly identified as LOEs - which would result in weights being applied to an attribute and not to the evidence. For example, in Attachment 1-9, page A9 (PF)-3, Bullets A & B, survival (the inverse of mortality) is an attribute, not an LOE. The LOEs refer to whether that attribute will be affected and, if so, to what extent. The proper analysis is therefore as follows:

> <u>Assessment endpoint:</u> Assessment entity + its assessment attribute(s).
> <u>Assessment entity:</u> An individual of Listed Species *X*.
> <u>Assessment attributes (for *X*):</u> Survival, growth, reproduction, behavior, sensory function, prey items, pollinators/diaspore dispersal vectors, plant habitat, obligate organisms. Note

that each attribute need not (and probably should not) be weighted the same relative to the other attributes.

Risk hypothesis: Exposure to Pesticide *Y* used according to registered labels (includes parent active ingredient, formulations, and degradates of concern) will adversely affect one or more of the attributes related to *X*.

Line-of-Evidence: (1) Level of exposure and (2) effect on attribute associated with that level of exposure (i.e., the exposure/response function). Evidence for characteristics might also be included here (as is alluded to by Bullet C).

The consequence of this conceptual failure is that the risk hypotheses as currently proposed (Section 1.3.2) are not set up to address the key factor/question in determining the risk to listed species. As written, there is an inherent assumption that exposure will occur, when one of the first questions that should be asked is whether or not there is a likelihood of exposure.

It is important to realize that the NAS/NRC 3 step approach is not an analysis plan or risk assessment scheme. It is simply a schematic of questions that been defined, seemingly arbitrarily, under the current regulatory scheme to meet the mandates of ESA. It is appropriate in describing the regulatory process, but is not particularly helpful in terms of planning the details of the risk assessment.

The main deficiency in the lines of evidence used in the BEs is the reality that, in effect, only a single line of evidence is brought into the analysis: toxicity. This is made clear in Attachment 1-9, page A9 (PF)-9, where risk is determined only by comparison of a point estimate of exposure to a variety of toxicity thresholds. The analysis is therefore confounded by associating these toxicity thresholds with attribute changes relevant to risk hypotheses (for which, in turn, lines of evidence are to be considered and evaluated (as outlined in the 1998 Guidelines). These attributes include (1) mortality, (2) reduced growth, and (3) reduced reproduction (see, for example, chlorpyrifos BE Chapter1, Table 1-4 and the related Figures 1-3 and 1-4).

The BEs' approach thus is inconsistent with prior published examples that follow a historically well-understood process. In those, the probability of mortality from direct acute (short-term) exposure is evaluated by bringing into the analysis plan individual lines of evidence of exposure (modeled, monitored, evaluated in field studies) paired with exposure/response information such as dose-response results (from laboratory, semi-field, and field studies). The atypical use in the draft BEs of attribute changes as lines of evidence expressed as toxicity thresholds rather than as assessment endpoints distorts the risk assessment process and represents a radical departure from the recommendations of the 1998 Guidelines. Further discussion of these concepts can be found in Clemow et al. (2016).

4. The Weight-of-Evidence Scheme is not consistent with established methods

Although Weight of Evidence (WOE) methods figure prominently in the draft BEs, there are no references to the existing – and not insubstantial – WOE literature in either Chapter 1 or Attachment 1-9. Thus there is no way to easily determine whether the WOE method outlined in these locations builds on (or is even cognizant of) prior research or whether it is a new and novel approach unique to this evaluation. But it appears that the latter is the case here. If so, it seems ill-advised to have embarked on a significant WOE analysis for a major biological evaluation without first having consulted the literature.

Consistently throughout the BEs, it is stated that best available and rigorously-reviewed data are used for the weight-of-evidence approach. However, this approach is no more than auto-generating data arrays which compile the range of sensitivities reported in often unqualified studies whose typicality is not described. The "weight" is limited to again automatically extracting the lowest value from the lowest end of the data array. And in many cases this value either cannot be linked to its original source, or can be demonstrated to be from a source not validated, not relevant, or not reliable. It thus appears that the WOE approach merely shows the range of potential values from various endpoints, with no scientifically defensible determination of what the lowest value actually means or how it was derived. It is surprising that the Agency can put such information forward and expect to retain credibility in their overall conclusions.

5. Refinements of use rates or percent treated area were not considered

The assumption of maximum use rates in all situations may be appropriate in some screen-leveling analyses, but the BEs missed the opportunity to consider more realistic use practices as a potential refinement of exposure. A relatively simple refinement to more typical rates (for uses supported by Dow AgroSciences) appears in Solomon et al. (2014) based upon label analysis and consultation with pest advisors and university experts. Indeed, since a there was a spatial aspect of the analysis, a relatively straight-forward refinement of use rates and frequencies could have been carried out at even a regional (e.g., HUC-2) level, based upon registrant, market survey, or academic information at Step 2 (such an analysis for chlorpyrifos was published by Solomon, et al., 2014).

In the evaluations of downstream dilution done for diazinon[2], the use of Percent Crop Areas (PCA)) or Percent Treated Areas (PTA) was proposed. To properly evaluate the agricultural uses of chlorpyrifos, this concept should be applied to all of the flow water bins. Especially at the sizes of the medium and high flow habitat watersheds, a 100% PCA will greatly contribute to the overestimates of aquatic exposure.

PCAs can be calculated based on aggregate use site footprints from multiple crop groups, and PTA, while based on state-level data, can be meaningfully included in the determination of EECs at Step 2. The US EPA has provided conservative estimates of all-cropped and crop-specific PCAs in recent guidance documents (Echeverria, et al., 2102; Bohaty, et al. 2014) at the HUC-2 level, but these were not used in the BEs. Further details on this point are contained in Winchell, et al. (2016b).

6. Measures of data quality, data relevance and uncertainty are not sufficiently addressed

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[2] This analysis was not done for chlorpyrifos or malathion because their action area was determined to be the entire county

Review of the BEs is greatly hampered by lack of understanding of the methods used for reviewing, analyzing, and summarizing the uncertainty in the “lines of evidence” supporting the risk assessment. An important example is evaluation of data quality and relevance. Review during the limited period allowed by EPA for preparation of comments has not revealed any systematic assignment of quality or relevance to data sources that are crucial to the risk characterization and indeed required under ESA as “best scientific data”. Therefore, in many cases it is not possible to judge the validity of lines of evidence contributing to risk conclusions.

For example, Chapter 1, Attachment 1-8 states that EPA used ECOTOX as a first screen of effects data. Given that the criteria for inclusion in ECOTOX are very minimal, this is appropriate for casting a wide net and as an initial screen. The Agency then stated they “intensively reviewed” studies in ECOTOX for inclusion in data arrays based upon their criteria for the use of data from the open literature. However, it appears only one of the criteria (data reported in environmentally-relevant units) was actually applied. This means studies with very low reliability and relevance may have become part of the arrays, essentially rendering the arrays useless. A detailed analysis of study reliability and relevance for chlorpyrifos studies is contained in Clemow et al. (2016) and Teed et al. (2016) for terrestrial organisms and Giddings and Winchell. (2016a, 2016b) for aquatic organisms.

Similarly, uncertainty was promised to be included in the effects arrays (Chapter 1, page-51), but it was not clear from the text that any quantitative evaluation of uncertainty was done. While the concept of presentation of a great deal of data visually using arrays is appealing, by including essentially all open literature without critical evaluation, EPA simply has presented a meaningless compilation of data.

The qualitative assessments for sea turtles, whales, deep sea fish, other marine mammals, cave dwelling invertebrate species, lichens, pinnipeds, and otters suffer from lack of available data and great acknowledged uncertainties. These risk characterizations are little more than opinion based on unvalidated screening and pre-screening models (which in turn are of limited value because they employ simplifying assumptions that do not correspond to actual characteristics of agroecosystem/natural ecosystem boundaries (beaches, estuaries, caves), stressor environmental behavior, or receptor absorption and metabolism). For example, in their determination for sea turtles, EPA discusses the likelihood of dermal exposure to juvenile and adult sea turtles on beaches. They note that there is uncertainty on a variety of factors that affects potential exposure including wind direction (and subsequent transportation of chlorpyrifos off field), duration of exposure (since juveniles only cross the beach once from the nest to the water), time of day (adult females only lay eggs at night), and day of application. EPA concludes that accounting for all of these factors, the likelihood of exposure and resulting effects although cannot be precluded but are expected to be low. However, in their statement concluding a “likely to adversely affect (LAA)” risk designation, EPA notes that “there is also concern for risk due to dermal exposures resulting from spray drift transport to adult and juvenile turtles on beaches.” This statement is patently misleading considering the number of factors that EPA noted that would likely decrease the potential for adult and juvenile exposure on beaches. Thus, the categories of low-medium-high risk are thus misleading at best: they do not appear to be based on anything more than non-transparent professional judgment.

7. The analysis is incomplete

The Weight of Evidence Summaries (Appendix 4-1) do not provide any information about which type of use results in each of the Risk/Confidence combinations. The implication, therefore, is all uses pose the same risk. But this is manifestly untrue and not even consistent with the analytical strategy used in BEs: under that strategy, some of the uses will result in a “No Effect” determination in Step 1 (i.e., no overlap of use with species range/habitat), and for many species, the only overlap is with mosquito control and wide area use (for chlorpyrifos and malathion).

The proposed ‘Federal Action’ potentially requiring consultation is really a collection of proposed actions: the approval through registration review of each separate use of each pesticide, as reflected in product labeling. For this reason, decisions at each step in the process must be made for each of the uses. This was done for Step 1 (Attachment 1-6), but because of the mosquito and wide-area uses for chlorpyrifos, it is not clear in the text that any of the use types with >1% overlap with the species range/habitat were evaluated in Step 2. In addition, no downstream dilution analysis was performed (Chapter 4, Section 6) for chlorpyrifos or malathion, so the potential aquatic impacts of the non-agricultural uses for these active ingredients at Step 2 are not provided. To complete the analysis and support further decision-making, this omission must be corrected.

8. Spatial data was not available for review or undocumented

Spatial files of use footprints and species ranges have not been released for review. Although EPA has stated they are seeking a way to make this data available[3] (but they have no timeframe for doing so), their non-availability renders a thorough analysis of these files as "best available" impossible.

Species presence by Hydrologic Unit Code region (HUC 2) is provided in Attachment 1-10, but the rationale behind using this very large unit and the methodology supporting these pairings is not provided. Presumably a county or sub-county GIS overlay of HUC regional boundaries against species range was performed, but this is not stated.

We doubt that there is any dispute that the highest resolution data should be used to represent species range. In this regard, Section 1.4.1.2 in Chapter 1 states that "FWS requested from the species experts in their Regional and Field Offices the most refined range data (*e.g., sub-county level where possible)* for all listed species under their jurisdiction." But based on the information provided in Attachment 1-10, it appears that less than 10% of the species range files used to assign HUCs were refined beyond county level. The use of county-level range data for the remaining 90+% of the species analyzed dramatically over-estimates extent and results in inaccurate and unrealistic HUC assignments (e.g., deep ocean Sei Whale in HUC 11 (the Arkansas, White and Red River drainages)). Moreover, the methodology used did not make use of the best scientific and commercial data available: as requested by EPA and USFWS for this pilot, the FIFRA Endangered Species Task Force (FESTF) generated and provided species range

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[3] Attachment to Guilaran, T-Y, "Request for Extension of the comment period for the draft biological evaluations for chlorpyrifos, diazinon, and malathion", letter dated 17-May-2016.

maps for each listed species.[4] But we have to date found no evidence that these data products were used for the evaluations in the BEs.

9. Exposure estimates are unrealistic

Aquatic systems

Return frequency: For aquatic exposure estimates, the analysis utilizes a 1-in-15 year return frequency. EPA justifies this choice as matching the hypothetical duration of the 15-year registration review cycle (Chapter 3, section 2.9). But there is no ecological relevance in the selection of this return frequency and it thus must be considered completely arbitrary.

Static water modeling: The aquatic bins are defined based on a fixed set of dimensions applied uniformly across the country. The assumption that all non-flowing aquatic habitats can be represented by waterbodies with dimensions fixed to 3 options is a severe limitation of the assessment. The BEs include descriptions of the environments the bins are meant to represent, such as bin 5 representing “vernal pools, small ponds, floodplain habitats that are cut off from main channel flows, underground pools, and seasonal wetlands.” Bin 5 is described as having a volume of 0 – 100 m^3. As is stated in the BE document, all of the static aquatic bins were parameterized using the low end of the volume range. In the case of Bin 5, a volume of 0.1 m^3 was assumed. This 1 square meter in area, 10 cm deep water body, which can most accurately be described as a puddle, would not be identifiable as a feature on most agricultural landscapes. Their presence would occur immediately after rainfall events, and rapidly disappear due to infiltration and evaporation. The notion that chlorpyrifos EECs in this sized water body have a direct bearing on the protection of listed species has not been defended in a rigorous enough scientific manner, particularly for use in a Step 2 analysis. The evaluations should include additional discussion and justification how a single set of dimensions represents this wide range

[4] See MRID 49575201, 49643401, 49880801.

of listed landscape features. Further discussion of the point can be found in Winchell, et al. (2016b).

In addition, the assumptions of drainage areas to support the static water bins modeled by VVWM are extreme. Especially in arid portions of the country, the drainages are so large that even with a non-extreme rainfall event, runoff and direct precipitation would be of such a volume that the entire volume of the receiving water body would be exceeded. In these cases, even a completely empty pond's capacity would be exceeded, which cannot be accounted for in the conceptual model of the static aquatic bins. (Winchell et al, 2016b details this analysis).

Flowing water modeling: The Bin 2 flowing water Peak EECs are impossibly high due to flaws in the modeling. This is readily demonstrated by comparing receiving water concentrations presented in the BE to model-simulated 1 in 15-year edge-of-field concentration. This analysis shows the receiving water to be drastically (often by an order of magnitude or more) higher than runoff flowing into the same water body. This is physically impossible and inconsistent with all conceptual understandings of the dilution process, as one would intuitively expect dissolved receiving water EECs to be lower than edge of field dissolved EECs. This disconnect from physical reality indicates a fatal flaw in the conceptual model of flowing water bodies in the BEs. A detailed analysis appears in Winchell, et al. (2016b).

The analysis goes on to note that modeled concentrations in the larger flowing water bins (bins 3 and 4) were often exceeding the limit of solubility of the compounds. This should have led to a critical re-examination of the conceptual model of the bins analysis, which summarily assigned bin 3 as 1/5 the concentration of bin 2 and bin 4 as 1/10 the value for bin 2. The failure to do so demonstrates the arbitrariness of the assignments and lack of technical basis. Applying these factors, along with the extreme EECs from bin 2, severely limits the believability of all of the flowing water estimates.

Marine scenarios: The Agency freely admitted that they had no model available to estimate concentrations in the 3 marine aquatic bins. Instead of researching this further (there in fact are well-defined and validated coastal models available), the values generated for similar freshwater bins were applied for the marine bins. These surrogates have inappropriate flow regimes for the marine bins in that the rate, magnitude, and frequency of tidal flushing and currents cannot be approximated by the steady stream inflow/outflow rates used in the surrogate freshwater bins. Pesticide aquatic exposure scenarios implementing appropriate marine and estuary water quality models that account for tidal hydraulics and currents, as well as methods for predicting the pesticide loading from the landscape into these marine systems, need to be developed to allow defensible predictions of pesticide EECs to be made in these types of habitats. In light of this, the marine bin exposures estimated can only be characterized as completely arbitrary.

Downstream dilution: The step 1 aquatic exposure discussion Chapter 1, Section 1.4) indicates several conservative assumptions that lead to an excessive footprint for aquatic exposure. For diazinon (as noted above, a dilution analysis was not done for chlorpyrifos or malathion), the concentrations generated for Bin 2 from the highest use rate are used in a downstream dilution tool that flags particular pixels for inclusion in the tool. Because concentrations are being generated for an extremely small flowing system from the highest use pattern, the starting value is an upper end estimate. This value is then applied to all land use pixels in the landscape (thus not accounting for different use patterns for different land uses), implicitly making the assumption that every pixel of land use is adjacent to a small flowing system and contributing runoff, erosion, and drift. All of these collective assumptions lead to a footprint downstream from a use pattern that causes the evaluation to cover a much larger area than is needed.

Improvements needed for Step 2. Aquatic exposure modeling at Step 2 should move beyond simple screening level approaches that use a single conservative PRZM simulation to predict EECs in flowing water bodies draining heterogeneous watersheds. Step 2 aquatic exposure modeling approaches should include the following attributes:

- Representation of the heterogeneous landscape through explicit simulation of the land uses and soils that comprise a given watershed.
- Spatial explicit predictions of EECs that can be associated with species habitat locations.
- An accounting for variability in pesticide application timing that occurs at the watershed scale.
- Incorporation of Percent Treated Area (PTA) that acknowledges that 100% of potential use sites do not get treated with a given pesticide.

Accounting for environmental variability and model assumption and input uncertainty will support a more robust probabilistic approach to predicting EECs that is required for meaningful risk characterization.

Terrestrial Systems

Terrestrial modeling: It was not possible to fully evaluate the validity of terrestrial exposure modeling due to lack of complete information on modeling inputs and assumptions and the lack of any independent review, validation, or QA/QC on these new or extensively modified models. From a preliminary evaluation, however, it is clear that in the development and implementation of the new assessment tools a number of errors and omissions occurred and led to exposure estimates beyond the realm of plausibility. To estimate exposure of listed terrestrial plants, vertebrates (i.e., birds, mammals and herptiles) and invertebrates to chlorpyrifos, EPA relied on the TEDtool which combines terrestrial models from EPA's standard toolbox including T-REX, T-HERPS, AgDRIFT and TerrPlant. In general, EPA fails to provide adequate description on many of their exposure estimate approaches, and often points instead to the corresponding model user manual located on their webpage. In some cases, however, EPA's method within the TEDtool is not consistent with the appointed model or there are calculation errors in the TEDtool worksheets. Additionally, the BE lacks transparency in the selection of input parameters for modeling purposes, and in the rationale and use of all exposure estimates.

Even in the refined probabilistic avian assessment with TIM and MCnest, exposure and risk were dramatically overestimated – the BE outcome suggests that use of the OP insecticides should have resulted in mass extinction of all bird species, which is clearly not the case. Detailed analysis of modeling input and processing errors can be found in Clemow, et al. (2016).

C. IMPROVED APPROACHES AND CASE STUDIES

In their instruction for commenting (docket reference EPA-HQ-OPP-2008-0850-0855), EPA states that they are seeking ideas on improving their interim BE approaches in a range of subject areas including the use of data, exposure modeling and effects characterization, among others.

In keeping with this request by the Agency, DAS has undertaken an effort to demonstrate improved approaches to the assessment of chlorpyrifos in a series of case studies for terrestrial and aquatic organisms and hopes that the findings can be a constructive addition to the ongoing stakeholder conversations in the advancement of risk assessment science and policy. The case studies show how the application of risk-based approaches at all stages of the assessment of listed species and their habits can make the assessments more reflective of reality and potentially lead to efficiency gains in the process while still being mindful of the goals of the ESA.

The refinements for these case studies are still highly protective and retain many overly conservative elements of the chlorpyrifos BE prepared by EPA. The retention of those elements is not an endorsement of their appropriateness. While showing the impact of scientific improvement, they also demonstrate that even improving the science of the current approach would still result in a process that would utterly fail to meet the timelines established by Congress for bringing pesticide products to market or reevaluating them under registration review. Therefore as stated earlier in these comments, DAS strongly urges EPA and the Services to fundamentally rethink and replace the Interim Approaches employed in the draft BE.

C.1. Terrestrial Species

C.1.1. An improved Step 1 approach

A Problem Formulation and first step of a National Endangered Species Assessment (NESA) for terrestrial listed species and critical habitats within the continental United States[5] was carried out by Teed et al. (2016). The analysis employed methodology consistent with the NAS report, but refined by the execution of a formal risk-based assessment consistent with the EPA Guidelines for Ecological Risk Assessment (1998) in the earliest stage of the assessment. This was accomplished as three sub-phases of the NAS Step 1: 1) a screening-level ecological risk assessment (SLERA) to characterize the potential risk for whole taxa, 2) determination of the proximity of species to the chemical's action area for a range of agricultural uses, and 3)

[5] Species and critical habitats in AK, HI, PR and the territories were not considered at this analysis

application of simple species-specific filters, based on specific life history information and species' presence on federally-managed lands.

C.1.1.1. Problem Formulation

A problem formulation followed the EPA formal process by considering current product use patterns, the environmental chemistry, fate and transport of chlorpyrifos (CPY), the material's toxicity and mode of action, and potential routes of exposure. This analysis yielded two different conceptual models to account for the different exposure routes for flowable (i.e., applied as liquid solution/suspension) and granular formulations of CPY.

In the resulting analysis plan, special attention was given to acute exposure, due to the short half-life of CPY on foliage and environmental matrices, although chronic exposure was also considered as the flowable formulations may be applied multiple times during a cropping season.

In this analysis, a wider range of application rates and retreatment intervals were evaluated than were examined in the draft BE for terrestrial species. The NESA employed a realistic range of application types (based on the analysis of Solomon, et al.) with maximum single application rates as high as 5.64 lb/acre (flowable, CA/AZ citrus); in total, 30 flowable (applied by ground, air and airblast equipment) and 13 granular (ground equipment only) product use patterns were evaluated.

Direct and indirect effect thresholds for the analysis were determined based upon the criteria outlined in the Interim Approaches document. The effects data evaluated concentrated upon guideline, GLP studies and were selected based upon a rigorous quality and relevance assessment.

As a demonstration of potential refinement of the Step 1 analysis carried out in the CPY BE, the Step 1 analysis was broken into three stages.

C.1.1.2. Step 1 – stage 1

In the SLERA, exposure for all taxa was evaluated on the treated field, with the exception of plants, which were evaluated at the edge of the field (assuming listed plants would not inhabit an agricultural field due to repeated disturbance). Exposure for wildlife and invertebrates was evaluated with what essentially the same methods as the BE – T-REX, TerrPlant and T-Herps, while exposures to terrestrial plants was evaluated with AgDRIFT. EPA bundled these same tools (plus an earthworm fugacity tool and a BCF-based model for drinking water) in the TED toolbox. However, the TED tool has not been extensively evaluated/validated, so it is unknown at the present time if similar exposure estimates would result. Off-field exposures from spray drift as a function of distance were also calculated for use in stage 2.

For terrestrial wildlife, the CPY residues on food items on treated areas were calculated and compared intake estimates to effects metrics. For terrestrial invertebrates, the CPY residues on the arthropods food item were considered equal to contact exposure for non-target organisms. For terrestrial plants, edge-of-field spray drift curves (for flowable products) were used to estimate CPY exposure residues and these exposures were compared to effects metrics for monocotyledonous (monocots) and dicotyledonous (dicots) plants (also used as surrogates for listed lichens and ferns). For wetland plants (those with both aquatic and terrestrial lifeforms), combined exposures of spray drift and runoff were estimated in TerrPlant and compared to the terrestrial plant effects metrics.

For flowable CPY, the exposures exceeded the effect threshold for 594 (direct effects) and 555 (indirect effects) of 681 species evaluated. The majority of species removed from further consideration were monocot terrestrial plants and wildlife that are presumed extinct or recently delisted. For granular CPY, 198 of 242 species potentially exposure were in exceedence in the SLERA.

C.1.1.3. Step 1 – stage 2

For stage 2, a proximity analysis of product use patterns and potential species ranges/critical habitat was performed. The use footprint was determined for agricultural uses on (DAS does not support non-crop uses) the same mapping of crop groups to a 5-year composite Cropland Data Layer (CDL) data layer recommended by EPA; however, crop groupings were subdivided into the flowable and granular product types.

Where sub-county species ranges and critical habitat information were available, the spatial data developed by FESTF in consultation with the Services and EPA was used; otherwise county-level information was included.

The two spatial dataset were analyzed to generate a proximity distance database to give the complete set of nearest distances between CPY used areas and species ranges/critical habitat. The resulting database was analyzed in combination with the off-field exposure distances calculated in the SLERA to determine overlap of the use footprint and species locations. This is conceptually identical to the approach taken by EPA in the BE, except that the granularity of different use patterns and formulation types was maintained here.

From this portion of the analysis, an additional 14 species were removed from consideration for the flowable formulation and a single granular-exposure species was removed.

C.1.1.4. Step 1 - stage 3

In this stage, simple species-specific filters were applied: 1) specific life history information that clearly precludes exposure, and 2) species (or critical habitat) presence is solely on federally managed lands. These simple filters were chosen because they can be applied to all species quickly and efficiently to help focus the assessment and resources on species and their critical habitat that are more likely to be exposed. The life history attributes precluding exposure were developed by FESTF from a variety of well-documented sources and included species that are only found at high elevations, deep within forests, in the ocean, or in another unique habitats that would preclude exposure from the use of OPs in agricultural crops. The complete findings by species/county record are documented in an attachment the report summarized here.

The other filter applied to those species and species locations residing wholly on lands administered by the Federal Government or on Indian lands. Before pesticides can be used on

Federal Lands and Indian lands, a plan for their use must be developed under the National Environmental Policy Act (NEPA) followed by consultation under Section 7 of ESA. Therefore, species located only on these lands are protected and not considered part of the federal action of registration or re-registration under FIFRA.

Upon application of the filters, an additional 117 species were determined to not be of concern for flowable product applications, with a corresponding 52 species for granular uses.

C.1.1.5. Final findings

At the conclusions of the refined Step 1 process, 463 of 681 species remained to be evaluated at Step 1 for flowable uses, while for the granular use, 145 species remained.

This analysis showed that the uncomplicated application of ERA concepts at an early step of the ESA assessment process has the possibility to nominally streamline the assessment process. In addition, the increased detail in use patterns and formulation types in line with a detailed conceptual model for exposure can offer options to identify specific use practices that might be a greatest concern.

C.1.2. Step 2 case study

As part of the chlorpyrifos BE, EPA conducted refined risk assessments for 13 selected listed bird species as a case study of a refined Step 2 analysis (Moore, et al., 2016). The species included the Kirtland's warbler (*Setophaga kirtlandii*), an endangered migratory species that nests exclusively in young jack pine stands in Michigan and Wisconsin, and winters in the Bahamas.

EPA's refined risk assessment for the Kirtland's warbler relied on the probabilistic Terrestrial TIM and MCnest models. Despite being probabilistic models, the models are highly conservative in many aspects with regard to determining risks of CPY to the Kirtland's warbler. For example, TIM assumes that Kirtland's warblers spend a significant portion of their foraging effort in and immediately adjacent to treated pastures during the breeding season. Decades of intense observation, however, have shown that warblers only forage in young jack pine forests during the breeding season, where there are no labeled uses for CPY. Other inputs used in TIM were also highly conservative. For example, EPA relied on a generic nomogram for terrestrial invertebrate residue levels which is at least 4-fold higher than a CPY-specific nomogram derived for foliage-dwelling invertebrates in orchards based on the results of well conducted field studies. MCnest also has a number of overly conservative assumptions. For example, if the conservative estimate of chronic exposure from TIM exceeds the most sensitive avian reproduction NOEL, complete nest failure is assumed. Perhaps not surprisingly, given the combination of conservative assumptions in TIM and MCnest, the models predicted very high mortality and near total reproductive failure for Kirtland’s warblers annually for the wide area and pasture use patterns, two of the three use patterns investigated. No bird species, listed or otherwise, could withstand such catastrophic effects without going extinct. The reality is that the Kirtland’s warbler has dramatically increased in abundance in recent decades despite widespread usage of chlorpyrifos. This contradiction between EPA’s model predictions and the real world indicates that a more scientifically defensible modeling effort is required for Kirtland’s warblers potentially exposed to flowable CPY.

Probabilistic, species-specific exposure models were developed to assess risks of flowable CPY to Kirtland’s warblers during the breeding season and during spring and fall migrations. The breeding area model simulates acute and chronic exposure and risk to each of 10,000 birds over a 60-day period following initial CPY application. The model is highly species-specific with regard to the foraging behavior of Kirtland’s warblers during the breeding season. In addition, the model inputs used CPY-specific data when available. For the breeding area assessment, a representative use pattern for each of the eight crop classes that could be within 3 km of the breeding areas of Kirtland’s warbler was simulated. In all cases, it was assumed that the maximum application rate and number of applications, as well as the minimum treatment interval, were used.

The migration model simulates 10,000 birds during the course of their 12 to 23 day migration between their breeding area and the Bahamas. The model takes advantage of over a century of observations of when, where and for how long Kirtland's warblers forage in different habitats during the course of their migration. The data indicate that warblers only infrequently stopover in habitats that could be treated with CPY (e.g., apples in the Northeast, pecans in Georgia, oranges in Florida).

C.1.2.1. Final findings

Using these more realistic and species-specific breeding area and migration models and inputs resulted in predictions of very low acute and chronic risk of CPY to Kirtland's warblers. These refined risk assessments deliberately erred on the side of conservatism (e.g., assuming maximum applications rates, assuming 100% crop treatment in the breeding area model, and using the most sensitive chronic NOEL and LOEL for effects). Thus, the quantitative risk predictions should be considered as upper bounds. These results clearly indicate that the labeled use of chlorpyrifos poses *de minimis* risk to Kirtland's warblers.

This case study clearly demonstrates that application of probabilistic and realistically-parameterized modeling can yield assessments more reflective of real-world observations.

C.2. Aquatic Species

C.2.1. An improved Step 1 approach

A problem formulation and Step 1 analysis for the agricultural uses of chlorpyrifos was carried out to assess the potential risk to aquatic species in the continental US by Giddings and Winchell (2016a). The analysis employed methodology consistent with the NAS report, but refined by the execution of a formal risk-based assessment consistent with the EPA Guidelines for Ecological Risk Assessment (1998) in the earliest stage of the assessment. At Step 1, the process was subdivided into distinct stages: 1) a county-level and listed species co-occurrence; 2) a Screening Level Ecological Risk Assessment (SLERA); 3) an action area-habitat co-occurrence analysis; 4) an application of addition species-species filters based on biological factors and occurrence in federal lands.

C.2.1.1. Problem Formulation and analysis plan

The formal problem formulation reviewed available information about CPY uses, environmental properties, and aquatic toxicity to develop a conceptual model of potential routes of exposure of aquatic organisms to CPY; to identify assessment endpoints; and to outline an analysis plan that will guide the assessment of risks to threatened and endangered aquatic species potentially exposed to CPY. The resulting Step 1 analysis plan focused upon aquatic phase amphibians, corals, crustaceans, fish, insects, mollusks, and plants. Terrestrial species, as well as birds, mammals, and reptiles in aquatic habitats, are not included. Aquatic birds, mammals, and reptiles will be evaluated in Step 2 of the CPY assessments, to be submitted at a later date.

Chlorpyrifos use patterns and extent were based upon an analysis of chlorpyrifos labels (Solomon et al, 2014) and aggregated species location information to yield the initial area of analysis.

Effects thresholds were derived consistent with the EPA Interim Approach guidance, based upon acute and chronic toxicity data taken from an analysis by Giddings et al. (2014). A rigorous data quality and relevance rubric was applied to the toxicity studies and SSDs were formed where appropriate for threshold-setting.

As a demonstration of potential refinement of the Step 1 analysis carried out in the CPY BE, the Step 1 analysis was broken into four distinct stages.

C.2.1.2. Step 1 – stage 1

Based upon the county use-species records extracted from the FESTF IMS, 306 species and 11,108 species-county records were found to co-occur with CPY use sites, with 281 species and 4831 species-county records of no concern and removed from further analysis.

C.2.1.3. Step 1 - stage 2

For the SLERA worst-case exposure scenarios for PRZM modeling were defined for 13 chlorpyrifos-specific CDL cropping group that applied within each HUC2. These were linked with species-appropriate static and flowing water aquatic bins; drainage areas were rationalized to appropriate drainage area to normal capacity ratios. In contrast to the BEs, the Surface Water Assessment Tool (SWAT) was used to represent the flow water bins, due to its ability to more realistically simulate flowing channel hydrology.

For acute effects, 105 species (6 fish and 99 molluscs) received a No Effect finding, however, when chronic effects were considered only 91 mollusc species were removed from consideration, corresponding to 1401 species-county records.

C.2.1.4. Step 1 - stage 3

The third stage is an assessment of listed species co-occurrence with the CPY Action Area, defined as the area where CPY may be used plus the area where CPY transported by runoff, spray drift, or downstream flow may exceed the effects thresholds for the most sensitive species. Unlike stage 1, which is based on county-level species location data, this stage uses spatial data on the location of species and designated critical habitat.

The analysis resulting in 106 species in 312 species-county records receiving a No Effect finding. .

C.2.1.5. Step 1 – stage 4

Additional information on species habitat and occurrence on lands administered by the Federal government or Indian tribes is examined in the fourth stage. Species whose habitat requirements preclude exposure to CPY, and species residing wholly on Federal and tribal lands (and therefore outside of the Federal action), are designated “No Effect.”

There were No Effect findings at the stage for 42 species due to habitat exclusions; these comprised 26 fish, 1 insect, 10 mollusks, and 5 amphibians, while due to federal land exclusions, there were No Effect findings for 27 species: 14 fish, 6 crustaceans, 1 insect, 6mollusks, and 1 amphibian..

C.2.1.6. Final findings

Overall, 35% of the species received No Effect findings and can be considered "resolved", with at least one No Effect finding in all counties where they occur. The greatest percentage of resolved species (55%) was found for mollusks; amphibians (26%), fish (24%) and insects (20%) were intermediate; and only 5% of crustaceans, and no coral species were resolved. Across all taxa, 36% of species-county records were resolved, mostly for mollusks, amphibians, and fish.

Under this multi-stage approach, 204 species, as well as aquatic birds, mammals, and reptiles (which were not included in this assessment), would be further evaluated in a Step 2 assessment. The goal of Step 2 will be to apply refined assessment methods to distinguish species which CPY may affect, but is not likely to adversely affect, from those which CPY is likely to adversely affect and which therefore require consultation between EPA and FWS or NMFS. It is also possible that Step 2 will reveal that additional species warrant a No Effect finding.

C.2.2. Step 2 case study

A case study, demonstrating a refined chlorpyrifos aquatic exposure modeling approach applied to species inhabiting flowing water habitats in the Ohio River basin, HUC2 05, was performed by Winchell, et al. (2016a). The assessment evaluated 23 endangered crustaceans, mollusks, and fish[6] that may inhabit water bodies with EPA habitat Bin 2, Bin 3, and Bin 4 characteristics. This study was motivated by the recognized need to develop methods that quantitatively account for uncertainty and variability in environmental and agronomic factors that impact the potential effects of pesticide use on endangered species, and to address the need for a watershed-scale flowing water modeling approach capable of routing from small headwater catchments to main stem regional rivers. The approach presented in this study was designed to fit within Step 2 of the endangered species effects determination process when decisions of "likely to adversely affect" or "not likely to adversely affect" are made.

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[6] The 23 species were a subset of the species that could not be assigned a "no effect" determination with the updated Step 1 analysis in Giddings and Winchell (2016a) (summarized in Section C.2.1, above).

The refined Step 2 aquatic exposure modeling approach differed significantly from the Step 2 aquatic exposure modeling approach or flowing water presented in EPA's CPY BE, and followed many of the NAS panel recommendations on approaches for estimating risks to endangered species from pesticides (NRC, 2013). The most significant differences between the Step 2 modeling approach demonstrated in this assessment and EPA's Step 2 approach can be categorized as follows:

- Species exposure relevance: The exposure predictions generated in this assessment were specific to individual species ranges based on the best available species location data. The exposure predictions in EPA's Step 2 analysis were at the HUC2 scale.
- Receiving water and routing model: The Soil and Water Assessment Tool (SWAT) was implemented as the receiving water and stream channel routing model in this assessment. SWAT is as a watershed scale model capable of making predictions in small headwater streams to major continental scale rivers, and for decades has been implemented internationally by scientists studying water quality issues in flowing water systems. The EPA used the VVWM model, parameterized as a constant volume water body that can overflow, to represent stream and river systems draining small headwaters to major river basins.
- Baseflow in streams and rivers: The HAWQS implementation of the SWAT model was used to generate HUC12-specific, daily varying baseflow contributions to streamflow. Baseflow accounts for greater than 50% of total flow in many watersheds across the US, and varies from annual to daily time scales. EPA's approach in Step 2 modeling did not account for baseflow.
- Use of best available spatial data: This assessment used best available crop, soils, and weather spatial datasets to characterize the critical exposure-influencing landscape conditions in watersheds that drain to flowing water habitat within specific species ranges. EPA's assessment used a single representation of landscape conditions per crop group and one to two weather conditions to represent all species habitat within a HUC2 region.
- Agronomic practices: Variability in chlorpyrifos application timing following regionally specific practices was accounted for in this assessment to achieve a more realistic estimate of resulting exposure. This variability in applications was represented both temporally and spatially and allowed for a realistic watershed-scale pattern of applications to occur. The approach followed by EPA considered only a single application date sequence per crop group and HUC2, and included no variability in timing across a watershed.
- Pesticide use: This assessment included a refinement of the percent treated area based on six years of recent chlorpyrifos use data. The EPA's assessment assumed 100% treated area for all crops.

- Probabilistic analysis: The modeling approach presented considered an ensemble of model simulations that accounted for uncertainty in pesticide environmental fate, baseflow hydrology, and channel routing velocity. The approach also incorporated the spatial distribution of flowing water habitat segments throughout a species range to determine the probability of species co-occurrence in watersheds with variable exposure. EPA's Step 2 modeling for chlorpyrifos considered multiple chlorpyrifos use patterns per crop group within a HUC 2, but did not account for other uncertainties in their final EECs or develop probability distributions based upon more than 1 model simulation.

The spatially explicit, probabilistic aquatic exposure modeling approach followed in this study resulted in refined worst-case EECs that were four orders of magnitude or more lower than the EPA results. These probabilistic estimates of exposure could in turn be combined with distributional representations of aquatic effects in a species-specific risk assessments. These model-predicted EECs were still more than 10 times higher than the maximum monitored concentration in the same HUC2 region and are likely to still be conservative estimates of real-world concentrations.

The flowing water modeling approach presented offers a possible path forward in addressing challenges faced in deriving meaningful exposure predictions in flowing water bodies that encompass a wide range of locations sizes, and characteristics. This methodology is readily reproducible and extendable to assess aquatic species in the other HUC2 watersheds across the United States and will continually be improved as the research continues and better data and computational methods become available.

D. SUBMISSIONS TO DOCKET EPA-HQ-OPP-2008-0850

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E. ADDITIONAL REFERENCES CITED

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