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Response to EPA's Final Biological Evaluation for Chlorpyrifos

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This report represents data generated after the effective date of the EPA FIFRA Good Laboratory Practice Standards.

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This study does not meet requirements of 40 CFR Part 160

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EXECUTIVE SUMMARY

Registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (*FIFRA*) constitutes a federal action under the Endangered Species Act (*ESA*). The *ESA* Section 7 prescribes that under some circumstances, the Environmental Protection Agency (EPA or "the Agency") must consult with the Fish and Wildlife Service and/or National Marine Fisheries Service ("the Services") to ensure that a pesticide's registration (a federal action) is not likely to result in the destruction or adverse modification of designated critical habitat or jeopardize the continued existence of federally endangered and threatened species (hereafter, "listed species"). The EPA, in association with the Services and United States Department of Agriculture (USDA), prepared Biological Evaluations (BEs) for three pilot pesticides (chlorpyrifos, diazinon and malathion). These BEs were intended as initial case studies of how to conduct complex, large scale risk assessments for hundreds of listed species from the use of a pesticide in the United States.

The BEs were developed following the "Interim Approaches" process agreed to by EPA, the Services and USDA (Agencies, 2013) to implement some of the recommendations from the National Academy of Science's National Research Council (NRC) report "Assessing Risks to Endangered and Threatened Species from Pesticides" (NRC, 2013). The NRC recommended a three-step process to evaluate potential risks and satisfy EPA's consultation obligations under the *ESA* Section 7. At each step of the process, EPA assigns an effects determination (also referred to as a "call") to each species and/or critical habitat. In Step 1 a "No Effect (NE)/May Affect (MA)" call is made based on a co-occurrence analysis and the most sensitive effects threshold. If a MA call is made for a species or critical habitat in Step 1, it proceeds to Step 2 where a "Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)" call is made based on taxon-specific exposure and effects estimates. Species and/or critical habitats receiving a MA/NLAA finding are subject to informal consultation with the Services to determine concurrence. Species and/or critical habitats that are MA/LAA enter Step 3, where a formal consultation occurs with the Services. The Services produce a Biological Opinion (BiOp) with the goal of making a "Jeopardy/No Jeopardy" finding for listed species and an "Adverse Modification/No Adverse Modification" determination for the designated critical habitat.

On April 11th, 2016, EPA released the draft BEs for public comment in support of registration review for the pilot pesticides. The release of the draft BEs marked the start of a 60-day public comment period, which terminated on June 10th, 2016. Despite requests for an extension on the comment period from many stakeholders, made primarily because of the massive amount of information contained in each BE (for chlorpyrifos, 125 files of approximately 3.5 GB, not including the supporting WoE Tools), EPA did not adjust the comment deadline. The Agency cited a court-mandated deadline that they and the Services were working under, as well as the early release of parts of the draft BEs in December 2015, as the primary reasons for denying extension of the comment period. Comprehensive review of the draft BEs was unachievable within the comment period, and this was complicated by multiple draft versions (i.e., December 2015 and March 2016 releases). Despite these impediments, thousands of comments were submitted by stakeholders, in which a number of substantive concerns, including critical errors, were identified. Nearly seven months from the close of the comment period, the Agency released the final BEs for the pilot chemicals (January 17th, 2017; EPA, 2017a). The final BEs were accompanied by a short memorandum summarizing how public comments were addressed (EPA, 2017b).

The EPA memorandum indicated that EPA opted to primarily address errors or transparency issues. Notwithstanding numerous concerns regarding the Agency's methods, EPA (2017b) admitted that they made few changes to the processes employed in the BEs, citing only the revised modeling approach for flowing waterbodies. The Agency professed that in response to comments, it was "incorporating those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December, 2017."

EPA's revised chlorpyrifos BE (EPA, 2017a) attempted to evaluate the risk of adverse effects for all ESA listed species, proposed species, and candidate species in the United States. In the final BE, EPA (2017a) reached the MA/LAA determination for 1778 out of 1835 assessed species (i.e., 97%) and 784 of the 794 assessed critical habitats (98%), a result that is almost identical to the draft chlorpyrifos BE. These final calls mean that formal consultation and biological opinions are required for almost all species and critical habitats evaluated. Completing formal consultations on this scale is a near impossible task for the Services. While it is acknowledged that considerable effort went into the development of the pilot BEs, it is apparent that using the Interim Approaches (Agencies, 2013), as applied, has resulted in a weighty, ineffective, and indefensible process for assessing risks posed by pesticide use to listed species.

Dow AgroSciences LLC (DAS), a registrant of chlorpyrifos, had serious concerns regarding the effects determinations made in the draft chlorpyrifos BE (EPA, 2016a). These were documented in responses submitted to the Agency during the public comment period for the draft BEs (Clemow et al., 2016; Giddings and Winchell, 2016a; CLA, 2016; FESTF, 2106). The response document contained initial comments on the technical aspects of the draft chlorpyrifos BE, with particular emphasis given to methods, data used, and assumptions made. EPA's draft chlorpyrifos BE fell far short of being scientifically defensible.

DAS still has serious concerns regarding the effects determinations presented in the final BE (EPA, 2017a). This response document reviewed the primary comments made by DAS and other stakeholders (Crop Life America and FESTF) on the chlorpyrifos draft BE, described how EPA addressed some of these comments, and revisited those issues that went unaddressed. As before, particular emphasis was given to methods, data used, and assumptions made.

The chief concern DAS had with the draft chlorpyrifos BE was that, in contrast to the NRC (2013) recommendations, risk quotients (RQs) were used to determine risk designations in Step 2. The NRC (2013) specifically stated that "[Risk quotients] are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes." The NRC conclusion is consistent with recommendations in the EPA agency-wide guidelines for ecological risk assessment (ERA) (EPA, 1998), which are cited in the NRC report. The EPA ERA guidance highlights the importance of the explicit treatment of uncertainty, including distributions of values ignored in risk quotients that are better described by probability statements. NRC (2013) recommended "using a probabilistic approach that requires integration of the uncertainties (from sampling, natural variability, lack of knowledge, and measurement and model error) into the exposure and effects analyses by using probability distributions rather than single point estimates for uncertain quantities. The distributions are integrated mathematically to calculate the risk as a probability and the associated uncertainty in that estimate. Ultimately, decision-makers are provided with a risk estimate that reflects the probability of exposure to a range of pesticide concentrations and the magnitude of an adverse effect (if any) resulting from such exposure." Regrettably, the Agency did not opt to rectify the fault of persistent use of RQs in the final BEs.

A number of concerns identified in the draft BEs by DAS and other stakeholders (CLA, 2016; FESTF, 2016) went unaddressed by EPA in the final chlorpyrifos BE. Several of the concerns of higher consequence for the risk characterizations are listed below.

- **Data Quality Assurance**. Many studies selected by EPA for threshold values were not evaluated for data quality and relevance, and when evaluated, many evaluations did not follow EPA's own study quality criteria. EPA used threshold values from studies deemed invalid by the Agency, or deemed acceptable for quantitative use when quantitative criteria were not met. When the quality of the data driving the assessment is questionable, so are the results. EPA failed to make use of best available chemical-specific data in the BE. For example, high quality amphibian data provided in the peer reviewed article by Wackmans et al. (2006) should have been considered by EPA.

- **Model Quality Assurance**. In comments submitted on the draft BE, a number of errors in the WoE tools were identified. Many of these errors were not corrected for the final BE. We remain concerned that EPA has not sought an independent evaluation of the quality and utility of the WoE tools. Though the principal model in the WoE tools (TEDtool) is purportedly derived from existing EPA toolbox applications, considerable changes have been made in the changeover that are noted herein. We recommend that the WoE tools be independently reviewed before being used in a regulatory capacity.

- **Unsubstantiated Endpoints**. DAS is concerned with the use of toxicological effects metrics ("thresholds") that were not explicitly linked to apical ecological risk assessment endpoints (mortality, growth and reproduction), nor demonstrably associated with the stated protection goal of individual fitness. The binary, most-conservative-RQ-based effects determinations were mostly driven by thresholds that do not necessarily relate to the protection goals of the biological evaluation.

- **Rudimentary Spatial Analysis**. The Agency made the assumption that mosquito adulticide applications may be made anywhere in the United States. Similarly, for other uses, EPA assumed that all label uses can be carried out anywhere in the United States, without accounting for where particular crops are grown, timing of application, and legitimate co-occurrence.

- **Inappropriate Use of Aquatic Exposure Models**. The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for chlorpyrifos, these models were used to simulate landscape and aquatic fate processes in continental-scale watersheds and rivers. Even from a screening-level perspective, this approach was a gross overextension of the models' capabilities. The results obtained from these models and applied to represent environments they were never designed for are not acceptable.

- **Overgeneralization of Aquatic Exposure Predictions.** The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by the same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact, their occurrence is typically constrained to very specific locations (they are endangered). The over-generalization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to the misinterpretation of the extent of exposure and concomitant risk.

- **Omission of Best Available Spatial Data and Tools.** High resolution spatial datasets representing, crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed-scale hydrologic and water quality models (e.g., Soil and Water Assessment Tool - SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions did not account for the critical landscape and agronomic variability known to exist in reality and were based on modeling methods that are incapable of reflecting the complexities of the environmental processes they were attempting to simulate.

- **Compounding of Conservatism**. Multiple deterministic exposure model inputs are "upper bound" or biased high (e.g., on-field exposure, upper bound RUDs, 90th percentile on the mean half-lives), and thus the resulting exposure estimates are expected to be conservative and unlikely. Accordingly, the Agency concluding LAA for any species based on threshold exceedance with these biased and deterministic exposure estimates is nonsensical.

- **Illogical RQs**. Discrepancies remain between exposure durations in toxicological studies and EECs used to generate RQs in the chlorpyrifos BE. Risk designations are unsound when effects metrics generated from long exposure durations (e.g., several days to months) are compared to daily average EECs, because they do not account for the exposure time required to elicit measured effects, nor any recovery when exposure is diminished or removed.

- **Lack of Transparency.** EPA attempted to address the transparency issues in the final chlorpyrifos BE. However, the effort was inadequate and many transparency concerns persisted. For example, key cells in the WoE tools used in making species calls remained hidden and locked. In addition, drift models were unreferenced and unexplained, and methods were not consistently presented, with numerous contradictions found throughout the final document and across prescribed methods (e.g., Agencies, 2013).

- **Outstanding Errors.** Notwithstanding the fact that EPA did correct some of the errors identified during the public comment period, many remained in the final BE. For example, major errors remained in the dermal exposure and body mass scaling equations (herptiles) in the TEDtool. Further, the terrestrial EECs presented in the chlorpyrifos BE did not match those generated in the associated TEDtool.

- **No Weight of Evidence**. Despite claiming use of a weight of evidence approach, it seems that EPA based almost all of their effects determinations solely on the most conservative RQ of a suite of RQs generated for each species and critical habitat. EPA gave equal "weights" to threshold exceedances associated with direct effects to survival, growth and reproduction as they did to exceedances of sublethal thresholds that were not explicitly linked to individual fitness/the protection goal (e.g., endpoints for avoidance behavior, AChE inhibition, etc.). Furthermore, other lines of evidence (e.g., incident reports, field studies, monitoring data, etc.) were not directly considered in species and critical habitat calls.

- **A Lack of Risk Estimates/ Probabilistic Methods.** As articulated above, NRC (2013) discouraged the use of RQs and endorsed probabilistic methods for the assessment of risks to listed species by pesticide use. Risk is the probability or likelihood of a particular outcome. The Agency did not estimate risk to listed species in their BEs (with the possible exception of the 13 birds analyzed with TIM/MCnest). The spatial and temporal variability and input/process uncertainty of chlorpyrifos exposure is significant. A scientifically valid analysis of exposure requires that probabilistic methods be employed to determine the likelihood of particular effect levels.

The issues itemized above resulted in adverse outcomes (LAA) for individuals of the majority of listed species considered in the BE. DAS contends that the production of the three pilot BEs has demonstrated that the Interim Approaches (Agencies, 2013) and their application require reform. The chlorpyrifos BE did not deliver a scientifically sound foundation on which to make effects determinations under the ESA. Although the Agency did correct some of the errors and oversights found in the draft BE, EPA neglected to address key concerns raised by stakeholders regarding the overly conservative exposure assessments and the faulty "weight-of-evidence" approach. Finally, EPA did not actually estimate risks to listed species nor their critical habitat, which fundamentally requires probabilistic methods (NRC, 2013).

TABLE OF CONTENTS

LIST OF TABLES

1.0 INTRODUCTION

The Environmental Protection Agency (EPA or "the Agency"), in conjunction with National Marine and Fisheries Service (NMFS), the Fish and Wildlife Service (FWS), and the United States Department of Agriculture (USDA), prepared draft Biological Evaluations (BEs) for three pilot chemicals: chlorpyrifos, diazinon and malathion. These draft BEs represented the first case studies for national assessments of the potential effects of pesticides to listed species (threatened or endangered) and the critical habitat on which they depend, carried out by the federal government.

On April 6th, 2016, the EPA released the draft BEs for review. This date marked the start of a 60-day public comment period. On April 29th, 2016, a 120-day extension of the public comment period was requested by Dow AgroSciences LLC (DAS), Makhteshim Agan of North America, Inc. (ADAMA), and FMC Corporation because the 60-day comment period was deemed by these registrants as insufficient for review of the contents of the draft BEs. The draft BEs exceeded 12,000 pages and contained links to Excel files and model output files with millions of lines of data, and contained a number of omissions and errors (including broken links), making comprehensive review impossible. Extension requests were also submitted to EPA by Edward M. Ruckert, representing the American Mosquito Control Association (May 10th, 2016), CropLife America (May 6th, 2016), and James Callan, representing 39 grower groups (May 9th, 2016). The request for extension was denied by EPA in a formal letter sent via e-mail on the 17th of May, 2016 to the counsel for the registrants (David B. Weinberg and David E. Menotti). In the justification, the Agency cited a court-mandated deadline under which they and the Services were working, as well as the early release of parts of the BEs in December 2015 (allowing for some review prior to the official comment period). However, substantial changes made to the draft documents posted in December required additional efforts by affected parties to identify and evaluate modifications made to the documents, supporting data, broken links, and other errors in the draft BEs.

Dow AgroSciences LLC (hereafter referred to as DAS) contracted Intrinsik Corp. (hereafter referred to as Intrinsik) and Stone Environmental (hereafter referred to as Stone) to assist in the review and evaluation of the portions of the chlorpyrifos BE pertaining to the assessment of risk to terrestrial and aquatic listed species (or species that have an aquatic or terrestrial component of their life cycle).

On January 17, 2017, EPA released their final or “revised” biological evaluations (EPA, 2017a), along with a document outlining how they addressed the public comments they received on their draft BEs (EPA, 2017b). EPA’s response document outlined how they categorized each of the 78,000 comments, with 120 substantive comments that were noted to merit detailed review. EPA said that they intended to incorporate those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December 2017. As such, EPA stated that the major revisions made to the draft BEs included, but were not limited to: a revised modeling approach for flowing aquatic waterbodies; error correction and improved transparency; the addition and deletion of species based on changes in listing status; and refinements to some of the aquatic species ranges. Upon review of the final BEs, DAS is providing comments on how EPA addressed the original comments provided by DAS on the draft BEs as per Clemow et al. (2016).

In general, there were several limitations to the revisions made by EPA in the final BE. As such, similar to the formatting of the original response document (Clemow et al., 2016), this response document first addresses the effects assessment conducted by EPA (Section 2.0), followed by the exposure assessments for terrestrial (Section 3.0) and aquatic receptors (Section 4.0), and the Agency's effects determinations for listed terrestrial species in the chlorpyrifos BE (Section 5.0). The document concludes with a summary of the overarching problems identified in the BE (Section 6.0).

2.0 EFFECTS ENDPOINTS AND DERIVATION OF THRESHOLDS

DAS (Clemow et al., 2016) and CLA (2016) expressed a number of concerns with the way EPA selected effects thresholds to assess direct and indirect effects of chlorpyrifos to listed terrestrial vertebrates, plants and terrestrial invertebrates in their draft BE (EPA, 2016a). Upon review of the final BE (EPA, 2017a), it is apparent that only a limited number of comments submitted by Clemow et al. (2016) for the selected effects metrics were considered. As such, this section outlines the major concerns DAS has with the selected thresholds. Similar to the previous review, this chapter contains comments focusing on the following areas: data selection and evaluation process (Section 2.1); consideration of endpoints of uncertain ecological relevance (Section 2.2); inappropriate use of NOELs as effects thresholds (Section 2.3); and taxon-specific review and critique of effects characterizations (Section 2.4). The last section (Section 2.4) is organized by taxon to facilitate review.

2.1 Data Selection and Evaluation Process

In their response to comments memorandum, EPA (2017b) indicated that they had increased the transparency of their work in the final BE (EPA, 2017a). However, EPA (2017a) did not address many of the comments and concerns reported by DAS (Clemow et al., 2016), particularly on the selection and evaluation of data used to develop effects thresholds. As noted previously by DAS, the process by which toxicity data are identified plays a critical role in the eventual outcome of any risk assessment (Clemow et al., 2016), and while EPA itself has developed a number of guidance documents to aid in the internal evaluation of toxicity studies (EPA, 2002; 2003; 2004a, b; 2011a), it is questionable as to whether or not these criteria were consistently followed by the Agency for the draft and final BEs.

EPA (2016s) stated that registrant-submitted studies were reviewed using “the Agency’s Standard Evaluation Procedures (SEP)”. However, in the draft BE, these evaluation procedures were not described in any associated attachment or appendix, nor was an external link to a publicly-available description of these procedures provided. This remained true of the final BE documents (EPA, 2017a). Additionally, neither the study evaluations nor the final study classifications for these registrant-submitted studies were provided anywhere in the draft or final

BEs (EPA, 2016a; 2017a). As noted previously by DAS (Clemow et al., 2016), to maintain clarity and transparency, EPA should provide the study Data Evaluation Records (DERs) for all reviewed registrant-submitted studies considered in the BE. Similarly, in the draft BE, the process for evaluating open literature was carried out “largely using the approach outlined in the agency’s guidance for evaluating ecological toxicity data in the open literature” with modifications from guidance detailed in Attachment 1-8 of the BE (EPA, 2016a). Although the Agency fixed the broken hyperlink relating to guidance for reviewing open literature from the draft BE (EPA, 2016a), there remained no explanation in the final BE (EPA, 2017a) for why these studies should receive a less stringent review than registrant-submitted studies. Following this guidance, studies that have not undergone a thorough and stringent review would be included in species sensitivity distributions (SSDs). This practice is in direct disagreement with EPA’s insistence that they are “committed to using the best scientific and commercial data for ESA-FIFRA analyses” (EPA, 2017b). EPA (2017a) also used studies for which the chemical characterization was identified as “unknown” to build their SSDs in the final BE. DAS continues to highlight the fact that the indistinct approach to open literature used by EPA is scientifically unsound and questions how EPA is justified in using toxicity data from studies that have not properly characterized the tested chemical for relevance.

As previously noted by Clemow et al. (2016), DAS continues to support the outcome of the SETAC Pellston workshop entitled “Improving the usability of Ecotoxicology in Regulatory Decision-making”, which recognizes that all studies should be evaluated using a common scheme to identify best available data for risk assessment, and not solely focus on the most sensitive data regardless of the data quality. Further, the transparency of the evaluation scheme is critical to the reproduction of evaluations. The National Research Council (NRC, 2013) has also noted the lack of formal and consistent approaches in defining “best available data” among EPA reports, and has stated that lower quality data should not be used to drive risk assessments. As such, a quality review process is recommended. The fundamental use of data quality and best available data has not been improved for the final BE.

2.2 Consideration of Endpoints of Uncertain Ecological Relevance

In their final BE, EPA (2017a) maintained its ignorance of the Interagency Approaches (Agencies, 2013), which states that "Establishing "May Affect" thresholds for given taxa may also, when supported by professional judgment, be based on toxicity studies that are conducted at the sub-organism level (*e.g.*, on organs or cells), provided they can be linked to environmentally relevant exposures that can influence survival, growth, or reproduction". There were no changes made to Attachment 1-4 in the final BE (EPA, 2017a) compared to the draft BE (EPA, 2016a), where EPA describes the process for determining effects thresholds. As such, EPA did not address the comments pertaining to clarity for how sub-organismal data could be used in the BEs to establish thresholds, especially given the difficulty of relating such endpoints to effects on apical endpoints (survival, growth or reproduction).

As noted by NRC (2013) and highlighted by Clemow et al. (2016), to properly incorporate sublethal effects into an ecological risk assessment, it is necessary to provide an explicit relationship (not solely based on professional judgement) between the sublethal effect in question and apical endpoints (i.e., survival, growth, and/or reproduction). In many cases, where EPA (2016a; 2017a) had presented sublethal endpoints (e.g., the inclusion of biochemical, cellular, and behavioral effects in many of the 'data arrays'), there was no evidence or even discussion provided as to the ecological relevance of these endpoints. Without establishing this relationship, it is unclear how these effects can be considered in a weight of evidence approach. This comment applies to all of the 'data arrays' presented in the BE. As it stands, EPA did not account for this comment in their final BE.

2.3 Inappropriate Use of NOELs as Effect Thresholds

In their response to EPA's draft BE, Clemow et al. (2016) provided comments on the inappropriate use of NOELs as effects thresholds in the draft BE for chlorpyrifos. It is a concern of DAS, that ultimately, NOELs are the effects thresholds driving most, if not all of the risk designations, and in turn the species and critical habitat calls in the final chlorpyrifos BE. The use of NOELs in ecological risk assessment has long been criticized due to the inherent deficiencies of the metrics as relative measures of toxicity, which rely directly on the selected treatment levels, sample size and issues of low statistical power (Hoekstra and Van Ewijk, 1993; Moore and Caux, 1997; Landis and Chapman, 2011; Jager, 2012; Murado and Prieto, 2013). Accordingly, regulatory risk assessors have moved away from the use of NOELs in favor of ECx values (e.g., OECD, 1998; CCME, 2007). Considering such criticism, it is surprising that the Agency has consistently used these metrics in an evaluation that is purported to be based on best available scientific information. As described in the comments on the draft BEs, Clemow et al. (2016) commented that the Interim Approaches recommended the use of ECx values in the interim approach (Agencies, 2013). However, it seems that EPA opted to dodge data analyses and simply use the author-reported NOELs from toxicity studies (EPA, 2016a; 2017a). In some cases, the use of NOELs may be practical. For instance, when sample size is large it may make sense to use a NOEL as a cursory screening-level metric and/or when the data are not conducive to generating a meaningful dose-response. However, in a succeeding refined analysis, such as Step 2, the Agency should be giving precedence to more refined metrics (e.g., dose-response curves) when possible.

All of these discussion points were described by Clemow et al. (2016) in the comments from DAS on EPA's draft BE (EPA, 2016a). In response to the submitted comments, EPA (2017b) dually noted that endpoint changes were only going to be considered for malathion, and not diazinon or chlorpyrifos because it was "determined that they would not impact the effect determinations for any listed species and/or designated critical habitat." As such, it is clear that endpoint review was not considered in EPA's final BE for chlorpyrifos. The issues discussed above on the use of NOELs in the biological evaluations remain important to DAS and pertinent for EPA to address.

2.4 Taxon Specific Review and Critique of Effects Characterizations Presented and Used by EPA (2016a)

In response to the NRC (2013) recommendations, the Agencies (2013) developed their Interim Approaches for national-level endangered species assessment. The interim approach recommends that the following endpoints be used to assess the potential for direct and indirect effects to endangered species (see Table 2-1).

Table 2-1 Prescribed endpoints as per the Interim Approaches (Agencies, 2013)

Taxon	*Mortality*		*Sublethal Effects*	
	Direct Effects	*Indirect Effects*	*Direct Effects*	*Indirect Effects*
Birds Mammals Reptiles Terrestrial-phase amphibians Terrestrial invertebrates	Dose that would result in a 1 in a million chance of causing mortality to an individual[a]	Dose that would result in a 10% decrease of individuals[a]	The lowest available NOEL or other scientifically defensible effect threshold (EDx)[b]	Lowest available LOEL for growth or reproduction
Terrestrial plants - monocots Terrestrial plants - dicots Terrestrial plants - non-angiosperm	None	None	Concentration equal to the lowest value among the NOAEC and EC5 values from the available seedling emergence and vegetative vigor studies	Concentrations equal to the lowest available LOAEC and EC25 values from the available seedling emergence and vegetative vigor studies

[a] Calculated using the HC5 of an SSD of LC50/EC50 values and a representative slope. If an SSD cannot be derived, the most sensitive LC50 or EC50 is used.

[b] Endpoints will generally be a) from *in vivo* studies that are conducted with whole organisms and b) linked to environmentally relevant exposures.

In the effects characterization chapter (Chapter 2) of the draft BE, EPA (2016a) presented the thresholds that were selected to assess direct and indirect effects to listed terrestrial vertebrates, invertebrates and plants. DAS provided comments to EPA on the thresholds selected for use in the draft BEs (Clemow et al., 2016). In response to all submitted comments on the draft BEs, EPA (2017b) indicated that endpoint review was not considered for chlorpyrifos (or diazinon) because it was determined that the effects determinations would not change. DAS disagrees with EPA on this point and maintains their concerns about endpoint selection in the draft and final BEs. In brief, Clemow et al. (2016) discussed issues including:

- Inconsistent reporting of thresholds between Chapter 2 and the TEDtool WoE matrices (Appendix 3-6: TEDtool inputs). Some thresholds that drive the species calls in the WoE matrices were not presented in the Effects Characterization chapter.

- EPA failed to provide important assumptions on animal body weights when dietary endpoints (mg a.i./kg diet) were converted to dose-based endpoints (mg a.i./kg bw). However, in their final BE, EPA (2017a) did include a statement in Chapter 2, Section 8.2 (Threshold Values for Mammals) indicating that "if the endpoints were originally presented in terms of diet (mg a.i./kg diet), then the effect concentrations were converted to a dose-based value (mg a.i./kg bw) using a body weight, when available (i.e. WHO, 2009 Dose Conversion Table)". Despite this slight clarification, EPA still failed to provide the selected body weight assumptions throughout Chapter 2.

- EPA failed to provide reviews of open literature studies that they used for effects thresholds. This is contradictory to their data selection and review process (as previously noted; See Comments in Section 2.1.1- Data Selection and Evaluation Process). In fact, in Appendix 2-3, where EPA presented their review of open literature studies, EPA noted that some of the studies deemed for "quantitative" use had not undergone secondary review and that such review would be completed for the final BE. The lack of completed reviews for studies considered for use in the BE is concerning, especially for those studies used for quantitative purposes. A lack of proper review creates even more uncertainty with respect to the quality of data used in the BE and ultimately casts doubt on species designation calls (See Chapter 4.2 in this response).

2.4.1 Mammals

This Section of the response document outlines the concerns presented to EPA on the effects thresholds selected for mammals in their draft BE (Clemow et al., 2016), and a discussion of the extent to which EPA considered the comments.

Marty and Andrus (2010 [MRID 48139301]); Hoberman (1998 [MRID 44556901]); Mattsson et al. (1998 [MRID 44648101])

DAS commented on EPA's dose-based and dietary thresholds of 0.03 mg a.i./kg bw and 0.6 mg a.i./kg diet, respectively, which reportedly represented 10% inhibition of AChE in brain and red blood cells in Norway rats (*Rattus norvegicus*). In the WoE tools, the dietary concentration of 0.6 mg a.i./kg diet was "converted from a mortality threshold (dose-based) to dietary-based standard FDA lab rat conversion." Although not a mortality endpoint, we presume the approach was applied to the dose-based sublethal AChE inhibition endpoint. This reported method is not presented in the BE.

Clemow et al. (2016) also noted that the ecological relevance of these measures of effects is unknown and was not reported by EPA (2016a). EPA (2016a, 2017a) did not demonstrate how this endpoint is related to the protection goal of individual fitness.

Cometa et al. (2007; E93364)

In their draft and final BEs for chlorpyrifos, EPA (2016a; 2017a) used a variety of thresholds estimated from Cometa et al. (2007; E93364) (Table 2-2) to assess effects of chlorpyrifos to mammals. Cometa et al. (2007; E93364) is an open literature study that EPA reviewed and accepted for the ECOTOX database. It was selected for use in the BE because it provided the lowest LD50 value of 60 mg a.i./kg bw of all reviewed mammalian studies.

Table 2-2 Toxicity data from Cormeta et al. (2007) used to assess direct and indirect effects to mammals

Measure of Effect	Threshold	Value	Units	Notes
Direct effects	1/million	5.2	mg a.i./kg bw	Based on LD50 = 60 mg/kg bw, Default slope= 4.5
Direct and indirect effects	Lowest LD50	60	mg a.i./kg bw	Value reported from study; not explicitly reported as metric in Chapter 2
Indirect effects (mammals as prey)	10% mortality	31	mg a.i./kg bw	Based on LD50 = 60 mg/kg bw, Default slope= 4.5
Direct (dietary)	1/million	36.4	mg a.i./kg diet	Not explicitly reported as metric in Chapter 2; Description not provided
Indirect (dietary, mammals as prey)	10% mortality	217	mg a.i./kg diet	Not explicitly reported as metric in Chapter 2; Description not provided

However, there are a number of limitations with the study that are also duly noted by EPA in their review (Appendix 2-3), including:

- The raw data were not provided in the study. In their review of the draft BE, Clemow et al. (2016) noted that because the raw data were not provided, the estimated 1/million effects threshold of 5.2 mg/kg was not the most appropriate approach given the availability of other acceptable studies for which the raw data were available. DAS supports and recommends the use of the 1/million threshold of 10.4 mg/kg estimated using the data provided in McCollister et al. (1974) (Teed et al., 2016). However, EPA did not consider this study for their final BE (EPA, 2017a).

- In response to the draft BE, Clemow et al. (2016) questioned the selection of 20 g as the body weight parameter for estimating body mass scaled thresholds for mice for data from Cometa et al. (2007). The study authors reported a group average body weight on day 0 of 26.02 ± 0.47 g for control animals. In their final BE, EPA (2017a) did account for this comment and used a body weight of 26 g. This information, however, was only located within the TEDtool workbook files (and Appendix 3-6, TEDTool inputs), and was not made transparent throughout the document text (Chapter 2).
- In the TEDtool inputs and Appendix 3-6 of the draft BE, EPA (2016a) presented dietary thresholds of 36.4 mg a.i./kg diet and 217 mg a.i./kg diet for 1/million and 10% mortality thresholds, respectively, from Cometa et al. (2007; E93364). It was noted by Clemow et al. (2016) that these values were not presented in Chapter 2. Moreover, Clemow et al. (2016) described concerns that EPA was not clear on how their reported dietary metrics were estimated, considering the mice from this study were exposed via oral gavage. As noted previously, it is not standard practice to derive dietary doses using oral gavage exposure data. More often, dietary doses are estimated using dietary concentrations, body weights and food ingestion rates from the study. The opinion of DAS still remains that without any discussion of these parameters from the study, nor a discussion on the assumptions made by EPA, it is impossible to recreate EPA's estimated metrics (Clemow et al., 2016).

Maurissen et al. (2011; E82431)

To assess direct and indirect effects of chlorpyrifos on mammal reproduction, EPA (2016a) selected dietary concentrations of 20 and 100 mg a.i./kg diet, a NOEL and LOEL, respectively, that corresponded to a 30% loss of pups within post-natal days (PND) 0 to 4 (Maurissen et al., 2011; E82431). As noted previously by Clemow et al. (2016), this study was not reviewed by EPA (2016a) in their Appendix 2-3 (Open literature Review), despite its use as a lowest reported dose for sublethal effects (see comment in Section 2.1 of this response document). DAS reported a number of concerns with the study and metrics that EPA (2017a) maintained the final BE (Clemow et al., 2016), for example:

- The selected metric was only reported in the TEDtool effects metrics input page (Appendix 3-6) and not described anywhere in Chapter 2.
- The source or estimation of the dietary concentrations reported to be from this study are unclear. Maurissen et al. (2011; E82431) exposed pregnant Sprague-Dawley rats via oral gavage to daily doses of 0.3, 1.0 and 5.0 mg a.i./kg chlorpyrifos/d from gestation day (GD) 6 to lactation day (LD) 10. The animals were monitored until PND 70 for signs and symptoms of neurotoxicity and reproductive endpoints. The study authors reported that 30% of the fetuses born to dams dosed with 5 mg a.i./kg/d died during PND 0-1, compared to 1-2% mortality in all other groups. Being an oral gavage study, the author reported all exposures as dietary doses (mg a.i./kg bw). EPA did not indicate the methods or assumptions that were made using these data to estimate dietary concentrations (i.e. assumed body weight and water content of feed item) in Chapter 2 or Attachment 1-4 (Process for determining effects thresholds).
- It is not appropriate to estimate dietary concentrations using dose-based exposure concentrations because dietary-based concentrations do not account for the gross energy and assimilation energy associated with the dietary item, nor would the feed consumed in an experimental study likely model the same diets consumed in the field. As such, without proper documentation, EPA's (2017a) dietary effects metrics cannot be reproduced, nor are they appropriate for use in risk assessment.

Mansour et al. (2011; E160389)

In the TEDtool inputs of the draft BE, EPA (2016a) presented a LOEC for growth of 20 mg a.i./kg based on a 16.35% reduction in body weight of pregnant Wistar rats exposed to 1.00 mg a.i./kg bw chlorpyrifos via oral gavage from PND 0 to 21 (Mansour and Mossa, 2011; E160389). Clemow et al. (2016) were concerned that the authors of the study presented only dose-based endpoints, but EPA presented a derived dietary endpoint, with no explanation. In their final BE, however, EPA (2017a) added text in the TEDtool input tab next to the metric indicating that "Converted mortality threshold (dose-based) to dietary-based standard FDA lab rat conversion".

Despite this clarification, EPA (2017a) still did not present the calculations or methods for this conversion in their final BE.

EPA (2017a) reviewed this study in Appendix 2-3 (Open literature Review Summaries for Chlorpyrifos). Their description of use in the document was rated as QUALITATIVE with a note stating that "due to more sensitive sublethal endpoints available, otherwise could be considered for quantitative use". This sentence is not clear. Study limitations listed by EPA included the lack of weights provided, stats could not be verified, it was unclear if body weight loss was treatment related or from decrease in food consumption (food consumption data not provided), and the use of corn oil as a vehicle may have increased uptake of chlorpyrifos (as per authors discussion). Notably, in their rationale for use comments, EPA stated that "this information will be used qualitatively in discussions on sublethal effects of chlorpyrifos on mammalian species". As such, EPA should not have included these metrics in their quantitative assessment based on their own review. It is concerning that this metric is actually used in the risk designation call for growth effects for listed mammals in the final BE (EPA, 2017a).

Jacobsen et al. (2004; E90929)

In their draft BE, EPA (2016a) used the NOEC and LOECs of 3.12 and 11.4 mg a.i./kg diet, respectively, for behavior (decreased food consumption) in their risk call designations for listed mammalian species (Jacobsen et al., 2004; E90929). In response to the draft BE, DAS (Clemow et al., 2016) provided EPA with a few notable comments about these metrics, including: 1) EPA did not provide these endpoints in their effect metrics tables located in Chapter 2 (Effects Assessment); 2) Jacobson et al. (2004) is an open literature study, but EPA provided no review on the study in Appendix 2-3 (Review of Open Literature Studies); and 3) the effects metrics reported by EPA were not found in corresponding study.

In the TEDtool inputs tab and Appendix 3-6 of the final BE, EPA (2017a) changed their behavior endpoints from those selected in their draft BE. They selected a LOEL of 4 mg a.i./kg diet, with no associated NOEL, from a study referenced merely as E160360, and noted that the dietary endpoint was "reported in Chapter 2 as equivalent dose in mg/kg bw". This threshold was used to make behavioral risk designations for mammals in the TEDtool. In Chapter 2, EPA

(2017a) reported the LOEL of 0.6 mg/kg bw as being the most sensitive behavioral endpoint based on food consumption in mice (E160360). The full reference for this study was not reported in the TEDtool or Chapter 2, nor was a study review included. Without a full reference or a study summary, it is impossible for DAS to confirm the data selected. This is a large concern for DAS.

2.4.2 Birds

In Section 5.2 of Chapter 2 of the draft BE, EPA (2016a) summarized their threshold values for birds. In response, DAS provided EPA with comments on the data used in the effects assessment for birds (Clemow et al., 2016). Some major concerns that were identified included: the relevance of data collected from handbooks, improper referencing of endpoints, the use of studies that were not confirmed as reviewed by EPA prior to use, and non-verifiable references or data points. Details on EPA's response to these issues in their final BE are presented below.

As noted by Clemow et al. (2016), many of the metrics used in the SSD in the draft and final BEs were derived from toxicity data handbooks (i.e. Hudson et al., 1984 (E50386); Smith, 1987 [MRID 41043901]). Handbooks often lack complete descriptions of the individual test systems and methods, fail to follow internationally-recognized standard test protocols, do not provide the source of the test article, nor provide the methods for the statistical analysis used to develop the reported effects metrics. As such, data sources from handbooks are not appropriate for use in quantitative risk assessments unless their data can be validated from the original studies. Specifically, Clemow et al. (2016) commented that EPA (2016a) incorrectly referenced LD50s of 108 and 157 mg a.i./kg bw for the mallard duck and ringed turtle dove, respectively, from Smith (1987 [MRID 41043901]). In the final BE, it appears that EPA (2017a) edited the reference for the ringed turtle dove (E37111), but did not provide an alternate reference for the mallard duck endpoint.

Appropriate study reviews were not provided by EPA (2016a) in Appendix 2-3 for numerous studies that were included in the SSD in the draft BE (e.g. Tucker and Haegele (1971; E35499); Al-Badrany and Mohammad (2007; E108196); Hudson et al. (1984; E50386); Smith (1987 [MRID 41043901]); Miyazaki and Hodgson (1972; E37995)). This comment holds true for the final BE, since EPA did not add any additional reviews for avian studies to Appendix 2-3 (EPA, 2017a). As such, the quality of the studies that were used in the SSD and ultimately the SSD itself remained questionable.

The study durations were not the same for all effects metrics used in the SSD. In Attachment 1-5 (Method of deriving SSDs for use in pesticide effects determinations for listed species), EPA indicated that it is important to standardize variables, including study duration, to limit the variables that could "confound" the relative sensitivities of species. For example, Clemow et al. (2016) noted that EPA included a 7-day endpoint of 157 mg a.i./kg bw for the ringed turtle dove in the SSD. EPA (2017a) removed 7-day endpoint from the SSD from the final BE, as indicated with the removal of the asterisk in Chapter 2, Table 5-3. Additionally, EPA removed the asterisk from the 14-day value of 108 mg a.i./kg bw for the mallard duck (MRID 41043901). However, EPA did not provide any discussion on why this was done, and there still remained endpoints for other durations in the SSD. As such, DAS still has concerns about the SSD used in the final BE (EPA, 2017a).

It was also noted by Clemow et al. (2016) that the full references for MRID 40378401 and MRID 160000, as reported in EPA's table of LD50s for birds, could not be located in the BE (Appendix 2-2 or 2-3). The Agency should provide complete references to help facilitate review of their assessment and to maintain transparency of their methods. As Table 2-3 below stands, the data from these studies cannot be verified. This comment remains true of the final BE, since EPA did not include these full references as requested.

Table 2-3 Available median lethal doses (LD_{50}, oral) for birds exposed to chlorpyrifos as TGAI or formulation, including those used in SSD (EPA, 2017a)

Genus	Species	Common Name	LD50 (mg a.i./kg-bw)	TGAI/ Formulation (F)	Duration (d)	MRID/ECOTOX ref #
Quiscalus	*Quiscula*	Common Grackle	5.62*	TGAI	14	**Full reference not reported by EPA [MRID 160000]**
Phasianus	*Colchicus*	Ring-Necked Pheasant	7.95*	TGAI	14	Tucker and Haegele, 1971 (35499)
Columba	*Livia*	Common Pigeon	10*	TGAI	14	**Full reference not reported by EPA [MRID 160000]**
Passer	*Domesticus*	House Sparrow	10*	TGAI	14	**Full reference not reported by EPA [MRID 160000]**

Table 2-3 Available median lethal doses (LD_{50}, oral) for birds exposed to chlorpyrifos as TGAI or formulation, including those used in SSD (EPA, 2017a)

Genus	Species	Common Name	LD50 (mg a.i./kg-bw)	TGAI/ Formulation (F)	Duration (d)	MRID/ECOTOX ref #
Agelaius	*Phoeniceus*	Red-winged blackbird	13.1*	TGAI	14	**Full reference not reported by EPA [MRID 160000]**
Coturnix	*Japonica*	Coturnix quail	13.3*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Coturnix	*Japonica*	Japanese Quail	15.03*	TGAI	14	Tucker and Haegele, 1971 (35499)
Grus	*Canadensis*	Sandhill Crane	25*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Phasianus	*Colchicus*	Ring-Necked Pheasant	17.7*	TGAI	14	Hudson et al., 1984 (E50386)
Coturnix	*Japonica*	Japanese Quail	17.8*	TGAI	14	Hudson et al., 1984 (E50386)
Gallus	*Domesticus*	Domestic Chicken	18.14	F	1	Al-Badrany et al. (2007 (E108196))
Passer	*domesticus*	House Sparrow	19.85*	TGAI	14	Tucker and Haegele, 1971 (35499)
Passer	*domesticus*	House Sparrow	21*	TGAI	14	Hudson et al., 1984 (E50386)
Grus	*canadensis*	Sandhill Crane	25*	TGAI	14	Hudson et al., 1984 (E50386)
Branta	*canadensis*	Canada Goose	40*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Columba	*Livia*	Rock Dove	25.42*	TGAI	14	Tucker and Haegele, 1971 (35499)
Branta	*canadensis*	Canada Goose	40*	TGAI	14	Hudson et al., 1984 (E50386)
Grus	*canadensis*	Sandhill Crane	50*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Colinus	*virginianus*	Northern Bobwhite Quail	32*	TGAI	7	Hill and Camardese, 1984 (37111)
Gallus	*domesticus*	Domestic Chicken	34.77*	TGAI	1	Miyazaki and Hodgson (1972; MRID 242149/37995)
Alectoris	*chukar*	Chukar	57.36*	TGAI	14	Tucker and Haegele, 1971 (35499)
Alectoris	*chukar*	Chukar	61.1*	TGAI	14	Hudson et al., 1984 (E50386)
Callipepla	*californica*	California Quail	68.3*	TGAI	14	Hudson et al., 1984 (E50386)
Anas	*Platyrhynchos*	Mallard Duck	71.44*	TGAI	14	Tucker and Haegele, 1971 (35499)
Anas	*Platyrhynchos*	Mallard Duck	108	TGAI	14	Smith (1987 [MRID 41043901]

Table 2-3 Available median lethal doses (LD_{50}, oral) for birds exposed to chlorpyrifos as TGAI or formulation, including those used in SSD (EPA, 2017a)

Genus	Species	Common Name	LD50 (mg a.i./kg-bw)	TGAI/ Formulation (F)	Duration (d)	MRID/ECOTOX ref #
Anas	*Platyrhynchos*	Mallard duck	112*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Sturnus	*vulgaris*	Starling	75*	TGAI	14	**Full reference not reported by EPA [MRID 40378401]**
Colinus	*virginianus*	Northern Bobwhite Quail	93	TGAI	0.1667	Maguire and Williams (1987 [MRID 44585402/39749])
Colinus	*virginianus*	Northern Bobwhite Quail	108	F	7	Hill and Camardese, 1984 (37111)
Passer	*domesticus*	House Sparrow	94	TGAI	14	Gallagher et al. (1996a [MRID 44057102]
Passer	*domesticus*	House Sparrow	109	F	14	Gallagher et al (1996b [MRID 44057101])
Streptopelia	*risoria*	Ringed Turtle-Dove	157	TGAI	7	Hill and Camardese, 1984 (37111)
Anas	*Platyrhynchos*	Mallard Duck	476*	TGAI	14	Roberts and Phillips (1987 [MRID 40854701]
Colinus	*virginianus*	Northern Bobwhite Quail	545	F	14	Campbell et al. (1970 [MRID 41885201])

* = Value used to derive SSD

2.4.3 Herptiles

EPA (2016a) noted that there is only one study available for reptiles (Lacertid lizard, *Podarcis bocagei seoane*) exposed to chlorpyrifos (Amaral et al., 2012 (E159933)). The NOEL and LOEL from the study associated with 70% brain cholinesterase activity were 0.12 and 1.57 mg a.i./kg bw, respectively. Clemow et al. (2016) noted that EPA (2016a) did not report the use of the corresponding dietary concentration thresholds (2.38 and 23.68 mg a.i./kg diet) in Chapter 2 of the BE, despite their use in the WoE matrices and for risk call designation (based on effects on behavior) for listed terrestrial herptiles. However, in the final BE, EPA (2017a) added the text:

"In this dietary study, lacertid lizards, *Podarcis bocagei*, were exposed to chlorpyrifos at doses of 0.12 mg a.i./kg bw (0.05 – 0.17 mg a.i./kg-bw) and 1.57 mg a.i./kg-bw (1.46 – 1.65 mg a.i./kg-bw) for 20 days through spiked food (corresponding to approximately 2.38 mg/kg-diet at low dose and 23.68 mg/kg-diet at high dose)."

Although EPA provided the dietary estimates, EPA (2017a) noted that they were approximate estimates and did not include the values in their study review. DAS maintains the opinion that it is not appropriate to compare dietary or concentration-based effects thresholds with dose-based exposure estimates.

For all other thresholds used to assess effects to herptiles in their final BE, EPA (2017a) continued to rely on bird effects data as a surrogate. As noted by Clemow et al. (2016), it is standard practice for EPA to use bird toxicity data as a surrogate for terrestrial-phase herptiles (EPA, 2008). However, there is no justification for doing so beyond the paucity of data for herptile species. Birds and herptiles belong to different taxonomic classes, and therefore, have different physiological attributes (i.e. metabolic rates, respiratory system, and diets) and overall ecologies. Based on reports that present both avian and terrestrial herptile effects data (e.g. Hudson et al., 1984), herptile toxicity data for organophosphates are generally less sensitive than toxicity data for birds. Toxicity data reported in Hudson et al. (1984) indicate species sensitivities ratios between amphibian and avian species range from <0.02 to <0.28 (Table 2-4). As such, using bird toxicity data as a surrogate for herptiles would likely overestimate risk.

Table 2-4 Comparison of amphibian and avian oral LD50s for chlorpyrifos

Avian Species LD50 (mg/kg bw)	Amphibian Species LD50 (mg/kg bw)	Range of Species Sensitivity Ratios[a]	Data Source
Pheasant (8.41 - 17.7), Japanese quail (15.9 -17.8), house sparrow (21), sandhill crane (25 - 50), rock dove (26.9), Canada goose (40 - 80), chukar (60.7 - 61.1), California quail (68.3), mallard (75.6), mallard duckling (112)	Bullfrog, *Rana catesbeiana* (>400)[a]	<0.02 - <0.28	Hudson, et al., 1984 [MRID 00160000]

[a] Species sensitivity ratios calculated by dividing the avian LD50s by the lowest available amphibian LD50. A ratio < 1 indicates that the avian receptor is more sensitive than the amphibian receptor

2.4.4 Terrestrial plants

In their draft BE, EPA (2016a) selected sensitive threshold values for dicots and monocots from pre- and post-emergent studies (See Table 2-5 and Table 2-6, below). In a review of EPA's draft BE, DAS (Clemow et al., 2016) provided a number of comments on the terrestrial plant endpoints selected by EPA to assess effects to listed plant species. As noted previously in this response document, EPA (2017a) failed to address the majority of comments that were highlighted by DAS. As such, many of the concerns still remain, including:

- The threshold values that EPA presented in Chapter 2, did not represent the comprehensive list of thresholds that were incorporated into the TEDtool and WoE matrices (Appendix 3-6) and ultimately used to make effect determinations. For example, to assess direct and indirect effects to plants based on mortality and reproductive endpoints, EPA (2017a) used 6 lb a.i./A. This rate represented the maximum labelled single application rate for chlorpyrifos and the use of this value was not described in the effects characterization section (Chapter 2).
- To assess direct and indirect effects to dicot plant species, EPA selected a NOAEC and LOAEC for lettuce of 0.362 and 0.724 lb a.i./A (0.4 and 0.8 kg a.i./ha), respectively, based on reduced mean shoot fresh weight for lettuce (Bergfield, 2012a [MRID 49307202]) (Table 2-5). Authors of the study noted, however, that "there was a significant reduction in the 0.8 kg/ha treatment for shoot fresh weight in lettuce, but it was not considered to be concentration-dependent because the two higher treatment levels were not significantly reduced. Therefore, the NOEL is reported as 3.2 kg a.i./ha (2.85 lb a.i./A)". The author-reported value is more appropriate than the value used by EPA (2016a; 2017a).
- To assess indirect effects to monocot species, EPA selected a post emergence LOAEC of 0.999 lb a.i./A for reduced photosynthetic rate and stomatal conductance in corn exposed to chlorpyrifos after 3, 8 and 14 days (Godfrey and Holtzer, 1992 (E064451) (Table 2-6). The environmental relevance of this measure of effect is questionable, since there was no evidence to suggest that decreases in photosynthetic rate ultimately caused effects on corn growth or reproduction. In fact, there were no obvious differences in biomass noted, and the authors stated that photosynthetic rates were only affected during 1988, a year

with dry soil conditions. As such, the effects on rate of photosynthesis appear to have been confounded by climate and weather conditions and not directly related to pesticide application alone.

- Based on the table of selected effects thresholds presented in Chapter 2 and Appendix 3-6, EPA (2016a; 2017a) did not provide a reference for the selected NOAEC of 0.001 lb a.i./A used to assess direct effects to monocots (pre-emergence) (Table 2-6). This threshold was exceedingly low, being five hundred times lower than the lowest reported plant endpoint by EPA. It is unclear why EPA generated such a conservative threshold value when an EC05 could have been generated using a relevant effects study, as recommended by NRC (2013). Moreover, in the absence of data EPA (2017a) should have indicated an "NA", as they did for their post emergence direct effects threshold. In assessing effects to terrestrial plants, DAS supports the use of data from their registrant-submitted studies. See Table 2-7 below for recommended values for screening purposes (Teed et al., 2016).

Table 2-5 Thresholds for dicot species

Threshold/ Endpoint Type	Threshold/ Endpoint Description	Value (lb a.i./A)	Source	Comment
Direct	Pre-emergence* NOEC (growth)	0.362	Bergfield, 2012a [MRID 49307202]	Reduced fresh weight and length in lettuce. **Although significant, the authors noted that the effect was not concentration-dependent. As such, the study authors reported a NOAEC of 3.2 kg a.i./ha (2.85 lb a.i./A)**
Direct and Indirect	Pre-emergence* LOEC (growth)	0.724	Bergfield, 2012a [MRID 49307202]	
Indirect	Pre-emergence* EC25 (growth)	2.03	Bergfield, 2012a [MRID 49307202]	Reduced weight in lettuce
Direct	Post-emergence** NOEC (growth)	0.125	Ahrens, 1990 (E068422)	Reduced weight in soybeans
Direct and Indirect	Post-emergence** LOEC (growth)	0.25		
Indirect	Post-emergence** EC25 (growth)	5.7 (>5.7)	Bergfield, 2011 [MRID 48602604]	Reduced weight in lettuce
Direct	Mortality	6	The NOAEC represents the maximum labeled single application rate for chlorpyrifos (*i.e.*, 6.0 lbs a.i./A)	**This metric assumption is not presented in Chapter 2 of the BE**
Indirect	Mortality	6		
Direct	Reproduction	6		
Indirect	Reproduction	6		

*Pre-emergence includes seedling emergence studies
**Post-emergence includes vegetative vigor studies

Table 2-6 Thresholds for monocot species				
Threshold/ Endpoint Type	**Threshold/ Endpoint Description**	**Value (lb a.i./A)**	**Source**	**Comment**
Direct	Pre-emergence* NOEC (growth)	0.001	NR	**No reference for this exceedingly low threshold**
Direct and Indirect	Pre-emergence* LOEC (growth)	0.5	Castro et al., 1995 (E101148)	Reduced height in sorghum
Indirect	Pre-emergence* EC25 (growth)	5.7 (>5.7)	Bergfield, 2012a [MRID 49307202]	No growth effects noted
Direct	Post-emergence** NOEC (growth)	NA	NA	**No data available. Why not generate an EC05 based on interim guidance?**
Direct and Indirect	Post-emergence** LOEC (growth)	0.999	Godfrey and Holtzer, 1992 (E064451)	**Effects on photosynthetic rate and stomatal conductance. Environmental relevance is questionable.**
Indirect	Post-emergence** EC25 (growth)	(>5.7)	Bergfield, 2012b [MRID 49307201]	No growth effects noted monocots
Direct	Mortality	6	The NOAEC represents the maximum labeled single application rate for chlorpyrifos (*i.e.*, 6.0 lbs a.i./A)	**This metric assumption is not presented in Chapter 2 of the BE**
Indirect	Mortality	6		
Direct	Reproduction	6		
Indirect	Reproduction	6		

*Pre-emergence includes seedling emergence studies
**Post-emergence includes vegetative vigor studies

Table 2-7 Screening-level effect metrics selected for terrestrial listed species assessment of chlorpyrifos (Teed et al. 2016)				
Test	***Species***	***Endpoint***	***Effects Metric***	***Reference [MRID]***
Monocots, seedling emergence	All species tested	LOEL	>5.7 lb a.i./A[1]	Bergfield, 2011a [MRID 48602603]; 2012a [MRID 49307202]
		NOEL	≥5.7 lb a.i./A	
Monocots, vegetative vigor	All species tested	LOEL	>5.7 lb a.i./A	Bergfield, 2011b [MRID 48602604]; 2012b [MRID 49307201]
		NOEL	≥5.7 lb a.i./A	
Dicots, seedling emergence	Cucumber (*Cucumis sativus*) (shoot weight)	LOEL	1.43 lb a.i./A	Bergfield, 2012a [MRID 49307202]
		NOEL	0.71 lb a.i./A	
Dicots, vegetative vigor	All species tested	LOEL	>5.7 lb a.i./A	Bergfield, 2011b [MRID 48602604]

2.4.5 Terrestrial Invertebrates

There were a number of issues with the threshold values selected for terrestrial invertebrates in the draft BE (EPA, 2016a) that were previously identified by Clemow et al. (2016). In their final BE, EPA (2017a) failed to address any of the comments provided on terrestrial invertebrate effects endpoints used in risk determinations for listed terrestrial invertebrate species. As such, DAS maintains the opinion that the comments presented in Clemow et al. (2016) remain applicable to EPA's final BE for chlorpyrifos (EPA, 2017a). These comments include:

- EPA (2016a; 2017a) used four effects metrics derived from De Silva and van Gestel (2009). This open literature study has many limitations that should have made it unacceptable under the Agency's review process. De Silva and van Gestel (2009) does not meet a number of quality criteria required by EPA (2011). Some examples of requirements include: a reported concurrent environmental concentration/dose or application rate, a reported number of test organisms, and sufficient information must be provided [in the open literature study] to substantiate/evaluate whether the study conclusions were accurate. As such, this study should have been deemed unacceptable. This study also used a non-standard source of organic matter (Paddy husks) for earthworm toxicity testing (OECD, 1984, 2004a, b; EPA, 2012a).
- A number of metrics were used in the assessment, but were either briefly discussed in Chapter 2 of the draft and final BEs or not discussed at all (i.e. 1/million threshold of 0.1 mg/kg dw soil, lowest LC50 of 142 mg/kg dw soil). DAS believes that any metric used within the TEDtool framework should have been presented in Table 9-1 ("Chlorpyrifos Thresholds for Terrestrial Invertebrate Species").
- To estimate the 1/million mortality threshold of 0.1 mg/kg dw soil, the EPA assumed a default probit slope of 4.5. The appropriateness of this default slope is unknown, given the lack of data provided in the study (not even a figure was provided). This, taken with the limitations of the study, demonstrates that the 1/million mortality threshold estimate of 0.01 mg/kg dw soil is not credible.

DAS (Clemow et al. 2016) highlighted a number of concerns with the dietary concentration threshold of 0.0027 mg/kg food (Atkins and Kellum, 1986 (E070351)) used in the draft BE for terrestrial invertebrates (EPA, 2016a). Specifically, this value was used in the TEDtool threshold input table, but was not mentioned at all in Chapter 2 (Effects Assessment). This is a concern, since it was ultimately used to make species and critical habitat risk determinations. The study authors reported, among other endpoints, an LD10 of 0.001 µg/individual honey bee larva (Atkins and Kellum, 1986 (E070351)). The comment in the TEDtool file associated with the threshold states: "From Bee-Rex calculator; based on bee larval study, calculated using LC10, used 3-day duration for study." However, we were unable to reproduce this estimate using the Bee-Rex calculator. Using the calculator, it appears that a pollen and nectar concentration of ~52 mg/kg food is approximately equivalent to the author reported lowest LD10 of 0.001 µg/individual honey bee larvae (Atkins and Kellum, 1986 (E070351)). Beyond this discrepancy, there were also important limitations of the study that should have made it unacceptable for quantitative use in the risk assessment. As reported by the EPA reviewer in Appendix 2-3, "Raw data were not available to confirm calculations and statistics. It is uncertain whether data were corrected for percent technical (in the absence of additional information, it was assumed that the author corrected for % a.i.). The test concentrations in the dilution series were not reported; therefore, it is unknown whether the resulting LDx values were within the range of test concentrations or if they were extrapolated values." Such conditions should have made the study unacceptable as previously noted by DAS (Clemow et al. 2016).

In the response to the draft BE, DAS highlighted concern that a "sensory" threshold of 0.45 mg/kg dw soil (Santos et al., 2012) was selected and used in the quantitative risk assessment (Clemow et al., 2016). In the draft BE, EPA (2016a) incorrectly referenced the study as an effect on springtails (*Collembola spp*.), when it should have been *Folsomia candida*. Moreover, in Appendix 2-3, the study was categorized as invalid due to contamination in the control. Clearly, the study should not have been used by EPA in the quantitative analysis. In their final BE, EPA (2017a) corrected the species note in the TEDtool file for which *Collembola* was noted as the test species. However, EPA still used the study, despite its invalidity for the reasons described above. Further, the relevance of avoidance as an adverse effect potentially leading to effects on fitness is dubious, particularly for when such effects are quickly reversible, and should be reconsidered by the Agency.

Finally, Clemow et al. (2016) contested the use of the threshold values derived from Addison and Barker (2006). In their draft BE, EPA (2016a) used a NOEL and LOEL of 0.00089 and 0.0046 lb a.i./A, respectively, for both direct and indirect, lethal and sublethal effects to terrestrial invertebrates. Notably, in the draft BE, there was only one EPA reviewer (Appendix 2-3; EPA, 2016a) who noted that the raw data were not provided and application rates were not measured. In the final BE, a second review was conducted for this study, but there were no changes to the study notes. As such, due to the lack of raw data and measured application rates, as required by EPA guidance (EPA, 2011), DAS maintains the opinion that the results from Addison and Barker (2006) should not be used quantitatively. Unfortunately, EPA (2017a) still used this study and endpoints in the final BE.

2.4.6 Fish and Aquatic-phase Amphibians

Despite the submission of comments on the effects thresholds for fish and aquatic-phase amphibians used in EPA's (2016a) draft BE (Giddings and Winchell, 2016a), EPA made no changes for their final BE (EPA, 2017a). Specifically, EPA (2016a; 2017a) used fish toxicity data as surrogates for aquatic-phase amphibians for some thresholds, despite the availability of amphibian toxicity data. Giddings and Winchell (2016a) asserted that this practice was not justified. If suitable toxicity data are available for aquatic-phase amphibians, these taxon-specific data should be applied to assess risk. EPA guidance indicates that data for under-represented taxa are preferred over surrogate species data, regardless of whether the endpoints are more or less sensitive (EPA, 2011).

For acute effects to aquatic-phase amphibians, EPA (2017a) used an LC50 of 121.87 µg/L for the Pacific chorus frog (*Pseudacris regilla*) from Kerby (2006). Kerby (2006) is a PhD thesis, not a peer-reviewed study, and was reviewed by Giddings et al. (2014). Giddings et al. (2014) found Kerby (2006) to be unacceptable because it used a formulation and scored poorly for procedures and transparency. EPA (2017a) highlighted that toxicity studies performed with technical products were preferred over those conducted with formulations. In light of this and the wide variation in taxonomic groups within amphibians, Giddings and Winchell (2016b) selected two acute effects thresholds for aquatic-phase amphibians for their endangered species risk assessment for chlorpyrifos that were applied based on taxonomic similarity. The thresholds included an LC50 of 236 µg/L for the green frog (*Lithobates clamitans clamitans*) and an LC50 of 134 µg/L for the African clawed frog (*Xenopus laevis*) (Wacksman et al., 2006). It should be noted that the LC50s selected by Giddings and Winchell (2016b) are similar to those selected by EPA (2016a; 2017a), but are of higher quality.

To assess sublethal effects to aquatic-phase amphibians, EPA (2016a; 2017a) used an AChE activity study that showed decreased AChE activity in the limb tissue of frogs. However, this endpoint was an order of magnitude lower than the next closest threshold, and the applicability of AChE activity to survival, growth, or reproduction is not supported and was not described by EPA (2017a). Therefore, the use of this endpoint, as is, has no scientific merit.

Giddings and Winchell (2016a) commented on the separation of freshwater fish from estuarine/marine species and the lack of consideration for the potential differences in sensitivity between the two groups. EPA (2016a; 2017a) chose to construct two SSDs; one for freshwater fish and one for estuarine/marine fish. The HC5 values from these SSDs were 5.94 µg/L and 0.79 µg/L, respectively. EPA (2016a; 2017a) also presented an HC5 (1.44 µg/L) calculated from an SSD that was constructed from both freshwater and estuarine/marine fish data, but did not use that HC5 in any analyses. There was a clear overlap in the range in toxicity data between freshwater and estuarine/marine species, but it was unclear why EPA (2016a; 2017a) chose to use separate SSDs rather than a combined SSD. Given the wide range in taxonomic groups within "fish", Giddings and Winchell (2016b) applied seven acute effects thresholds in their ESA based on taxonomic similarity. This approach ensured that the most appropriate data were used to assess the potential of effects for a specific receptor.

2.4.7 Aquatic Invertebrates

For their draft BE, EPA (2016a) constructed three SSDs to assess acute risks to aquatic invertebrates. These SSDs were for freshwater invertebrates, estuarine/marine invertebrates, and freshwater and estuarine/marine combined. However, there was considerable overlap in ranges of toxicity data. Therefore, for the final BE, EPA (2017a) used a single combined, or pooled data SSD for all freshwater and estuarine/marine invertebrate receptors. EPA (2017a) noted that mollusks were considerably less sensitive to chlorpyrifos than other aquatic invertebrates, but included all invertebrate categories in the SSD. Due to this wide range of sensitivity, it is inappropriate to assess the risks to mollusks using an SSD that is heavily weighted with more sensitive receptors. DAS recommends the use of separate effects thresholds for crustacean, insect, and mollusk species. This method was also employed by Giddings and Winchell (2016b) in their endangered species risk assessment. Giddings and Winchell (2016b) selected two acute thresholds for mollusks (*Bivalvia* and *Gastropoda*), two acute thresholds for crustaceans (*Branchiopoda* and *Malacostraca*), and constructed an SSD from only insect data. Similarly, individual sublethal NOECs were identified for crustaceans, mollusks, and insects. This ensured that the most appropriate toxicity data were applied to each receptor.

To assess sublethal effects to freshwater invertebrates, EPA (2016a; 2017a) used an AChE activity study that showed a 41% decrease in AChE activity in the amphipod (*Hyalella azteca*) (Anderson and Lydy, 2001). However, this endpoint only represents the LC01, or 1% mortality concentration, and the applicability of AChE activity to survival, growth, or reproduction is not supported and was not described by EPA (2017a). Therefore, the use of this endpoint has no scientific merit.

2.4.8 Aquatic Plants

In the draft BE, EPA (2016a) selected a NOEC of 0.001 mg a.i./L for growth of the freshwater diatom (*Navicula pelliculosa*) (Birmingham and Colman, 1976 [E2704]). Upon re-evaluation of the data, EPA (2017a) found that the reduction in growth rate observed in the study was accompanied by a poor dose response relationship, with no effects observed at 0.1 mg a.i./L. We commend EPA for identifying this issue and amending their effects threshold. For the final BE, EPA (2017a) selected a NOEC of 0.01 mg a.i./L for the freshwater green algae (*Chlorella pyrenoidosa*) (Birmingham and Colman, 1976 [E2704]). However, both endpoints were derived from the same study, and EPA (2017a) listed several study limitations, including limited reporting of water quality parameters, no raw data, statistics could not be verified, and a negative solvent effect for one species. These limitations highlight the uncertainty of this study and endpoints derived by the study authors could not be verified.

The quality of studies selected by EPA (2017a) to represent effects thresholds for aquatic plants is dubious. In a number of cases, EPA (2017a) could not identify the chlorpyrifos product used for the toxicity study (technical product or formulation), including its purity, percent active ingredient, or source. EPA (2016a; 2017a) also selected endpoints for species that were not relevant to the United States. For example, EPA (2017a) selected an IC50 for *Kamyophoron minutum*, a plant from Pakistan, and a NOAEC for *Pistia stratioles*, a plant from Thailand. A comparison of sensitivities of these plants to aquatic plants found in the US was not provided and is unknown.

EPA (2017a) provided study evaluations for only five aquatic plant toxicity studies. For at least two of the studies, raw data were not provided and statistical conclusions could not be verified. The majority of species were not native to the US, information on chemical identity was not provided, and raw data were unavailable. These pitfalls represent severe limitations of the studies chosen for effects thresholds for aquatic plants.

3.0 METHODS FOR ESTIMATING EXPOSURE OF TERRESTRIAL ORGANISMS TO CHLORPYRIFOS

Clemow et al. (2016) described several issues relating to the Agency's approach to estimating terrestrial exposure in the draft BE for chlorpyrifos (EPA, 2016a). These concerns included the compounding conservatism of "upper bound" inputs, the identification of several transcriptional and calculation errors, and an overall lack of transparency in the exposure assessment. In their final BE (EPA, 2017a), the Agency's exposure estimates and related documents were provided in Chapter 3 (Exposure Assessment), Attachment 1-7 (Methodology for Estimating Exposures to Terrestrial Animals), Attachment 1-16 to 1-20 (Biological information on listed birds, mammals, and herptiles), and the TEDtool root files (TEDtool_v1.0_alt.xlsx and TEDtool_v1.0.xlsx).

Regarding Attachment 1-7 of the final BE for chlorpyrifos, EPA (2017a) made several changes to increase the transparency of their approach. The Agency added missing units, corrected invalid and missing references, provided justification for certain assumptions, and corrected typographical errors. However, with respect to Chapter 3, subsection 3, in which estimated exposure concentrations were presented for terrestrial organisms, almost no changes were made to the text (excluding tables). These edits were limited to a footnote being added to point to "additional EECs" in the TEDtool and minor typographical edits. Despite these minor changes to the text, we have noted that most of the EECs presented in Table 3-21 (previously Table 3-17) were changed from the draft version of the BE (see further discussion of this below).

DAS remains concerned about several aspects of the exposure assessment, which have important implications for the results of the BE. This section contains a discussion of persisting and critical issues relating to the Agency's methodology for the assessment of terrestrial organisms.

3.1 Terrestrial Vertebrates

Clemow et al. (2016) commented on several aspects of the exposure assessment for terrestrial vertebrates in the draft chlorpyrifos BE (EPA, 2016a). Concerns included a lack of transparency, inconsistent approaches across EPA tools (e.g., earthworm fugacity, T-HERPS vs. TEDtool), outdated metabolic rate data, unrealistic exposure scenarios, and several explicit errors in the application of model equations (Clemow et al., 2016).

In Attachment 1-7 of the final BE for chlorpyrifos (EPA, 2017a), specific prey guilds were described and the body burden approach was provided in some detail, which differs from the T-HERPS model that is still reported to be the model employed in Table 3-21 of the final BE. Several other details were also provided:

- Aquatic EECs used for aquatic feed items were presented.
- Dose estimates from different exposure route scenarios were considered separately.
- Definitions for elements of equations, such as the vapor dose equation (Equation 23 in Attachment 1-7 of the final BE) were provided.
- Part of the error in the dermal dose equation in the TEDtool was addressed, which has been causing erroneously high estimates of dermal exposure for birds.
- The default relative diffusion rate across the pulmonary membrane (FAM) was adjusted for birds to match the value of 3.4 specified in the text.

However, several comments, many of which have direct and significant bearing on the results of the BE for chlorpyrifos, remained unaddressed. In the final BE, the Agency continued to use outdated field metabolic rate data, generated food ingestion rate estimates with faulty dietary assumptions, and compared dietary concentrations of inequivalent feed items (i.e., laboratory vs. food consumed in the wild). Additionally, one of the major concerns is the reliance on compounding upper bound conservative inputs, as opposed to risk-based probabilistic approaches (as recommended by NRC, 2013). Although EPA (2017b) stated that they would address errors and issues of transparency in the final BE for chlorpyrifos, many of the shortcomings remained in the Agency's terrestrial vertebrate exposure assessment.

The Agency did not correct the error in the applications of body mass scaling for herptiles. As identified by Clemow et al. (2016): Columns V, W, and X in the "Min rate doses" and "Max rate doses" worksheets in the TEDtool_v1.0 and TEDtool_v1.0_alt files hold the body mass-adjusted dose-based effects metrics for all listed terrestrial vertebrate species in the TEDtool. For birds, it is clear that the body mass scaling applied in T-REX is retained here. However, for herptiles, an exponent of one is applied in the avian body mass scaling equation (Equation 3-1), which is equivalent to a scaling factor of two. This scaling factor is 1.7 times higher than the avian default of 1.15, and results in the 1/million dose estimate being multiplied by the ratio of the body weights of the species being assessed and the test species. This leads to much lower effects metrics for herptiles because they are typically smaller than the test species (a standard bird test species). There is no justification for this scaling factor anywhere in the document and it is clearly in error, as the recommendation is actually a scaling factor of one (see T-HERPS Version 1.0, May, 2007). A scaling factor of one would lead to an exponent of zero and ultimately, no body mass scaling for herptiles (see Equation 3-1). Body mass scaling should have been omitted entirely for terrestrial herptiles given the paucity of data to support this approach.

$$Adjusted\ LD_{50} = LD_{50}\left(\frac{AW}{TW}\right)^{(X-1)}$$

Equation 3-1

Where,

$Adjusted\ LD_{50}$	=	Adjusted LD50 (mg/kg bw)
LD_{50}	=	Endpoint reported from study (mg/kg bw)
AW	=	Body weight of assessed animal
AW	=	Body weight of tested animal
X	=	Scaling factor (default is 1.15, from T-REX; for herptiles default is 1 from T-HERPS)

EPA (2016a; 2017a) applied body mass scaling to all threshold values in the worksheets, including sublethal thresholds. This is inconsistent with the T-REX and T-HERPS models, which apply body mass scaling to terrestrial vertebrate LD50s only. The one exception is mammals, as body mass scaling is applied to mammalian NOELs in T-REX. The Agency provided no evidence that body mass scaling was warranted for sublethal endpoints for any of the listed species assessed.

Although the Agency did correct the identified calculation error for avian dermal dose, the error in the dislodgeable foliar residue adjustment factor (F_{dfr}) was not addressed. This input was used to estimate the dermal contact dose for birds and mammals.

The Agency corrected the error in their estimation of dermal LD50 based on Equation 15 in Attachment 1-7 of the final BE, but problems still persisted in their estimation of dermal contact dose. In the Min and Max rate dose worksheets in the TEDtool, the following equation was used in Column O for birds and mammals to estimate the upper bound dermal dose for contact exposure (with foliage).

$$D_{contact(t)} = \frac{C_{plant(t)} * F_{dfr} * R_{foliar\ contact} * 8 * (SA_{total} * 0.079) * 0.1}{BW} * F_{red}$$

Equation 3-2

Where,

$D_{contact(t)}$	=	Contact dose (µg a.i./g bw; reportedly calculated on a daily time scale assuming eight hours of activity)
$C_{plant(t)}$	=	Concentration of the pesticide in crop foliage at time *t* (mg a.i./kg)
F_{dfr}	=	Dislodgeable foliar residue adjustment factor (kg/m^2; default = 0.62).
$R_{foliar\ contact}$	=	Rate of foliar contact (default = 6.01; cm^2 foliage/cm^2 body surface per hour)
SA_{total}	=	Total surface area of bird (cm^2)
BW	=	Body weight (g)
F_{red}	=	Dermal route equivalency factor

Equation 3-2 was sourced from the TIM technical manual (EPA, 2015a). In Attachment 1-7 and also in the TIM manual, the Agency stated, “in this equation, a factor of 0.1 is used to generate $D_{contact(t)}$ value with units in µg a.i./g-bw.”

The description of the F_{dfr} value used in Equation 3-2 as described in the TIM manual suggests a major flaw in the $D_{contact(t)}$ equation.

In Section 6.2.1 of the TIM manual, it was stated that the F_{dfr} value is necessary because “total residues are commonly expressed in terms of mass of pesticide per unit fresh mass of vegetation, while dislodgeable residues are commonly expressed in terms of mass of pesticide per unit surface area of the vegetation”. The following formula was provided for calculating F_{dfr} on the basis of dislodgeable pesticide residues (DPRs) and total pesticide residues (TPR) measured immediately following application:

$$F_{dfr} = \frac{DPR}{TPR}$$

Equation 3-3

Where,

F_{dfr}	=	Fraction of dislodgeable foliar residues (kg/m^2)
DPR	=	Dislodgeable pesticide residues (mg/m^2)
TPR	=	Total pesticide residues (mg/kg)

In the absence of chemical-specific data, the TIM manual recommends a default value for F_{dfr} of 0.62 that can be calculated by setting DPR to 28 mg/m^2 and TPR to 45 mg/kg. The TPR value is said to be “the mean for the total pesticide residue value on broadleaf plants.” (no reference given). The DPR value is stated to be “based on the Health Effects Division’s default assumption that at day 0, the dislodgeable foliar residue value is 25% of the application rate (in lb a.i./A) (Section D.6.2 of Appendix D of EPA, 2012b)”. Note that this value was converted from lb a.i./A to mg/m^2.” However, the conversion from 25% of the application rate (in lb a.i./A) to 28 mg/m^2, with no mention of application rate, is clearly incorrect. Mathematically, 25% of the application rate (in lb a.i./A) would also equal 25% of the application rate (in mg/m^2 or any other unit) and cannot be estimated independently of the actual application rate.

Review of the actual HED document (EPA, 2012b) clarifies that, contrary to what was stated in the TIM manual, field studies have been performed to quantify dislodgeable residue amounts <u>as a fraction of the application rate</u> for various types of crops and various active ingredients. On the basis of these data, HED recommends that “when chemical-specific data are unavailable, the recommended default value for the fraction of application rate as dislodgeable foliar residue for both liquid and solid formulations following application is 0.25 (25%)." This value was presented as the arithmetic mean of 60 measured values in Table D-20 of the HED document (EPA, 2012b). Therefore, if the HED assumption of 25% application rate as dislodgeable foliar residues was a reasonable assumption for the NESA assessment, then F_{dfr} in the dermal contact equation should have a default value of 0.25 and *Cplant* should be replaced with the application rate in mg/m^2.

The following example shows the implication for the BE estimates:

We take the single application rate of 4 lb a.i./A and consider the dermal contact exposure of the Northern aplomado falcon (*Falco femoralis septentrionalis*). EPA estimated an upper bound dermal contact dose of 58.9 mg a.i./kg bw in the final chlorpyrifos BE. The estimated body weight was 325 g. The surface area based on the equation provided in Attachment 1-7 was 473.6 cm^2 (this was correctly calculated in the TEDtool for this species).

First, 4 lb a.i./A = 1,814,368 mg a.i./A = 448.3 mg/m^2. The dermal route equivalency factor, F_{red}, based on an avian LD50 of 7.95 mg/kg bw (from BE; lowest LD50), was 0.318.

Using Equation 3-2 above, with the application rate in mg/m^2 replacing *Cplant*, and a default F_{dfr} of 0.25, we calculate the following:

$$D_{contact(t)} = \frac{(448.3\,\frac{mg}{m^2}) * (0.25) * \left(\frac{6.01\ \mathrm{cm^2 foliage}}{\mathrm{cm^2\ body\ surface\ per\ hour}}\right) * 8\,hour(473.6\,cm^2 * 0.079) * 0.1}{325\,g} * 0.318$$

$$D_{contact(t)} = 19.7\,mg\,a.i./kg\,bw$$

This value is nearly three times lower than EPA's estimate (58.9 mg a.i./kg bw) for this species.

3.2 Terrestrial Plants

DAS (Clemow et al., 2016) noted concerns with the transparency of the terrestrial plant assessment in the draft chlorpyrifos BE (EPA, 2016a). These concerns included a lack of clarity regarding the differences between the TerrPlant model and what was calculated and presented in the TEDtool model. The Agency also provided minimal discussion of the exposure results in the draft assessment of terrestrial plants. Additionally, it is not clear why the Agency did not use their newly developed Audrey III model in their BE, despite its use in the sulfonylurea assessment conducted prior to the chlorpyrifos BE (EPA, 2015b).

Few clarifications or discussions of results were made in the final BE for chlorpyrifos (EPA, 2017a, b). EPA noted in the README tab of the TEDtool that only the runoff portion of TerrPlant was used, which added some clarity to the differences between the TerrPlant and TEDtool models. However, EPA did not provide details on the calculations, nor were the exposure results presented in the text. Thus, EPA has not addressed DAS's concerns on the transparency of the terrestrial plant assessment for the final BE for chlorpyrifos.

3.3 Terrestrial Invertebrates

In Clemow et al. (2016) it was noted that EPA did not present a method for deriving EECs for listed terrestrial invertebrate species in the draft BE for chlorpyrifos. It was also noted that EECs for listed terrestrial invertebrate species were not presented in any of the draft BE chapters (EPA, 2016a). DAS (Clemow et al., 2016) and CLA (2016) were specifically concerned that the dose-based EECs for terrestrial invertebrates were not presented in the draft BE (Attachment 1-7) or the TEDtool. Moreover, as indicated in DAS's response to EPA's draft BE (Clemow et al., 2016), an assumption of body weight is required to estimate dose-based concentrations for terrestrial invertebrates (for the conversion of mg a.i./kg diet to mg a.i./kg bw). No such information was provided in Chapter 3 or in Attachment 1-7 of the final BE. In addition, Clemow et al. (2016) noted a mistake that was made in estimating the "number of exceedances of thresholds and endpoints for upper bound and mean EECs". For above-ground and soil dwelling arthropods, EPA (2016a) compared dose-based thresholds with dietary exposure concentrations. This is an incorrect approach, as dietary EECs and dose-based effects metrics have differing units and do not reflect the same measures.

In their final BE for chlorpyrifos, EPA (2017a) did not address the above concerns within Chapter 3, Attachment 1-7, or in the TEDtool calculations. In EPA's response to the letter requesting comment period extension (EPA, 2016b), an attempt was made to clarify the location of the missing terrestrial invertebrate dose-based EEC results. This explanation noted that the results were located throughout Section 4 and 5 of Attachment 1-7, as well as in the TEDtool tabs "min and max rate concentrations". However, the location of these results cannot be found in either the draft or final BEs (EPA 2016a; 2017a).

CLA (2016) made note of the fact that it is Agency policy to use exposure estimates from BeeREX to assess the risk of pesticides to all pollinator species, and that the predicted exposure is approximately 50 times higher using T-REX (via the TEDtool) than the corresponding estimates from BeeREX. Regarding this approach, CLA (2016) also noted that the use of the TEDtool instead of BeeREX resulted in "highly exaggerated exposure and risk estimates for listed insect pollinator species and listed species that prey upon them or listed plant species that are reliant on them for pollination".

As a response to CLA's comment, EPA (2017a) added text to Attachment 1-7 stating, "the contact-based exposure approach integrated into the BeeREX model was not used because that approach includes residues that are specific to honey bees. It is assumed here that the arthropod residue values in the T-REX model generally apply to more species. Residues from the two approaches are generally similar." Assuming this was the case, why did the Agency not incorporate BeeREX into their BE to assess risks to pollinator species for which honeybees are an appropriate surrogate? This is a clear demonstration of inconsistency for which EPA chose to apply different screening-level models to the same taxa.

3.4 Spray Drift

Spray drift estimates were not used to make effects determinations for terrestrial species. However, EPA did estimate setback distances for various effects metrics using the spray drift models presented in Attachment 1-7 of the chlorpyrifos BE. DAS (Clemow et al., 2016) and CLA (2016) noted issues with transparency and inappropriate use of drift models employed in the draft BE (EPA, 2016a). These issues were not addressed by EPA (2017a) in the final BE, with the exception of providing units (e.g., ft) where missing and providing an updated link to the related AgDrift software.

In Attachment 1-7 (Equation 1), the Agency presented a model for estimating "the distance where risk extends" based on "an analysis of the deposition curves generated in AgDrift (v. 2.1.1)". Equation 1 is (Equation 1 in Attachment 1-7; Equation 2-3 herein):

$$d_t = \frac{\left(\frac{c5}{F_{AR}}\right)^{\frac{1}{b5}} - 1}{a5}$$

Equation 2-3

Where,

F_{AR} is the fraction of the application rate that is equivalent to the threshold, and
d_t is the distance where the risk extends.

EPA also made reference to **Table A 1-7.1**, which was found on the subsequent page (page A7 (PF)-2) and contained numerical values for the parameters a5, b5 and c5 for aerial, ground and airblast application methods for a range of droplet size spectra.

A reference for Equation 2-3 was not given. However, in the same paragraph, a footnote referenced AgDrift (v.2.1.1). The most recent AgDrift User's Manual (Teske et al., 2003) that is available in the regulatory version download (file name: agdrift_2.1.1.zip; retrieved from: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#atmospheric; March 29, 2016) contains the following equation used for Tier I ground sprayer assessment (Equation 2-21 in manual):

$$D(x) = \frac{c}{[1+ax]^b}$$

Equation 2-4

Where,

D(x) is the deposition level relative to the nominal application rate, x is the downwind distance (in feet), and a, b and c are model parameters.

This equation can be rearranged to give Equation 2-5, as follows (assuming *x* in the User's Manual is d_t, and $D(x)$ is F_{AR}):

$$[1+ax]^b = \frac{c}{D(x)}$$

Equation 2-5

$$x = \frac{\left(\frac{c}{D(x)}\right)^{\frac{1}{b}} - 1}{a}$$

Equation 2-6

Presumably then, the Agency obtained Equation 2-21 from the AgDrift User's Manual. However, in the User's Manual this equation applied to *low boom ground sprayer applications* and described models fit to *empirical ground sprayer data* only. It is unclear how EPA determined the three parameters for any of the application methods (ground, aerial or airblast), as even the parameter values for ground spray did not match those presented in the User's Manual. The Agency referred to an analysis of AgDrift output that was not presented, nor cited. Finally, EPA (2016a; 2017a) did not specify how many swaths the model and associated parameters (Equation 1 and Table A 1-7.1 in Attachment 1-7) apply to. In the AgDrift User's Manual, a, b and c parameters were estimated for a single swath only. AgDrift v.2.1.1 does not provide numerical values for *a, b* or *c* in any of the software's output.

3.5 Chemical Specific Comments on Selected Input Parameters

The comments provided below are focused on the chemical-specific assumptions made by EPA (2016a; 2017a) in their terrestrial exposure modeling. This section provides comments on the input parameters selected for use in the TEDtool (Section 2.5.1through 2.5.5), as well as chemical-specific results presented in the BE (Section 2.5.6). Some comments also apply to descriptions and references presented in Attachment 1-7 and Chapter 3. Comments are organized based on the chemical specific inputs for: daily fraction retained, aerobic metabolism half-life. Log Kow, Koc, Henry's Law constant and bioconcentration factors (BCFs).

In general, EPA (2016a) failed to provide appropriate references for all chemical specific-parameters in each location where the data were used. Moreover, EPA failed to provide a discussion on the relevance of the studies and rationale for selected parameters where appropriate in their draft BE (EPA, 2016a). This made review and interpretation of results within the BE a difficult task. The comments below outline what EPA addressed, or failed to address, in their final biological evaluation (EPA, 2017a).

3.5.1 Daily Fraction Retained

In their draft BE, EPA (2016a) was not consistent in describing their approaches for estimating dietary exposure estimates and metabolism of daily intake. As such, it was difficult to understand their approach without accessing and reviewing the calculations located in the TEDtool. DAS commented on a number of inconsistencies throughout the draft BE on this issue (Clemow et al., 2016).

For their final BE, EPA (2017a) added some clarifying text in Attachment 1-7, noting that in their approach for estimating upper bound and mean concentrations of pesticides in birds, mammals, reptiles, and amphibians (in addition to referring to T-HERPs for more detail), "concentrations in mammals and birds are decreased on a daily basis based on elimination or metabolism." And that … "the amount of chemical that is retained from one day to the next is based on chemical-specific magnitude on the residue studies with chickens and rats." This added text outlined the lack of consideration for elimination and metabolism in the exposure estimates.

A description of how "daily fraction retained" was selected and used in the calculations of exposure was not provided. Moreover, in their draft BE, EPA (2016a) used daily fraction retained values of 0.82 for both birds and mammals, without providing references. In the final BE (EPA, 2017a), daily fraction retained values of 0.47 for mammals (MRID 40458901) and 0.895 for birds (MRID 00161743) were reported in the TEDtool inputs page. However, the studies and data used were not described in Chapter 3 or Attachment 1-7 of the document. As such, it is unclear as to why the values were changed. To maintain transparency, EPA (2017a) should have provided detailed summaries of the studies and a description of the data that were used to estimate all parameters used in their exposure modeling.

3.5.2 Aerobic Metabolism Half-life, Log Kow, Koc and Henry's Law Constant

EPA (2016a) did not provide appropriate references for many of the fate properties used in the TEDtool templates of the draft BE, including aerobic soil metabolism, Log Kow, Koc, and Henry's Law constant. EPA attempted to clarify the location of these references in their response to the request for an extension to the comment period (See Comment H-14 in their response; EPA, 2016b, c). However, to maintain full transparency and efficiency for review, it was noted by DAS (Clemow et al., 2016) that EPA should provide full references for each value or assumption presented in the TEDtool and throughout the document.

After thorough review of the final BE (EPA, 2017a), it appears that EPA provided reference MRID numbers for their selected aerobic metabolism half-life value of 170.6 and Koc value of 6040 in the final TEDtool and Table 3-1 of Chapter 3 (Cranor, 1990 [MRID 42144911]; Acc # 260794). However, it remains unclear where the full references for these studies can be located within the document.

In the final BE, EPA (2017a) added the reference of Tomlin (2004) to the TEDtool input pages for both the Henry's law constant and LogKow values. However, this reference was not provided within Chapter 3 (exposure assessment), nor could the full reference be located in any of the fate reference appendices (3-1 or 3-2). The absence of this reference impedes the transparency of the assessment. Further, DAS previously recommended the use of a LogKow value of 5 from

MacKay et al (2014). EPA did not consider this recommendation in their final BE for chlorpyrifos (EPA, 2017a).

3.5.3 BCFs

DAS (Clemow et al., 2016) reported a number of concerns with the transparency of the bioconcentration factors (BCFs) selected for use in the terrestrial exposure modeling of the draft BE (EPA, 2016a). Specifically, references were not provided within the TEDtool input parameter table and the full data sets (typically n = 3) for empirically-derived BCFs were not provided in Chapter 3. As such, the selected values reported in Chapter 3 (Table 3-1) did not match those used in the TEDtool.

DAS (Clemow et al. 2016) noted that in Chapter 3, EPA (2016a) lacked details on the BCF of 2407 µg a.i./kg per µg a.i./L that was estimated for plants and algae using KABAM. A description of the model and associated assumptions should have been provided, and were not included in the final BE (EPA, 2017a).

Additionally, it was noted by Clemow et al. (2016) that in their draft BE, EPA (2016a) reported mean and upper bound BCFs for aquatic invertebrates of 585 and 796 µg a.i./kg per µg a.i./L, respectively, with a corresponding range of 400-874 µg a.i./kg per µg a.i./L. As was discussed in the comments on the draft BE (Clemow et al., 2016), a max and mean BCF of 874 and 585 µg a.i./kg ww per µa.i./L, respectively, were reported in Chapter 3 (section 3.3.2), and in Table 3-1, a BCF of 874 µg a.i./kg ww per µa.i./L for eastern oyster (whole organism) was reported as "80% of total radioactivity at the end of the study excluding transformation products (Thacker et al. 1992 [MRID 42495406])". If 874 µg a.i./kg ww per µa.i./L is the maximum than what does the selected BCF of 796 µg a.i./kg ww per µa.i./L represent? EPA (2016a) should have provided a data table and description of how they selected their BCF values. A similar issue existed with the BCFs reported for fish. It the draft and final TEDtool (EPA, 2016a; 2017a), the reported mean and upper bound BCF values were 1513 and 3058 µg a.i./kg per µg a.i./L, respectively, when the BCF reported in Table 3-1 of Chapter 3 was 874 µg a.i./kg per µg a.i./L. These clarifications should have been made by EPA to increase the transparency of the selection process and data used to estimate BCFs.

Finally, DAS noted that EPA failed to provide a justification for the selection of 10 and 100 µg a.i./L as the water concentration assumptions to estimate exposure (Clemow et al., 2016). In their final BE, EPA (2017a) did not further clarify their selection of water concentrations, but instead changed the text in Attachment 1-7 to suggest that the selected concentrations represented "a bound of the lower and upper range of aquatic EECs generated by PWC (i.e., 10 and 100 µg a.i./L, respectively)". Further discussion was still missing from EPA (2017a) to justify these concentrations (i.e., model inputs, assumptions, output, and statistics).

3.5.4 Exposure Results

DAS (Clemow et al., 2016) noted a number of errors in EPA's draft BE exposure results, Table 3-17 (EPA, 2016a). Specifically, the reported mean and upper bound dietary EECs for small herbivorous mammals and small insectivorous amphibians could not be verified within the draft TEDtool files. Additionally, Clemow et al. (2016) indicated a total lack of clarity in the range of EECs reported for aquatic plants, invertebrates and fish. In Table 3-17 of their draft BE and Table 3-21 of the final BE, EPA (2016a; 2017a) indicated that water concentrations ranged from 0.01 to 100 µg/L, when in reality within the TEDtool framework, only water concentrations of 10 µg/L and 100 µg/L were used to estimate "min" and "max" aquatic exposure scenarios. The reason for the mismatching ranges of aquatic values was not made clear in the draft and final BEs (EPA, 2016a; 2017a).

Upon thorough comparison of the exposure results reported in Table 3-21 of the final BE (EPA, 2017a) and the final TEDtool files, these errors have not been fixed and the upper bound and mean dietary EECs reported for birds, mammals and amphibians as dietary items were incorrectly reported in Table 3-21 for all use patterns. Moreover, all dietary item EECs were incorrectly reported for the use patterns of 4 lb a.i./A applied two times per season.

DAS (Clemow et al., 2016) also highlighted the mistake made in the water concentration assumption for the upper bound concentration in the diet of the Chiricaluna leopard frog (*Rana chiricahuensis*), where a water concentration of 100 µg a.i./L was used (Input cell C66) instead of 10 µg a.i./L (input cell C65). EPA did not fix this mistake for their final BE TEDtool files

(EPA, 2017a). This mistake led to an upper bound concentration in the diet that was 10x higher than it should have been.

4.0 AQUATIC EXPOSURE MODELING

4.1 Spatial Analysis

4.1.1 Agricultural Crop Footprint Development and Use of the NASS Census of Agriculture Dataset (CoA)

The methodology for agricultural crop footprint development described in the draft BE (EPA, 2016a) included the use of the NASS Census of Agriculture (CoA) county-level crop acreage data to serve as a benchmark for adjusting the CDL-based footprints. DAS (Winchell et al., 2016a) provided several arguments challenging the validity and need for this approach. These included the following:

- Not accounting for the uncertainty bounds associated with the CoA dataset
- The assumption that the CoA dataset is inherently more accurate than the CDL, requiring that CDL-estimated acreages be adjusted to match CoA.
- That the expansion method employed by EPA to match CoA data is arbitrary and may result in more errors in land use/crop pixel classification than improvements over the native CDL data

Additional concerns that DAS (Winchell et al., 2016a), FESTF (2016), and CLA (2016) expressed regarding the development of agricultural crop footprints included:

- Not using additional high quality land use datasets (e.g., the NLCD) to provide further support in generating crop footprints
- Applying the crop group lumping strategy to address errors of omission in the raw data, but not in any way accounting for errors of omission.
- Certain geographic restrictions on chlorpyrifos use (e.g., on wheat) were not accounted for in EPA’s crop footprint development.

- Use restriction specifics on current pesticide labels were not accounted for in EPA's derivation of crop footprints

- Crop groupings that are too broad, contain too many crops, and that should be split into smaller crop groupings to achieve more refined estimates of potential use extent.

The CDL classes that EPA assumed for the "Other Grains", "Vegetables and Ground Fruit", Orchards and Grapes", and "Pasture/Hay" crop groups each contained multiple crops that are not part of the chlorpyrifos labels. This was explicitly pointed out in the comments by Winchell et al. (2016a), but not addressed in the final BE or in responses to the draft BE comments.

The final BE did not modify the methodology for the agricultural crop footprint development and did not specifically comment on any of the concerns raised by DAS in the comments to the draft BE (Winchell et al., 2016a).

It was noted in FESTF's comments (FESTF, 2016) that some local (state) spatial datasets were not included in the development of crop footprints that would have provided added value (e.g., Washington State Department of Agriculture and the California Farmland Mapping and Monitoring Program).

Suggestions were made by DAS (Winchell et al., 2016a), FESTF (2016) and CLA (2016) to quantitatively incorporate the CDL accuracy reports into the derivation of the crop footprints. Ultimately, it was recommended that national probabilistic crop footprints that take into account uncertainty in classification, as demonstrated by Budreski et al. (2015), should be adopted. The EPA has not indicated that these probabilistic approaches will be pursued.

4.1.2 Potential Pesticide Use Sites for Non-Agricultural Uses

The use of NCLD Open Space Developed land use categories were used by EPA in the draft BE (EPA, 2016a) to represent non-agricultural uses, but it was unclear what specific use patterns were assigned to each land use class. The final BE (EPA, 2017a) did not provide any further clarification on this issue.

The cattle ear tag uses were mapped spatially to rangeland, but use only occurs when pest pressure is high (FESTF, 2016). The suggestion was made to use cattle density information to refine the footprint for this use pattern. The final BE did not incorporate these suggested changes.

4.1.3 Use Site Footprint for Nursery Uses

In the comments on the draft BE, DAS (Winchell et al., 2016a) noted that the dataset used to derive the footprint for nurseries (Dun & Bradstreet (D&B)) was not publicly available, thus was difficult to evaluate.

The final BE listed the reference for the Dun & Bradstreet dataset and provided a web link (http://igeo.epa.gov/data/Restricted/OEI/Agriculture/DunAndBradstreet_Agriculture.zip). This web link was tested and was determined to be non-functional. Therefore, there remains an issue with accessibility of the data required to derive the nursery use site footprint.

4.1.4 Species Habitat and Range Data

DAS commented on the draft BE (Winchell et al., 2016a) that the species habitat and range data used by EPA in the co-occurrence analysis were not made publicly available as part of the BE documentation. The lack of transparency and availability of species location data was discussed in detail in the FESTF comments to the draft BEs (FESTF, 2016)

At the time of the final BE publication, the spatial datasets used by the EPA and the services were still not available. Making this data publicly available should be a requirement for the pilot OP BEs and all subsequent BEs prior to finalization of the reports.

In addition, FESTF (2016) challenged that the EPA's spatial data used to represent species locations appeared to be only at the county level for the vast majority (~90%) of species. This led to a significant over-representation of the spatial extent of the locations for these 90% of species. The final BEs (EPA, 2017a) did not indicate any changes to the spatial data used in the assessment, thus still over-predict species extents and co-occurrence with potential use sites.

FESTF (2016) described in their comments the use of species attribute information, including special habitat preferences and requirements, in the refinement of a co-occurrence analysis. Both the EPA and FESTF have compiled these types of species attributes, but the EPA did not appear to directly use this information in compiling the final BE. DAS supports this level of refinement in final effects determinations.

4.1.5 Action Area and Overlay Analysis

The offsite transport zone due to spray drift was determined based upon the most sensitive aquatic habitat (Bin 5) and assumed to apply for all species. Winchell et al. (2016a) disagreed with this approach because many species do not occupy the small static (Bin 5) habitat, and thus an action area that is based upon exposure potential in this type of water body is irrelevant. This approach has the potential to result in some species falling within the action area that should not. The alternative proposed by DAS was to derive more refined action areas that are appropriate for each species or taxon. The final BE (EPA, 2017a, b) did not comment on the proposed alternative approach and included the same approach as was used in the draft BE.

The method EPA used for the overlay analysis of use sites with species habitat/range was implemented as a raster-based computation that is limited to 30-meter resolution. A vector-based approach to overlap analysis was recommended by DAS (Winchell et al., 2016a) as being a more accurate alternative that is able to resolve overlap and proximity at distances less than a single 30-meter pixel. The final BE approach remained unchanged from the draft BE on this topic and no comment was provided on the DAS recommendations (EPA, 2017a, b).

It was suggested by FESTF (2016) and CLA (2016) that temporal factors be considered in co-occurrence and overlay analysis. The example of migratory birds was given to show some species are only present in portions of their range for limited amounts of time. The temporal nature of species locations was not considered in the final BE.

4.2 Aquatic Exposure Modeling for Chlorpyrifos

4.2.1 Environmental Fate Data and Model Input Derivation

DAS (Winchell et al., 2016a) commented on the selection of environmental fate inputs for the aquatic modeling summarized in Table 3-5 of the draft BE (EPA, 2016a) (Table 3-6 of the final BE; EPA, 2017a). These comments noted that a comprehensive and exhaustive analysis of the wealth of chlorpyrifos environmental fate data was reported in Giesy and Solomon (2014), and that the conservative aquatic modeling exposure model parameters derived in the Giesy and Solomon (2014) report were the appropriate values to use in Step 2 ESA modeling. The screening level methods used to derive the aquatic exposure input parameters in the chlorpyrifos BE did not accurately reflect chlorpyrifos behavior in the environment and contributed to overly-conservative predictions of aquatic exposure. There were no changes made to the environmental fate model input assumptions in the final BE (EPA, 2017a), nor were the concerns expressed by DAS addressed in the EPA responses to comments (EPA, 2017b).

4.2.2 PFAM Modeling

DAS (Winchell et al. 2016a) commented specifically that the draft BE incorrectly stated that the EECs for cranberry uses modeled with PFAM were in the range of the EECs generated using PRZM5/VVWM. This was not true, as the EECs simulated using PRZM/VVWM were, at times, several orders of magnitude higher than PFAM EECs. With change in the final BEs to consider 24-hour average instead of instantaneous peak EECs, the PRZM/VVWM EECs were closer to the PFAM EECs, but still substantially higher in some cases. This issue was not specifically addressed in EPA's responses to comments on the draft BEs (EPA, 2017b).

CLA (2016) also noted that a conceptual model for the use patterns modeled with PFAM was not sufficiently presented, and that details of the cranberry use simulations were not provided. No changes were observed in the final BE that addressed the documentation deficiency of the PFAM simulations.

4.2.3 Spray Drift Modeling and Contributions to Exposure

4.2.3.1 General Conservatism in Drift Modeling

The drift methods applied in the BE were standard Tier 2 FIFRA methods that can significantly over predict exposure potential. The assumption of a 10 mph wind always blowing from a treated field to the water body, without accounting for the use of spray drift reduction technologies, leads to predictions of drift loadings into nearby waters that are too high. Recommendations were made by CLA (2016) and DAS (Winchell et al., 2016) to include a probabilistic representation of drift loading in the BE, along the lines of suggestions by the NAS panel report (NAS, 2013). The suggested refinements in the drift modeling were not adopted nor addressed by the EPA in the final BE.

4.2.3.2 Selection of Drift Models

The EPA used the AgDRIFT Tier I model in the simulation of drift contributions to aquatic habitat (aside from the mosquito adulticide uses where the AGDISP model was applied). For ground spray modeling, CLA (2016) suggested the use of the RegDisp model, which allows for the selection of specific nozzles, spray quality, and wind speed. The AgDRIFT model is not representative of current spray equipment used in practice and greatly over-predicts spray deposition compared to current practices. For aerial applications, it was suggested that AGDISP, which is parametrized for current spray nozzles and typical wind speeds, would be the most appropriate model to use. No changes to the spray drift models were made for the final BE.

4.2.3.3 Drift Fraction Calculations

The DAS comments on the draft BE (Winchell et al., 2016a) noted that the selection of orchard airblast drift fractions based on “sparse (young, dormant)” conditions was not reflective of conditions for chlorpyrifos applications (DAS, 2015). The most representative orchard condition for chlorpyrifos applications available in the AgDRIFT model would be the combination orchard option of “Orchard”, which combines “apple, almond, orange, grapefruit, small grapefruit, pecan, and dormant apples”. The final BE did not modify the orchard condition as suggested, nor did the responses to the draft BE comments address this issue (EPA, 2017a,b).

4.2.4 Effects of Current Mitigations on Exposure

Winchell et al. (2016a) commented on EPA's statement in the malathion BE (also applicable to chlorpyrifos) that, "while spray drift buffers reduce exposure to aquatic environments from direct deposition of finished spray on water via drift, they do not impact modeled estimates of run-off received by the waterbody." DAS (Winchell et al., 2016a) provided evidence and citations that spray buffers will, in fact, have an effect of reducing runoff related exposure to aquatic water bodies (e.g., USDA, 2000; Poletika et al., 2009)

The final BE (EPA, 2017a) did not address this comment. While it would be typical to not include effects of runoff and erosion reduction from vegetated buffers in screening level exposure assessments, they should be accounted for in refined assessments. At the very least, it should be acknowledged in a qualitative sense that runoff-based exposure contributions to receiving water are mitigated by the presence of vegetation between the edge of field and a receiving water body, regardless of whether that buffer area is a well-maintained grass buffer of natural vegetation.

4.2.5 Application Timing Effects on Exposure

Winchell et al. (2016a) was concerned with the statement by EPA in the malathion BE (also applicable to chlorpyrifos) that, "moving single application dates in which 100% of a watershed is treated in a single day in small increments can have a substantial impact on peak EECs and smaller impacts on chronic EECs. Though EEC differences can be substantial, changes of application day by less than one week should not be construed as a model refinement and should only be considered a demonstration of model sensitivity." In EPA's modeling, only a single conservative application date was chosen. DAS (Winchell et al., 2016a) argued that application timing is a sensitive parameter in runoff-driven aquatic exposure modeling. To properly evaluate the likelihood of pesticide exposure, the range of possible application dates needs to be accounted for in exposure predictions.

EPA's final BE (EPA 2017a) did not address this comment nor modify the modeling approach to account for the recommendation. While the selection of a single "worst case" date within a known application window is appropriate for initial screening-level exposure modeling, the Step

2 of EPA's assessment should have more rigorously considered the variability of application timing when predicting chlorpyrifos EECs. Accounting for the uncertainty in application timing using probabilistic methods would have resulted in lower EECs than only accounting for a conservative, "worst case", application date.

Another point concerning application timing that was made in CLA's (2016) response to the draft BE (EPA, 2016a) was that EPA stated, "efforts may be made to avoid pesticide application right before precipitation events", however this did not appear to be considered in the parameterization of the models. This issue was not further addressed in the final BE and remains an important consideration in refining the potential for exposure.

4.2.6 Aquatic Exposure Modeling Results

4.2.6.1 General Comments

DAS (Winchell et al., 2016a) provided extensive comments on the EEC results presented in the draft BE (EPA, 2016a) and provided numerous arguments demonstrating how unrealistic and implausible they were. DAS also provided extensive data analysis to support these positions. Some of the primary arguments supporting how unrealistic the EECs were included:

- Predicted concentrations in aquatic habitats that were approximately two to nearly four orders of magnitude higher than the highest monitoring data reported.
- Modeled medium flow (Bin 3) and high flow (Bin 4) concentrations that were 30 to 86,000 times higher than the solubility limit of chlorpyrifos.
- Flowing water concentrations (in all size bins) many times higher than in static water habitat bins.
- Predicted concentrations in receiving waters that were multiple orders of magnitude higher than the edge of field concentrations.

Recommendations made by DAS to address the significant over-predictions across the range of aquatic habitat bins included the following:

- For flowing water habitat screening level EECs:
  - Incorporate a baseflow rate equal to the minimum of the flow range associated with each habitat bin.
  - Constrain the watershed areas to those that can drain into a main channel within one day.
  - Apply Percent Cropped Area (PCA) adjustments at a minimum to Bin 3 and Bin 4.
  - Replace VVWM with a receiving water model designed to simulate pesticide fate and transport in a flowing channel. The Soil and Water Assessment Tool (SWAT) has this capability and has been shown to produce realistic peak exposure values for small, medium, and large flowing water bodies (refer to Giddings and Winchell, 2016 for details).
- For static water habitat screening-level EECs:
  - Correct the assumption that the entire watershed's pesticide mass generated in one day arrives at the receiving water body instantaneously (equivalent to daily average instead of peak EECs, and applied to flowing water as well).
  - Constrain the watershed areas of the static water body habitats to areas based on typical bin-specific water body configurations on the landscape, as opposed to allowing climatologically-driven water balance calculations to wholly determine the watershed area.
  - The watershed areas should also be constrained to allow a limited amount of regional variability. The significant amount of watershed area variability in the BE static bin scenarios across the HUC2s has led to an artificially-wide range in EECs that cannot be justified based on monitoring data or our conceptual understanding of hydrology and aquatic exposure pathways. Constraining the watershed areas within a regionally-limited range will allow for a clearer interpretation of the relative risk of pesticide use based on regional variability in precipitation, soils and slopes, and use patterns

- For refined modeling of all aquatic EECs:
    - Representation of the heterogeneous landscape through explicit simulation of the land uses and soils that comprise a given watershed.
    - Spatially-explicit predictions of EECs that can be associated with species habitat locations.
    - Account for variability in pesticide application timing that occurs at the watershed scale.
    - Incorporate Percent Treated Area (PTA) that acknowledges that 100% of potential use sites do not get treated with a given pesticide.
    - Account for environmental variability and model assumption and input uncertainty through a more robust probabilistic approach to predicting EECs. Examples of the approaches are described in Padilla and Winchell (2016) for static water and Winchell et al. (2016) for flowing water.

The draft BE comments from CLA (2016) provided a long list of similar suggestions for ways in which the aquatic exposure modeling should be refined. The main themes of these suggestions were, (1) account for much greater spatial variability and landscape heterogeneity; (2) use EEC predictions with higher resolution (spatially explicit); (3) use best available spatial datasets; and (4) incorporate probabilistic model inputs and outputs. These higher tier modeling recommendations were not incorporated to the final BEs; however, EPA has indicated that some of these types of refinements will be considered as their overall ESA process evolves.

The final BE did have several important changes in the aquatic exposure modeling that were reported in the main body of Chapter 3. These included:

- Reporting of daily (24-hour) mean concentrations instead of peak concentrations for all flowing and static habitat bins.

- Incorporation of baseflow into the Bin 3 and Bin 4 flowing water predictions.

An additional update to the aquatic exposure modeling that was discussed in the final BE, but not incorporated into the updated modeling of EECs, was accounting for the variability in the "time-of-travel" to a watershed outlet for the medium and large flowing water habitats (Bin 3 and Bin 4). It was suggested that this conceptual change in the modeling of Bin 3 and Bin 4 exposure would be implemented in the BEs being prepared for carbaryl and methomyl.

DAS supports these updates made to the exposure modeling presented in the final chlorpyrifos BE (EPA, 2017a).

These changes adopted by EPA for the final BE resulted in significant reductions of EECs for the flowing water habitat Bin 2, ranging from no change (HUC 7) to a maximum concentration that was 15.5 times lower (HUC 12b). For Bin 3 and Bin 4, the modified flowing water modeling approach brought down EECs from values several orders of magnitude above solubility, to ranges closer to the Bin 2 EECs, but still reached solubility limits in some scenarios. The EECs for the static water habitats (Bin 5, Bin 6, and Bin 7) were generally a little lower than those presented in the draft BE (mean of 1.1 times lower), but oddly, there was one case where the EECs in the final BE were higher (HUC 3). We do support the inclusion of baseflow to Bin 2, in addition to Bin 3 and Bin 4, as low flow streams will have baseflow as well. We also believe that the "time-of-travel" being explored by EPA for future BEs has the potential to lead to further improvements in realism of the EECs in each aquatic habitat.

The aquatic EECs in the final BE (EPA, 2017a) were an improvement over the EECs in the draft BE (EPA, 2016a) due to the incorporation of more realistic assumptions and adopting the daily average concentrations instead of the erroneous peak concentrations. Nevertheless, there are still reasons for concern regarding the EECs reported in the final BE. A review of these EECs in Table 3-8 shows the following for the 1 in 15 year annual maximum daily average water column EECs:

- Bin 2 maximum EECs were lower than Bin 3 in 10 of 30 HUC2/weather groups. Overall, the ratio between Bin 2 and Bin 3 maximum EECs ranged between 0.5 and 1.5 (median of 1.1). In their draft BE, EPA conservatively estimated that Bin 3 EECs should be at least 5 times lower than Bin 2. These results indicate Bin 3 EECs were very near to, or sometimes higher than, Bin 2.

- Bin 2 maximum EECs were lower than Bin 4 EECs in 8 of 30 HUC2/weather groups. Overall, the ratio between Bin 2 and Bin 4 maximum EECs ranged between 0.36 and 2.8 (median of 1.2). In their draft BE, EPA conservatively estimated that Bin 4 EECs should be at least 10 times lower than Bin 2. These results indicate Bin 4 EECs were very near to, or sometimes higher than, Bin 4. This trend disagrees with our conceptual understanding of exposure variation between small and large flowing water bodies.

- The static water EECs in Bin 5 were generally slightly higher than the Bin 2 flowing EECs (median of 2.3 times higher). There were a few notable exceptions, particularly Bin 5 in HUC2 1, 4, 17a, and 17b, where the Bin 5 EEC was more than 15 times higher (maximum 17.7 in HUC 1) than the Bin 2 EEC. Because the Bin 2 and Bin 5 habitats both represent very shallow, low volume, high vulnerability habitat, we would expect EECs to be similar, but slightly higher in Bin 5. In the final BE modeling, the Bin 2 EECs were higher than the Bin 5 EECs in 20 out of 30 HUC2/weather groups.

- The large flowing (Bin 4) habitat EECs were up to 43.5 times higher than the large static (Bin 7) EECs (a median of 1.8 times higher). While referred to as a “large static” habitat, Bin 7 represents a small pond, and is equivalent to EPA’s standard “farm pond” that is considered to be a high vulnerability water body in ecological risk assessment under FIFRA.

These observations indicate that, from a conceptual standpoint, the simulated EECs in the medium and large flowing habitats (Bin 3 and Bin 4) are still grossly over-predicted. Both Bin 3 and Bin 4 EECs should be at least 5 to 10 times lower than Bin 2. Furthermore, both Bin 3 and Bin 4 EECs should be multiple times lower than the high vulnerability standard farm pond (Bin 7). The current set of screening-level EECs did not match with our basic understanding of pesticide concentrations across water bodies of a range of characteristics and sizes.

4.2.6.2 Exceedances of Chlorpyrifos Solubility Limit

In both the draft and final BEs, EPA aquatic modeling resulted in EECs for multiple scenarios that exceeded a high-end estimate of chlorpyrifos solubility (2 mg/L). In comment on the draft BE (Winchell et al., 2016a), DAS noted that the predictions of EECs well in excess of a conservative solubility limit points to deficiencies in the modeling approach, as we would expect concentrations at these levels to never occur in the environment. In the modeling for the final BE, the solubility limit was exceeded in at least one HUC2 watershed for each of the six habitat bins modeled, with solubility exceedances most prevalent for the urban use scenarios.

In their responses to comments on the daft BEs, EPA (2017b) did not directly address the concern over the prevalence of chlorpyrifos EECs above solubility. DAS continues to be concerned over this phenomenon in the modeling, and strongly believes that it serves as an indicator of the flawed structure and assumptions in the modeling approach that need to be investigated further.

4.2.6.3 Comparison of EECs with Edge of Field Concentrations

In the DAS comments on the draft BE (Winchell et al., 2016a), an analysis was presented demonstrating that for many of the habitat bins modeled (Bin 2, 5, 6, and 7), the simulated edge of field chlorpyrifos concentrations were often greater than the simulated receiving water concentrations. This was especially true for Bin 2, Bin 5, Bin 6, and in HUC2s with the larger assumed watersheds associated with each habitat. This phenomenon was extremely problematic, and in large part due to the erroneous calculation of an instantaneous “peak” concentration, which has been addressed by EPA in choosing to report the daily average concentrations instead of the peak daily values.

A similar analysis comparing modeled edge of field concentrations to the modeled receiving water concentrations was not conducted with the updated EECs from the final BE. We believe that there may still remain some conceptual errors in some of the modeling for both the flowing and static habitat bins that has led to these apparently erroneous concentrations. We recommend that EPA look into this issue in greater detail to ensure that receiving water concentrations do not exceed edge of field concentrations.

4.2.7 Aquatic Exposure Modeling Sensitivity Analysis

The aquatic exposure sensitivity analysis was only conducted for environmental fate parameters and application dates. The DAS comments on the draft BE (Winchell et al., 2016a), suggested that, given that the flowing water scenarios and modeling approaches were brand new, a sensitivity analysis that included additional parameters would have been valuable. Some recommended parameters to add to the sensitivity analysis were: water body dimensions, water body flow rates within the range of the bin, watershed area, and flow-through options.

The final BE updated the sensitivity analysis section to include two additional bins (Bin 3 and Bin 4) and included the results based on the updated EECs. However, the final BE did not add any of the additional parameters that were suggested. We maintain that, given the novelty of the new aquatic habitat water bodies, additional sensitivity analyses should be conducted.

4.2.8 Evaluation of Monitoring Data

In comments on the draft BE (Winchell et al., 2016a), DAS noted that while monitoring data were discussed, they were not explicitly used as a line of evidence in the risk assessment. DAS further recommended the use of new statistical approaches for deriving concentration time series from monitoring data such as the SEAWAVEQ being developed by EPA scientists and robust bias factor approaches (Mosquin, 2012). The final BE did not make any further use of monitoring data than the draft BE. Our position remains that more rigorous analysis of the monitoring data is needed, and that monitoring data need to be considered as a line of evidence in the weight of evidence analysis.

The monitoring data reported by EPA in both the draft and final BEs showed that out of 68,000 samples taken since 1988, the highest chlorpyrifos detections were 14.7 and 3.96 µg/L. Even after the improvements to the aquatic modeling for the final BE, the highest modeled concentrations of chlorpyrifos across the different HUC2s for each of the six habitat bins ranged as follows (including agricultural and urban uses):

- Bin 2: 129 – 2,000 µg/L
- Bin 3: 117 – 2,000 µg/L

- Bin 4: 117 – 2,000 μg/L
- Bin 5: 67 – 2,000 μg/L
- Bin 6: 16 – 2,000 μg/L
- Bin 7: 6 – 2,000 μg/L

The chlorpyrifos concentrations modeled by EPA were often multiple orders of magnitude higher than the highest chlorpyrifos concentrations ever measured in the environment, from low flow and small static water bodies where samples temporally overlap with pesticide use. This significant discrepancy continues to point to hyper-conservatism, and significant adjustments to the modeling are still required to obtain reasonable screening-level exposure estimates.

4.2.9 WARP Model and Extrapolation of Monitoring Results

The WARP model, a conservative exposure screening tool, was used to estimate concentrations of chlorpyrifos. WARP-predicted concentrations provide valuable information about potential locations and upper bounds on the magnitude of pesticide exposure that should be considered in a weight of evidence approach. Upper 95th percent confidence bound WARP concentrations were several orders of magnitude lower than concentrations predicted with PRZM/VVWM models.

Winchell et al. (2016a) commented that due to the significant discrepancies between the WARP and PRZM/VVWM predictions, further investigation into the reasons for the discrepancies and the legitimacy of the PRZM/VVWM-based exposure predictions should have been conducted. Furthermore, they noted that the results of the WARP analysis were not accounted for in the LAA/NLAA determinations. No changes were made to the final BE for how the WARP modeling was considered in the exposure assessment or effects determination, and the concerns raised by DAS were not addressed in EPA's responses to comments on the draft BE (EPA, 2017b).

4.2.10 Uncertainties in Aquatic Modeling and Monitoring Estimates

DAS (Winchell et al., 2016a) described several important sources of uncertainty that were not accounted for in the draft BEs. These included:

- Static water body volume;
- Watershed sizes;
- Flowing water body volume and baseflow;
- Shallow subsurface (interflow) variability and contributions;
- Multiple conservative drift modeling assumptions, including wind speed, wind direction, vegetation interception, BMPs followed by applicators; and
- Chlorpyrifos application dates.

The final BEs did not further address any of these issues, other than to add a constant baseflow component to the medium and large flowing water habitats.

In addition, Winchell et al. (2016a) critiqued EPA's discussion on the uncertainty in the modeling of Bin 3 and Bin 4 habitats. However, this discussion in EPA's final BE (EPA, 2017a) has not changed. There was still general acknowledgement that PRZM and VVWM are field scale models, and that extrapolating the use of those models to medium and large watersheds neglects some important watershed scale-landscape and hydrodynamic processes. In the comments to the draft BE, DAS recommended that a full watershed scale model, such as SWAT (Gassman et al., 2014), be adopted in part or in entirety as the appropriate model for predicting flowing water habitat concentrations of pesticides for use in endangered species aquatic exposure assessments.

There remains a need for a true watershed and flowing water modeling approach for the BE process. It has been shown previously that the current iteration of aquatic exposure modeling in flowing water bodies still significantly over-predicts expected screening -level concentrations. This is in part due to the selection of inappropriate models. The use of appropriate models (such as SWAT) that are properly parameterized would lead to much more realistic exposure predictions both at the screening level or refined level.

4.3 Aquatic Exposure Modeling for Endangered Species Assessments, Methodology Development

The topics discussed in this section are focused on the generic methodology that EPA developed for modeling aquatic exposure as part of the endangered species risk assessment process. These methods are detailed in Attachment 3-1 of the BE.

4.3.1 ESA Modeling Compared to Traditional Ecological Modeling Approach

DAS commented on several aspects of the summary of model processes described in Table A3-1.1 (Winchell et al., 2016a). One of the primary descriptions of the conceptual model for endangered species aquatic modeling was concerning water body/flow dilution. The following statement did not reflect EPA's modeling approach to derive EECs in the BEs: "downstream dilution may be used from the edge of the use area, which consists of a percent use area adjustment. Concentrations are reduced by the use area adjustment factor until concentrations are below levels of concern". This concept was considered in the Action Area determination, but was not applied in deriving EECs. This comment remains of concern for DAS, as it does not accurately reflect how exposure values were estimated for use in the risk assessment. The result of not accounting for dilution of percent use area was that EECs were higher than would be found in the real world.

A change in the aquatic exposure modeling for endangered species from what has been traditionally done for ecological exposure modeling under FIFRA was to adopt a 1 in 15 year maximum concentration rather than the standard 1 in 10 year annual maximum concentration. The comments in Winchell et al. (2016a) raised concern over the justification for this change, which EPA connected to the re-registration cycle of 15 years. DAS feels that this change in policy was not appropriately vetted from a scientific standpoint and that 1 in 10 year annual maximum concentrations still represent very conservative and protective exposure estimates.

The conceptual model for the aquatic exposure habitat bins provided in Figure A 3-1.1 was questioned in the draft BE comments by Winchell et al. (2016a). There was uncertainty concerning the source of the 30-m runoff zone threshold, a distance beyond which only spray drift entered static water bodies, as well as how this threshold was implemented in practice. DAS also had concerns regarding the appropriateness of this conceptual model, which represents field scale processes, in simulating pesticide concentrations in medium and large flowing watersheds on the order of the Bin 3 and Bin 4 habitat.

The final BE added some source information to support the notion that runoff as sheet flow becomes channelized after a distance of 30 meters, leading to the assumption that runoff does not connect to static water bodies, but rather becomes a small flowing water body after that distance. The final BE also provided some additional explanation of this assumption.

The additional explanation is helpful; however, it is still unclear how this notion of no runoff contributions to static water bodies beyond 30 meters from the edge of a field was implemented in practice. This concept would require detailed spatial analysis of use site proximity to static water bodies within a species habitat range to determine what portions of endangered species populations would or would not be exposure to pesticide transported via runoff and erosion. In the final BE, it appears that this 30-meter threshold was not considered in any way in deriving EECs or prediction exposure likelihood.

Winchell et al. (2016a) also noted that the aquatic exposure conceptual model was largely built around a “farm pond” type simulation configuration, consisting of a single treated field adjacent to a single receiving water body. The concept of a single treated field immediately adjacent to a receiving water body (over its entire length) is a much less appropriate representation of watershed-scale processes affecting flowing water bodies, and even less so for any of the marine aquatic habitats. Thus, the applicability of this single conceptual model to pesticide transport processes at the medium and large watershed scale remains questionable. It is DAS’s position that an entirely different conceptual model is required for these larger watersheds and their receiving water bodies. In EPA’s responses to comments to the draft BEs (EPA, 2017b), they noted that in future biological evaluations, watershed-scale modeling would be considered when simulating EECs in flowing water bodies. DAS believes this approach should be applied to chlorpyrifos as well. A case study submitted by DAS demonstrating the implementation of a watershed scale modeling approach showed the potential significant effect that this refined approach would have on the prediction of EECs (Winchell et al., 2016b).

4.3.2 Spatial Resolution of Modeling Analysis

The EPA's approach was built upon the HUC2 watershed region as the spatial unit for which the exposure modeling and risk analysis were conducted. Following this structure, only one exposure scenario per crop group was simulated to represent the entire HUC2 (in the case of HUC2 17, the Pacific Northwest, an area of 177,523,042 acres). In their comment on the draft BE, CLA (2016) argued that this was insufficient spatial resolution on which to conduct an exposure assessment, and that much more variability needed to be accounted for. Suggestions were made for development of an exposure scenario at a scale at least as refined as a HUC6 watershed. These suggestions were not adopted or addressed in the final BE, nor were these concerns responded to in the response to comments document (EPA, 2017a, b).

4.3.3 Selection of Crop Scenarios

The two most important comments that DAS (Winchell et al. 2016a) provided for this section were: 1) concerning the methodology and criteria for assigning surrogate PRZM scenarios to crop groups and HUC2s where a PRZM scenario did not already exist, and 2) the criteria applied to determine whether a large range of precipitation existed within a HUC2 watershed, requiring multiple weather stations used in exposure modeling. In the draft BE, both of these methods were not fully explained.

In the final BE, there was no additional information provided concerning the methodology and criterion used to assign surrogate PRZM scenarios to other crop groups and regions. Providing this additional detail would help make the process for scenario selection more transparent. Concerning the weather station data, EPA did provide the necessary details to understand how the decision was made to split the weather for a HUC2 into two representative stations as opposed to only one.

4.3.4 Aquatic Habitat Bins

4.3.4.1 Use of Generic Habitat Bins

Concerning the draft BE, DAS (Winchell et al. 2016) commented on the statement made by EPA that, "the nine aquatic habitat bins are used in the BEs for both Step 1 and Step 2 and will be used for the Biological Opinions in Step 3." DAS recommended that the nine generic bins be used in the screening-level (Step 1) analysis, but that at Step 2 and Step 3 of the Interim Approach, more refined and spatially-explicit aquatic habitat characteristics be used. The draft BE comments from CLA (2016) echoed these same ideas, suggesting that the nine aquatic bins were too generic for accurate estimates of exposure concentrations. For many species, data were available that describe the specific water bodies they inhabit and more detailed information concerning their habitat characteristics. Additional concern was expressed by CLA that the characterization and parameterization of the new aquatic habitat bins had not been fully vetted for modeling purposes.

The final BE used the same language as the draft BE, indicating that refinement in the aquatic habitat characteristics would not be pursued in later steps on the ESA process. DAS strongly recommends generic habitat bins be limited to screening-level stages of endangered species risk assessments, and that additional datasets to support realistic aquatic habitat characteristics be incorporated into the later stages of refinement.

4.3.4.2 Flowing Habitat Bin 2 Characteristics

DAS (Winchell et al. 2016a) provided several comments concerning the characteristics of the low flow (Bin 2) habitat. It was noted that the extremely low velocities assumed for this aquatic habitat (1 ft/min) was atypical of the vast majority of low flow streams, including the slope and roughness that must be assumed to match the characteristics for this water body. In addition, while a range of flow rates defines habitat Bin 2, only the minimum flow rate for the range was considered.

EPA (2017a) did not make any modification to the language of the final BE to address these issues, nor did they provide a rationale for the representativeness of their assumptions. The result of this is an extremely conservative parameterization that represented a fraction of actual low flow habitats observed in nature.

An additional issue that DAS pointed out in the comments to the draft BE (Winchell et al., 2016a) was that the equation used by EPA in estimating a flow velocity for Bin 2 was inaccessible. In the final BE, the EPA inserted the formula used directly into the report, so it can now be readily reviewed.

DAS commented generally on the flowing water habitat flow rate assumptions (Winchell et al., 2016). For each of the three habitat bins, the flow rates were defined to span a range (e.g., 1 m^3/s - 100 m^3/s for Bin 3). Nevertheless, each of the habitat bins was modeled based on assuming the minimum flow within the range. While acceptable for a screening-level analysis (i.e., Step 1), the full range of flows would need to be considered at Step 2 and beyond. The final BE did not make any changes to this assumption and the responses to comments (EPA, 2017b) did not provide any justification for maintaining this assumption.

4.3.4.3 Static Habitat Bin Characteristics

DAS (Winchell et al., 2016a) challenged the use of static water body characteristics that represent only the most vulnerable end of the spectrum based on the habitat definitions that FWS/NMFS provided. While potentially acceptable as an initial screening approach, a more complete range of water body characteristics would need to be considered in Step 2 and Step 3. Furthermore, the relevance of Bin 5 (small static habitat) was challenged. Concerns surrounded the ecological relevance and feasibility of protecting puddle-sized areas of standing water that are largely temporary features on the landscape. The issue of reasonably being able to model these water features with available modeling tools was also raised.

These concerns were not addressed in the content of the final BE (EPA, 2017a). Because Bin 5 EECs, in particular, were some of the highest generated in the exposure modeling, they largely drove the outcome of the risk assessment for many species. It is important to better identify the relevance of this exposure scenario and the approach to modeling it.

4.3.4.4 Estuarine and Marine Bins

DAS (Winchell et al. 2016a) agreed with EPA's statement in the draft BE that, "current pesticide models do not account for transport via tidal and wind generated currents in marine systems", but does not agree with the selection of "surrogate bins". Further comments on the modeling of estuarine and marine habitat are made later in the response document. No changes to the final BE were made in response to DAS comments on this issue, and EPA provided no rationale for not considering these suggested changes.

4.3.5 Watershed Size Determination

4.3.5.1 Flowing Aquatic Habitat Bins

Comments provided by DAS (Winchell et al., 2016a) on flowing water bin watershed sizes suggested that the regression equations EPA derived to calculate watershed size as a function of flow rate (from the NHDPlus V2 dataset) could be improved for some HUCs if linear regressions were used instead of log-transformed regression equations. A more significant comment by DAS was that the watershed sizes that were calculated for flowing water habitats were unreasonably large given the constraints of the modeling approach and the use of the VVWM model as a receiving water model. In many HUC2s, the watershed area was considerably larger than could be expected to drain to the outlet within a single day. One of the largest concerns related to watershed size was the assumption of instantaneous loading of pesticide into the water body and the use of the corresponding peak EEC in the risk assessment.

The final BE did not change the methodology for estimating watershed sizes associated with each flowing water habitat bin, and EPA's response to comments did not address these concerns. The one change made in the flowing water modeling that relates to DAS comments on watershed size was the change from using a peak concentration predicted by VVWM to a daily average concentration. The use of a daily average concentration reduces the impacts of very large watersheds on unreasonably large concentration predictions. Despite this improvement in the final BE, simulating watersheds the size of any of the Bin 3 and Bin 4 using PRZM/VVWM is beyond the intended use of those models, and alternative watershed scale modeling approaches should be developed and implemented.

4.3.5.2 Static Aquatic Habitat Bins

Comments concerning static bin habitat watershed sizes from DAS (Winchell et al., 2016) focused on the unreasonably large watershed sizes assumed for some of the HUC2 regions. The approach followed to derive watershed sizes was a water balance-based methodology. The effect of following this approach was for much larger watersheds sizes associated with each static water body to be estimated for warm dry areas compared to the watershed sizes in cool and wet areas. This methodology resulted in drainage area to normal capacity ratios (DA/NC) that ranged over two to three orders of magnitude across HUC2 regions, depending upon the Bin. This phenomenon was not supported by any landscape-level data, making the resulting watershed areas purely hypothetical. One result was that tremendous amounts of runoff and pesticide could be generated from such large areas. EPA's modeling methodology assumed zero dilution from runoff water in static receiving waters, while often grossly over-predicted the EECs.

This issue of watershed size for static habitat bins was not addressed in EPA's final BE (EPA, 2017a), and EPA did not provide a justification to support the gigantic range in static water body watershed sizes used in the final BE. Our position remains that watershed areas derived for the static habitat in many of the HUC2s were unrealistically large, which led to significant over-prediction of pesticide loadings to the water bodies. Methods to refine these watershed areas should include evaluating actual static water body watersheds determined from topographic data.

4.3.5.3 Estuarine and Marine Aquatic Habitat Bins

The use of surrogate freshwater aquatic habitat bins to represent marine and estuarine habitats was introduced in this section of the BE. Winchell et al. (2016a) made extensive comments concerning the inappropriateness of the freshwater bins that EPA assigned to the marine and estuarine habitats. The final BE did not modify EPA's original methodology concerning surrogate freshwater bins, but suggested that improved methods for estimating exposures in estuarine/marine habitats would be a longer term goal. Our position is that the freshwater EECs assumed by the EPA have no relevance to the marine/estuarine systems that they are intended to represent. The EECs derived in the final BE for these marine/estuarine habitats were very likely several orders of magnitude higher than reasonably conservative screening- level EECs would be.

4.3.6 Application Data Selection

Winchell et al. (2016a) commented that the draft BE (EPA, 2016a) was unclear concerning how information other than weather was used in selecting application dates. The final BE (EPA, 2017a) added a statement that provided clarification to this question. The statement was as follows: "if pest pressure or agronomic practice information is available to restrict the application period, then the wettest month during this period will be selected." Thus, it appears as though pest pressure data served as an additional constraint for the application window.

4.3.7 Issues Modeling Medium- and High-Flowing Waterbodies

DAS (Winchell et al. 2016a) provided extensive comments concerning the excessively high concentrations of chlorpyrifos predicted in the original modeling conducted by EPA (EPA, 2016a). Many of these were in agreement with what EPA identified in the draft BE as reasons for the overly high predictions. One or the primary points made by Winchell et al. (2016a) was that many of the issues identified for the medium and high flow habitat bins also applied to the low flow (Bin 2) habitat.

The final BE contained modified modeling of the Bin 3 and Bin 4 habitats that included baseflow and a daily average concentration instead of a peak concentration (EPA, 2017a). The baseflow changes were applied to only Bin 3 and Bin 4, and the daily average EEC change applied to all three of the flowing water habitats. Other factors leading to excessively high EECs that were identified in the draft BE comments (e.g., very high DA/NC ratio and assumption of 100% area of the watershed treated on the same day) were not addressed in the final BE. This continues to be a concern for DAS and led to the over-prediction of EECs in all of the flowing water habitat bins.

4.3.7.1 Modifications Considered But Not Incorporated

The draft and final BEs (EPA, 2016a; 2017a) were unchanged in this section of the document. This section outlined model refinements/modifications that were considered by EPA in their initial efforts at flowing water modeling, but were not actually tested in their exploratory modeling. These items were as follows:

- Incorporation of Baseflow: This model modification was originally dismissed by EPA in their modeling, but ultimately included in the flowing water modeling reported in the final BE (Bin 3 and Bin 4 only). DAS supports this change.

- Percent Use Area and Percent Use Treatment Adjustment Factors: This model modification was strongly supported by DAS (Winchell et al., 2016a), but was not adopted by EPA in their final BE modeling. EPA noted in their response to comments that they are, "evaluating the appropriate scale at which to incorporate percent crop area/crop treated in the exposure assessments."

- Adjustment of Water Body Length: This model modification was not believed to be of significant importance by either EPA or DAS.

- Spreading Out Applications: The EPA chose not to incorporate variable application timing into their modeling for the final BE. DAS believes this to be critical to making accurate predictions of chlorpyrifos concentrations in flowing water bodies draining medium and large sized watersheds.

DAS's position is that several of these model modifications originally considered by EPA, specifically percent use area, percent treated area, and spreading out applications, are necessary to obtain realistic predictions of chlorpyrifos concentrations at the watershed-scale. Not accounting for these factors results in higher concentration than would occur under reasonable worst case conditions.

4.3.7.2 Modifications Explored and Incorporated into Modeling

The draft and final BEs (EPA, 2016a; 2017a) were unchanged in this section of the document. This section outlined model refinements/modifications that were considered by EPA in their initial efforts at flowing water modeling and then tested in their exploratory modeling. These items were as follows:

- Curve Number Adjustment: This model modification was evaluated in some of EPA's original modeling for Bin 3 and Bin 4, but was not adopted in the updated modeling in the final BE. Varying the CN value accounts for differences in soils and land cover/crop type, as occurs in real landscapes. Different CN values account for natural variability in runoff generation across the landscape and is a real phenomenon. Accounting for this variability, as opposed to the assumption of worst case runoff conditions across an entire watershed, is necessary for aquatic modeling beyond the screening level, particularly for medium- to large-sized watersheds. DAS still recommends a watershed-scale approach that accounts for variability in runoff processes.

- Daily Flow Averaging: This model modification is simply that the flow through the water body on a given day is representative of the runoff entering the water body on that day. The alternative is that flow through the water body is the average of an entire 30-year period. It appears that the final BE did not incorporate daily flow averaging in the modified flowing water modeling. This model parameterization should be required, as the alternative (a 30-year average), does not capture the real dynamics that occur in flowing water systems.

- Adjustment of Water Body Dimensions: This option sought to change the representative length of a receiving water body to reflect a small mixing cell. This concept did not end up being applied in the final BE modeling and was not supported by DAS.

- Use of Daily Average EECs: The draft BE modeling reported instantaneous peak EECs. Daily average EECs were considered in the EPA's original exploratory modeling. Daily EECs were ultimately adopted for the final BE and we support this adjustment.

4.3.7.3 Modifications Evaluation, Final Approach for OP Pilot Chemicals

In the draft BE, this section focused on the final approach followed in the draft BE to estimate Bin 3 and Bin 4 EECs from the simulated Bin 2 EECs. The methodology for deriving scaling factors for Bin 2 to Bin 3 and Bin 2 to Bin 4 EECs was heavily based on evaluation of atrazine monitoring data. In DAS's comments on the draft BE (Winchell et al., 2016a), this scaling was critiqued in favor of a more physically-based modeling approach.

The final BEs adopted a different approach to predicting Bin 3 and Bin 4 EECs than was done in the draft BE. Therefore, in the final BE, this section of Attachment 3-1 focuses on a discussion of the modifications to the flowing water modeling that were considered and those that were ultimately adopted in the final modeling. The modeling modifications considered were:

- Adopting 24-hour mean concentrations in place of peak concentrations, which was done for all static and flowing aquatic habitat bins
- Incorporating baseflow into the flowing water Bins 3 and 4
- Accounting for a time lag (or time of travel) in how pesticide generated throughout the watershed reaches the outlet of the receiving water body

The first two modifications were the ones included in the Bin 3 and Bin 4 modeling of the final BE. The accounting of watershed time of travel was still under development and not yet ready to incorporate into the final BE for chlorpyrifos; however, EPA stated that this approach will be introduced in future BEs.

DAS supports the incorporation of baseflow into all of the flowing aquatic habitat bins, not only the medium and large flowing water bodies. It is typical in many areas of the country for small, low flow streams to have continuous water in them. In addition, hydraulic characteristics that have been defined for Bin 2 suggest a water body with such low flow that it would have nearly continuous water within it at the depth and flow rate specified by the bin characteristics. We also support a modification to the modeling approach that accounts for watershed dynamics, including travel times and watershed heterogeneity from both an agronomic perspective and a landscape perspective.

4.3.8 Downstream Dilution Modeling

In Appendix 3-5 of the BE (EPA, 2016a), it was noted that downstream dilution was not conducted for chlorpyrifos "because of the widespread use of chlorpyrifos and the uncertainty with where the adulticide, wide area, and non-agricultural uses could occur, the entire United States is considered the action area for chlorpyrifos for Step I." The same rationale was applied for Step 2. Winchell et al. (2016a) argued that because there are certain agricultural crops where chlorpyrifos applications are not allowed (e.g., rice), it is incorrect to assume that non-agricultural wide-area uses (such as mosquito control) could occur in these areas. Therefore, a downstream dilution analysis would be relevant for chlorpyrifos.

In the final BE, EPA (2017a) did not make any changes to downstream dilution analysis for chlorpyrifos. DAS believes that the action area for chlorpyrifos was over-represented by not properly accounting for the land uses and crops where chlorpyrifos cannot be used. With a properly defined action area that excludes some areas from treatment, a downstream dilution analysis would be necessary to correctly delineate the action area. This would potentially result in some species' habitat areas falling outside the action area, resulting in no effects.

5.0 EFFECTS DETERMINATIONS

In Chapter 4 of EPA's chlorpyrifos BE, the Agency presented its effects determinations (i.e., species and critical habitat calls) for the updated 1835 listed species considered in their assessment. DAS (Clemow et al., 2016) has noted a number of problems with the effects determinations made in Chapter 4 of the draft chlorpyrifos BE (EPA, 2016a). The Agency has admittedly not made any changes for their final BE (EPA, 2017a) to the process presented in the draft BEs. Despite claims of increased transparency in the final BEs, we note persisting issues in this area, which are further discussed below and in the subsections of this chapter. The salient concerns of DAS, with respect to the final chlorpyrifos BE remain: (1) an overall lack of transparency in the methods employed to make species and critical habitat calls; (2) the on-going use of overly conservative risk quotients in the effects determinations and the absence of probability-based risk estimates; and (3) inconsistencies among the interim guidance (Agencies, 2013), the analysis plan (Section 1.4), Chapter 4 text, and what was actually carried out in the WoE tools to determine the species and critical habitat calls.

EPA's effects determinations lacked the complete transparency needed with respect to how risk designations and "calls" were made. In the final BE (EPA, 2017a), effects threshold values presumably used to conduct Step 2 were presented in Chapter 2 of the BE (effects characterization), and notably, thresholds for Step 1 were not explicitly presented. However, these effects thresholds were not solely those that were used to make risk designations in Step 2. For example, for freshwater fish, 12 thresholds were tabled for direct and indirect thresholds in Table 2-1 and 2-2 of the final chlorpyrifos BE (EPA, 2017a). When these values were compared to the thresholds in the WoE tools, we found that an *additional* 10 endpoint values were in the tool as threshold inputs that were not listed as thresholds in Table 2-1 or 2-2 of the BE. Similarly, six aquatic invertebrate endpoints not tabled in Chapter 2 of the final chlorpyrifos BE were input into the AquaWoE_v1.0 tool for use as thresholds, and eight endpoints for birds were found in the TEDtool_v1.0 threshold inputs that were not tabled in Chapter 2. No effort was made on the part of the Agency to enable readers to make sense of the process or outcomes, despite relayed criticism of the convolutedness of the draft BEs and associated supplemental materials and WoE tools. Key elements of the WoE tools used to establish risk designations remained hidden and locked in the spreadsheets.

Notwithstanding the lack of transparency, it is clear that the Agency missed the mark on several key recommendations from NRC (2013). EPA persisted in using risk quotients, which according to NRC are "…not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes." Further, with the possible exception of refined analyses carried out for selected bird species, the Agency did not employ any probabilistic methods, though this was a principal recommendation of NRC (2013).

Each of the mortality, reproduction, growth, behavioral, sensory, and "indirect effects" thresholds were essentially assigned an equal weight in EPA's WoE tools, in that exceedance of even one threshold led to a "Likely to Adversely Affect" call. This approach is illogical and did not account for the fact that experienced sublethal effects may or may not lead to adverse effects on individual fitness. If sublethal effects do lead to adverse effects on individual fitness, the degree of effect was in no way accounted for. Clearly, individuals may recover from sublethal effects, whereas effects on survival and reproduction cannot be undone at the individual level.

As previously documented by DAS (Clemow et al., 2016) and unaddressed by the Agency in the final chlorpyrifos BE (EPA, 2017a), EPA's effects determinations diverged from the analysis plan. Though the EPA referenced use of exposure distributions in their final chlorpyrifos BE (e.g., Table 1-5), species and critical habitat calls in the WoE tools were, in fact, based solely on comparison of upper bound point exposure estimates with the most sensitive effects metrics as threshold values. The Agency's Step 2 process was essentially an overly conservative screening-level assessment that employed only a modicum of refinement over Step 1 for taxon-specific thresholds. As asserted by DAS, EPA needed to consider distributions of both exposure and effects and make statements of estimated probability of adverse effects to individual fitness (Clemow et al., 2016).

Table 1-5 also described the use of qualitative lines of evidence, such as incident reports. In the final BE for chlorpyrifos, other lines of evidence such as monitoring data, incident reports, mesocosm studies and field studies were presented. However, this information was not considered in the calls for NLAA or LAA using the purported "weight-of-evidence" approach. These so-called "lines of evidence" seemed to carry absolutely no weight. The Agency described a "weight-of evidence approach" as a "systematic method of evaluating confidence in risk information from multiple sources." It is not clear if and how EPA applied weight-of-evidence in their BEs. In the WoE Tools, it is apparent that the highest risk quotients drove the species and critical habitat call, and that the evaluation of confidence in risk designations was ineffectual.

In Section 1.4, EPA stated that AgDrift and AgDISP were employed in their Step 2 LAA/NLAA determinations for terrestrial species. However, though drift distances to thresholds were estimated in the TEDtool, species and critical habitat calls were based solely on on-field application exposure estimates. Accordingly, drift distances to thresholds had no bearing on risk designations or calls for terrestrial species or their critical habitat. In Table 1-5 of the BE (EPA, 2017a), the exposure values and measures of effects presented were inconsistent for the data used to generate the effects determinations in the WoE tools. For example, the lines of evidence of direct effects included a "distribution of estimated exposure values" to be assessed against toxicity data (e.g., LC50/LD50 and slope data from laboratory toxicity studies). However, if even one exposure estimate exceeded the lowest threshold, the effects determination for the assessed species was LAA.

5.1 WoE Tools and Species and Critical Habitat Calls

A number of concerns regarding EPA's WoE tools were raised by DAS (Clemow et al., 2016) and CLA (2016). One of the major criticisms of the tools was a noted lack of transparency and related consistency issues. Specific examples included, but were not limited to:

- Inaccessible spreadsheet cells used directly in species and critical habitat calls;
- Discrepancies between methods described in the document and those employed in the WoE tools;
- Thresholds applied in the WoE model that were not presented in the document;
- Misleading "risk" and "confidence" designations that in reality had no bearing on species or critical habitat calls;
- Groupings of effects that, although documented, had no bearing on species or critical habitat calls; and

- A presentation of, but lack of consideration for monitoring data, incident reports, mesocosm or field studies in species and critical habitat calls.

Upon review of the final chlorpyrifos BE, these listed concerns persist (EPA, 2017a). A comparison of the draft and final WoE tools revealed that, as acknowledged by the Agency, no significant changes were made to the methods used to make species and critical habitat calls. As such, most of the detailed comments made in Clemow et al. (2016) on the draft chlorpyrifos BE remained applicable to the final WoE tools.

The noted exception was the major error previously identified in the determination of the risk designation for mortality of terrestrial vertebrates. This included a comparison of dose-based thresholds in units of mg/kg bw with concentrations in diet in units of mg/kg diet. This error was corrected in that mg/kg bw effects thresholds were compared with total daily intake (mg/kg bw/d) in the final BE.

The vast majority of the species (1686/1835) and critical habitats (763/794) considered in the final BE screened through Step 1 and were assessed using the Agency's WoE tools (https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments#woe). The exceptions were only:

- Species with no critical habitat that were presumed extinct by the U.S. FWS, who received the call of "No Effect" (reportedly 16 spp.);
- Species with no critical habitat that no longer occur in the US, who received the call of "No Effect" (reportedly 0 spp.);
- Species with no critical habitat that only exist in captivity, who received the call of "No Effect" (reportedly 0 spp.);
- Species found outside the action area, who received the call of "No Effect" (reportedly 0 spp.);
- Species that only co-occur within the cattle ear tag footprint were assessed separately (reportedly 0 spp.); and

- Sea turtles (6 spp.), whales (11 spp.), deep sea fish (4 spp.), marine mammals (excluding whales; 11 spp.), cave-dwelling invertebrates (22 spp.), and lichens (unspecified number of spp.) were all reportedly assessed separately.

Species and critical habitat calls were presented on the Summary Sheet of the species template file. Table 1-6 in the Problem Formulation suggested that the only way to definitively get a NLAA effects determination was to have a low risk designation with high confidence. If the risk designation and confidence pairs were:

- Medium risk with low confidence,
- Low risk with medium confidence, or;
- Low risk with low confidence,

the Agency stated in the footnote of the table that selection of the appropriate effects determination may require additional discussion with FWS and NMFS. However, there was no further mention in the chapter of any discussions with FWS or NMFS to establish species or critical habitat calls for such pairings. There was no text describing any departures from the calls made in the WoE tools. Further, "NLAA" was not an output of any function in the cells that provided species calls on the Summary Sheet in the species template files, with the exception of terrestrial plants, for which numerous species had unexplained overriding calls built into the summary sheet.

Table 1-8 ("Step 2 Thresholds") in Section 1.4 described the thresholds to be used in the effects determinations. For terrestrial animals, the table listed four thresholds:

1. Mortality – direct effects: 1/million mortality (based on Agencies, 2013; from which Table 1-8 was reproduced);
2. Mortality – indirect effects: "Concentration (or dose) that would result in a decrease of 10% of individuals (i.e. the EC_{10}). This is calculated by using HC_{05} of SSD of LC_{50}/LD_{50} or EC_{50} values and representative slope. If SSD cannot be derived, most sensitive LC_{50}/LD_{50} or EC_{50} will be used.";

3. Sublethal – direct effects: "Lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (EC_x) that can be linked to survival or reproduction of a listed individual will be used."; and
4. Sublethal – indirect effects: "LOAEC/LOAEL for growth or reproduction will be used (see text for details)."

However, as noted earlier in this chapter, many more thresholds were employed in the WoE tools for the species and critical habitat calls. Some of the measures of effects were alluded to in discussions of lines of evidence (e.g., Table 1-5), but these additional thresholds were not presented as such. The text of the analysis plan referred only to mortality and sublethal threshold categories, whereas the WoE tools took into account endpoints falling into ten distinct categories of effects, seven of which were actually employed in the species and critical habitat calls. One of these was mortality and the rest can be considered sublethal. The Agency stated that its sublethal threshold for direct effects was the "lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (EC_x) that can be linked to survival or reproduction of a listed individual will be used." In apparent contrast to this, the WoE tools determined exceedances of the following thresholds in their risk designations:

1. Growth NOELs and LOELs and application-rate based growth thresholds in lb a.i./A;
2. Reproduction NOELs and LOELs and application-rate based reproduction thresholds in lb a.i./A;
3. Behavioral NOELs and LOELs and application-rate based behavioral thresholds in lb a.i./A;
4. The assigned direct sublethal threshold in mg/kg diet, which was assessed in the behavioral risk designation calculations; and
5. Sensory NOELs and LOELs and application-rate based sensory thresholds in lb a.i./A.

Exceedances of these thresholds were used to determine risk designations and ultimately, species and critical habitat calls. First, the Agency persisted with general inconsistency in what they said they would do in their assessment and what was actually carried out. Despite criticisms in this regard, the EPA did not harmonize their final chlorpyrifos BE. Again, the Agency should document their processes accurately and transparently. Further, DAS is not in agreement with the use of effects metrics that are not directly connected to listed protection goals. More specifically, endpoints that are not linked directly to effects on fitness, and ultimately, persistence of populations and species are insupportable as thresholds in the biological evaluation.

For both terrestrial and aquatic animals, a likely to adversely affect (LAA) call was made for risk designations of one or more of was medium (MED) or\f high (HIGH) in the WoE tools, irrespective of confidence designation:

- Mortality,
- Growth,
- Reproduction,
- Behavioral,
- Sensory,
- Indirect-prey, or
- Indirect-habitat

Risk designations were founded entirely on highly conservative exposure estimates that exceeded even one threshold, regardless of whether the threshold was associated with any observed effects on the apical endpoints of survival, growth or reproduction. This, and the lack of weight or consideration for other lines of evidence (e.g., incident reports, field studies), remained contradictory to a valid weight of evidence approach. Comparable approaches were taken for terrestrial and aquatic plants, as detailed in Clemow et al. (2016).

For sublethal effects to animals, EPA decided to use NOELs as threshold values. Repeatedly, if a NOEL was exceeded by a conservative estimate of peak exposure, the species call was “Likely to Adversely Affect” (LAA). There was no justification for such a conclusion, given that no significant effects were observed at the threshold value in the supporting toxicity test. Also, by definition, the upper bound exposure estimates were in fact unlikely. In the context of the protection goals, there was no evidence to suggest that NOEL exceedance would result in adverse effects to individual fitness. This was perhaps particularly afflicting when considering the sublethal behavioral and sensory thresholds as inputs that have not been demonstrably related to effects on individual fitness.

NOELs were compared to peak exposure estimates. This was done without accounting for the fact that the exposures in the chronic toxicity tests supporting the selected threshold likely exceeded one day and it may have been weeks, months or even years before effects were observed in the LOEL treatment group. The conclusion that a NOEL exceedance for one day establishes that a species is likely to be adversely affected is inadequate on its own, let alone that the exposure estimates were upper bound and worst-case.

EPA did not provide any data to support the 1/million mortality threshold *on treated fields* as being directly relevant to the individual fitness of a listed species. If a species does not often use managed lands on which pesticides are applied, the 1/million mortality threshold on treated fields seems excessively conservative.

Despite the concerns of stakeholders, including DAS, the fact remains that the species calls in the final chlorpyrifos BE were based on a binary assessment of whether or not the most sensitive effects thresholds were exceeded by the highest exposure point estimates. If even one effects threshold was exceeded, the species call was LAA. Confidence designations were disregarded in the effects determinations. The species calls made by the Agency were not based on actual risk estimates, but instead based on risk quotients. The chlorpyrifos BE would be more robust if complete effects and exposure distributions were considered and EPA were to evaluate the probability associated with exceeding various levels of effect. This would be consistent with the NRC (2013) recommendation to use probabilistic methods. Clearly this is a recommendation that has been persistently overlooked by the EPA.

5.2 Qualitative Analyses

In Section 7 of Chapter 4, EPA (2017a) presented their qualitative analyses for sea turtles, whales and deep sea fish, marine mammals (excluding whales), cave-dwelling invertebrates, cattle ear tag use of chlorpyrifos, mosquito adulticide, seed treatment, and granular analyses. EPA made species calls and critical habit calls (if applicable) of “LAA” for all sea turtle and cave-dwelling invertebrate species, and “NLAA” for all whale and deep sea fish species, except for the killer whale (Southern resident DPS). For marine mammals (excluding whales), EPA made species calls and critical habit calls (if applicable) of “LAA” for the Guadalupe fur seal, southern sea otter, Steller sea lion, Hawaiian monk seal, Pacific harbor seal, and West Indian manatee, and "NLAA" for the northern sea otter (Southwest Alaska DPS), bearded seal, Pacific walrus, spotted seal (Southern DPS), and polar bear.

Although Section 7 of Chapter 4 was titled "Qualitative Analyses", in most cases EPA (2017a) derived quantitative estimates of exposure and compared these to effects thresholds to characterize risk. As previously described in other sections of this response document, DAS disagrees with many of the effects metrics selected for the qualitative assessments, with the use of surrogate bins to estimate EECs for marine and estuarine environments, and with the comparison of dietary exposure concentrations to dietary effects metrics. EPA (2017a) made unrealistically conservative assumptions regarding the potential for dermal exposure of sea turtles, dietary exposure of cave-dwelling invertebrates, and dietary and inhalation exposures of animals from the chlorpyrifos cattle ear tag use. Many of these assumptions were based solely on professional judgment and not any reliable or best available commercial or scientific data. All the quantitative assessments were deterministic and did not consider the probability of species actually being exposed to chlorpyrifos. Furthermore, even when EPA (2017a) stated that the likelihood of exposure was low (e.g., sea turtles and cave-dwelling invertebrates), species still received LAA effects determinations.

Throughout the qualitative analyses, EPA (2017a) categorized the risk and confidence as low, medium and high for various lines of evidence, including those based on professional judgment. Although EPA's criteria for establishing low, medium and high conclusions for risk and confidence were provided in Attachment 1-9 of the BE, these criteria were only based on EEC exceedances of effects thresholds and could not be applied for qualitative information. Thus, there was no transparency in EPA's risk and confidence conclusions for several aspects of their qualitative analyses.

5.2.1 Sea Turtle Analysis

In Chapter 4, EPA (2016a) reported that an aquatic plant BCF of 2407 was estimated using the Kow (based) Aquatic BioAccumulation Model (KABAM) and used to calculate aquatic thresholds (in µg a.i./L) for sea turtles consuming aquatic plants. As noted in Clemow et al. (2016), the assumptions and data used to obtain this BCF in KABAM were not included anywhere in Chapter 3 of EPA's draft BE, nor in the TEDtool (EPA, 2016a). Despite EPA (2017b) stating that errors and transparency of information would be amended for the final BE, EPA (2017a) still reported a BCF of 2407 for aquatic plants with no explanation as to how this value was derived in KABAM.

DAS (Clemow et al., 2016), CLA (2016), and FESTF (2016) all raised concerns over the methods used by EPA (2016a) to determine effect levels for sea turtles (Chapter 4, Table 4-7.2). EPA (2017a) made no amendments to their methods. The aquatic thresholds in Table 4-7.2 of Chapter 4 (EPA, 2016a; 2017a) were based on the assumption that if concentrations in prey items (plants, aquatic invertebrates, and fish) reach a level equal to an avian dietary effects threshold, then sea turtles will be adversely affected. This approach does not take account of differences between the gross energies and assimilation efficiencies of the laboratory test diet and prey items and food intake rates of receptors in the wild. Pesticide concentrations in the diet are not exposure estimates, and as such, the direct comparison of pesticide concentrations in dietary items to dietary LC50s is inappropriate.

In both the draft and final BEs, EPA (2016a; 2017a) used EECs for Bin 2 (low flow), Bin 3 (medium flow), and Bin 5 (low volume static) as surrogates for intertidal nearshore areas (Bin 8), subtidal nearshore waterbodies (Bin 9), and tidal pools (Bin 8), respectively. It is unclear why EPA (2017a) used only one designated bin for both intertidal nearshore areas and tidal pools when separate surrogate freshwater bins were assigned to the two types of environments. Furthermore, the use of freshwater bins as surrogates for estuarine and marine environments led to the extreme overestimation of EECs. See the comments included in Section 4.0 for further details.

The methodology used by EPA (2016a) to calculate freshwater EECs for green sea turtles was also critiqued in Clemow et al. (2016). In their draft BE, EPA (2016a) did not actually model

EECs for Bins 3 and 4, but instead estimated EECs for these bins assuming that they were 5 times and 10 times lower than the EECs calculated for Bin 2 (low volume flowing), since the parameterization of this bin resulted in nonsensical EECs being generated. Although it appears as though EPA (2017a) has generated Bin 3 and 4 EECs in their final BE, the Agency still does not provide any justification as to why Bins 3 and 4 make good surrogates for the tidally-affected bins. Furthermore, DAS still disagrees with their approach. See Section 4.0 for more information.

The updated Bin 3 and 4 EECs presented in the final BE (EPA, 2017a) were up to an order of magnitude greater than the EECs presented in the draft BE (EPA, 2016a). Furthermore, the range of average daily EECs (2 to 13,600 μg a.i./L) and 4-day average EECs (0.025 to 3950 μg a.i./L) for estuaries, nearshore areas and freshwater environments exceeded the solubility limit for chlorpyrifos (2000 μg a.i./L). The maximum EECs for estuaries, nearshore areas and freshwater environments were up to four orders of magnitude higher than the highest surface water concentration reported for chlorpyrifos in Appendix 1-10 of the final BE (14.7 a.i./L; STORET Data Warehouse). However, EPA (2017a) stated in Appendix 1-10 that "while there are many individual samples collected and analyzed for chlorpyrifos (or chlorpyrifos-oxon) across the United States, it would not be appropriate to combine these data sources to generate exposure estimates or to use these datasets to represent exposure on a national or even regional basis". As stated in EPA's guidance for the "Evaluation and Use of Water Monitoring Data in Pesticide Aquatic Exposure Assessments" (EPA, 2014), even if not used quantitatively in the assessment, monitoring data can still be useful for comparison to modeled EECs to assess the realism of estimated concentrations. Instead, EPA (2016a; 2017a) completely dismissed the surface water monitoring data presented in Appendix 1-10 and failed to discuss the plausibility of the modeled EECs in the context of observed measured concentrations of chlorpyrifos.

Finally, in both the draft and final BEs, EPA (2016a; 2017a) discussed the likelihood of dermal exposure of juvenile and adult sea turtles on beaches. EPA stated that when accounting for all factors such as wind direction, 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, the likelihood of exposure and resulting effects cannot be precluded, but are expected to be low. However, in their statement concluding a "LAA" risk designation, EPA noted that "there is also concern for risk due to dermal exposures resulting from spray drift transport to adult and juvenile turtles on beaches". As expressed in Clemow et al. (2016), this statement was misleading considering the number of factors that were noted by EPA (above) that would likely decrease the potential for adult and juvenile exposure on beaches.

5.2.2 Whale and Deep Sea Fish Analysis

EPA (2016a; 2017a) made "NLAA" determinations for all whales and deep sea fish except for the killer whale (Southern resident DPS) in the draft and final versions of the chlorpyrifos BE. On page 4-17 of Chapter 4, EPA (2017a) stated that the killer whale is an obligate with the Pacific salmon. In Chapter 1, EPA stated that obligate relationships occur "when one species is interdependent with or highly reliant on another species in a way that one cannot survive without the other". However, Table 4-7.8 of EPA's BE indicated that killer whales consume other fish species (e.g. herring), squid and marine mammals in addition to salmon. Although NMFS (2008) stated in their recovery plan that southern resident killer whales have a strong preference for Chinook salmon, other fish, squid and marine mammals are also consumed. These other prey items could replace salmon in the killer whale diet if reductions in salmon were to occur. As such, there is no obligate relationship between the killer whale and Pacific salmon, and a "LAA" determination should not be made for the killer whale (Southern resident DPS) based on effects to salmon.

5.2.3 Marine Mammals (excluding Whales) Analysis

As discussed in Section 4.3.1 (Sea Turtle Analysis), the final BE (EPA, 2017a) addressed some of the recommendations made by Clemow et al. (2016), including modeling EECs for bins 3 and 4 rather than applying adjustment factors to bin 2 EECs. However, most comments, such as those relating to the KABAM-estimated BCF for aquatic plants, the comparison of dietary exposure concentrations to dietary effects metrics, and the rationales behind selecting particular aquatic bins, were not addressed in the refined BE (EPA, 2017a). In addition, the modeled EECs for estuaries, nearshore areas and freshwater environments were unrealistically high and available surface water monitoring data were not used to evaluate the plausibility of the predicted exposure concentrations.

5.2.4 Cave Dwelling Invertebrate Species Analysis

DAS (Clemow et al., 2016) and CLA (2016) advised that EPA's LAA designations for terrestrial cave-dwelling invertebrates were based on extremely conservative assumptions that did not represent the Agencies' own guidance for completing refined assessments (Agencies, 2013). The Agency did not alter their conclusions in the final BE (EPA, 2017a). Only one minor issue was addressed, in which the full text citations for four references (Eidels et al., 2007; Land, 2001; McFarland, 1998; and Sandel, 1999) were provided. However, the pesticide residues detected in these studies were still not presented or discussed within the context of their potential effects to cave-dwelling invertebrates.

5.2.5 Cattle Ear Tag Use Analysis

EPA presented their assessment for the cattle ear tag use of chlorpyrifos in Appendix 4-4 of the final BE (EPA, 2017a). There is only one registration for chlorpyrifos for cattle ear tags (Reg. No. 39039-6). Although DAS does not support cattle ear tag use, there were a number of concerns with the cattle ear tag use analysis that were identified in Clemow et al. (2016) for EPA's draft BE (EPA, 2016a). EPA (2017a) did not address any of DAS's comments in their final BE.

Although EPA (2017a) did not make any LAA/NLAA determinations for species exposed to chlorpyrifos based on the cattle ear tag analysis, their statement that this analysis will be used in the overall weight of evidence is extremely misleading because, LAA vs. NLAA determinations are only based on RQs exceeding one for specific lines of evidence (i.e., mortality, growth, reproduction, behavior, sensory effects, exceedance of indirect effects thresholds for prey and habitat). As noted by Clemow et al. (2016), there were numerous issues related to EPA's methods for calculating risk that were not addressed in EPA's final BE. These included the selection of inappropriate effects thresholds, the use of an LD90 for the corn rootworm as an exposure estimate for taxa consuming insects, the comparison of pesticide concentrations in the diet to both dietary- and dose-based effects thresholds, and the unrealistically conservative assumptions made for assessing exposure via inhalation.

5.2.6 Mosquito Adulticide

Appendices 4-5 and 3-3 of the chlorpyrifos BE described EPA's approach to addressing potential risk of mosquitocide use (EPA, 2017a). Although DAS does not support mosquitocide use of chlorpyrifos, there were numerous problems with EPA's draft BE (EPA, 2016a) that were discussed in Clemow et al. (2016). None of these issues were addressed in the EPA's final BE (EPA, 2017a).

Clemow et al. (2016) commented that DP Barcode 407817, 3/18/2013 was provided as a reference for the assumption that ground applied adulticides were determined to have the same deposition fractions as aerial applications, and the information obtained from this source should be presented in the BE to support this assumption. No further information on DP Barcode 407817 was included in the final chlorpyrifos BE (EPA, 2017a). However, Supplement B-3-3.2 in Appendix 3-3 of the final malathion BE (EPA, 2017c) summarized the data obtained from this source. The information presented in Supplement B-3-3.2 should also be included in the final chlorpyrifos BE.

Of additional concern was the edit that EPA made to the final BE (EPA, 2017a) relating to mosquitocide application. The Agency stated in Appendix 4-5: "a limited number of terrestrial species (listed in Table A 4-5.1) are identified where the only **buffered** use that overlapped with their species range is the mosquito adulticide use for malathion and mosquito adulticide and wide area use (e.g., general outdoor treatments around perimeters and ant mounds for pests) for chlorpyrifos." The bolded word in that sentence did not appear in the draft BE (EPA, 2016a), and this change in wording meant that EPA re-evaluated the species of interest in the Appendix. The two new species evaluated were entirely different from the six previously evaluated. DAS is concerned with the Agency introducing new species into the assessment without allowing the public to review its work given the number of errors identified with the draft BE (EPA, 2016a). Further, this edit did not address the initial comment made by DAS, namely that the Agency did not comment on why it expects that all species and critical habitat were expected to be exposed given the multitude of data available that quantitatively identify the locations where adulticide active ingredients have been and are currently being applied and the timing at such applications (Clemow et al., 2016).

The memorandum "Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion' issued on January 17, 2017 by EPA (DP Barcode: 434736) was also reviewed in addition to the final chlorpyrifos BE. In the BE memorandum issued by EPA (2017b), the following text describes EPA's request for use site data that better characterize the use of the three organophosphate (OP) chemicals (malathion, chlorpyrifos, and diazinon).

"EPA acknowledged they are committed to using the best scientific and commercial data for ESA-FIFRA analyses. Interested parties are invited to submit data that better define pesticide use areas and practices (especially for non-agricultural and mosquitocide/wide area uses), and state or local listed species protection practices, that should be considered as part of future ESA effect determinations and associated consultations for pesticides.

EPA appreciates the comments detailing how mosquito adulticide applications are made, especially the spatial aspects illustrated by the maps of sprayed areas provided in the public comments. EPA is exploring the possibility of using this information to better define areas where mosquito adulticide applications are reasonably expected to occur."

Although EPA acknowledged that additional spatial data were provided, there was no change to the final chlorpyrifos BE with respect to how mosquitocide adulticides were actually used. The main assumption in the final BE was that adulticides 'could' be applied anywhere in the US and territories. Thus, all listed species were potentially exposed, which is false.

In a response to a comment from the Northwest Center for Alternative to Pesticides (NCAP), EPA (2017b) acknowledged that "given that there are no geographical restrictions on the chlorpyrifos and malathion labels regarding wide-area use patterns, the agencies agreed to treat wide-area uses such as mosquito adulticide applications as overlapping 100% of all species range since the use area is the entire U.S. EPA recognizes that this assumption overestimates the likelihood of exposure and is of limited utility as a Step 1 screen. We are working with mosquito control districts and others to better define the likely areas of mosquito adulticide applications so that the action area may be narrowed."

Although it is clear that mosquito adulticides are not used over the entire spatial extent of the United States (and Territories), the assumption that use is 100% overlapping with all listed species ranges was still made in the final BE and is entirely flawed. Standard pesticide labels for most agricultural use patterns (e.g. corn) also do not have geographical restrictions and are applied over wide-areas (e.g. the US mid-west), yet spatial data were available to delineate where the use patterns exist (e.g., USDA Cropland Data Layer). Similarly, there are existing spatial data that capture where adulticides are and have been applied through the American Mosquito Control Associations, states, and public health entities in the US. Therefore, the assumption that 100% of the US is treated remains unsupported.

5.2.7 Seed Treatment and Granular

As opposed to assessing the seed treatment and granular uses of chlorpyrifos and quantitatively including results in their risk designations, the Agency included these uses in their qualitative analyses. DAS identified some concerns with the approach EPA (2016a) took for assessing seed treatments and granular chlorpyrifos in the draft BE, including their use of deterministic concentration estimates on seed following flowable application to such seeds as an exposure and their failure to take into account the probability of individuals actually consuming chlorpyrifos granules (Clemow et al., 2016). Neither of these issues were addressed in EPA's final BE (EPA, 2017a). In fact, there were no changes made to the seed treatment and granular use analyses (Appendix 4-6) between publication of the draft and final BEs for chlorpyrifos (EPA, 2016a; 2017a).

6.0 CONCLUSION

Of the concerns flagged by DAS (Clemow et al., 2016) and raised by CLA (2016) and FESTF (2016) that persist in the final chlorpyrifos BE, the following have been identified as critical to the outcome of the BE: data and model quality, unsubstantiated thresholds, inaccurate and crude spatial analysis, inappropriate use of exposure models, over-generalization of aquatic exposure predictions, omission of best available data and tools, not providing probabilistic exposure predictions, compounding conservatism in exposure assessment, inappropriate contrasts/comparisons between incongruous EECs and effects metrics, an on-going lack of transparency, outstanding errors in both weight of evidence (WoE) tools and text, a flawed and convoluted "weight-of-evidence" approach, and most importantly, an absence of risk estimation through probabilistic methods. These issues are further discussed below.

Many of the studies selected by EPA as threshold values were not evaluated for data quality and relevance, and when evaluated, many did not follow EPA's own study quality criteria. EPA used threshold values from studies deemed invalid by the Agency or deemed acceptable for qualitative use when criteria for quantitative use were not met. When the quality of the data driving the assessment is questionable, so too are the results.

In previous evaluations of the WoE tools, a number of errors were relayed to the Agency, and as noted, not all have been dealt with. DAS is concerned that the WoE tools have not undergone formal independent evaluation to gauge their quality and utility. The model was purportedly derived from an existing model; however, we have noted that the TEDtool differed from the standard toolbox models in a number of significant ways.

DAS disagrees with the continued use of thresholds that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction) and not demonstrably associated with the protection goal of individual fitness. The most conservative RQ-based effects determinations were principally driven by metrics that did not necessarily even relate to the protection goals of the biological evaluation.

EPA made the assumption that mosquito adulticide applications may be made anywhere in the United States. Baselessly, calls were made assuming that all label uses can be made anywhere in the United States, without drawing any distinctions between use patterns, timing of application, locations, and actual co-occurrence. Accordingly, there are likely species that will never come into contact with biologically relevant concentrations of chlorpyrifos that have been determined to be "LAA."

The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for chlorpyrifos, these models were used to simulate landscape and aquatic fate processes in continental-scale watersheds and rivers. Even from a screening-level perspective, this approach was a gross overextension of the models' capabilities. The results obtained from these models and applied to represent environments they were never designed for are not acceptable.

The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by that same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact, their occurrence is typically constrained to very specific locations (they are endangered). The overgeneralization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to misrepresentation of the extent of exposure risk.

High resolution spatial datasets representing, crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed-scale hydrologic and water quality models (e.g. SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions did not account for the critical landscape and agronomic variability known to exist in reality and were based on modeling methods that are incapable of reflecting the complexities of the environmental processes they were attempting to simulate.

When multiple deterministic exposure model inputs are “upper bound” or biased high, like in the final chlorpyrifos BE (e.g., on-field exposure, upper bound RUDs, 90th percentile on the mean half-lives), the resulting exposure estimates are expected to be overly conservative (i.e., unrealistically high). Such exposures are by definition unlikely (i.e., having a low probability of occurring). It is therefore nonsensical that the Agency would make “Likely to Adversely Affect” calls based on their exceedance.

There remain discrepancies between exposure durations in toxicological studies and EECs used to generate RQs in the BE. Risk quotients were inflated when effects metrics generated from long exposure durations (e.g., several days to months) were compared to daily average EECs. The EPA should give some credence to this in their assessment of reproductive and sublethal risks.

The Agency did deal with *some* of the transparency issues in the chlorpyrifos BE; however, many transparency concerns persisted within the final BE. Critically, key cells in the WoE tools remained hidden and locked, drift models continued to go unreferenced and unexplained, and methods were illogically presented and applied.

Notwithstanding that the Agency did correct some of the errors identified during the public comment period, a number remained. Critical errors remained in the dermal exposure and body mass scaling equations (herptiles) in the TEDtool. Also, the terrestrial EECs presented in the chlorpyrifos BE did not match those generated in the WoE tools.

Though the Agency claims a weight-of-evidence approach, EPA made almost all of their effects determinations based solely on the most conservative RQ of a suite of RQs generated for each species. EPA gave equal “weights” to threshold exceedances associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds. This included equal weighting of measures of effects that may not be linked to individual fitness (e.g., endpoints for behavior, AChE inhibition, etc.), which was purportedly the protection goal of the BE. Other lines of evidence were not directly considered in species and critical habitat calls (e.g., incident reports, field studies, monitoring data, etc.), though presented as if they would be accounted for in the risk characterization.

NRC (2013) discouraged the use of RQs and recommended probabilistic methods instead. Risk is defined as the probability or likelihood of a particular outcome. However, EPA did not estimate risk to listed species in their BEs using probabilistic methods, with the exception of the 13 bird species assessed with TIM/MCnest.

DAS requests that EPA give careful consideration to the comments provided in this document, as well as the comments presented in Clemow et al. (2016), Giddings and Winchell (2016a), and Winchell et al. (2016a), and strongly urges the Agency to incorporate real risk estimates (i.e., the probabilities of exceeding various magnitudes of effects) into their biological evaluations, as was recommended by NRC (2013) for assessing to risk posed to listed species by pesticide use.

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SCIENCE INTEGRITY KNOWLEDGE

RESPONSE TO THE BIOLOGICAL EVALUATION FOR DIAZINON

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

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This statement supersedes any other claim of confidentiality that may appear in this report.

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Statement of Good Laboratory Practice Compliance

This document is a response to EPA's final Biological Evaluation (BE) for diazinon. It is not required to comply with 40CFR Part 160.

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EXECUTIVE SUMMARY

Registration and/or re-registration of pesticides under the *Federal Insecticide, Fungicide, and Rodenticide Act* (“FIFRA”) constitutes a federal action under the *Endangered Species Act* (“ESA”). In some circumstances under ESA Section 7, the Environmental Protection Agency (“EPA” or “the Agency”) must consult with the Fish and Wildlife Service and/or the National Marine Fisheries Service (“the Services”) to ensure that a pesticide’s registration (considered the federal action) is not likely to jeopardize the continued existence of federally endangered and threatened species (hereafter, “listed species”) or result in the destruction or adverse modification of designated critical habitat. The EPA, in conjunction with the Services and United States Department of Agriculture (“USDA”), prepared Biological Evaluations (“BEs”) for three pilot pesticides (chlorpyrifos, diazinon and malathion) as case studies for how to conduct these complex, large-scale assessments. The BEs purported to provide nationwide assessments of the potential for effects of the pilot pesticides to listed species and their designated critical habitat. Potential effects on candidate species and species proposed for listing under Section 7 of the ESA were also considered.

EPA developed the BEs following the “Interim Approaches” process agreed to by EPA, the Services, and USDA (Agencies, 2013) to implement some of the recommendations from the National Academy of Science’s National Research Council (“NRC”) report “Assessing Risks to Endangered and Threatened Species from Pesticides” (NRC, 2013). The NRC recommended a three-step process to evaluate potential risk and satisfy EPA’s consultation obligations under Section 7 of the ESA. At each step, EPA assigned a risk finding to each species and/or critical habitat (i.e., Step 1: “No Effect/May Affect (MA)” determination, Step 2: “Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)”). Under this procedure, species and/or critical habitat receiving a “MA/NLAA” finding are subject to informal consultation with the Services to determine concurrence. Species and/or critical habitat that are considered MA/LAA enter Step 3, where a formal consultation with the Services is to occur. A biological opinion is generated by the Services with the goal of making a “Jeopardy/No Jeopardy” finding for listed species and “Adverse Modification/No Adverse Modification” determination for their designated critical habitat. Lessons learned from this process are intended to be used by EPA and the Services to modify the Interim Approaches for future biological evaluations.

On April 11th, 2016, EPA released the draft BEs for public comment in support of registration review for the pilot pesticides. This date marked the start of a 60-day public comment period, which ended on June 10th, 2016. Despite requests for an extension of the public comment period from many stakeholders, made primarily because of the sheer magnitude of information contained in the BEs, the EPA did not adjust the comment deadline. The Agency cited a court-mandated deadline that they and the Services were working under, as well as the early release of parts of the draft BEs in December 2015. Comprehensive review of the draft BEs was unfeasible within the comment period, and this was complicated by multiple draft versions (i.e., December 2015 and March 2016 releases). Notwithstanding these challenges, stakeholders submitted thousands of comments, in which a number of substantive concerns, including critical errors, were identified. Approximately seven months after the close of the comment period, the EPA released their final Biological Evaluations for the pilot chemicals.

The final Biological Evaluations were released on January 17th, 2017, with a brief memorandum summarizing how public comments were addressed (EPA, 2017a,b). Ultimately, the EPA opted to principally address errors or transparency issues. Despite a myriad of concerns regarding the Agency's methods, EPA acknowledged that they made few changes to the processes employed in the BEs, citing only the revised modeling approach for flowing waterbodies. EPA stated that, in response to comments, it was "incorporating those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December, 2017."

EPA's draft and revised diazinon BEs attempted to evaluate risk of diazinon exposure for all ESA listed species, proposed species, and candidate species in the United States. In the final BE, EPA reached the MA/LAA determination for 1437 out of 1835 assessed species (i.e., 78%) and 385 of the 794 assessed critical habitats (48%), a result that is almost identical to the draft diazinon BE. These final effects determinations mean that formal consultation and biological opinions are required for almost all species and half of critical habitats evaluated. Completing formal consultations on this scale is near impossible. While it is recognized that considerable effort went into the development of the pilot BEs, it is clear that using the Interim Approaches (Agencies, 2013), as applied, has resulted in a cumbersome, inefficient, and indefensible process for assessing pesticides to determine whether they pose potential risks to listed species or their critical habitat.

ADAMA still has serious concerns regarding the effects determinations presented in the final BE (EPA, 2017a) for listed species potentially exposed to diazinon. This response document reviewed the principal comments made by ADAMA and other stakeholders (CropLife America and FESTF) on the diazinon draft BE (and pilot BEs in general), discussed how EPA addressed some of these comments, and described comments and concerns that went unaddressed. Particular emphasis was given to methods, data used, and assumptions made.

One major and persistent concern ADAMA has with the final diazinon BE is that, in contrast to the NRC (NRC, 2013) recommendations, risk quotients (RQs) were used to determine risk designations in Step 2. RQs can eliminate the negligible risk scenarios, freeing up resources to use refined, probabilistic approaches for the remaining species. However, an ecological risk assessment should not/cannot conclude on the results of a cursory RQ screen. The NRC (NRC, 2013) specifically stated that "[Risk quotients] are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes." The NRC conclusion is consistent with recommendations in the EPA agency-wide guidelines for ecological risk assessment (EPA, 1998), which are cited in the NRC report, and it points out the importance of the explicit treatment of uncertainty during problem formulation. In direct contrast to this, the EPA has maintained its use of RQs, and it bases species and habitat risk characterization on the most conservative RQs. The NRC (2013) recommended "using a probabilistic approach that requires integration of the uncertainties (from sampling, natural variability, lack of knowledge, and measurement and model error) into the exposure and effects analyses by using probability distributions rather than single point estimates for uncertain quantities. The distributions are integrated mathematically to calculate risk as a probability and the associated uncertainty in that estimate. Ultimately, decision-makers are provided with a risk estimate that reflects the probability of exposure to a range of pesticide concentrations and the magnitude of an adverse effect (if any) resulting from such exposure."

A number of concerns identified in the draft BE by ADAMA and other stakeholders (CropLife America (CLA, 2016) and the FIFRA Endangered Species Task Force (FESTF, 2016)) went unaddressed by EPA in the final diazinon BE. Several of the concerns of higher consequence for the characterization of risk are listed below.

- **Data Quality Assurance**. Many studies selected by EPA for threshold values were not evaluated for data quality and relevance, and when evaluated, many evaluations did not follow EPA's own study quality criteria. EPA used threshold values from studies deemed invalid by the Agency, or else deemed them acceptable for quantitative use even when criteria for quantitative use were not met. When the quality of the data driving the assessment is questionable, so are the results. EPA failed to make use of best available chemical-specific data in the BE. Notably, all registrant-commissioned data should have been considered by EPA. In particular, the Agency should have, by their own decree (EPA, 2011), made use of the GLP amphibian toxicity data, instead of relying on data from a different taxon. Similarly, EPA did not derive independent effects endpoints for estuarine/marine receptors (invertebrates, fish, aquatic plants).

- **Model Quality Assurance**. In past reviews of the WoE tools/TEDtool, a number of errors were reported, and as noted herein, not all have been addressed. ADAMA remains concerned that EPA has not submitted the TEDTool to a Scientific Advisory Panel ("SAP") for an independent evaluation of its quality, credibility and utility. Even though the model is purportedly derived from existing EPA toolbox applications, substantial changes have occurred with the models since the last SAP. Therefore, we believe that use of the TEDTool warrants another SAP review prior to use in a regulatory capacity.

- **Unsubstantiated Endpoints**. ADAMA is concerned with the use of toxicological effects metrics ("thresholds") that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction), and further not demonstrably associated with the protection goal of individual fitness. Thus, the binary, most-conservative RQ-based effects determinations were primarily driven by effects metrics that do not necessarily even relate to the protection goals of the biological evaluation.

- **Rudimentary Spatial Analysis**. Erroneous species and critical habitat effect determinations were made assuming that application to all possible label uses are made anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use, or co-occurrence. Accordingly, there are species that will never come into contact with biologically relevant concentrations of diazinon that have been determined to be “LAA”.

- **Inappropriate Use of Exposure Models**. The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for diazinon, these models were used to simulate landscape and aquatic fate processes in continental-scale watersheds and rivers. Even from a screening level perspective, this approach was a gross overextension of the model’s capabilities. The results obtained from these models, and applied to represent environments they were never designed for, are not acceptable.

- **Overgeneralization of Aquatic Exposure Predictions.** The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by that same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact their occurrence is typically constrained to very specific locations (they are endangered). The overgeneralization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to misrepresentation of the extent of exposure risk.

- **Omission of Best Available Data and Tools.** High resolution spatial datasets representing crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed-scale hydrologic and water quality models (e.g., SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions did not account for the critical landscape and agronomic variability known to exist in reality and were based on modeling methods that are incapable of reflecting the complexities of the environmental processes they were attempting to simulate.

- **Not Providing Probabilistic Exposure Prediction.** The spatial variability and input and process uncertainty surrounding diazinon exposure in aquatic environments is significant. A meaningful and scientifically valid analysis of exposure in this situation requires that probabilistic methods be employed to determine the likelihood of exposure endpoints being exceeded. This probabilistic approach, which was endorsed by the NAS panel (NRC, 2013), was not followed in the BE.

- **Compounding of Conservatism**. When multiple deterministic exposure model inputs are "upper bound" or biased high, as was the case in the BE (e.g., on-field exposure, upper bound RUDs, 90th percentile on the mean half-lives), the resulting exposure estimates are expected to be overly conservative (i.e., unrealistically high).

- **Nonsensical RQs**. There remain disparities between exposure durations in toxicological studies and EECs used to generate RQs in the BE. Risk characterizations were overly exaggerated when effects metrics generated from long exposure durations (e.g., several days to months) were compared to daily average EECs.

- **Lack of Transparency.** Though the Agency attempted to deal with some of the transparency issues in the text of the final diazinon BE, their effort was insufficient, and many transparency concerns persisted. For example: key cells in the WoE tools remained hidden and locked, drift models continued to go unreferenced and unexplained, and methods were not consistently presented.

- **Outstanding Errors.** Despite the fact that the Agency did correct some of the errors identified during the public comment period, many remained in the final BE. For example, critical errors remained in the dermal exposure and body mass scaling equations for herptiles in the TEDtool. Further, the terrestrial EECs presented in the diazinon BE did not match those generated in the associated TEDtool.

- **No Weight of Evidence**. Despite claiming a weight of evidence approach, it seems EPA based all of their effects determinations solely on the most conservative RQ of a suite of RQs generated for each species. EPA gave equivalent "weights" to exceedances of thresholds associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds that were not necessarily linked to individual fitness/the protection goal (e.g., endpoints for avoidance behavior, AChE inhibition, etc.). Further, other lines of evidence were not directly considered in species and critical habitat calls (e.g., incident reports, field studies, monitoring data, etc.). We note that aquatic EECs were orders of magnitude higher than monitoring data. Nowhere in the final BE was this taken into account.

- **A Lack of Risk Estimates/ Probabilistic Methods.** As articulated above, NRC (NRC, 2013) discouraged the use of RQs and recommended probabilistic methods. Risk is the probability or likelihood of a particular outcome. Accordingly, EPA did not estimate risk to listed species in their BEs (with the possible exception of the 11 birds analyzed with TIM/MCnest). The spatial variability and input and process uncertainty surrounding diazinon exposure is significant. A meaningful and scientifically valid analysis of exposure in this situation requires that probabilistic methods be employed to determine the likelihood of exposure endpoints being exceeded.

The issues listed above resulted in adverse outcomes (LAA) for individuals of the majority of listed species addressed in the final diazinon BE. Cheminova has submitted numerous examples to the EPA for using the best available scientific data and appropriate refined methods to characterize risk to individual listed species from other organophosphates. Cheminova has submitted four refined effects determinations for malathion conducted on the Kirtland's warbler, the California red-legged frog, the California tiger salamander, and the delta smelt (Moore et al., 2016 [MRID 49949506]; Breton et al., 2013 [MRID 49211702]; 2016b,c [MRIDs 49949505 and 49949504]), as well as an effects determination on the California red-legged frog (Breton et al., 2012 [MRID 48895502]) and risk assessment paper on salmon (Aslund et al., 2016) for dimethoate. Species-specific exposure assessments for over 20 species in a range of static and flowing water habitats across the Ohio River basin (HUC2 05) also demonstrate how refined approaches can be used to characterize risk (Padilla and Winchell., 2016 [MRID 49949507]; Winchell et al., 2016 [MRID pending]). Cheminova's effects determinations demonstrate that when complete risk assessments are carried out using the best available data, realistic exposure assumptions, and consideration of all lines of evidence, effects determinations can be quite different. Such refined assessments should be conducted when potential risks are identified at the screening level (e.g., NRC, 2013; EPA, 1998, 2004a).

ADAMA believes that the exercise of producing the three pilot BEs has demonstrated that the Interim Approaches require severe restructuring. The final diazinon BE did not provide a scientifically sound basis on which to make effects characterizations. Although the EPA did correct some of the obvious errors and oversights found in the draft BE, the Agency neglected to address important concerns regarding the hyper-conservative nature of the exposure assessments and the flawed "weight-of-evidence" approach. Moreover, EPA did not actually estimate risks to listed species nor their critical habitat, which would inherently require probabilistic methods (NRC, 2013).

RESPONSE TO EPA'S FINAL BIOLOGICAL EVALUATION FOR DIAZINON

Table of Contents

Page

List of Tables

Page

RESPONSE TO EPA'S FINAL BIOLOGICAL EVALUATION FOR DIAZINON

1.0 INTRODUCTION

The Environmental Protection Agency (EPA or "the Agency"), in conjunction with the Fish and Wildlife Services (FWS), National Marine and Fisheries Service (NMFS) and United States Department of Agriculture (USDA), prepared draft Biological Evaluations (BEs) for three pilot chemicals: chlorpyrifos, diazinon and malathion. These draft BEs represented the first case studies for national assessments of the potential effects of pesticides to listed species (threatened or endangered) carried out by the federal government.

On April 6th, 2016, the EPA released the draft BEs for review. This date marked the start of a 60-day public comment period. On April 29th, 2016, a 120-day extension to the comment period was requested by Dow AgroSciences LLC, Makhteshim Agan of North America, Inc. (ADAMA) and Cheminova because the 60-day comment period was deemed by these registrants as insufficient for review of the contents of the draft BEs. The draft BEs, (1) exceeded 12,000 pages and contained links to Excel files and model output files with millions of lines of data, and (2) contained a number of omissions and errors (including broken links), making comprehensive review impossible. Extension requests were also submitted to EPA by Edward M. Ruckert, representing the American Mosquito Control Association (May 10th, 2016), CropLife America (May 6th, 2016), and James Callan, representing 39 grower groups (May 9th, 2016). The request for extension was denied by EPA in a formal letter sent via e-mail on the 17th of May, 2016 to the counsel of the registrants (David B. Weinberg and David E. Menotti). In the justification, the Agency cited a court-mandated deadline under which they and the Services were working, as well as the early release of parts of the draft BEs in December 2015 (allowing for some review prior to the official comment period). However, substantial changes made to the draft documents posted in December required additional efforts by affected parties to identify and evaluate modifications made to the documents, supporting models, the missing data, broken links, and other errors in the draft BEs. In addition, the court-mandated deadline was not a reasonable excuse for not allowing a fair and substantive review of the draft BEs by affected parties.

ADAMA is the sole manufacturer and registrant of diazinon in the United States. ADAMA contracted Intrinsik Corp. (hereafter referred to as Intrinsik) and Stone Environmental (hereafter referred to as Stone) to assist in the review and evaluation of the portions of the diazinon BE pertaining to the assessment of risk to aquatic and terrestrial listed species. Given the limited time available for public comment due to the denial of a public comment extension period, the original comments submitted by ADAMA (Breton et al., 2016a) contained only Intrinsik's and Stone's preliminary review and evaluation of the draft diazinon BE.

On January 17 2017, EPA released their "revised" or final biological evaluations (EPA, 2017a), along with a document (EPA, 2017b) responding to how they addressed the numerous public comments they received on their draft BEs. EPA's response document outlined how they categorized each of the 78,000 comments, with 120 substantive comments that were noted to merit detailed review. EPA said that they intended to incorporate those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December 2017. As such, EPA outlined that the major revisions that were made to the draft BEs included, but were not limited to: a revised modeling approach for flowing aquatic waterbodies; error correction and improved transparency; the addition and deletion of species based on changes in listing status; and refinements to some of the aquatic species ranges. Upon review of the final BEs, ADAMA is providing comments on how EPA addressed ADAMA's original comments on the draft BEs as per Breton et al. (2016a). This document contains ADAMA's comments on the final BEs.

Similar to the formatting of ADAMA's original response document (Breton et al., 2016a), this response document first addresses the exposure assessment conducted by EPA (Sections 2.0 and 3.0), followed by the effects assessment (Section 4.0) and the Agency's effects determinations (Section 5.0) for listed aquatic and terrestrial species. It concludes with a summary of the overarching problems identified in the final BE (Section 6.0).

2.0 METHODS FOR ESTIMATING EXPOSURE TO TERRESTRIAL ORGANISMS TO DIAZINON

With respect to terrestrial exposure estimates generated by EPA (2016a) in the draft BE for diazinon, Breton et al. (2016a) documented a number of issues. Principally, ADAMA was concerned about: (1) a general lack of transparency in the methods used to generate exposure estimates; (2) the use of multiple “upper bound” inputs leading to compounding and unrealistic conservatism of exposure estimates; and (3) several calculation and transcriptional errors.

The EPA’s terrestrial exposure assessment is presented in Section 3 of Chapter 3 in the final BE for diazinon (EPA 2017a). Exposure estimates for terrestrial organisms were primarily based on information presented in Attachment 1-7 (Methodology for Estimating Exposures to Terrestrial Animals (mammals, birds, reptiles, amphibians and invertebrates), Attachment 1-16 to 1-20 (Biological information on listed birds, mammals, herptiles) and the TEDtool root files (TEDtool_v1.0_alt.xlsx and TEDtool_v1.0.xlsx).

The Agency’s changes to the diazinon terrestrial exposure assessment based on stakeholder comments were minor. With regards to methodology (Attachment 1-7), modifications included: (1) fixing invalid references to locations in the document and on the web; (2) providing additional references to locations in the document; (3) presenting missing units; (4) providing additional justification for selected assumptions; and (5) making several edits to the text reflecting typographical errors.

With respect to the text of the exposure assessment for terrestrial organisms, as presented in Chapter 3, changes were limited to:

1) Removal of text referring to future iterations of the document;
2) Addition of a footnote to point the reader to other EECs presented only in the TEDtool; and
3) Improved description of bird and mammal prey, including size, feeding guild and surrogacy.

Accordingly, few changes to the EECs in terrestrial animal feed items (Table 3-24 in the final BE) were expected. However, without explanation, over half of the EECs presented in Table 3-24 were changed in the final BE for diazinon (EPA, 2017a).

We note that in the supporting TEDtool root files, the Agency did not change any of the inputs used in the terrestrial exposure assessment. Despite some corrections to the equations in the supporting TEDtool root files, ADAMA still has a number of concerns that have not been addressed. The following subsections discuss persisting and critical issues relating to EPA’s methodology for assessing exposure of terrestrial organisms to diazinon.

2.1 Terrestrial Vertebrates

A number of comments regarding EPA's (2016a) methods for estimating exposure of terrestrial vertebrates in the draft BE were compiled by Breton et al. (2016a). These comments covered issues of transparency, the use of inconsistent approaches across EPA tools (e.g., earthworm fugacity, and T-HERPS vs. TEDtool), the use of out-of-date field metabolic rate data, overly conservative and unrealistic exposure scenarios, and blatant errors in model equations.

In the final diazinon BE, EPA (2017a) did describe the body burden approach taken to estimate concentrations in prey. Notably, this approach differs from the total daily intake approach used in the T-HERPS model, which is still purported to be the model employed in Table 3-24 of the final BE. The Agency did clarify why certain prey guilds were selected as representative food for carnivores. EPA also explained that dose estimates from different exposure routes were considered separately. The Agency provided explicit definitions for elements in equations that had been omitted in the draft, and also provided the range of aquatic EECs used to estimate concentrations in aquatic feed items of terrestrial organisms. Importantly, the Agency did address part of the error in the dermal dose equation in the TEDtool that was resulting in erroneously high estimates of dermal exposure for birds. Also, the default relative diffusion rate across the pulmonary membrane (F_{AM}) was fixed to match the value of 3.4 described in the text.

However, ADAMA is still concerned with a number of issues that were not addressed by EPA (2017a) in the terrestrial vertebrate exposure assessment. In particular, ADAMA is concerned with unaddressed points that have direct and significant bearing on the results of the diazinon BE. In the final BE, EPA (2017a) continued with its use of out-of-date field metabolic rate data for terrestrial vertebrates, and generated food ingestion rates from incorrect assumptions about diet. Further, the Agency continued to compare concentrations in inequivalent feed items (e.g., laboratory food vs. grass). A main concern is the persistent dependence on compounding 'upper bound' inputs, despite the recommendation of risk-based probabilistic approaches from NRC (2013).

Though EPA stated that they would address errors and issues of transparency, the Agency did not make their assessment wholly transparent, nor did they correct all of the errors pointed out by stakeholders. Key persisting errors are discussed further below.

EPA (2017a) did not correct the error in the application of body mass scaling for herptiles. As previously articulated in Breton et al. (2016a), Column V, W, X in the "Min rate doses" and "Max rate doses" worksheets are supposed to hold the body mass-adjusted dose-based effects metrics for all listed terrestrial vertebrate species in the TEDtool. For birds, it is clear that the body mass scaling applied in T-REX was retained here. However, for herptiles, an exponent of 1 was applied in the avian body mass scaling equation. This is equivalent to a scaling factor of 2, and results in multiplication of the test 1/million dose estimate by the ratio of the body weights of the species being assessed and the test species. This leads to much lower effects metrics for herptiles, which are typically smaller than the test species (compared to birds). There is no justification for this scaling factor anywhere in the document. It is presumed to be an error, where body mass scaling should have been omitted due to a lack of data supporting body mass scaling for herptiles.

Further, EPA (2017a) applied body mass scaling to all wildlife threshold values in the BE, including sublethal thresholds. This is inconsistent with the T-REX and T-HERPS models, which only apply body mass scaling to LD50 estimates for birds and herptiles. In T-REX body mass scaling is also applied to NOELs for mammals, but not to birds. The Agency provided no evidence that body mass scaling was warranted for sublethal endpoints.

Although the Agency corrected the error in their estimation of dermal LD50 based on equation 15 in Attachment 1-7 of the final BE, problems persisted in their estimation of dermal contact dose. In the Min and Max rate dose worksheets in the TEDtool, the following equation was used in Column O for birds and mammals to estimate the upper bound dermal dose for contact exposure (with foliage).

$$D_{contact(t)} = \frac{C_{plant(t)} * F_{dfr} * R_{foliar\ contact} * 8 * (SA_{total} * 0.079) * 0.1}{BW} * F_{red}$$

Equation 2-1

Where,

$D_{contact(t)}$	=	Contact dose (µg a.i./g bw; reportedly calculated on a daily time assuming eight hours of activity)
$C_{plant(t)}$	=	Concentration of the pesticide in crop foliage at time *t* (mg/kg)
F_{dfr}	=	Dislodgeable foliar residue adjustment factor (kg/m^2; default = 0.62).
$R_{foliar\ contact}$	=	Rate of foliar contact (default = 6.01; cm^2 foliage/cm^2 body surface per hour)
SA_{total}	=	Total surface area of bird (cm^2)
BW	=	Body weight (g)
F_{red}	=	Dermal route equivalency factor

This equation comes directly from the TIM technical manual (EPA, 2015a). In Attachment 1-7, and also in the TIM manual, the Agency states that “In this equation, a factor of 0.1 is used to generate $D_{contact(t)}$ value with units in µg a.i./g-bw.”

The description of the F_{dfr} value used in Equation 2-1, as described in the TIM manual, suggests a major flaw in the $D_{contact(t)}$ equation.

In Section 6.2.1 of the TIM manual, it is stated that the F_{dfr} value is necessary because “total residues are commonly expressed in terms of mass of pesticide per unit fresh mass of vegetation, while dislodgeable residues are commonly expressed in terms of mass of pesticide per unit surface area of the vegetation”. The following formula is then provided for calculating F_{dfr} on the basis of dislodgeable pesticide residues (DPRs) and total pesticide residues (TPR) measured immediately following application:

$$F_{dfr} = \frac{DPR}{TPR}$$

Equation 2-2

Where,

F_{dfr}	=	Fraction of dislodgeable foliar residues (kg/m^2)
DPR	=	Dislodgeable pesticide residues (mg/m^2)
TPR	=	Total pesticide residues (mg/kg)

In the absence of chemical specific data, the TIM manual indicates that a default value for F_{dfr} of 0.62 can be calculated by setting DPR to 28 mg/m^2 and TPR to 45 mg/kg. The TPR value is said to be "the mean for the total pesticide residue value on broadleaf plants." (no reference given). The DPR value is stated to be "based on the Health Effects Division's default assumption that at day 0, the dislodgeable foliar residue value is 25% of the application rate (in lb a.i./A) (Section D.6.2 of Appendix D of EPA, 2012b)". Note that this value was converted from lb a.i./A to mg/m^2." However, the conversion from 25% of the application rate (in lb a.i./A) to 28 mg/m^2 (with no mention of application rate) is clearly incorrect. Mathematically, 25% of the application rate (in lb a.i./A) would also equal 25% of the application rate (in mg/m^2 or any other unit) and cannot be estimated independently of the actual application rate.

Review of the actual HED document (EPA, 2012) clarifies that, contrary to what is stated in the TIM manual, field studies have been done to quantify dislodgeable residue amounts <u>as a fraction of the application rate</u> for various types of crops and various active ingredients. On the basis of these data, HED recommends that "when chemical-specific data are unavailable, the recommended default value for the fraction of application rate as dislodgeable foliar residue for both liquid and solid formulations following application is 0.25 (25%)." This value is presented as the arithmetic mean of 60 measured values in Table D-20 of the HED document (EPA, 2012). Therefore, if the HED assumption of 25% application rate as dislodgeable foliar residues is a reasonable assumption for the NESA assessment, then F_{dfr} in the dermal contact equation should have a default value of 0.25, and the $C_{plant(t)}$ should be replaced with A_{rate} (application rate in mg/m^2).

The example below shows the implication for the BE estimates.

We take the single application rate of 4 lb a.i./A and consider the dermal contact exposure of the Northern aplomado falcon (*Falco femoralis septentrionalis*). EPA (2017a) estimated a dermal contact dose of 28.5 mg a.i./kg bw in the final BE. The estimated body weight is 325 g. The surface area based on the equation provided in Attachment 1-7 is 473.6 cm^2 (this is correctly calculated in the TEDtool for this species).

First, 4 lb a.i./A = 1,814,368 mg a.i./A = 448.3 mg/m^2. The dermal route equivalency factor, F_{red}, based on an avian LD50 of 1.18 mg a.i./kg bw, is 0.154.

Using Equation 2-1 above, with the suggested modifications, we calculate the following:

$$D_{contact(t)} = \frac{(448.3\frac{mg}{m^2}) * (0.25) * \left(\frac{6.01\ \text{cm}^2\text{foliage}}{\text{cm}^2\ \text{body surface per hour}}\right) * 8\ hour(473.6\ cm^2 * 0.079) * 0.1}{325\ g} * 0.154$$

$$D_{contact(t)} = \frac{9.55\ mg\ a.i.}{kg\ bw}$$

This value is nearly three times lower than EPA's estimate (28.5 mg a.i./kg bw) for this species.

2.2 Terrestrial Plants

ADAMA (Breton et al., 2016a) provided comments to EPA on some concerns with the transparency of how the terrestrial plant assessment was conducted in their draft assessment (EPA, 2016a). Specifically, EPA (2016a) did not 1) describe the differences between the TerrPlant model and the results calculated using the TEDtool model, or 2) discuss the exposure assessment results for terrestrial plants throughout the main text of the document (Chapter 3). In the final BE, EPA (2017a) attempted to clarify some differences between the TerrPlant and TEDtool model by noting in the README tab of the TEDtool that only the runoff portion of TerrPlant was used in estimating exposure. However, EPA still has not provided additional details on the calculations or presented exposure results in the text of Chapter 3 (EPA, 2017a).

Breton et al. (2016a) also discussed that it was not clear why EPA (2016a) did not use their newly developed Audrey III model in their final BE, despite its use in the sulfonylurea assessment conducted by EPA (2015b) that was completed prior to the BE for diazinon. This issue was also not elaborated on in EPA's final BE for diazinon (EPA, 2017a).

2.3 Terrestrial Invertebrates

In ADAMA's response to EPA's (2016a) draft BE, Breton et al. (2016a) noted that EPA (2016a) did not present a method for deriving EECs for listed terrestrial invertebrate species, nor did they present the EECs for listed terrestrial invertebrates in the draft BE Chapters, Attachment 1-7 or in the TEDtool. CLA (2016) also made a similar comment in their response to the draft BE. In a response to the submitted letter of request for comment period extension, EPA (2016b) indicated that dose-based EECs are presented in Attachment 1-7 and the TEDTool, but dose-based EECs for terrestrial invertebrates cannot be found in those locations. An assumption on terrestrial invertebrate body weight is required to estimate dose-based concentrations (to convert mg a.i./kg diet to mg a.i./kg bw). These data were also not provided in the draft or final BEs. As such, there remain transparency issues in the final BE in the matter of the estimation of the dose-based EECs used to estimate risk for listed terrestrial invertebrates.

Another comment that ADAMA (Breton et al., 2016a) made on the draft BE (EPA, 2016a) was based on a mistake made in estimating the "number of exceedances of thresholds and endpoints for upper bound and mean EECs". For terrestrial arthropods (above ground) and soil dwelling arthropods, EPA (2016a) compared dose-based thresholds to dietary exposure concentrations. This approach is incorrect because dietary EECs and dose-based effects metrics are not the same measures and have different units. This comment was not accounted for by EPA in the final BE (EPA, 2017a), and remains an inappropriate comparison.

CLA (2016) provided comments to EPA on the draft BE based on their own review. Included in their comments was a concern that it is Agency policy to use exposure estimates from BeeREX to assess the risk of pesticides to all pollinator species. EPA did not discuss why they chose to use the TEDtool to replace the BeeREX methods for pollinators. Moreover, it was noted that the predicted exposure using T-REX (via the TEDtool) was approximately 50 times higher than the corresponding estimates from BeeREX. CLA (2016) noted that the use of the TEDtool instead of BeeREX resulted in "highly exaggerated exposure and risk estimates for listed insect pollinator species and listed species that prey upon them or listed plant species that are reliant on them for pollination". This issue was not addressed in the final BE (EPA, 2017a).

2.4 Spray Drift

Spray drift estimates were generated, but apparently not used to make effects determinations in the "weight of evidence" tools. In the final BE (EPA, 2017a), the Agency stated that spray drift was accounted for in the generation of the footprint of the action area. However, Attachment 1-3, which discusses the methodology for generating the footprint, did not discuss how drift models were incorporated. The Agency calculated various setback distances based on models presented in Attachment 1-7 of the BE. Both CLA (2016) and Breton et al. (2016a) commented on the lack of transparency and potentially inappropriate used of drift models used in the draft BE. The Agency did not address these issues in the final BE, with the exceptions of providing omitted distance units and an updated weblink to AgDrift software.

In Attachment 1-7, the Agency presented Equation 1, which reportedly gives "the distance where the risk extends" based on "an analysis of the deposition curves generated in AgDrift (v. 2.1.1)". Equation 1 in Attachment 1-7 is Equation 2-3 below:

$$d_t = \frac{\left(\frac{c5}{F_{AR}}\right)^{\frac{1}{b5}} - 1}{a5}$$

Equation 2-3

Where,

F_{AR} is the fraction of the application rate that is equivalent to the threshold, and
d_t is the distance where the risk extends.

EPA (2017a) made reference to Table A 1-7.1, which is found on the subsequent page (page A7 (PF)-2) and contains numerical values for the parameters a5, b5 and c5 for aerial, ground and airblast application methods for a range of droplet size spectra.

A reference for Equation 2-3 was not given. In the same paragraph, a footnote was provided for AgDrift (v.2.1.1). The most recent AgDrift User's Manual (Teske et al., 2003) that is available in the regulatory version download (file name: agdrift_2.1.1.zip; retrieved from: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#atmospheric; March 29, 2016) contains the following equation used for Tier I ground sprayer assessment (Equation 2-4):

$$D(x) = \frac{c}{[1+ax]^b}$$

Equation 2-4

Where,

D(x)	is the deposition level relative to the nominal application rate,
x	is the downwind distance (in feet), and
a, b and c	are model parameters.

This equation can be rearranged to give Equation 2-5, as follows (assuming *x* in the User's Manual is d_t, and *D(x)* is F_{AR}):

$$[1 + ax]^b = \frac{c}{D(x)}$$

Equation 2-5

$$x = \frac{\left(\frac{c}{D(x)}\right)^{\frac{1}{b}} - 1}{a}$$

Equation 2-6

The Agency presumably obtained Equation 2-3 from the AgDrift User's Manual. However, in the User's Manual this equation applies *to low boom ground sprayer applications*, and describes models fit to empirical *ground sprayer data only*. It is unclear how EPA determined the three parameters for any of the application methods (ground, aerial or airblast), as even the parameter values provided for ground spray do not match those presented in the User's Manual. The Agency referred to an analysis of AgDrift output that was not presented, nor cited (EPA, 2017a). Also, EPA (2017a) did not specify how many swaths/passes the model accounted for (Equation 1 and Table A 1-7.1 in Attachment 1-7). In the AgDrift User's Manual, a, b and c parameters are estimated for a single swath only. AgDrift v.2.1.1 does not provide numerical values for *a, b* or *c* in any of the software's output.

2.5 Chemical Specific Comments

ADAMA (Breton et al., 2016a) noted concerns with the selection of a number of chemical specific input parameters used in the exposure assessment of EPA's draft BE (EPA, 2016a), including: residue unit doses (RUDs), aerobic metabolism half-life, daily fraction retained, logKow, Koc, Henry's law constant, solubility in water, and selected bioconcentration factors (BCFs). A discussion on whether EPA considered these reported concerns in their final BE is provided below.

2.5.1 Aerobic Metabolism Half-life

In their comments on the draft BE, ADAMA (Breton et al. 2016a) noted that the full reference for their selected aerobic metabolism half-life value of 34 days was not provided and Chapter 3 lacked a discussion of the data. It was assumed that the half-life of 34 days was associated with the studies Seyfried (1994 [MRID 46867004]), Spare (1990 [MRID 44746001]) and Haynes (2004 [MRID 46386605]) from Chapter 3. In their final BE, EPA (2017a) failed to address this lack of clarity, and did not provide the full references in the TEDtool, nor present additional details on the data within the Chapter 3 framework. ADAMA maintains the opinion that to ensure transparency in the final BE, all references should be included consistently in the document where appropriate (i.e., throughout TEDTool, Chapters, Appendices, and Attachments).

2.5.2 Daily Fraction Retained

In their draft BE, EPA (2016a) was not consistent in describing their approaches for estimating dietary exposure estimates and how they addressed metabolism of their daily intake. As such, it was difficult to understand their approach without accessing and reviewing the calculations located in the TEDtool. ADAMA commented on a number of inconsistencies throughout the draft BE (Breton et al., 2016a).

EPA (2017a) added some clarification text in Attachment 1-7 of the final BE. EPA (2017a) noted that in their approach for estimating upper bound and mean concentrations of pesticides in birds, mammals, reptiles, and amphibians (in addition to referring to T-HERPs for more detail), "concentrations in mammals and birds are decreased on a daily basis based on elimination or metabolism." And that … "The amount of chemical that is retained from one day to the next is based on chemical-specific magnitude on the residue studies with chickens and rats." This added text supports EPA's consideration of elimination and metabolism in their exposure estimates. However, their definition of the metric "daily fraction retained" remains unclear and further discussion on how the metric was selected and used in their calculations of exposure is required.

In summary, although EPA made attempts to clarify ADAMA's comments on the daily fraction retained metric, EPA (2017a) failed to provide full references or discussions in Chapter 3 or Attachment 1-7 on the studies from which the input parameters were derived (e.g., values of 0.1 and 0.214 from Capps (1989 [MRID 41108901]) and Simoneaux (1989 [MRID 41225901]). To maintain transparency, EPA should provide detailed summaries of the studies, a description of the data that were used to estimate the “daily fraction retrained” values, and provide full references where the data were used.

2.5.3 LogKow, Koc, Henry’s Law Constant, and Solubility in Water

In their draft BE, EPA (2016a) failed to present the full references on the TEDtool input parameters page for LogKow, Koc, Henry’s law constant, and solubility in water. In their final BE, EPA (2017a) did not address this comment and did not provide appropriate references within the TEDtool for these inputs. In their response to the request for comment period extension (Comment H-14, EPA, 2016a), EPA indicated that the references could be found in Chapter 3. Despite this being the case, ADAMA maintains the position that any input parameter cited or used in exposure modeling tools should be referenced appropriately and in the places where used.

ADAMA also commented that EPA (2016a) did not provide the full reference anywhere (Chapters, appendices, attachments) in the draft BE for the LogKow value of 3.81, which was reportedly from USNLM (2009). This comment remains true in the final BE (EPA, 2017a), in that EPA has not provided the full reference.

In their draft and final BE’s, EPA (2016a; 2017a) selected a Koc value of 618 L/kg OC from Sparrow (2000, [MRID 49091901]). In response to a data gap for fate studies identified by EPA, ADAMA has commissioned a more recent adsorption/desorption study (Yeomans, 2016 [MRID Pending]) that was submitted to EPA. ADAMA highlighted this study in the response to the draft BE (Breton et al. 2016a), but EPA (2017a) did not consider the study for the final BE. This new study should be used to estimate the Koc value for modeling.

Additionally, the value or reference to Henry’s law constant (of 0.00000045 atm-m^3/mol) used in the TEDtool was not provided in Chapter 3. ADAMA maintains the recommendation that a Henry’s law constant of 1.13 x 10^{-7}, as reported in Fendinger et al. (1989), should be used.

In Chapter 3 of their draft and final BE’s, EPA (2016a, 2017a) presented two values for solubility of diazinon in water; 59.5 mg/L (pH 6.07) and 65.5 (pH not reported). This discrepancy was noted by ADAMA (Breton et al., 2016a) in their response to the draft BE, but EPA (2017a) did not clarify. As such, it is still unclear why EPA selected the value of 65.5, especially since the pH of the system in which the test was conducted was not provided.

2.5.4 Bioconcentration Factors

In response to the draft BE for diazinon (EPA, 2016a), ADAMA (Breton et al. 2016a) raised a few concerns about the selected BCFs that EPA used in estimating the concentration of diazinon in aquatic prey. The application of these comments to the final BE (EPA, 2017a) are discussed below.

Breton et al. (2016a) noted that EPA (2016a) 1) failed to provide details on the KABAM model itself or the data assumptions that were selected as inputs for estimating a BCF for aquatic algae/plants in the draft BE; 2) provided citations for the empirically-derived BCFs for aquatic invertebrates and fish in the TEDtool, but failed to provide the full references or additional information on these studies in Chapter 3; and 3) failed to provide a justification for the selection of the water concentrations used for estimating exposure of aquatic prey to diazinon.

In their final BE, EPA (2017a) did not fully address these comments. The only edit that was made was a change in text in Attachment 1-7 to suggest that the selected concentrations represented “a bound of the lower and upper range of aquatic EECs generated by PWC (i.e., 10 and 100 µg a.i./L, respectively)”. Further discussion was missing from, EPA (2017a) to justify these concentrations for diazinon (i.e., model inputs, assumptions, output, statistics).

2.5.5 Exposure Results

In their draft BE, EPA (2016a) reported mean and upper bound dietary EECs generated using the TEDtool. ADAMA (Breton et al., 2016a) noted errors in EPA’s draft BE exposure results (Table 3-24, EPA, 2016a). In the final BE for diazinon, EPA (2017a) made a number of changes to the EECs. This is despite the fact that they appear to have not modified any of the input parameters to the exposure model. Critically, over half of the EECs reported in the final diazinon BE in Table 3-24 do not match the EECs presented in the corresponding TEDTool. This demonstrates clear defects in the biological evaluation system as applied to diazinon.

Further, the Agency did not correct errors in reported aquatic feed item concentrations. As previously noted by Breton et al. (2016a): The concentration range of 0.28-280 (units were not provided but are presumably in mg/kg ww) for aquatic plants was incorrect. The range of EECs found in the TEDtool was 2.8-28 mg /kg ww, which make sense given the BCF of 280 µg a.i./kg ww per µg/L water with assumed water concentrations of 10 and 100 µg/L. The Agency reported a range in error that was 10-fold off of the actual estimates. See the example calculation for aquatic plants (BCF 280 µg a.i./kg ww per µg/L) below using the maximum water concentration assumed (C_{H2O} = 100 µg/L).

$$Dietary\ Conc\ Aq.Plants\left(\frac{mg}{kg}ww\right) = C_{H20} * \frac{BCF}{1000}$$
$$= 100\ \mu\frac{g}{L} * \frac{\left(280\ \frac{\mu g}{kg}ww\ per\ \frac{\mu g}{L}\right)}{1000}$$
$$= 28\frac{mg}{kg}ww$$

Since the minimum water concentration assumed was 10 µg/L, the range of EECs for aquatic plants should be 2.8 to 28 mg/kg ww.

There was a similar issue for the range presented for aquatic invertebrates (0.03 – 0.82 mg/kg ww). The upper bound and mean BCF values for aquatic invertebrates were 25 and 82 µg a.i./kg ww per µg a.i./L, respectively. As such, using the two assumed water concentrations (10 and 100 µg/L), the dietary concentration range should have been presented as 0.25 to 8.2 mg/kg ww. Again, EPA reported a range 10-fold off of what it should be, but in the opposite direction this time.

For fish as prey, another error persisted in Table 3-24. The bottom end of the range was not reported. Thus, a " -720" is in the place where the correct range of 0.88 to 21.3 mg/kg ww should have been reported.

Some of this confusion could stem from the tab labelled "Aquatic organism tissue concentrations". This tab provided tissue concentration estimates based on a larger range of environmental concentrations (0.01 to 100 µg/L). These were not the environmental concentrations used to estimate dietary doses for each species, so it was inappropriate to include these ranges in the dietary concentration estimates.

Secondly, only the mean and upper bound EECs in small herbivorous mammal (an assumed prey for bird species) for the lowest application rate (0.5 lb a.i./A) could be verified based on the values presented in the min dose rate worksheet in the TEDtool files (mean and upper bound EECs of 41 and 114 mg a.i./kg diet, respectively). None of the other food item EECs could be verified when Table 3.25 was cross-referenced with the appropriate TEDtool root files.

Thirdly, the dietary EECs presented for terrestrial organisms reflected a range of EECs that considered all sizes and diets of the organisms (i.e., small, medium and large herbivorous mammals). This range of EECs presented per taxa was not representative of what was actually assessed in the BE (EPA, 2017a). As such, only the mean and upper bound EECs for small herbivorous mammals (15 g), small insectivorous birds (20 g) and small insectivorous amphibian/reptile (2 g) should have been provided in Table 3-24.

2.6 Summary of Concerns Regarding the Terrestrial Exposure Analysis

As described above, ADAMA has persisting concerns with respect to the terrestrial exposure assessment conducted in the final BE for diazinon (EPA, 2017a). The issues we deem fundamental are summarized below:

- EPA failed to demonstrate use of best available data in the final BE. In many cases, out-of-date, generic, or improperly referenced input values were used to parameterize the terrestrial exposure models.
- The newly developed TEDtool model purportedly integrates many of EPA's standard toolbox models (i.e., T-REX, T-HERPS, TerrPlant, and earthworm fugacity model). However, we contend that EPA inappropriately used this exposure tool for risk assessment before it had been fully evaluated, quality assured and peer reviewed. We have noted a number of differences between the standard toolbox models and the TEDtool, including: body mass scaling of sublethal endpoints for herptiles and birds, inappropriate default body mass scaling (herptiles), and body burden estimates for prey

rather than total daily intake. Further, we have also noted persisting errors in the TEDtool. These issues, as well as the lack of sufficient information for reviewers to evaluate or replicate the terrestrial exposure assessment, very much complicated the review process.

- A number of hyper-conservative assumptions were employed without the consideration of realistic exposure scenarios, ultimately leading to an overly conservative exposure assessment. EPA failed to comply with recommendations as per the NRC panel (NRC, 2013) to conduct probabilistic assessment wherever possible, thus leading to highly conservative results without context of the probability of risk.
- Specific calculation errors were noted, including the major errors in the dislodgeable residue assumptions (derived from the TIM user manual). This error continued to have a major impact on results, leading to dermal exposure estimates that were three-fold higher than corrected estimates.

There remained a number of serious shortcomings in the terrestrial exposure assessment of the final BE that led to unrealistic (or completely wrong) exposure estimates for diazinon. ADAMA also reiterates that EPA failed to comply with many of the recommendations of NRC (2013). Therefore, the effects determinations for listed species based on this final terrestrial exposure assessment are questionable.

3.0 AQUATIC EXPOSURE MODELING

3.1 Spatial Data and Analysis

3.1.1 Agricultural Crop Footprint Development and Use of the NASS Census of Agriculture Dataset (CoA)

The methodology for agricultural crop footprint development described in the draft BE (EPA, 2016a) included the use of the NASS Census of Agriculture (CoA) county-level crop acreage data to serve as a benchmark for adjusting the Cropland Data Layer (CDL)-based footprints. ADAMA (Breton et al., 2016a) provided several arguments challenging the validity and need for this approach. These included the following:

- Not accounting for the uncertainty bounds associated with the CoA dataset;
- The assumption that the CoA dataset is inherently more accurate than the CDL, requiring that CDL-estimated acreages be adjusted to match CoA; and
- That the expansion method employed by EPA to match CoA data is arbitrary and may result in more errors in land use/crop pixel classification than improvements over the native CDL data.

Additional concerns that ADAMA, FESTF, and CLA expressed regarding the development of agricultural crop footprints included:

- Not bringing in additional high quality land use datasets (e.g., the NLCD) to provide further support in generating crop footprints;
- Applying the crop group lumping strategy to address errors of omission in the raw data, but not in any way accounting for errors of omission;
- Certain geographic restrictions on diazinon use were not accounted for in EPA's crop footprint development;
- Use restriction specifics on current pesticide labels were not accounted for in EPA's derivation of crop footprints; and
- Crop groupings that were too broad, contained too many crops, and that should have been split into smaller crop groupings to achieve more refined estimates of potential use extent.

The final BE (EPA, 2017a) did not modify the methodology for the agricultural crop footprint development and did not specifically comment on any of the concerns raised by ADAMA in the comments to the draft BE (Breton et al., 2016a).

It was noted in FESTF's comments (FESTF, 2016) that some local (state) spatial datasets that would have provided added value were not included in the development of crop footprints (e.g., Washington State Department of Agriculture and the California Farmland Mapping and Monitoring Program).

Suggestions were made by ADAMA (Breton et al., 2016a), FESTF (FESTF, 2016), and CLA (CLA, 2016) to quantitatively incorporate the CDL accuracy reports into the derivation of the crop footprints. Ultimately, it was recommended that national probabilistic crop footprints that take into account uncertainty in classification, as demonstrated by Budreski et al. (2015), should be adopted. However, the EPA has not indicated that these probabilistic approaches will be pursued.

3.1.2 Use Site Footprint for Nursery Uses

In the comments on the draft BE, ADAMA (Breton at al. 2016a) noted that the dataset used to derive the footprint for nurseries (Dun & Bradstreet (D&B)) was not publicly available, thus difficult to evaluate.

The final BE listed the reference information for the D&B dataset, and also provided a web link (http://igeo.epa.gov/data/Restricted/OEI/Agriculture/DunAndBradstreet_Agriculture.zip). This web link was tested and determined to be non-functional. Therefore, there remains an issue with accessibility of the data required to derive the nursery use site footprint.

3.1.3 Species Habitat and Range Data

ADAMA commented on the draft BE (Breton et al., 2016a) that the species habitat and range data used by EPA in the co-occurrence analysis were not made publicly available as part of the BE documentation. The lack of transparency and availability of species location data was discussed in detail in the FESTF comments to the draft BEs (FESTF, 2016).

At the time of the final BE publication, the spatial datasets used by the EPA and the services were still not available. Making this data publicly available should be a requirement for the pilot BEs and all subsequent BEs prior to the finalization of reports.

In addition, FESTF (FESTF, 2016) challenged that the EPA's spatial data used to represent species locations appeared to be only at the county level for the vast majority (~90 percent) of species. This led to a significant over-representation of the spatial extent of the locations for these 90 percent of species. The final BE (EPA, 2017a) did not indicate any changes to the spatial data used in the assessment, thus still over-predicted species extents and co-occurrence with potential use sites.

FESTF described in their comments (FESTF, 2016) the use of species attribute information, including special habitat preferences and requirements, in the refinement of a co-occurrence analysis. Both the EPA and FESTF have compiled these types of species attributes, however the EPA did not appear to directly use this information in compiling the final BE. ADAMA supports this level of refinement in final effects determinations.

3.1.4 Action Area and Overlay Analysis

The offsite transport zone due to spray drift was determined based upon the most sensitive aquatic habitat (Bin 5) and assumed to apply for all species. Breton et al. (2016a) disagreed with this approach because many species do not occupy the small static (Bin 5) habitat, and thus an action area that is based upon exposure potential in this type of water body is irrelevant. This approach has the potential to result in some species falling within the action area that should not. The alternative proposed by ADAMA (Breton et al., 2016a) was to derive more refined action areas that are appropriate for each species or taxon. The final BE (EPA, 2017a) did not comment on the proposed alternative approach, and instead used the same approach as the draft BE.

The method EPA used for the overlap analysis of use sites with species habitat/range was implemented as a raster-based computation that was limited to 30-meter resolution. A vector-based approach to overlap analysis was recommended by ADAMA (Breton et al., 2016a) as being a more accurate alternative and able to resolve overlap and proximity at distance less than a single 30-meter pixel. However, the approach used in the final BE remained unchanged from the draft BE and no comment was provided on the ADAMA recommendations.

It was suggested by FESTF and CLA that temporal factors be considered in co-occurrence and overlay analysis. The example of migratory birds was given, suggesting that some species are only present in portions of their range for limited amounts of time. The temporal nature of species locations was not considered in the final BE.

3.2 Aquatic Exposure Modeling for Diazinon

3.2.1 PFAM Modeling

CLA (CLA, 2016) noted that a conceptual model for the use patterns modeled with PFAM was not sufficiently presented and that details of the cranberry use simulations were not provided. No changes were observed in the final BE that addressed documentation deficiency of the PFAM simulations.

3.2.2 Spray Drift Modeling and Contributions to Exposure

3.2.2.1 General Conservatism in Drift Modeling

The drift methods applied in the BEs were standard Tier 2 FIFRA methods and can significantly over predict exposure potential. The assumption of a 10 mph wind always blowing from a treated field to the water body, without accounting for the use of spray drift reduction technologies, leads to predictions of drift loadings into nearby waters that are too high. In addition, EPA’s modeling did not account for reductions in spray drift deposition in receiving water bodies resulting from drift BMPs of riparian areas/vegetative barriers. Recommendations were made by CLA (2016) and ADAMA (Breton at al., 2016a) to include a probabilistic representation of drift loading in the BE, along the lines of suggestions by the NAS panel report

(NRC 2013). However, the suggested refinements in the drift modeling were not adopted nor addressed by the EPA in the final BE.

3.2.2.2 Selection of Drift Models

The EPA used the AgDRIFT Tier I model to simulate drift contributions to aquatic habitat. For ground spray modeling, CLA (2016) suggested that EPA should use the RegDisp model, which allows for the selection of specific nozzles, spray quality, and wind speed. The AgDRIFT model is not representative of current spray equipment used in practice, and greatly over-predicts spray deposition compared to current practices. For aerial applications, it was suggested that AGDISP, parametrized for current spray nozzles and typical wind speeds, would be the most appropriate model to use. No changes were made in the spray drift models used in the final BE.

3.2.2.3 Drift Modeling Assumptions

ADAMA's comments on the draft BE (Breton at al., 2016a) noted that EPA assumed a droplet size distribution of "very fine to fine" for ground spray and "fine to medium" for aerial applications. However, ADAMA is only in support of spray quality with medium droplet size or coarser for both ground and aerial applications. The final diazinon BE did not address this concern or make corrections to the spray drift modeling to account for the supported droplet size range.

3.2.3 Application Timing Effects on Exposure

ADAMA (Breton et al., 2016a) expressed concern that EPA only used a single application date (chosen to be conservative) in modeling potential pesticide exposure. ADAMA argued that application timing is a very sensitive parameter in runoff-driven aquatic exposure modeling, and that to properly evaluate the likelihood of pesticide exposure, the range of possible application dates needs to be accounted for in exposure predictions. This would lead to the generation of probabilistic exposure distributions, which are appropriate for a Step 2 analysis under the current interim framework.

EPA's final BE (EPA, 2017a) did not address this comment about application timing or modify the modeling approach to account for the recommendation. While the selection of a single "worst case" date within a known application window is appropriate for initial screening level exposure modeling, Step 2 of EPA's assessment should have more rigorously considered the variability of application timing when predicting diazinon EECs. Accounting for this uncertainty in application timing with probabilistic methods would have resulted in lower EECs than only using a highly conservative, "worst case" application date.

Another point concerning application timing that was made in CLA's response to the draft BE (CLA, 2016) (and also on diazinon end-use labels) was that EPA stated, "efforts may be made to avoid pesticide application right before precipitation events." However, this did not appear to be considered in the parameterization of the models. This issue was not further addressed in the final BE and remains an important consideration in refining the potential for exposure.

3.2.4 *Aquatic Exposure Modeling Results*

3.2.4.1 General Comments

ADAMA (Breton et al., 2016a) provided extensive comments on the EEC results presented in the draft BE and provided numerous arguments demonstrating how unrealistic and implausible they were. ADAMA also provided extensive data analysis to support these positions. Some of the primary arguments supporting how unrealistic the EECs were included:

- Predicted concentration in aquatic habitats that were greater than diazinon solubility;
- Modeled medium flow (Bin 3) and high flow (Bin 4) concentrations that were greater than low flow (Bin 2) concentrations;
- Flowing water concentrations (in all size bins) many times higher than in static water habitat bins; and
- Predicted concentrations in receiving waters multiple orders of magnitude greater than the edge of field concentrations.

Recommendations made by ADAMA to address the significant over-predictions across the range of aquatic habitat bins included the following:

- For flowing water habitat screening-level EECs:
  - Incorporate a baseflow rate equal to the minimum of the flow range associated with each habitat bin;
  - Constrain the watershed areas to that which can drain into a main channel within one day;
  - Apply Percent Cropped Area (PCA) adjustments at a minimum to Bin 3 and Bin 4; and
  - Replace VVWM with a receiving water model designed to simulate pesticide fate and transport in a flowing channel. The Soil and Water Assessment Tool (SWAT) has this capability and has been shown to produce realistic peak exposure values for small, medium, and large flowing water bodies (refer to Teed et al., 2016 for details).
- For static water habitat screening-level EECs:
  - Correct the assumption that the pesticide mass generated in one day for the entire watershed arrives at the receiving water body instantaneously (equivalent to daily average instead of peak EECs, and applied to flowing water as well);
  - Constrain the watershed areas of the static water body habitats to areas based on typical bin-specific water body configurations on the landscape, as opposed to allowing climatologically driven water balance calculations to wholly determine the watershed area; and
  - The watershed areas should also be constrained to allow a limited amount of regional variability. The significant amount of watershed area variability in the BE static bin scenarios across the HUC2s has led to an artificially wide range in EECs, which cannot be justified based on monitoring data or our conceptual understanding of hydrology and aquatic exposure pathways. Constraining the

watershed areas within a limited regional range would allow for a clearer interpretation of the relative risk of pesticide use based on regional variability in precipitation, soils and slopes, and use patterns.

- For refined modeling of all aquatic EECs:
    - 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; and
    - Incorporation of Percent Treated Area (PTA) that acknowledges that 100% of potential use sites do not get treated with a given pesticide.

The comments from CLA (2016) on the draft BE provided a long list of similar suggestions for ways in which the aquatic exposure modeling should be refined. The main themes of these suggestions were:

1. Account for much greater spatial variability and landscape heterogeneity,
2. Use higher resolution (spatially explicit) EEC predictions,
3. Use best available spatial datasets, and
4. Incorporate probabilistic model inputs and outputs.

These higher tier modeling recommendations were not incorporated into the final BEs. However, EPA has indicated that some of these types of refinements will be considered as their overall ESA process evolves.

Several important changes in the aquatic exposure modeling were incorporated into the final BE. These included:

- Reporting of daily (24-hour) mean concentrations instead of peak concentrations for all flowing and static habitat bins; and
- Incorporation of baseflow into the Bin 3 and Bin 4 flowing water predictions.

An additional update to the aquatic exposure modeling that was discussed in the final BE, but not incorporated into the updated modeling of EECs, was accounting for the variability in the “time-of-travel” to a watershed outlet for the medium and large flowing water habitats (Bin 3 and Bin 4). It was suggested that this conceptual change in the modeling of Bin 3 and Bin 4 exposure would be implemented in the BEs that will be prepared for carbaryl and methomyl. ADAMA supports these updates to EPA’s exposure modeling in the final diazinon BE. These changes resulted in significant reductions of EECs for the flowing water habitat bins of generally around an order of magnitude (10x). The EECs for the static water habitats (Bin 5, Bin 6, and Bin 7) were generally a little lower than those presented in the draft BE, but oddly, there were a few cases where the EECs in the final BE were higher (e.g., HUC 1, Bin 5). We do support the inclusion of baseflow in Bin 2, in addition to Bin 3 and Bin 4, as low flow streams will also have baseflow. We also believe that the “time-of-travel” being explored by EPA for future BEs has the potential to lead to further improvements in the realism of the EECs in each aquatic habitat.

The aquatic EECs in the final BE are an improvement over the EECs in the draft BE due to the incorporation of more realistic assumptions and the adoption of daily average concentrations instead of the erroneous peak concentrations. Nevertheless, there are still reasons for concern regarding the EECs reported in the final BE. A review of these EECs in Table 3-10 of the final BE (EPA, 2017a) shows the following for the 1-in-15 year annual maximum daily average water column EECs:

- Bin 2 maximum EECs were between 2.6 and 18.5 times higher (median of 8.1) than Bin 3 EECs. In their draft BE, EPA (2016a) stated that Bin 3 EECs should be approximately 5 times lower than Bin 2 EECs. However, Bin 3 EECs were unrealistically high, which indicates that the overestimation of Bin 2 EECs was even more significant in the final BE.
- Bin 2 maximum EECs were between 2.5 and 23 times higher (median of 8.9) than Bin 4 EECs. In their draft BE, EPA (2016a) said that Bin 4 EECs should be approximately 10 times lower than Bin 2. However, Bin 4 EECs were unrealistically high, which further signifies the overestimation of Bin 2 EECs in the final BE.
- The medium flowing (Bin 3) habitat EECs were only up to 1.7 times higher than the large flowing (Bin 4) EECs. The median ratio of Bin 3 to Bin 4 EECs is 1.0, indicating equal exposure. In 7 out of the 30 HUC2 region/weather station combinations reported, the Bin 4 EECs were less than the Bin 3 EECs
- The large flowing (Bin 4) habitat EECs were up to 26.4 times higher than the large static (Bin 7) EECs (a median of 3.4 times higher). While referred to as a “large static” habitat, Bin 7 represents a small pond and is equivalent to EPA’s standard “farm pond” considered to be a high vulnerability water body in ecological risk assessment under FIFRA.

These observations indicate that, from a conceptual standpoint, the simulated EECs in the medium and large flowing habitats (Bin 3 and Bin 4) were still grossly over-predicted. Conceptually, the large flowing water EECs for Bin 4 should be significantly lower than EECs in the standard farm pond (Bin 7). The Bin 7 EECs were already extremely conservative, yet the Bin 4 EECs were up to 26.4 times higher. Furthermore, while the low flow (Bin 2) EECs should, in theory, be higher than Bin 4 EECs, they should not be as much as 23 times higher. The differences between EECs in Bin 3 and Bin 4 were also nonsensical, as we would expect the Bin 4 EECs to be at least 5 times lower than Bin 3 EECs; yet in some cases, the Bin 4 EECs are higher than Bin 3 EECs. The current set of screening-level diazinon concentrations do not match with our basic conceptual understanding of pesticide concentrations across water bodies of a range of characteristics and sizes. This puts into serious question the validity of the EECs presented in the Final BE.

3.2.4.2 Comparison of EECs with Edge of Field Concentrations

In ADAMA's comments on the draft BE (Breton et al., 2016a), an analysis was presented demonstrating that for many of the habitat bins modeled (Bin 2, 5, 6, and 7), the simulated edge of field diazinon concentrations were often greater than the simulated receiving water concentrations. This was especially true for Bin 2 and Bin 5. This phenomenon was extremely problematic and in large part due to the erroneous calculation of an instantaneous "peak" concentration, which has been changed by EPA to daily average concentrations.

A similar analysis comparing modeled edge of field concentrations to the modeled receiving water concentrations was not conducted with the updated EECs from the final BE. However, we believe that there may still remain some conceptual errors in some of the modeling for both the flowing and static habitat bins that has led to erroneously high concentrations. We recommend that EPA look into this issue in greater detail to ensure that receiving water concentrations do not exceed edge of field concentrations.

3.2.5 Aquatic Exposure Modeling Sensitivity Analysis

The aquatic exposure sensitivity analysis was only conducted for environmental fate parameters and application dates. Given that the flowing water scenarios and modeling approaches were brand new, ADAMA (Breton et al., 2016a) recommended a sensitivity analysis that includes additional parameters. Some recommended parameters to add to the sensitivity analysis were: water body dimensions, water body flow rates within the range of the bin, watershed area, and flow-through options.

The final BE updated the sensitivity analysis section to include two additional bins (Bin 3 and Bin 4), as well as results based on the updated EECs. However, no additional parameters recommended for the sensitivity analysis were incorporated into the final BE. We maintain that given the novelty of the new aquatic habitat water bodies, additional sensitivity analyses should have been conducted.

ADAMA's comments on the draft BE (Breton et al. 2016a) also noted the level of sensitivity of the EECs to the application date selected. In order to obtain a conservative exposure estimate, EPA chose a high vulnerability application date for the modeling in Step 2. This approach is acceptable in an early Tier screening level assessment; however, we maintain that it is too simplistic for a refined exposure analysis, as should be conducted at Step 2. The final BE did not reflect these recommendations by ADAMA, nor did it provide justification for not adopting the more rigorous consideration of application timing in the derivation of EECs.

3.2.6 Evaluation of Monitoring Data

In comments on the draft BE, ADAMA (Breton et al., 2016a) noted that, while monitoring data were discussed, the data were not explicitly used as a line of evidence in the risk assessment. ADAMA suggested the use of new statistical approaches for deriving concentration time series information from monitoring data, such as the SEAWAVEQ being developed by EPA scientists and robust bias factor approaches (Mosquin et al. 2012). The final BE did not make any further use of monitoring data than the draft BE. Our position remains that a more rigorous analysis of the monitoring data is needed and that monitoring data must be considered as a line of evidence in the weight of evidence analysis.

The monitoring data reported by EPA in both the draft and final BE showed that, out of 98,000 samples taken since 1986, diazinon was detected at 10 µg/L in 15 of those samples (0.02%). Even after the improvements in the aquatic modeling in the final BE, the modeled maximum 24-hour average concentrations of diazinon across the different HUC2s for each of the six habitat bins ranged as follows:

- Bin 2: 2260 – 2960 µg/L
- Bin 3: 127 – 918 µg/L
- Bin 4: 102 – 947 µg/L
- Bin 5: 2860 – 6070 µg/L
- Bin 6: 112 – 2810 µg/L
- Bin 7: 11.3 – 592 µg/L

These updated diazinon concentrations modeled by EPA in the final BE were often multiple orders of magnitude greater than the highest diazinon concentration ever measured in the environment (61.9 µg/L). The 99.98th percentile concentration in the monitoring data (approximately 10 µg/L) is one-to-two orders of magnitude lower than the range of EECs for large flowing water bodies. This significant discrepancy continues to point to hyper-conservatism and significant adjustments to the modeling still required to obtain reasonable screening level exposure estimates.

3.2.7 WARP Model and Extrapolation of Monitoring Results

ADAMA (Breton et al., 2016a) identified the significant discrepancy between the EECs predicted by the WARP-MP model and those predicted by the PRZM/VVWM model. The WARP-MP model predictions were several orders of magnitude lower than the PRZM/VVWM EECs. ADAMA recommended that the EPA further investigate the causes for these major differences in exposure predictions. The final BE did not address this issue, nor was it mentioned in EPA's response to comments (EPA, 2017b) on the draft BE.

3.2.8 Uncertainties in Aquatic Modeling and Monitoring Estimates

ADAMA (Breton et al., 2016a) described several important sources of uncertainty that were not accounted for in the draft BEs. These included:

- Static water body volume;
- Flowing water body volume and baseflow;
- Multiple conservative drift modeling assumptions, including wind speed, wind direction, vegetation interception, and BMPs followed by applicators; and
- Diazinon application dates.

The final BEs did not further address any of these issues, other than to add a constant baseflow component to the medium and large flowing water habitats. In addition, Breton et al. (2016a) noted EPA's discussion on the uncertainty of modeling the Bin 3 and Bin 4 habitats. This discussion in EPA's final BE (EPA, 2017a) has not changed. There was still the general acknowledgement that PRZM and VVWM are field-scale models, and that extrapolating the use of those models to medium and large watersheds neglects some important watershed-scale landscape and hydrodynamic processes. In the comments to the draft BE, ADAMA recommended that a full watershed-scale model, such as SWAT (Gassman et al. 2014), be adopted in part or entirety as the appropriate model for predicting flowing water habitat concentrations of pesticides for use in endangered species aquatic exposure risk assessments.

There remains a need for a true watershed and flowing water modeling approach for the BE process. It has been previously shown that the current iteration of aquatic exposure modeling in flowing water bodies still significantly over-predicts expected screening level concentrations. This is in part due to the selection of inappropriate models. The use of appropriate models (such as SWAT) that are properly parameterized, would lead to much more realistic exposure predictions, whether at the screening level or refined level.

3.3 Aquatic Exposure Modeling for Endangered Species Assessments, Methodology Development

The topics discussed in this section are focused on the generic methodology that EPA developed for modeling aquatic exposure as part of the endangered species risk assessment process. The methods were detailed in Attachment 3-1 of the BE (EPA, 2017a).

3.3.1 ESA Modeling Compared to Traditional Ecological Modeling Approach

ADAMA (Breton et al., 2016a) commented on several aspects of the summary of model processes described in Table A3-1.1. One of the primary descriptions of the conceptual model for endangered species aquatic modeling concerned water body/flow dilution.

The following statement did not reflect EPA's modeling approach to derive EECs in the BEs: "Downstream dilution may be used from the edge of the use area, which consists of a percent use area adjustment. Concentrations are reduced by the use area adjustment factor until concentrations are below levels of concern." This concept was considered in the Action Area determination, but was not applied in deriving EECs. This comment remains of concern for ADAMA, as it does not accurately reflect how exposure values were estimated for use in the risk assessment. By not accounting for dilution of the percent use area, EECs were higher than would be found in the real world.

A change in the aquatic exposure modeling for endangered species, from what has been traditionally done for ecological exposure modeling under FIFRA, was to adopt a 1-in-15 year maximum concentration instead of the standard 1-in-10 year annual maximum concentration. The comments in Breton et al. (2016a) raised concern over the justification for this change, which EPA connected to the re-registration cycle of 15 years. ADAMA feels that this change in policy was not appropriately vetted from a scientific standpoint and that 1-in-10 year annual maximum concentrations still represent a very conservative and protective exposure estimate.

The conceptual model for the aquatic exposure habitat bins provided in Figure A 3-1.1 was questioned by Breton et al. (2016a). There was uncertainty concerning the source of the 30-meter runoff zone threshold, a distance beyond which only spray drift entered static water bodies, as well as how this threshold was implemented in practice. ADAMA also had further concerns regarding the appropriateness of this conceptual model, which represents field-scale processes, in simulating pesticide concentrations in medium and large flowing watersheds on the order of the Bin 3 and Bin 4 habitat.

The final BE added some source information to support the notion that runoff as sheet flow becomes channelized after a distance of 30-meters, leading to the assumption that runoff does not connect to static water bodies, but rather becomes a small flowing water body after that distance. The final BE also provided some additional explanation of this assumption.

The additional explanation was helpful, but it was still unclear how this notion of no runoff contributions to static water bodies beyond 30-meters from the edge of a field was implemented in practice. This concept would require detailed spatial analysis of use site proximity to static water bodies within a species habitat range to determine which portions of endangered species populations would or would not be exposed to pesticide transported via runoff and erosion. In the final BE, it appears that this 30-meter threshold was not considered in any way in deriving EECs or prediction exposure likelihood. Furthermore, the conceptual model's applicability to pesticide transport processes at the medium and large watershed scale remains questionable. It is ADAMA's position that an entirely different conceptual model is required for these larger watersheds and their receiving water bodies.

3.3.2 Spatial Resolution of Modeling Analysis

The EPA's approach was built upon the HUC2 watershed region as the spatial unit for which exposure modeling and risk analysis was conducted. Following this structure, only one exposure scenario per crop group was simulated to represent the entire HUC2 (in the case of

HUC2 17, the Pacific Northwest, and area of 177,523,042 acres). In their comments on the draft BE, CLA (2016) argued that this was insufficient spatial resolution on which to conduct an exposure assessment, and that much more variability needed to be accounted for. Suggestions were made for development of exposure scenario at a scale at least as refined as a HUC6 watershed. These suggestions were not adopted or addressed in the final BE, nor were these concerns responded to in the response to comments document (EPA, 2017b).

3.3.3 Selection of Crop Scenarios

The two most important comments that ADAMA (Breton et al., 2016a) provided in this section were:

1. concerning the methodology and criterion for assigning surrogate PRZM scenarios to crop groups and HUC2s where a PRZM scenario did not already exist, and
2. concerning the criteria applied to determine whether a large range of precipitation existed within a HUC2 watershed, requiring multiple weather stations to be used in the exposure modeling.

Neither of these two methods were fully explained by EPA in the draft BE (EPA, 2016a).

In the final BE (EPA, 2017a), no additional information was provided concerning the methodology and criteria used to assign surrogate PRZM scenarios to other crop groups and regions. Providing this additional detail would help make the process for scenario selection more transparent. Concerning the weather station data, EPA did provide the necessary details to understand how the decision was made to split the weather for a HUC2 into two representative stations as opposed to only one.

3.3.4 Aquatic Habitat Bins

3.3.4.1 Use of Generic Habitat Bins

EPA (2016a) stated that, “the nine aquatic habitat bins are used in the BEs for both Step 1 and Step 2 and will be used for the Biological Opinions in Step 3.” ADAMA (Breton et al., 2016a) suggested that the nine generic bins be used in screening level (Step 1) analysis, but that at Step 2 and Step 3 of the Interim Approach, more refined and spatially-explicit aquatic habitat characteristics be used. The comments from CLA (2016) echoed these same ideas, suggesting that the nine aquatic bins were too generic for accurate estimates of exposure concentrations. For many species, data are available that describe the specific water bodies they inhabit and more detailed information concerning their habitat characteristics. Additionally, CLA (2016) was concerned that the characterization and parameterization of the new aquatic habitat bins had not been fully vetted for modeling purposes.

The final BE used the same language as the draft BE, indicating that refinement in the aquatic habitat characteristics would not be pursued in later steps on the ESA process. ADAMA strongly recommends that generic habitat bins be limited to screening level stages of endangered species risk assessments, and that additional datasets to support realistic aquatic habitat characteristics be incorporated into the later stages of refinement.

3.3.4.2 Aquatic Habitat Bin 2 Characteristics

ADAMA (Breton et al., 2016a) provided several comments concerning the characteristics of the low flow habitat (Bin 2). It was noted that the extremely low velocity assumed for this aquatic habitat (1 ft/min) was atypical of the vast majority of low flow streams, including the slope and roughness that must be assumed to match the characteristics assumed for this water body. In addition, while a range of flow rates defines habitat Bin 2, only the minimum flow rate for the range was considered.

EPA did not make any modifications to the language of the final BE to address these issues, nor did they provide a rationale for their assumptions. As a result of this, the extremely conservative parameterization of habitats represents a fraction of actual low flow habitats observed in nature.

3.3.4.3 Static Habitat Bin Characteristics

ADAMA (Breton et al., 2016a) challenged the use of static water body characteristics that represent only the most vulnerable end of the spectrum based on the habitat definitions that FWS/NMFS provided. While potentially acceptable as an initial screening approach, a more complete range of water body characteristics needs to be considered in Step 2 and Step 3. Furthermore, ADAMA challenged the relevance of Bin 5 (small static habitat). In particular, the ecological relevance and feasibility of protecting puddle-sized areas of standing water threats are largely temporary features on the landscape. ADAMA also raised the issue of reasonably being able to model these water features given available modeling tools.

These concerns were not addressed in the content of the final BE. Because Bin 5 EECs, in particular, were some of the highest generated in the exposure modeling, they largely drove the outcome of the risk assessment. It is important to better identify the relevance of this exposure scenario and the approach to modeling it.

3.3.4.4 Estuarine and Marine Bins

ADAMA (Breton et al., 2016a) agreed with EPA’s statement in the draft BE that, “current pesticide models do not account for transport via tidal and wind generated currents in marine systems,” but does not agree with the selection of “surrogate bins.” Further comments on the modeling of estuarine and marine habitat were made later in the response document. No changes to the final BE were made in response to ADAMA’s comments on this issue, and EPA provided no rationale for not considering these suggested changes.

3.3.5 Watershed Size Determination

3.3.5.1 Flowing Aquatic Habitat Bins

Comments provided by ADAMA (Breton et al., 2016a) on flowing water bin watershed sizes suggested that the regression equations EPA derived to calculate watershed size as a function of flow rate (from the NHDPlus V2 dataset) could be improved for some HUCs if linear regressions were used instead of log transformed regression equations. A more significant comment by ADAMA was that the watershed sizes calculated for flowing water habitats were unreasonably large given the constraints of the modeling approach and the use of the VVWM model as a receiving water model. In many HUC2s, the watershed area was considerably larger than could be expected to drain to the outlet within a single day. One of the biggest concerns related to watershed size was the assumption of instantaneous loading of pesticides into the water body and the use of the corresponding peak EEC in the risk assessment.

The final BE (EPA, 2017a) did not change the methodology for estimating watershed sizes associated with each flowing water habitat bin, and EPA's (2017b) response to comments did not address these concerns. The one change made in the flowing water modeling that relates to ADAMA's comments on watershed size was the change from using a peak concentration predicted by VVWM to a daily average concentration. The use of a daily average concentration reduces the impacts of very large watersheds on unreasonably large concentration predictions. Despite this improvement in the final BE, simulating watersheds the size of the Bin 3 and Bin 4 using PRZM/VVWM is beyond the intended use of those models, and alternative watershed-scale modeling approaches should be developed and implemented.

3.3.5.2 Static Aquatic Habitat Bins

Comments concerning static bin habitat watershed sizes focused on the unreasonably large watershed sizes assumed for some of the HUC2 regions (Breton et al. 2016a). The approach used to derive watershed sizes was a water balance-based methodology. In following this approach, much larger watersheds associated with each static water body were estimated for warm dry areas as compared to cool and wet areas. This resulted in drainage area to normal capacity ratios (DA/NC) that ranged over two to three orders of magnitude across HUC2 regions, depending upon the Bin. This phenomenon was not supported by any landscape level data, making the resulting watershed areas to be purely hypothetical. One result was that tremendous amounts of runoff and pesticide could be generated from such large areas, and because EPA's modeling methodology assumes zero dilution from runoff water in static receiving waters, the predicted EECs were often grossly over-predicted.

This issue of watershed size for static habitat bins was not addressed in EPA's final BE, and EPA did not provide any justification to support the large range in static water body watershed sizes. Our position remains that watershed areas derived for the static habitat in many of the HUC2s are unrealistically large, which leads to significant over-prediction of pesticide loadings to the water bodies. Methods to refine these watershed areas should include evaluating actual static water body watersheds determined from topographic data.

3.3.5.3 Estuarine and Marine Aquatic Habitat Bins

The use of surrogate freshwater aquatic habitat bins to represent marine and estuarine habitats was introduced in this section of the BE. Breton et al. (2016a) made extensive comments concerning the inappropriateness of the freshwater bins EPA assigned to the marine and estuarine habitats. The final BE did not modify EPA's original methodology concerning surrogate freshwater bins, but suggested that improved methods for estimating exposures in estuarine/marine habitats would be a longer-term goal. Our position is that the freshwater EECs assumed by EPA have no relevance to the marine/estuarine systems that they are intended to represent. The EECs derived in the final BE for these marine/estuarine habitats are very likely several orders of magnitude higher than reasonably conservative screening-level EECs should be.

3.3.6 Application Date Selection

Breton et al. (2016a) commented that the draft BE was unclear concerning how information other than weather was used in selecting application dates. The final BE added a statement that provided clarification to this question: "If pest pressure or agronomic practice information is available to restrict the application period, then the wettest month during this period will be selected." Thus, it appears as though pest pressure data served as an additional constraint to the application window.

3.3.7 Issues Modeling Medium- and High-Flowing Waterbodies

ADAMA (Breton et al., 2016a) provided extensive comments concerning the reasons for the excessively high concentrations of diazinon predicted in the original modeling conducted by EPA. Many of these were in agreement with what EPA identified in the draft BE as reasons for the overly high predictions. One or the primary points made by Breton et al. (2016a) was that many of the issues identified for the medium and high flow habitat bins also apply to the low flow (Bin 2) habitat.

The final BE contained modified modeling of Bin 3 and Bin 4 habitats that included baseflow and a daily average concentrations instead of peak concentrations. The baseflow changes were applied to only Bin 3 and Bin 4, while the daily average EEC changes applied to all three of the flowing water habitats. Other factors leading to excessively high EECs, as identified in the draft BE comments (very high DA/NC ratio and assumption of 100% area of the watershed treated on the same day) were not addressed in the final BE. This continues to be a concern for ADAMA and leads to the over prediction of EECs in all of the flowing water habitat bins.

3.3.7.1 Modifications Considered but Not Incorporated

The draft and final BE were unchanged in this section of the document, which outlines model refinements/modifications that were considered by EPA in their initial efforts for flowing water modeling, but were not actually tested in their exploratory modeling. These items were as follows:

- **Incorporation of Baseflow**: This model modification was originally dismissed by EPA in their modeling, but ultimately included in the flowing water modeling reported in the final BE (Bin 3 and Bin 4 only).
- **Percent Use Area and Percent Use Treatment Adjustment Factors:** This model modification was strongly supported by ADAMA (Breton et al., 2016a), but was not adopted by EPA in their final BE modeling. EPA (2017b) noted in their response to comments that they are, "evaluating the appropriate scale at which to incorporate percent crop area/crop treated in the exposure assessments."
- **Adjustment of Water Body Length:** This model modification was not believed by either EPA or ADAMA to be of significant importance.
- **Spreading Out Applications:** The EPA chose not to incorporate variable application timing into their modeling for the final BE. ADAMA believes this to be critical for making accurate predictions of diazinon concentrations in flowing water bodies draining medium and large sized watersheds.

ADAMA's position is that several of these model modifications originally considered by EPA, specifically percent use area, percent treated area, and spreading out applications are necessary to obtain realistic predictions of diazinon concentrations at the watershed scale. Not accounting for these factors results in higher concentration than would occur under reasonable worst case conditions.

3.3.7.2 Modifications Explored and Incorporated into Modeling

The draft and final BE are unchanged in this section of the document. This section outlined model refinements/modifications that were considered by EPA in their initial efforts at flowing water modeling, and then tested in their exploratory modeling. These items were as follows:

- **Curve Number Adjustment:** This model modification was evaluated in some of EPA's original modeling for Bin 3 and Bin 4, but was not adopted in the updated modeling in the final BE. Varying the CN value accounts for differences in soils and land cover/crop type, as occurs in real landscapes.
- **Daily Flow Averaging:** This model modification is simply that the flow through the water body on a given day is representative of the runoff entering the water body on that day. The alternative is that flow through the water body is the average of an entire 30-year period. It appears that the final BE did not incorporate daily flow averaging in the modified flowing water modeling. This model parameterization should be required, as the alternative (a 30-year average), does not capture the real dynamics that occur in flowing water systems.
- **Adjustment of Water Body Dimensions**: This option sought to change the representative length of a receiving water body to reflect a small mixing cell. This concept did not end up being applied in the final BE modeling, and was not supported by ADAMA.

- **Use of Daily Average EECs**: The draft BE modeling reported instantaneous peak EECs. Daily average EECs were considered in EPA's original exploratory modeling, and ultimately adopted for the final BE. We support this adjustment.

3.3.7.3 Modifications Evaluation, Final Approach for OP Pilot Chemicals

In the draft BE, this section focused on the final approach followed in the draft BE to estimate Bin 3 and Bin 4 EECs from the simulated Bin 2 EECs. The methodology for deriving scaling factors for Bin 2 to Bin 3 and Bin 2 to Bin 4 EECs was heavily based on the evaluation of atrazine monitoring data. In ADAMA's comments on the draft BE (Breton et al., 2016a), this scaling was critiqued in favor a more physically-based modeling approach.

The final BEs adopted a different approach to predicting Bin 3 and Bin 4 EECs than was used in the draft BE. Therefore, in the final BE, this section of Attachment 3-1 focused on a discussion of the modifications to the flowing water modeling that were considered and those that were ultimately adopted in the final modeling. The modeling modifications considered included:

- Adopting 24-hour mean concentrations in place of peak concentrations, which was done for all static and flowing aquatic habitat bins;
- Incorporating baseflow into the flowing water Bins 3 and 4; and
- Accounting for a time lag (or time of travel) in how pesticide generated throughout the watershed reaches the outlet of the receiving water body.

The first two modifications were included in the Bin 3 and Bin 4 modeling for the final BE. The accounting of watershed time of travel was still under development and not yet ready to incorporate into the final BE for diazinon; however, EPA stated that this approach will be introduced in future BEs.

ADAMA supports the incorporation of baseflow into all of the flowing aquatic habitat bins. It is typical in many areas of the country for low flow, small streams to have continuous water in them. In addition, hydraulic characteristics that have been defined for Bin 2 suggest a water body with such a low flow that it would have nearly continuous water within it at the depth and flow rate specified by the bin characteristics. We also support a modification to the modeling approach that accounts for watershed dynamics, including travel times and watershed heterogeneity from both an agronomic perspective and a landscape perspective.

3.3.8 Downstream Dilution Modeling

A downstream dilution approach was applied by EPA to determine which species where within the diazinon Action Area as a result of off-site transport resulting from runoff. This process was applied at both Step 1 and Step 2 of EPA's analysis. ADAMA provided a series of comments concerning the downstream dilution modeling that was described in the draft BE (Breton et al., 2016a). One of the overarching comments was that the downstream dilution methodology represented a vastly simplified watershed-scale modeling approach and did not account for a significant number of important processes required to quantify pesticide exposure in flowing water bodies over a range of watershed and stream/river sizes. While the draft and final BEs included sections on uncertainty in the downstream dilution discussion, the uncertainty discussion did not include anything about the modeling approach. The concerns that ADAMA expressed regarding the simplification of watershed-scale modeling were also not addressed in EPA's (2017b) responses to comments.

The downstream dilution analysis in Step 1 used EPA's "right of way" PRZM scenario to represent runoff from all potential diazinon use sites. ADAMA (Breton et al., 2016a) noted that this assumption was highly inappropriate, even in the Step 1 screening-level implementation of the approach. Furthermore, the downstream dilution analysis in Step 1 continued to use the single highest EEC derived using the "right of way" scenario to represent all potential diazinon use sites, resulting in unrepresentative use site assumptions combined with irrelevant weather assumptions being used to determine potential runoff exposure nationwide. ADAMA (Breton et al., 2016a) specifically commented on this incorrect assumption. The analysis in the final BE did not change these unrealistic PRZM scenario assumptions, nor were the assumptions adequately justified or supported.

The draft BE discussed the potential cattle ear tag use sites as being included as part of the crop footprint in the Step 1 downstream dilution analysis. ADAMA argued that ear tags are not a potential source for runoff exposure and suggested these use sites be removed from consideration at Step 1 (Breton et al., 2016a). The final BE section on downstream dilution made no mention of cattle ear tags, so it is unclear if the land use classes associated with these potential use sites were part of the final analysis for either Step 1 or Step 2.

Another overly conservative assumption noted in ADAMA's comments on the draft BE (Breton et al. 2016a) was the selection of a single effects metric from the most sensitive taxon to calculate the dilution factor in the Step 1 downstream dilution analysis. This assumption was not changed in the final BE (EPA, 2017a), nor were ADAMA's concerns addressed in the responses to the draft BE comments (EPA, 2017b).

The downstream dilution analysis conducted in Step 2 incorporated some of the assumptions that ADAMA suggested were appropriate for the Step 1 analysis. This included taxon-specific effects metrics and the use of crop specific PRZM scenarios in the determination of the runoff EEC. In the comments on the draft BE, ADAMA (Breton et al., 2016a) suggested that an appropriate refinement for the Step 2 analysis would have been to take the average EECs in cases where multiple diazinon use crops overlapped, as opposed to the maximum concentration, as was done in the draft BE. No changes were made by EPA in their modeling approach for Step 2, indicating that the EECs used in determining the overlap of the Action Area with species were still very conservative. Responses to ADAMA's comments on this issue were not found in EPA's (2017b) response to comments.

A significant change in the downstream dilution analysis between the draft BE and the final BE was that 24-hour average EECs were used rather than instantaneous peak EECs. ADAMA's

(Breton et al. 2016a) stated that peak EECs were inappropriate and EPA made the suggested changes in the final BE.

3.3.9 Spatial Overlay Analysis in Not Likely to Adversely Affect Determination

The EPA used a threshold in the overlap between the Action Area and species range to make not likely to adversely affect (NLAA) decisions in Step 2 of their analysis. Diazinon was determined to not likely adversely affect a species in cases where there was less than one percent overlap. ADAMA (Breton et al., 2016a) questioned the selection of the one percent threshold in their comments on the draft BE, as scientific justification for this threshold was not provided. The final BE (EPA, 2017a) and EPA's responses to draft BE comments (EPA, 2017b) did not provide any further justification for this threshold.

3.3.10 Aquatic Exposure Modeling Summary Recommendations

ADAMA (Breton et al 2016a) provided a summary of concerns and recommendations regarding the aquatic exposure modeling presented in EPA's draft BE for diazinon. The most important recommendation that EPA adopted in the final BE was the use of daily average EECs instead of instantaneous peak EECs. EPA also adopted the suggestion of including baseflow in Bin 3 and Bin 4 simulations, but did not include baseflow in Bin 2, as suggested. A long list of recommended refinements to EPA's modeling approach for both static and flowing water bodies made by ADAMA have not yet been incorporated into EPA's modeling approach. In EPA's responses to the draft BE comments, EPA indicated that BEs conducted for compounds assessed in the future will likely include some of these additional suggested refinements.

4.0 EFFECTS ENDPOINTS AND DERIVATION OF THRESHOLDS

4.1 General Comments

4.1.1 SETAC Pellston Workshop on Improving the Usability of Ecotoxicology in Regulatory Decision Making

ADAMA (Breton et al., 2016a) and CLA (2016) expressed a number of concerns with the selection of endpoints and the methods used to derive effects thresholds in the draft BE (EPA, 2016a). The majority of these comments pertained to the quality and relevance of the studies used by EPA (2016a) and the lack of transparency in EPA's method for evaluating the studies. Breton et al. (2016a) reminded EPA of the conclusions of a Pellston Workshop attended by the Agency, which highlighted a multitude of limitations of using open-literature data to support risk assessment decisions. Despite these comments, the Agency still used many open-literature studies that have not been properly verified for data relevance and data quality in the final BE (EPA, 2017a).

4.1.2 Data Selection and Evaluation Process

In their response to comments memorandum, EPA (2017b) indicated that they had increased the transparency of their work in the final BE. However, EPA (2017a) did not address many of the comments made by ADAMA, particularly the selection and evaluation of data, resulting in the use of many studies of poor quality. Further, despite their claim of greater transparency, the Agency has not yet released their criteria for "Standard Evaluation Procedures (SEP)" for evaluating registrant-submitted studies. Although the Agency fixed the broken hyperlink relating to guidance for reviewing open literature from the draft BE (EPA, 2016a) for the final BE (EPA, 2017a), there still remains no explanation for why these studies should receive a less stringent review than registrant-submitted studies. Following this guidance, studies that have not undergone a thorough and stringent review would be included in SSDs. This practice is in direct disagreement with EPA's insistence that they are "committed to using the best scientific and commercial data for ESA-FIFRA analyses" (EPA, 2017a). EPA (2017a) also used studies to build their SSDs in the final BE for which the chemical characterization was identified as "unknown". ADAMA cannot emphasize enough that this is scientifically unsound and again questions how EPA is using toxicity data from studies that have not properly characterized the tested chemical for relevance.

Toxicity studies conducted using end-use products currently registered in the US are generally considered relevant to US risk assessments, and many older formulations contained inerts that are no longer approved for use in the US today. Many registrants have proactively replaced older inerts with less harmful solvents, emulsifiers, etc. Therefore, even toxicity data submitted years ago for a formulation that is currently registered may no longer be representative of the current end-use products. To account for these issues, Breton et al. (2014a,b [MRIDs 49351401, 49333901]) developed a method for screening and evaluating toxicity studies. Using this method, ADAMA rated many of the studies used to calculate EPA's thresholds as "unacceptable" for risk assessment.

ADAMA disagrees with EPA's procedure for evaluating chronic risk to aquatic and terrestrial species. Chronic guideline studies typically use continuous pesticide exposures ranging from 21 days for aquatic invertebrates to greater than 10 weeks for birds and mammals. However, such exposures are unrealistic because diazinon would, in reality, degrade rapidly between applications, making pulse exposures far more relevant than maintained chronic exposures. For example, in a study in aquatic systems, Corden (2004 [MRID 46386604]) estimated an aerobic metabolism half-life of 9.9 to 11.6 days. Likewise, residues on foliage dissipate quickly with half-lives ranging from 0.4 to 5.3 days (Willis and McDowell, 1987).

ADAMA (Breton et al. 2016a) expressed concern with the Agency's approach to choosing effects thresholds for chronic exposures. In the final BE (EPA, 2017a), NOELs drove many of the risk designations, and in turn, the species and critical habitat calls. The use of NOELs in ecological risk assessment has long been criticized (Hoekstra and Van Ewijk, 1993; Moore and Caux, 1997; Landis and Chapman, 2011; Jager, 2012; Murado and Prieto, 2013). This criticism stems from the inherent deficiencies of the metric as a relative measure of toxicity, which includes an absolute dependence on the selected treatment levels and sample size, and related issues of low statistical power. As a result, regulatory risk assessors are moving away from the use of NOELs in favor of ECx values (e.g., OECD, 1998; CCME, 2007). Given the criticism in the peer-reviewed scientific literature of using NOELs in ecological risk assessment, it is surprising that the Agency would consistently use these metrics in an evaluation that is purported to be based on best available scientific information. In the Interagency Interim Approaches, the Agencies (2013) stated that ECx values would be considered in the interim approach. However, it seems that EPA (2017a) primarily opted to circumvent data analyses and simply use the author-reported NOELs from toxicity studies.

4.1.3 Consideration of Endpoints of Uncertain Ecological Relevance

EPA (2017a) ignored the Interagency Interim Approaches (Agencies, 2013) for selecting toxicity studies for use in establishing "may affect" thresholds. The Agencies (2013) stated that "Establishing "may affect" thresholds for given taxa may also, when supported by professional judgment, be based on toxicity studies that are conducted at the sub-organism level (e.g., on organs or cells), provided they can be linked to environmentally relevant exposures that can influence survival, growth, or reproduction". In Attachment 1-4 of the final BE (EPA, 2017a), EPA noted that "Establishing "may affect" thresholds for given ESA-listed taxa may also be based on toxicity studies that are conducted at the suborganismal level (e.g., on organs or cells), provided data are consistent with other criteria for use." However, it was not further explained how such suborganismal data could be used in the BEs to establish thresholds, especially given the difficulty of relating such endpoints to effects on survival, growth or reproduction. This difficulty is reflected by the Agency's own admission that "AChE inhibition is not, by itself, a reliable predictor of survival, growth, and reproductive effects at the individual level. Moreover, anticholinesterase effects appear to be highly variable in terms of test concentrations, exposure duration, magnitude, recovery time, and species" (EPA, 2017a).

To properly incorporate sublethal effects into an ecological risk assessment, it is necessary to provide an explicit relationship between the sublethal effect in question and apical endpoints (i.e., survival, growth, and/or reproduction). In many cases where EPA (2017a) presented sublethal endpoints (e.g., the inclusion of biochemical, cellular, and behavioral effects in many of the 'data arrays'), there was no discussion as to the ecological relevance of these endpoints. Without establishing this relationship, it is unclear how these effects can be considered in a weight of evidence approach.

4.1.4 Mismatch of Exposure Duration Between Toxicity Endpoints and Estimated Environmental Concentrations (EECs)

In the draft BE, EPA (2016a) predicted acute risk to aquatic organisms by comparing instantaneous aquatic peak EECs to threshold values derived from toxicity tests wherein organisms were exposed to constant concentrations of diazinon for much longer exposure durations. For example, EPA (2017a) relied on 96-hour toxicity tests to derive acute effects thresholds for fish and 48-hour or 96-hour toxicity tests to derive acute effects thresholds for aquatic invertebrates. It is highly unlikely that aquatic organisms would be exposed to a 'peak' concentration of diazinon for a 48- or 96-hour period under realistic conditions. For their final BE, EPA (2017a) used 24-hour average EECs to estimate acute risks. This remains a highly conservative assumption, but is preferred when compared to peak EECs.

ADAMA has previously demonstrated (Breton et al., 2016a) that LC50 values are much higher at shorter exposure durations for diazinon for amphibians, fish, and aquatic invertebrates. Furthermore, toxicity tests for organophosphorus and carbamate compounds using various aquatic test species have found that pulsed exposure rather than a single peak exposure of equal total duration caused significantly less toxicity (Kallander et al., 1997; Jarvinen et al., 1988). ADAMA maintains that comparing existing acute effects data with time weighted average exposure concentrations compatible with appropriate toxicity test durations will more appropriately estimate risk.

4.1.5 Degradates of Concern

EPA (2017a) included a qualitative discussion of diazoxon as a potential degradate of concern of diazinon. As previously discussed by ADAMA (Breton et al., 2016a), diazoxon should not be considered a degradate of concern because it will not be produced in the environment in amounts that would cause harm to organisms. Therefore, the Agency should not have included diazoxon toxicity in the final BE.

4.1.6 Incident Reporting

Incidents since the 2006 RED (EPA, 2006) are few and do not have strong evidence linking them to currently registered diazinon formulations.

4.2 Taxon-specific Review and Critique of Effects Characterizations Presented in Chapter 2 of EPA (2017a)

4.2.1 Fish and Aquatic-phase Amphibians

ADAMA (Breton et al., 2016a) had a number of concerns with the effects metrics selected by EPA (2016a) to assess risks to fish and aquatic-phase amphibians. Specifically, freshwater fish, estuarine/marine fish, and aquatic-phase amphibians have very different sensitivities to diazinon, but these taxonomic groups were combined for the selection of effects thresholds by EPA (2016a). In their final BE, EPA (2017a) maintained the use of combined thresholds. ADAMA disagrees with this approach. If suitable toxicity data are available for aquatic-phase amphibians, these taxon-specific data should be applied to assess risk. EPA guidance indicates that data for under-represented taxa are preferred over surrogate species data, regardless of whether the endpoints are more or less sensitive (EPA, 2011). Notably, ADAMA (Breton et al., 2016a) has identified acceptable chronic toxicity data for aquatic-phase amphibians (Lee et al., 2011 [MRID 48616101]) and recommends applying taxon-specific data when available.

To derive an acute mortality-based threshold, EPA (2016a) generated an SSD from 49 toxicity endpoints for fish and aquatic-phase amphibians from 29 studies. Study evaluations for the studies used were largely unavailable in the draft BE (EPA, 2016a) or in any of the associated appendices or attachments. For their final BE, EPA (2017a) used identical data to generate an SSD for fish and aquatic-phase amphibians and did not provide any additional study evaluations. Given the importance of study evaluation, as outlined in Section 4.1.2 of this response document, EPA (2017a) did not provide sufficient information to suggest that the data relied on were of adequate quality to be used in risk assessment (Breton et al., 2016a; CLA, 2016). Eleven of the studies used by EPA (2017a) have previously been reviewed by ADAMA as part of their National Endangered Species Assessment for diazinon (Greer et al., 2016). Following the study evaluation criteria described in Breton et al. (2014a,b [MRIDs 49351401, 49333901]), ten of those studies were rated as unacceptable and only one was rated as acceptable. The lack of data quality employed by EPA (2017a) to select studies for their SSD went against the principles outlined by EPA (2011), NRC (2013), and Agencies (2013).

Breton et al. (2016a) also identified duplicate data points used by EPA (2016a) to construct their SSD. For example, EPA (2016a) reported two identical LC50s for the rainbow trout (*Oncorhynchus mykiss*) (Mayer and Ellersieck, 1986 [E6797] [MRID 40098001] and Johnson and Finley, 1980 [MRID 40094602]) and two identical LC50s for the sheepshead minnow (*Cyprinodon variegatus*) (Mayer, 1987 [MRID 40228401] and Goodman et al., 1979 [MRID 40914801; E5604]). Mayer and Ellersieck (1986 [E6797] [MRID 40098001]), Johnson and Finley (1980 [MRID 40094602]), and Mayer (1987 [MRID 40228401]) are all toxicity handbooks that summarize the results of other published and unpublished papers and reports. Although EPA (2016a) calculated geometric mean values when multiple endpoints were available for the same species, this duplication may have resulted in skewed mean LC50s for some species. EPA (2017a) failed to address these errors in their final BE and did not change their SSD.

EPA (2016a) considered five potential distributions (log-normal, log-logistic, log-triangular, log-gumbel, and Burr) to construct their aquatic vertebrate SSD. Ultimately, EPA (2016a) chose a model-averaged SSD from the five distributions, but provided no explanation as to why a model-averaged SSD was chosen rather than the best-fitting distribution (logistic). This methodology is also inconsistent with the SSD constructed for aquatic invertebrates. For their final BE, EPA (2017a) made no changes to the SSD and provided no additional explanations for their choices.

Breton et al. (2016a) and CLA (2016) also critiqued the use of an AChE inhibition endpoint (Dzul-Caamal et al., 2012 [E160182]) as a threshold value by EPA (2016a). A 25% diazinon formulation was used by Dzul-Caamal et al. (2012 [E160182]) to assess AChE inhibition in Atlantic silverside (*Chirostoma jordani*). However, EPA (2016a) stated in Section 2.4.1 of Chapter 2 of their draft BE that this formulation is not comparable to products currently registered in the US and is of limited relevance to risk assessment. Further, the biological significance of AChE inhibition (23% observed by Dzul-Caamal et al., 2012 [E160182]) with regard to clinical signs of toxicity that could affect growth, reproduction, or survival is unknown. Therefore, use of this threshold value is unwarranted. In their final BE, EPA (2017a) chose to again include this endpoint, despite its limited relevance to risk assessment.

In addition to the threshold values chosen by EPA (2016a), a table of most sensitive sublethal effects data was also provided. No changes were made to the sublethal data for the final BE (EPA, 2017a). ADAMA (Breton et al., 2016a) highlighted a number of issues with the effects data chosen, particularly use of low quality data. The studies did not provide information on the test substance, lacked solvent controls, did not provide control results, and/or reported effects that were not considered biologically relevant (e.g., swimming behavior, AChE inhibition). Throughout the assessment, EPA (2017a) relied on qualitative, low quality data, despite an assertion in Table 2-5 of Chapter 2 that qualitative data were only used for purposes of characterization. The use of qualitative data to make NLAA and LAA species calls is unwarranted and should be re-evaluated (Breton et al., 2016a; CLA, 2016).

4.2.2 Aquatic Invertebrates

EPA (2016a) generated an SSD for aquatic invertebrates using 84 endpoints from 41 studies. EPA (2016a) specifically stated that only endpoints calculated using technical grade diazinon would be included. However, EPA (2016a) also included one data point for a diazinon formulation (Sucahyo et al., 2008 [E100785]). This error was not fixed in the final BE (EPA, 2017a). In fact, EPA (2017a) made no changes to the aquatic invertebrate SSD constructed for the draft BE (EPA, 2016a). Study evaluations were largely unavailable in the draft and final BEs (EPA, 2016a; 2017a), and sufficient information was not provided by EPA (2016a; 2017a) to demonstrate that the data relied on in the SSD were of adequate quality for risk assessment (Breton et al., 2016a; CLA, 2016).

Breton et al. (2016a) also identified duplicate data points used by EPA (2016a) to construct their aquatic invertebrate SSD. For example, an LC50 for rotifers (*Brachionus calyciflorus*) was reported twice. The first entry was an unpublished report (Snell, 1991 [E17689]), while the second entry was an open literature study from the same lead author and same dataset (Snell and Moffat, 1992 [E3963]). Duplication was also identified for caddisfly larvae (*Hydropsyche angustipennis*) endpoints (Van der Geest et al., 1999 [E20217]; Stujifzand et al., 2000 [E54582]). Although EPA (2016a) calculated geometric mean values when multiple endpoints were available for the same species, this duplication may have resulted in skewed mean LC50s for some species. EPA (2017a) failed to address these errors in their final BE and did not change their SSD.

EPA (2016a) selected a sublethal freshwater invertebrate threshold value from Deanovic et al. (2014 [E161081]). Deanovic et al. (2013 [E161081]) evaluated the effects of technical diazinon to the reproduction and survival of the water flea (*Ceriodaphnia dubia*) under static conditions. This study was rated supplemental by ADAMA (Breton et al., 2016a) because it failed to prove maintenance of test concentrations over the exposure period and only initial concentrations were measured. This study was also used by EPA (2017a) for their final BE. ADAMA recommends a chronic GLP study for the water flea (*Daphnia magna*) that was rated acceptable (Breton et al., 2016a) and reported a NOEC of 0.17 µg a.i./L for survival (Surprenant, 1988a [MRID 40782302]).

4.2.3 Aquatic Plants

ADAMA (Breton et al., 2016a) questioned the selection of direct and indirect effects thresholds by EPA (2016a) for their draft BE. These effects thresholds were unchanged for the final BE (EPA, 2017a). For direct effects to aquatic plants, EPA (2016a; 2017a) selected a NOEC of 500 µg a.i./L for reduction in biomass of green algae (*Scenedesmus quadricauda*) from Ma et al. (2005 [E102905]). This study was rated quantitative by EPA (2016a; 2017a), but was rated unacceptable by ADAMA (Breton et al., 2016a) because test concentrations were not renewed or measured and insufficient details were provided for control growth rates and test conditions.

For indirect effects to aquatic plants in Step 1, EPA (2016a; 2017a) selected a seven-day biomass EC50 of 3700 µg/L for green algae from Hughes (1988 [E13002; MRID 40509806]). EPA (2016a; 2017a) did not provide an evaluation for this study and it was rated supplemental by ADAMA. However, the author-reported EC50 was 6400 µg a.i./L, not 3700 µg/L as reported by EPA (2016a; 2017a). Furthermore, it is unclear as to why EPA (2016a; 2017a) selected an EC50 endpoint as their indirect effects threshold when they stated in Table 1-10 of Chapter 1 that the concentration equal to the lowest available LOEC or EC25 would be used. A LOEC (1000 µg a.i./L) from Ma et al. (2005 [E102905]) was also reported in Appendix 3-6 and AquaWoE_v1.0.xls of the BEs (EPA, 2016a; 2017a). Although this endpoint was used to make LAA and NLAA determinations in Step 2, use of this endpoint was not described in the BEs. It is also unclear why EPA (2016a; 2017a) applied a lower threshold in Step 2 than Step 1. Breton et al. (2016a) and CLA (2016) critiqued the lack of transparency inherent in the draft BE (EPA, 2016a) and no further clarification was provided in the final BE (EPA, 2017a).

EPA (2016a; 2017a) used endpoints from qualitative studies to make LAA and NLAA species determinations. For example, NOEC and LOEC values from Worthley and Schott (1971 [E9184]) were used as the growth endpoints for aquatic vascular plants in Step 2. However, this study was rated as qualitative by EPA (2016a; 2017a) and no indication was given as to how this effects endpoint was used. Additionally, EPA (2016a; 2017a) used a more sensitive growth endpoint for non-vascular plants in Step 2 than their indirect effects threshold for aquatic plants in Step 1. Threshold values and most sensitive endpoints rated qualitative should not be used in a quantitative manner to make LLA and NLAA determinations and conservativeness should decrease with progression through the steps of the assessment, not increase. (Breton et al., 2016a; CLA, 2016).

4.2.4 Birds, Reptiles and Terrestrial-phase Amphibians

ADAMA agrees with EPA (2016a; 2017a) that there are no acceptable or supplemental toxicity data available to assess herptiles. The use of avian toxicity data as a surrogate for herptiles is standard practice in the absence of appropriate data for this receptor group (EPA, 2004a). However, this extrapolation has little, if any, empirical support. That is, the extrapolation is made out of necessity due to a paucity of herptile toxicity data, not because of scientific justification. Birds and herptiles belong to different taxonomic classes, and therefore have different metabolic rates, diets, respiratory and reproductive systems and ecology in general.

In Section 6.2 of Chapter 2, EPA (2016a) summarized the threshold values chosen for birds. EPA (2016a) considered studies that exposed birds to technical grade diazinon and “formulations that are representative of current registration”. However, it is not clear how EPA (2016a) confirmed relevancy of the formulations because only seven study evaluations were provided and no information on test substance was reported. Despite a declaration for increased transparency (EPA, 2017a), EPA (2017a) did not provide any additional data quality information in their final BE.

EPA (2016a) derived an SSD for mortality using 19 acute oral avian toxicity values representing seven species. The purities of the test compounds ranged from 86.6 to 99% active ingredient, but purities for two endpoints were reported only as “TGAI” (Appendix 2-9 of EPA, 2016a). Study evaluations were largely unavailable in the BE and at least two endpoints were reported from a handbook (Hudson et al., 1984), which is not the primary source of the data and reports nothing more than the species names and LD50 values. For their final BE, EPA (2017a) made no changes to their SSD and provided no additional information to assist with transparency of data selection. Given the importance of study evaluation (Breton et al., 2016a; CLA, 2016), EPA (2016a; 2017a) did not present sufficient information to suggest that the data relied on in the SSD were of sufficient quality.

EPA (2016a) also reported a threshold value in units of lb a.i./A (Vyas et al., 2006 [E85970]). Vyas et al. (2006 [E85970]) exposed juvenile Canada geese to Bermuda grass fields treated with a diazinon formulation under semi-field conditions. Two to three months prior to study initiation, the grass fields were treated with 2,4-D-amine-4, and it was not confirmed whether residual herbicide was present on the field during the study. EPA (2016a) reported that the study had limitations and that the Bermuda grass may have cause a fog behavior in the exposed birds. Therefore, the results of the semi-field exposure cannot be considered to represent effects of diazinon exposure alone. ADAMA reviewed this study and rated it as unacceptable because very few study details were provided (Breton et al., 2016a). EPA (2017a) also listed this endpoint in their final BE, but did not appear to use the endpoint in any analyses. It is unclear why EPA (2016a; 2017a) presented the data.

EPA (2016a) selected a dietary sublethal threshold value of 4.0 mg a.i./kg diet that was based on AChE inhibition in mallard ducks (Marselas, 1989 [MRID 41322901]). EPA (2017a) maintained this endpoint for their final BE. However, as noted by NRC (2013), Breton et al. (2016a) and CLA (2016), to properly incorporate sublethal effects into an ecological risk assessment, it is necessary to show an explicit relationship between the sublethal effect in question and apical endpoints (i.e., survival, growth, and/or reproduction). EPA (2016a; 2017a) did not provide any information to confirm the relevance of AChE inhibition in birds. Therefore, use of an AChE endpoint by EPA (2017a) is unwarranted. ADAMA recommends using the NOEC and LOEC for reproduction of 8.3 and 16.33 mg a.i./kg diet, respectively (Marselas, 1989 [MRID 41322901]).

In their draft and final BEs, EPA (2016a; 2017a) also selected a dose-based sublethal threshold value for the mallard duck (Fletcher and Pedersen, 1988 [MRID 40895301]). A NOEL of 0.316 mg a.i./kg bw was reported for behavior (sitting, inability to walk). However, the study authors noted “total remission of all signs [of toxicity] was achieved by the end of test day 1”. This indicates that recovery was rapid and birds quickly returned to normal health. No statistical procedures were provided to confirm an effect level. Moreover, EPA (2016a; 2017a) failed to link this temporary behavioral effect to survival, growth or reproduction. Therefore, this endpoint is not relevant for risk assessment.

4.2.5 Mammals

For their final BE, EPA (2017a) made no changes to the mammal threshold values originally selected for their draft BE (EPA, 2016a). EPA (2016a; 2017a) selected an LD50 value of 105 mg/kg bw (Mufti and Ullah, 1991 [E85110]) for their mortality threshold. EPA (2016a; 2017a) rated this study as Quantitative for maternal toxicity and Qualitative for reproductive toxicity. The study did not report any statistical endpoints and the LD50 was calculated by the study reviewer. ADAMA rated this study unacceptable because it did not provide information on the purity or source of the formulated test material, and the study lacked detail on the test organisms used and overall experimental setup. This study is unacceptable for use in risk assessment. ADAMA recommends using an acceptable rat mortality study that reported an LD50 of 864 mg a.i./kg bw (Dreher, 1997).

For sublethal effects, EPA (2016a; 2017a) relied on AChE inhibition data from a comparative cholinesterase assay intended for human health risk assessment (Parker, 2003 [MRID 46166302]). As mentioned previously, the suitability of AChE inhibition to derive a sublethal threshold value is questionable because an explicit relationship between AChE inhibition and effects to survival, growth or reproduction of mammals has not been demonstrated by EPA (2016a; 2017a). The values chosen by EPA (2016a; 2017a) were benchmark dose values used in their human health risk assessment for diazinon. EPA (2016a; 2017a) noted that the data were subject to “internal EPA peer review by an expert panel of toxicologists”. However, nowhere did EPA provide a study quality review or further details on how the endpoints were selected. While ADAMA found this study to be supplemental in quality, the endpoint selected by EPA (2016a; 2017a) is not considered relevant for use in an ecological risk assessment. ADAMA recommends a NOEC of 10 mg/kg diet for growth and reproduction from Giknis (1989 [MRID 41158101]) to assess sublethal risks to mammals.

4.2.6 Terrestrial Invertebrates

In their draft BE, EPA (2016a) summarized a variety of threshold values for terrestrial endpoints. However, the thresholds did not all consistently align with the thresholds presented in the TED Tool (Appendix 3-6). Notably, the two honeybee studies presented as threshold values by EPA (2016a) did not appear in the TED tool. ADAMA (Breton et al., 2016a) evaluated all of EPA’s (2016a) thresholds for terrestrial invertebrates. All studies were rated unacceptable because they lacked sufficient details on the test system and methods, test material, and control results. EPA (2017a) made no changes to the effects thresholds used for their final BE and did not add any of the missing endpoints to the TED tool. EPA (2017a) did not fix the errors highlighted by ADAMA (Breton et al., 2016a) or improve the transparency of their methods. It is unclear why certain threshold values were presented in Chapter 2, but not used in the TED tool (Appendix 3-6).

4.2.7 Document Errors and Technical Corrections

The following errors were present in both the draft (EPA, 2016a) and final (EPA, 2017a) BEs, and were previously summarized by ADAMA (Breton et al., 2016a):

- In Section 2.1 of Chapter 2, EPA (2016a; 2017a) stated that “no registrant-submitted toxicity data are available for amphibians”. However, this statement is untrue. An amphibian metamorphosis assay conducted by Lee (2011 [MRID 48616001]) is available and was presented in Appendix 2-4 of both the draft and final BEs (EPA, 2016a; 2017a).
- EPA (2016a; 2017a) rounded up several of the LC50 values used in their aquatic vertebrate SSD (Table 2-3 of Chapter 2). For example, EPA (2016a; 2017a) used an LC50 of 1100 µg/L for brook trout (Allison and Hermanutz, 1977 [E664]), but the study authors reported an LC50 of 1050 µg/L. In is unclear why these values were rounded.

- In Table 4-2 of Chapter 2, EPA (2016a; 2017a) presented a NOEC of 1 mg/L and LOEC of 5 mg/L for watermeal (*Wolffia brasiliensis*) from Worthley and Schott (1971 [E9184]). However, these values correspond to an increase in growth following diazinon exposure. Reductions in growth were only observed at 50 mg/L and above (Worthley and Schott, 1971 [E9184]). Therefore, the NOEC and LOEC for growth should be 10 and 50 mg/L, respectively.
- In Table 4-3 of Chapter 2, EPA (2016a; 2017a) presented 4- and 7-day EC50s of 3.7 and 4.14 mg/L for green algae (*Selenastrum capricornutum*), respectively (Hughes, 1988 [E13002; MRID 40509806]). However, these values were not reported by the study authors. It is unclear how these values were derived.

4.3 Errors and Discrepancies in Aquatic and Terrestrial Threshold Values

EPA's (2016a; 2017a) effects thresholds were presented in several locations throughout the draft and final BEs:

- Chapter 2;
- Appendix 3-6 (TED tool); and
- AquaWoE_v1.0.xls.

Several discrepancies between the threshold values presented in Chapter 2 and the metrics used as inputs for the risk characterization have been identified. In some cases, values presented in Chapter 2 were absent from the risk characterization, and in other instances, inputs used in the risk characterization were not presented as threshold values in Chapter 2. There were also several instances of erroneous details in the study endpoints and/ or references. Details of these discrepancies and errors are further described in Table 4-1 and Table 4-2. Note that this discussion does not include reference to the quality of the studies presented. Some of these studies were previously discussed in Section 4.2 of this response document.

It is not clear how EPA selected some of the thresholds used in the modeling exercises. In Chapter 2, there are tables of threshold values for each taxon to be used in the Step 1 analysis. For some taxa, but not consistently for all, there are tables of endpoints to be used as 'potential refinements', which are presumably for the Step 2 analyses. However, it is not explicitly explained which endpoints were selected for Step 2, how they were selected, or how they were used.

Table 4-1 Discrepancies between EPA thresholds and effects endpoints for aquatic organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	*Endpoint*	*Chapter 2*		*Appendix 3-6 and AquaWoE_v1.0.xls*		*Comments*
		Value (µg/L)	*Reference*	*Value (µg/L)*	*Reference*	
Aquatic amphibians	lowest LC50	1700	E118706	3400	E118706	The lowest amphibian LC50 in Table 2-3 of Chapter 2 is the foothill yellow-legged frog (*Rana boylii*) value of 1700 µg/L. This does not align with the value reported in Appendix 3-6.
Aquatic amphibians, freshwater fish and marine fish	Sensory endpoint - NOAEC	NR	-	NA	E45079	Although this study was described in Chapter 2, no sensory endpoint was included in Table 2-5 (Most sensitive sublethal endpoints).
	Sensory endpoint - LOAEC	NR	-	1		
Marine invertebrates	lowest LC50	2.7	E373146	4.2	MRID 40625501	The lowest marine invertebrate LC50 in Table 3-3 of Chapter 2 is the *Palaemonetes pugio* value of 2.7 µg/L. This does not align with the value reported in Appendix 3-6.
	Behavior endpoint - NOAEC	NR	-	NA	E120752	EPA did not indicate in Chapter 2 that they would use freshwater invertebrate endpoints as surrogates for marine invertebrates.
	Behavior endpoint - LOAEC	NR	-	1		
Invertebrates overall - FW and E/M	Mortality - Direct	0.044	Aquatic invertebrate SSD	20.9	SSD (FISH and Amp pooled)	EPA erroneously listed the fish mortality thresholds for direct and indirect effects for aquatic invertebrates.
	Mortality - Indirect	0.259		123.5		
Aquatic plants - vascular	Growth endpoint - NOAEC	NR	-	1000	E9184	These endpoints were not included in Table 4-1, which listed the aquatic plant thresholds in

Table 4-1 Discrepancies between EPA thresholds and effects endpoints for aquatic organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Endpoint	Chapter 2		Appendix 3-6 and AquaWoE_v1.0.xls		Comments
		Value (µg/L)	Reference	Value (µg/L)	Reference	
	Growth endpoint - LOAEC	NR	-	5000		Chapter 2. EPA presented a table of NOEC and LOEC values considered during selection of effect thresholds (Table 4-2), but did not indicate that any additional values would be considered. Furthermore, in the "Mag/Effect" column of the "All aq thresholds" worksheet (Appendix 3-6 and AquaWoE_v1.0.xls), EPA stated that these concentrations were associated with a decrease in biomass at 5.0 mg/L. However, these values corresponded to an increase in growth following diazinon exposure and reductions in growth were only observed at levels of 50 mg/L and above (Worthley and Schott, 1971 [E9184]).
Aquatic non-vascular plants	Growth endpoint - LOAEC	NR	-	1000	E102905	This endpoint was not included in Table 4-1, which listed the aquatic plant thresholds in Chapter 2. EPA presented a table of NOEC and LOEC values considered during selection of effect threshold (Table 4-2), but did not indicate that any additional values would be considered.

NR = not reported
NA = not applicable

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6 and TEDtool_v1.0.xls		Comments
			Value	Reference	Value	Reference	
Mammals	Direct and indirect	Rat dermal LD50	NR	-	455 mg/kg bw	From ATSDR document (Gaines, 1960)	There was no mention of this endpoint or reference in Chapter 2 of the BE
	Direct and indirect	Rat inhalation LD50	NR	-	120 mg/kg bw	MRIDs 42307236, 43665605, 42993303	There was no mention of this endpoint or the MRIDs in Chapter 2 of the BE.

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6 and TEDtool_v1.0.xls		Comments
			Value	Reference	Value	Reference	
	Direct	1/million mortality	2.38 mg/kg bw	E85110	2.38 mg/kg bw (15.9 mg/kg diet)	E85110 converted using multiplier of 6.67 (WHO, 2009)	It is not generally acceptable to convert a gavage dose-based endpoint to a dietary concentration. The oral gavage exposure route excludes the elements of natural dietary matrices, feeding patterns, and metabolism and elimination throughout the day, and thus a simple conversion to dietary concentration is not biologically accurate.
	Indirect	10% mortality	37.8 mg/kg bw		37.8 mg/kg bw (252 mg/kg diet)		
	Direct and indirect	Lowest LD50/ Lowest LC50	105 mg/kg bw		105 mg/kg bw (700 mg/kg diet)		
	Direct and indirect	Growth LOEC	0.18 mg/kg bw	E039570	0.19 mg/kg bw (3.8 mg/kg diet)	E039570 converted using multiplier of 20 (FDA conversion)	Firstly, this endpoint was not present in any tables in Chapter 2, but rather in the text of Section 9.4.2.1, "Effects on Growth of Mammals". It was reported as 0.18 mg/kg bw rather than 0.19 mg/kg bw, which was reported in Appendix 3-6. Secondly, it is not generally acceptable to convert a gavage dose-based endpoint to a dietary concentration. The oral gavage exposure route excludes the elements of natural dietary matrices, feeding patterns, and metabolism and elimination throughout the day, and thus a simple conversion to dietary concentration is not biologically accurate. Furthermore, EPA was inconsistent in their approach for converting dose to dietary endpoints, as the conversion factor applied for other endpoints was 6.67 for mice rather than 20.

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6 and TEDtool_v1.0.xls		Comments
			Value	Reference	Value	Reference	
	Direct and indirect	Reproduction LOEC	NR	-	0.67 mg/kg bw (13.4 mg/kg diet)	MRID 41158101	This endpoint was not presented anywhere in Chapter 2, but the MRID was presented along with a LOEL of 80 mg/kg bw for "convulsions" in Section 9.4.2.3 "Effects on Behavior of Mammals". Additionally, it is not generally acceptable to convert a gavage dose-based endpoint to a dietary concentration. The oral gavage exposure route excludes the elements of natural dietary matrices, feeding patterns, and metabolism and elimination throughout the day, and thus a simple conversion to dietary concentration is not biologically accurate.
	Direct	Behavior NOEC	NR	-	0.005 mg/kg bw (0.1 mg/kg diet)	E118944 converted using multiplier of 20 (FDA conversion)	There was no mention of these endpoints or the ECOTOX ID in Chapter 2 of the BE. Additionally, it is not generally acceptable to convert a gavage dose-based endpoint to a dietary concentration. The oral gavage exposure route excludes the elements of natural dietary matrices, feeding patterns, and metabolism and elimination throughout the day, and thus a simple conversion to dietary concentration is not biologically accurate.
	Direct and indirect	Behavior LOEC	NR		0.05 mg/kg bw (1 mg/kg diet)		
	Direct	Sublethal	0.35 mg/kg bw	MRID 46166302	0.35 mg/kg bw (2.3 mg/kg diet)	MRID 46166302 converted using multiplier of 6.67 (WHO, 2009)	It is not generally acceptable to convert a gavage dose-based endpoint to a dietary concentration. The oral gavage exposure route excludes the elements of natural dietary matrices, feeding patterns, and metabolism and elimination throughout the day, and thus a simple conversion to

Table 4-2	Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)					
Taxon	***Threshold Type***	***Threshold Description***	***Chapter 2***		***Appendix 3-6 and TEDtool_v1.0.xls***		***Comments***
			Value	***Reference***	***Value***	***Reference***	
	Indirect	Sublethal	0.52 mg/kg bw		0.52 mg/kg bw (10.4 mg/kg diet)	MRID 46166302 converted using multiplier of 20 (FDA conversion)	dietary concentration is not biologically accurate. Furthermore, EPA was inconsistent in their approach for converting dose to dietary endpoints, using the WHO (2009) multiplier for mice of 6.67 for the direct endpoint, and the FDA multiplier of 20 for rats (which was the study organism) for the indirect endpoint.
Birds (surrogate for herptiles)	Direct	Sublethal	0.316 mg/kg bw	MRID 40895301	0.316 mg/kg bw	MRID 40895301	While the same endpoint and reference were reported in Chapter 2 and Appendix 3-6, a body weight of 1580 g was listed in Appendix 3-6. The actual average mallard body weight from the study was approximately 1070 g, which is much lower than the weight selected by EPA. This incorrect input had significant impact on the effects metrics used in the listed species assessment.
	Indirect	Sublethal	0.681 mg/kg bw		0.681 mg/kg bw		
	NR	Growth	2 lb a.i./A	E35250	2 lb a.i./A	E35250	This endpoint was not reported in any table in Chapter 2, but it was mentioned briefly in the text of Section 6.4.2.1 "Effects on Growth of Birds". EPA stated that growth would not be used as a threshold.
	NR	Behavior	>2 lb a.i./A	E40041	2 lb a.i./A	E40041	This study was reported in both Table 6-7 "Reproductive Effects Observed in Studies Involving Diazinon" and Table 6-8 "Behavioral Effects Observed in Studies Involving Diazinon". This field study (E40041) involved only one application rate of 2 lb a.i./A. The endpoint reported by EPA in Appendix 3-6, "26% decrease in number of fledglings", aligns with the reproductive endpoint from Chapter 2. However, EPA reported this study as a behavioral endpoint, which should have been for "increased time sitting on nest".
	Direct	1/million mortality	0.0032 lb a.i./A	E85970	NR	-	While these field study endpoints were presented as direct and indirect effects

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	*Threshold Type*	*Threshold Description*	*Chapter 2*		*Appendix 3-6 and TEDtool_v1.0.xls*		*Comments*
			Value	*Reference*	*Value*	*Reference*	
	Indirect	10% mortality	0.091 lb a.i./A		NR		thresholds in Chapter 2 of the BE (Table 6-1 and 6-2), they were not presented in Appendix 3-6 or applied in TEDtool_v1.0.xls. It is not clear why EPA did not include these endpoints in their analyses.
Terrestrial Invertebrates	Direct and indirect	Lowest LC50	NR	-	0.15 mg/kg bw	E100430	EPA incorrectly labeled the lowest LD50 of 0.15 mg/kg bw as the lowest LC50 in Appendix 3-6 and TEDtool_v1.0.xls.
		Lowest LD50	0.15 mg/kg bw	E100430	NA	-	
	Direct	Growth NOEC	100 mg/kg food	E084972	NA	E084972	According to Table 10-8 "Sublethal Effects in Terrestrial Invertebrates Exposed to Diazinon Residues in the Diet" in Chapter 2 of the BE, the NOEC/LOEC from this study are 100/>100. However, in Appendix 3-6 the NOEC was reported to be "NA".
	Direct and indirect	Growth LOEC	>100 mg/kg food		100 mg/kg food		
	Direct and indirect	Reproduction LOEC	NR	-	0.097 mg/kg soil	E160446	These endpoints were not reported in Chapter 2 of the BE. In fact, EPA said in Chapter 2 that no sensory data were available for diazinon.
		Sensory LOEC	NR		1.75 mg/kg soil		
	Direct	Behavior NOEC	9 mg/kg soil	E082065	NA	E082065	According to Table 10-7 "Sublethal Effects in Terrestrial Invertebrates (Adults) Exposed to Diazinon Residues through Contact with Soil or Substrate" in Chapter 2 of the BE, the NOEC/LOEC from this study are 9/12 mg/kg soil. However, in Appendix 3-6 the NOEC was reported as "NA" and the LOEC was reported as 9 mg/kg soil.
	Direct and indirect	Behavior LOEC	12 mg/kg soil		9 mg/kg soil		
	NR	Reproduction	NR	-	1.34 lb a.i./A	E086162	This endpoint was not reported in Chapter 2 of the BE. EPA noted in cell G46 of Appendix 3-6 that the study was not reviewed beyond the ECOTOX screen.
	Direct	1/million mortality	0.02 µg/bee	E0704542	NR	-	These bee mortality thresholds were presented in Table 10-1 "Direct and Indirect

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial organisms reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6 and TEDtool_v1.0.xls		Comments
			Value	Reference	Value	Reference	
	Indirect	10% mortality	0.04 μg/bee		NR		Effects Thresholds Based on the Most Sensitive Acute (>96 hr) Mortality Endpoints (LC50 or LD50)" of Chapter 2. However, they were not included in Appendix 3-6 or TEDtool_v1.0.xls as terrestrial invertebrate endpoints. It is unclear why these endpoints were excluded.
	Direct and indirect	NR (mortality)	1.2×10^{-7} μg/bee	E070351	NR	-	This larval LD10 was presented in Table 10-2 "Direct and Indirect Effects Thresholds Based on the Most Sensitive Endpoints for All Exposure Durations" in Chapter 2 of the BE. However, it was not included in Appendix 3-6 or TEDtool_v1.0.xls as a terrestrial invertebrate endpoint. It is unclear why this endpoint was excluded.

NR = not reported
NA = not applicable

4.4 Summary of Concerns Regarding the Effects Characterization

ADAMA has a number of concerns with the effects characterization presented in Chapter 2 of EPA's (2017a) BE for diazinon. ADAMA's major issues with EPA's data selection process and presentation of selected effects metrics are summarized as follows:

- EPA (2017a) was not transparent in its data quality evaluations for selection of effects thresholds and most sensitive endpoints. EPA has published several guidance documents to aid in the internal evaluation of toxicity studies (EPA, 2002, 2003, 2004a,b, 2011). However, it is questionable whether these criteria were consistently followed by reviewers, and evaluations were not provided for the majority of studies presented in EPA's effects characterization. Furthermore, it appears that EPA included data in their SSDs from studies that were not formally evaluated by EFED.
- Many of the studies relied on by EPA (2017a) were rated as 'unacceptable' for risk assessment by ADAMA. The fundamental question of data quality and use of "best available data" does not appear to have been addressed in the BE.
- NOELs were the effects thresholds driving most, if not all of the risk designations. The use of NOELs in ecological risk assessment has long been criticized (Hoekstra and Van Ewijk, 1993; Moore and Caux, 1997; Landis and Chapman, 2011; Jager, 2012; Murado and Prieto, 2013) due to the inherent deficiencies of the metrics as a relative measure of toxicity, which include an absolute dependence on the selected treatment levels and sample size, and related issues of low statistical power. EPA stated in its Interagency Interim Approaches (Agencies, 2013) that ECx values would be considered. However, it seems that in most cases EPA (2017a) opted to circumvent data analyses and simply use the author-reported NOELs from toxicity studies. Although the use of NOELS may be practical in some instances (e.g., when sample size is large and/or when the data are not conducive to generating a meaningful dose-response), the Agency should give precedence to more refined metrics (e.g., dose-response curves, benchmark doses) when possible.
- EPA (2017a) selected thresholds based on sublethal endpoints (e.g., biochemical, cellular, and behavioral effects) without providing evidence of any qualitative or quantitative link between these endpoints and survival, growth or reproduction. Endpoints without a direct link to specific apical adverse effects are not considered to be biologically significant (Breton et al., 2016a; CLA, 2016). EPA (2016a) should not rely on these endpoints when selecting their thresholds values and most sensitive endpoints.
- ADAMA disagrees with EPA's procedure for evaluating chronic risk to aquatic and terrestrial species. Chronic guideline studies typically use continuous pesticide exposures ranging from 21 days for aquatic invertebrates to greater than 10 weeks for birds and mammals. However, such exposures are unrealistic because diazinon would, in reality, degrade rapidly between applications. Pulse exposures are far more relevant than maintained chronic exposures.
- A number of discrepancies were identified between the thresholds presented in Chapter 2 of the final BE (EPA, 2017a) and the effects metrics used as inputs for the risk

characterization presented in Appendix 3-6 and the AquaWoE_v1.0.xls / TEDtool_v1.0.xls files. In some cases, values presented in Chapter 2 were absent from the TED tool model inputs spreadsheets, and in other instances there were endpoints in Appendix 3-6 and the TED tool inputs that were not presented as threshold or endpoint values in Chapter 2 of the draft BE. There were also several instances of erroneous details in the study endpoints and/or references between these files.

- Finally, it is unclear how EPA (2017a) selected some of the thresholds used in the modeling exercises. In Chapter 2, there are tables of threshold values to be used in the Step 1 analysis for each taxon. For some taxa, but not consistently for all, there are tables of endpoints to be used as 'potential refinements', which are presumably for the Step 2 analyses. However, it was not explained which endpoints were selected for Step 2, how they were selected, or how they were used.

5.0 EFFECTS DETERMINATIONS (RISK CHARACTERIZATION)

5.1 General Comments

Concerns relating to the effects determinations made by EPA (2016a) for the draft diazinon BE have been raised by a number of stakeholders (Breton et al., 2016a; CLA, 2016, FESTF, 2016). These comments included: (1) a noted lack of transparency in how "calls" were made; (2) the contrast of dubious sublethal "effects" thresholds with unrealistically high exposure estimates, and the persistent use of risk quotients; (3) equivalent weighting of a broad range of endpoints from mortality to behavioral and sensory effects, despite tenuous or missing links between these endpoints and the protection goals of the assessment (i.e., individual fitness); (4) a disregard for other lines of evidence, including incident reports and field studies; (5) accounting for confidence in species calls; and (6) calculation errors.

Some of the calculation errors identified in the WoE tools were addressed. However, ADAMA's principle concerns with the Agency's diazinon BE have not been addressed in the final document.

Additional issues have surfaced upon further examination of the draft and final BEs for diazinon. With respect to co-occurrence of species and designated critical habitat, EPA did not specify what setback distance was used to establish the drift setback used to buffer the use site layer. In Chapter 1, the Agency stated that: "The analysis with AgDRIFT indicates that for aerial and ground spray applications, drift deposited at the bounds of the model (*i.e.*, 1,000 feet for ground and 2,500 feet for aerial) exceeds the endpoints for terrestrial invertebrates [*i.e.*, LD10 = 1.2e-7 ug/bee for honey bee larvae, E070351)." Later in the same chapter, the text referred to Attachment 1-6 (Co-Occurrence Analysis), which is an MS Excel® workbook. The spreadsheet names and column headers in the workbook were ambiguous and generally did not provide units of measure, nor definitions of acronyms, rendering the results nearly impossible to decipher. We were unsuccessful in determining what setback distance was actually used in co-occurrence analyses for terrestrial organisms (though limits were reported for aquatic modelling in Chapter 1). It was also unclear which use patterns were used to generate setback distances based on drift estimates (was more than one considered?). Further, a separate workbook presented the "NE" and "NLAA" calls based on the co-occurrence analyses (Appendix 4-1), but this workbook was not directly linked to Attachment 1-6. There was a clear lack of transparency in how the co-occurrence analysis was conducted and how results translated to the species and critical habitat calls presented in Chapter 4.

5.2 Weight-of-Evidence Tools and Species and Critical Habitat Calls

ADAMA (Breton et al., 2016a) and CLA (2016) reported numerous problems with the Agency's WoE tools used to make most species and critical habitat calls. Breton et al. (2016a) detailed a major lack of transparency, as well as associated issues of inconsistency, which included, but were not limited to:

1) inaccessible spreadsheet cells used directly in species and critical habitat calls;
2) inconsistencies between methods described in text and those carried out in the WoE tools;
3) thresholds used in the WoE model that were not presented as thresholds in the text;
4) misleading risk and confidence categories that had no bearing on species or critical habitat calls;
5) categories of effects that, although assessed, had no bearing on species or critical habitat calls; and
6) a presentation of, but lack of consideration for monitoring data, incident reports, or mesocosm or field studies in species and critical habitat calls.

These problems persisted in the final diazinon BE (EPA, 2017a). Based on a comparison of the draft and final WoE tools, it seems that no significant modifications were made to the process of establishing species and critical habitat calls in the tool. As such, most of the detailed comments made by Breton et al. (2016a) on the draft diazinon BE WoE tools still apply.

The critical error identified in the determination of the risk designation for mortality of terrestrial vertebrates where dose-based thresholds in units of mg/kg bw were compared with estimates of concentration in diet in units of mg/kg diet was corrected in the final version of the BE.

The Agency has stated that its selected sublethal threshold for direct effects would be the lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (ECx). Additionally, EPA has said that the threshold should be linked to survival or reproduction of a listed individual. However, in the WoE tools, EPA used thresholds representing exceedances of behavioral and sensory endpoints that are not demonstrably linked to survival or reproduction in both their risk designations and species calls. Accordingly, these thresholds were not associated with the stated protection goal of individual fitness.

In the WoE tools for both terrestrial and aquatic animals, a likely to adversely affect (LAA) call was made if the risk designation representing one or more of mortality, growth, reproduction, behavioral, sensory, indirect-prey, or indirect-habitat was medium (MED) or high (HIGH) in the WoE tools. This was done regardless of confidence designations. Risk designations were based wholly on the highest of highly conservative exposure estimates exceeding any one of the employed thresholds. This was done even if the threshold was not demonstrably linked to the protection goal. This methodology and the lack of weight or consideration given to other lines of evidence (e.g., incident reports, field studies) remains inconsistent with a legitimate weight of evidence approach that accounts for evidence both for and against a particular risk hypothesis. Similar approaches were taken for terrestrial and aquatic plants, as detailed in Breton et al. (2016a).

For sublethal effects to animals, EPA persisted in using NOELs as threshold values. If a NOEL was exceeded by a conservative estimate of peak exposure, the species call was 'Likely to Adversely Affect' (LAA). However, this conclusion was unjustified given that no significant effects were observed at the threshold value in the supporting toxicity test. Further, by definition, the upper bound exposure estimates are unlikely to even occur with the compounding conservatism of the inputs and assumptions used (e.g., upper bound residues and dissipation half-lives, 100% of diet coming from the treated field, and peak one-day exposure being taken as a chronic exposure estimate). In the context of the protection goals, there is no evidence to suggest that NOEL exceedance would result in adverse effects to individual fitness.

The Agency provided no evidence to support the 1/million mortality threshold *on treated fields* as being directly relevant to the individual fitness of a listed species. If a species does not regularly use managed lands to which pesticides are applied, the 1/million mortality threshold on treated fields is tremendously inappropriate.

Regardless of the concerns of stakeholders, including ADAMA, the species calls in the final diazinon BE were in fact based on a binary assessment of whether or not the most sensitive effects thresholds were exceeded by the highest exposure point estimate generated. If even only one effects threshold was exceeded, the species call was LAA. Confidence designations were not considered in the effects determinations. Overall, the species calls lacked actual risk estimates. As noted by NRC (2013): “The RQ approach does not estimate risk—the probability of an adverse effect—itself but rather relies on there being a large margin between a point estimate that is derived to maximize a pesticide’s environmental concentration and a point estimate that is derived to minimize the concentration at which a specified adverse effect is not expected.” The BE would be improved if effects and exposure distributions were considered, and EPA were to evaluate the probability associated with exceeding various levels of effect. This would be more in line with the NRC (2013) recommendation to use probabilistic methods. This is a recommendation that has been persistently overlooked by the Agency.

5.3 Effects Determinations of NLAA/LAA: Qualitative Analyses

EPA (2017a) presented their qualitative analyses for sea turtles, whales, deep sea fish, marine mammals, cave dwelling invertebrates, and cattle ear tag use of diazinon in Section 7 of Chapter 4 of the BE. EPA made species calls and critical habit calls (if applicable) of “LAA” for all sea turtle species, and “NLAA” species and habitat calls for all whale and deep sea fish species except for the killer whale (Southern resident DPS). For marine mammals (excluding whales), EPA made species calls and critical habit calls (if applicable) of “LAA” for the Guadalupe fur seal, southern sea otter, Steller sea lion, Hawaiian monk seal, Pacific harbor seal and West Indian Manatee, and “NLAA” for the northern sea otter (Southwest Alaska DPS), bearded seal, Pacific walrus, spotted seal (Southern DPS), and polar bear. For cave-dwelling invertebrates, species and habitat calls of “LAA” were applied to all species, except the icebox cave beetle, heleotes mold beetle (“NLAA” for habitat only), and Braken Bat Cave meshweaver (“NLAA” for habitat only).

Although this section is titled “Qualitative Analyses”, in most cases, EPA (2017a) derived quantitative estimates of exposure and compared these to effects thresholds to characterize risk. As described in other sections of this response document, ADAMA is concerned with many of the effects metrics selected for the qualitative assessments, with the use of surrogate bins to estimate EECs for marine and estuarine environments, and with the comparison of dietary exposure concentrations to dietary effects metrics. Furthermore, EPA (2017a) made unrealistically conservative assumptions regarding the potential for dermal exposure to sea turtles, dietary exposure to cave-dwelling invertebrates, and dietary and inhalation exposures to animals from the cattle ear tag use of diazinon. Many of these assumptions were based solely on professional judgement and not on any reliable data. All the quantitative assessments were deterministic and did not consider the likelihood of species actually being exposed to diazinon. Furthermore, even when EPA (2017a) stated that the likelihood of exposure was low (e.g., cave-dwelling invertebrates and cow tag analyses), species still received LAA effects determinations.

Throughout the qualitative analyses, EPA (2017a) categorized the risk and confidence as low, medium and high for various lines of evidence, including those based on professional judgement. Although EPA's criteria for establishing low, medium and high conclusions for risk and confidence were provided in Attachment 1-9 of the BE, these criteria were only based on EEC exceedances of effects thresholds and cannot be applied for qualitative information. Thus, there was no transparency in EPA's risk and confidence in conclusions for several aspects of their qualitative analyses.

5.3.1 Sea Turtle Analysis

In Chapter 4, EPA (2016a) estimated an aquatic plant BCF of 280 using the Kow (based) Aquatic BioAccumulation Model (KABAM). However, there was no discussion on the model inputs or how KABAM was used to calculate the BCF. For their final BE, EPA (2017a) added no new information or explanation on how the BCF was calculated. Further, EPA (2017a) stated that the selected BCF is "uncertain because it is based on a model estimate that does not account for metabolism of diazinon by plants". Therefore, ADAMA is skeptical of the methods employed by EPA (2017a) to derive their BCF and has little confidence in the value.

EPA (2016a) also used avian effects data to estimate risks to sea turtles. The sublethal threshold used by EPA (2016a) in the draft BE and maintained in the final BE (EPA, 2017a) was an AChE endpoint for mallard duck (Marselas, 1989 [MRID 41322901]) and is considered inappropriate for risk assessment (Breton et al., 2016a; CLA, 2016). An explicit relationship between AChE inhibition and effects to survival, growth, or reproduction was not demonstrated by Marselas (1989 [MRID 41322901]) or EPA (2016a; 2017a). Therefore, its use in risk assessment is not supported.

Breton et al. (2016a), CLA (2016) and FESTF (2016) raised concerns over the methods used by EPA (2016a) to determine effect levels for sea turtles. EPA (2017a) made no amendments to their methods. The aquatic thresholds in Table 4-3 of Chapter 4 (EPA, 2016a; 2017a) were based on the assumption that sea turtles would be adversely affected if the concentration of diazinon in prey items (i.e., plants, aquatic invertebrates and fish) reached or exceeded the avian dietary effects threshold. However, this approach does not account for differences between the gross energies and assimilation efficiencies associated with birds consuming a laboratory test diet and the prey items and food intake rates experienced by sea turtles in the wild. Pesticide concentrations in the diet are not exposure estimates and the direct comparison of pesticide concentrations in dietary items to dietary LC50s is inappropriate.

Breton et al. (2016a) critiqued the designation of marine bins by EPA (2016a) and requested greater transparency. However, EPA (2017a) did not update or change any of the text for their final BE. It is unclear why EPA (2016a; 2017a) has only designated one habitat bin (bin 8) for both marine intertidal nearshore areas and marine tidal pools when separate surrogate freshwater bins are assigned to the two types of environments (bins 2 and 5). Furthermore, the use of freshwater bins as surrogates for estuarine and marine environments leads to extreme overestimation of EECs. See comments included in Section 3.0 for further details.

Breton et al. (2016a) criticized the estuarine/marine EECs estimated by EPA (2016a) for being one to four orders of magnitude higher than any measured concentration of diazinon in estuarine/marine environments (≤1 µg a.i./L; Smalling and Orlando, 2011). Even if monitoring data are not used quantitatively in a risk assessment, they can still be useful for comparison to modeled EECs to assess the realism of estimated concentrations. The EECs were updated in EPA (2017a) to 4-day average EECs, but were still exceedingly high. The highest EEC, 4330 µg a.i./L, was predicted for bin 5 HUC 15. Therefore, some EECs were still four orders of magnitude higher than concentrations measured in natural environments. Although EPA (2017a) acknowledged that the estuarine/marine EECs likely greatly overestimated risk, no attempts were made to refine the EECs or derive EECs that are more likely to be encountered by sea turtles.

Breton et al., (2016a) critiqued the methodology used by EPA (2016a) to calculate EECs for green sea turtles, as EECs for bins 3 and 4 were simply estimated by applying adjustment factors to bin 2 EECs. Although, it appears that EPA (2017a) has instead calculated actual EECs for bins 3 and 4, ADAMA still does not approve of the approach used.

To assess the risk of dermal exposures for sea turtles, EPA (2016a; 2017a) compared drift deposition data to the 1/million mortality threshold. The threshold endpoints were obtained from a semi-field study conducted by Vyas et al. (2006 [E85970]), which assessed the effects of combined dermal and dietary exposures of diazinon on mortality and AChE inhibition. ADAMA found this study to be unacceptable because it lacked sufficient details on test conditions (Breton et al., 2016a). Further, EPA (2016a; 2017a) noted that substantial differences in toxicity were observed by Vyas et al. (2006 [E85970]) between the laboratory and semi-field study components. These differences were likely the result of toxic-producing fungi on the Bermuda grass that the geese were fed in the semi-field study component (Vyas et al., 2006 [E85970]). EPA (2016a; 2017a) also stated that there is “considerable uncertainty in using the data from the Vyas et al. study for the purpose of quantifying effects due to dermal exposure as these endpoints are due to a combination of dietary and dermal exposure”. EPA (2016a; 2017a) also assumed that dermal absorption of diazinon would be similar in birds and turtles, but turtles have shells that would greatly limit their exposure to diazinon compared to birds. Given the uncertainties associated with this analysis and the unlikelihood that dermal exposure would even occur, EPA (2016a; 2017b) should not have concluded that dermal exposure was a risk concern for sea turtles.

5.3.2 Whale and Deep Sea Fish Analysis

ADAMA (Breton et al., 2016a) critiqued EPA's (2016a) "LAA" determination for the killer whale (Southern resident DPS), which was based on an obligate relationship with Chinook salmon, because such a relationship does not exist according to NMFS (2008). Killer whales consume other prey items that could replace salmon, such as other fish, squid, and marine mammals. EPA (2017a) has not addressed our comment and has not altered their effects determination conclusion.

5.3.3 Marine Mammals Analysis (Excluding Whales)

The final BE (EPA, 2017a) addressed few of the recommendations made by ADAMA (Breton et al., 2016a), including completing EEC modeling for bins 3 and 4, which are more representative of the freshwater habitat of manatees and Steller sea lions, and no longer utilizing benchmark doses from a human health assessment. However, EPA (2017a) still used threshold endpoints from studies identified by ADAMA as unacceptable or supplemental. Further, the endpoints from the supplemental study were for AChE inhibition, an endpoint for which EPA has not demonstrated an explicit relationship connected to survival, growth, or reproduction.

The Agency's use of surrogate bins for intertidal nearshore areas, subtidal nearshore waterbodies, and tidal pools in the final BE remains problematic, as they combined intertidal nearshore areas and tidal pools into one bin. More importantly, EPA (2017a) used freshwater bins as surrogates for estuarine and marine environments, which led to an overestimation of EECs. EPA (2017a) did not discuss the realism of the EECs generated for these surrogate bins in the context of observed measured concentrations of diazinon, as in Smalling and Orlando (2011).

EPA (2017a) also used endpoints from studies conducted with rodents for the assessment of marine mammals. EPA (2017a) noted that this extrapolation approach was an "uncertainty". However, ADAMA deems this approach to be totally inappropriate and scientifically unsound.

5.3.4 Cave Dwelling Invertebrate Species Analysis

ADAMA (Breton et al., 2016a) critiqued EPA's (2016a) LAA designations for terrestrial cave-dwelling invertebrates, which were based on extremely conservative assumptions that do not represent the Agencies' own guidance for completing refined assessments (Agencies, 2013). For their final BE, EPA (2017a) made few changes to their conclusions for cave dwelling invertebrates. However, one species call (*pseudoanophthalmus frigidus*) was changed to NLAA because exposure would only be related to cattle ear tag use, and effects were considered minimal.

5.3.5 Cattle Ear Tag Use Analysis

EPA (2017a) did not address the majority of ADAMA's (Breton et al., 2016a) comments in their final BE. The risk assessment of invertebrates consuming insects was changed slightly and the Helotes mold beetle (*Batrisodes venyivi*) was re-evaluated because "exposures from the cattle eartag use are not expected" (EPA, 2017a). However, despite not making a conclusion on direct effects for this species, EPA (2017a) ultimately concluded an LAA determination for the mold beetle. This is against the Agency's own reasoning, evidenced by their statement that "potential indirect effects to listed species that rely upon invertebrates as a food source are considered discountable."

Unaddressed comments by EPA were numerous and significant. The Agency evaluated risk for the Florida scrub-jay (*Aphelocoma coerulescens*), a species for which the Agency did not present a diet that would indicate potential exposure. An LAA determination was included for the Virginia big-eared bat (*Corynorhinus townsendii*) without any direct effects being determined for the species. The determination for this species appears to have been based on exceedances of incorrectly calculated mammalian effects thresholds by using unacceptable studies and comparing the LD90 for bees to mammalian effects thresholds. This procedure was also inappropriately applied to birds, amphibians, and reptiles that consume insects. This approach does not take into account differences between gross energies and assimilation efficiencies of prey items and food intake rates of receptors. Simply, pesticide concentrations in the diet are not equivalent to exposure estimates. Many thresholds were also inappropriately calculated, either from unacceptable studies for use in risk assessment or from sublethal endpoints that do not directly correlate with effects to survival, growth, or reproduction. The Agency (EPA, 2017a) also did not address the unrealistically conservative assumptions made for assessing exposure via inhalation.

5.4 Refined Risk Analysis for 11 Listed Bird Species: TIM-MCnest Analysis

EPA (2017a) used the TIM and MCnest models to estimate risk to 11 selected listed bird species. Several issues exist with these models and their application to risk assessment. Herein, we discuss general issues with the models, as well as specific issues with how the models were applied in the final BE for diazinon.

Despite being probabilistic models, the models are highly conservative in many aspects with regard to determining risks of diazinon to birds. For example, the fraction of edge habitat in TIM receiving spray drift is, by default, equal to 1.

The Agency did not provide input values for several important parameters in TIM and MCnest. As a result, their model runs cannot currently be replicated and evaluated. For example, the Agency did not specify the assumed droplet spectrum, feeding times by birds, proportion of feeding occurring in the morning, and field fidelity factor. Each of these variables influences the risk predictions from TIM.

EPA (2017a) appears to have incorrectly interpreted the results of their own analyses. In Appendix 4-7, Section 3.1 Table B 4-7.8, EPA presented the "likelihood of mortality to ≥1 individual out of 100 exposed per year." For the Lesser prairie chicken, for example, this probability of ≥1/100 mortality is >0.999 for orchards, assuming high sensitivity for the listed species (i.e., HC_{05} on the species sensitivity distribution [SSD]) or median sensitivity (i.e., HC_{50} on the SSD). According to EPA (2017a), if the Lesser prairie chicken is highly tolerant (i.e., HC95 on the SSD), the probability of ≥1/100 mortality is 0.337 for orchard uses. However, EPA then used these results to conclude in Section 4.8 of their final BE that there "is a high probability (83.4% or greater) of mortality to an exposed individual of […]". This conclusion is misleading because it does not follow that a high chance of observing at least one mortality out of 100 birds is equivalent to a high chance of each individual bird dying. The conclusion also ignores the very low likelihood of mortality if the Lesser prairie chicken is actually a tolerant bird species.

The Agency acknowledged uncertainties throughout their modeling but only in a manner that emphasized the potential for underestimation of risk. For example, EPA (2017a) stated that their approach for determining the potential number of exposed individuals may have underestimate the true number of individuals if they are "grouped in an area that overlaps with a diazinon use site." While true, this statement ignores the more probable likelihood that they have overestimated risk due to individuals grouping in an area away from disturbances and diazinon use sites. Throughout their assessment, the Agency inappropriately ignored uncertainty that might decrease their assessment of risk, while highlighting those that might have increased their assessment.

Issues exist with the scientific reasoning behind the MCnest model. The model predicts total nest failure if any avian NOAEL is exceeded. In the past, to assess the conservatism introduced by this assumption, EPA completed analyses using LOAELs instead of NOAELs (EPA, 2016c). However, in the final BE for diazinon, EPA (2017a) neither addressed this conservativism nor completed alternate sensitivity analyses to explore its importance. Furthermore, alternative analyses would still fail to address the actual problem with MCnest, namely that it uses a binary variable where a continuous distribution (e.g., nestling body weight) or Poisson distribution (e.g., number of eggs) is required. Total nest failure, or indeed any adverse effects, would not necessarily be expected for an exceedance of the NOAEL for many endpoints.

5.5 Summary of Concerns Regarding the Risk Characterization

We have noted a number of problems with the effects determinations made in the final BE (EPA, 2017a). Our major concerns include the following:

- There is an overall lack of transparency in how species and critical habitat calls were made.
- EPA used risk quotients alone in the effects determinations and did not provide valid (probability-based) risk estimates.

- There were major discrepancies between the Interagency Interim Approaches (Agencies, 2013), the analysis plan (Section 1.4), Chapter 4 text, and what was actually carried out in the WoE tools.
- Species calls and critical habitat calls were made for all uses of diazinon, assuming that all label uses can be made anywhere in the United States, without drawing any distinctions between use patterns, locations and co-occurrence.
- With the exception of the Agency's overly conservative RQs, other lines of evidence were not directly considered in species and critical habitat calls in the weight-of-evidence tools (e.g., incident reports, monitoring data, other toxicity data, etc.).
- EPA inappropriately gave equivalent "weights" to exceedances of thresholds associated with direct effects to survival, growth or reproduction, as they did to exceedances of sublethal thresholds not necessarily linked to adverse effects on individual fitness (e.g., endpoints for avoidance behavior, AChE inhibition, etc.).
- There were critical errors in the comparison of effects thresholds and exposure estimates in the WoE tools.

ADAMA strongly urges EPA to follow the EPA agency-wide guidelines for ecological risk assessment (EPA, 1998) as well as the more recent NRC (2013) recommendations, by incorporating genuine (probabilistic) risk estimates into their biological evaluations.

6.0 CONCLUSIONS

Of the concerns discussed in Breton et al. (2016a) and raised by CLA (2016) and FESTF (2016) that remain unaddressed by the Agency in the final diazinon BE, the following have been identified as critical to the outcome of the risk assessment: data and model quality, unsubstantiated thresholds, inaccurate and crude spatial analysis, compounding conservatism in exposure assessment, inappropriate contrasts/comparisons between incongruous EECs and effects metrics, an ongoing lack of transparency, outstanding errors in both weight-of-evidence (WoE) tools and text, a flawed and obscure “weight-of-evidence” approach, and most importantly, a lack of risk estimation based on probabilistic methods. These issues are further discussed below.

Many of the studies selected by EPA as threshold values were not evaluated for data quality and relevance, and when evaluated, many did not follow EPA’s own study quality criteria. EPA used threshold values from studies deemed invalid by the Agency or deemed acceptable for qualitative use when criteria for quantitative use were not met. When the quality of the data driving the assessment is questionable, so are the results.

EPA failed to make use of best available chemical-specific data in the BE. For example, all registrant-commissioned data should have been considered by EPA. In particular, the Agency should have, by their own decree (EPA, 2011), made use of the GLP amphibian toxicity data, instead of relying on data from a different taxon. Similarly, EPA did not derive independent effects endpoints for estuarine/marine receptors (invertebrates, fish, and aquatic plants).

In past reviews of the WoE tools/TEDtool, a number of errors were reported, and as noted herein, not all have been addressed. ADAMA remains concerned that EPA has not submitted the TEDTool to a Scientific Advisory Panel (SAP) for an independent evaluation of its quality, credibility and utility. Even though the TEDTool is purportedly derived from existing EPA toolbox models, changes to the models have been substantial and warrant another SAP review prior to use.

ADAMA is concerned with the use of toxicological effects metrics (“thresholds”) that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction), and further, not demonstrably associated with the protection goal of individual fitness. Thus, the binary, most-conservative RQ-based effects determinations, were primarily driven by effects metrics that do not necessarily relate to the protection goals of the biological evaluation.

Erroneously, species calls and critical habitat calls were made by assuming that all label uses can be made anywhere in the United States, without drawing any distinctions between use patterns, timing of application, locations and co-occurrence. Accordingly, there are species that will never come into contact with biologically-relevant concentrations of diazinon that have been determined to be “LAA.”

The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for diazinon, these models were used to simulate landscape and aquatic fate processes in continental scale watersheds and rivers. Even from a screening-level perspective, this approach was a gross overextension of the model's capabilities. The results obtained from these models and applied to represent environments they were never designed for, are not acceptable.

The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by that same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact, their occurrence is typically constrained to very specific locations (they are endangered). The overgeneralization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to misrepresentation of the extent of exposure risk.

High resolution spatial datasets representing, crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed-scale hydrologic and water quality models (e.g. SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions did not account for the critical landscape and agronomic variability known to exist in reality and were based on modeling methods that are incapable of reflecting the complexities of the environmental processes they were attempting to simulate.

When multiple deterministic exposure model inputs are "upper bound" or biased high, as in the case of the BE (e.g., on-field exposure, upper bound RUDs, 90th percentile on the mean half-lives), the resulting exposure estimates are expected to be overly conservative (i.e., unrealistically high).

Though the Agency attempted to deal with some of the transparency issues in the text of the diazinon BE, many transparency concerns persisted within the final BE. For example: key cells in the WoE Excel tools remained hidden and locked, drift models continued to go unreferenced and unexplained, and methods were not consistently presented.

Despite the fact that the Agency did correct some of the errors identified during the public comment period, many remained. For example: critical errors remained in the dermal exposure and body mass scaling equations (herptiles) in the TEDtool. Further, the terrestrial EECs presented in the diazinon BE did not match those generated in the associated TEDtool.

Despite purporting a weight-of-evidence approach, it seems EPA made all of their effects determinations based solely on the most conservative RQ of a suite of RQs generated for each species. EPA gave equivalent “weights” to threshold exceedances associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds that may not be linked to individual fitness or the protection goal (e.g., endpoints for avoidance behavior, AChE inhibition, etc.). Further, other lines of evidence were not directly considered in species and critical habitat calls (e.g., incident reports, field studies, monitoring data, etc.). We noted that aquatic EECs were orders of magnitude higher than monitoring data. Nowhere in the biological evaluation was this taken into account.

NRC (2013) discouraged the use of RQs and recommended probabilistic methods. Risk is the probability or likelihood of a particular outcome. EPA did not estimate risk to listed species using probabilistic methods in their BE, with the possible exception of the 11 bird species analyzed with TIM/MCnest. However, the TIM/MCnest analysis was highly conservative and likely significantly overestimated risk for all 11 species.

Because of the issues listed above, the final diazinon BE implied adverse outcomes (LAA) for the majority of listed species. ADAMA requests that EPA give careful consideration to the comments provided in this document and strongly recommends that the Agency incorporate real risk estimates (i.e., the probabilities of exceeding various magnitudes of effects) in their biological evaluations, as was concluded by NRC (2013).

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RESPONSE TO THE BIOLOGICAL EVALUATION FOR MALATHION

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STATEMENT OF CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B) or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA sec. 10(g).

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Statement of Good Laboratory Practice Compliance

This document is a response to EPA's final Biological Evaluation (BE) for malathion. It is not required to comply with 40CFR Part 160.

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RESPONSE TO THE BIOLOGICAL EVALUATION FOR MALATHION

Table of Contents

Page

List of Tables

Page

EXECUTIVE SUMMARY

Registration and/or re-registration of pesticides under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) constitutes a federal action under the *Endangered Species Act* (ESA). Under ESA Section 7, in some circumstances the Environmental Protection Agency (EPA or “the Agency”) must consult with the Fish and Wildlife Service and/or National Marine Fisheries Service (the Services”) to ensure that a pesticide’s registration (considered the federal action) is not likely to jeopardize the continued existence of federally endangered and threatened species (hereafter, “listed species”) or result in the destruction or adverse modification of designated critical habitat. The EPA in conjunction with the Services and United States Department of Agriculture (USDA) prepared Biological Evaluations (BEs) for three pilot pesticides, chlorpyrifos, diazinon and malathion, as case studies in how to conduct these complex, large scale assessments. The BEs purported to provide nationwide assessments of the potential for effects of the pilot pesticides to listed species and their designated critical habitat. Potential effects on candidate species and species proposed for listing under Section 7 of the ESA were also considered.

EPA developed the BEs following the “Interim Approaches” process agreed to by EPA, the Services and USDA (Agencies, 2013) to implement some of the recommendations from the National Academy of Science’s National Research Council (NRC) report “Assessing Risks to Endangered and Threatened Species from Pesticides” (NRC, 2013). The NRC recommended a three-step process to evaluate potential risk and satisfy EPA’s consultation obligations under Section 7 of the ESA. At each step, EPA assigns a risk finding to each species and/or critical habitat (i.e., Step 1: “No Effect/May Affect (MA)” determination, Step 2: “Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)”). Under this procedure, species and/or critical habitat receiving a “MA/NLAA” finding are to be subject to informal consultation with the Services to determine concurrence. Species and/or critical habitat that are considered MA/LAA enter Step 3, where a formal consultation with the Services is to occur. A biological opinion is generated by the Services with the goal of making a “Jeopardy/No Jeopardy” finding for listed species and “Adverse Modification/No Adverse Modification” determination for their designated critical habitat. Lessons learned from this process are intended to be used by EPA and the Services to modify the Interim Approaches for future biological evaluations.

On April 11th, 2016, EPA released the draft BEs for public comment in support of registration review for the pilot pesticides. This date marked the start of a 60-day public comment period, which ended on June 10th, 2016. Despite requests for an extension of the public comment period from many stakeholders, made primarily because of the sheer magnitude of information contained in the BEs, the EPA did not adjust the comment deadline. The Agency cited a court-mandated deadline that they and the Services are working under, as well as the early release of parts of the draft BEs in December 2015. Comprehensive review of the draft BEs was unfeasible within the comment period, and this was complicated by multiple draft versions (i.e., December 2015, and March 2016 releases). Notwithstanding these challenges, stakeholders submitted thousands of comments, in which a number of substantive concerns, including critical errors, were identified. Approximately seven months after the close of the comment period, the EPA released the final Biological Evaluations for the pilot chemicals.

The final Biological Evaluations were released on January 17th, 2017, with a brief memorandum summarizing how public comments were addressed (EPA, 2017a). Ultimately, the EPA opted to principally address errors or transparency issues. Despite a myriad of concerns regarding the Agency's methods, EPA acknowledged that they made few changes to the processes employed in the BEs, citing only the revised modeling approach for flowing waterbodies. EPA stated that in response to comments it was "incorporating those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December, 2017."

Cheminova A/S (hereafter referred to as "Cheminova") is the sole manufacturer and primary registrant in the United States for the technical form of malathion (CAS Registry Number 121-75-5). All other registrants of technical malathion obtain their material from Cheminova and all end-use products registered in the United States are produced from Cheminova's technical malathion. In 2015, Cheminova A/S and Cheminova, Inc., were acquired by FMC Corporation (FMC). Cheminova, Inc.'s end-use product registrations have been transferred to FMC. Although we often only refer to Cheminova or FMC in this document, the comments contained herein reflect the positions of both companies.

EPA's draft and revised malathion BE attempted to evaluate risk of malathion exposure for all ESA listed species, proposed species, and candidate species in the United States. In the final BE, EPA reached the MA/LAA determination for 1778 out of 1835 assessed species (i.e., 97%) and 780 of the 794 assessed critical habitats (98%), a result that is almost identical to the draft malathion BE. These final effects determinations mean that formal consultation and biological opinions are required for almost all species and critical habitats evaluated. Completing formal consultations on this scale is a near-impossible undertaking for the Services. While it is recognized that considerable effort went into the development of the pilot BEs, it is clear that using the Interim Approaches (Agencies, 2013), as applied, has resulted in a cumbersome, inefficient, and indefensible process for assessing pesticides to determine whether they pose potential risks to listed species or their critical habitat.

We still have serious concerns regarding the effects determinations for listed species potentially exposed to malathion presented in the final BE (EPA, 2017a). This response document reviews the principal comments made by Cheminova and other stakeholders (CropLife America and FESTF) on the malathion draft BE (and pilot BEs in general), discusses how EPA addressed some of these comments, and describes those comments and concerns that went unaddressed. Particular emphasis is given to methods, data used, and assumptions made. One major and persistent concern Cheminova has with the final malathion BE is that in contrast to the NRC (NRC, 2013) recommendations, risk quotients (RQs) were used to determine risk designations in Step 2. RQs can eliminate the negligible risk scenarios, freeing up resources to use refined, probabilistic approaches for the remaining species. However, an ecological risk assessment should not/cannot conclude on the results of a cursory RQ screen. The NRC (NRC, 2013) specifically stated that “[Risk quotients] are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes.” The NRC conclusion is consistent with recommendations in the EPA agency-wide guidelines for ecological risk assessment (EPA, 1998), which are cited in the NRC report, and it points out the importance of the explicit treatment of uncertainty during problem formulation. In direct contrast to this the EPA has maintained its use of RQs, and it bases species and habitat risk characterization on the most conservative RQs. The NRC (NRC, 2013) recommended “using a probabilistic approach that require integration of the uncertainties (from sampling, natural variability, lack of knowledge, and measurement and model error) into the exposure and effects analyses by using probability distributions rather than single point estimates for uncertain quantities. The distributions are integrated mathematically to calculate risk as a probability and the associated uncertainty in that estimate. Ultimately, decision-makers are provided with a risk estimate that reflects the probability of exposure to a range of pesticide concentrations and the magnitude of an adverse effect (if any) resulting from such exposure.”

A number of concerns identified in the draft BEs by Cheminova and other stakeholders (CropLife America and FESTF) went unaddressed by EPA in the final malathion BE. Several of the concerns of higher consequence for the characterization of risk are listed below.

- **Data Quality Assurance**. Many studies selected by EPA for threshold values were not evaluated for data quality and relevance, and when evaluated, many evaluations did not follow EPA’s own study quality criteria. EPA used threshold values from studies deemed invalid by the Agency, or else deemed them acceptable for quantitative use even when criteria for quantitative use were not met. When the quality of the data driving the assessment is questionable, so are the results. EPA failed to make use of best available chemical-specific data in the BE. Notably, all registrant-commissioned data should have been considered by EPA. In particular, the Agency should have, by their own decree (EPA, 2011), made use of the GLP amphibian toxicity data, instead of relying on data from a different taxon. Similarly, EPA did not derive independent effects endpoints for estuarine/marine receptors (invertebrates, fish, aquatic plants).

- **Model Quality Assurance**. In past reviews of the WoE tools/TEDtool, a number of errors were reported, and as noted herein, not all have been addressed. We remain concerned that EPA has not submitted the TEDTool to a Scientific Advisory Panel (SAP) for an independent evaluation of its quality, credibility and utility. Even though the model is purportedly derived from existing EPA toolbox applications, substantial changes have occurred with the models since the last SAP. We, therefore, believe that TEDTool warrants another SAP review prior to use in a regulatory capacity.

- **Unsubstantiated Endpoints**. We remain concerned with the use of toxicological effects metrics ("thresholds") that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction), and further not demonstrably associated with the protection goal of individual fitness. Thus, the binary, most-conservative-RQ-based effects determinations are primarily driven by effects metrics that do not necessarily even relate to the protection goals of the biological evaluation.

- **Rudimentary Spatial Analysis**. EPA made the assumption that adulticide applications may be made anywhere in the United States, when data clearly show this is not the case. Erroneous species and critical habitat effect determinations were made assuming that application to all possible label uses are made anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use or co-occurrence. Accordingly, there are prospectively species that will never come into contact with biologically relevant concentrations of malathion that have been determined to be "LAA".

- **Inappropriate Use of Exposure Models**. The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for malathion, these models have been used to simulate landscape and aquatic fate processes in continental-scale watersheds and rivers. Even from a screening level perspective, this approach is a gross overextension of the model's capabilities. The results obtained from these models, applied to represent environments they were never designed for, are not acceptable.

- **Overgeneralization of Aquatic Exposure Predictions.** The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by that same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact, their occurrence is typically constrained to very specific locations (they are endangered). The overgeneralization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to misrepresentation of the extent of exposure risk.

- **Omission of Best Available Data and Tools.** High resolution spatial datasets representing, crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed scale hydrologic and water quality models (e.g. SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions do not account for the critical landscape and agronomic variability known to exist in reality and are based on modeling methods that are incapable of reflecting the complexities of the environmental processes they are attempting to simulate.

- **Not Providing Probabilistic Exposure Prediction.** The spatial variability and input and process uncertainty surrounding malathion exposure in aquatic environments is significant. A meaningful and scientifically valid analysis of exposure in this situation requires that probabilistic methods be employed to determine the likelihood of exposure endpoints being exceeded. This probabilistic approach, which was endorsed by the NAS panel (NRC, 2013), was not followed in the BE.

- **Compounding of Conservatism**. When multiple deterministic exposure model inputs are "upper bound" or biased high, as in the case of the BE (e.g., on-field exposure, upper bound RUDs, 90^{th} percentile on the mean half-lives), the resulting exposure estimates are expected to be overly conservative (i.e., unrealistically high).

- **Nonsensical RQs**. There remain disparities between exposure durations in toxicological studies and EECs used to generate RQs in the BE. Risk characterizations are overly exaggerated when effects metrics generated from long exposure durations (e.g., several days to months) are compared to peak EECs.

- **Lack of Transparency.** Though the Agency attempted to deal with some of the transparency issues in the text of the final malathion BE, their effort was insufficient, and many transparency concerns persist. For example: key cells in the WoE tools remain hidden and locked, drift models continue to go unreferenced and unexplained and methods are not consistently presented.

- **Outstanding Errors.** Despite the fact that the Agency did correct some of the errors identified during the public comment period, many remain. For example, critical errors remain in the dermal exposure and body mass scaling equations for herptiles in the TEDtool. Further, the terrestrial EECs presented in the malathion BE do not match those generated in the associated TEDtool.

- **No Weight of Evidence**. Despite claiming a weight of evidence approach, it seems EPA made all of their effects determinations based solely on the most conservative RQ of a suite of RQs generated for each species. EPA gave equivalent "weights" to exceedances of thresholds associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds not even necessarily linked to individual fitness/the protection goal (e.g., endpoints for avoidance behavior, AChE inhibition, etc.). Further, other lines of evidence were not directly considered in species and critical habitat calls (e.g., incident reports, field studies, monitoring data, etc.). We note that aquatic EECs were orders of magnitude higher than monitoring data. Nowhere in the final BE was this taken into account.

- **A Lack of Risk Estimates/ Probabilistic Methods.** As articulated above, NRC (NRC, 2013) discouraged the use of RQs, and recommended probabilistic methods. Risk is the probability or likelihood of a particular outcome. Accordingly, EPA did not estimate risk to listed species in their BEs (with the possible exception of the 13 birds analyzed with TIM/MCnest). The spatial variability and input and process uncertainty surrounding malathion exposure is significant. A meaningful and scientifically valid analysis of exposure in this situation requires that probabilistic methods be employed to determine the likelihood of exposure endpoints being exceeded.

The issues listed above result in adverse outcomes (LAA) for individuals of the majority of listed species addressed in the final malathion BE. Cheminova submitted four refined effects determinations for malathion conducted on the Kirtland's warbler, the California red-legged frog, the California tiger salamander and the delta smelt (Moore et al., 2016 [MRID 49949506]; Breton et al., 2013 [MRID 49211702]; 2016c,d [MRIDs 49949505 and 49949504]), as well as an effects determination and risk assessment paper on the California red-legged frog and salmon, respectively, for dimethoate (Breton et al. 2012 [MRID 48895502]; Whitfield Aslund et al. 2016), to provide additional examples of how individual listed species assessments could be conducted to determine risk using the best available scientific data, and appropriate refined methods to characterize risk. Species-specific exposure assessments for over 20 species in a range of static and flowing water habitats across the Ohio River Basin (HUC2 05) also demonstrate how refined approaches can be used to characterize risk (Padilla and Winchell., 2016 [MRID 49949507]; Winchell et al., 2016 [MRID pending]). Cheminova's effects determinations demonstrate that when complete risk assessments are carried out using the best available data, realistic exposure assumptions, and consideration of all lines of evidence, effects determinations can be quite different. Such refined assessments should be conducted when potential risks are identified at the screening level (e.g., NRC, 2013; EPA, 1998, 2004, 2013).

FMC believes that the exercise of producing the three pilot BEs has demonstrated that the Interim Approaches require severe restructuring. The final malathion BE does not provide a scientifically sound basis on which to make effects characterizations under the ESA or FIFRA. Although the EPA did correct some of the obvious errors and oversights found in the draft BE, the Agency neglected to address important concerns regarding the hyper-conservative nature of the exposure assessments and the flawed "weight-of-evidence" approach. Moreover, EPA did not actually estimate risks to listed species nor their critical habitat (which inherently require probabilistic methods; NRC, 2013).

RESPONSE TO THE BIOLOGICAL EVALUATION FOR MALATHION

1.0 INTRODUCTION

The Environmental Protection Agency (EPA or “the Agency”), in conjunction with the Fish and Wildlife Services (FWS), National Marine and Fisheries Service (NMFS) and United States Department of Agriculture (USDA) prepared draft Biological Evaluations (BEs) for three pilot chemicals: chlorpyrifos, diazinon and malathion. These draft BEs are the first case studies for national assessments of the potential effects of pesticides to listed species (threatened or endangered) carried out by the federal government.

On April 6th, 2016, the EPA released the draft BEs for review. This date marked the start of a 60-day public comment period. On April 29th, 2016, a 120-day extension to the comment period was requested by Dow AgroSciences LLC, Makhteshim Agan of North America, Inc. (Adama) and Cheminova because the 60-day comment period was deemed by these registrants as insufficient for review of the contents of the draft BEs which (1) exceeded 12,000 pages, and contain links to Excel files and model output files with millions of lines of data, and (2) contained a number of omissions and errors (including broken links), making comprehensive review impossible. Extension requests were also submitted to EPA by Edward M. Ruckert, representing the American Mosquito Control Association (May 10th, 2016), CropLife America (May 6th, 2016) and James Callan, representing 39 grower groups (May 9th, 2016). The request for extension was denied by EPA in a formal letter sent via e-mail on the 17th of May, 2016 to the counsel of the registrants (David B. Weinberg and David E. Menotti). In the justification, the Agency cited a court-mandated deadline under which they and the Services are working, as well as the early release of parts of the draft BEs in December, 2015 (allowing for some review prior to the official comment period). However, substantial changes made to the draft documents posted in December required additional efforts by affected parties to identify and evaluate modifications made to the documents, supporting models, the missing data, broken links, and other errors in the draft BEs. In addition, the court-mandated deadline is not a reasonable excuse for not allowing a fair and substantive review of the draft BEs by affected parties.

Cheminova A/S (hereafter referred to as “Cheminova”) is the sole manufacturer and primary registrant in the United States for the technical form of malathion (CAS Registry Number 121-75-5). All other registrants of technical malathion obtain their material from Cheminova and all end-use products registered in the United States are produced from Cheminova’s technical malathion. In 2015, Cheminova A/S and Cheminova, Inc., were acquired by FMC Corporation (FMC). Cheminova Inc.’s end-use product registrations have been transferred to FMC. Although we often only refer to Cheminova or FMC in this document, the comments contained herein reflect the positions of both companies.

Given the limited time available for public comment due to the denial of a public comment extension period, the original comments submitted by Cheminova (Breton et al., 2016c) contained only a preliminary review and evaluation of the portions of the malathion draft BE pertaining to the assessment of risk to aquatic and terrestrial listed species (or species that have an aquatic or terrestrial component of their life cycle). The Agency stated in the letter denying extension of the comment period that the Interagency Interim Approaches is subject to further refinement, and there will be further opportunities for stakeholder feedback in the future."

On January 19, 2017, EPA released their "revised" or final biological evaluations, along with a document responding to how they addressed the numerous public comments they received on their draft BEs. EPA's response document outlined how they categorized each of the 78,000 comments, with 120 substantive comments that were noted to be meriting detailed review. EPA noted that they intended to incorporate those recommendations that could feasibly be addressed in time to meet the legal obligation to complete the Biological Opinions (BiOps) for the three pilot chemicals by December 2017. As such, EPA outlined that the major revisions that were made to the draft BEs included (but not limited to): a revised modeling approach for flowing aquatic waterbodies; error correction and improved transparency; the addition and deletion of species based on changes in listing status; and refinements to some of the aquatic species ranges. Upon review of the final BEs, FMC is providing comments on how EPA addressed Cheminova's original comments on the draft BEs as per Breton et al. (2016c). This document contains FMC's comments on the final BEs.

Similar to the formatting in Cheminova's original response document (Breton et al., 2016c), FMC's response to the final BE first addresses the exposure assessment conducted by EPA (Sections 2.0 and 3.0), followed by the effects assessment (Section 4.0) and the Agency's effects determinations (Section 5.0) for listed aquatic and terrestrial species in the draft malathion BE. It concludes with a summary of the overarching problems identified in the portion of the final BE dealing with the aquatic and terrestrial listed species (Section 6.0).

2.0 METHODS FOR ESTIMATING EXPOSURE OF TERRESTRIAL ORGANISMS TO MALATHION

Breton et al. (2016c) detailed a number of concerns related to terrestrial exposure estimates in the draft BE for malathion. Mainly, Cheminova was concerned with (1) a lack of transparency in the exposure assessment, (2) compounding conservatism of “upper bound” inputs, and (3) a number of transcriptional and calculation errors.

Most of the information provided by EPA on their final BE exposure estimates are presented in Chapter 3 (Exposure Assessment), Attachment 1-7 (Methodology for Estimating Exposures to Terrestrial Animals (mammals, birds, reptiles, amphibians and invertebrates), Attachment 1-16 to 1-20 (Biological information on listed birds, mammals, herptiles) and the TEDtool root files (TEDtool_v1.0_alt.xlsx and TEDtool_v1.0.xlsx).

With respect to Attachment 1-7 of the malathion BE, the Agency made a number of changes to increase transparency in their approach. Modifications made to the final BE in Attachment 1-7 include: (1) correcting invalid references to locations in the document and on the web, (2) adding additional references to locations in the document, (3) adding missing units, (4) providing additional justification for selected assumptions, and making several edits to the text reflecting typographical errors.

Regarding the contingent Chapter 3, subsection 3, in which estimated exposure concentrations are presented for terrestrial organisms, very few changes were made to the text. Edits were limited to:

(1) The removal of a reference to “a complete analysis” being provided in a future iteration of the document.
(2) A footnote being added to point to “additional EECs” in the TEDtool.
(3) Changing the Log Kow from 3.3 to 2.8.
(4) Adding a single reference to the reference section.

Despite these limited in-text changes, approximately 40% of the EECs provided in Chapter 3 for terrestrial organisms (Table 3-12) were modified, with no explanation. This is further discussed in Section 2.6 below.

Regarding the supporting TEDtool root files, we note that a few inputs related to terrestrial exposure were changed (daily fraction retained in birds, log Kow and aquatic invertebrate BCF). These changes in the TEDtool are consistent with updated *lower* dietary concentrations in aquatic invertebrates, reptiles and amphibians, birds and soil-dwelling invertebrates. However, these values were not presented in Chapter 3, and inconsistencies remain between the TEDtool and terrestrial exposure results presented in the final BE (see Section 2.6 below).

Despite some appropriate changes to the exposure assessment for terrestrial organisms, Cheminova still has a number of concerns that have not been addressed that have important implications for the results of the BE. This section contains a discussion of persisting and critical issues relating to EPA's methodology for the assessment of terrestrial vertebrates, plants and invertebrates (Sections 2.1 to 2.3), spray drift estimates that apply to all taxa (Section 2.4), as well as chemical specific comments and results (Section 2.5 and 2.6).

2.1 Terrestrial Vertebrates

Breton et al. (2016), made a number of comments regarding the handling of exposure of terrestrial vertebrates in the draft BE. Comments addressed some transparency issues, the use of inconsistent approaches across EPA tools (e.g., earthworm fugacity, and T-HERPS vs. TEDtool), the use of outdated metabolic rate data, unrealistic exposure scenarios, and explicit errors in the application of model equations (Breton et al., 2016).

In the final version of the malathion BE, EPA did clarify why specific prey guilds were selected, and did outline the body burden approach taken (which notably differs from the T-HERPS model which is still purported to be the model employed in Table 3-12 of the final BE). The Agency also did present the aquatic EECs used to estimate concentrations in aquatic feed items. Also, EPA did clarify that dose estimates from different exposure route scenarios where considered separately. In the final BE, the Agency did provide explicit definitions for elements of equations, such as the vapor dose equation (Equation 23 in Attachment 1-7 of the final BE). Critically, EPA did also address part of the error in the dermal dose equation in the TEDtool that was leading to erroneously high estimates of dermal exposure for birds. The default relative diffusion rate across the pulmonary membrane (F_{AM}) was also adjusted for birds to match the value of 3.4 specified in the text.

FMC remains concerned with unaddressed comments that have direct and significant bearing on the results of the BE. In the final BE, the Agency persists in using outdated field metabolic rate data, generating food ingestion rate estimates with faulty dietary assumptions, and comparing dietary concentrations of inequivalent feed items (i.e., laboratory vs. food consumed in the wild). The reliance on compounding upper bound conservative inputs, as opposed to risk-based probabilistic approaches (as recommended by NRC (2013)), remains a chief concern of FMC.

Further, though EPA did state that they would address errors and issues of transparency in the final BE for malathion, these drawbacks still remain in the Agency's exposure assessment for terrestrial vertebrates.

In particular, the Agency neglected to correct the error in the applications of body mass scaling for herptiles. As noted in Breton et al. (2016): Column V, W, X in the "Min rate doses" and "Max rate doses" worksheets in the TEDtool_v1.0 and TEDtool_v1.0_alt files, hold the body mass-adjusted dose-based effects metric for all listed terrestrial vertebrate species in the TEDtool. For birds, it is clear that the body mass scaling applied in T-REX is retained here. However, for herptiles, an exponent of 1 is applied in the avian body mass scaling equation. This is equivalent to a scaling factor of 2 (which is baseless), and results in the test 1/million dose estimate being multiplied by the ratio of the body weights of the species being assessed and the test species. This leads to much lower effects metrics for herptiles which are typically smaller than the test species (compared to birds). There is no justification for this scaling factor anywhere in the document. The default scaling factor in T-HERPS is 1, which results in an exponent of 0, and therefore no body mass scaling is applied to herptiles, by default. It is clearly an error in the TEDtool that an exponent of 1 (and equivalently, a Mineau scaling factor of 2) was applied. Body mass scaling should have been omitted entirely for terrestrial herptiles given the paucity of supporting data.

Further, EPA applied body mass scaling to all threshold values in these worksheets, including sublethal thresholds. This is inconsistent with the T-REX and T-HERPS models which, only apply body mass scaling to LD50 estimates for birds and heptiles. The Agency provides no evidence that body mass scaling is warranted for sublethal endpoints.

Also, although the Agency did correct the identified calculation error for avian dermal dose, they did not address the error in the dislodgeable foliar residue adjustment factor (F_{dfr}). This input is used to estimate the dermal contact dose for birds and mammals.

The following equation is used in Column O for birds and mammals to estimate the upper bound dermal dose for contact exposure (with foliage).

$$D_{contact(t)} = \frac{C_{plant(t)} * F_{dfr} * R_{foliar\ contact} * 8 * (SA_{total} * 0.079) * 0.1}{BW} * F_{red} \qquad \textbf{Equation 2-1}$$

Where,

$D_{contact(t)}$	=	Contact dose (µg a.i./g bw; reportedly calculated on a daily time assuming eight hours of activity)
$C_{plant(t)}$	=	Concentration of the pesticide in crop foliage at time *t* (mg/kg)
F_{dfr}	=	Dislodgeable foliar residue adjustment factor (kg/m^2; default = 0.62).
$R_{foliar\ contact}$	=	Rate of foliar contact (default = 6.01; cm^2 foliage/cm^2 body surface per hour)
SA_{total}	=	Total surface area of bird (cm^2)
BW	=	Body weight (g)
F_{red}	=	Dermal route equivalency factor

This equation comes directly from the TIM technical manual (EPA, 2015a). In Attachment 1-7, and also in the TIM manual, the Agency states that “In this equation, a factor of 0.1 is used to generate $D_{contact(t)}$ value with units in µg a.i./g-bw.”

The description of the F_{dfr} value used in Equation 2-2 as described in the TIM manual suggests a major flaw in the $D_{contact(t)}$ equation (Equation 2-1).

In Section 6.2.1 of the TIM manual, it is stated that the F_{dfr} value is necessary because “total residues are commonly expressed in terms of mass of pesticide per unit fresh mass of vegetation, while dislodgeable residues are commonly expressed in terms of mass of pesticide per unit surface area of the vegetation". The following formula is then provided for calculating F_{dfr} on the basis of dislodgeable pesticide residues (DPRs) and total pesticide residues (TPR) measured immediately following application:

$$F_{dfr} = \frac{DPR}{TPR}$$ **Equation 2-2**

Where,

F_{dfr}	=	Fraction of dislodgeable foliar residues (kg/m^2)
DPR	=	Dislodgeable pesticide residues (mg/m^2)
TPR	=	Total pesticide residues (mg/kg)

In the absence of chemical specific data, the TIM manual indicates that a default value for F_{dfr} of 0.62 can be calculated by setting DPR to 28 mg/m^2 and TPR to 45 mg/kg. The TPR value is said to be "the mean for the total pesticide residue value on broadleaf plants." (no reference given). The Dislodgeable Pesticide Residue (DPR) value is stated to be "based on the Health Effects Division's default assumption that at day 0, the dislodgeable foliar residue value is 25% of the application rate (in lb a.i./A) (Section D.6.2 of Appendix D of USEPA, 2012b)". Note that this value was converted from lb a.i./A to mg/m^2." However, the conversion from 25% of the application rate (in lb a.i./A) to 28 mg/m^2 (with no mention of application rate) is clearly incorrect. Mathematically, 25% of the application rate (in lb a.i./A) would also equal 25% of the application rate (in mg/m^2 or any other unit) and cannot be estimated independently of the actual application rate.

Review of the actual HED document (EPA, 2012) clarifies that, contrary to what is stated in the TIM manual, field studies have been done to quantify dislodgeable residue amounts <u>as a fraction of the application rate</u> for various types of crops and various active ingredients. On the basis of these data, HED recommends that "when chemical-specific data are unavailable the recommended default value for the fraction of application rate as dislodgeable foliar residue for both liquid and solid formulations following application is 0.25 (25%)." This value is presented as the arithmetic mean of 60 measured values in Table D-20 of the HED document (EPA, 2012). Therefore, if the HED assumption of 25% application rate as dislodgeable foliar residues is a reasonable assumption for the NESA assessment, the default F_{dfr} should be corrected to 0.25, and $C_{plant(t)}$ should be replaced with the application rate in mg/m^2.

A worked through example will show the implication for the final BE estimates.

We take the single application rate of 5.1 lb a.i./A, and consider the dermal contact exposure of the Northern aplomado falcon (*Falco femoralis septentrionalis*). EPA estimated a dermal contact dose of 220.9 mg a.i./kg bw in the final BE for malathion. The upper bound dietary dose for a diet of arthropods was 110.3 mg a.i./kg bw. The estimated body weight is 325 g. The surface area based on the equation provided in Attachment 1-7 is 473.6 cm^2 (this is correctly calculated in the TEDtool for this species).

F_{red}, according to the Agency is 0.94, based on an oral LD50 of 136 mg a.i./kg bw. Using Equation 2-1 above, with an F_{dfr} of 0.25, we calculate the following:

First, 5.1 lb a.i./A = 2,313,319.2 mg a.i./A = 571.633 mg/m^2

$$D_{contact(t)} = \frac{(571.633\,\frac{mg}{m^2}) * (0.25) * \left(\frac{6.01\ \text{cm}^2\text{foliage}}{\text{cm}^2\ \text{body surface per hour}}\right) * 8\ hour(473.6\ cm^2 * 0.079) * 0.1}{325\ g} * 0.94$$

$$D_{contact(t)} = \frac{74.4\ mg\ a.i.}{kg\ bw}$$

This value is almost three times lower than EPA's estimate for this species, and remains notably lower than the upper bound dietary dose estimate of 110.3 mg a.i./kg bw for the bird consuming arthropods.

2.2 Terrestrial Plants

In their response to EPA's BE (EPA, 2016), Cheminova noted some concerns with the transparency of how the terrestrial plant assessment was conducted, including the lack of clarity on the differences between the TerrPlant model and what was calculated and presented in the TEDtool model. Moreover, EPA (2016) provided very little discussion on their exposure results in their assessment of terrestrial plants. Additionally, it is not clear why EPA did not use their newly developed Audrey III model in their BE's despite its use in the sulfonylurea assessment conducted by EPA which was completed prior to the BE for malathion.

Very little clarifications or discussions of results were made by EPA in their final BE (EPA, 2017a,b). In an attempt to clarify some differences between the TerrPlant and TEDtool mode, EPA (2017b) noted in the README tab of the TEDtool that only the runoff portion of TerrPlant was used. However, EPA still has not provided additional details on the calculations, nor presents exposure results in text. EPA has not addressed all of Cheminova's concerns on the transparency of the terrestrial plant assessment in the final BE.

2.3 Terrestrial Invertebrates

In Cheminova's response to EPA's draft BE, Breton et al. (2016c) noted that EPA did not present a method for deriving EECs for listed terrestrial invertebrate species. Moreover, it was noted that EECs for listed terrestrial invertebrate species were not presented in any of the draft BE chapters (EPA, 2016a). Specifically, Cheminova and CLA (2016) were concerned with the fact that the dose-based EECs for terrestrial invertebrates were not presented in the draft BE (Attachment 1-7) nor in the TEDtool. Moreover, as indicated in Cheminova's response document to EPA's draft BE, an assumption on terrestrial invertebrate body weight is required to estimate dose-based concentrations (to convert mg a.i./kg diet to mg a.i./kg bw). There is no such information available in Chapter 3 or in Attachment 1-7 of the final BE. Cheminova also provided their concerns with a mistake made in estimating the "number of exceedances of thresholds and endpoints for upper bound and mean EECs". For terrestrial arthropods (above ground) and soil dwelling arthropods, EPA (2016a) compared dose-based thresholds with dietary exposure concentrations. This approach is incorrect because dietary EECs and dose-based effects metrics are not the same measures and have different units.

In their final BE, EPA (2017a) did not address the above concerns within the text of Chapter 3, Attachment 1-7 nor in the TEDtool calculations. In their response to the letter submitted requesting comment period extension, EPA (2016b) attempted to clarify the location of the missing terrestrial invertebrate dose-based EEC results. In brief, it was noted that the results were located throughout Section 4 and 5 of Attachment 1-7 as well as in the TEDtool tabs "min and max rate concentrations". The location of these results was unclear in the draft BE as well as in the final BEs (EPA, 2016a, EPA, 2017a).

CLA (2016) also commented on the fact that it is Agency policy to use exposure estimates from BeeREX to assess the risk of pesticides to all pollinator species, and that the predicted exposure using T-REX (via the TEDtool) is approximately 50 times higher than the corresponding estimates from BeeREX. CLA (2016) noted that the use of the TEDtool instead of BeeREX results in "highly exaggerated exposure and risk estimates for listed insect pollinator species and listed species that prey upon them or listed plant species that are reliant on them for pollination".

In response, EPA (2017a) added text to Attachment 1-7 stating that "The contact-based exposure approach integrated into the BeeREX model was not used because that approach includes residues that are specific to honey bees. It is assumed here that the arthropod residue values in the T-REX model generally apply to more species. Residues from the two approaches are generally similar." Assuming this is the case, why didn't the Agency incorporate BeeREX into their BE, to assess risks to pollinator species for which honeybees are an appropriate surrogate? There is a clear inconsistency here, in which EPA is choosing to apply different screening-level models to the same taxa.

2.4 Spray Drift

For terrestrial species, spray drift estimates were not used to make effects determinations. However, the EPA did estimate setback distances to various effects metrics based on spray drift models presented in Attachment 1-7 of the BE. Breton et al. (2016) and CLA (2016) noted transparency issues and inappropriate use of drift models employed in the draft BE. The Agency neglected to address these issues in the final BE, with the exception of providing units (e.g., ft), where missing, and an updated link to the related AgDrift software.

The Agency presents Equation 1 in Attachment 1-7, which reportedly gives "the distance where the risk extends" based on "an analysis of the deposition curves generated in AgDrift (v. 2.1.1)". Equation 1 is (Equation 1 in Attachment 1-7; Equation 2-3 herein):

$$d_t = \frac{\left(\frac{c5}{F_{AR}}\right)^{\frac{1}{b5}} - 1}{a5}$$ **Equation 2-3**

Where,

F_{AR} is the fraction of the application rate that is equivalent to the threshold, and
d_t is the distance where the risk extends.

EPA makes reference to **Table A 1-7.1**, which is found on the subsequent page (page A7 (PF)-2) and contains numerical values for the parameters a5, b5 and c5 for aerial, ground and airblast application methods for a range of droplet size spectra.

A reference for Equation 2-3 is not given. In the same paragraph a footnote is provided to AgDrift (v.2.1.1). The most recent AgDrift User's Manual (Teske et al., 2003) that is available in the regulatory version download (file name: agdrift_2.1.1.zip; retrieved from: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#atmospheric; March 29, 2016) contains the following equation used for Tier I ground sprayer assessment (Equation 2-21):

$$D(x) = \frac{c}{[1+ax]^b}$$ **Equation 2-4**

Where,

D(x)	is the deposition level relative to the nominal application rate,
x	is the downwind distance (in feet), and
a, b and c	are model parameters.

This equation can be rearranged to give Equation 2-4, as follows (assuming *x* in the User's Manual is d_t, and *D(x)* is F_{AR}):

$$[1 + ax]^b = \frac{c}{D(x)}$$

Equation 2-5

$$x = \frac{\left(\frac{c}{D(x)}\right)^{\frac{1}{b}} - 1}{a}$$

Equation 2-6

Presumably then, the Agency obtained Equation 2-21 from the AgDrift User's Manual. However, in the User's Manual this equation applies to low boom ground sprayer applications, and describes models fit to empirical ground sprayer data only. It is unclear how EPA determined the three parameters for any of the application methods (ground, aerial or airblast), as even the parameter values for groundspray do not match those presented in the User's Manual. The Agency refers to an analysis of AgDrift output that is not presented, nor cited. Finally, EPA does not specify how many swaths the model and associated parameters (Equation 1 and Table A 1-7.1 in Attachment 1-7) apply to. In the AgDrift User's Manual, a, b and c parameters are estimated for a single swath only. AgDrift v.2.1.1 does not provide numerical values for *a, b* or *c* in any of the software's output.

2.5 Chemical Specific Comments on Selected Input Parameters

In their response to the draft BE's, Cheminova noted a number of concerns on the selection of specific input parameters for malathion that were used in the terrestrial exposure modeling including: residue unit doses (RUDs), foliar dissipation half-life aerobic metabolism half-life, daily fraction retained, LogKow, and BCFs.

2.5.1 Residue Unit Doses (RUDs)

Cheminova (Breton et al., 2016c) commented on the EPA's use of the conservative Hoerger and Kenaga (1972 [MRID 47299308]) nomogram upper bound RUDs for specific plant items, and their upper bound and mean RUD for terrestrial arthropods of 94 and 65 mg a.i./kg ww per lb a.i./A, respectively. The Hoerger-Kenaga nomograms have been characterized as being overly conservative (Trask et al. 2010) and that they rely on data reflective of outdated application practices and analytical methods. Although we agree that these more recent arthropod RUDs are more appropriate than their past use of foliar RUDs as a surrogate, FMC maintains the opinion that probabilistic residue estimates should be used if the data are available as per the NAS panel (NRC, 2013) who indicated that "model predictions can be only as accurate as the parameter estimates. If the relevant parameter values and their variances are poorly known the model predictions will be uncertain and difficult to use in decision making." As such, Cheminova recommended that EPA consider the residue data for terrestrial plants as per Moore et al. (2014 [MRID 43989301]) (Table 2-1). Additionally, Cheminova recommended that EPA consider residue unit doses estimated by Cheminova using EPAs data, along with additional sources, in which RUDs (and their variances) are available for multiple arthropod types (See Breton et al. (2014b [MRID 49400601]; 2016d [MRID 50133301]) for a complete list of references (Table 2-2).

In their comments on the draft BE's, CLA (2016) also declared that the difference between chemical specific and generic RUDs can be quite profound due chemical properties, use situations and application rates as well as environmental factors. They recommend that if chemical specific data are available, it should be used to estimate chemical specific RUDs. FMC agrees that this is true for all chemicals and continues to recommend the use of malathion specific RUDs as discussed above.

Table 2-1 Estimated RUDs for malathion on vegetation (mg a.i./kg ww per lb a.i/A)			
Feed Item	***EPA Upper Bound RUD[a]***	***Cheminova's Malathion-Specific RUD[b]***	
		Mean	***95th Percentile***
Short grass	240	77.4	238
Long/tall grass	110	45.4	191
Forage/ leafy crops	135	28.3	90.0
Small fruit/Seeds	15	1.70	6.99
Large Fruit	NA	0.540	2.82

[a] Hoerger-Kenaga nomograms (Hoerger and Kenaga, 1972 [MRID 47299308]) as modified by Fletcher et al. (1994), and applied in T-REX v.1.4.1.
[b] As calculated by Moore et al. (2014 [MRID 49389301]).

Table 2-2 Summary of estimated lognormal distributions of insecticide RUDs for arthropods for use in refined risk assessment								
Arthropod Type	***No. Trials***	***Mean of Natural logarithms of trial RUDs***	***Standard Deviation of Natural Logarithms of Trial RUDs***	***Percentiles of Estimate RUD Distribution (mg a.i./kg ww per lb a.i./A)***				
				5th	25th	50th	75th	95th
Flying Insects	7	0.154	1.60	0.0833	0.395	1.17	3.45	16.4
Orchard Crop-dwellers	19	2.56	0.99	2.54	6.63	12.9	25.1	65.5
Ground Crop-dwellers	15	2.02	1.21	1.03	3.34	7.56	17.1	55.3
Orchard Ground-dwellers	15	0.697	0.946	0.424	1.06	2.01	3.80	9.51
Ground Crop Ground-dwellers	20	1.16	1.15	0.477	1.46	3.18	6.91	21.2

EPA did not consider any of Cheminova's recommendations on the development and use of foliar and terrestrial invertebrate RUDs in their final BE. It is important to note that FMC maintains the opinion that EPA should use the most current and up to date information in estimated exposure and effects to endangered species. The use of outdated data as seen in the Hoerger-Kenaga nomograms creates overly conservative exposure estimates to non-target species consuming malathion in the environment. Moreover, the lack of probabilistic methods prevents EPA from understanding the potential range of exposure.

2.5.2 Foliar Dissipation Half-life

Cheminova reported concerns with EPA's use of a foliar dissipation half-life of 6.1 days estimated from Willis and McDowell (1987). EPA noted that they used a 90th % mean on 37 malathion residue foliar persistence half-lives ranging from 0.3 to 10.9 from this study. Specifically, Cheminova commented that EPA did not present the data that were considered in their half-life derivation; and noted that EPA failed to consider any of the more recent plant residue studies that were submitted by the registrant to the agency. Moreover, EPA's use of a plant half-life for terrestrial invertebrates is inappropriate, given the availability of terrestrial invertebrate specific data (Knäbe, 2004 [MRID 46525902]; Hanebeck and Staedtler, 2011 [MRID 49086411]; Staedtler et al., 2011 [MRID 49086410]). Further, Cheminova recommended that EPA consider estimated malathion specific foliar DT50s of 2.28 days, 6.69 days and 3.80 days for foliar crops, small fruits/seeds/pods and large fruit and the arthropod specific T90 of 3.54 days as estimated in Moore et al. (2014 [MRID 49389301]) and Breton et al. (2016d [MRID 50133301]) for plant and arthropod half-lives, respectively.

FMC maintains the opinion that EPA should consider the most recent and appropriate data to estimate chemical specific foliar half-lives, and that EPA needs to be transparent in their approaches by presenting the data specifically considered in their half-life estimation. In their response to the draft BEs, CLA (2016) also noted that the most recent chemical specific data should be used in estimating foliar dissipation half-lives for use in exposure assessments.

2.5.3 Aerobic Metabolism Half-life

Cheminova commented on concerns regarding the selected aerobic soil metabolism half-life of 1 day that was selected by EPA in their draft BE for malathion. Specifically, Cheminova noted that references for this value were not presented within the TEDtool inputs page. Moreover, Cheminova discussed concerns about EPA's use of data collected from Saxena (1998 [MRID 47834301]) in the derivation of the aerobic soil metabolism half-life. Saxena (1998 [MRID 47834301]) is one of three registrant submitted studies (in addition to Blumhorst, 1990 [MRID 41721701]; Knoch et al., 2001a [MRID 46769501]), in which EPA derived their value. However, EPA previously classified Saxena (1998 [MRID 47834301]) as unacceptable based on a number of factors (EPA, 2011a). Therefore, consistent with EPA policy, Cheminova removed this study from their half-life derivation calculation. Because EPA has concluded that the study by Saxena (1998 [MRID 47834301]) is invalid, Cheminova recommended that it be removed from its calculations. Moreover, Cheminova noted how EPA's estimation of its aerobic soil metabolism half-life was incorrect, and seemed arbitrary in terms of their doubling of the half-life for a number of reasons. Cheminova calculated a mean soil half-life from five half-life estimates from the two available (and accepted) aerobic soil GLP studies (0.21 days from Blumhorst (1990 [MRID 41721701]); and, 0.17, 0.18, 0.25, and 0.25 days from Knoch et al. (2001a [MRID 46769501])). The estimated 90th percentile upper confidence bound on the mean soil half-life is 0.24 days. To be consistent with the Agency's guidelines, the mean soil half-life of 0.24 days was recommended to be used as the aerobic soil metabolism input into EPA's environmental modeling for the malathion BE.

Upon review of Chapter 3 and the TEDtool, we note that EPA did not change their soil metabolism half-life of 1 day. The only notable change EPA made was to the TEDtool inputs page, where reference was made to only two of the three original studies (Blumhorst, 1990 [MRID 41721701]; Knoch et al., 2001a [MRID 46769501]). Additionally, the data from Saxena

(1998 [MRID 47834301]) were not removed from Chapter 3, nor was the description for estimating the half-life edited.

It is FMC's opinion that EPA is inappropriately using data that were deemed unacceptable for use in risk assessment by EPA themselves, and that their method for estimating a half-life of 1 day using these data is incorrect and inconsistent with their own guidance.

2.5.4 Daily Fraction Retained

In their draft BE, EPA was not consistent in describing their approaches for estimating dietary exposure estimates and how they address metabolism of their daily intake. As such, it was difficult to understand their approach without accessing and reviewing the calculations located in the TEDtool. Cheminova commented on a number of inconsistencies throughout the draft BE on this issue (Breton et al., 2016).

In response, in their final BE EPA (2017a) has added some clarification text in Attachment 1-7 of the final BE noting that in their approach for estimating upper bound and mean concentrations of pesticides in birds, mammals, reptiles and amphibians (in addition to referring to T-HERPs for more detail), "concentrations in mammals and birds are decreased on a daily basis based on elimination or metabolism." And that … "The amount of chemical that is retained from one day to the next is based on chemical-specific magnitude on the residue studies with chickens and rats." This added text outlines the fact that EPA does consider elimination and metabolism in their exposure estimates (which was lacking in the draft BE). However, it still does not describe the metric of "daily fraction retained" that was selected and how it is considered in their calculations of exposure.

Despite their minor added clarification on the use of the input parameters of "fraction retained" as noted above, EPA (2017a) continues to fail to provide full references or discussions in Chapter 3 or Attachment 1-7, on the studies in which these input parameters were derived (Reddy et al. 1989 [MRID 41367701] and Cannon et al. 1993 [MRID 42715401]). To maintain transparency, EPA should provide detailed summaries of the studies and a description of the data that were used to estimate the "daily fraction retrained" values used in their exposure modeling.

2.5.5 LogKow

Cheminova commented on EPA's use and lack of reference provided for a LogKow of 3.3 in the TEDtool. It is assumed that EPA selected the highest LogKow reported from the range of 195 to 2000 provided in a footnote in Chapter 3. In response, Cheminova recommended that EPA consider the LogKow of 2.75 as reported in the registrant submitted study, Mangels (1987 [MRID 40944108]). It appears that EPA did adjust their LogKow value in their TEDtool to a LogKow of 2.8, and notes that the LogKow was derived from the Kow of 628 reported in MRID [00157054]. The full reference for this study was not provided by EPA. However, the cited MRID is associated with Hill Top research (1985), which is a screening study for acute oral toxicity, acute dermal, skin irritation, and primary eye irritation study on a chemical that is not identifiable as malathion (i.e., single formulation not identified). EPA's use of this study to estimate a LogKow is inappropriate. FMC maintains its recommended LogKow value of 2.75 as reported by Mangels (1987 [MRID 40944108]).

2.5.6 Bioconcentration Factors (BCFs)

Cheminova identified a number of concerns with the BCFs that EPA used in estimating the concentration of malathion in aquatic prey (i.e., aquatic plants/algae, aquatic invertebrates and fish). Firstly, Breton et al. (2016c) noted that EPA (2016a) was not consistent in their description of their methodology in deriving the empirically derived BCFs for aquatic invertebrates between Chapter 3 and Attachment 1-7, nor were full references presented. Secondly, EPA (2016a) used an empirically derived BCF of 131 µg a.i./kg ww per µg a.i./L from MRID 43106401, which corresponds to a group of documents (procedure and raw data) for a study conducted by Forbis and Leak (1994 a,b [MRID 43106401, 43106401]) and Kammerer and Robinson (1994 [MRID 43340301]). This study actually reports a BCF for bluegill of 103. Because EPA failed to provide a discussion on the study and data used to determine the BCF, it was impossible to identify the discrepancy between the BCFs. As such, it seems that EPA (2016a) reported a BCF of 131 from this study in error. Thirdly, for aquatic invertebrates, EPA (2016a) noted that there are no empirically derived BCFs and states that KABAM was used to estimate a BCF of 72 µg a.i./kg ww per µg a.i./L. Other than stating that KABAM was be used, there was no discussion in the TEDtool or Chapter 3 on any of the assumptions or data used for this modeling. Lastly, Cheminova presented the lack of clarity about how the water EECs used to estimate concentrations in the aquatic species were selected. EPA (2016a) only stated that a "representative range of water concentrations were estimated using the PRZM5 and VVWM models.

In their final BE, EPA (2017a) did not address any of Cheminova's comments. The only change to BCFs was an edit made to the LogKow (EPA, 2017a changed it to 2.8, See Section 2.5.5 for a discussion on this) used in KABAM to estimate a BCF of 24 µg a.i./kg ww per µg a.i./L for aquatic invertebrates, replacing the previous BCF of 72 µg a.i./kg ww per µg a.i./L. EPA also did not further clarify their selection of water concentrations, but instead changed the text in Attachment 1-7 to suggest that the selected concentrations represent "a bound of the lower and upper range of aquatic EECs generated by PWC (i.e., 10 and 100 µg a.i./L, respectively)". Further discussion is still missing in EPA (2017a) to justify these concentrations (i.e., model inputs, assumptions, output, statistics).

2.6 Exposure Results

Cheminova noted errors in EPA's draft BE exposure results (Table 3-12; EPA, 2016a). In their draft BE, EPA (2016a) reported mean and upper bound dietary EECs generated using the T-REX and T-HERPS functionality within the TEDtool framework. EECs that were reported in Table 3-12, specifically for dietary items including terrestrial invertebrates, birds, mammals and amphibians, could not be verified within the TEDtool results. Additionally, Cheminova (Breton et al., 2016c) indicated a total lack in clarity in the range of EECs reported for aquatic plants, invertebrates and fish. In Table 3-12 of their draft and final BEs, EPA (2016a, 2017a) indicated that water concentrations used for the ERA ranged from 0.01 to 100 µg/L, when in reality within the TEDtool framework, only water concentrations of 10 µg/L and 100 µg/L were used to estimate "min" and "max" aquatic exposure scenarios. The reason for the mismatching ranges of aquatic values was not made clear in the draft and final BEs (EPA, 2016a, 2017a).

It appears that EPA (2017a) corrected their reported terrestrial dietary EECs for birds, mammals and amphibians to the old draft versions of the TEDtool (corresponding to EPA, 2016a), and not to the newest and up to date versions (EPA, 2017a). The new dietary EECs are in fact lower than the dietary EECs using the final TEDtool. In fact, EPA is reporting in Chapter 3 (Table 3-12) dietary concentrations that are up to 3 times higher than those actually estimated in the current TEDtool. This discrepancy needs to be clarified.

Despite the change in the LogKow used by EPA to estimate EECs (in KABAM) for aquatic invertebrates (is now assuming a log Kow of 2.8 based on malathion specific data), the range of EEC's is still reported in error based on the assumed water concentrations used in the assessment of 0.01 to 100 µg/L. See Section 2.5.6 for additional comments.

In their comments on the draft BE (Breton et al., 2016c), Cheminova noted that a mistake was made for the upper bound concentration in the diet of the Chiricahua leopard frog (*Rana chiricahuensis*) where the water concentration of 100 µg a.i./L was used (Input cell C66) instead of 10 µg a.i./L (input cell C65). This error was not corrected in the TEDTool workbook of the final BE. This mistake estimates an upper bound concentration in the diet that is 10x higher than it should be.

2.7 Summary of Concerns Regarding the Terrestrial Exposure Analysis

Despite some effort on the part of EPA to address errors and transparency issues in their final malathion BE, FMC is concerned that a number of such problems remain in the terrestrial exposure assessment. Further, many issues related to methods and process were deliberately left unaddressed (reportedly due to time constraints), even though they have significant implications for the terrestrial exposure assessment. FMC's major concerns regarding the terrestrial exposure assessment still include:

- EPA's failure to make use of best available chemical specific data in the draft BE. In many cases, they used outdated or generic input values to parameterize the terrestrial exposure models. Notably, all registrant commissioned data should be considered by EPA for use in the BE. For Malathion, a comprehensive list and review of these studies is presented in Breton et al. (2014a [MRID 49333901]; 2016d [MRID 50133301]).
- EPA's TEDtool integrates many of EPA's standard toolbox models (i.e., T-REX, T-HERPS, TerrPlant, and earthworm fugacity model). CropLife America and FMC remain concerned that EPA has not submitted the TEDTool to a Scientific Advisory Panel (SAP) for an independent evaluation of its scientific quality, credibility and utility. The changes

to the models in the TEDTool since those models were previously evaluated by SAPs have been substantial and warrant another SAP review.
- EPA fails to comply with recommendations as per the NRC panel (NRC, 2013) to conduct probabilistic assessment wherever possible, thus leading to highly conservative results without context of the probability of risk. CLA (2016) also raised this issue in their response to the draft BEs.
- A number of hyper-conservative assumptions are employed without the consideration of realistic exposure scenarios, ultimately leading to an overly conservative exposure assessment.
- Specific calculation errors were noted, including: (1) the major error in the dislodgeable residue assumptions (derived from the TIM user manual), and (2) the use of body mass scaling for terrestrial herptile species. Neither were corrected, and persist as obvious errors in the final BE. These errors have significant impact on the results.
- Exposure estimates presented in the document, in many cases, do not match the values presented in the final version of the TEDtool. This indicates profound quality assurance issues with the Agency's process and results.

Accordingly, FMC maintains that species risk designations based on the terrestrial exposure assessment of the final BE are scientifically unsound and are not based on best available data nor based on best risk assessment practices as recommended by NRC (2013).

3.0 AQUATIC EXPOSURE MODELING

3.1 Spatial Analysis

3.1.1 Agricultural Crop Footprint Development and Use of the NASS Census of Agriculture Dataset (CoA)

The methodology for agricultural crop footprint development described in the draft BE included the use of the NASS Census of Agriculture (CoA) county-level crop acreage data to serve as a benchmark for adjusting the CDL-based footprints. Cheminova (Breton et al., 2016c) provided several arguments challenging the validity and need for this approach. These included the following:

- Not accounting for the uncertainty bounds associated with the CoA dataset
- The assumption that the CoA dataset is inherently more accurate than the CDL, requiring that CDL-estimated acreages be adjusted to match CoA.
- That the expansion method employed by EPA to match CoA data s arbitrary in may result in more errors in land use/crop pixel classification than improvements over the native CDL data

Additional concerns that Cheminova, FESTF, and CLA expressed regarding the development of agricultural crop footprints included:

- Not bringing in additional high quality land use datasets (e.g., the NLCD) to provide further support in generating crop footprints
- Applying the crop group lumping strategy to address errors of omission in the raw data, but not in any way accounting for errors of commission.
- Certain geographic restrictions on malathion use were not accounted for in EPA's crop footprint development.
- Use restriction specifics on current pesticide labels were not accounted for in EPA's derivation of crop footprints
- Crop groupings that are too broad, contain too many crops, and that should be split into smaller crop groupings to achieve more refined estimates of potential use extent.

The final BE did not modify the methodology for the agricultural crop footprint development and did not specifically comment on any of the concerns raised by Cheminova in the comments to the draft BE (Breton et al., 2016c).

It was noted in FESTF's comments (FESTF, 2016) that some local (state) spatial datasets were not included in the development of crop footprints that would have provided added value (e.g., Washington State Department of Agriculture and the California Farmland Mapping and Monitoring Program).

Suggestions were made by Cheminova (Breton at al., 2016c) FESTF (FESTF, 2016) and CLA (CLA, 2016) to quantitatively incorporate the CDL accuracy reports into the derivation of the crop footprints. Ultimately, it was recommended that national probabilistic crop footprints that take into account uncertainty in classification, as demonstrated by Budreski et al. (2015) should be adopted. The EPA has not indicated that these probabilistic approaches will be pursued.

3.1.2 Potential Pesticide Use Sites for Non-Agricultural Uses

The use of NCLD Open Space Developed land use categories were used by EPA in the draft BEs to represent non-agricultural uses, but it was unclear what specific use patterns were assigned to each land use class. The final BE did not provide any further clarification on this issue.

The cattle ear tag uses were mapped spatially to rangeland, however use only occurs when pest pressure is high (FESTF, 2016). The suggestion was made to use cattle density information to refine the footprint for this use pattern. The final BE did not incorporate these suggested changes.

3.1.3 Use Site Footprint for Nursery Uses

In the comments on the draft BE, Cheminova (Breton at al. 2016c) noted that the dataset used to derive the footprint for nurseries (Dun & Bradstreet (D&B)) was not publicly available, thus difficult to evaluate.

The final BE lists the reference for the Dun & Bradstreet dataset, and also provided a web link (http://igeo.epa.gov/data/Restricted/OEI/Agriculture/DunAndBradstreet_Agriculture.zip). This web link was tested and was determined to be non-functional. Therefore, there remains an issue with accessibility of the data required to derive the nursery use site footprint.

3.1.4 Species Habitat and Range Data

Cheminova commented on the draft BE (Breton et al. 2016) that the species habitat and range data used by EPA in the co-occurrence analysis were not made publicly available as part of the BE documentation. The lack of transparency and availability of species location data was discussed in detail in the FESTF comments to the draft BEs (FESTF, 2016)

At the time of the final BE publication, the spatial datasets used by the EPA and the services were still not available. Making this data publicly available should be a requirement for the pilot OP BEs and all subsequent BEs prior to finalization of the reports.

In addition, FESTF (FESTF, 2016) challenged that the EPA's spatial data used to represent species locations appeared to be only at the county level for the vast majority (~90%) of species. This led to a significant over-representation of the spatial extent of the locations for these 90% of species. The final BEs did not indicate any changes to the spatial data used in the assessment, thus still over-predict species extents and co-occurrence with potential use sites.

FESTF described in their comments (FESTF 2016) the use of species attribute information, including special habitat preferences and requirements, in the refinement of a co-occurrence analysis. Both the EPA and FESTF have compiled these types of species attributes, however the EPA did not appear to directly use this information in compiling the final BE. FMC supports this level of refinement in final effects determinations.

3.1.5 Action Area and Overlay Analysis

The offsite transport zone due to spray drift was determined based upon the most sensitive aquatic habitat (Bin 5) and assumed to apply for all species. Breton et al. (2016c) disagreed with this approach, because many species do not occupy the small static (Bin 5) habitat, and thus an action area that is based upon exposure potential in this type of water body irrelevant. This approach has the potential to result in some species falling within the action area that should not. The alternative proposed by Cheminova was to derive more refined action areas that are appropriate for each species or taxa. The final BE did not comment on the proposed alternative approach, and included the same approach as was used in the draft BE.

The method EPA used for the overlap analysis of use sites with species habitat/range was implemented as a raster based computation that is limited to 30-meter resolution. A vector-based approach to overlap analysis was recommended by Cheminova (Breton et al. 2016) as being a more accurate alternative, and able to resolve overlap and proximity at distance less than a single 30-meter pixel. The final BE approach remained unchanged from the draft BE on this topic and no comment was provided on the Cheminova recommendations.

It was suggested by FESTF and CLA that temporal factors be considered in co-occurrence and overlay analysis. The example of migratory birds was given suggesting that some species are only present in portions of their range for limited amounts of time. The temporal nature of species locations was not considered in the final BE.

3.2 Aquatic Exposure Modeling for Malathion

3.2.1 Environmental Fate Data and Model Input Derivation

Cheminova (Breton et al., 2016c) commented on the summary environmental fate data provided in this section and in Table 1 of the draft BE (EPA 2016a). The main concern was related to the referencing of studies used to derive the range of values summarized in the table to allow readers to trace and determine which studies the report values came from.

Small updates have been made to this summary table to point readers to the group of studies used to derive environmental fate parameters for modeling. Some additional source information has been provided in Section 2.7, Table 3.5, Table 3.7 (EPA 2017a). Furthermore, Appendix 3-2 provides a bibliography of studies considered. While the documentation identifying sources of data to derive environmental fate characteristics is sufficient, a table similar to Table 3.7 that details the specific fate values associated with each study used in deriving a model parameter would be helpful for other fate parameters in addition to the aerobic soil metabolism.

Cheminova (Breton et al., 2016c) commented that EPA followed new NAFTA guidelines in calculating half-life values from metabolism study datasets; however, not enough information was provided in the BE main chapters or appendices to be able to reproduce the calculations of these parameter values. Based on our review, these details (e.g., actual inputs and result from PestDF), have not been provided.

Additional comments made by Cheminova concerning the draft BE focused on specific environmental fate parameter derivations done by EPA.

- Aerobic Aquatic Metabolism and Hydrolysis: Cheminova supports an aerobic aquatic biolysis half-life of 3.4 days and a hydrolysis half-life of 6.21 days. EPA's draft BE showed an aerobic aquatic half-life of 3.29 days with stable hydrolysis. EPA appears to have incorrectly interpreted Cheminova's position by adopting an aerobic aquatic half-life of 3.4 day, but keeping hydrolysis stable. Cheminova's comments to the draft BE (Breton et al., 2016) provide the scientific justification for separate aerobic aquatic and hydrolysis half-life values of 3.4 days and 6.21 days respectively.
- Soil Aerobic Metabolism: In the draft BE, EPA calculated an aerobic soil metabolism half-life of 0.5 days based on seven half-life values determined from registrant submitted studies. They then provided a justification for doubling this value to 1 day. Cheminova (Breton et al. 2016c) provided scientific arguments for why this doubling of the half-life values was arbitrary and outside of the normal standard EPA policies. Cheminova supports an aerobic soil metabolism half-life of 0.24 days based on the analysis conducted by Reiss (2013 MRID 49211704]). The final BE did not contain any modifications to address Cheminova's concerns regarding the EPA's determination of a model input value for the soil half-life. It remains our position that the EPA used a value that was four times too high, leading to the overly conservative predictions of malathion EECs.
- Foliar Half-Life: Cheminova (Breton et al. 2016c) commented on EPA's selection of a foliar half-life of 6.1 days, challenging that EPA did include all suitable guideline studies in their calculations. FMC supports a foliar half-life of 4.1 days for non-ULV formulations of malathion. The list of references used to derive this model input value was provided in Cheminova's comments on the draft BE. The final BE did not contain any re-evaluation of the foliar half-life input parameter value based on the recommended studies provided by Cheminova (Breton et al. 2016c). While the difference in EPA's and Cheminova's supported values is less than a factor of two, EPA's assumption adds to the conservatism of their reported EECs.

3.2.2 PFAM Modeling

Cheminova (Breton et al. 2016c) commented that not enough information was provided in the draft BE concerning the inputs and scenarios for the PFAM modeling the EPA conducted, making the results unreproducible. CLA (CLA, 2016) also noted that a conceptual model for the use patterns modeled with PFAM was not sufficiently presented, and that details of the cranberry use simulations were not provided. No changes were observed in the final BE that addressed documentation deficiency of the PFAM simulations.

3.2.3 Spray Drift modeling and Contributions to Exposure

3.2.3.1 General Conservatism in Drift Modeling

The drift methods applied in the BEs were standard Tier 2 FIFRA methods, and can significantly over predict exposure potential. The assumption of a 10 mph wind always blowing from a treated field to the water body, without accounting for the use of spray drift reduction technologies leads to predictions of drift loadings into nearby waters that are too high. Recommendations were made by CLA (2016) and Cheminova (Breton at al., 2016c) to include a probabilistic representation of drift loading into the BE, along the lines of suggestions by the NAS panel report (NAS, 2013). The suggested refinements in the drift modeling were not adopted nor addressed by the EPA in the final BE.

3.2.3.2 Selection of Drift Models

The EPA used the AgDRIFT Tier I model in the simulation of drift contributions to aquatic habitat (aside from the mosquito adulticide uses where the AGDISP model was applied). For ground spray modeling, CLA (CLA, 2016) suggested the use of the RegDisp model, which allows for the selection of specific nozzles, spray quality, and wind speed. The AgDRIFT model is not representative of current spray equipment used in practice, and greatly over-predicts spray deposition compared to current practices. For aerial applications, it was suggested that AGDISP, parametrized for current spray nozzles and typical wind speeds, would be the most appropriate model to use. No changes were made in the sprat drift models used in the final BE.

3.2.3.3 Drift Fraction Calculations for Non-ULV and ULV Applications (Non-Adulticide Applications)

Cheminova's comments on the draft BE (Breton at al. 2016c) captured that the assumptions made by EPA concerning the droplet sizes for aerial and ground applications (both non-ULV and ULV) did not follow the malathion label requirements, resulting in drift fractions that were higher than would actually occur in practice.

In their final BE, the EPA adopted the recommended changes in drift modeling assumptions made by Cheminova for the non-adulticide applications.

3.2.3.4 Drift Modeling of Adulticide Applications

The drift modeling of adulticide malathion applications in draft BE did not refer to existing literature on concerning field measurements of drift from these types of applications. This lack of an evaluation of the predicted drift compared to measured drift from adulticide applications was identified in Cheminova's comments on the draft BE (Breton et al., 2016c).

In the final BE, EPA did reference and review the study by Mickle et al. (2005) and made comparisons of the measured drift amounts in the study to those modeled by AGDISP. EPA concluded that AGDISP was appropriately predicting spray drift from these adulticide applications.

3.2.4 Effects of Current Mitigations on Exposure

Cheminova (Breton et al., 2016c) commented on EPA's statement that, "While spray drift buffers reduce exposure to aquatic environments from direct deposition of finished spray on water via drift, they do not impact modeled estimates of run-off received by the waterbody." Cheminova provided ample evidence and citations that spray buffers will, in fact, have an effect of reducing runoff related exposure to aquatic water bodies (e.g., USDA, 2000; Poletika et al., 2009 [MRID 47834101]), and that even EPA's 2006 RED required language encouraging vegetation between treated fields and adjacent receiving waters ("a level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff.").

The final BE did not address this comment. While it would be typical not to include effects of runoff and erosion reduction from vegetated buffers in screening level exposure assessments, they should be accounted for in refined assessments. At the very least, it should be acknowledged in a qualitative sense that runoff-based exposure contributions to receiving water is mitigated by the presence of vegetation between the edge of field and a receiving water body, regardless of whether that buffer area is a well-maintained grass buffer of natural vegetation.

Accounting for the existing buffers on the malathion labels, either quantitatively of qualitatively, would lead to reductions in predicted exposure concentrations in all aquatic habitat bins that were considered. A qualitative consideration of these buffers could be addressed as part of the weight of evidence analysis.

3.2.5 Application Timing Effects on Exposure

Cheminova (Breton et al., 2016) was concerned with the statement by EPA that, "moving single application dates in which 100% of a watershed is treated in a single day in small increments can have a substantial impact on peak EECs and smaller impacts on chronic EECs. Though EEC differences can be substantial, changes of application day by less than one week should not be construed as a model refinement and should only be considered a demonstration of model sensitivity." In EPA's modeling, only a single application date (chosen to be conservative) was chosen. Cheminova argued that application timing is a very sensitive parameter in runoff-driven aquatic exposure modeling, especially for malathion with a very short soil half-life, and that to properly evaluate the likelihood of pesticide exposure, the range of possible application dates needs to be accounted for in exposure predictions.

EPA's final BE (EPA 2017a) did not address this comment or modify the modeling approach account for the recommendation. While the selection of a single "worst case" date within a known application window is appropriate for initial screening level exposure modeling, the Step 2 of EPA's assessment should have more rigorously considered the variability of application timing when predicting malathion EECs. Accounting for this application timing uncertainty probabilistically would have resulted in lower EECs than only accounting for a conservative, "worst case", application date.

Another point concerning application timing that was made in CLA's response to the draft BE (CLA, 2016) (and also on malathion end-use labels) was that EPA stated, "efforts may be made to avoid pesticide application right before precipitation events", however this did not appear to be considered in the parameterization of the models. This issue was not further addressed in the final BE, and remains an important consideration in refining the potential for exposure.

3.2.6 Modeling of Exposure Associated with Ultra Low Volume Wide Area Uses

Cheminova (Breton et al., 2016c) identified several sources of conservatism in the modeling of aquatic exposure due to Ultra Low Volume (ULV) Wide Area uses. This included the standard screening level assumption that the wind is always in the direction of the application site to a receiving water body throughout multiple application cycles. Cheminova pointed out how unlikely these wind conditions would be. Cheminova also raised the issue of whether runoff was or should be considered in aquatic exposure modeling for ULV wide area uses of malathion. Given the design of ULV applications to stay airborne as an adulticide application, it is our position (Breton et al., 2016c) that runoff is not an aquatic exposure pathway of concern for this malathion use.

The Final BE did not specifically address these comments. It is FMC's position that for a refined assessment, the potential for aquatic exposure due to drift needs to be accounted for using best available spatial data (to better understand the proximity of use areas to aquatic habitat) and account for variability in wind speed and direction. Accounting for these sources of environmental and weather variability would result to lower estimates of malathion concentrations.

Cheminova (Breton et al., 2016) also commented on missing information needed to reproduce the AgDISP modeling for malathion ULV uses and the lack of referencing of an important malathion specific ULV study (Mickle et al. 2005). The final BE for malathion includes additional information on the AgDISP modeling within the main body text of Section 2.6.1, along with complete documentation of inputs in Appendix 3.3. The final BE also now includes a reference to and information contained with the Mickle et al. (2005) paper.

3.2.7 Modeling of Homeowner Uses of Malathion

Cheminova (Breton et al., 2016c) provided multiple comments and concerns regarding EPA's modeling of homeowner uses of malathion. These comments challenged the new conceptual model of residential uses that EPA presented, including: 1.) lot size justification, 2.) neighborhood level characteristics, and 3.) the relative fractions of different potential use sites covering the lot area. Additional comments concerned the parameterization of the modeling used to predict off-site transport of malathion, which was shown to be overly conservative. A final set of comments concerned the relevance of the conceptual model to the larger watershed scales represented by the medium flowing (Bin 3) and large flowing (Bin 4) aquatic habitat.

EPA did not address any of these comments in the final BE. Our position remains that the conceptual model of malathion homeowner uses needs greater justification, and the parametrization of the scenario is unrealistic in both the aerial extent of malathion use on a house lot, the assume total use of malathion across a residential watershed, and amount of runoff generated for chemical transport in the scenarios selected. These factors all results in unrealistically high predictions of malathion concentrations in all aquatic habitat bins.

3.2.8 Aquatic Exposure Modeling Results

3.2.8.1 General Comments

Cheminova (Breton et al. 2016c) provided extensive comments on the EEC results presented in the draft BE and provided numerous arguments demonstrating how unrealistic and implausible they were. Cheminova also provided extensive data analysis to support these positions. Some of the primary arguments supporting how unrealistic the EECs were included:

- Predicted concentration in aquatic habitats that were greater than malathion solubility
- Modeled medium flow (Bin 3) and high flow (Bin 4) concentrations that were greater than low flow (Bin 2) concentrations
- Flowing water concentrations (in all size bins) may times higher than in static water habitat bins
- Predicted concentrations in receiving waters multiple orders of magnitude greater than the edge of field concentrations

Recommendations made by Cheminova to address the significant over-predictions across the range of aquatic habitat bins included the following:

- For flowing water habitat screening level EECs:
    - Incorporating a baseflow rate equal to the minimum of the flow range associated with each habitat bin
    - Constraining the watershed areas to that which can drain into a main channel within 1 day
    - Applying Percent Cropped Area (PCA) adjustments at a minimum to Bin 3 and Bin 4

  - Replacing VVWM with a receiving water model designed to simulate pesticide fate and transport in a flowing channel. The Soil and Water Assessment Tool (SWAT) has this capability and has been shown to produce realistic peak exposure values for small, medium, and large flowing water bodies (refer to Teed et al., 2016 for details)

- For static water habitat screening level EECs:
  - Correcting the assumption that the entire watershed's pesticide mass generated in 1 day arrives at the receiving water body instantaneously (equivalent to daily average instead of peak EECs, and applied to flowing water as well)
  - Constraining the watershed areas of the static water body habitats to areas based on typical bin-specific water body configurations on the landscape, as opposed to allowing climatologically driven water balance calculations to wholly determine the watershed area
  - The watershed areas should also be constrained to allow a limited amount of regional variability. The significant amount of watershed area variability in the BE static bin scenarios across the HUC2s has led to an artificially wide range in EECs, which cannot be justified based on monitoring data or our conceptual understanding of hydrology and aquatic exposure pathways. Constraining the watershed areas within a limited range regionally will allow for a clearer interpretation of the relative risk of pesticide use based on regional variability in precipitation, soils and slopes, and use patterns

- For refined modeling of all aquatic EECs:
  - 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

The draft BE comments from CLA (CLA, 2016) provided a long list of similar suggestions for ways in which the aquatic exposure modeling should be refined. The main themes of these suggestions were, 1.) accounting for much greater spatial variability and landscape heterogeneity, 2.) higher resolution (spatially explicit) EEC predictions, 3.) use of best available spatial datasets, 3.) incorporating probabilistic model inputs and outputs. These higher tier modeling recommendations were not incorporated to the final BEs; however, EPA has indicated that some of these types of refinements will be considered as their overall ESA process evolves.

The final BE did have several important changes in the aquatic exposure modeling that were reported on the main body of Chapter 3. These included:

- Reporting of daily (24-hour) mean concentrations instead of peak concentrations for all flowing and static habitat bins
- Incorporation of baseflow into the Bin 3 and Bin 4 flowing water predictions

An additional update to the aquatic exposure modeling that was discussed in the final BE, but not incorporated into the updated modeling of EECs, was accounting for the variability in the "time-of-travel" to a watershed outlet for the medium and large flowing water habitats (Bin 3 and Bin 4). It was suggested that this conceptual change in the modeling of Bin 3 and Bin 4 exposure would be implemented in the BEs being prepared for carbaryl and methomyl.
FMC supports these updates to the modeling that EPA made in the exposure modeling presented in the final malathion BE. These changes resulted in significant reductions of EECs for the flowing water habitat bins of generally around an order of magnitude (10x). The EECs for the static water habitats (Bin 5, Bin 6, and Bin 7) were generally a little lower than those presented in the draft BE, although oddly, there were a few cases where the EECs in the final BE were higher (e.g., HUC 1, Bin 5). We do support the inclusion of baseflow in Bin 2 in addition to Bin 3 and Bin 4, as low flow streams will have baseflow as well. We also believe that the "time-of-travel" being explored by EPA for future BEs has the potential to lead to further improvements in realism of the EECs in each aquatic habitat.

The aquatic EECs in the final BE are an improvement over the EECs in the draft BE due to the incorporation of more realistic assumptions, and adopting the daily average concentrations instead of the erroneous peak concentrations. Nevertheless, there are still reasons for concern regarding the EECs reported in the final BE. A review of these EECs in Table 3-8 shows the following for the 1 in 15 year annual maximum daily average water column EECs:

- Bin 2 maximum EECs are between 1.4 and 6.3 times higher (median of 2.6) than Bin 3 EECs. In their draft BE, EPA conservatively estimated than Bin 3 EECs should be at least 5 times lower than Bin 2.
- Bin 2 maximum EECs are between 1.4 and 7.0 times higher (median of 2.7) than Bin 4 EECs. In their draft BE, EPA conservatively estimated than Bin 4 EECs should be at least 10 times lower than Bin 2.
- The static water EECs in Bin 5 are generally slightly higher than the Bin 2 flowing EECs (median of 1.1x higher). There are a few notable exceptions, particularly Bin 5 in HUC2 13, where the Bin 5 EEC is 13.3 times higher than the Bun 2 EEC. Because the Bin 2 and Bin 5 habitats both represent very shallow, low volume, high vulnerability habitat, we would expect EECs to be similar, but slightly higher in Bin 5.
- The large flowing (Bin 4) habitat EECs are up to 37.6 times higher than the large static (Bin 7) EECs (a median of 5.1 times higher). While referred to as a "large static" habitat, Bin 7 represents a small pond, and is equivalent to EPA's standard "farm pond" considered to be a high vulnerability water body in ecological risk assessment under FIFRA.

These observations indicate that, from a conceptual standpoint, the simulated EECs in the medium and large flowing habitats (Bin 3 and Bin 4), are still grossly over-predicted. Both Bin 3 and Bin 4 EECs should be at least 5 to 10 times lower than Bin2 respectively. Furthermore, both Bin 3 and Bin 4, EECs should be multiple times lower than the high vulnerability standard farm pond (Bin 7). The current set of screening level malathion concentrations do not match with our basic understanding of pesticide concentrations across water bodies of a range of characteristics and sizes.

3.2.8.2 Comparison of EECs with Edge of Field Concentrations

In Cheminova's comments on the draft BE (Breton et al. 2016), an analysis was presented demonstrating that for many of the habitat bins modeled (Bin 2, 5, 6, and 7), the simulated edge of field malathion concentration were often greater than the simulated receiving water concentrations. This was especially true for Bin 2 and Bin 5. This phenomenon was extremely problematic, and in large part due to the erroneous calculation of an instantaneous "peak" concentration, which has been addressed by EPA in choosing to report the daily average concentrations instead of the peak daily values.

A similar analysis comparing modeled edge of field concentrations to the modeled receiving water concentrations was not conducted with the updated EECs from the final BE. However, EPA's draft BE modeling showed that the maximum modeled edge of field malathion concentrations were 603 µg/L (EPA, 2016a). Looking at the maximum receiving water EECs reported in EPA's final BE (EPA, 2017a), there is at least one case in each of the habitat bins where the EECs are higher than 603 µg/L, and many cases where this occurs in Bin 2 and Bin 5. We believe that there may still remain some conceptual errors in some of the modeling, in both the flowing and static habitat bins, that is leading to these apparently erroneous concentrations. We recommend that EPA look into this issue in greater detail to ensure that receiving water concentrations do not exceed edge of field concentrations.

3.2.9 Aquatic Exposure Modeling Sensitivity Analysis

The aquatic exposure sensitivity analysis was only conducted for environmental fate parameters and application dates. Cheminova's comments on the draft BE (Breton et al. 2016), suggested that, given that the flowing water scenarios and modeling approaches are brand new, a sensitivity analysis that included additional parameters would have been valuable. Some recommended parameters to add to the sensitivity analysis were: water body dimensions, water body flow rates within the range of the bin, watershed area, and flow-through options.

The final BE updated the sensitivity analysis section to include two additional bins (Bin 3 and Bin 4) and included the results based on the updated EECs. The final BE did not add any of the additional parameters that were suggested into the sensitivity analysis. We maintain that given the novelty of the new aquatic habitat water bodies, additional sensitivity analysis should have been conducted.

3.2.10 Evaluation of Monitoring Data

In comments on the draft BE (Breton et al. 2016c [MRID 49949501]), Cheminova noted that while monitoring data were discussed, it was not explicitly used as a line of evidence in their risk assessment. Cheminova further suggested the use of new statistical approaches to deriving concentration time series from monitoring data such as the SEAWAVEQ being developed by EPA scientists, and robust bias factor approaches (Mosquin, 2012). The final BE did not make any further use of monitoring data than the draft BE. Our position remains that more rigorous analysis on the monitoring data is needed, and that monitoring data needs to be considered as a line of evidence in the weight of evidence analysis.

The monitoring data reported by EPA in both the draft and final BE showed that out of 70,000 samples taken since 1983, malathion was detected at concentrations between 1 and 22 µg/L in 53 of those samples (0.08%). Even after the improvements in the aquatic modeling in the final BE, the modeled concentrations of malathion across the different HUC2s for each of the six habitat bins ranged as follows:

- Bin 2: 737 – 1370 µg/L
- Bin 3: 145 – 652 µg/L
- Bin 4: 124 – 635 µg/L
- Bin 5: 782 – 9880 µg/L
- Bin 6: 68.2 – 1780 µg/L
- Bin 7: 11.5 – 651 µg/L

Cheminova (Breton et al. 2016c [MRID 49949501]) provided additional measured malathion concentration data from two separate, highly targeted monitoring studies (Gulka et al., 2016; Bahr et al., 2016). These studies focused on high vulnerability low flow and static water bodies in Oregon and Washington states. The maximum malathion detection between these two studies was 7.8 µg/L, which the result of a worst-case scenario where vegetation was less than 2 m (Bahr et al. 2016). Scenarios where riparian buffers were taller (2-6 m) resulted in much lower concentrations (maximum of 0.28 µg/L in grab samples).

The malathion concentrations modeled by EPA are often multiple orders of magnitude greater than the highest malathion concentration ever measured in the environment, from low flow and small static water bodies. This significant discrepancy continues to point to hyper-conservatism and significant adjustments to the modeling still required to obtain reasonable screening level exposure estimates.

3.2.11 Uncertainties in Aquatic Modeling and Monitoring Estimates

Cheminova (Breton et al. 2016c [MRID 49949501]) described several important sources of uncertainty that were not accounted for in the draft BEs. These included:

- Static water body volume
- Flowing water body volume and baseflow
- Multiple conservative drift modeling assumptions, including wind speed, wind direction, vegetation interception, BMPs followed by applicators
- Malathion application dates

The final BEs did not address any of these issues any further, other than to add a constant baseflow component to the medium and large flowing water habitats.

In addition, Breton et al. (2016c [MRID 49949501]) noted EPA's discussion on the uncertainty of modeling the Bin 3 and Bin 4 habitats. This discussion in EPA's final BE (EPA, 2017a) has not changed. There is still general acknowledgement that PRZM and VVWM are field scale models, and that extrapolating the use of those models to medium and large watersheds neglects some important watershed scale landscape and hydrodynamic processes. In the comments to the draft BE, Cheminova recommended that a full watershed scale model such as SWAT (Gassman et al., 2014), should be adopted in part or its entirety as the appropriate model for predicting flowing water habitat concentrations of pesticides for use in endangered species aquatic exposure risk assessments.

There remains a need for a true watershed and flowing water modeling approach for the BE process. It has been shown previously that the current iteration of aquatic exposure modeling in flowing water bodies still over-predicts expected screening level concentrations significantly. This is in part due to the selection of inappropriate models. The use of appropriate models (such as SWAT), properly parameterized, would lead to much more realistic exposure predictions, whether at the screening level or refined level.

3.3 Aquatic Exposure Modeling for Endangered Species Assessments, Methodology Development

The topics discussed in section are focused on the generic methodology that EPA developed for modeling aquatic exposure as part of the endangered species risk assessment process. These are detailed in Attachment 3-1 of the BE.

3.3.1 ESA Modeling Compared to Traditional Ecological Modeling Approach

In Breton et al. (2016c [MRID 49949501]), Cheminova commented on several aspects of this summary of model processes described in Table A3-1.1. One of the primary descriptions of the conceptual model for endangered species aquatic modeling was concerning water body/flow dilution. The following statement did not reflect EPA's modeling approach to derive EECs in the BEs: "Downstream dilution may be used from the edge of the use area, which consists of a percent use area adjustment. Concentrations are reduced by the use area adjustment factor until concentrations are below levels of concern". This concept was considered in the Action Area determination, but was not applied in deriving EECs. This comment remains of concern for FMC, as it does not accurately reflect how exposure values were estimated for use in the risk assessment. The result of not accounting for dilution of percent use area was that EECs were higher than would be found in the real world.

A change in the aquatic exposure modeling for endangered species from what has been traditionally done for ecological exposure modeling under FIFRA was to adopt a 1 in 15 year maximum concentration as opposed to the standard 1 in 10 year annual maximum concentration. The comments in Breton et al. (2016c [MRID 49949501]), raised on concern over the justification for this change, which EPA connected to the re-registration cycle of 15 years. FMC feels that this change in policy was not appropriately vetted from a scientific standpoint and that 1 in 10 year annual maximum concentrations still represent a very conservative, and protective, exposure estimate.

The conceptual model for the aquatic exposure habitat bins provided in Figure A 3-1.1 was questioned in the draft BE comments by Breton et al. (2016c [MRID 49949501]). There was uncertainty concerning the source for the 30-m runoff zone threshold, a distance beyond which only spray drift entered static water bodies, as well as how this threshold was implemented in practice. Cheminova also had further concerns with regarding the appropriateness of this conceptual model, which represents field scale processes, in simulating pesticide concentrations in medium and large flowing watersheds on the order of the Bin 3 and Bin 4 habitat.

The final BE added some source information to the support the notion that runoff as sheet flow becomes channelized after a distance of 30 meters, leading to the assumption that runoff does not connect to static water bodies, but rather becomes a small flowing water body after that distance. The final BE also provided some additional explanation of this assumption.

The additional explanation is helpful; however, it is still unclear how this notion of no runoff contributions to static water bodies beyond 30 meters from the edge of a field was implemented in practice. This concept would require detailed spatial analysis of use site proximity to static water bodies within a species habitat range to determine what portions of endangered species populations would or would not be exposure to pesticide transported via runoff and erosion. In the final BE, it appears that this 30-meter threshold was not considered in any way in deriving EECs or prediction exposure likelihood. Furthermore, the conceptual model's applicability to pesticide transport processes at the medium and large watershed scale remains questionable. It is FMC's position that an entirely different conceptual model is required for these larger watersheds and their receiving water bodies.

3.3.2 Spatial Resolution of Modeling Analysis

The EPA's approach was built upon the HUC2 watershed region as the spatial unit for which exposure modeling and risk analysis was conducted. Following this structure, only one exposure scenario per crop group was simulated to represent the entire HUC2 (in the case of HUC2 17, the Pacific Northwest, and area of 177,523,042 acres). In their comment on the draft BE, CLA (CLA, 2016) argued that this was insufficient spatial resolution on which to conduct an exposure assessment, and that much more variability needed to be accounted for. Suggestions were made for development of exposure scenario at a scale at least as refined as a HUC6 watershed. These suggestions were not adopted or addressed in the final BEs, nor were these concerns responded to in the response to comments document.

3.3.3 Selection of Crop Scenarios

The two most important comments that Cheminova (Breton et al. 2016c [MRID 49949501]) provided in this section were: 1.) concerning the methodology and criterion for assigning surrogate PRZM scenario to crop groups and HUC2 where a PRZM scenario did not already exist, and 2.) the criteria applied to determine whether a large range of precipitation existed within a HUC2 watershed, requiring multiple weather stations used in exposure modeling. In the draft BE, both of these methods were not fully explained.

In the final BE, there was no additional information provided concerning the methodology and criterion used to assign surrogate PRZM scenarios to other crop groups and regions. Providing this additional detail will help make the process for scenario selection more transparent. Concerning the weather station data, EPA did provide the necessary details to understand how the decision was made to split the weather for a HUC2 into 2 representative stations as opposed to only 1.

3.3.4 Aquatic Habitat Bins

3.3.4.1 Use of Generic Habitat Bins

Concerning the draft BE, Cheminova (Breton et al. 2016c [MRID 49949501]) commented in the statement by EPA that, "The nine aquatic habitat bins are used in the BEs for both Step 1 and Step 2 and will be used for the Biological Opinions in Step 3." Cheminova suggested that the 9 generic bins be used in screening level (Step 1) analysis, but that at Step 2 and Step 3 of the Interim Approach, more refined and spatially explicit aquatic habitat characteristics be used. The draft BE comments from CLA (CLA, 2016) echoed these same ideas, suggesting that the nine aquatic bins were too generic for accurate estimates of exposure concentrations. For many species, data are available that describe the specific water bodies they inhabit and more detailed information concerning their habitat characteristics. Additional concern was expressed by CLA that the characterization and parameterization of the new aquatic habitat bins had not been fully vetted for modeling purposes.

The final BE used the same language as the draft BE, indicating that refinement in the aquatic habitat characteristics would not be pursued in later steps on the ESA process. FMC strongly recommends generic habitat bins be limited to screening level stages of endangered species risk assessments, and that additional datasets to support realistic aquatic habitat characteristics be incorporated into the later stages of refinement.

3.3.4.2 Aquatic Habitat Bin 2 Characteristics

Cheminova (Breton et al. 2016c [MRID 49949501]) provided several comments concerning the characteristics of the low flow (Bin 2) habitat. It was noted that the extremely low velocities assumed for this aquatic habitat (1 ft/min) was atypical of the vast majority of low flow streams, including the slope and roughness that must be assumed to match the characteristics assumed for this water body. In addition, while a range of flow rates defines habitat Bin 2, only the minimum flow rate for the range was considered.

EPA did not make any modification to the language of the final BE to address these issues, nor did they provide a rationale for the representativeness of their assumptions. The result of this is an extremely conservative parameterization that represents a fraction of actual low flow habitats observed in nature.

An additional issue that Cheminova pointed out in the comments to the draft BE (Breton et al., 2016c) was that the equation used by EPA in estimating a flow velocity for Bin 2 was inaccessible. In the final BE, the EPA inserted the formula used directly into the report, so it can now be readily reviewed.

3.3.4.3 Static Habitat Bin Characteristics

Cheminova (Breton et al. 2016c [MRID 49949501]) challenged the use of static water body characteristics that represent only the most vulnerable end of the spectrum based on the habitat definitions that FWS/NMFS provided. While potentially acceptable as an initial screening approach, to more complete range of water body characteristics would need to be considered in Step 2 and Step 3. Furthermore, the relevance of the Bin 5 (small static habitat was challenged). Concern was over the ecological relevance and feasibility of protecting puddle sized areas of standing water threat are largely temporary features on the landscape. The issue of reasonably being able to model these water features given available modeling tools was also raised.

These concerns were not addressed in the content of the final BE. Because Bin 5 EECs in particular were some of the highest generated in the exposure modeling, thus they are largely driving the outcome of the risk assessment, it is important to better identify the relevance of this exposure scenario and the approach to modeling it.

3.3.4.4 Estuarine and Marine Bins

Cheminova (Breton et al. 2016c [MRID 49949501]) agreed with EPA's statement in the draft BE that, "Current pesticide models do not account for transport via tidal and wind generated currents in marine systems.", but does not agree with the selection of "surrogate bins". Further comments on the modeling of estuarine and marine habitat were made later in the response document. No changes to the final BE were made in response to FMC's comments on this issue, and EPA provided no rationale for not considering these suggested changes.

3.3.5 Watershed Size Determination

3.3.5.1 Flowing Aquatic Habitat Bins

Comments provided by Cheminova (Breton et al. 2016c [MRID 49949501]) on flowing water bin watershed sizes suggested that the regression equations EPA derived to calculate watershed size as a function of flow rate (from the NHDPlus V2 dataset) could be improved for some HUCs if linear regressions were used instead of log transformed regression equations. A more significant comment by Cheminova was that the watershed sizes that were calculated for flowing water habitats were unreasonably large given the constraints of the modeling approach and the use of the VVWM model as a receiving water model. In many HUC2s, the watershed area was considerably larger than could be expected to drain to the outlet within a single day.

One of the largest concerns related to watershed size was the assumption of instantaneous loading of pesticide into the water body and the use of the corresponding Peal EEC in the risk assessment.

The final BE did not change the methodology for estimating watershed sizes associated with each flowing water habitat bin, and EPA's response to comments did not address these concerns. The one change made in the flowing water modeling that relates to Cheminova's comments on watershed size was the change from using a peak concentration predicted by VVWM to a daily average concentration. The use of a daily average concentration reduces the impacts of very large watersheds on unreasonably large concentration predictions. Despite this improvement in the final BE, simulating watersheds the size of any of the Bin 3 and Bin 4 using PRZM/VVWM is beyond the intended use of those models, and alternative watershed scale modeling approaches should be developed and implemented.

3.3.5.2 Static Aquatic Habitat Bins

Comments concerning static bin habitat watershed sizes by Cheminova (Breton et al. 2016c [MRID 49949501]) focused on the unreasonably large watershed sizes assumed for some of the HUC2 regions. The approach followed to derive watershed sizes was a water balanced based methodology. The effect of following this approach was for much larger watersheds sizes associated with each static water body to be estimated for warm dry areas compared to the watershed sizes in cool and wet areas. This methodology resulted in drainage area to normal capacity ratios (DA/NC) that ranged over 2 to 3 orders of magnitude across HUC2 regions, depending upon the Bin. This phenomenon was not supported by any landscape level data, making the resulting watershed areas to be purely hypothetical. One result was that tremendous amounts of runoff and pesticide could be generated from such large areas, and because EPA's modeling methodology assume zero dilution from runoff water in static receiving waters, the predicted EECs were often grossly over-predicted.

This issue of watershed size for static habitat bins was not addressed in EPA's final BE, and EPA did not provide a justification to support gigantic range in static water body watershed sizes. Our position remains that watershed areas derived for the static habitat in many of the HUC2s are unrealistically large, which leads to significant over prediction of pesticide loadings to the water bodies. Methods to refine these watershed areas should include evaluating actual static water body watersheds determined from topographic data.

3.3.5.3 Estuarine and Marine Aquatic Habitat Bins

The use of surrogate freshwater aquatic habitat bins to represent marine and estuarine habitats was introduced in this section of the BE. Breton et al. (2016c [MRID 49949501]) made extensive comments concerning the inappropriateness of the freshwater bins that EPA assigned to the marine and estuarine habitats. The final BE did not modify EPA's original methodology concerning surrogate freshwater bins, but suggested that improved methods for estimating exposures in estuarine/marine habitats would be a longer term goal. Our position is the freshwater EECs assumed by the EPA have no relevance to the marine/estuarine systems that they are intended to represent. The EECs derived in the final BE for these marine/estuarine habitats are very likely several orders of magnitude higher than reasonably conservative screening level EECs should be.

3.3.6 Application Data Selection

Breton et al. (2016c [MRID 49949501]) commented that the draft BE was unclear concerning how information other than weather was used in selecting application dates. The final BE added a statement that provided clarification to this question. The statement was as follows: "If pest pressure or agronomic practice information is available to restrict the application period, then the wettest month during this period will be selected." Thus, it appears as though pest pressure data served as an additional constrain to the application window.

3.3.7 Issues Modeling Medium- and High-Flowing Waterbodies

Cheminova (Breton et al. 2016c [MRID 49949501]) provided extensive comments concerning the reasons for the excessively high concentrations of malathion predicted in the original modeling conducted by EPA. Many of these were in agreement with what EPA identified in the draft BE as reasons for the overly high predictions. One or the primary points made by Breton et al. (2016c [MRID 49949501]) was that many of the issues identified for the medium and high flow habitat bins also apply to the low flow (Bin 2) habitat.

The final BE contained modified modeling of the Bin 3 and Bin 4 habitats that included baseflow and a daily average concentration instead of a peak concentration. The baseflow changes were applied to only Bin 3 and Bin 4, and the daily average EEC changed applied to all three of the flowing water habitats. Other factors leading to excessively high EECs that were identified in the draft BE comments (very high DA/NC ratio and assumption of 100% area of the watershed treated on the same day) were not addressed in the final BE. This continues to be a concern for FMC and leads to over prediction of EECs in all of the flowing water habitat bins.

3.3.7.1 Modifications Considered But Not Incorporated

The draft and final BE are unchanged in this section of the document. This section outlined model refinements/modifications that were considered by EPA in their initial efforts at flowing water modeling, but weren't actually tested in their exploratory modeling. These items were as follows:

- Incorporation of Baseflow: This model modification was originally dismissed by EPA in their modeling, but ultimately included in the flowing water modeling reported in the final BE (Bin 3 and Bin 4 only).
- Percent Use Area and Percent Use Treatment Adjustment Factors: This model modification was strongly supported by Cheminova (Breton et al. 2016c [MRID 49949501]), but was not adopted by EPA in their final BE modeling. EPA noted in their response to comments that they are, "evaluating the appropriate scale at which to incorporate percent crop area/crop treated in the exposure assessments."

- Adjustment of Water Body Length: This model modification was not believed to be of significant importance by either EPA or FMC.
- Spreading Out Applications: The EPA chose not to incorporate variable application timing into their modeling for the final BE. FMC believes this to be critical to making accurate predictions of malathion concentrations in flowing water bodies draining medium and large sized watersheds.

FMC's position is that several of these model modifications originally considered by EPA, specifically percent use area, percent treated area, and spreading out applications are necessary to obtain realistic predictions of malathion concentrations at the watershed scale. Not accounting for these factors results in higher concentration than would occur under reasonable worst case conditions.

3.3.7.2 Modifications Explored and Incorporated into Modeling

The draft and final BE are unchanged in this section of the document. This section outlined model refinements/modifications that were considered by EPA in their initial efforts at flowing water modeling, and then tested in their exploratory modeling. These items were as follows:

- Curve Number Adjustment: This model modification was evaluated in some of EPA's original modeling for Bin 3 and Bin 4, but was not adopted in the updated modeling in the final BE. Varying the CN value accounts differences in soils and land cover/crop type, as occurs in real landscapes.
- Daily Flow Averaging: This model modification is simply that the flow through the water body on a given day is representative of the runoff entering the water body on that day. The alternative is that flow through the water body is the average of an entire 30-year period. It appears that the final BE did not incorporate daily flow averaging in the modified flowing water modeling. This model parameterization should be required, as the alternative (a 30-year average), does not capture the real dynamics that occur in flowing water systems.
- Adjustment of Water Body Dimensions: This option sought to change the representative length of a receiving water body to reflect a small mixing cell. This concept did not end up being applied in the final BE modeling, and was not supported by Cheminova.

Use of Daily Average EECs: The draft BE modeling reported instantaneous peak EECs. Daily average EECs were considered in the EPA's original exploratory modeling. Daily EECs were ultimately adopted for the final BE and we support this adjustment.

3.3.7.3 Modifications Evaluation, Final Approach for OP Pilot Chemicals

In the draft BE, this section focused on the final approach followed in the draft BE to estimate Bin 3 and Bin 4 EECs from the models-simulated Bin 2 EECs. The methodology for deriving scaling factors for Bin 2 to Bin 3 and Bin 2 to Bin 4 EECs was heavily based on evaluation of atrazine monitoring data. In Cheminova's comments on the draft BE (Breton et al. 2016c [MRID 49949501]), this scaling was critiqued in favor a more physically based modeling approach.

The final BEs adopted a different approach to predicting Bin 3 and Bin 4 EECs than was done in the draft BE. Therefore, in the final BE, this section of Attachment 3-1 focuses on a discussion of the modifications to the flowing water modeling that were considered and those that were ultimately adopted in the final modeling. The modeling modifications considered were:

- Adopting 24-hour mean concentrations in place of peak concentrations, which was done for all static and flowing aquatic habitat bins
- Incorporating baseflow into the flowing water Bins 3 and 4
- Accounting for a time lag (or time of travel) in how pesticide generated throughout the watershed reaches the outlet of the receiving water body

The first two modifications were the ones included in the final BE Bin 3 and Bin 4 modeling. The accounting of watershed time of travel was still under development and not yet ready to incorporate into the final BE for malathion; however, EPA stated that this approach will introduced in future BEs.

FMC supports the incorporation of baseflow into all of the flowing aquatic habitat bins, not only the medium and large flowing water bodies. It is typical in many areas of the countries for low flow, small streams to have continuous water in them. In addition, hydraulic characteristics that have been defined for Bin 2 suggest a water body with such low flow that is would have nearly continuous water within it at the depth and flow rate specified by the bin characteristics. We also support a modification to the modeling approach that accounts for watershed dynamics, including travel times and watershed heterogeneity from both an agronomic perspective and a landscape perspective.

3.3.8 Downstream Dilution Modeling

In Appendix 3-5 of the BE, it was noted that downstream dilution was not conducted for malathion "Because of the widespread use of malathion and the uncertainty with where the adulticide, wide area, and non-agricultural uses could occur, the entire United States is considered the action area for malathion for Step I." The same rationale was applied for Step 2. Breton et al. (2016c [MRID 49949501]) argued that because there are certain agricultural crops where malathion applications are not allowed (e.g., soybeans), it is incorrect to assume that non-agricultural wide-area uses (such as mosquito control) could occur in these areas. Therefore, a downstream dilution analysis would be relevant for malathion.

In the final BE, EPA did not make any changes to downstream dilution analysis for malathion. FMC believes that the action area for malathion was over-represented by not properly accounting for the land uses and crops where malathion cannot be used.

4.0 EFFECTS ENDPOINTS AND DERIVATION OF THRESHOLDS

4.1 General Comments

4.1.1 SETAC Pellston Workshop on Improving the Usability of Ecotoxicology in Regulatory Decision Making

Cheminova expressed a number of concerns in Breton et al. (2016c [MRID 49949501]) and CLA (2016) expressed a number of concerns with the selection of endpoints and the methods by which thresholds were derived in the draft BE (EPA, 2016a). The majority of these comments involved issues with the quality and relevance of the studies utilized by EPA (2016a), and the lack of transparency with EPA's method for evaluating the studies. Breton et al. (2016c [MRID 49949501]) reminded EPA of the conclusions of a Pellston Workshop in which the Agency took part, which highlighted a multitude of limitations of using open-literature data to support risk assessment decisions. The Agency is still using many open-literature studies that have not been properly verified for data relevance and data quality in the final BE (EPA, 2017a).

4.1.2 Data Selection and Evaluation Process

In their response to comments memorandum (EPA, 2017b), EPA indicated that they had increased the transparency of their work in the final BE. However, the Agency did not address many of the comments made by Cheminova (Breton, et al. 2016c [MRID 49949501]) and CLA (2016) as it pertains to the selection and evaluation of data, resulting in many of the studies used by EPA to make their risk assessments being of poor quality. Further, despite their claim of greater transparency, the Agency has still not released the criteria for their "Standard Evaluation Procedures (SEP)" for evaluating registrant-submitted studies nor have they provided DERs for many of the studies submitted by Cheminova to the Agency, despite multiple requests. Although the Agency fixed the broken hyperlink from the draft BE (EPA, 2016a) for the final BE (EPA, 2017a) relating to guidance for reviewing open literature, there still remains no explanation for why these studies should receive a less stringent review than registrant-submitted studies. Additionally, as discussed by Breton et al. (2016c [MRID 49949501]) and CLA (2016), following this guidance means that studies will be included in SSDs without undergoing a thorough and stringent review. This practice is in direct opposition with EPA's insistence that they are "committed to using the best scientific and commercial data for ESA-FIFRA analyses" (EPA, 2017b). Furthermore, EPA (2017a) utilized studies to build their SSDs for which the chemical characterization is identified as "unknown" in the final BE. FMC cannot emphasize enough that this is scientifically unsound and again questions how EPA is using toxicity data from studies that have not properly characterized the tested chemical for relevance.

Cheminova and FMC strongly disagrees with the Agency's assertion that there is not compelling information to exclude toxicity data due to the source of technical malathion or age of the study. As elucidated in Breton et al. (2016c [MRID 49949501]), Cheminova is the only producer of technical malathion in the US and, therefore, only studies involving malathion produced by Cheminova are relevant for current risk assessments of the chemical. Older regulatory studies were conducted using technical malathion manufactured by American Cyanamid, while Cheminova has conducted all of the newer regulatory studies using its technical malathion. For the vast majority of the studies where both products have been tested on the same species, Cheminova's technical malathion has been shown to be less toxic (Hillwalker and Reiss, 2014 [MRID 49316501]). For example, comparison studies were conducted on rats using currently sold malathion vs malathion formerly sold by American Cyanamid (and has a different impurity profile) (Fischer 1991a, b [MRIDs 49127003, 49127004]). Results showed that the current technical malathion is 2.6 times less toxic compared to the malathion previously sold by American Cyanamid. This strongly indicates that impurity levels influence the results of earlier tests and, therefore, data from ecotoxicity tests conducted more recently with technical malathion manufactured by Cheminova are more reliable and preferred for use in malathion risk assessments (Hillwalker and Reiss, 2014 [MRID 49316501]). Studies conducted by American Cyanamid should only be used for risk assessment in cases where data from Cheminova's technical malathion are not available. In appendix 2-3 of the final BE, EPA acknowledged that not reporting the purity of malathion limits the utility of a study, but the Agency continued to utilize these studies to derive their thresholds. To account for these issues, Cheminova has developed a screening and evaluation method for studies, briefly presented in Breton et al. (2016c [MRID 49949501]), that would aid in the Agency's selection of studies. Regardless, EPA (2017a) continues to include studies with amounts of impurities of malathion, including malaoxon, isomalathion, and (O,O,S-trimethyl phosphorothioate), that are greater than in the malathion produced by Cheminova today, which has less of these impurities than malathion produced in the past by American Cyanamid or Chem Service. EPA (2017a) also continued to stand by the conclusion that toxicity data for malathion of different impurities are comparable if they are "well within one order [of magnitude] of each other." As stated in Breton et al. (2016c [MRID 49949501]), this should not be the case for every species, and where possible, EPA should default to Cheminova-derived data. This point is further emphasized by the inclusion of inerts in malathion, for which Cheminova only knows the inert profile of the malathion produced by Cheminova and American Cyanamid and, therefore, cannot be certain that toxicity of malathion produced with a different inert profile would be similar.

Cheminova disagrees with EPA's procedure for evaluating chronic risk to aquatic and terrestrial species. Chronic guideline studies typically use continuous pesticide exposures ranging from 21 days for aquatic invertebrates to greater than 10 weeks for birds and mammals. However, such exposures are unrealistic because malathion would, in reality, degrade rapidly between applications, particularly in marine environments, making pulse exposures far more relevant than maintained chronic exposures. For example, in a targeted monitoring study conducted by Gulka et al. (2016 [MRID 49949503]), malathion concentrations in two Oregon streams were measured at least every six hours over a two-month period of intensive malathion use on cherries. Using the data from Gulka et al. (2016 [MRID 49949503]), 21-day rolling averages of malathion concentrations were calculated for Mill Creek and Three Mile Creek. Samples with non-detectable levels of malathion were estimated to be equal to half the LOD of 0.010 µg/L. The 21-day average concentrations ranged from 0.0218 to 0.0561 µg/L and from 0.0154 to 0.0364 µg/L for Mill Creek and Three Mile Creek, respectively, and are both below the most sensitive chronic NOEL for *Daphnia magna* (0.06 μg/L; Blakemore and Burgess, 1990 [MRID 41718401]).

(Breton et al. 2016c [MRID 49949501]) and CLA (2016) expressed concern with the Agency's approach to choosing effects thresholds for chronic exposures. In the final BE, NOELs drive many of the risk designations, and in turn the species and critical habitat calls (EPA 2017a). The use of NOELs in ecological risk assessment has long been criticized (Hoekstra and Van Ewijk, 1993; Moore and Caux, 1997; Landis and Chapman, 2011; Jager, 2012; Murado and Prieto, 2013). This criticism stems from the inherent deficiencies of the metrics as a relative measure of toxicity, which include an absolute dependence on the selected treatment levels and sample size, and related issues of low statistical power. As a result, regulatory risk assessors are moving away from the use of NOELs in favor of ECx values (e.g., OECD, 1998; CCME, 2007). Given the criticism of using NOELs in ecological risk assessment in the peer-reviewed scientific literature, it is surprising that the Agency would consistently use these metrics in an evaluation that is purported to be based on best available scientific information. In the Interagency Interim Approaches, the Agencies (2013) stated that ECx values would be considered in the interim approach. However, it seems that in most cases the EPA opted to circumvent data analyses and simply use the author-reported NOELs from toxicity studies.

4.1.3 Consideration of Endpoints of Uncertain Ecological Relevance

Cheminova (Breton et al., 2016c [MRID 49949501]) and CLA (2016) disagree with the method by which EPA (2017a) has ignored the Interagency Interim Approaches (Agencies, 2013) in selecting toxicity studies for use in establishing "may effect" thresholds. The Agencies (2013) stated that "Establishing "may effect" thresholds for given taxa may also, when supported by professional judgment, be based on toxicity studies that are conducted at the sub-organism level (*e.g.*, on organs or cells), provided they can be linked to environmentally relevant exposures that can influence survival, growth, or reproduction". However, in Attachment 1-4 of the final BE (EPA, 2017a), EPA notes that "Establishing "may affect" thresholds for given ESA-listed taxa may also be based on toxicity studies that are conducted at the suborganismal level (e.g., on organs or cells), provided data are consistent with other criteria for use." It is not explained further how such suborganismal data could be used in the BEs to establish thresholds, especially given the difficulty of relating such endpoints to effects on survival, growth or reproduction.

To properly incorporate sublethal effects into an ecological risk assessment, it is necessary to provide an explicit relationship between the sublethal effect in question and the protection goals (e.g., individual fitness). In many cases, where EPA (2017a) has presented sublethal endpoints (e.g., the inclusion of biochemical, cellular, and behavioral effects in many of the 'data arrays'), there is no discussion as to the ecological relevance of these endpoints with respect to the protection goals of the assessment. Without establishing this relationship, it is unclear how these effects can be considered in a weight of evidence approach.

4.1.4 Mismatch of Exposure Duration Between Toxicity Endpoints and Estimated Environmental Concentrations (EECs)

As in the draft BE, EPA (2017a) predicted acute risk to aquatic organisms by comparing instantaneous aquatic peak EECs to threshold values derived from toxicity tests wherein organisms were exposed to constant concentrations of malathion for much longer exposure durations. For example, EPA (2017a) relied on 96-hour toxicity tests to derive acute effects thresholds for fish and 48-hour or 96-hour toxicity tests to derive acute effects thresholds for aquatic invertebrates. However, malathion degrades very quickly in aqueous systems, with estimated half-lives ranging from 0.3 to 3.3 days (Blumhorst, 1991 [MRID 42271601]; Knoch, 2001b [MRID 46769502]; Hiler and Mannella, 2012 [MRID 48906401]). It is highly unlikely that aquatic organisms would be exposed to a 'peak' concentration of malathion for a 48- or 96-hour period under realistic conditions. Therefore, the EPA (2017a) risk assessment approach conservatively assumes that exposure to a peak malathion concentration followed by rapid dissipation/ degradation will result in the same effects on fish and aquatic invertebrates as exposure to a constant concentration of malathion for a 48- or 96-hour duration.

Cheminova has previously demonstrated (Breton et al., 2016c [MRID 49949501]) that LC50 values are much higher at shorter exposure durations for malathion for freshwater and marine/estuarine fish and aquatic invertebrates. As malathion is rapidly degraded and dissipated in water bodies, the EPA approach is likely to overestimate risk for both acute and chronic exposures. Cheminova maintains that comparing existing acute effects data with time weighted average exposure concentrations compatible with appropriate toxicity test durations will more appropriately estimate risk.

4.1.5 Degradates of Concern

In Breton et al. (2016c [MRID 49949501]), Cheminova disputed EPA's (2016a) assertion that malaoxon is a "significant concern for ecological risk." EPA (2017a) maintains this conclusion in the final BE and provides a qualitative assessment for malaoxon. Cheminova disagrees, as based on the available fate and toxicity data for malaoxon, it is unlikely to contribute significantly to ecological risk of organisms compared to the parent compound. Specifically, although malaoxon has been demonstrated to be slightly more toxic than malathion to some aquatic species, the fate and behavior of malaoxon suggests that it is likely not produced in the aquatic environment. Moreover, malaoxon degrades rapidly in water, sediment and soil samples. On the rare occasions when it is detected, malaoxon is found only at small percentages of applied malathion. As such, malaoxon is unlikely to be transported at environmentally relevant concentrations in which exposure would cause significant effects on growth, reproduction and survival. In the terrestrial environment, malaoxon has half-lives shorter than one day, indicating that malaoxon degrades quickly on arthropods and vegetation, which are important feed items for terrestrial organisms. Given the above, risk associated with malaoxon exposure is likely negligible for birds and mammals.

4.1.6 Incident Reporting

Cheminova and CLA have previously identified issues with EPA's (2016a) incident reporting sections not following their written guidance (EPA, 2011b) that were not modified in EPA (2017a), including:

- Incidents in the "unlikely" and "unrelated" certainty categories were not evaluated for accuracy per EPA guidance.
- EPA did not evaluate the results for applicability to currently registered uses and products.
- EPA did not determine if mitigation measures have been put in place since the incident to prevent similar incidents from re-occurring.

Further, EPA still presents a lobster incident with no causative link between pesticide exposure and the observed incident (Pearce and Balcom, 2005) and improperly discusses aggregate plant incidents in the section covering incidents to aquatic plants.

4.2 Taxon-specific Review and Critique of Effects Characterizations Presented in Chapter 2 of EPA (2017a)

4.2.1 Fish and Aquatic-phase Amphibians

Cheminova identified a number of concerns with the effects metrics selected by EPA (2016a) to assess risks to fish and aquatic-phase amphibians. Data quality is of very high concern. Many of the studies relied upon by EPA (2016a) were of dubious relevance and quality, and study evaluations were often not provided by EPA (2016a) to confirm study ratings. Reliance on all available data without a data quality evaluation is unacceptable (Breton et al., 2016c [MRID 49949501]; CLA, 2016).

EPA (2017a) has not remedied the situation. EPA (2017a) included only one additional open-literature study evaluation for fish and did not evaluate any additional registrant-submitted studies, nor did they explain why. Given the importance of study evaluation for quality and relevance, EPA (2017a) does not present sufficient information to suggest that the data relied on in the final BE are of adequate quality to be used in risk assessment per guidance provided by EPA (2011c), NRC (2013), and FMC (Breton et al., 2014a [MRID 49333901]).

Additionally, EPA (2016a) used surrogate fish toxicity data to estimate effects to aquatic-phase amphibians, despite the availability of high quality toxicity data for amphibians. EPA guidance indicates that data for under-represented taxa are preferred over surrogate species data, regardless of whether the endpoints are more or less sensitive (Section 2.1.2 in EPA, 2011c).

EPA (2017a) has maintained the use of fish toxicity data as surrogates for aquatic-phase amphibians, despite the availability of high quality taxon-specific data. We disagree with this approach because fish and aquatic-phase amphibians have very different sensitivities to malathion. Cheminova has previously identified acute and chronic malathion toxicity data for the African clawed frog (*Xenopus laevis*) from Palmer et al. (2011a,b [MRID 48409302, 48617501], as reviewed by Breton et al., 2014a [MRID 49333901]). The acute LC50 and chronic NOEC derived by Palmer et al. (2011a,b [MRID 48409302, 48617501]) for the African clawed frog are 4700 and ≥320 µg a.i./L, respectively. When compared to the HC5 from the fish SSD (12.3 µg a.i./L) and the chronic NOEC (8.2 µg a.i./L) for the sheepshead minnow (*Cyprinodon variegatus*) (Hurd and Sharpe, 2011 [MRID 48705301]), it is obvious that aquatic-phase amphibians are substantially less sensitive to malathion than fish. Therefore, it is inappropriate to use fish toxicity data to assess the potential for risk to aquatic-phase amphibians from malathion application. Use of fish toxicity data in place of high quality toxicity data for aquatic-phase amphibians could greatly overestimate the potential for risk.

4.2.2 Aquatic Invertebrates

Cheminova (Breton et al., 2016c [MRID 49949501] and CLA (2016)) critiqued the lack of transparency in the effects assessment for aquatic invertebrates. Many study evaluations for open-literature data were not provided and registrant-submitted studies were not evaluated. EPA provided no explanation as to why these studies were not evaluated for relevance and data quality. EPA (2016a) did not present sufficient information to suggest that the data relied on in the SSD were of sufficient quality to be used in a risk assessment. Of the 60 studies used by EPA (2016a) in their SSD, 32 have been previously reviewed by Cheminova (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]). Only five of the evaluated studies were rated acceptable, one was supplemental, and 26 were unacceptable. Therefore, the majority of studies used by EPA (2016a) to construct their acute SSD for aquatic invertebrates were of unacceptable quality. EPA (2017a) included only two additional open literature study evaluations for aquatic invertebrates and did not evaluate any registrant-submitted studies. Thus, sufficient information was not provided to support a scientifically defensible SSD.

Cheminova also identified a transcription error in Table 3-3 of EPA (2016a), where an EC/LC50 value for *Palaemonetes pugio* was incorrectly entered as 67,000 µg/L, rather than 67 µg/L (MRID 49534902). EPA (2017a) has since corrected that error and it appears that the corresponding SSD has also been updated. However, the erroneous endpoint value is still referred to in the text on p. 2-73 and again on p. 2-103.

To assess chronic effects to aquatic invertebrates, EPA (2016a) selected a capture net abnormalities/AChE endpoint from Tessier et al. (2000 [E65789]). This study was rated as unacceptable by Cheminova because no explicit link was demonstrated between the reported endpoint (capture net abnormalities/AChE) and standard risk assessment endpoints (i.e., survival, growth, and/or reproduction). For use in risk assessment, the selected endpoint must demonstrate biological significance by representing a level of inhibition during a realistic timeframe of exposure (i.e., exposure to the particular life stage during a time when peak malathion would be experienced), that is associated with a clinical sign of toxicity that could affect growth, reproduction, or survival. However, EPA (2017a) has changed this endpoint for their final BE, and has selected a NOEC of 0.06 µg/L for reproduction of *Daphnia magna*, which is consistent with the chronic endpoint selected by Cheminova (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]).

EPA (2017a) did not identify an independent chronic endpoint for estuarine/marine invertebrates. Instead, EPA (2017a) selected the freshwater *D. magna* endpoint, despite the availability of high quality studies for estuarine/marine invertebrates. Given the large difference in sensitivity between freshwater (*D. magna* NOEC = 0.06 µg/L; Blakemore and Burgess, 1990 [MRID 41718401]) and estuarine/marine invertebrates (*Americamysis bahia* NOEC = 0.29 µg/L; Claude et al., 2012 [MRID 48752901]), EPA (2017a) may have significantly overestimated the potential for risk to estuarine/marine invertebrates. FMC recommends the use of estuarine/marine data when available as per EPA guidance which indicates that sensitive marine/estuarine invertebrate studies should be selected to assess effects to such species belonging to this taxa (EPA, 2011c).

4.2.3 Aquatic Plants

In their draft BE, EPA (2016a) relied on a single study to assess the potential for effects to aquatic plants. However, this study (Yeh and Chen, 2006 [MRID 48078001] [E85816]) was rated as unacceptable by Cheminova because it lacked information about study methods, test item purity, and control performance (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]). Additionally, use of a single effects endpoint for aquatic plants does not allow for differentiation between vascular and non-vascular or freshwater and estuarine/marine receptors. However, in their final BE, EPA (2017a) updated effects metrics for their final BE and selected endpoints for both vascular and non-vascular plants. FMC agrees with the studies selected for vascular plants (Dobbins et al., 2012a [MRID 48998003]) and non-vascular plants (Dobbins et al., 2012b [MRID 48963311]) and has rated both studies as acceptable. However, EPA (2017a) failed to address risks to estuarine/marine non-vascular plants, despite the availability of a high-quality study (Dobbins et al., 2012c [MRID 48998002]), and has yet to update the summary text in Section 4.8 of Chapter 2 regarding aquatic plant threshold values.

4.2.4 Aquatic Communities

EPA (2016a) summarized 13 higher-tier (e.g., mesocosm, microcosm) studies that evaluated the effects of malathion on aquatic communities (invertebrates, plants, amphibians). However, Cheminova (Breton et al., 2016c [MRID 49949501]) highlighted a number of missing references in EPA's (2016a) list and provided 13 additional references that EPA (2016a) did not include. Cheminova also identified a number of references that were not completed or were not provided, and requested greater transparency from EPA to consider key studies. Although, EPA (2017b) stated that attempts were made to increase transparency of EPA (2017a), numerous reference citations were still not provided and many studies missing from the draft BE were still not considered in the final BE.

4.2.5 Birds

Cheminova reviewed the effects metrics selected by EPA (2016a) for birds, reptiles and terrestrial-phase amphibians (Breton et al., 2016c [MRID 49949501]). Although EPA (2016a) constructed an acute SSD from available toxicity data for birds, three of the five studies used in the SSD were rated as unacceptable upon evaluation by Cheminova (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]). Therefore, there were insufficient high quality data to generate an SSD and Cheminova recommended the use of a single effects value for birds.

EPA (2017a) chose to eliminate the bird SSD and instead chose sensitive acute oral (Hubbard and Beavers, 2012a [MRID 48963305]) and dietary (Gallagher et al., 2003 [MRID 48153106]) toxicity studies to derive effects metrics. Cheminova (rated both studies as acceptable and agrees with the selected effects metrics (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]).

To assess chronic sublethal effects to birds, EPA (2016a) selected a chronic dose-based study (Day et al., 1995 [E63276]) that Cheminova rated as unacceptable because it lacks information on study methods and control results (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]). Additionally, the endpoint reported in Day et al. (1995 [E63276]) is based on sublethal AChE inhibition and is used as a threshold value. EPA (2017a) has maintained this threshold value in their final BE. Inhibition of AChE is not biologically relevant unless it is directly associated with an observed, standard, adverse measure of effect (i.e., survival, growth, or reproduction) (CLA, 2016). Furthermore, studies have shown that AChE inhibition in birds has been found to return to control levels within 24 hours of sublethal doses of malathion (Pym et al., 1984; Mehrotra et al., 1967). In birds, malathion is rapidly absorbed, filtered, and metabolized to non-toxic metabolites then excreted via urine (Cannon et al., 1993 [MRID 42715401]; Gupta and Paul, 1977). In addition, birds have demonstrated avoidance behavior to dietary items treated with malathion. In the laboratory, birds often reduce their feeding rate when exposed to acutely toxic pesticides in their food, particularly organophosphates and carbamates (Kononen et al., 1987; Bennett, 1989; Grue et al., 1997; EFSA, 2005; Fischer et al., 2005; Stafford, 2007; Springborn Smithers Laboratories, 2008). The reduction in feeding rate may be due to: (i) repellent taste or odor (e.g., methiocarb; Kononen et al., 1987), or (ii) post-ingestional toxicity, which is a common mechanism for acetylcholinesterase-inhibiting pesticides (Grue et al., 1997; Fischer et al., 2005). For malathion, avoidance has been noted during field studies. Hill et al. (1971) and McLean et al. (1975) reported that bird populations may emigrate away from or avoid foraging in malathion-treated areas. Further, birds exhibiting sublethal signs of toxicity (e.g., lethargy, ruffled appearance, wing droop, loss of coordination, etc.) following exposure to malathion returned to normal condition within two hours to eight days and did not exhibit gross pathological changes. Clinical findings and necropsies of birds suggest that individuals recover quickly from sublethal toxicity (Breton et al., 2016c [MRID 49949501]). Therefore, the link between AChE inhibition and apical endpoints (i.e., survival, growth and/or reproduction) is unclear, particularly for wild bird species. As noted by NRC (2013) and CLA (2016), to properly incorporate sublethal effects into an ecological risk assessment, it is necessary to provide an explicit relationship between the sublethal effect in question and protection goals (e.g., individual fitness). The use of an AChE endpoint by EPA (2017a) is unwarranted.

4.2.6 Reptiles and Terrestrial-phase Amphibians

In their draft BE, EPA (2016a) applied their acute bird SSD and chronic bird endpoints to assess risk to reptiles and terrestrial-phase amphibians (herptiles). As with the bird assessment, EPA used a single bird LD50 instead of a bird SSD in their final BE (EPA, 2017a). The similarity in sensitivity among birds, reptiles and terrestrial-phase amphibians is unknown. Cheminova has conducted a GLP acute oral toxicity test on the bullfrog (*Lithobates catesbeianus*) (Fort, 2015 [MRID 49693705]). This study has been rated acceptable according to Cheminova's study evaluation criteria (Breton et al., 2015 [MRID 49692301]). Since taxon-specific data are now available, FMC does not support using bird toxicity data to assess risk to herptiles. This is also supported by existing EPA guidance, which states that data for under-represented taxa are preferred over surrogate species data (EPA, 2011c). Therefore, FMC suggests that data from Fort (2015 [MRID 49693705]) should be applied to assess risk to herptiles rather than grouping herptiles with birds.

Lacking any chronic toxicity data for herptiles, it is appropriate to calculate an acute-to-chronic ratio (ACR) to estimate a chronic effects threshold. Using acceptable toxicity studies, ACRs for malathion were developed by Cheminova for three vertebrate species: northern bobwhite (*Colinus virginianus*), mallard (*Anas platyrhynchos*), and rat (*Rattus norvegicus*). The ACRs were developed using acute LD50s and chronic NOELs (in mg a.i./kg bw/d; Rodgers, 2002 [MRID 48153114]; Beavers et al., 1995 [MRID 43501501]; Hubbard and Beavers, 2012b [MRID 48963307]; Pedersen and Fletcher, 1993 [MRID 42782101]; Moore, 2003 [MRID 48153112]; Schroeder, 1990 [MRID 41583401]). For bobwhite, mallard and rat, the calculated ACRs were 27.4, >20.6 and 5.10, respectively. The most conservative ACR (27.4) was applied to the LD50 from the acute bullfrog study (1672 mg a.i./kg bw; Fort, 2015 [MRID 49693705]), resulting in a chronic NOEL of 61.0 mg a.i./kg bw/d. A similar process was used to estimate a chronic LOEL of 164 mg a.i./kg bw/d. These values can be used in place of bird toxicity data for the risk assessment.

4.2.7 Mammals

To derive their acute effects threshold for mammals, EPA (2016a) used a study categorized as qualitative in their open literature review summary (Mendoza, 1976 [MRID 45046301, E35348]). EPA (2016a) clearly noted in their problem formulation that only quantitative data can be used as a threshold value. The reliance on this study to generate a threshold value is questionable given that control performance was not reported in Mendoza (1976 [MRID 45046301, E35348). Therefore, it was unclear if the observed response in the treated pups was statistically different from control. Moreover, a 1-day old rat feeds only on the mother's milk. It would not be exposed to outside dietary exposure at that young age except through the milk thus the results are not representative of exposure possibilities in the wild. In fact, results of Fulcher (2001 [MRID 45566201) showed that in 4-day old pups, with potential exposure to malathion only through dam's milk, maternal exposures of 5 to 150 mg/kg bw/d (for approximately three week prior to post-natal day 4) resulted in no AChE inhibition in red blood cells, plasma and brain. Mendoza (1976 [MRID 45046301]) was rated as unacceptable by Cheminova due to lack of control data (Breton et al., 2016c [MRID 49949501]).

EPA (2017a) has updated their effects metrics for their final BE. For acute effects, EPA (2017a) selected an LD50 of 1560 mg/kg bw from Fischer (1991a [MRID 49127003]). This study was rated as supplemental by Cheminova, but is not appropriate for use because the test substance was formerly registered by American Cyanamid, is no longer produced or sold in the US, was produced by American Cyanamid using a process no longer relevant in the US, and contains a different impurity profile compared to Cheminova's technical malathion. A companion study was conducted using the malathion technical produced by Cheminova's improved manufacturing process identified an LD50 of 4016 mg/kg bw (Fischer, 1991b; MRID 49127004). Comparison of the results for these two studies shows that Cheminova's malathion technical is 2.6 times less toxic compared to the malathion technical previously produced by American Cyanamid and is primary evidence showing the importance of the impurity profile in determining the toxicity of the technical form of malathion. Additional information on this topic was provide in Hillwalker and Reiss (2014 [MRID 49316501]).

Given the presence of isomalathion in the technical product administered by Fischer (1991a [MRID 49127003]), Cheminova recommends using the oral gavage LD50 of 2,010 mg a.i./kg bw for the rat as a conservative screening-level effects concentration for assessing acute risk to mammals (Moore, 2003 [MRID 48153112]). This is a GLP study conducted with technical grade malathion and was rated acceptable based on Cheminova's study evaluation criteria. The endpoint is supported by the results of other acceptable and supplemental studies (Fischer, 1991b [MRID 49127004]; Kuhn, 1996 [MRID 49127002]; Kynoch, 1986 [MRID 00159876]; and Terrell et al., 1978 [MRID 00113245]), all of which report higher oral gavage LD50s for mammals.

To derive their chronic effects threshold for mammals, EPA (2016a) incorrectly selected an effects study for malaoxon (Daly, 1996a [MRID 43975201]). Further, this study evaluated AChE inhibition, and the link between AChE inhibition and effects to survival, growth or reproduction are unknown (CLA, 2016). For their final BE, EPA (2017a) changed their chronic effects threshold. However, EPA (2017a) again selected an AChE inhibition study (Barnett, 2006 [MRID 46822201]). As stated previously, the applicability of AChE inhibition to effects on survival, growth and reproduction is unclear (CLA, 2016). To use AChE inhibition as an effect threshold, EPA must identify the level of AChE inhibition necessary to affect growth, reproduction or survival. This was demonstrated.

Cheminova recommends the two-generation reproduction NOEL and LOEL for male parental body weight of 394 mg a.i./kg bw/d and 612 mg a.i./kg bw/d (Schroeder, 1990 [MRID 41583401]), respectively. This is a GLP and guideline-compliant study conducted with technical grade malathion and was rated supplemental using Cheminova's study evaluation criteria. The supplemental rating is based on the use of technical malathion produced by the American

Cyanamid Company, but Cheminova is generally aware of the purity and impurity profile of the malathion used in American Cyanamid studies. Although other acceptable chronic mammalian studies are available, Schroeder (1990 [MRID 41583401]) was the only two-generation reproduction toxicity test conducted for malathion.

In addition to the screening-level effects thresholds, EPA (2017a) provided a table of additional sublethal effects data to be used for refinements. These data were the same as those presented by EPA (2016a) and we maintain the same concerns. Specifically, none of the studies were evaluated for study quality by EPA, and only one (Schroeder, 1990 [MRID 41583401]) of five was rated as acceptable by Cheminova. The others received unacceptable ratings. Geraldi et al. (2008 [E153607]) was a limit test (one test concentration) whereby malathion (formulation not reported) was sprayed homogeneously over a monolayer of food pellets. This is not a standard protocol for dietary studies. In Acker et al. (2011 [E162509]), validation of behavior results to ensure detection of meaningful and age-appropriate behavioral changes was not documented. Siglin (1985 [MRID 40812001]) exposed rabbits (not rats, as documented in EPA, 2017a) to malathion (92.4% a.i.; American Cyanamid Cythion) via an irrelevant exposure pathway whereby animals were dosed daily for 12 consecutive days. Finally, information pertinent to study methods, including test substance, control results, test concentrations used, and physical properties of the testing environment, were missing from Samaan et al. (1989 [E74457]), and no NOEC was calculated. Therefore, FMC does not recommend using these studies for any refinements.

4.2.8 Terrestrial Invertebrates

In their draft BE, EPA (2016a) generated effects thresholds for terrestrial invertebrates from three studies that were rated unacceptable by Cheminova (Robertson et al., 1975 [E89288]; Panda and Sahu, 1999 [E052962]; Lingappa et al., 1985 [E94337]). These studies did not report control mortality, lacked sufficient details, and/or used an invalid malathion formulation. Cheminova (Breton et al., 2016c [MRID 49949501]) suggested that EPA use higher quality data that follow recognized guidelines.

EPA (2017a) updated their effects thresholds in favor of higher quality data. Their pollinator threshold was derived from a study rated acceptable by Cheminova and appropriate for use in risk assessment (Sindermann and Porch, 2013a [MRID 49270301]). Likewise, their earthworm threshold was derived from a GLP registrant-submitted study (Stäbler, 2001 [MRID 49086402]), but is not considered by Cheminova to be best available data because the test substance was a formulation comprised of nearly 60% uncharacterized ingredients. Cheminova recommends using an OECD guideline study with a known technical product. For example, Wüthrich (1991 [MRID 49086403]) investigated the acute toxicity of Fyfanon technical grade malathion (96.2% purity) to earthworms (*Eisenia fetida* Savigny). The reported 7-day and 14-day LC50s were 641 and 590 mg a.i./kg dw soil, respectively. As this study was performed under GLP conditions using technical grade malathion of known composition and supplied by Cheminova, it was considered the best available data.

EPA (2017a) maintained their original threshold value for non-target terrestrial invertebrates (Robertson et al., 1975 [E89288]). This study was non-guideline, control mortality was not reported, and the source of the malathion used for testing was not provided.

4.2.9 Terrestrial Plants

In their draft assessment, EPA (2016a) used acceptable GLP studies to assess effects to monocots and dicots (Sindermann et al., 2013a, 2013b [MRIDs 49076001; 49076002]), but used a separate study for "all terrestrial plants" (Ahrens, 1990 [E068422]). Cheminova rated Ahrens (1990 [E068422]) as unacceptable because it lacked information on test substance purity, source, and contents of the formulation, and didn't use a solvent control. Additionally, although EPA (2016a) indicated in their study review of Ahrens (1990 [E068422]) that statistically significant reductions in plant fresh weight were observed for plants treated at a rate of 0.5 lb/acre, no indication of statistical significance is provided in the original study, and raw data were unavailable.

For their final assessment, EPA (2017a) updated their effects thresholds and used the acceptable Sindermann et al. (2013a, 2013b [MRIDs 49076001; 49076002]) studies for all thresholds. FMC agrees with the use of these studies for risk assessment.

4.3 Errors and Discrepancies in Aquatic and Terrestrial Threshold Values

EPA's (2017a) threshold values are presented in several locations throughout the BE:

- Chapter 2;
- Appendix 3-6;
- AquaWoE_v1.0.xls ('Species Summary' and 'Spray Drift all' worksheets); and,
- TEDtool_v1.0.xls and TEDtool_v1.0_alt.xls ('inputs' worksheets).

Several discrepancies have been identified between the threshold values presented in Chapter 2 of the final BE (EPA, 2017a) and the effects metrics used as inputs for the risk characterization presented in Appendix 3-6 and the AquaWoE_v1.0.xls / TEDtool_v1.0.xls files of the final BE (EPA, 2017a). In some cases, values presented in Chapter 2 are absent from the TED tool model inputs spreadsheets, and in other instances there are endpoints in Appendix 3-6 and the TED tool inputs that are not presented as threshold or endpoint values in Chapter 2 of the final BE. This includes the presentation of some endpoints with no references available to identify the studies they originate from. There are also several instances of erroneous details in the study endpoints and/or references between these files. Details of these discrepancies and errors are further described in Table 4-1 and Table 4-2. Note that this discussion does not include reference to the quality of the studies presented. Some of these studies were previously discussed in Section 4.2 of this response document.

It is not clear how EPA (2017a) selected some of the thresholds used in the modeling exercises. In Chapter 2, there are tables of threshold values for each taxon to be used in the Step 1 analysis. For some taxa, but not consistently for all, there are tables of endpoints to be used as 'potential refinements', which are presumably for the Step 2 analyses. However, it is not explicitly explained which endpoints were selected for Step 2, how they were selected, or how they were used.

A number of errors and discrepancies identified by FMC (Breton et al., 2016c [MRID 49949501]) during review of the draft BE (EPA, 2016a) were fixed by EPA (2017a) in their final BE. These errors included discrepancies between HC5s listed in Chapter 2 and Appendix 3-6, citation errors, incorrect pairing of NOEC and LOEC values, and inclusion of unnecessary endpoints. In their response to the BE comments, EPA (2017b) stated that they will address comments on malathion effects endpoint review if it is "regarding the potential changes in the toxicity of malathion as it degrades over time and impurities that may be present with malathion". Despite their commitment to addressing comments on malathion toxicity and general error correction, EPA did not amend the majority of reported errors on malathion effects. These errors are described in the tables below.

Table 4-1 Discrepancies between EPA thresholds and effects endpoints for aquatic receptors reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	*Endpoint*	*Chapter 2*		*Appendix 3-6*		*Comments*
		Value (µg/L)	*Reference [MRID]*	*Value (µg/L)*	*Reference [MRID]*	
Aquatic amphibians, freshwater fish and marine fish	Reproduction endpoint – NOAEC/LOAEC	220/690	Palmer et al., 2011c [48617506]	220/690	Palmer et al., 2011c [48617506]	The NOEAC presented in Table 2-2 of Chapter 2 (NOEC = 220 µg a.i./L) differs from the value reported in Section 2.4.2.2 of Chapter 2 (NOEC = 250 µg a.i./L). The author-reported NOEC was 250 µg a.i./L (Palmer et al., 2011 [MRID 48617506]). EPA (2017a) did not describe how they derived the NOEC of 220 µg a.i./L. Measured malathion concentrations are presented in Table 3 of Palmer et al. (2011 [MRID 48617506]). Day 21 concentrations were not included in the calculation of mean measured concentrations due to a sample handling or analysis error. However, EPA appears to have included the day 21 samples in their calculation of mean measured concentrations. Furthermore, EPA appears to have averaged all sample measurements together rather than averaging the day 0, 7, 14 and 21 averages. This practice biases the mean towards the day 0 and day 21 concentrations since four samples were analyzed on these days, whereas only two samples were analyzed for days 7 and 14.
Marine fish	Growth endpoint - NOAEC	>18	Hansen and Parrish, 1977 (E5074); Hurd and Sharpe, 2011 [48705301]	21	Cohle, 1989 [41422401]	The NOEC of >18 ug a.i./L for effects to growth and reproduction in sheepshead minnow was presented for marine fish in Table 2-2 of Chapter 2. However, the growth endpoints for freshwater fish were presented in Appendix 3-6. Moreover, neither of the studies EPA references in chapter 2 (Hansen and Parrish, 1977 (E5074) and Hurd and Sharpe, 2011 [MRID 48705301] report endpoints of >18 µg/L"
	Growth endpoint - LOAEC	>18		44		

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial receptors reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6		Comments
			Value	Reference [MRID]	Value	Reference [MRID]	
Birds	Direct and indirect	Sublethal	87.4 mg/kg bw	E63276	87.4 mg/kg bw	E63275	Firstly, the ECOTOX ID is incorrect in Appendix 3-6. The correct ID is E63276, as reported in Chapter 2. Secondly, the organism weight applied in Appendix 3-6 is 1135 g, which is a default weight assigned to ring-necked pheasants. However, the ring-necked pheasants in the toxicity study weighed between 400 and 500 g. This apparent error has significant impact on the effects metrics used in the listed species assessment.
Herptiles	Direct	Sublethal	87.4 mg/kg bw (ring-necked pheasant)	Hubbard and Beavers, 2012a [48963305]	670 mg/kg bw (bullfrog)	Fort, 2015 [49693705]	It appears that rather than relying solely on avian toxicity data as a surrogate for terrestrial-phase amphibians and reptiles (which is stated to be the approach in Chapter 2), the bullfrog toxicity study was selected for the sublethal values for herptiles (Appendix 3-6). However, it is not clear how those data will be used in the effects determination. Further, the bullfrog study is based on acute exposure and the effects endpoints are for short-term, sublethal effects, not chronic.
	Indirect	Sublethal	87.4 mg/kg bw (ring-necked pheasant)		1030 mg/kg bw (bullfrog)		
	Not specified	Various	Various	Various	Not Reported	-	There are several endpoints reported in both Table 7-1 "Toxicity Data for Reptiles" and 8-1 "Toxicity Data for Terrestrial-phase Amphibians" of Chapter 2 that are not applied in Appendix 3-6 or the 'inputs' tab of TEDtool_v1.0.xls. It is not clear how EPA decided between avian surrogate toxicity data and herptile data when available.
Mammals	Direct and indirect	Sublethal (AChE inhibition)	9.1 mg a.i./kg bw	Barnett, 2006 [46822201]	20 mg/kg diet	[43942901]	EPA (2017a) incorrectly cited the MRID as 43942901 (Daly, 1996b) in Appendix 3-6, when the correct MRID for this study is 43975201 (Daly, 1996a). However, this study used malaoxon rather than malathion as the test substance. EPA (2017a) updated this effects threshold in Chapter 2 since the draft BE (EPA, 2016a), but failed to update Appendix 3-6, cells E98 and E107.

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial receptors reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2		Appendix 3-6		Comments
			Value	Reference [MRID]	Value	Reference [MRID]	
	Direct	Reproduction NOEC	25 mg/kg bw	Siglin, 1985 [40812001]	825 mg/kg diet	Siglin, 1985 [40812001]	In Chapter 2 of the BE, this study is presented in Table 9-3. Although the test species is listed as a rat, this is a developmental rabbit study. The endpoint reported in Appendix 3-6 and the 'inputs' tab of TEDtool_v1.0.xls is reportedly converted to mg/kg diet. However, the test organism weight is not provided and it is not clear how EPA converted this endpoint.
	Direct and indirect	Reproduction LOEC	50 mg/kg bw		1650 mg/kg diet		
	Direct and indirect	Behavior LOEC	100 mg/kg bw	Acker et al., 2011 (E162509)	Not Reported	-	This endpoint is presented in Table 9-3 of Chapter 2, but it is not clear how it was used in Step 2 of the BE. It does not appear to have been used in Appendix 3-6 (or the 'inputs' tab of TEDtool_v1.0.xls).
	Direct and indirect	Growth LOEC	10 mg/kg bw	Samaan et al., 1989 (E74457)	NR	-	This endpoint is presented in Table 9-3 of Chapter 2, but it is not clear how it will be used in Step 2 of the BE. It does not appear to have been used in Appendix 3-6 (or the 'inputs' tab of TEDtool_v1.0.xls).
	Direct and indirect	Reproduction NOEC	7500 mg/kg diet	Schroeder, 1990 [41583401]	Not Reported	-	This endpoint is presented in Table 9-3 of Chapter 2, but it is not clear how it was used in Step 2 of the BE. It does not appear to have been used in Appendix 3-6 (or the 'inputs' tab of TEDtool_v1.0.xls).
Terrestrial Invertebrates	Direct and indirect	Lowest LC50; sublethal	0.38 µg a.i./bee	[05001991, 05004151]	1.3 mg/kg food	Bee Rex calculator (based on LC50 of 0.38 µg a.i./bee; MRIDs 05001991, 05004151)	The 1.3 mg/kg food endpoint is not presented in Chapter 2. There is no mention of the use of Bee Rex in Chapter 1 or Chapter 2 of the BE.
	Direct and Indirect	Reproduction LOEC	1100 mg/kg soil	Not Reported	1100 mg/kg soil	Panda and Sahu, 1999 (E52962)	While this endpoint is presented as the reproduction LOEC for terrestrial invertebrates in Appendix 3-6 and the 'inputs' tab of TEDtool_v1.0.xls, in Chapter 2 the endpoint value is mentioned only in the text of Section 10.4.2 of the BE, and without reference details.

Table 4-2 Discrepancies between EPA thresholds and effects endpoints for terrestrial receptors reported in Chapter 2 of EPA's BE (EPA, 2017a)

Taxon	Threshold Type	Threshold Description	Chapter 2 Value	Chapter 2 Reference [MRID]	Appendix 3-6 Value	Appendix 3-6 Reference [MRID]	Comments
	Direct and Indirect	Growth LOEC	0.456 lb a.i./A	Not Reported	0.456 lb a.i./A	(E158669)	While this endpoint is presented as the growth and reproduction LOEC for terrestrial invertebrates in Appendix 3-6 and the 'inputs' tab of TEDtool_v1.0.xls, in Chapter 2 the endpoint value is mentioned only in the text of Section 10.4.2 7 (and without reference details).
	Direct and indirect	Reproduction LOEC					
Terrestrial Plants	Direct	Mortality	2.94 lb a.i./A (Dicots)	Jennings et al., 2012 (E162475)	2.94 lb a.i./A (Monocots and dicots)	Jennings et al., 20121 (E162475)	In Chapter 2, this study is not presented in the table of threshold values (Table 11-1). Rather this study is presented in Table 11-2 "Effects of Malathion on Pink Sundew and Venus Flytrap Survival". In Appendix 3-6 and the 'inputs' tab of TEDtool_v1.0.xls, this value is used for both monocots and dicots, but it is a dicot study. Moreover, EPA cited the year of this study incorrectly. The ECOTOX number E162475 corresponds to Jennings et al., 2012 as per Appendix 2-2.
	Direct and windirect	Reproduction NOEC	Not Reported	-	5.1 lb a.i./A	Not Reported	The 5.1 lb a.i./A endpoint is not presented in Chapter 2. There is no reference provided in Appendix 3-6 or the 'inputs' tab of TEDtool_v1.0.xls. It is unclear where this endpoint comes from.

4.4 Summary of Concern Regarding the Effects Characterization

We have a number of concerns with the effects characterization presented in Chapter 2 of the draft and final biological evaluations for malathion (EPA, 2016a; 2017a). Despite including these concerns in Cheminova's preliminary response document (Breton et al., 2016c [MRID 49949501]), EPA (2017a) failed to incorporate greater transparency and clarity into many of their decisions. Cheminova's major issues with EPA's data selection process and presentation of selected effects thresholds were summarized previously by Breton et al. (2016c [MRID 49949501]) and are summarized again below:

- EPA (2017a) is not transparent in its data quality evaluations and selection of effects thresholds and endpoints for 'potential refinement'. EPA has published several guidance documents to aid in the internal evaluation of toxicity studies (EPA, 2002, 2003, 2004a,b, 2011c). However, it is questionable whether these criteria were consistently followed by reviewers, and evaluations were not provided for the majority of studies presented in EPA's effects characterization. Furthermore, it appears that EPA (2017a) included data in their SSDs from studies that were not formally evaluated by EFED.
- Most studies used by EPA (2017a) as threshold values are classified as unacceptable for risk assessment based on Cheminova's data quality criteria (Breton et al., 2014a [MRID 49333901]; 2015 [MRID 49692301]). The fundamental question of data quality and use of "best available data" does not appear to have been addressed in the final BE.
- Cheminova is the only producer of technical malathion sold in the US. In 1992, Cheminova submitted an updated confidential statement of formula (CSF) with higher malathion purity and reduced impurities. EPA (2017a) did not account for relevance of the test chemical in their data quality evaluations, as many of the studies used to construct SSDs in the BE had a chemical characterization identified as "unknown". This practice is scientifically unsound and goes against the recommendations made in NRC (2013).
- NOELs were the effects thresholds driving most, if not all of the risk designations. The use of NOELs in ecological risk assessment has long been criticized (Hoekstra and Van Ewijk, 1993; Moore and Caux, 1997; Landis and Chapman, 2011; Jager, 2012; Murado and Prieto, 2013) due to the inherent deficiencies of the metrics as relative measures of toxicity. These include an absolute dependence on the selected treatment levels and sample size, and related issues of low statistical power. EPA stated in its Interagency Interim Approaches (Agencies, 2013) that ECx values would be considered. However, it seems that in most cases EPA (2017a) opted to circumvent data analyses and simply use the author-reported NOELs from toxicity studies. Although the use of NOELs may be practical in some instances (e.g., when sample size is large and/or when the data are not conducive to generating a meaningful dose-response), the Agency should give precedence to more refined metrics (e.g., dose-response curves, benchmark doses) in a succeeding analysis, such as Step 2, when possible.
- EPA (2017a) selected thresholds based on sublethal endpoints (e.g., biochemical, cellular, and behavioral effects) without providing evidence of any qualitative or

quantitative link between these endpoints and survival, growth or reproduction. Endpoints without a direct link to specific apical effects are not considered to be biologically significant. EPA (2017a) should not rely on these endpoints when selecting their threshold values and endpoints for 'potential refinement'.

- Cheminova disagrees with EPA's (2017a) procedure for evaluating chronic risk to aquatic and terrestrial species. Chronic guideline studies typically use continuous pesticide exposures ranging from 21 days for aquatic invertebrates to greater than 10 weeks for birds and mammals. However, such exposures are unrealistic because malathion would, in reality, degrade rapidly between applications, particularly in marine environments. Pulse exposures are far more relevant than maintained chronic exposures.
- A number of discrepancies were identified between the thresholds presented in Chapter 2 of the final BE and the effects metrics used as inputs for the risk characterization presented in Appendix 3-6 and the AquaWoE_v1.0.xls / TEDtool_v1.0.xls files. In some cases, values presented in Chapter 2 were absent from the TED tool model inputs spreadsheets, and in other instances there were endpoints in Appendix 3-6 and the TED tool inputs that were not presented as threshold or endpoint values in Chapter 2 of the BE. There were also several instances of erroneous details in the study endpoints and/or references between these files.
- Finally, it is unclear how EPA selected some of the thresholds used in the modeling exercises. In Chapter 2, there are tables of threshold values to be used in the Step 1 analysis for each taxon. For some taxa, but not consistently for all, there are tables of endpoints to be used as 'potential refinements', which are presumably for the Step 2 analyses. However, it is not explained which endpoints were selected for Step 2, how they were selected, or how they were used.

5.0 EFFECTS DETERMINATIONS

5.1 General Comments

Cheminova and other stakeholders had a number of concerns relating to the effects determinations made by EPA on the draft BE (Breton et al., 2016c [MRID 49949501]; CLA, 2016; FESTF, 2016). These comments covered: (1) a noted lack in transparency in how "calls" were made, (2) the combination of unrealistically high exposure estimates compared with dubious "effects" thresholds as decision tools and the persistent use of risk quotients, (3) equal weighting of a wide range of measures of effects (mortality to behavioral and sensory effects), despite the tenuous or missing links between apical measures of effects (mortality, growth and reproduction), and potential observed effects on behavior or senses, (4) disregard for evidence (e.g., incident reports, field studies), including degrees of confidence in designations, in final species and critical habitat calls, and (5) calculation errors. Although some critical calculation errors were addressed in the final BEs, the crux of Cheminova's concerns regarding EPA's malathion final BE have in no way been addressed.

5.2 Weight-of-Evidence Tools

Cheminova and CLA (2016) raised a number of concerns regarding the Agency's WoE tools used to make most species and critical habitat calls. Breton et al. (2016c [MRID 49949501]) conveyed that there was a major lack of transparency and associated inconsistency issues, which included, but were not limited to:

1) inaccessible spreadsheet cells used directly in species and critical habitat calls;
2) inconsistencies between methods described in text, and those carried out in the WoE tools;
3) thresholds used in the WoE model that were not presented as thresholds in the text,
4) misleading risk and confidence categories that had no bearing on species or critical habitat calls;
5) categories of effects that although assessed had no bearing on species or critical habitat calls, and;
6) a presentation of, but lack of consideration for monitoring data, incident reports, mesocosm or field studies in species and critical habitat calls.

We note that all of these issues persist in the final malathion BE. Further, a comparison of the draft and final WoE tools suggests that no significant changes were made to the process of establishing species and critical habitat calls. Accordingly, most of the detailed comments made by Breton et al. (2016c [MRID 49949501]) on the draft malathion BE WoE tools also apply to the final WoE tools.

One exception is the critical error identified in the determination of the risk designation for mortality of terrestrial vertebrates where *dose-based thresholds* in units of mg/kg bw were compared with estimates of *concentration in diet* in units of mg/kg diet. This error was corrected, in that mg/kg bw effects thresholds are now compared with mg/kg bw/d, total daily intake.

Although, the Agency states in both the draft and final BEs that its sublethal threshold for direct effects will be the lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (EC_x) that can be linked to survival or reproduction of a listed individual will be used, in the WoE tools, the EPA employs exceedances of behavioral and sensory endpoints that are not demonstrably linked to survival or reproduction in both their risk designations and species calls.

For both terrestrial and aquatic animals, a likely to adversely affect (LAA) call was made if the risk designation for one or more of:

- mortality,
- growth,
- reproduction,
- behavioral,
- sensory,
- indirect-prey, or;
- indirect-habitat

is medium (MED) of high (HIGH) in the WoE tools, irrespective of confidence designation. Risk designations were based entirely on highly conservative exposure estimates exceeding even one employed threshold. Even if said threshold was not associated with any observed effects on the apical endpoints of survival, growth or reproduction. This and the lack of weight or consideration given to other lines of evidence (e.g., incident reports, field studies) remains contradictory to a legitimate weight of evidence approach that accounts for evidence both for and against a particular risk hypothesis. Comparable approaches were taken for terrestrial and aquatic plants, as detailed in Breton et al. (2016c [MRID 49949501]).

For sublethal effects to animals, EPA has decided to use NOELs as threshold values. Repeatedly, if a NOEL is exceeded by a conservative estimate of peak exposure, the species call is ‘Likely to Adversely Affect’ (LAA). There is no justification for such a conclusion, given that no significant effects are observed at the threshold value in the supporting toxicity test. Also, by definition the upper bound exposure estimates are in fact unlikely. In the context of the protection goals, there is no evidence to suggest that NOEL exceedance would result in adverse effects to individual fitness.

These NOELs are compared to peak exposure estimates, with no accounting for the fact that the exposures in the chronic toxicity tests supporting the effects metrics likely exceeded one day and may have been weeks, months or even years before effects were observed in the LOEL treatment group. The conclusion that a NOEL exceedance for one day establishes that a species is likely to be adversely affected is inadequate on its own, let alone that the exposure estimates are peak or upper bound, and worst-case.

The Agency provides no evidence to support the 1/million mortality threshold *on treated fields* as being directly relevant to a listed species individual fitness. If a species doesn't regularly use managed lands to which pesticides are applied, the 1/million mortality threshold on treated fields is tremendously inappropriate.

Despite the concerns of stakeholders, including Cheminova, the fact remains that the species calls in the final malathion BE are in fact based on a binary assessment of whether or not the most sensitive effects thresholds are exceeded by the highest exposure point estimates. If even one effects threshold is exceeded, the species call is LAA. Confidence designations are not considered in the effects determinations. Overall the species calls lack actual risk estimates. As noted by NRC (2013): "The RQ approach does not estimate risk—the probability of an adverse effect—itself but rather relies on there being a large margin between a point estimate that is derived to maximize a pesticide's environmental concentration and a point estimate that is derived to minimize the concentration at which a specified adverse effect is not expected." The BE would be more robust if complete effects and exposure distributions were considered, and EPA were to evaluate the probability associated with exceeding various levels of effect. This would be consistent with the NRC (2013) recommendation to use probabilistic methods. Clearly this is a recommendation that has been persistently overlooked by the EPA.

5.3 Effects Determinations of NLAA/LAA: Qualitative Analyses

EPA (2017a) presented their qualitative analyses for sea turtles, whales, deep sea fish, marine mammals, and cave dwelling invertebrates in Section 7 of Chapter 4 of the BE. EPA made species calls and critical habit calls (if applicable) of "LAA" for all sea turtle and cave-dwelling invertebrate species, and "NLAA" for all whale and deep sea fish species except for the killer whale (Southern resident DPS). For marine mammals (excluding whales), EPA made species calls and critical habit calls (if applicable) of "LAA" for the Guadalupe fur seal, southern sea otter, Steller sea lion, Hawaiian monk seal, Pacific harbor seal and West Indian Manatee, and "NLAA" for the northern sea otter (Southwest Alaska DPS), bearded seal, Pacific walrus, spotted seal (Southern DPS) and polar bear.

Although this section is titled "Qualitative Analyses", in most cases, EPA (2017a) derived quantitative estimates of exposure and compared these to effects thresholds to characterize risk. As described in other sections of this response document, FMC takes issue with many of the effects metrics selected for the qualitative assessments, with the use of surrogate bins to estimate EECs for marine and estuarine environments, and with the comparison of dietary exposure concentrations to dietary effects metrics. Furthermore, EPA (2017a) made unrealistically conservative assumptions regarding the potential for dermal exposure to sea turtles and dietary exposure to cave-dwelling invertebrates. Many of these assumptions were based solely on professional judgement and not on any reliable data. All the quantitative assessments were deterministic and did not consider the likelihood of species actually being exposed to malathion. Furthermore, even when EPA (2017a) stated that the likelihood of exposure was low (e.g., cave-dwelling invertebrates), species still received LAA effects determinations.

Throughout the qualitative analyses, EPA (2017a) categorized the risk and confidence as low, medium and high for various lines of evidence, including those based on professional judgement. Although EPA's criteria for establishing low, medium and high conclusions for risk and confidence are provided in Attachment 1-9 of the BE, these criteria were only based on EEC exceedances of effects thresholds and cannot be applied for qualitative information. Thus, there is no transparency in EPA's risk and confidence conclusions for several aspects of their qualitative analyses.

5.3.1 Sea Turtle Analysis

In Chapter 4, EPA (2016a) incorrectly cited a BCF of 131 for fish from MRID 43106401. This MRID corresponds to a group of documents for studies conducted by Forbis and Leak (1994a,b [MRID 43106401, 43106402]) and Kammerer and Robinson (1994 [MRID 43340301]). This registrant-submitted study reports a BCF for bluegill (*Lepomis macrochirus*) of 103. EPA (2016a) did not provide a discussion of the study or data used to determine the BCF. Therefore, it is impossible to identify the discrepancy in BCFs and FMC believes that the BCF was used in error.

Despite EPA (2017b) stating that errors and transparency of information would be amended for the final BE, EPA (2017a) failed to address the BCF discrepancy. Instead, EPA (2017a) maintained their original BCF and removed the MRID reference from the text. As a result, even less information is now provided for reviewers to identify or confirm the source of the BCF.

EPA (2016a) estimated an aquatic invertebrate BCF of 72 using the Kow (based) Aquatic BioAccumulation Model (KABAM). However, there was no discussion on the model inputs or how KABAM was used to calculate the BCF. EPA (2017a) has since changed their aquatic invertebrate BCF to 24, but has added no new information or explanation for the change. Further, EPA (2017a) states that the selected BCF is "uncertain because it is based on a model estimate that does not account for metabolism of malathion by aquatic invertebrates". Therefore, FMC is skeptical of the methods employed by EPA (2017a) to derive their BCF and has little confidence in the value.

Breton et al. (2016c [MRID 49949501]), CLA (2016) and FESTF (2016) raised concerns over the methods used by EPA (2016a) to determine effect levels for sea turtles (Chapter 4, Table 4-7.2). EPA (2017a) made no amendments to their methods. The aquatic thresholds in Table 4-7.2 of Chapter 4 (EPA, 2016a; 2017a) were based on the assumption that sea turtles would be adversely affected if the concentration of malathion in prey items (i.e., plants, aquatic invertebrates and fish) reached or exceeded the avian dietary effects threshold. However, this approach does not account for differences between the gross energies and assimilation efficiencies associated with birds consuming a laboratory test diet and the prey items and food intake rates experienced by sea turtles in the wild. Pesticide concentrations in the diet are not exposure estimates and the direct comparison of pesticide concentrations in dietary items to dietary LC50s is inappropriate.

Breton et al. (2016c [MRID 49949501]) critiqued the designation of marine bins by EPA (2016a) and requested greater transparency. However, EPA (2017a) did not update or change any of the text for their final BE. It is unclear why EPA (2016a; 2017a) has only designated one habitat bin (bin 8) for both marine intertidal nearshore areas and marine tidal pools when separate surrogate freshwater bins are assigned to the two types of environments (Bins 2 and 5). Furthermore, the use of freshwater bins as surrogates for estuarine and marine environments leads to extreme overestimation of EECs. See comments included in Section 3.0 for further details.

Breton et al. (2016c [MRID 49949501]) criticized the estuarine/marine EECs estimated by EPA (2016a; Chapter 4, Sections 7.1.1 and 7.1.2) for being one to four orders of magnitude higher than any measured concentration of malathion in estuarine/marine environments (≤5.5 µg a.i./L; Smalling and Orlando, 2011). Even if monitoring data are not used quantitatively in a risk assessment, they can still be useful for comparison to modeled EECs to assess the realism of estimated concentrations. The EECs were updated in EPA (2017a) to 1-day average EECs, but were still exceedingly high. The highest EEC, 9880 µg a.i./L, was predicted for bin 5 HUC 13. Therefore, some EECs are still four orders of magnitude higher than concentrations measured in natural environments. Although EPA (2017a) acknowledged that the estuarine/marine EECs likely greatly overestimated risk, no attempts were made to refine the EECs or derive EECs that are more likely to be encountered by sea turtles.

Breton et al., (2016c [MRID 49949501]) critiqued the methodology used by EPA (2016a) to calculate EECs for green sea turtles, as EECs for Bins 3 and 4 were simply estimated by applying adjustment factors to bin 2 EECs. Although it appears that EPA (2017a) has instead calculated actual EECs for Bins 3 and 4 in their final BE, Cheminova still disagrees with their approach. See Section 3.3.5.3 for more information.

5.3.2 Whale and Deep Sea Fish Analysis

Cheminova commented that EPA's "LAA" determination for the killer whale (Southern resident DPS) is based on an obligate relationship with Chinook salmon but that such a relationship does not exist according to NMFS (2008). Killer whale consume other prey items that could replace salmon such as other fish, squid, and marine mammals. EPA (2017a) has not addressed our comment and has not altered their effects determination conclusion.

5.3.3 Marine Mammals (excluding whales) Analysis

The final BE (EPA, 2017a) addressed a few of the recommendations made by Cheminova (Breton et al., 2016c [MRID 49949501]), including completing EEC modeling for Bins 3 and 4, which are more representative of the freshwater habitat of manatees and Steller sea lions, and no longer utilizing a sublethal dietary toxicity threshold that tested malaoxon instead of malathion (Daly, 1996 [MRID 43975201]). However, the study now selected for this threshold by EPA (2017a) evaluated AChE inhibition (Barnett, 2006 [MRID 46822201]), an effects endpoint for which EPA still has not demonstrated an explicit relationship connected to survival, growth, or reproduction. EPA also appears to have updated the aquatic invertebrate BCF from 72 to 24 for use in KABAM modeling, but still references the value of 72 in the text. The Agency's use of surrogate bins for intertidal nearshore areas, subtidal nearshore waterbodies, and tidal pools in the final BE remains problematic, as they combined intertidal nearshore areas and tidal pools into one bin, and more importantly, use of freshwater bins as surrogates for estuarine and marine environments leads to overestimation of EECs (Breton et al., 2016d [MRID 50133301]; CLA 2016). This issue is apparent since EPA (2017a) does not discuss the realism of the EECs generated for these surrogate bins in the context of observed measured concentrations of malathion, as in Smalling and Orlando (2011).

EPA (2017a) did not update other issues with their draft BE (EPA, 2016a). The BCF utilized for marine mammals is given as 131 but references a study for bluegill [MRID 43106401] for which the calculated BCF was 103. Further, utilizing BCF for other species does not take into account for differences between the gross energies and assimilation efficiencies of the laboratory test diet items and food intake rates of receptors in the wild. EPA continues to utilize reproduction endpoints from a study rated unacceptable by Cheminova (Siglin, 1985 [MRID 40812001]), and moreover is using endpoints from studies conducted with rodents for the assessment of marine mammals. EPA (2017a) notes this extrapolation approach as an "uncertainty". Cheminova deems this approach as totally inappropriate and scientifically unsound.

5.3.4 Cave Dwelling Invertebrate Species Analysis

Cheminova (Breton et al., 2016c [MRID 49949501]) and CLA (2016) advised that EPA's LAA designations for terrestrial cave-dwelling invertebrates were based on extremely conservative assumptions that do not represent the Agencies' own guidance for completing refined assessments (Agencies, 2013). The Agency did not alter their conclusions in the final BE (EPA, 2017a). One minor issue was addressed, in which the full text citations for four references (Eidels et al., 2007; Land, 2001; McFarland, 1998; and Sandel, 1999) were given.

5.3.5 Mosquitocide Use

Appendix 4-5 of the final BE (Terrestrial species with species range and/or critical habitat overlap only with mosquito adulticide uses) and Appendix 3-3 (Spray drift considerations for malathion) describes the EPA approach to addressing potential risk of mosquitocide use. Additional text is available in the Chapter 1 and Chapter 4 main reports. This text was reviewed to determine what changes have been made from the second draft BE and whether any of the comments provided by Cheminova or CropLife America have been addressed in the report. In addition, the memorandum "Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion' issued on January 17, 2017 by EPA (DP Barcode: 434736) was also considered.

Memorandum (EPA, 2017)

In the BE memorandum issued by EPA (January 17th, 2017) the following text describes EPA's request for use site data that better characterizes the use of the three organophosphate (OP) chemicals (malathion, chlorpyrifos, and diazinon). EPA also acknowledged the spatial data that were supplied by Cheminova.

> "*EPA acknowledged they are committed to using the best scientific and commercial data for ESA-FIFRA analyses. Interested parties are invited to submit data that better define pesticide use areas and practices (especially for non-agricultural and mosquitocide/wide area uses), and state or local listed species protection practices, that should be considered as part of future ESA effect determinations and associated consultations for pesticides.*
>
> *EPA appreciates the comments detailing how mosquito adulticide applications are made, especially the spatial aspects illustrated by the maps of sprayed areas provided in the public comments. EPA is exploring the possibility of using this information to better define areas where mosquito adulticide applications are reasonably expected to occur.*"

Although EPA acknowledges the provided spatial data, there was no change to the final malathion BE with respect to how mosquitocide adulticides are actually used. The main assumption in the final BE is that adulticides 'could' be applied anywhere in the US and territories. Thus, all listed species are assumed to be exposed which is false.

EPA in a response to a comment from the Northwest Center for Alternative to Pesticides (NCAP) acknowledged that "*Given that there are no geographical restrictions on the chlorpyrifos and malathion labels regarding wide-area use patterns, the agencies agreed to treat wide-area uses such as mosquito adulticide applications as overlapping 100% of all species range since the use area is the entire U.S. EPA recognizes that this assumption overestimates the likelihood of exposure and is of limited utility as a Step 1 screen. We are working with mosquito control districts and others to better define the likely areas of mosquito adulticide applications so that the action area may be narrowed.*"

Although it is clear that mosquito adulticides are not used over the entire spatial extent of the United States (and Territories), the assumption that use is 100% overlapping with all listed species ranges is still made in the final BE which is entirely flawed. Standard pesticide labels for most agricultural use patterns (e.g. corn) also do not have geographical restrictions and are applied over wide-areas (e.g. the US mid-west), yet spatial data are available delineating where the use patterns exist (e.g., USDA CropData Layer). Similarly, spatial data exist that capture where adulticides are and have been applied through the American Mosquito Control Associations, states, and public health entities in the US. Therefore the assumption that 100% of the US is treated remains unsupported.

Final Biological Evaluation – Malathion (EPA, 2017)

EPA reports that the AGDISP model (version 8.26, December 2011) was used in the evaluation of mosquitocide exposure. EPA identified the AGDISP Gaussian extension as being used for specific circumstances such as aerial application of mosquito adulticides and other pesticides with very fine to fine droplet size spectra at release heights of 50 ft above ground. Cheminova provided extensive comments on the proper parameterization of AGDISP for mosquitocide applications using the recommendations of Mickle et al. (2005) in the response to the draft BE (Paul Whatling, FMC Corporation – https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0059). In the final BE (Appendix 3-3) the Agency indicated that they reviewed the Mickle et al (2005) study but that they found it was not conducted with parameters (e.g. release height, drop size distribution, etc) that would result in peak exposure based on the approved label conditions. The intent of Cheminova's comment was to help EPA identify the appropriate inputs to parameterize AGDISP for use in modelling adulticide application. Release height and droplet size can all be adjusted within the model itself to allow EPA to closely model the labeled instructions for this use pattern. Ultimately, this was not done by the Agency, and in fact quantitative modeling seems irrelevant as modeling spray drift for adulticides was not ever used quantitatively in the BE to help better determine the spatial extent of potential exposure. From the "Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion' issued on January 17, 2017 by EPA (DP Barcode: 434736) EPA acknowledges that "*the Agencies agreed to treat wide-area uses such as mosquito adulticide application as overlapping with 100% of all species range*." Therefore, it appears that although EPA acknowledges that a specific model should be used to evaluate adulticide drift, that model was never used for that purpose in the final BE.

The analysis undertaken in Appendix 3-3 was used to justify the application of the spray drift estimates in the new TED tool. However, the justification provided is lacking and does not capture the unique aspects of adulticide application when estimating deposition in the water bodies modeled. Adulticide delivery systems are designed to ensure the active ingredient stays in the air as long as possible to facilitate contact with adult mosquitoes. High deposition close to the point of application would be highly inefficient and has been shown by to be incorrect in field studies (Teske et al., 2015; Mickle, 2005). Maximum deposition is usually observed between 500 and 1000 m downwind Mickle (2005) depending on wind speed and droplet size distribution. Given the above, spray drift exposure estimates in the TED tool remain questionable for the purpose of estimating exposure from adulticide applications.

Of additional concern is the edit which EPA made to the final BE (EPA, 2017a) relating to mosquitocide application. The Agency states in Appendix 4-5 (emphasis Cheminova's): "A limited number of terrestrial species listed in Table A 4-5.1) are identified where the only **buffered** use that overlapped with their species range is the mosquito adulticide use for malathion and mosquito adulticide and wide area use (*e.g.,* general outdoor treatments around perimeters and ant mounds for pests) for chlorpyrifos." The bolded word in that sentence did not appear in the draft BE (EPA, 2016a), and this change in wording means that EPA re-evaluated the species of interest in the Appendix. The two new species evaluated are entirely different than the six previously evaluated. Cheminova is concerned about the Agency introducing new species into the assessment without allowing the public to review its work given the number of errors Cheminova identified with the draft BE (EPA, 2016a). Further, this edit does not address the initial comment made by Cheminova, namely that the Agency does not comment on **why** it expects that all species and critical habitat are expected to be exposed to malathion given the multitude of data available that quantitatively identify the locations where adulticide active ingredients have been and are currently being applied and the timing at which application occurs.

5.3.6 Refined Risk Analysis for 13 Listed Bird Species: TIM/MCnest Analysis

EPA (2017a) used the TIM and MCnest models to estimate risk to 13 selected listed bird species. Several issues exist with these models and their application to risk assessment. Herein, Cheminova discusses specific issues with how the models were applied in the Biological Evaluation for malathion as well as general issues with the models.

The Agency did not provide input values for several important parameters in TIM and MCnest. As a result, their model runs cannot currently be replicated and evaluated. For example, the Agency did not specify the assumed droplet spectrum, feeding times by birds, proportion of feeding occurring in the morning, and field fidelity factor. Each of these variables influences the risk predictions from TIM.

EPA stated that the sensitive reproductive NOAELs were for a decrease in number of eggs laid per hen, decrease in the percent of viable eggs per eggs set, and decrease in eggshell thickness and were from MRID 48153114. However, MRID 48153114 is an acute oral LD_{50} study, thus it is unclear where EPA found the NOAELs used in the MCnest analyses. Several input values selected by EPA were incorrect or from unacceptable studies. For example, EPA used an acute effect LD_{50} for rats of 1560 mg/kg bw from Fischer (1991 [MRID 49127003]). In Section 4.2.7 of this document, Cheminova discusses why this study is not acceptable and recommends a more appropriate rat acute LD_{50}. Additionally, EPA assumed a half-life in puddles of 15.9 days for malathion, referencing Table 3-5. EPA's guidance for selection of this parameter states that the puddle half-life should be the 90th percentile confidence bound on the mean from the aerobic soil metabolism half-life in days (EPA, 2015). According to Table 3-5, this value should be 1 day.

The Agency appears to have incorrectly interpreted the results of their own analyses. In Appendix 4-7, Section 3.1, Table B 4-7.8, EPA presents the "likelihood of mortality to ≥1 individual out of 100 exposed per year." For Kirtland's warbler, for example, this probability of ≥1/100 mortality is 0.99 assuming high sensitivity for the listed species (i.e., HC_{05} on the species sensitivity distribution [SSD]) or median sensitivity (i.e., HC_{50} on the SSD). According to the Agency, if the Kirtland's warbler is highly tolerant (i.e., HC95 on the SSD), the probability of ≥1/100 mortality is <0.01. However, EPA then uses these results to conclude in Section 4.8 of their final BE that there "is a high probability (99% or greater) of mortality to an exposed individual for […] Kirtland's warbler." This conclusion is misleading, because it does not follow that a high chance of observing at least one mortality out of 100 birds is equivalent to a high chance of each individual bird dying. The conclusion also ignores the very low likelihood of mortality if the Kirtland's warbler is a tolerant bird species. The more appropriate risk conclusion is later presented by EPA as the "magnitude of mortality," which for Kirtland's warbler was given as 15 to 35%.

EPA also overstated their risk conclusion related to the MCnest output by claiming that "fecundity declines were observed for all species throughout the breeding season." Two species, the Inyo California Towhee and Yellow-billed Cuckoo, had maximum fecundity declines of 7% or less (a maximum of 1% for Inyo California Towhee). These declines may not have a significant effect at the population level. Further issues exist with the scientific logic behind the MCnest model. The model predicts total nest failure if any avian NOAEL is exceeded. In the past, to assess the conservatism introduced by this assumption, EPA completed analyses using LOAELs instead of NOAELs (EPA, 2016c). However, in the final BE for malathion, EPA neither addresses this conservativism nor completes alternate sensitivity analyses to explore its importance. Furthermore, alternative analyses still fail to address the actual problem with MCnest, namely that it uses a binary variable where a continuous distribution (e.g., nestling body weight) or Poisson distribution (e.g., number of eggs) is required. Total nest failure or indeed any adverse effects would not necessarily be expected for an exceedance of the NOAEL.

6.0 DISCUSSION AND CONCLUSION

Of the concerns discussed in Breton et al. (2016c [MRID 49949501]) and raised by CLA and FESTF that remain unaddressed by the Agency in the final malathion BE, the following have been identified as critical to the outcome of the final BE: data and model quality, unsubstantiated thresholds, inaccurate and crude spatial analysis, inappropriate use of exposure models, overgeneralization of aquatic exposure predictions, omission of best available data and tools, not providing probabilistic exposure predictions, compounding conservatism in exposure assessment, inappropriate contrasts/comparisons between incongruous EECs and effects metrics, an on-going lack of transparency, outstanding errors in both weight of evidence (WoE) tools and text, a flawed and obscure "weight-of-evidence" approach, and most importantly, a lack of risk estimation via probabilistic methods. These issues are further discussed below.

Many studies selected by EPA as threshold values were not evaluated for data quality and relevance, and when evaluated, many did not follow EPA's own study quality criteria. Use of threshold values from studies deemed invalid by the Agency, or deemed acceptable for quantitative use when criteria for quantitative use were not met. When the quality of the data driving the assessment is questionable, so are the results. EPA failed to make use of best available chemical specific data in the final BE. For example, all registrant commissioned data should have been considered by EPA. In particular, the Agency should have, by their own decree (EPA, 2011c), made use of the GLP amphibian toxicity data, instead of relying on data from a different taxon. Similarly, EPA did not derive independent effects endpoints for estuarine/marine receptors (invertebrates, fish, and aquatic plants).

In past reviews of the WoE tools/TEDtool, a number of errors were reported, and as noted herein, not all have been addressed. Cheminova remains concerned that EPA has not submitted the TEDTool to a Scientific Advisory Panel (SAP) for an independent evaluation of its quality, credibility and utility. Even though the model is purportedly derived from existing EPA toolbox applications, substantial changes have occurred with the models since the last SAP. We, therefore, believe that TEDTool warrants another SAP review.
Cheminova is concerned with the use of toxicological effects metrics ("thresholds") that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction), and further not demonstrably associated with the protection goal of individual fitness. Thus, the most-conservative-RQ-based effects determinations, are primarily driven by effects metrics that do not necessarily even relate to the protection goals of the biological evaluation.

EPA made the assumption that adulticide applications may be made anywhere in the United States, when data clearly show this is not the case. Erroneously, species calls and critical habitat calls were made assuming that all label uses can be made anywhere in the United States, without drawing any distinctions between use patterns, timing of application, locations and co-occurrence. Accordingly, there are species that will never come into contact with biologically relevant concentrations of malathion that have been determined to be "LAA."

The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulated single agricultural fields and small, static water bodies. In the BE for malathion, these models have been used to simulated landscape and aquatic fate processes in continental scale watersheds and rivers. Even from a screening level perspective, this approach is a gross overextension of the model's capabilities. The results obtained from these models, applied to represent environments they were never designed for, are not acceptable.

The aquatic exposure predictions determined in the BE were at the HUC2 watershed region scale. With results and interpretation at this scale, the exposure predictions associated with a given crop group were assumed to occur across the entire HUC2, and any species occurring within that HUC2 was assumed to be impacted by that same exposure. The amount of variability in the environmental conditions that influence pesticide runoff and exposure in aquatic systems is huge, which leads to significant variability in exposure. Furthermore, species are not located uniformly across a HUC2, and in fact, their occurrence is typically constrained to very specific locations (they are endangered). The overgeneralization and lack of accounting for spatial variability in aquatic exposure predictions, coupled with minimal specificity of species location co-occurrence, has led to misrepresentation of the extent of exposure risk.

High resolution spatial datasets representing, crops, soils, weather, topography, and hydrography are readily available nationwide. These datasets are routinely coupled with existing watershed scale hydrologic and water quality models (e.g. SWAT) for making environmental decisions concerning water quality. These best available datasets and tools were not incorporated into the BE aquatic exposure modeling. As a result, exposure predictions do not account for the critical landscape and agronomic variability known to exist in reality and are based on modeling methods that are incapable of reflecting the complexities of the environmental processes they are attempting to simulate.

The spatial variability and input and process uncertainty surrounding malathion exposure in aquatic environments is significant. A meaningful and scientifically valid analysis of exposure in this situation requires that probabilistic methods be employed to determine the likelihood of exposure endpoints being exceeded. This probabilistic approach, which endorsed by the NAS panel, was not followed in the BE.

When multiple deterministic exposure model inputs are “upper bound” or biased high, as in the case of the final BE (e.g., on-field exposure, upper bound RUDs, 90th percentile on the mean half-lives), the resulting exposure estimates are expected to be overly conservative (i.e., unrealistically high).

There remain disparities between exposure durations in toxicological studies and EECs used to generate RQs in the BE. Risk characterizations are overly exaggerated when effects metric generated from long exposure durations (e.g., several days to months) are compared to peak EECs.

Though the Agency attempted to deal with some of the transparency issues in the text of the malathion BE, many transparency concerns persist within the final BE. For example: key cells in the WoE Excel tools remain hidden and locked, drift models continue to go unreferenced and unexplained, and methods are not consistently presented.

Despite the fact that the Agency did correct some of the errors identified during the public comment period, many remain. For example: critical errors remain in the dermal exposure and body mass scaling equations (herptiles) in the TEDtool. Further, the terrestrial EECs presented in the malathion BE do not match those generated in the associated TEDtool.

Despite claiming a weight-of-evidence approach, it seems EPA made all of their effects determinations based solely on the most conservative RQ of a suite of RQs generated for each species. EPA gave equivalent “weights” to threshold exceedances associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds that may not be linked to individual fitness/the protection goal of the BE (e.g., endpoints for avoidance behavior, AChE inhibition, etc.). Further, other lines of evidence were not directly considered in species and critical habitat calls (e.g., incident reports, field studies, monitoring data, etc.). We note that aquatic EECs were orders of magnitude higher than monitoring data. Nowhere in the final BE was this taken into account.

NRC (2013) discouraged the use of RQs and recommended probabilistic methods instead. Risk is defined as the probability or likelihood of a particular outcome. However, EPA did not estimate risk to listed species in their BEs using probabilistic methods, with the exception of the 13 bird species assessed with TIM/MCnest. However, as discussed in Section 5.3.6, TIM/MCnest are overly conservative and grossly overestimated risks to the 13 listed bird species.

Because of the issues listed above, the final malathion BE implies adverse outcomes (LAA) for the majority of listed species individuals. Cheminova submitted four refined effects determinations for malathion conducted on the Kirtland’s warbler, the California tiger salamander, the delta smelt and the California Red-legged frog (Moore et al., 2016 [MRID 49949506]; Breton et al., 2013 [MRID 49211702]; 2016c,d [MRIDs 49949505 and 49949504]), and additional assessments on the California red-legged frog and salmon for dimethoate (Breton et al. 2012 [MRID 48895502]; Whitfield Aslund et al. 2016) to provide additional examples of how individual listed species assessments could be conducted to screen out cases that do not warrant formal consultation with the Services. Species-specific exposure assessments for over 20 species in a range of static and flowing water habitats across the Ohio River Basin (HUC2 05) also demonstrate how refined approaches can be used to characterize risk (Padilla and Winchell., 2016 [MRID 49949507]; Winchell et al., 2016 [MRID pending]). Cheminova’s effects determinations demonstrate that when complete risk assessments are carried out using the best available scientific data, realistic exposure assumptions, and consideration of all lines of evidence, probabilistic effects determinations can be illuminating and provide much more realistic estimates of risk when all available data are considered.

The issues primarily listed above result in adverse outcomes (LAA) for individuals of the majority of listed species addressed in the final malathion BE. Cheminova submitted four refined effects determinations for malathion conducted on the Kirtland's warbler, the California red-legged frog, the California tiger salamander and the delta smelt (Moore et al., 2016 [MRID 49949506]; Breton et al., 2013 [MRID 49211702]; 2016c,d [MRIDs 49949505 and 49949504]), as well as an effects determination and risk assessment paper on the California red-legged frog and salmon, respectively, for dimethoate (Breton et al. 2012 [MRID 48895502]; Whitfield Aslund et al. 2016), to provide additional examples of how individual listed species assessments could be conducted to determine risk using the best available scientific data, and appropriate refined methods to characterize risk. Species specific exposure assessments for over 20 species in a range of static and flowing water habitats across the Ohio River Basin (HUC2 05) also demonstrate how refined approaches can be used to characterize risk (Padilla and Winchell., 2016 [MRID 49949507]; Winchell et al., 2016 [MRID pending]). Cheminova's effects determinations demonstrate that when complete risk assessments are carried out using the best available data, realistic exposure assumptions, and consideration of all lines of evidence, effects determinations can be quite different. Such refined assessments should be conducted when potential risks are identified at the screening-level (e.g., NRC, 2013; EPA, 1998, 2004, 2013).

FMC requests that EPA give careful consideration to the comments provided in this document and strongly recommends that the Agency incorporate real risk estimates (i.e., the probabilities of exceeding various magnitudes of effects) in their biological evaluations, as was concluded by NRC (2013).

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