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OFFICE OF
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MEMORANDUM January 17, 2016

SUBJECT: Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion

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On March 31st, 2016, EPA posted for public comment the draft biological evaluations (BEs) for chlorpyrifos, diazinon, and malathion in support of registration review. Registration review is EPA' s periodic review of pesticide registrations to ensure that each pesticide continues to perform its intended function without unreasonable adverse effects. As part of the registration review process, EPA has completed comprehensive BEs for all chlorpyrifos, diazinon, and malathion uses. These BEs represent

the first nationwide assessments of these pesticides to federally endangered and threatened species (*i.e.*, listed species) and designated critical habitat. The BEs also include analysis of impacts to candidate and proposed species and critical habitat proposed for listing under section 7 of the Endangered Species Act (ESA). The interim scientific methods used in these draft BEs were developed collaboratively with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS), hereafter referred to as the Services, based on recommendations from the April 2013 National Academy of Sciences (NAS) report titled "Assessing Risks to Endangered and Threatened Species from Pesticides". As part of this effort, the U.S. Department of Agriculture has provided information on crop production and pesticide uses and assistance with the use of the National Agricultural Statistics Service Cropland Data Layer to help define the footprint of agricultural use patterns. All three federal agencies (EPA, NMFS, and FWS; hereafter referred to as "the agencies") intend to work collaboratively, with input from USDA and other partners, to improve the current approach for endangered species risk assessment.

At the close of the comment period on June 6th, 2016, EPA had received 78,000 comments related to various aspects of the draft postings with 120 substantive comments meriting detailed review. A significant number of comments were received as part of letter-writing campaigns that were not substantive. Substantive comments regarding the interim approach employed in the BEs for chlorpyrifos, diazinon, and malathion are discussed below. The comments were initially categorized according to level of detail ("general" versus "detailed") and then were further categorized according to topic or type of suggestion ("error correction" versus "process improvement," etc.). This document identifies each comment received, by category, and provides a link to the original comment in the regulatory docket, for reference. Since many of the comments are similar in nature and apply to all three pilot chemicals, EPA responses are generally provided by category; more detailed responses are provided for certain, chemical-specific comments.

The Agencies intend to refine the interim methods used in the first three pilot BEs based on a phased and iterative approach. In these BEs EPA is 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. The major revisions made to the final BEs include (but are 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. Other recommendations for process improvement that will require further development in collaboration with the Services are not included in the final three pilot BEs, but will be considered for future pesticide consultations. Other recommendations, which will be explored for future BEs include: a substantial reduction in the size and complexity of the assessments; a move toward more probabilistic approaches; refinements in geospatial data used to define species ranges and potential use sites; the utilization of watershed-level aquatic exposure models; improved methods for estimating exposures in riverine and estuarine/marine habitats; improved characterization and consideration of magnitude of effects; and a consideration in the timing and duration of potential pesticide exposures (e.g., linking exposure with life-history variables). Additionally, we are exploring ways to use species-specific toxicity data earlier in the first step of the BE process to refine, but still maintain, a protective screening process. We aim to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.

Detailed Comments on the Biological Evaluations

EPA appreciates the numerous detailed comments received on the draft BEs for chlorpyrifos, diazinon, and malathion (detailed in **Table 1**). Given the extensive details provided in several of the comments and accompanying documents, EPA developed a strategy to categorize and prioritize the individual comments detailed within the larger documents for incorporation into the final BEs. Comments that fell into one or more of the following categories were incorporated into the final BEs for chlorpyrifos, diazinon and malathion:

- **Error Correction**: A comment was placed into this category if it pointed to any errors noted in the documents, including: missing or incorrect references, typographical errors, or calculation errors. For example, it was noted in several comment documents that Section 1 of Attachment 1-7 incorrectly references "appendices x-y", which do not exist. Attachment 1-7 has been corrected to instead reference "Attachments 1-16 through 1-19".
- **Transparency**: A comment was placed into this category if it suggested a lack of clarity in the methods described in the documents. For example, Attachment 1-7 (Methodology for Estimating Exposures to Terrestrial Animals) has been updated to clarify several aspects of the terrestrial exposure modeling used in the final BEs, including how concentrations in aquatic organisms are estimated as dietary food items and how doses in drinking water are calculated.
- **Endpoint Review (malathion only)**: A comment was placed into this category if it was related to one or more malathion threshold values discussed in Chapter 2, the Effects Characterization, or were used as a malathion input value in the Terrestrial Effects Determination tool (TEDtool, v. 1.0). This category was only considered for incorporation into the final BE for malathion to address comments regarding potential changes in the toxicity of malathion as it degrades over time and impurities that may be present with malathion; this issue is not relevant to chlorpyrifos or diazinon. While EPA attempted to address this concern in Section 1.4.2.2.f of the BE problem formulation by conducting a comparison of the available toxicity data, further evaluation of the information suggests that it is appropriate to consider the source of the test substance when determining threshold values. Chapter 2 is being updated to reflect this decision.
- **Process Improvements – Stakeholder Discussion**: In June 2016, EPA and the Services held a two-day meeting that provided a forum for stakeholder suggestions for refining some of the interim scientific methods used in the April 2016 draft BEs. The meeting included opening and closing plenary sessions and breakout sessions intended to address inter-agency developed charge questions related to potential refinements for aquatic modeling, spatial and non-spatial refinements to Step 2 (*i.e.,* EPA's determination of "likely to adversely affect" or "not likely to adversely affect"), and refinements to the weight-of-evidence (WoE) approach for plants and animals. Several recommendations for ways to refine the aquatic modeling that were proposed at the stakeholder meeting were also detailed in the public comments listed in **Table 1**. In response to these recommendations, a number of changes to the aquatic modeling for flowing waters (bins 3 and 4) have been made to provide more realistic estimates of exposure. These include expressing peak concentrations as daily averages rather than instantaneous peaks, incorporating base flow, and incorporating "time-of-travel". More details on these changes can be found in Attachment 3-1 of the final BEs.

Comments that fell into one or more of the following categories were considered but were ultimately not incorporated into the final BEs for chlorpyrifos, diazinon and malathion because they could not feasibly be addressed in time to meet the legal obligation to complete the three BiOps by December, 2017. While these comments are not directly addressed in the final BEs, EPA intends to address them in future BEs as the interim approach is refined and amended to reflect only those aspects of the analysis that are essential to inform the BiOp, or which are necessary to arrive at a No Effect (NE) or Not Likely to Adversely Affect (NLAA) determination. Refinements to the interim approach that address the following categories will be developed in consultation with the Services.

- **Process**: A comment was placed into this category if it was related to the interim approaches developed by the agencies for ESA consultation or if it was related to standard EPA approaches for evaluating risk. Comments in this category included broad critiques of the methods, assumptions and data used in the BEs without providing a clear alternative.
- **Process Improvements**: A comment was placed in this category if it provided an alternative to the interim approaches described in the BEs, including: suggestions for streamlining the analysis, alternative models or model assumptions, or alternative data for consideration. Modifications to the interim method developed by the agencies will require further discussion and agreement with the Services.
- **Model Assumptions**: A comment was placed in this category if it was related to the assumptions of one or more of the models employed for evaluating risk. While many of the model assumptions used in the BEs are based on standard EPA approaches, those that are specific to the interim methods developed collaboratively with the Services for the pilot chemicals will be re-evaluated based on the public comments for future BEs.
- **Endpoint Review (chlorpyrifos and diazinon)**: A comment was placed into this category if it was related to a chlorpyrifos or diazinon threshold value discussed in Chapter 2, the Effects Characterization, or was used as an input value in the TEDtool. Thresholds and endpoints for chlorpyrifos and diazinon were not changed based on public comments because it was determined that they would not impact the effect determinations for any listed species and/or designated critical habitat.

Table 1. Summary of Detailed Comments on the Biological Evaluations

Commenter	Summary of Comments	Link to Comment	Comment Category
David B. Weinberg, Wiley Rein LLP, Counsel to Dow AgroSciences LLC and Makhteshim Again of North America, Inc. d/b/a ADAM and David E. Menotti, Crowell & Moring LLP, Counsel to FMC Corporation/Cheminova A/S	Overly conservative BEs would lead to unsound & unlawful decisions; current method not sustainable	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0898	Process
Council for Dow AgroSciences, LLC, ADAMA, and FMC	Comment period extension request along with 26 pages of	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0038	Process, Error Correction, Transparency

Commenter	Summary of Comments	Link to Comment	Comment Category
	missing, omitted, or incorrect information in the BEs.[1]		
Dow AgroSciences	Chlorpyrifos calculations/ transcription BE comments; overly conservative and lack of process transparency; use of invalid studies	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0920	Error Correction, Transparency, Endpoint Review, Process, Process Improvement, Model Assumptions
Yvonne Clemow, Dow AgroSciences LLC et al.	Chlorpyrifos calculations/transcription BE comments; overly conservative and lack of process transparency; use of invalid studies	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0921	Error Correction, Transparency, Endpoint Review, Process, Process Improvement, Process Improvement-Stakeholder Discussion, Model Assumptions
Croplife America	Overly conservative; ignores FIFRA; unsustainable; tools and models comments; specific BE improvement recommendations	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0063	Error Correction, Transparency, Endpoint Review, Process, Process Improvement, Process Improvement-Stakeholder Discussion, Model Assumptions
ADAMA	Diazinon calculations/ transcription BE; Recommendations for Step 1; legal and policy comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0075	Error Correction, Transparency, Endpoint Review, Process, Process Improvement, Process Improvement-Stakeholder Discussion, Model Assumptions
Michael Dobbs, Bayer	Overly conservative approach; need to weigh usage; tool and model comments; exclude use of foreign incident reports and un-reviewed studies for effects thresholds	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0078	Error Correction, Transparency, Endpoint Review, Process, Process Improvement, Model Assumptions
G. Oliver, Dow Agrosciences LLC	Recommendations for Steps 1 & 2	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0926	Process, Process Improvements
Dan Campbell, Chair, Administrative Committee, FIFRA Endangered Species Task Force (FESTF)	Comments on spatial data; methods for overlap of use and species; mosquitocide application	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0906	Process, Process Improvements
Paul Whatling, FMC Corporation	Malathion BE comments; registrant's risk assessment examples	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0059	Error Correction, Transparency, Endpoint Review,

Commenter	Summary of Comments	Link to Comment	Comment Category
			Process, Process Improvement, Process Improvement-Stakeholder Discussion, Model Assumptions
The Center for Biological Diversity (CBD)	Numerous process related comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0901	Process
The National Sorghum Producers (NSP)	Numerous process related comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0051	Process

[1] Comments were previously addressed (April 11, 2016; DP Barcode 433625).

General Process Related Comments on Spatial Data and Modeling Assumptions

EPA received numerous comments related to the inability of the available spatial data and modeling assumptions to provide an effective screen at Step 1 or a realistic predictor of risk at Step 2 (detailed in **Table 2**). The agencies' interim approaches to ESA consultation in the FIFRA context are necessarily in flux. Given that methodology development is ongoing, there are a number of exploratory efforts reflected in the draft BEs that may not be continued in future BEs as the essential parts of the analysis are identified and refined following the development of the BiOps. The agencies plan to reduce and refine these and future BEs to only those elements that are necessary for construction of the BiOp, or which are necessary to arrive at a NE or NLAA determination. We aim to streamline the process to a point where it is protective of species, timely for FIFRA decisions, feasible within the agencies' resource constraints, and transparent to the public.

The majority of models used in the draft BEs are based on existing models that have been used for some time to define exposure and effects of pesticides. QA/QC activities on any additional components to these models are ongoing to ensure that they function as intended. The agencies will consider revisiting effect thresholds and exposure estimates as we gain experience in defining which effects are of realistic concern, and which may be insignificant or discountable based on the results of the BiOps. Additionally, we are exploring ways to use species-specific toxicity data earlier in the first step of the BE process to refine, but still maintain, a protective screening process.

EPA is continuing to develop geographic data sets that better represent the overlap of pesticide use areas with listed species habitat identified in Steps 1 and 2. Coupled with data on seasonal species presence, pesticide application timing, and life history, this information will in the future allow for more spatially-explicit effects determinations in Steps 1 and 2 than was possible in the three pilot BEs.

EPA is committed to using the best scientific and commercial data for ESA-FIFRA analyses. We invite interested parties 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. .

Table 2. Process Related Comments on Spatial Data and Modeling Assumptions

Commenter	Summary of Comments	Link to Comment	Comment Category
Reece Langley, Vice President - Washington Operations, National Cotton Council	Overly conservative; need streamlined approach; lacking in science; unsustainable	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0892	Process
Minor Crop Farmer Alliance	These chemicals are important for minor crops/IPM/public health; need to use best science; inadequate comment period; need to re-work whole process	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0072	Process
Manatee County (FL) Mosquito Control District	Support malathion use; mosquito adulticide use	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0050	Process
Pesticide Policy Coalition	Overly complicated and resource intensive without meaningful policy or procedure improvements; inadequate comment period; ignores information on cause of species decline/recovery; ramifications leading to registration delays, increase cost, impractical use directions, and unpredictable decisions	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0061	Process
Responsible Industry for a Sound Environment (RISE)	Inadequate comment period; overly conservative [Step 2]; not effective screen in Step 1; results are precautionary, not predictive; meaningless thresholds; need to consider actual usage than assuming ubiquitous use; improvement suggestions	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0077	Process
Agricultural Retailers Association	Approach leads to Services having to consult on every chemical rather than only difficult or unusual cases; unrealistic exposure and risk results; lack of science; need to streamline process; process is hampering new product availability	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0068	Process
National Association of Wheat Growers	Overly complicated; not meaningful; no process improvement; modeling results are not realistic or provide for more ES protection	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0065	Process, Modeling Assumptions

Commenter	Summary of Comments	Link to Comment	Comment Category
Dale Moore, Executive Director, Public Policy, American Farm Bureau Federation (AFBF)	Inadequate review period; flawed methods; overly conservative; inconsistent with law	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0894	Process
Washington Friends of Farms and Forests	Current process not supported by law or science or results that are realistic; runoff not an issue with low-to-no rainfall during growing season; monitoring data show chemicals concentrations are not at level of concern	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0052	Process, Modeling Assumptions
National Council of Farmer Cooperatives	Not meaningful approach to effectively screen risk; overly conservative, complicated, and resource intensive relative to results; improvement suggestions	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0070	Process

General Process Related and Specific Comments on Urban Pesticide Use Modeling

EPA appreciates the comments on indoor uses, discharges to Waste Water Treatment Plants (WWTPs), consideration of urban use patterns in risk assessment, and Clean Water Act issues (detailed in **Table 3**). We are open to specific suggestions for improvement of urban pesticide use modeling, but caution that if such approaches are not sufficiently sensitive to address urban use across the nation they will be of limited utility in conducting effects determinations.

Because the BEs are intended to support compliance with the ESA under EPA's FIFRA registration review program, specifically, issues related to Clean Water Act (CWA) compliance are not explicitly addressed. Similarly, while the BEs contain much of the information that would be included in a broader FIFRA assessment (*e.g.,* an evaluation of the toxicity and exposure potential for aquatic and terrestrial habitats), they necessarily have a different format since they are focused on listed species and designated critical habitat rather than all potential ecological effects. EPA intends to use the information provided in the BEs to inform regulatory decisions under CWA and FIFRA by identifying the potential for risk at the taxa level. For example, in addition to the detailed evaluation of ecological toxicity provided in the BEs, aquatic exposure values for several types of static and flowing waterbodies are presented in the BEs for mosquito adulticide and agricultural uses and can be used to inform CWA impacts in urban and agricultural areas, respectively. EPA anticipates that any mitigations resulting from the BiOps will help to alleviate both CWA and FIFRA related concerns, at least in part.

Human health considerations are covered by the EPA-OPP Health Effects Division's risk assessments. Complete or partial draft human health assessments are currently available for chlorpyrifos (EPA-HQ-OPP-2008-0850-0200) and malathion (EPA-HQ-OPP-2009-0317-0075). A refined drinking water assessment for chlorpyrifos is also available (EPA-HQ-OPP-2015-0653). These documents include human drinking water exposure analysis from both agricultural and urban uses and address many of the exposure issues raised in the comments. EPA has proposed to revoke all food tolerances for

chlorpyrifos[1]; if this is implemented, it would profoundly change the use pattern and would have large implications for the ESA analysis.

In addition to the process related comments, there were a few specific questions related to potential malathion exposures from WWTPs and the formation of malaoxon during waste water treatment. Malathion is subject to several degradation processes in the environment which would limit its presence in WWTPs. Soil half-lives for malathion are on the order of a day or less, and hydrolysis rates are also quick (several days at pH7 and about half a day at pH9). Neither of these degradation pathways has malaoxon as a product. Rather, they produce malathion monocarboxylic acid and malathion dicarboxylic acid, neither of which are of ecotoxicological concern. Malaoxon formed in the WWTP by chlorination of any remaining malathion would also be subject to further hydrolysis and biodegradation during treatment. Hydrolysis of malaoxon is also rapid (7 hours at pH9). For these reasons, discharges of malathion and malaoxon from WWTPs and resulting exposure to aquatic listed species are expected to be well below those from agricultural exposures.

Table 3. General Process Related Comments on Urban Pesticide Use Modeling

Commenter	Summary of Comments	Link to Comment	Comment Category
National Association of Clean Water Agencies (NACWA)	[similar to BACWA comments] additional runoff and water contamination-specific comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0054	Process
San Francisco Bay Regional Water Quality Control Board (Water Board)	See BACWA comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0048	Process
California Stormwater Quality Association (CASQA)	BE not a replacement for Registration Review (RR) ecological assessment; CWA compliance needs to be an integral part of BEs and RR assessment; BE too complex; urban uses not handled in a manner to lead to practical or effective mitigation	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0044	Process
Bay Area Clean Water Agencies (BACWA)	Certain run off factors not evaluated; listed various missing areas of the BE; BE not a replacement for RR ecological assessment	https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0049	Process

General Comments Related to Benefits, Public Health and Usage Data

EPA received numerous comments related to benefits, public health and usage data for chlorpyrifos, diazinon and malathion (detailed in **Table 4**). Responses to these comments are provided in the following subsections.

[1] https://www.federalregister.gov/documents/2015/11/06/2015-28083/chlorpyrifos-tolerance-revocations

Benefits, IPM, Resistance Management

Many comments indicated that chlorpyrifos, diazinon and malathion offer many benefits to crop producers and other entities that rely on insect control. The benefits offered include economical broad-spectrum activity that facilitates control of multiple insect pest species simultaneously, quick knock-down of pests, and effectiveness against many invasive and difficult to control insects. The three organophosphate (OP) insecticides may be applied by a variety of methods which helps to make them important tools in season-long control of insects that infest bark, wood, foliage and fruit. Users of these insecticides rely on them because of cancellation or loss of other broad-spectrum insecticides. Also, compared to some alternative insecticides, these three OPs often result in fewer adverse effects to beneficial insects. These benefits contribute to the importance of chlorpyrifos, diazinon and malathion in integrated pest management (IPM) programs in many scenarios. Moreover, because most insecticide alternatives exert their effectiveness through other mechanisms of action, the three OPs are important for managing resistance to their alternatives. Other commenters noted that it is important to maintain chlorpyrifos, diazinon and malathion because many of their more selective alternatives do not have established maximum residue levels (MRLs) which can reduce export markets of products treated with these alternatives.

EPA agrees that chlorpyrifos, diazinon and malathion are broad-spectrum insecticides and that they have benefits to producers. EPA also agrees that they are effective against a wide range of insect pests in a variety of agricultural and non-agricultural scenarios, and typically are efficacious against new and difficult to control insects. It is also agreed that chlorpyrifos, diazinon and malathion are important in IPM programs and to help manage insect resistance to other mechanisms of action. However, these considerations are not relevant in determining whether these pesticides may affect listed species and habitat, which is the function of the BEs. With that said, the Services must consider the economic feasibility of mitigation in developing any Reasonable and Prudent Alternatives (RPAs) for avoiding jeopardy in the Services' BiOps and economic considerations are also relevant to the development of any Reasonable and Prudent Measures (RPMs) to minimize the impact of take. Therefore, the specific information regarding the utility of diazinon, chlorpyrifos and malathion in various insect control scenarios will be considered to the extent RPAs and RPMs are developed.

Public Health

EPA thanks the mosquito control districts for their comments. EPA agrees that there are important public health uses of OP insecticides. We also agree that there are a dwindling number of mosquito adulticides available and that malathion is particularly important to rotate with pyrethroids for resistance management to ensure effective control of mosquitoes that vector diseases. EPA will consider this factor as it proceeds with its work on these three insecticides.

Usage Data

Several comments referred to sources of pesticide usage data, e.g., the USDA's National Agricultural Statistics Service and the California Department of Pesticide Regulation's Pesticide Usage Report. These data show that in California more than 1 million acres are treated annually with chlorpyrifos, diazinon

and malathion. The Agencies are exploring ways of incorporating usage data into the Step 3 process as part of the RPA and RPM discussion.

Table 4. General Comments Related to Benefits, Public Health and Usage Data

Commenter	Summary of Comments	Link to Comment	Comment Category
Cranberry Institute	Cranberry growers need both chlorpyrifos and diazinon. Both are used in IPM programs. Recently, growers are seeing new and different insects, need both to control newer insects. Both cost effective and provide broad spectrum control. Chlorpyrifos the only tool available for false blossom disease	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0050	Benefits
Cherry Marketing Institute	Chlorpyrifos important for tart cherries, resistance management	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0873	Benefits
West Integrated Pest Management Center	Diazinon important for pineapple, and various crops in Guam	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0064	Benefits
California Farm Bureau Federation	OPs important for insect resistance management and IPM; inadequate comment period	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0908	Benefits
Colusa Mosquito Abatement District, CA	IPM for mosquitoes, malathion is key (need chlorpyrifos as well); use table	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0049	Benefits
Western Growers	OPs are important; approach not sustainable and need significant revision; BEs too complicated and resource intensive; inadequate comment period	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0073	Process, Benefits
Western IPM Center	Important for IPM; use information; chlorpyrifos tolerance revocation comments	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0905	Benefits
California Cotton Ginners and Growers Association	Chlorpyrifos and malathion benefits for cotton; overly conservative; inadequate comment period; cotton production more challenging if these valuable tools are taken away	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0057	Benefits
California Fresh Fruit Association	Chlorpyrifos and diazinon importance in IPM	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0051	Benefits
California Specialty Crops Council	These OPs are valuable; need careful, thoughtful, scientific approach and review of all data before making final decision	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0069	Benefits

Commenter	Summary of Comments	Link to Comment	Comment Category
Western Agricultural Processors Association	These chemicals are important (notes certain important chemical-crops and pests); overly conservative; comments on listed species not occurring in ag. regions that received LAA determinations; concern for losing these pesticide tools	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0071	Benefits
NW Horticultural Council	Chlorpyrifos important in IPM (deciduous tree fruit); exposure modeling does not reflect NW growing conditions	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0054	Benefits
The Sutter-Yuba Mosquito and Vector Control District, CA	Process related comments as well as comments related to the importance of OPs in IPM strategies	https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0048	Benefits

Individual Responses to General Comments

The following are responses to comments based on letter-writing campaigns, or technical comments not grouped in Tables 1-4.

Letter-writing campaign

EPA received comments from more than 78,000 private citizens (via a mass mail campaign organized through Care2) urging EPA to place a ban on the use of chlorpyrifos, diazinon, and malathion until these chemicals can be proven to not adversely affect endangered species. EPA will consider these comments as part of the registration review process for chlorpyrifos, diazinon, and malathion. The effects determinations detailed in the BEs for chlorpyrifos, diazinon, and malathion reflect estimated risk to one or more individuals of a listed species, and do not assess the effects of the action on the population. The biological opinions for these chemicals, slated to publish in 2017, will evaluate population level risks and the extent to which use of three pilot chemicals will result in jeopardy to the continued existence of the listed species and/or adverse modification to designated critical habitat. EPA will continue to work with the Services to refine the endangered species risk assessment methodology.

EPA received anonymous comments from a handful of private citizens expressing concern for risks to listed species, human health, and concern for risks to non-listed species such as bees and other beneficial insects. EPA appreciates these comments and will consider them prior to making a regulatory decision for chlorpyrifos, diazinon, and malathion.

Technical Comments not grouped in Tables 1 -4

In addition, EPA received numerous general comments related to the BE process, potential process improvements, and model assumptions that were not readily grouped into one of the above sections. The individual comments and responses are detailed below:

1. The Northwest Center for Alternatives to Pesticides (NCAP) submitted a comment expressing concern about the involvement of the FIFRA Endangered Species Task Force (FESTF) in numerous aspects of the BE process (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0076).

FESTF is an industry consortium established in 1997 to supply information to EPA and the Services in support of ESA consultation activities. FESTF has been instrumental in gathering species location and life history information that is needed for FIFRA-ESA analyses. This included the creation of "map kits" based on NatureServe and other data, which were supplied to USFWS field offices to enable creation of GIS listed species range data that served as the basis for the draft BEs. Although efforts are ongoing to continue refinements to the current set of listed species range maps, the available information has been vetted by USFWS as reliable for use in ESA analyses. FESTF submitted a detailed response to this comment, which is provided in **Attachment A**.

In addition, NCAP submitted various detailed comments related to transparency and potential process improvements. These comments were related to various issues, such as overlap of pesticide use areas with species range, mosquitocide use areas, effects thresholds, use of most sensitive species, use of safety factors, spray drift versus run-off exposure modeling, modeling of spray drift at local scales, incorporation of "usage data," consideration of abiotic factors, double-cropping, and species bin assignments. EPA's response to these detailed comments follows:

- Attachment 1-6 provides a summary of the percentage of overlap of a listed species' range with the particular Crop Data Layer (CDL) or other use (e.g., urban) layer.
- 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. .
- The 1-in-1-million effect level was used as a screening threshold in Step 1 and Step 2. In some cases, the effect threshold was below any measured effect level. Also, the 1-in-1-million threshold is similar to the FIFRA-based endangered species LOC, (1/20 of the LC50) assuming a default slope of the dose-response curve. The agencies intend to revisit the 1-in-1-million threshold to ensure that it does not reflect effects that are "insignificant" or "discountable."
- For indirect effects, a default dose-response slope of 4.5 was recommended by the 2004 Overview Document (https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf), which describes EPA's methods for endangered species risk assessments. When other slopes are justified by the data in hand, they are used.

- Use of the most sensitive species tested was also recommended in the 2004 Overview Document, and represents a conservative risk assessment assumption. We have also incorporated species sensitivity distributions (SSDs) and data arrays to better visualize the range of toxicity data. Techniques to estimate effect thresholds to listed species are available, like the Interspecies Correlation Estimator (ICE) developed by EPA's Office of Research and Development may also be used to explore uncertainty in species sensitivity.
- The use of the No-Observed-Adverse-Effects-Concentration or Level (NOAEC or NOAEL) is also recommended by the 2004 Overview Document. The basis for developing a 'safety factor' such as 0.25 * study NOAEC is unsupported given the statistical uncertainty in deriving this value. In addition, the 2013 NAS report recommended against using safety factors in ecological risk assessment. When there is great statistical uncertainty in the terrestrial plant NOAEC, a 5% effect level (EC_{05}) is derived instead.
- The use of technical active ingredient toxicity data for runoff exposure assessment is based on the observation that the components of a pesticide formulation (active and other ingredients) degrade and are transported away from the application site at different rates. Thus, organisms exposed to runoff are not exposed to the entire formulation in its original form. In the case of spray drift, it is reasonable to assume that the formulation reaches the receiving water body intact, and that this is what the organism could be exposed to on an acute basis. In combining runoff and spray drift, it is appropriate to use technical active ingredient toxicity data since the active ingredient is the stressor present in both exposure routes. Data for the formulated product are considered in risk characterization if shown to be more toxic than the active ingredient for a particular taxon.
- Non-agricultural uses have been modeled, including: forestry, rights-of-way, nurseries, and homeowner uses. Modeling of spray drift in structurally complex environments (*i.e.,* forests), on a nationwide basis, is beyond the capabilities of EPA's spray drift exposure models at this time.
- The BEs evaluated a range of "high" and "low" maximum label application rates corresponding to different pesticide use patterns. EPA is evaluating the appropriate scale at which to incorporate percent crop area/crop treated in the exposure assessments. Private sector surveys (GfK) or government analyses (USDA NASS and USGS) that estimate pesticide use intensity on a nationwide basis are useful information, and may be factored into our ESA analysis as appropriate in the future.
- The agencies are currently evaluating the influence of abiotic factors on a qualitative basis. Increased temperatures may increase toxicity to some taxa (*e.g*., fish), but they can also promote faster pesticide degradation, which would tend to decrease exposure.
- Regarding the modeling of double-cropping, EPA is confident that the conservative nature of the exposure modeling accounts for this uncertainty, by assuming 100% crop treated at field scale, that all treatment occurs on one calendar day, that all spray drift is deposited in the water body, etc. Modeling of Ultra-Low Volume (ULV) applications is done with both the AgDrift and AGDISP models, as they have complementary strengths.
- The list of species that may occur in aquatic bins 3 and 4 is found in Attachment 1-10: Aquatic Bin Assignments.

2. The Center for Regulatory Effectiveness (CRE) submitted comments related to the use of un-validated ESA models and what steps EPA should take to 'comply' (https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0052).

EPA thanks CRE for its comments on the validity of the models used in the draft BEs. The underlying models used in the draft BEs have undergone extensive peer-review by the Scientific Advisory Panel, the regulated community, and within the scientific literature. EPA does internal QA/QC of its models before using them in risk assessments. The modifications of EPA's models used in the BEs are now undergoing external QA/QC as a result of public comments. Errors identified within these models as part of the public comment process have been corrected in the versions released with the final BEs. EPA anticipates completing the formal QA/QC process before any regulatory decision is made regarding the pilot chemicals.

3. The California Department of Pesticide Regulation (CDPR) submitted comments related to potential process improvements, including use of their PRESCRIBE database to refine listed species range maps (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0074).

EPA appreciates CDPR's comments on its state-specific program for the protection of listed species from pesticide use. We are actively discussing the use of more detailed state-level data sets, such as PRESCRIBE, in the nation-wide FIFRA-ESA process. We encourage CDPR to collaborate with local USFWS and NMFS field offices to ensure the use of consistent and best available data on species range maps as EPA considers the Services to be the expert and authoritative source on range maps for listed species and designated critical habitat.

4. The Xerces Society for Invertebrate Conservation submitted various process related comments regarding potential mixtures and use data as well as a recommendation that conservation measures be implemented upon completion of consultation (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0881).

The Agencies are exploring ways of incorporating usage data into the Step 3 process as part of the RPA and RPM discussion.

EPA agrees that protection measures do not need to wait for completion of the BiOp. EPA's public process, including Focus meetings with registrants, provides a forum for proposals of early mitigation, including label changes and conservation measures in advance of formal consultation. We encourage the submission by registrants of suggested protection measures that may be implemented either on labels or through Bulletins. We believe that this may be feasible especially for listed species with small, well-defined ranges.

5. The Almond Hullers and Processors Association (AHPA) (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0055) and California Citrus Quality Council (CCQC) (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-

0850-0904) submitted various process related comments, including recommendations for how to incorporate usage information and Integrated Pest Management (IPM) strategies.

EPA thanks AHPA and CCQC for their comments. We would be interested in how the IPM programs for chlorpyrifos and diazinon, developed with CDPR and the University of California statewide IPM team, interact with endangered species protection programs such as PRESCRIBE. Specifically, any IPM practices that are intended to protect listed species and could be translated into ESPP bulletins would be useful.

6. The IR-4 Project submitted comments related to model assumptions, potential process improvements, and the importance of resistance management (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0924).

EPA thanks IR-4 for its comments. We agree that public health uses of OP insecticides are important, since the OP class is only one of two insecticide classes registered for use as mosquito adulticides. The benefits of OP insecticides in specialty agriculture are also important. The RPAs and RPMs from the BiOps will take economic feasibility into consideration if changes to public health or specialty agriculture uses are contemplated.

Given the current size and complexity of the BEs, EPA is working toward identifying the portions of the BEs that are essential to the BiOp, so that future analyses can be streamlined, produced in a more timely fashion, and be transparent to the public. .

We also recognize that a combination of low effect thresholds and conservative exposure estimates have resulted in a large number of Likely to Adversely Affect (LAA) determinations. It's important to reiterate that a LAA determination within the BE is meant to signify an effect to one or more individuals of a listed species, rather than to an entire population of the listed species. As the BiOps are developed, EPA intends to re-evaluate the interim approach in collaboration with the Services, including both the exposure modeling and effect thresholds.

EPA welcomes IR-4's assistance in better defining the area and intensity of mosquitocide applications in the pesticide consultation process. Probabilistic methods are also being considered, and EPA welcomes IR-4's input in this area.

7. The American Bird Conservancy (ABC) submitted process related comments as well as comments regarding model assumptions specific to the chlorpyrifos BE (https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0893).

EPA appreciates ABC's comments on the chlorpyrifos BE. EPA would like to clarify that a finding of LAA in the BE is based on the likelihood of adverse effects to a single individual of a listed species, and does not constitute a finding that the species population as a whole is in jeopardy. The determination of jeopardy/no jeopardy and adverse modification to designated critical habitat/no adverse modification to designated critical habitat is reserved for the BiOp.

ABC's comments on the inability of the TEDtool to model granular products and seed treatments are well-taken. However, these uses were evaluated and considered when making effects determinations as detailed in Appendix 4-6.

FESTF

FIFRA Endangered Species Task Force

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October 19, 2016

Dana Friedman
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Dear Ms. Friedman, Ms. Nguyen, and Mr. Snyderman:

The FIFRA Endangered Species Task Force (FESTF) respectfully submits this letter to address incorrect assertions by certain advocacy groups regarding the Task Force's FIFRA-authorized role as an industry-wide Task Force formed in response to U.S. Environmental Protection Agency (EPA) data requirements related to potential impacts of pesticides on threatened and endangered species:

- In a June 10, 2016 letter posted to the dockets for EPA-OPP's draft Biological Effects determinations on chlorpyrifos, diazinon, and malathion, the Northwest Center for Alternatives to Pesticides and several other public interest groups criticized reliance by the EPA and the Services (the U.S. Fish & Wildlife Service and the National Marine Fisheries Service) (collectively, the Agencies) on FESTF data collection and analysis -- including FESTF-generated maps for aggregated species location information. As described below in Section A, reliance on FESTF data by EPA and the Services is fully consistent with applicable Federal law and each Agency's mandate to require and consider the best available data in connection with regulatory decisions that concern pesticide registrations.

- In a separate June 10, 2016 letter posted to the same dockets, the Center for Biological Diversity (CBD) and other public interest groups baselessly dismiss the value of FESTF's data by misrepresenting the scope and purpose of confidentiality claims that apply to FESTF's submissions. As described below in Section B, FESTF is required by binding contract terms to protect the confidentiality of certain proprietary information belonging to FESTF's third-party data licensor, the highly-regarded NatureServe organization. In this context, FESTF has appropriately limited its confidentiality claims to those that are required to comply with FESTF's specific contract obligations. The final GIS maps generated and utilized by EPA and the Services on the basis of FESTF-submitted data are not subject to any separate or additional confidentiality claims by FESTF. Indeed, FESTF has long supported the Agencies' maps being made available for review by stakeholders and the wider public consistent both with the statutory data

protection obligations that may apply to each Agency, and with FESTF's right to obtain data compensation from pesticide companies that have not joined FESTF but rely on FESTF's work.

In all circumstances, FESTF is committed to the appropriate and responsive development of the highest quality data for endangered species assessment and has generated and will continue to develop useful, reliable data for species assessment as has been specifically required by EPA and the Services under their governing laws and regulations. We will continue to work with the EPA and the Services in addressing such needs.

A. Agency Reliance On FESTF Data Is Fully Consistent With Federal Mandates

Without question, consideration of FESTF data by EPA and the Services provides the Agencies with some of the best data currently available to make national-scale determinations required under the Endangered Species Act (ESA) in response to consultation arising from FIFRA actions. This reliance is fully authorized and mandated by Federal law. As provided under Section 3(c)(2)(B)(ii) of FIFRA, pesticide registrants may join together to share in the costs of developing data required by EPA to maintain existing product registrations, and the formation of many industry task forces to address numerous regulatory issues have enabled EPA to receive and consider the most complete and scientifically sound data ever generated in connection with the Agency's continuing evaluation of pesticides under Federal law.

FESTF was formed in 1997 in direct response to EPA's demands presented to a number of pesticide registrants that the companies provide significant additional information about pesticide product use and endangered species locations across the United States in order for these companies to maintain their registrations, including by allowing EPA to comply with provisions of the Endangered Species Act (ESA). FESTF's establishment and critical data development role was formally recognized by EPA-OPP's Pesticide Regulation Notice 2000-2 (April 17, 2000), as well as in many EPA-OPP documents generated since.

Accordingly, FESTF and its members have been required under FIFRA to generate and submit their data to meet express EPA regulatory requirements, and EPA is obligated under FIFRA and ESA to consider these submitted data in support of FESTF member registrations. The Services are also expressly required to rely on the "best scientific and commercial data available" when conducting consultations under the ESA. ESA Section 7(a)(2). In considering the scope of data considered under the ESA in the context of species listings, the Services routinely consider data submitted by applicants and other interested parties and consult with "interested parties and organizations" as "sources of information and relevant data" when considering the best scientific and commercial data available. *See* 50 C.F.R. Section 424.13.

Notably, a challenge to EPA's reliance on the data generated by FESTF was squarely rejected in 2004 by the U.S. District Court for the Western District of Washington. According to the Court, FESTF's operation, data generation efforts, and interactions with EPA are fully appropriate and consistent with Federal law. *See Washington Toxics Coalition, et. al. v. EPA,* 357 F.Supp.2d 1266, 1274 (W.D. Wash. 2004) (describing how FESTF works to "provide EPA with data to attempt to ensure that pesticides will remain or become registered in accordance with FIFRA" and recognizing that "[c]ommunication between EPA and FESTF regarding the validity of [FESTF-compiled] data was entirely appropriate").

B. FESTF's Confidentiality Claims Are Limited To The Protection of Its Licensor's Proprietary Information

FIFRA mandates the disclosure of a wide range of information related to pesticide product tests and safety (subject to FIFRA's key prohibition against disclosure to foreign and multinational pesticide producers). At the same time, and consistent with Exemption 4 of the Freedom of Information Act (FOIA) and well-established federal policies addressing the need to protect confidential business information, FIFRA Section 10(b) recognizes and anticipates the need to protect the confidentiality of certain other information that relates to trade secrets or commercial or financial information. In this context, FESTF has asserted confidentiality claims over its submissions only to the extent required to protect specific trade secret and proprietary information belonging to its third-party data licensor, NatureServe, as FESTF is obligated to do consistent with FESTF's license agreement with that highly regarded non-profit organization. Far from seeking to impose confidentiality restrictions "solely" for FESTF's "own benefit" (as charged by CBD), FESTF has in fact asserted no confidentiality claims beyond those required by the license governing its own use of proprietary NatureServe data. Notably, data submitted by FESTF at resolutions below the threshold established by the terms of its license are not subject to any independent FESTF confidentiality claims. In any case, CBD's sweeping charge that confidential information submitted to an Agency is "useless" solely due to its confidential nature ignores FIFRA's careful balancing of the need to encourage the generation and submission of the most sensitive types of information while promoting and ensuring transparency at key stages of pesticide regulatory decision-making.[1]

The confidentiality claims that FESTF has asserted over the proprietary aspects of its own submissions in no way prevent EPA or the U.S. Fish & Wildlife Service (FWS) from making their subsequently generated GIS maps available for review by stakeholders and the general public. To the contrary, consistent with any other applicable data protection obligations, FESTF encourages both Agencies to upload or otherwise make their final GIS maps available for public review at a spatial resolution that complies with the terms of FESTF's license agreement with NatureServe. FESTF fully agrees with the need for the public to be provided with an opportunity to review the GIS maps to support a greater understanding of the Agencies' conclusions for each listed species.

Thank you for your consideration.

Sincerely,

Bernalyn McGaughey

Bernalyn McGaughey, Project Manager FESTF

cc: Anita Pease (EPA OPP EFED)
Yu-Ting Guilaran (EPA OPP PRD)
Patrice Ashfield (FWS ESP BNC)
Cathy Tortorici (NMFS OPR F/PR5)

[1] Separately, CBD incorrectly asserts that FWS does not have access to confidential FESTF studies and requests that FWS be provided with such access going forward. In fact, FESTF has submitted all of its confidential information to both Agencies and FWS has always had full access to FESTF's data submissions, whether classified as CBI or otherwise.