May 2, 2022

Elissa Reaves
Director of Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Via Regulations.gov: EPA-HQ-OPP-2022-0172

Re: CropLife America Comments to the U.S. Environmental Protection Agency on the "*NMFS Draft Revised Biological Opinion on Chlorpyrifos, Diazinon, and Malathion*" EPA-HQ-OPP-2022-0172

Dear Ms. Reaves,

CropLife America (CLA) appreciates the opportunity to offer the below and attached comments on the National Marine Fisheries Service's (NMFS) Draft Revised Biological Opinion (draft BiOp) on the Environmental Protection Agency's (EPA's) Registration Review of Pesticide Products containing Chlorpyrifos, Malathion, and Diazinon, EPA-HQ-OPP-2022-0172.

Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA represents its members by monitoring legislation, federal agency regulations and actions, and litigation that impact the pesticide and pest control industries and participating in such actions when appropriate as well as communicating the benefits of pesticides to a variety of audiences. CLA's members produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers. CLA and its members are committed to the protection of endangered species and their habitats and have long been engaged in improving the process for registration of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and review under the Endangered Species Act (ESA).

Given the inherent tension between FIFRA and the ESA—each imposing different regulatory standards to achieve different objectives—EPA, NMFS, the U.S. Department of Agriculture (USDA), and the U.S. Fish and Wildlife Service (FWS) (collectively, the Agencies) have historically struggled to implement an efficient process for ESA review of registered pesticides. Over the past decade, however, the Agencies have developed a cooperative framework to conduct consultation under the ESA. Although this framework still requires improvement and additional resources for the Agencies, it has demonstrated that interagency cooperation and stakeholder engagement are crucial to any efficient and practical ESA review process. CLA seeks to work with the Agencies and other interested stakeholders to help improve

and refine the ESA review process and to ensure the continued safe registration and use of pesticide products.

Background

The current draft BiOp marks the latest development in nearly fifteen years of administrative proceedings, interagency consultation, and litigation concerning NMFS's BiOp on chlorpyrifos, diazinon, and malathion. NMFS first completed the first nationwide BiOp on the three active ingredients in 2008, which was challenged by various stakeholders. In 2013, the U.S. Court of Appeal for the Fourth Circuit vacated the 2008 BiOp, finding it was arbitrary and capricious because it "relied on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Servs.,* 707 F.3d 462, 475 (4th Cir. 2013). As such, the court remanded the 2008 BiOp to NMFS for a "renewed agency process." *Id.*

NMFS completed the next iteration of the BiOp in December 2017 pursuant to a court-ordered deadline, but the agency acknowledged that it did not have sufficient time to "fully account for the need to coordinate on a different process for [ESA review] or to fully engage the public."[1] Accordingly, EPA requested to reinitiate consultation with NMFS to obtain greater input from stakeholders, further interagency discussion on analytical methodology, and consider additional data and analyses, including usage data that EPA would provide to NMFS and FWS (collectively, the Services).[2] Following the reinitiated consultation, NMFS transmitted the current draft BiOp to EPA on February 24, 2022.

Despite its long history of revision, the current draft BiOp does not include stakeholders' input and best available data. As a result, the draft BiOp is overly conservative in its risk analysis and proposes unduly burdensome alternatives. For example, when NMFS was addressing the deficiencies in the Federal Columbia River Power System (FCRPS)[3] BiOps between 2005 and 2008, there were "272 PWG [Policy Working Group] and Technical Workgroup meetings involving more than 150 participants from 26 organizations." In contrast, FMC, as applicant of Malathion, so far has been allowed only three meetings in the two years that elapsed between the delivery of the Organophosphate (OP) Applicant Engagement Plan in 2020 and the Final BiOp planned for release in June 2022. This lack of meaningful engagement has direct impacts on BiOp defensibility and the consequences of regulatory actions that may arise from a final BiOp.

In addition, engagement with topic specific groups (e.g., grower and other user groups) can often provide national-level data and information of relevance and a better understanding of how pesticides are used on the ground; what avoidance, minimization, and conservation options are available; existing agronomic practices employed by growers; and how current label restrictions are implemented. NMFS should therefore engage more deeply with stakeholders to

[1] NOAA Fisheries National Marine Fisheries Service, Biological Opinion for Pesticide: Chlorpyrifos, Diazinon, and Malathion (Dec. 29, 2017), at https://www.fisheries.noaa.gov/resource/document/biological-opinion-pesticides-chlorpyrifos-diazinon-and-malathion.

[2] Letter from Richard P. Keigwin, Jr., Director, Office of Pesticide Programs, U.S. Environmental Protection Agency to Donna S. Wieting, Director, Office of Protected Resource, National Marine Fisheries Service 1 (Feb. 21, 2018), at https://www.regulations.gov/document/EPA-HQ-OPP-2018-0141-0004.

[3] FCRPS BiOp Federal Columbia River Power System Biological Opinion | NOAA Fisheries

get a greater technical understanding of the actual exposure and risks, consult with its counterpart agencies, including USDA, FWS, and EPA to incorporate best available data in its analysis, and revise its proposed Reasonable and Prudent Measures (RPMs) and Reasonable and Prudent Alternatives (RPAs) to satisfy the ESA's legal standard.

NMFS's Obligation to Coordinate with its Counterpart Agencies and Stakeholders

In 2011, the Agencies requested the National Academy of Sciences (NAS) to make recommendations on tools and approaches for achieving FIFRA programmatic compliance with the ESA. The Agencies then relied on the resulting NAS report to develop joint interim approaches for assessing the risks of pesticides to listed species and their habitats.[4] In adopting NAS's recommendations, the Agencies agreed to "increase[e] the opportunities for stakeholder input" and acknowledged that "data submitted by pesticide registrants. . .will be used as a source for best available toxicity data."[5] The Agencies also committed to work collaboratively to develop an ESA review process based on shared assumptions, data, and methodologies that would be refined and improved over time.[6]

In addition to the Agencies' own initiative for developing a collaborative ESA consultation framework, Congress has repeatedly instructed the Agencies to coordinate with each other and with stakeholders in conducting ESA review of registered pesticides. Most recently, under section 10115 of the 2018 Farm Bill, Congress codified a FIFRA Interagency Working Group (IWG), which includes the Agencies and the White House Council on Environmental Quality.[7] To achieve its goal of improving the ESA consultation process, Congress instructed the Agencies to "develop scientific and policy approaches to increase the accuracy and timeliness of the process for [ESA] consultation" and "efficiently share data and coordinate analyses[.]"[8] Congress also recognized the importance of stakeholder input, and instructed the Agencies to consult with industry stakeholders and nongovernmental organizations.[9] As such, NMFS should comply with this statutory mandate by meaningfully engaging with applicants and other stakeholders and coordinating with USDA, FWS, and EPA in developing its BiOp.

NMFS Must Coordinate with Stakeholders, FWS, and EPA To Apply the Best Available Science and Commercial Data

The ESA requires that the Agencies "use the best scientific and commercial data available" in conducting ESA consultations.[10] Yet, the draft BiOp fails to satisfy this requirement for several reasons—namely by failing to consider and incorporate certain usage

[4] EPA, Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (Oct. 2015), at https://www.epa.gov/sites/default/files/2015-07/documents/interagency.pdf.
[5] *Id.* at 1, 3.
[6] *Id.* at 1.
[7] Agriculture Improvement Act of 2018 ("2018 Farm Bill"), Pub. L. No. 115-334, § 10115, 132 Stat. 4490, 4914 (2018).
[8] § 10115, 132 Stat. at 4914
[9] § 10115, 132 Stat. at 4917.
[10] *See* 16 U.S.C. § 1536(a)(2).

data. Instead, the draft BiOp's analyses, particularly its jeopardy determinations, relies on unsupported assumptions that results in overstated estimates of pesticide usage and inaccurate findings of risk.

As part of its own effort to draft a BiOp for EPA's registration of pesticide products containing chlorpyrifos, diazinon, and malathion, FWS requested that EPA provide usage data on all three active ingredients, finding the data to be necessary for formal consultation.[11] Given that NMFS is subject to the same regulatory standards as the FWS—EPA concluded that the usage data would be equally crucial to NMFS's consultation process. As set forth more fully in the attached Appendix-I, however, the NMFS analyses and interpretation of the applicability of usage data was highly flawed and runs counter to the findings of both EPA and the FWS. The draft BiOp explained that pesticide usage is underreported for certain smaller crops, and EPA's approach of assuming a percentage of crop treated in these cases carries unacceptable uncertainty. The draft BiOp's rejection of data in this instance is unsupported.

NMFS should consult with EPA and FWS to better understand the basis and implications of those agencies' assumptions and engage with industry stakeholders to reevaluate submitted usage data. Indeed, EPA recently demonstrated the regulatory efficiencies that can be achieved when an agency works with stakeholders to evaluate updated data concerning pesticides and listed species. In March 2022, EPA granted Corteva Agriscience's request to amend the labels for two herbicides, Enlist One and Enlist Duo, for use in 134 additional counties.[12] EPA conducted a new effects determination based on updated species range maps from FWS for the American Burying Beetle and concluded that the use of the Enlist herbicides in these additional counties, when applied in accordance with the label, was not likely to adversely affect listed species or their critical habitat. In addition, FWS's updated species range map demonstrated that the Eastern Massasauga rattle snake is no longer present in Minnesota, therefore obviating county restrictions for use of Enlist Duo in that state. In sum, EPA acknowledged its "commitment to work with stakeholders when new information becomes available to make regulatory decisions that reflect the best available science . . ."[13] NMFS should similarly follow EPA's lead in coordinating with its counterpart agencies, as well as engaging with stakeholders, to apply the best available science and commercial data.

NMFS Must Coordinate with Stakeholders and USDA to Develop Practicable RPAs and RPMs

The draft BiOps for pesticides are unique in that they are not tied to a specific, spatially isolated project, but rather evaluates the nationwide use of pesticide products containing the active ingredients at issue. Despite this draft BiOp's expansive scope and potentially significant effect on the American agricultural industry, it does not evaluate the practical impact of the

[11] *See* Letter from Richard P. Keigwin, Jr. to Donna S. Wieting, *supra* note 2, at 2.
[12] EPA, EPA Expands Use of Enlist Products to 134 Additional Counties for the 2022 Growing Season (Mar. 29, 2022), at https://www.epa.gov/pesticides/epa-expands-use-enlist-products-134-additional-counties-2022-growing-season.
[13] *Id.*

proposed RPAs and RPMs on the thousands of growers who currently rely on pesticide products containing chlorpyrifos, malathion, and diazinon. It may be that the enormous resource demands of the draft BiOp's scope hindered NMFS's efforts on this issue, but as explained below, the importance of coordination with agriculture stakeholders for prioritization of resources to obtain key inputs for RPAs and RPMs.

Crucially, the RPAs in the draft BiOp are overly burdensome on growers such that they are not economically feasible and thus do not satisfy the standard under 50 C.F.R. § 402.02.[14] For example, RPA Element 1(a) proposes removing label authorization for all applications within 300 meters of a listed species habitat. Given that thousands of growers currently use pesticides containing the at-issue active ingredients, eliminating their use in areas with certain geographic proximity to a listed species habitat will have significant adverse effects on growers' ability to protect their crops from destructive pests. With regard to this element of the RPA, the draft BiOp suggests that some growers "may find that it is preferable to choose an alternative pest control method" and notes that "there are hundreds of insecticide products currently registered for use in the United States that do not require any mitigation specific to the species covered by this RPA."[15] However, this fails to consider the cost and practicability of incorporating alternative pesticides into a particular grower's pest management practice. Growers must plan their pesticide use practices far in advance of the growing season, and many will suffer serious disruption should they have to alter their existing rotation of pesticide products—including from the need to purchase specialized application equipment or reverting to less effective pesticides that increase the risk of pest resistance.

Equally troubling is RPA Element 1(b), which imposes a 300 m no-spray buffer for all aerial applications, 150 m buffer for all ground applications, and 6 m vegetative filter strip for all applications (discussed in Appendix-I, Section 3). Notably, this RPA element is identical to the one proposed in the 2017 BiOp. Nonetheless, the draft BiOp does not address stakeholders' prior concerns regarding the prohibitive cost of installing ground, aerial, and vegetative strip buffers. More importantly, the draft BiOp's proposed uniform application of buffers ignores the unique circumstances of certain agricultural operations. As explained in USDA's comment on the 2017 BiOp, there are instances in which buffers increase pest pressure, allowing for the recolonizing of weeds, insects, and pathogens.[16] Thus, NMFS should engage with its counterpart agencies—particularly USDA which has technical expertise in the agricultural industry—and consult with applicants and pesticide users on the practical application of the proposed RPAs.

CLA and its members are appreciative of NMFS's effort in completing this nationwide assessment. However, we believe that further engagement with the Agencies and stakeholders is

[14] An RPA is an alternative action "that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that [NMFS or FWS] believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat." 50 C.F.R. § 402.02.

[15] NMFS, Draft Revised Biological Opinion on the Environmental Protection Agency's Registration Review of Pesticide Products Containing Chlorpyrifos, Malathion, and Diazinon, at 2547.

[16] USDA Comment on the National Marine Fisheries Service Biological Opinion Issued Under Endangered Species Act: Chlorpyrifos, Diazinon, and Malathion 18 (July 23, 2018), at https://www.regulations.gov/comment/EPA-HQ-OPP-2018-0141-0106.

necessary to develop and refine an accurate, defensible risk analysis, along with realistic and reasonable RPAs. CLA and its members are committed to leveraging our available resources and working with the Agencies and interested stakeholders to help develop an ESA consultation process that protects listed species and their habitat, while recognizing the important role that pesticides serve in agriculture and in the protection of property and human health. CLA welcomes the opportunity to work with NMFS on analyzing and incorporating usage data into the draft BiOp, and to develop a standardized list of mitigation measures that advance the protection of species without undue burden to growers and other pesticide users.

Should you have any questions or comments, please feel free to contact me at mbasu@croplifeamerica.org or (202) 296-1585.

Respectfully,

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Appendix-I

Technical Comments

1. NMFS Must Improve the Transparency of the BiOp Process

The draft BiOp suffers from a lack of transparency in the data sets applied and the analyses undertaken, thereby limiting the ability to duplicate or confirm results. For example, the draft BiOp fails to report the temporal extent of the data used in the analyses. NMFS used prometryn surface water data to demonstrate that monitoring does not completely overlap reported usage (Appendix E, Figure 811 in the draft BiOp). However, there is no indication of the temporal range of the monitoring data, the relevance of the data to the Kynetec data applied or to the prometryn label changes from recent EPA FIFRA actions, relevance to the organophosphates being evaluated (e.g., fate/behavior, persistence in aquatic systems), nor the relevance of surface water concentrations in the range of <0.75 µg/L given no detection limits or other information was provided.

NMFS also references the EPA Magnitude of Effect tool (MAGtool) in the draft BiOp (Section 4.4.5) but does not indicate which version of the MAGtool was applied, or provide the tool to evaluate assumptions, model input parameters, or other information.

Recommendations: NMFS should only use data relevant to the pesticide under review and share complete details of the analyses in the draft BiOp. This will allow stakeholders to evaluate the scientific defensibility of the assumptions, jeopardy (J)/destruction, or adverse modification (DAM) calls, and analyses undertaken to arrive at appropriate RPA/RPMs.

2. NMFS Must Use the Best Available Data

The draft BiOP (Appendix E) provided a justification for not considering historical malathion usage data when evaluating the magnitude and likelihood of exposure within each species range and critical habitat. This contrasts with recent Biological Evaluations produced by the EPA (e.g., EPA 2020a-c; EPA, 2021a-c) and the final FWS malathion BiOp (FWS, 2022), where usage data were used directly in quantifying the likelihood of exposure through an overlap analysis.

In the draft BiOp, NMFS conducted an overlap analysis between potential use sites and species range/critical habitat areas. This quantitative estimate of "percent overlap" is then used for establishing qualitative descriptions of the likelihood of exposure (low, medium, high). While the draft BiOp clearly indicates that percent overlap between potential use sites and species range/critical habitat not equivalent to a likelihood of exposure, the fact that percent crop treated (PCT) does not enter the equation when estimating likelihood of exposure incorrectly assumes that there is no difference in impact to a species when 1% of the acreage is treated versus 100% of the acreage treated. This approach assumes that a widely used pesticide will not result in a different likelihood of exposure than a rarely used pesticide, and that all approved pesticides for

an authorized use-site are used at once and at 100% label rate, thus leading to over-estimating the usage of the pesticide under review, and unreasonable mitigation measures.

In the draft BiOP, NMFS shared its concerns regarding usage data accuracy and included several examples:

1. *A map was used (Appendix E, Figure 811) to demonstrate that pesticide (prometryn) detections occurred where the usage was unreported*

The data used to substantiate this concern does not provide the year corresponding to the monitoring data, which may mean that detections occurred outside of the years for which pesticide usage data were mapped. Prometryn recently underwent registration review thus label changes, including rate reductions, mitigations, and use pattern adjustments, have not been accounted for. In addition, all the detections in western Washington (WA) and Oregon (OR) (the example area used to make the claim that monitoring detections do not align with usage) appear to be at concentrations less than 0.75 µg/L. No information is provided on detection limits or limits of quantification for the analytical methods used. Thus, based on this map on its own, we have no information to tell if the monitoring station points in western WA/OR are reporting quantifiable levels of the example pesticide, prometryn. It is also unclear what the relevance of prometryn, a herbicide, is to malathion, chlorpyrifos, and diazinon.

2. *Malathion use is reported in the California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) database, but not reported in the National and State Summary of Usage and Use Matrix (SUUM) based on the Kynetec agricultural marketing research data (AMRD), as evidence that significant amounts of usage go unreported, and that EPA's approach of assuming 2.5% PCT in these cases is not sufficient*

We used the data that was "unreported" in the SUUM but reported in the PUR database to calculate the acreage treated (assuming the maximum annual application rates modeled by EPA in its Final BE (EPA, 2017) associated with the average PUR usage reported by NMFS in its table in Appendix E (NMFS, 2022). Based on the average crop area grown, also reported in the SUUM, we calculated a PCT for each crop (see Table 1). These PCT values ranged from <0.01% for peaches to a maximum of 1.56% for beans. Only beans and cotton had PCTs greater than 1%. The total treated area over the entire state of California summed to 3,895 acres. Using EPA's current conservative assumption of 2.5% PCT for crops with no reported state-level usage, 37,235 acres of these example crops treated at maximum label rates nearly 10x higher than the "actual" usage reported in the PUR database.

This example is an excellent indicator of how, in situations where usage is unreported from reliable best available data sources, the actual usage is highly likely to be insignificant, and a conservative assumption, such as the 2.5% minimum PCT assumed by EPA, is likely to overestimate actual usage by a substantial amount.

Table 1. Percent Crop Treated for California Crops with Unreported Usage in the AMRD from Malathion SUUM					
Crop	**Avg. 2011 - 2015 Usage (lbs)[a]**	**Max Annual Rate (lbs/ac)[b]**	**Area Treated at Max Rate (ac)**	**Avg. Crop Area Grown (ac)[a]**	**Percent Crop Treated (%)**
Beans (succulent)	175	1.22	143.5	9,200	1.56
Cotton	22,411	7.5	2,988.1	293,000	1.02
Cucumbers	93	3.5	26.6	8,700	0.31
Peaches	15	9	1.6	52,500	0.00
Pears	10	2.5	4.1	13,500	0.03
Potatoes	353	3.12	113.0	34,700	0.33
Rice	720	2.5	288.2	511,200	0.06
Watermelons	144	5	28.8	10,600	0.27
Corn, Field	602	2	301.1	556,000	0.05

a) From EPA Malathion SUUM

b) From EPA Final Biological Evaluation, Appendix 1-3

3. *Past usage of a pesticide (5 years specifically) does not represent how much pesticide will be used in the future.*

In the draft BiOp, NMFS evaluated 3,269 use site/pesticide pairs. A use site/pesticide pair (e.g., use on almonds of diazinon) needed to have a recorded use 1) on or before 1998 to make sure the pesticide was in use at the start of the 20-yr period and 2) used at least once in the last 5 years (2013-2017) to make sure that the pesticide was still in use at the end of the 20-yr period. The results of this analysis suggested that past usage would underestimate actual future use of pesticides by more than 100%, approximately 29% of the time. However, the conclusions are not applicable to estimating future usage. Looking at 153 pesticides over a 20-year period, as the NMFS analysis did, many pesticides would have experienced changes in labels during re-registration, and other recently introduced pesticides would have had use pattern expansions approved by EPA under FIFRA. It is not surprising, looking across 153 pesticides and 248 use sites, that we see a high proportion of cases where pesticide acres treated increased by a substantial amount or decreased a substantial amount. However, this observation does not substantiate that an individual, well understood pesticide (like malathion) has a high likelihood of seeing an increase in usage over the next 15 years. Malathion has a long history from which to understand its role as a tool for growers, changes in its registered uses through EPA, and many years of usage data at state and national levels. For malathion, this data has shown that over the past 15 to 20 years, usage has remained steady, with expected year to year variability, with a general reduction over time. This trend can be seen in the extended EPA SUUM (EPA, 2017).

Given the mature markets of these insecticides, and EPA's regulatory authority over label changes, a future expansion of registered use patterns and increases in application rates are extremely unlikely. Therefore, we have a strong understanding of how historical usage will very likely be representative of future usage over the coming 15 years using the best available data,

and thus confidence in this projection is very high. If proposed label changes for these insecticides would lease to a significant expansion in use, EPA can reevaluate prior to approving such changes.

Recommendations: Reasonable estimates of pesticide usage are of paramount importance when estimating exposure likelihood and magnitude of pesticide exposure. Actual usage data are the best available data to characterize the realistic application of pesticide products. Without using this information, exposure estimates and RPAs/RPMs, may not be relevant or effective.

3. NMFS Must Develop Realistic RPAs and Consider Malathion Label Changes Based on FWS Malathion Consultation

The RPAs in the draft BiOp are applicable to "all high-risk applications," defined as applications within 300 m of "listed species habitat" for which J/DAM was determined (p. 2549, draft BiOp). NMFS "determined sensitive areas by identifying, for example, designated critical habitat within populations that have been identified in recovery plans as 'core' or 'essential' to the recovery of the species" (p. 29, draft BiOp). However, the species maps provided depict the species range and designated critical habitat with no indication of overlap, or sensitive areas. NMFS specifies that "these maps are provided for general reference only and do not necessarily represent the spatial data that was used later in the assessment (e.g., for generating overlap percentages in the effects analysis)" (p. 137, draft BiOp). NMFS does not provide any basis to support its recommendation of high-risk applications as being within 300 m of habitat nor a clear definition of which areas are identified as "listed species habitat." Therefore, these maps are of little value to understanding the analysis, extent of habitat, and determining where RPAs are needed.

Furthermore, the RPAs proposed in the malathion draft BiOp do not account for changes made to the malathion label during consultation with FWS. Several such label adjustments must be factored into aquatic exposure modeling, for example, and are likely to negate the need for any additional RPAs within some NMFS species ranges. NMFS has acknowledged that the malathion label commitments for registration review, as outlined in Table 1, Attachment A of the FWS Final malathion BiOp (FWS, 2022), will be considered in the NMFS Final BiOp. The impact of these agreed upon changes to label language, labeled rates and number of applications must be accounted for prior to addressing and finalizing RPAs.

Recommendations: NMFS should justify the 300 m "high-risk application" proximity distance, as it is not based on field observations or modeling studies to determine that applications within this distance to habitat resulted in exposure concentrations that exceeded a toxicity level of concern.

4. NMFS Must Address Deficiencies in the Draft BiOp Carried Forward From the 2017 BiOp

EPA recognized deficiencies in the previous draft BiOp (NMFS, 2017) and listed them in its 2018 Request for Re-initiation Letter. In addition, EPA compiled and summarized comments at NMFS' request in a letter dated August 20, 2019[17] and provided the main points of concern (noted below):

- A lack of application of use and usage data. EPA recognized that use and usage data were not considered in the 2017 Biological Evaluation, while EPA and FWS believe that application of use and usage data is necessary to fully inform formal consultation and provided NMFS with this data.
- A lack of a clear relationship between how effects at the individual level change species demographic rates, and by extension, have population impacts.
- No quantitative thresholds underpinning the definition of "jeopardy" (i.e., the exposure level or level of effects results in "jeopardy") have been articulated, without which there is no way to tie the mitigation options to levels that would no longer result in "jeopardy".
- The criteria used to evaluate the likelihood of exposure appears to be inconsistent (e.g., some of the criteria, such as persistence and multiple applications, are accounted for twice in the process).
- Assumptions of all pesticide applications occurring at the same time at the highest maximum use rate across all potential use sites are unrealistic.
- An element of the RPAs is based on a European system (MAgPIE), which EPA has not evaluated for use in the US pesticide regulatory context.

For the most part, NMFS has not yet addressed the concerns identified by EPA except consideration of usage data and withdrawal of the European MAgPIE system as an RPA method.

Recommendations: NMFS should apply usage data as done by EPA in its recent biological evaluations (e.g., EPA 2020a-c; EPA, 2021a-c) and FWS in its recent malathion BiOp (FWS, 2022) to realistically quantify percent crop treated and make reasonable exposure predictions based on this best available data.

5. NMFS Must Address Inputs to Exposure Modeling and Technical Issues

In the draft BiOp, the input parameter selection used for running the aquatic exposure modeling needs to be updated. For example, standard inputs to the aquatic exposure modeling led to significant over-estimation of the estimated environmental concentrations (EECs) as it did not account for current label restrictions. In addition, the spatial resolution of exposure model scenarios was insufficient to represent variability of exposure within a species range or critical habitat. Use of edge-of-field and the lowest flow streams' EECs to represent concentrations in all

[17] Letter from R. Keigwin Jr., EPA Office of Pesticide Products to Donna S. Wieting, Director, Office of Protected Resources, NOAA, NMFS. August 20th, 2019. Submitted to Public Docket EPA-HQ-OPP=2018-0141. https://www.regulations.gov/document/EPA-HQ-OPP-2018-0141-0138

flowing water habitat is scientifically incorrect and does not serve the necessary purpose of exposure estimations used to evaluate jeopardy for ESA listed species. The reported malathion EECs, for example, are several orders of magnitude higher than the highest surface water malathion concentration ever measured, despite significantly more labelled use patterns and higher applications being authorized historically relative to the current legal malathion labels.

Therefore, aquatic exposure estimates remain unrealistic and unreasonable, particularly given the availability of higher tiered studies (including targeted field studies, mesocosm studies, ambient water monitoring data in pesticide use areas, etc.) which were not used as lines of evidence yet were provided by the malathion applicant (see Teed et al. 2018; Rodney et al. 2018; NMFS 2022 – Appendix F). This issue is further compounded given no refined EECs were generated using readily available, calibrated flowing water models (e.g., Surface Water Assessment Tool) which would have been relevant to NMFS salmonid and steelhead species.

NMFS points out that the RPAs that were developed as part of the FWS final malathion BiOp (FWS, 2022) have not yet been incorporated into the draft BiOp.

Recommendations: RPAs that were developed as part of the FWS final malathion BiOp (FWS, 2022) should be incorporated into the final NMFS BiOp. Aquatic EECs require adjustment to address the technical issues identified, account for the higher tier additional lines of evidence, and additional RPAs.

6. NMFS Must Re-Evaluate Pesticide Mixtures in Freshwaters

The draft BiOp uses pesticide monitoring data (Section 10.2.3.1) from natural waterbodies (Gilliom et al., 2007) for the evaluation of the three OPs. However, these data are outdated relative to current labels and known regulatory activities relevant to the three OPs being evaluated (e.g., cancellation of use in California[18] and Hawaii[19]).

The BiOp also concludes that fish (and presumably aquatic invertebrates and plants) exposed to these mixtures (three OPs) may experience additive and synergistic effects. However, the National Research Council report on assessing risks to endangered and threatened species from pesticides (NRC, 2013) states that when evaluating the combined effect of pesticides to ecological species, "mixture components do not need to be considered when present at concentrations below their toxic thresholds." Covert et al. (2020) recently evaluated pesticide mixtures and their potential toxicity to aquatic life in U.S. streams (water years 2013 – 2017). They found that five or more pesticides were commonly found in about 88% of stream samples analyzed. Samples from agricultural sites had higher numbers of pesticides than those from developed or mixed land uses. The study applied the pesticide toxicity index (PTI) approach which assumes underlying additivity within the pesticide mixtures, to evaluate toxicity to fish, cladocerans, and benthic invertebrates. Overall, they found low potential toxicity to fish and

[18] Chlorpyrifos cancellation in California https://www.cdpr.ca.gov/docs/chlorpyrifos/index.htm#:~:text=The%20California%20Department%20of%20Pesticide,end%20by%20December%2031%2C%202020.
[19] Chlorpyrifos cancellation in Hawaii https://www.capitol.hawaii.gov/session2018/bills/SB3095_.HTM

slightly increased toxicity to cladocerans and benthic invertebrates. Covert et al. (2020) identified the fact that one pesticide found in any mixture contributes >50% to overall sample toxicity. This is the same conclusion arrived at by Raby et al. (2022) examining surface water samples (i.e., 21 sites; 2012-2019) in southwestern Ontario that were analyzed for hundreds of pesticides and their degradation products. Overall, the presence of pesticide mixtures and their degradants in surface water samples does not guarantee nor should they imply adverse effects either directly to fish or indirectly through their prey base (typically aquatic plants, invertebrates, and fish).

Recommendations: As pesticide labels are constantly in flux (i.e., Services' RPA/RPM for other chemicals, label amendments, registration withdrawal) evaluation of mixtures must involve a component of chemical specificity, and other relevant information (e.g., detects vs non-detects, magnitude of concentration, temporal information) when applying these data to regulatory actions. Furthermore, NMFS must re-evaluate the relevance of pesticide mixtures in freshwaters by considering state and federal restrictions on chlorpyrifos use.

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