United States Department of Agriculture

July 23, 2018

Richard Keigwin, Director
Office of Pesticide Programs (7501P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Keigwin,

USDA appreciates the opportunity to comment on the "National Marine Fisheries Service Biological Opinion Issued under Endangered Species Act: Chlorpyrifos, Diazinon, and Malathion" (EPA-HQ-OPP-2018-0141), announced by the Environmental Protection Agency (EPA) on March 23, 2018. Chlorpyrifos, diazinon, and malathion are crucial insecticides for protecting agricultural crops and animals, are critical to USDA plant protection programs mandated by Congress and carried out by the Agricultural Plant Health and Inspection Service (APHIS), and are key in the combat to protect public health from disease vectors including mosquitoes and other insects.

USDA has grave concerns about this biological opinion (BiOp) and strongly urges EPA to repudiate its findings and reinitiate consultation with the National Marine Fisheries Service (NMFS). This BiOp does not accurately assess the risk to endangered species, if any, posed by pesticides, because NMFS fails to establish that the data, assumptions, and analytical methods used, as well as the conclusions reached, are supported by facts and rational reasoning. USDA is concerned that the BiOp likely arrives at erroneous or unsupported jeopardy determinations and fails to address the shortcomings identified by the Fourth Circuit Court of Appeals in *Dow AgroSciences v. National Marine Fisheries Service*. This 2013 opinion found the previous version of the BiOp (for these same three chemicals) to be arbitrary and capricious and remanded it to NMFS for correction.

Further, it is critical to dispel any suggestion that inaccuracies or overestimates underlying the jeopardy determinations can be overlooked in favor of implementing the reasonable and prudent alternative (RPA) associated with this BiOp. Some may try to argue that the RPA offers a viable path forward by eliminating even a hypothetical possibility of jeopardy. This is manifestly not the case, as the RPA in this BiOp is ill-conceived, unsupported by facts, and could never be implemented. NMFS has failed to assess economic feasibility of the RPA in accordance with the Fourth Circuit opinion and at the same time has not even established that the proposed RPA

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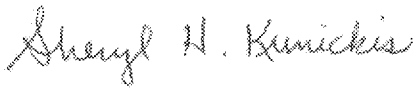
would successfully mitigate the supposed jeopardy determinations. The inability or unwillingness of NMFS to develop a truly *reasonable* and *prudent* RPA highlights the importance of developing accurate and reliable jeopardy determinations first.

USDA has attached comments outlining the Department's concerns. Section 1 is an executive summary, Section 2 provides brief responses to the questions posed by EPA in its Federal Register announcement, and Sections 3 and 4 contain the bulk of USDA's concerns and suggestions on the BiOp's jeopardy determinations and RPA, respectively.

America's farmers, ranchers, and foresters already protect, improve, and restore natural resources, including species habitat. Taxpayers, through USDA programs, along with partners across the country, have contributed to the protections of all species, including those that are threatened and endangered, while enjoying the abundance produced by farmers, ranchers, and foresters. These conservation programs may be a wiser investment than the thousands of work-hours that produced thousands of pages of information that cannot be implemented.

Sincerely,



Sheryl H. Kunickis, Ph.D.
Director

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SECTION 1: EXECUTIVE SUMMARY

This biological opinion (BiOp) for chlorpyrifos, diazinon, and malathion is the unfortunate, but not wholly unexpected, outcome of the gridlocked, contentious, and highly litigious process of interagency consultation for pesticide registration under Section 7 of the Endangered Species Act (ESA). One major factor contributing to these problems has been the National Marine Fisheries Service's (NMFS) steadfast refusal to conduct assessments based on reasonable assumptions, proper analytical methods, and the best available scientific and commercial data. This has occurred irrespective of the sustained objections of other agencies and over the course of several presidential administrations. This BiOp is, once again, the result of a floundering ESA consultation process for pesticide registrations that creates no positive outcomes:

- Endangered species are not protected because risk is not accurately calculated or characterized;
- Farmers may lose pest management tools not because they pose a risk, but because the federal government has repeatedly failed to meet its obligations under ESA;
- The federal government wastes significant resources on a duplicative and inefficient multi-agency assessment process for pesticide registrations.

USDA has outlined some of the major shortcomings of this BiOp in this document and strongly urges NMFS and its partner agencies to reconsider all parts of this highly problematic BiOp and of the larger pesticide consultation process.

Issues with Jeopardy Determination

The revised NMFS BiOp is based on findings of purported pesticide risk that are not adequately explained and appear to not be the product of reasoned decision-making.

- NMFS improperly attempts to estimate risk using the output from R-plot analyses, even though these are only valid for identifying worst-case risk pathways at a screening level.
- The standards for estimating the amount of overlap between pesticide usage areas and endangered species habitat are unsupported in the BiOp.
- NMFS skews uncertainty towards finding heightened risk by speculatively discussing "risk modifiers" such as future water temperatures and the "likely" effects of pesticide mixtures, without proper characterization of these modifiers or any consideration of other modifiers that may refine or lower the potential risk estimates.

Analyses were not based upon the best scientific data available and NMFS seemed to ignore available, reliable pesticide usage data. Instead, NMFS fell back on illogical assumptions that lead to overstated estimates of pesticide usage that bias the analysis heavily in favor of finding high risk. In one scenario, USDA found that NMFS' estimate of acres treated with malathion within a given area was a nearly 500-fold overestimate compared to actual, confirmed treated acreage (page 10, below). Rational consideration of best available pesticide usage data (even using conservative, state-level percent-crop-treated information to project county-level estimates) would greatly improve the risk estimates in this BiOp.

- NMFS' failure to utilize best available data conflicts with the National Research Council's report "Assessing Risks to Endangered and Threatened Species from Pesticides," which recommends that ESA risk assessments should avoid the use of data that are irrelevant and lacking a reasonable theoretical basis for extrapolation (p. 7). Additionally, the report recommends that "the agencies should, at a minimum, subject all information to a review based on OMB criteria of "objectivity, utility, and integrity," (p. 45), which to USDA's knowledge NMFS did not pursue for this BiOp.
- NMFS also seemed to ignore the directions of the Fourth Circuit Court of Appeals, which in its 2013 ruling remanded a previous version of this BiOp for containing many of the same infirmities USDA has identified in the current version. This BiOp continues to rely "on a selection of data, tests, and standards that [do] not always appear to be logical, obvious or even rational." See *Dow AgroSciences v. National Marine Fisheries Service*, 707 F.3d 462 (4th Cir. 2013).

On the whole, NMFS's methodology, decisions, and analytical opaqueness combine to make the BiOp's risk conclusions appear far more problematic than they actually are, resulting in a biased, arbitrary, and pre-judged assessment outcome for chlorpyrifos, diazinon, and malathion.

Issues with the RPA

NMFS does not provide (1) an explanation or justification for the proposed RPA and how it might prevent jeopardy of listed species, or (2) an economic and technological feasibility analysis for this RPA. Therefore, the "RPA" in this BiOp does not meet the requirements for an RPA set by 50 CFR 402.02, and USDA is concerned that its inclusion without a proper basis renders the BiOp arbitrary and capricious under the Administrative Procedure Act.

In addition to its legal shortcomings, the "RPA" is impractical and impossible to implement for American agriculture, because all RPA options are extremely burdensome and likely not economically feasible:

- Some growers could face major yield losses if certain pesticide uses are removed from the label (i.e. banned).
- Construction of wide, 300-meter (approximately 1,000-foot) buffers could cost growers between $2,000 and $22,000 per 1,000 feet of field perimeter, not including the cost of foregone income for in-field buffers or the cost of ongoing maintenance.
- The RPA incorporates a point system through which, in theory, growers could earn points for certain mitigation actions. Earning a certain number of points would allow them to continue using the three pesticides subject to this BiOp. However, this point system was adopted wholesale from one designed for agriculture in the European Union. Encouraging the use of a mitigation system designed for a wholly different continent and regulatory system is highly questionable, particularly without in-depth review or study. Ultimately this point system could force growers to adopt conservation practices costing thousands of dollars per acre that are not compatible with U.S. or regional agricultural practices.

SECTION 2: RESPONSES TO QUESTIONS EPA POSED IN THE FEDERAL REGISTER NOTICE ANNOUNCING THE BIOLOGICAL OPINION

1. *Comments on the scientific approaches and data sources used to support the BiOp and reach determinations for the listed species and critical habitat.*

In Section 3 of this document, USDA provides a detailed description of the shortcomings of the scientific approaches and data sources NMFS used to support the BiOp and, in particular, the jeopardy determinations for listed species and adverse modification determinations for designated critical habitat.

2. *Comments on the RPAs and RPMs. Can they be reasonably implemented? If not, describe why not. Are there different measures that may provide equivalent protection to the ones in the BiOp but result in less impact to pesticide users?*

The proposed RPAs and RPMs lack a firm grounding in facts and cannot be reasonably implemented. NMFS has failed to satisfy its obligation to ensure economic and technological feasibility of the RPA; it has not established that the proposed RPA would even prevent jeopardy; nor has it provided any defensible, quantitative connection between the proposed mitigations and risk reduction. Moreover, USDA strongly reiterates that no mitigation should be considered until reasonable, accurate, and reliable jeopardy determinations are made, which this BiOp has failed to do. Because the jeopardy determination methodology and conclusions are so flawed, USDA does not propose alternative RPAs or RPMs at this time. For a full discussion of the weaknesses of NMFS' proposed RPA, see Section 4 of this document.

3. *Comments on national- and state-level use and usage data and information. In particular, EPA is seeking usage data and information for non-agricultural use sites (e.g., nurseries, managed forests, pasture, rights-of-way, golf courses, and wide-area mosquito control). If possible, provide sources of data and information that should be considered.*

NMFS has repeatedly failed to address easily available and reliable pesticide usage data in favor of claiming that it must analyze *purely hypothetical and unrealistic* pesticide use scenarios extrapolated from maximum use authorizations and geographic use ranges derived from pesticide labels. To USDA's knowledge, NMFS has not provided a coherent justification for why such an approach (often referred to as "the label is the law") is necessary, advisable, or even allowable under ESA when reliable data describing how pesticides are *actually* used are readily available. Throughout this document, USDA provides numerous examples of how such data could be used to refine NMFS' risk and exposure estimates for jeopardy determinations.

Many reliable data sources that are in use by other agencies for non-agricultural use sites are available, including usage information collected by the California Department of Agriculture and industry-specific reports produced by the industry consulting group Kline and Company. Efforts are also currently underway by the Fish and Wildlife Service and other federal agencies to document the availability of pesticide usage data within the United States.

SECTION 3: RISK ASSESSMENTS AND JEOPARDY DETERMINATIONS

Introduction

The revised National Marine Fisheries Service (NMFS) Biological Opinion (BiOp) is based on conclusions about pesticide exposure that are not adequately explained or supported and are not the product of reasoned decision-making. The BiOp is not based on the best commercial and scientific data available, because it continues to ignore available pesticide usage data in favor of assuming that pesticides are used *everywhere* and *all the time* up to the theoretical maximum authorized by the pesticide label. NMFS makes these critical assumptions without adequate explanation or support. The BiOp uses highly conservative, screening-level, model-derived exposure estimates as proxies for "likely" exposure pathways when even a quick review of real-world pesticide usage practices and available data reveals that such exposure scenarios are not at all realistic. The connection between risk estimates and jeopardy determinations is not transparent, and the analysis is systemically biased towards inevitable mitigation of these unrealistic jeopardy determinations. No reasonable characterization of risk is provided and no satisfactory explanation was given for why such risk estimates would warrant mitigation, given the low likelihood of occurrence. As a result, the BiOp relies on a biased and arbitrary selection of data, assumptions, and risk standards that do not appear to be logical, obvious, or rational.

USDA is particularly concerned that this BiOp ignores guidelines provided by the Fourth Circuit Court of Appeals in its 2013 ruling that remanded a previous version of this BiOp back to NMFS.[1] Specifically, the Fourth Circuit concluded "that the BiOp was not the product of reasoned decision-making in that [NMFS] failed to explain or support several assumptions critical to its opinion." The court further criticized NMFS for relying "on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational" and for not explaining the choices made in the BiOp "with sufficient clarity to enable [the court] to review their reasonableness." USDA finds that the current, December 2017, BiOp suffers from significant infirmities that are very similar to those the Fourth Circuit cited as grounds for remanding the November 2008 BiOp back to NMFS.

For this and future BiOps, USDA strongly urges NMFS to clarify and adhere to an appropriate standard when determining which effects of the registration of these pesticides are too remote to consider. The Endangered Species Act (ESA) regulations in 50 CFR 402.02 identify indirect effects of an action as those that occur later in time, but are still reasonably certain to occur. Here, use of pesticides by growers and other private parties will occur after the action (registration review of the pesticide) has concluded and is properly classified as an indirect effect. Therefore, USDA calls on NMFS to explicitly limit its consideration of pesticide use to those types, locations, rates, and frequencies of use that are *reasonably certain to occur* based on the *best available data* that NMFS is required to use under the ESA. The remainder of our comments will demonstrate that NMFS has fallen short of this standard (or any other applicable

[1] *Dow AgroSciences v. National Marine Fisheries Service*, 707 F.3d 462 (4th Cir. 2013).

standard under the ESA or the Administrative Procedure Act) by basing its jeopardy determinations on a wide range of unrealistic and unjustified assumptions.

While NMFS repeatedly fails to integrate the best available state (and, in the case of California, even local-level) pesticide usage data, it presents as "likely" a number of risk outcomes that are derived from usage and application assumptions that pose issues. Despite making token changes from the EPA Biological Evaluations (BEs) and its own prior published BiOp, which had been remanded by the Fourth Circuit, the ultimate risk and likelihood determinations for endangered and threatened species and designated critical habitat are still opaque subjective determinations rather than transparent and quantitatively defensible risk-based conclusions. NMFS' analysis fails to take into account existing mitigation and commonly adopted usage practices, which have driven overall usage of organophosphate insecticides down over the past 20 years. Despite this readily available information, NMFS implicitly assumes usage of organophosphate pesticides would or could increase sharply in the future and points to this hypothetical potential for increased usage over the next 15 years as a reason to characterize even its highly conservative analysis as potentially not conservative enough. The BiOp assumes that usage of some organophosphate chemicals occurs on crops where they are not even registered and combines crops into groups in a way that projects usage on areas (and at times of the year) where usage is not plausible under current label limitations. It further assumes that pesticides are applied on an area-wide basis across crop groups (essentially simultaneously) at rates that are economically and biologically untenable, simply because such use is theoretically possible under labeled use directions. In doing so, NMFS fails to make use of the best available data and refuses to utilize more refined and more appropriate probabilistic methods and characterization tools that could assess jeopardy likelihood under far more realistic conditions.

In addition to unrealistic usage projections, the BiOp retains an unsupported assumption that species are exposed to toxic levels of pesticides for a four-day period for population modeling (despite available data on likely ecological fate and degradation) and fails to explain why this assumption was retained. It may give rise to an erroneous impression that probabilistic considerations were taken into account, when in reality, upper-bound usage and exposure assumptions (combined with conservative hazard endpoints) continue to fundamentally underpin all risk findings. The BiOp includes ill-supported and arbitrarily low standards for linking the amount of hypothetical overlap between habitat and cropland to a particular risk finding—essentially projecting "high" risk likelihood for any area that has 5% overlap with a crop where pesticide use is registered. The analysis further assumes, without scientific support, that tank mixtures of organophosphate pesticides with other active ingredients and increasing aquatic temperatures are both likely to occur and likely to widely increase risks. These were the only two "environmental baseline" parameters considered in the analysis, and both were projected to increase risks without any consideration of potential modifiers that could decrease risks.

On the whole, the BiOp systematically highlights potential variability that makes risk estimates worse, while simultaneously being dismissive of variability or available data that would potentially reduce risk estimates or better characterize the likelihood of risk. The ultimate jeopardy determinations are thus justified by opaque allusions to "professional judgement,"

which is in fact biased towards overstating actual risk. This approach results in an arbitrary, capricious, and pre-judged assessment outcome for chlorpyrifos, diazinon, and malathion.

R-plot Analysis: NMFS Inappropriately Uses This Screening-Level Tool in its Jeopardy Determinations

The R-plot tool presented by NMFS in Chapter 3 of the BiOp was used to summarize available toxicity and modeled exposure information by use site. USDA agrees that this graphical presentation could be useful to identify theoretically plausible routes of potential exposure. However, it is not a valid tool for evaluating the "effect of exposure" to groups of individuals and designated critical habitat in the absence of appropriate characterization. This analytical framework is heavily weighted toward finding high risk to the species and should merely be considered a *screening* tool. The resulting effects estimate is based upon distributions of the most sensitive endpoints identified, by taxa and effect measure. The linkage between the estimated environmental exposure concentration (EEC) shown in the R-plot graph and EEC data provided in the EPA BEs is unclear. Ideally the reader should be able to determine the simulation scenario and assumptions used by EPA to generate the EEC data depicted in R-plot, but it is not possible to ascertain any characteristics of the EEC other than the averaging period.

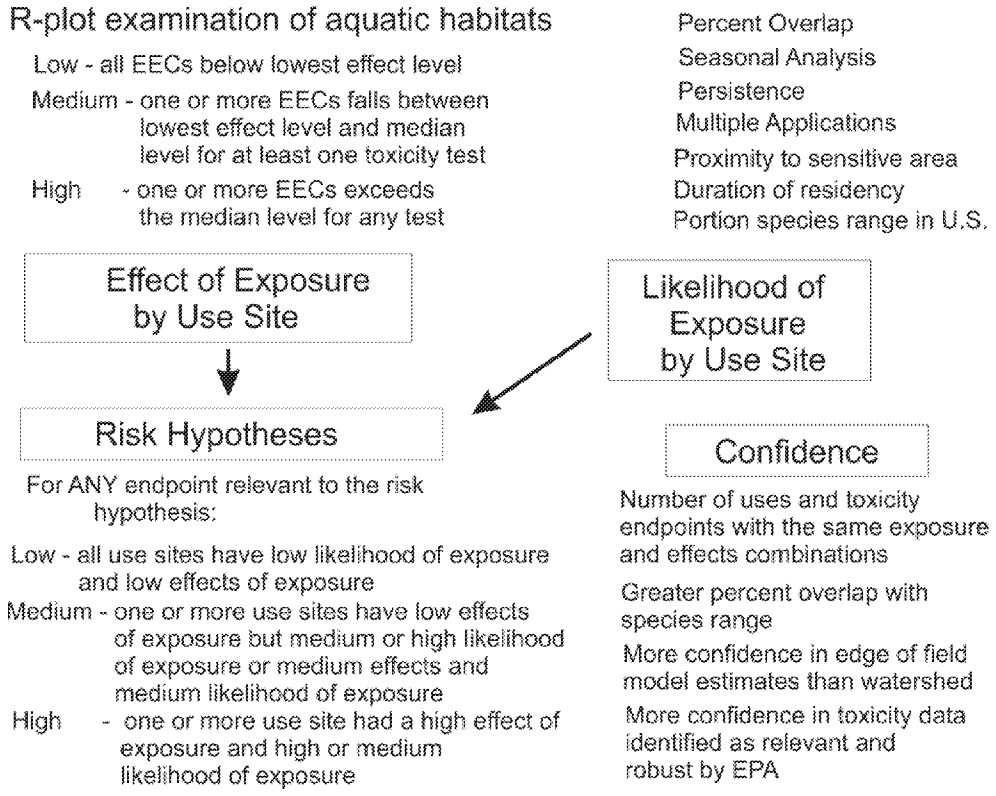
NMFS improperly uses this screening-level output, without real-world context, to rank the effects of the pesticides on species as "low," "medium," or "high." If any single EEC exceeds the median response endpoint of 50% for any toxicity test, the effects are ranked as "high" (see Fig. 1). This assumes all of the toxicity endpoints are equally important for species survival and viability and that all aquatic habitats are also equally important to the species. This analytical framework does not require estimation of actual environmental concentrations.

The likelihood-of-exposure assessment is based on a formulaic analysis of seven factors (see Fig. 1). Categorization is based on a series of yes/no questions as well as a crude estimate for species overlap with pesticide use sites or the duration of occupancy by the species in the habitat (see Fig. 1). High likelihood of exposure usually results when 5% or more of a species' range overlaps with a use site, making overlap an especially influential category (discussed later). There is also a yes/no designation for persistence, with any chemical that is expected to be detected in water for 100 days listed as "yes" even though it is not clear what constitutes a significant presence. Finally, there is a yes/no designation for multiple applications, but this is based solely on label directions and not on the actual likelihood of multiple applications for any given use, which should have been derived from available usage data.

By basing its analytical framework on these simplistic factors and by not explaining its underlying reasoning or consulting available usage data, NMFS fails to establish a rational connection between real-world environmental conditions and pesticide use on the one hand, and the results of the assessments contained in the BiOp on the other. The information used to assess confidence in the conclusions was not real-world data, instead it reflected the same worst-case scenarios that inform the framework. Moreover, the assumption used in the fish population modeling that species are exposed to the EECs for a continuous 96 hours was rejected by the Fourth Circuit in 2013, mostly because NMFS failed to explain how this assumption was

"appropriately reflective of conditions in the real-world environment," and was found to render the previous BiOp arbitrary and capricious. USDA points out that the current BiOp is not an improvement over the previous one in that respect, and that no valid explanation is given for the 96-hour exposure assumption.

Figure 1.



NMFS Used Highly Conservative Outputs from the EPA BEs without Further Refinement or Proper Characterization, Resulting in Misleading and Unrealistic Conclusions

While USDA's objections to the conclusions of the NMFS BiOp are multi-faceted, one primary source of conservatism used from the outset of the analysis are the modeled EECs from the EPA BEs. These EECs are derived from intentionally conservative assumptions and model inputs, which were developed for use by EPA for the purposes of screening-level analyses. EPA's pesticide water calculator (PWC) estimates pesticide concentrations in surface water by modeling movement of pesticide residues from treated fields (or drift from a pesticide application) into a non-flowing farm pond. For some habitat bins, EPA also adds modifiers to provide somewhat refined estimates for flowing water and marine habitats. But for all cases, runoff is modeled based upon historical weather data, with EECs derived from relatively rare (1-in-10-year or 1-in-30-year) precipitation events modeled to occur after pesticide applications at the highest possible label rates (i.e., these are worst-case, screening-level EECs). The PWC also looks at the drift component of off-field movement, which happens at the time of application,

utilizing the AgDrift model. AgDrift models movement of pesticide residue off-field for aerial and ground applications, accounting for various droplet sizes and wind speeds, among other factors (EPA, undated).

While these approaches are, again, quite valid for producing screening-level risk assessments in a pesticide regulatory context, their utility is limited for assessing likely risk outcomes in the natural environment (e.g., effects that must be reasonably certain to occur to be properly considered). The model inputs underpinning the PWC have room for refinement, but typically worst-case inputs are used for the percentage of area being treated within the model farm-pond watershed, worst-case soil parameters are used for runoff, and a 1-in-10-year precipitation event coinciding with label maximum levels of usage is the default setting. The BiOp fails to provide any useful characterization of the relative likelihood of these conservative inputs for eventual R-plot evaluation. Instead, it treats the outputs as estimates for what would actually be expected to happen in treated areas. There is no characterization of how rare such EEC occurrence is expected to be, when typical application dates, typical agronomic practices, commonly adopted runoff mitigations, likelihood of rainfall events, and actual proximity to water bodies are considered. The "percentiles" of EECs used in R-plots are not a distribution of actual likelihood of occurrence under typical usage conditions, but rather represent a distribution of highly conservative estimates derived from screening-level methodology. NMFS then uses these values with misplaced confidence that they represent the range of likely EECs that would be expected to occur, and without characterizing what the estimates truly represent. NMFS stretches the interpretation of the model output even further when it represents the risk for an entire cropping area within a given ESU without regard to its actual proximity to water bodies, except for a loose description of "confidence" (where NMFS states it has higher confidence in risk findings for near shore habitats and lower confidence for large bodies or marine habitats).

USDA notes that the drift component (AgDrift) of EEC calculation is also quite conservative. This is well illustrated by a recently published study that compared model outputs from a screening-level assessment with iterative outputs that accounted for various input refinements. Both were compared with results from a controlled field study (during a dry season, so that observed EECs could be attributed to drift, without a runoff component) to demonstrate the large difference in results from conservative screening-level assumptions. The authors found that screening-level assumptions resulted in 45-fold higher estimated concentrations compared to those associated with the field study and its accompanying model refinement. (Winchell et al, 2018). USDA again acknowledges that a conservative approach to drift modeling is appropriate for use in screening-level assessments, as long as scenarios that "fail" the screening-level assessment are refined and further investigated before final risk conclusions are drawn. Not only does NMFS fail to move beyond a screening-level assessment, it does not acknowledge the significant conservatism of this approach and fails to characterize the variability around these estimates that would be expected under real usage conditions. Even if refined models were not used to produce EECs (which USDA acknowledges could be difficult and onerous when assessing exposure for numerous ESUs), such characterization information would *greatly* inform the questions of exposure likelihood (or confidence) used in making jeopardy determinations, which is discussed further below.

NMFS Failed to Consider Available and Reliable Pesticide Usage Data, Leading to an Overestimate of Pesticide Use

Exposure estimates (which directly determine the likelihood of an adverse effect occurring) in this BiOp are derived from imprecise evaluation criteria. Use areas are based on a five-year crop data layer file, which assumes that any crop with a registered use for a pesticide is being treated to the fullest extent authorized by the pesticide label (i.e., maximum application rate, maximum number of applications, with annual treatment at this level). While a minimum, median, and maximum are reported for the percent overlap of each crop group (a marginal improvement over what was provided in the EPA BEs), the assumption that all cropped areas are "treated areas" skews the analysis toward a high-exposure conclusion. Most of the use groups that have more than 5% of an overlap with an ESU are categorized as "high" likelihood, and this designation is not adequately explained or justified, outside of the implicit assumption that all of that overlap area *must* be treated if it *could potentially* be treated. There are instances in which 5% or more overlap does NOT result in "high" likelihood of exposure. In Table 3 on page 34 of the BiOp, a high percent overlap in combination with a medium portion of the species range within the United States results in medium likelihood of exposure, whereas high percent overlap in combination with low persistence and category 2 of species duration of use (explained on p. 32) results in medium likelihood of exposure. Curiously, the first line and the 10th line of Table 3 are identical except one is labeled high likelihood of exposure while the other is labeled medium. From a practical standpoint, a likelihood call of either "medium" or "high" can still result in a positive jeopardy call regardless, and the reasons underlying this call are not clearly explained.

In any case, such broadly conservative estimates for use site overlap with ESU and critical habitat do not account for the low likelihood of usage at maximum label rates on a site-by-site basis. Nor does it account for the generally low likelihood of repeated applications, nor for label-limited timing on many uses that are inappropriately lumped together and are further unlikely to occur simultaneously. All of this information is readily available for probabilistic consideration using commercially and publicly available pesticide usage data, even at the state level. Instead, the BiOp assumes that 100% of each crop group area is treated at the maximum label rate and multiple times (in accordance only with label restrictions). Usage to this extent is unrealistic from both an economic and a pest-management standpoint. A projection based on this assumption would indicate application of one or more orders of magnitude more pesticide material (chlorpyrifos, diazinon, and malathion) in ESU areas alone than is currently produced and applied in the entirety of the United States.

The following two examples demonstrate the degree to which NMFS overestimated treated acreage in the BiOp when compared to reliable pesticide usage data from EPA- and USDA-recognized best available data sources (EPA and USDA use these data routinely for regulatory work on pesticides, including in human health and ecological risk assessments). Both agencies have made determinations of their quality as the best available data that are in compliance with the criteria set forth in the Data Quality Act. For the active ingredient malathion, USDA did a cross walk comparison of the ESU acres on the West Coast associated with use sites that were deemed to be high-risk uses by individual ESU (BiOp Chapter 26.2) with best-available use data

(MRD, 2013-2017). NMFS' estimated percent of high-risk use-site acreage associated with each of these ESUs was back-calculated from ESU acreage reports in Chapter 17 of the BiOp. USDA then compared NMFS' estimate of high-risk use-site acreage for a given ESU to the total reported number of treated acres *within the entire state(s)* in which that ESU was located. As an example, if NMFS identified the orchards and vineyards crop group as high risk in an ESU that straddles the California-Oregon border, USDA would compare the orchard/vineyard use-site acreage that NMFS claims exists within this ESU to the total malathion-treated orchard/vineyard acreage *in all of California and Oregon* (as derived from best-available pesticide usage data). USDA found that NMFS' estimate of how many acres were treated within a given ESU typically exceeded what the best-available data indicate should be the total number of treated acres for the *entire state (or states)* that contains the ESU. In fact, NMFS' estimate of ESU treated acres exceeded USDA's estimate of total state treated acres by more than *20-fold* (MRD, 2013-2017). Under no circumstances should an estimate that varies so widely from best-available data be used in a BiOp which is subject to the best-available data requirements of ESA and the prohibition on arbitrary and capricious decision-making codified in the Administrative Procedure Act.

USDA notes that the magnitude of the overestimate in the example above is probably even greater. While state-level data are the most reliable and best available data for most states, California presents a situation where more localized data are available. As an example, USDA analyzed these more granular reporting data produced by the California Department of Agriculture from the California Pesticide Usage Reporting Program (PUR). Since pesticide usage reporting is mandatory in California, the information collected is *census-like data*, as they represent a measure of actual usage across the entire sum of actual treated acres, as compared to *sample data*, which allow a projection based on a survey of a subset of treated acres. USDA analyzed PUR-reported malathion usage in the counties containing the Central Coast California Steelhead ESU.[2] NMFS identified orchards and vineyards (approximately 94,520 acres, or 3.21% overlap with the 824,556-acre ESU) and pasture (approximately 426,120 acres, or 14.47% overlap) to be the two agricultural use sites posing high risk to this ESU (Section 17.20, p. 2910).[3] Actual California usage data from PUR indicate that annual average total acres treated from 2013-2017 (which includes multiple treatments to a single acre of land in a given year) in all the counties touched by this ESU was 160 acres for pasture and 930 acres for orchard and vineyard crops. Assuming there is no overlap in acreage between these two use-site groupings, NMFS' estimate of 520,640 acres of high-risk orchard/vineyard and pasture use is an almost 500-fold overestimate in comparison to the 1,090 acres that were actually treated with malathion annually in these counties. NMFS declined to use California PUR census data—a gold-standard data source for pesticide usage—which appears to be in conflict with the requirement of the ESA that best available data be used.

[2] The Central California Steelhead ESU falls within the California counties of Alameda, Contra Costa, Marin, Mendocino, Napa, San Francisco, San Mateo, Santa Clara, Santa Cruz, Solano, and Sonoma.
[3] Wheat, other grains, and other crops appear to be erroneously included as high risk use sites in Table 7, 26.2.3.

NMFS' rejection of these data leads NMFS to assume that all use-site areas that could theoretically be treated actually are treated, which is presented as a default assumption in determining exposure likelihood. USDA reiterates that NMFS failed to provide any meaningful criteria or justification for their 3 levels of overlap (>=5%, 1-5%, and <1%) that correspond to high, medium, and low likelihood calls for exposure. But even if pesticide usage data were not used to refine such estimates quantitatively, available usage data could still help refine NMFS' categorization of low, medium, and high likelihood, given the drastic differences in observed real-world usage versus assuming that all acres that can be treated will be treated. Further, it would inform the confidence behind risk estimates. It poses an issue to conclude a high likelihood of exposure for a pesticide that is estimated quantitatively and conservatively to be used on a tiny proportion of a given use site's acreage.

NMFS insists that the lack of highly localized usage data prevents it from concluding low likelihood of exposure at any one site, since maximum label-rate usage is allowed by label directions. But in reality, the totality of NMFS' exposure estimates already presents a far more untenable and systemic overestimation of exposure by treating every acre of cropland where use is registered as a worst-case scenario. This is in spite of decades of historical data that indicate usage has never come remotely close to reaching such a high level, and that overall usage of organophosphate insecticides is actually trending downward over time.

The actual proximity of cropland to water bodies within a given ESU is not considered at all. It is simply assumed that usage will result in runoff to water bodies (i.e., habitat within the ESU), yielding EECs in line with those modeled by the EPA farm-pond scenario (and some bins further modified to account for flowing water). In reality, these runoff estimates would only be germane for the small fraction of cropland or use sites that are adjacent to actual aquatic habitat. NMFS does address water proximity nominally in terms of relative proximity to water for qualitative confidence (i.e., higher confidence in edge of field effects vs. watershed-wide, see Fig. 1).

NMFS' crop group "lumping" approach assumes that usage happens anywhere and everywhere where registered use sites exist, even if usage cannot actually occur on all the crops within each respective group. Worse, it also assumes that peak concentrations, driven by simultaneous application, would happen on all of the crops in a given use group on the same day, even though it is known that application dates would vary widely between crops, or even potentially between target pests within the same crop. Readily available pesticide usage data could have been used to show a proportional breakdown of pesticide application timing by use site, and would have illustrated how assuming simultaneous applications significantly overestimates usage.

Even without taking usage data into account, there are already a number of existing label mitigations and typical usage practices that are widely known for a number of uses. For example, for chlorpyrifos usage in tree fruits, most applications (except on sour cherries) are labeled only for pre-bloom or trunk-only spray use, the latter of which would have a much lower typical application rate per acre, and essentially zero potential for drift to surface water. For malathion, almonds are lumped into the "orchard and vineyard" crop group, based upon the approach proposed in the EPA BE, and almonds account for a high proportion of acreage in a number of

ESUs. However, malathion is not labeled for use on almonds (EPA, 2009), so counting this area in the crop grouping bin will lead to overstated usage assumptions.

The assumptions of 100% overlap between ESU and use site for mosquito control, wide-area, and forestry applications (used only for small spot treatments and APHIS-approved programs that already underwent ESA consultations to preclude impacts) lack a rational connection to facts. Even a cursory investigation of application practices would have practically eliminated these use sites from consideration as major sources of exposure, given the impracticability, cost, and likely poor efficacy of treating such wide areas. But because NMFS' assessment is based solely on existing label instructions, as opposed to common knowledge and best-available data on how pesticides are actually used, NMFS assumed that chemicals such as chlorpyrifos and malathion are widely and indiscriminately applied over massive geographic scales (including entire ESUs) at levels, and with resulting application costs, that do not align with reality.

While USDA understands and acknowledges that no single data source would be sufficient to fully document usage parameters for every square meter of critical habitat that overlaps with cropping area, state level usage data provide a very useful tool for risk characterization and provide evidence of the relatively low likelihood of the R-plot outputs for many cropping scenarios. State-level pesticide usage data are reliable for understanding the relative infrequency of application at the label maximum limitations and should have been used to develop more accurate characterization of exposure likelihood by use site and ESU. This is particularly true given the long period of time that these insecticides have been used (i.e., there are significant historical data to document overall usage trends) and the availability of monitoring data showing that current usage patterns are not likely to adversely affect a number of the taxa of concern (discussed more later).

Further, probabilistic approaches are available to conduct more refined assessments at watershed scales that take into account pesticide degradation (rather than assuming peak concentrations persist for 96 hours), varied land management practices, usage, etc. One example of this approach is Whitfield Aslund et al. (2017), which determined a de minimis risk to three salmon ESUs in California for the related organophosphate insecticide dimethoate.

Confidence Determinations Based on Mag-Tool and Salmon Population Models Are Circular, Self-Reinforcing and Thus Inherently Flawed

The BiOp uses additional simulations to determine the level of confidence in the results of the qualitative R-plots risk conclusions. This analysis expresses a higher degree of confidence in the risk determinations when the results of these simulations are in agreement with the qualitative assessments. At least one of these simulation tools (MagTool) is in a draft form and has not been peer reviewed or used for regulatory purposes by EPA. The salmon population model (only applicable for three taxa discussed in the BiOp) produces community- to population-level effects estimates, but little background or validation information on the model was provided.

While the outputs of these tools are compared to R-plots to provide "weight of evidence," in reality they still utilize the same EECs that are derived from upper-bound screening-level methodology. So in this way, the comparative value is circular. And from a practical standpoint,

the output does little to affect jeopardy determinations for most taxa (i.e., non-salmonids), since the magnitude of any given "high" risk outcome from an R-plot could be downgraded only to "medium" if the output of the tools disagreed. In most cases, "medium" and "high" designations for risk ultimately lead to the same jeopardy findings, so long as the exposure likelihood is classified as "high," meaning overlap with use-site locations exceeds the arbitrary 5% threshold.

Ultimately, NMFS' extrapolation of effects from individuals up to population levels is not transparent and does not address the realism of the various criteria underpinning a determination on the likelihood of risk and exposure. While the methodological approach is couched as "weight of evidence," the reality is that each of these tools rely upon the same flawed conservative inputs and thus add little to the analysis. Any "validation" these tools purportedly provide appears to be circular and self-reinforcing. For example, while watershed-level analyses are deemed "probabilistic" because they dispense with an assumption that all use groups would be treated on the same day, the ultimate analysis still relies on a reiteration of numerous upper-bound inputs and worst-case exposure scenarios, which combine to provide an outcome that is only useful for screening-level assessment purposes, not real-world jeopardy determinations.

Risk Modifiers: Risk Estimates Are Only Modified in One Direction

Information from the status of the species, environmental baseline, and cumulative effects are treated as risk modifiers for the effects and likelihood risk determination. These risk modifiers are evaluated qualitatively. Two of the modifiers – environmental baseline and cumulative effects – are evaluated based on defining only two characteristics. If one or both of these characteristics is negative, then the modifier is assigned a large negative effect. Taking the environmental baseline as an example, there is no further refinement to ascertain the actual exposure levels or effects due to the pattern of exposure to either elevated temperatures or pesticide mixtures.

The evaluation of pesticide mixtures assumes that mixtures will result in synergistic effects, even though the science of estimating impacts of mixtures is not a settled area. The BiOp cites a journal article finding increased inhibition of acetylcholinesterase and liver carboxylesterase activity in mixtures of the organophosphates ethoprop and malathion. However, the BiOp does not attempt to evaluate the types of mixtures expected in the environment and their spatial extent or temporal duration. There is no consensus on the application of mixtures tools employed by NMFS. The conclusion drawn in the BiOp is that the likelihood of mixtures occurring increases as a greater number of unique pesticides is used in a watershed, and that these mixtures will increase some deleterious effect to a significant level for the population. A quantitative treatment is not presented. The BiOp reduces the question of the effect of mixtures on a particular species to a finding of low or high risk of jeopardy from the environmental baseline based on whether and to what extent these mixtures are expected in the species' habitat. The use of this analysis in the overall jeopardy determination lacks sufficient detail to understand differences in risk determinations between species that individually have findings of exposure to pesticide mixtures and high temperatures.

The overall risk to the species is defined by the formulaic assignment of a risk category based on the three levels of likelihood of exposure and three levels of effects. The confidence associated with these risk categories is based on other simulations providing similar results. There is no independent review of these simulation models. The criteria for high confidence in the results of the qualitative assessments rely on circular reasoning. For example, the BiOp states that the greater the percentage of site overlap, the higher the confidence in a rank of high risk for a particular risk hypothesis. This assumes that usage results in exposure and that exposure results in risk. Further, since usage is assumed for all use sites without consideration of available data, then what really is being projected is that the existence of use sites results in risk. Site overlap is a component in the exposure assessment which is a component in the ranking of the risk hypothesis. This should express confidence that the series of qualitative assessments is functioning as expected rather than actual confidence in the result.

There is no analysis presented to address the impact of error associated with incorrect categorization in the effects, exposure, or overall qualitative assessments. The propagation of error in one of the foundational assessments—effects or exposure—is carried through to the finding of overall risk and jeopardy.

The Jeopardy Determinations Fail to Assess Likely, Real-World Risks and Should Be Disregarded

Because of these approaches discussed above, and the lack of defensible explanation for many of the skewed methodological choices, this BiOp mischaracterizes what "high" likelihood of pesticide exposure means within any real-world context. Screening-level assumptions and estimates are used from the outset of the analysis, based on the methodology of the EPA BEs, and the further additions of iterative upper-bound assumptions compound the likelihood overestimate throughout the course of the analysis. The BiOp's conclusions are particularly questionable given that the three pesticides assessed have been used for decades without any evidence of problematic environmental exposure on the order of what is being presented as "likely" by this BiOp. When actual monitoring data have been evaluated (including monitoring that was done prior to significant organophosphate mitigation in the mid-to-late 2000s), most concentrations fall well below those EECs used to support NMFS risk and jeopardy conclusions. For example, a multi-year surface-water monitoring analysis conducted by the Washington State Departments of Ecology and Agriculture concluded that "Pesticide concentrations found likely do not directly affect salmonids," though effects to salmon prey were discussed as plausible (Sargeant et al., 2013).

The NMFS analytical framework does not require estimation of actual environmental concentrations. The starting point for the risk analysis is not based on actual spatial and temporal concentrations in the environment but on assumptions of upper-bound exposure levels (and the risks associated with them), with a formulaic analysis of the factors contributing to likelihood of exposure used in the BiOp. The separate qualitative assessments are treated as independently reinforcing one another, but are actually correlated with one another. For example, species overlap in the exposure assessment should be associated with the effect of exposure aquatic habitat bin.

This approach delivers a set of risk estimates that are plainly unrealistic compared to likely organophosphate exposure outcomes in the real world, and NMFS leaves this level of conservatism unmodified (and ultimately unaddressed) in the BiOp. Generally, when high risk is indicated by a screening-level risk assessment, a more highly refined or probabilistic risk assessment must be conducted to provide a robust picture of risk and allow the decision maker to make management decisions based on actual risk rather than potential risk. NMFS has not shown any inclination toward conducting such a probabilistic analysis, despite the availability of examples of such analyses in the published literature. Instead, the NMFS BiOp provides no refinement or useful risk characterization, and simply carries forward the input of worst-plausible numbers into a risk analysis framework that is further inclined toward overestimating risk and risk likelihood. It intentionally carries this systematic error forward to culminate in jeopardy determinations that have almost no utility for managing ecological risks. This makes the approach ill-suited for the intended purpose of a BiOp, which is to assess likely, real-world risks to threatened and endangered species.

SECTION 4: REASONABLE AND PRUDENT ALTERNATIVE

Introduction

NMFS attempts to include a reasonable and prudent alternative (RPA) in this BiOp. As envisioned by ESA section 7 and the ESA regulations, issuing an RPA gives NMFS the opportunity to suggest to EPA an alternative course of action (in this case, additional conditions to be placed on the continued registration of the pesticide) that would avoid jeopardy. USDA's primary concern is that this BiOp does not accurately assess the risk to endangered species, if any, posed by pesticides, because NMFS fails to establish that the data, assumptions, and analytical methods used, as well as the conclusions reached, are supported by facts and rational reasoning. As discussed in the previous section, USDA is concerned that the BiOp likely arrives at erroneous or unsupported jeopardy determinations and fails to address the shortcomings identified by the Fourth Circuit in *Dow AgroSciences v. National Marine Fisheries Service*.[3] This 2013 opinion found the previous version of the BiOp (for these same three chemicals) to be arbitrary and capricious and remanded it to NMFS for correction.

Even though this BiOp's jeopardy determinations, without which no RPA would be necessary, are highly questionable, it is important to discuss why the RPA itself is also flawed and impractical. This is critical to dispelling any suggestion that inaccuracies or overestimates underlying the jeopardy determinations can be overlooked, because implementing the associated RPA would provide an easy "out" by eliminating even a hypothetical possibility of jeopardy. The RPA in this BiOp is ill-conceived, unsupported by facts, not feasible, and could never be implemented, highlighting the crucial need to develop reasonable, accurate, and reliable jeopardy determinations first.

Under the ESA regulations, RPAs are defined as "alternative actions identified during formal consultation 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 the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat."[4] In *Dow Agrosciences*, the Fourth Circuit chastised NMFS for failing to evaluate the economic impact of requiring uniform buffers as part of an RPA. Even though the court strongly implied that the regulations require RPAs to be economically feasible not just for the federal government, but for regulated industry as well, NMFS' response in the current BiOp argues that an RPA must only be feasible for the government (i.e., the action agency) to implement. NMFS bases its position on a couple of lower court and state court decisions, without addressing the far more recent 2013 Fourth Circuit opinion that *directed* NMFS to evaluate economic feasibility and strongly implied that economic feasibility under the regulations is broader than just the feasibility for the federal government.

USDA's position is that an RPA must be feasible not only for the action agency, but also for the regulated industry, including pesticide registrants and growers. To read 50 CFR 401.02 as requiring an RPA to be feasible only for the action agency would render the feasibility requirement entirely meaningless for every ESA consultation on a federal permitting action, because approving, disapproving, or modifying a permit will almost always be "economically

[3] 707 F.3d 462 (4th Cir. 2013).
[4] 50 CFR 401.02.

feasible" for the government. Moreover, an RPA that is not economically feasible for regulated industry or the applicant would also fail the parallel requirement that an RPA must be implementable in a manner consistent with the intended purpose of the action. For these reasons, interpreting the feasibility requirement as NMFS does makes little sense, a view which was echoed by the Fourth Circuit in *Dow Agrosciences*.

In addition to NMFS' failure to respond appropriately to *Dow Agrosciences*, USDA would like to emphasize the following three points of concerns with the RPA:

1. This BiOp fails to evaluate or explain whether the RPA is economically feasible for the government, the applicant, or growers.

NMFS made no attempt to analyze the economic and technological feasibility of the RPA. In *Greenpeace v. NMFS*, a decision which NMFS quotes in the BiOp (26-2, p.3456), the court concludes that "[i]t remains an open question whether this requirement [that an RPA be "economically and technologically feasible"] should be interpreted as referring only to whether the RPA is feasible for the agency, or whether it relates to the effects on third parties."[5] The 2013 opinion of the Fourth Circuit in *Dow Agrosciences* suggested that NMFS is responsible for analyzing both the impacts on the agency and the effects on industry. While bringing its jeopardy determinations into compliance with the legal requirements of ESA and the Administrative Procedure Act should be NMFS' highest priority (see Section 3 of these comments), it should then also perform an appropriate analysis of the economic and technological feasibility of any future RPA.

2. The RPA is so burdensome that it is likely not economically feasible.

Burden on Growers

RPA Element 1 (26-4, p. 3469) suggests three alternative methods to reduce pesticide loading for use sites deemed high risk. These alternatives, along with USDA's justifications for why they are not economically feasible, include:

- RPA Element 1(a): Remove label authorization for all high risk uses.

  Growers are rational individuals making business decisions, and ultimately will not employ pest management techniques unless they are necessary. With that said, it is impossible to not expect an impact on growers when the use of a pesticide that a grower is currently utilizing is eliminated. These impacts can be in the form of reduced yields or higher incidence of pest injury from the adoption of less efficacious alternatives, which can result in loss of market access. Additionally, growers may be impacted by limitations from label restrictions on alternative pesticides, increased costs for applications, or the need for specialized application equipment which a farm may not have at its disposal. For example, EPA (2015) found that in the absence of chlorpyrifos for use at planting, growers of brassica crops such as broccoli, cabbage, and cauliflower could face yield losses of nearly 50%. Furthermore, growers who have options to substitute other active

[5] 55 F. Supp. 2d 1248, 1267 (W.D. Wash. 1999)

ingredients may face issues with international trade in cases where Maximum Residue Levels (MRLs) are not established in other countries for these alternative compounds.

- RPA Element 1(b): Modify labels to include standard buffers and vegetative filter strips: 300 meter no-spray buffer for all aerial applications; 150 meter buffer for all ground applications; 6 meter vegetative filter strip for all applications.

  Buffers and filter strips are difficult for any farmer to implement and maintain, and successful implementation is affected by a variety of factors, including field size, soil type, geographic region, crop grown, and local climate. Feasibility can be further impacted by conflicting regulations or market-imposed requirements, such as food safety specifications that require areas of bare soil around fields without vegetation, as one example. A one-size-fits-all approach ignores the field-level practicalities of successful implementation that takes each of these variables into consideration. The ability of growers to avoid foregone income from in-field installations is another important consideration to account for when gauging the burden associated with this RPA.

  As discussed in Table 1 below, the estimated installation cost of buffers in California ranges from $90/acre to $1,000/acre. Thus, for fields receiving ground applications, a 150-meter (500-foot) buffer could cost about $1,000-$11,000 per 1,000 feet of field perimeter that is affected. Using the same assumptions, a 300-meter (approximately 1,000-foot) buffer for aerial applications could easily cost a grower $2,000-$22,000 per 1,000 feet of field perimeter. On top of this cost, vegetative filter strips have associated costs of around $55-$309/acre. This does not include the cost of on-going maintenance. Further, off-field buffers can be a potential source of infection and infestation and could allow for the recolonization of weeds, insects, and disease-causing pathogens. Depending on pest species and biology, there are instances where buffers have been documented to increase pest pressure and ultimately might be incompatible with certain agricultural operations and endangered species conservation efforts. For example, Ratnadass et al. (2012) shows that pressures from pests with a broad host range, high dispersal ability, and long overwintering mechanisms can make buffers infeasible for growers. While there are instances where buffers may be feasible, there is no simple one-size-fits-all solution for all growers of all crops. Again, it is critical that NMFS conduct a robust analysis of the economic feasibility to better understand the repercussions from this RPA.

- RPA Element 1(c) Point System: Implement a combination of risk reduction measures to reduce pesticide drift, runoff, and drainage.

  NMFS relied on a point system developed for the European Union called "Mitigating the Risks of Plant Protection Products in the Environment" (MAgPIE) that is pertinent to farming systems across Europe and the regulatory framework of those European countries. The average U.S. farm is ten times larger than the average European farm (Eurostat, 2016; USDA, 2018) and operates under laws and regulations of the United States, not European laws and regulations. Assumptions that what may work in Europe will work in the United States are without basis, as these mitigation measures have not been vetted for U.S. production systems. NMFS failed to explain both its reliance on

MAgPIE and why it chose to not rely on the USDA for information regarding agricultural conservation practices in the United States. NMFS states: "These RPAs were drafted using the best available information on current agricultural practices and pesticide reduction strategies . . . ." However, there is no indication in the BiOp that USDA or any agricultural conservation experts operating in the United States were ever contacted to provide feedback on what constituted best available information for U.S. cropping systems. The outreach of one federal agency to other expert agencies within the U.S. government on agricultural conservation is an obvious first step to pursue prior to proposing agricultural conservation practices that are required to use "best available data."

Not only is the European MAgPIE point system incompatible with U.S. agricultural practices, it is likely impossible for a grower to achieve the required 80-point score without incurring significant economic burden. Consider the following scenario: A grower applying malathion is subject to these risk reduction measures. The grower's reliance on malathion to manage specific pest pressures and avoid the development of resistance prohibits his or her ability to rely on a different active ingredient. Walking through the activities in Chapter 26-8 (p. 3473) that merit points under MAgPIE:

- Spray Drift Reduction Technology (DRT) (20-75 points): While growers could earn points for using DRT, the EPA DRT Program currently does not have any approved DRT products (EPA, 2018a). USDA questions how this RPA can be "technologically feasible" when growers have no EPA DRT-approved products available to them at this time.

- Spot Applications and/or Granular Treatments (80 points): The practicality of using spot applications or granular treatments is completely dependent on the active ingredient and the pest being targeted. For example, over the past five years (MRD, 2012-2017), malathion was never once reported as being used as a granular treatment across 60 surveyed crops. This is likely due to such products not even being registered for such use sites, which may indicate that such formulations or application methods are not technically or economically feasible. Further, if NMFS had used available data or done any basic research on typical usage practices in its jeopardy determination, it would have discovered that many of the use sites characterized as "high risk" are in fact only localized spot treatments to begin with. For example, the "wide-area" and "forestry" uses of chlorpyrifos are only applied as localized spot treatments and thus should never have been characterized as a high-risk scenario in the first place.

- Participation in Stewardship Programs (80 points): NMFS proposed that a grower can participate in NMFS' recognized Pesticide Stewardship Plans as a way to acquire points under MAgPIE. In the BiOp, NMFS provides an example of a certification program, Salmon-Safe, which can satisfy this requirement. However, Salmon-Safe (2018) has a list of banned chemicals that cannot be applied by farms seeking certification, which includes malathion, chlorpyrifos, and diazinon. This list is based

solely on hazard (i.e., acute aquatic LC50/EC50, without an exposure component, and thus is not based on the risk to salmonids). As NMFS quotes in the BiOp (p. 519), "Salmon-Safe has produced a list of 'high hazard' pesticides which, if used, would prevent a site from becoming certified. If a grower wants an exception, they must provide written documentation that demonstrates a clear need for use of the pesticide, that no safer alternatives exist, and that the method of application (such as timing, location, and amount used) represents a negligible risk to water quality and fish habitat." USDA questions what standards these independent certification entities would use in making a determination of "clear need," as it appears to be a subjective determination. Based on NMFS' example of an approved certifier, it is plausible that obtaining this certification requires a de facto ban on the use of these pesticides, which would lead to no grower ever viewing this as an option for accruing points under the point system. USDA is very concerned that a federal entity such as NMFS would outsource the awarding of points, which is essentially a decision as to whether a grower will remain in compliance with the BiOp, to a private, non-governmental organization that is not transparent regarding the criteria for their risk determinations or subject to any oversight or control by any branch of the federal government.

- Vegetative filter strips, "bunds" (a European term for edge-of-field embankments), vegetated ditches, riparian plantings, retention ponds, and functional riparian systems alongside waterways (varying points): All of these options cost a significant amount of money. Example estimates of these costs are provided in Table 1, per estimates for the state of California from USDA NRCS (2018a). Vegetated ditch costs reflect estimates from New England states, noting that this method of conservation is not even recorded as an implemented practice in many of the states under NMFS jurisdiction. For all these practices, significant technical limitations to their applicability exist, such as required topography, soil texture, field slope, and compatibility with particular cropping systems. For guidance on such limitations, refer to the NRCS Conservation Practice Standards (2018b).

Table 1. Examples of Costs for RPA MAgPIE Point System Agricultural Conservation Practices in California

BiOp Practice	Closest Matching Equivalent NRCS Practice	NRCS Practice Cost	Unit
No Spray Buffer[1]	Field Border	$90-$1,005	Per acre
Vegetative filter strips	Filter Strip	$165-$927	Per acre
Bunds (i.e., a European term for edge-of-field embankments)[2]	(1) Terrace	$3,500-$9,800	Per typical 2,500 foot terrace
	(2) Water Sediment Control Basin	$3,750-$3,960	Per typical 700 yd^3 of excavated earth

Vegetated Ditches[3]	Hillside Ditch with Vegetation (costs are additive)	$2.95-$3.13	Per cubic yard (channel equipment)
		$1.52-$1.88	Per foot (hand labor)
Retention Ponds[4]	Constructed Wetland	$1,420-$11,385	Small (0.1 acre) to Large (>0.5 acre)
Functional Riparian Systems Along Waterways	(1) Riparian Herbaceous Cover	$1,300-$13,500	Per acre
	(2) Riparian Forest Buffer	$211-$6,285	Per acre
No-Till or Reduced Tillage	(1) No-Till/Strip-Till	$20	Per acre
	(2) Residue and Tillage Management, Reduce Till	$21	Per acre
	(3) No-Till Adaptive Management	$245	Per acre
	(4) No-Till/Strip-Till with Herbicide and No Cover Crop	$45	Per acre

Source: USDA NRCS California Payment Schedule (USDA NRCS, 2018a). Cost estimates for different NRCS agricultural conservation practices are constructed from a variety of reliable sources, including feedback from local experts. Estimates differ across states and regions. The costs supplied in this table reflect installation costs; however, the ongoing cost of maintenance must also be considered, as well as the value of foregone income from installations that must be made in-field, with the cost of such installations greatly varying due to factors such as crop, region, and the shape and size of the field.

[1] The point system requires between a 10 to 300 meter (i.e., ~30 to 1,000 foot) buffer, depending on the intended mitigation.

[2] Depending on how bunds are defined, their NRCS equivalent term could either be considered terraces or water sediment control basins. Example costs for both terraces and water sediment control basins are provided.

[3] Hillside ditches are only implemented in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Costs reflect 2017 non-vegetated hillside ditch costs; vegetated hillside ditch costs are not a recognized NRCS practice and thus cost estimates provided here should be considered an underestimate due to the additional costs of installing and maintaining vegetation.

[4] Although it is unclear in the BiOp, it appears that MAgPIE intends for retention pond requirements to be a function of the contributing area to runoff. Thus a range of potential costs from NRCS scenarios are provided.

Given the issues with stewardship programs, DRT, and the use of granular formulations and spot treatment applications, the only option for a grower to earn a sufficient number of points to satisfy this system is to undertake one or more of the incredibly burdensome practices outlined in Table 1, which further demonstrates the need for NMFS to design RPAs that are economically feasible *for regulated industry*. NMFS should also provide concrete evidence that this is the case in their economic feasibility study, and discuss how the BiOp is consistent with *Dow Agrosciences.* Additionally, NMFS has established no quantitatively defensible, causal connection between the proposed mitigations and reduced pesticide exposure to endangered species. Without establishing causality between mitigating measures and exposure or harm averted, requiring the measures in this RPA is arbitrary and capricious and could force growers out of business, especially given the current agricultural financial climate.

Burden on Registrants:

In addition to the burden on growers, all three elements of the proposed RPA would result in economic hardship for registrants. Not only could the transition of growers to alternative pesticides or to lower volumes of the products they are currently using impact registrants' market shares temporarily, in many cases they could completely lose their customers as they may not have patent rights, labeled products, or access to alternative technical grade active ingredients that would allow them to quickly regain lost market share. The process of getting pesticides registered and on the market is no simple task, with the average cost for a new registration at over $600,000, new uses for an existing registered pesticide at nearly $200,000, and fees set to rise again in the near future. Furthermore it takes months if not years for these registrations to be approved (EPA, 2018b). Additionally, companies must be able to pay off the typical $250-$300 million and 11 years of research and development that goes into new products, which takes years of sales to recoup. Disrupting this recovery of investments is a disincentive for companies to pursue finding new chemistries and can stagnate technological advancements. Ultimately, this can lead to delayed registrations which can manifest a myriad of unintended consequences, such as the expedited development of pest resistance as growers may have a scarcer number of active ingredients representing fewer modes of action with which to rotate their application. This effect is also (ironically) counter-productive to the very ecological protection goals espoused by NMFS, because it delays the availability of newer and safer materials that would displace older chemistries over time.

3. The mitigations suggested by the RPA are unsupported by facts and reasoning, making it unclear whether this RPA, if it was even possible to implement, would actually avoid jeopardy.

In order to qualify as an RPA, a set of mitigating measures must be successful in preventing jeopardy. NMFS does not explain how this RPA would prevent jeopardy, and a review of the RPA's provisions provides little indication that it would do so.

- Major inconsistencies between chapters outlining use sites of concern versus those that are listed as necessitating RPAs exist. As stated on page 3470, "the point system is only required for high risk uses. High risk uses are those which received a high rating for effect of exposure and a high or medium rating for likelihood of exposure as presented in the Effects of the Proposed Action." However, in dozens of cases there are use sites where RPAs are suggested despite this standard not being met. In all cases, additional use sites were listed as requiring RPAs beyond those indicated in previous chapters. Errors such as this only further support the need for NMFS to carefully outline and fully disclose all assumptions and methods used in jeopardy and adverse modification determinations (see earlier comments for examples).

- As stated in the BiOp, Section 26.5 b: "Prohibit application of pesticide products when soil moisture is at field capacity, or when a storm event likely to produce runoff from the treated area is forecasted (by NOAA/National Weather Service, or other similar forecasting service) to occur within 48 hours following application." Since 2011, USDA has repeatedly attempted, unsuccessfully, to inform NMFS that this RPM (which has appeared in previous BiOps) is technically inaccurate and uses incorrect verbiage. The best timing for pesticide applications is when soil is at field capacity. It would appear that

NMFS is confusing field capacity with soil saturation. "Field capacity (Cc) corresponds to the superior limit of available water and represents the moisture of the soil after drainage of the water contained in the macropores by gravity action. This moisture condition favors higher absorption of water and nutrients by the plants" (Alves de Oliveira, 2015). Soil saturation is a condition in which all pore spaces between soil particles are temporarily or permanently filled with water, a condition at which pesticide product application is at high risk of runoff (FAO, 1985).

- Other Best Management Practice (BMP) efforts already in place have not been accounted for in determining the need for an RPA, nor does the BiOp make any clear link of causation between the measures and the impacts on endangered species. USDA is always available to assist NMFS in better understanding what practices are in place, especially those supported by NRCS.

Overall, NMFS fails to satisfy its legal obligations in promulgating the RPAs in this BiOp, because it does not provide (1) any explanation or justification for the proposed RPA and how it might prevent jeopardy, and (2) any economic and technological feasibility analysis for this RPA. USDA is very concerned that the "RPA" in this BiOp does not meet the requirements for an RPA set by 50 CFR 402.02, that its inclusion without a proper basis renders the BiOp arbitrary and capricious, and that, in addition to its legal shortcomings, this "RPA" is impractical and could not be implemented by American agriculture.

References:

Alves de Oliveira. 2015. Irrigation Management. Sugarcane Agricultural Production, Bioenergy, and Ethanol. 161-183.

Environmental Protection Agency (EPA). Undated. Models for Pesticide Risk Assessment (including AgDrift). Office of Pesticide Programs. Located at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Environmental Protection Agency (EPA). 2009. Re-registration Eligibility Decision for Malathion. Office of Pesticide Programs. Located at: https://archive.epa.gov/pesticides/reregistration/web/pdf/malathion-red-revised.pdf

Environmental Protection Agency (EPA). 2015. Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances. Office of Pesticide Programs, Biological and Economic Analysis Division.

Environmental Protection Agency (EPA). 2018a. Overview of the EPA Drift Reduction Technology Program. Located at: https://www.epa.gov/reducing-pesticide-drift/about-drift-reduction-technology-program

Environmental Protection Agency (EPA). 2018b. FY 2016/17 Fee Schedule for Registration Applications. Located at: https://www.epa.gov/pria-fees/fy-201617-fee-schedule-registration-applications

Eurostat. 2016. Small and Large Farms in the EU-Statistics from the Farm Structure Survey. Located at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Small_and_large_farms_in_the_EU_-_statistics_from_the_farm_structure_survey

Food and Agriculture Organization. 1985. Irrigation Water Management: Training Manual No. 1 - Introduction to Irrigation. Chapter 2: Soil and Water. Located at: http://www.fao.org/docrep/r4082e/r4082e03.htm#2.1%20the%20soil

Market Research Data (MRD). 2012-2017. Data collected and sold by a private market research firm. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statically valid results, typically at the state level.

Ratnadass, A., Fernandes, P., Avelino, J. and Habib, R. 2012. Plant species diversity for sustainable management of crop pests and diseases in agroecosystem: a review. Agron. Sustain. Dev. 32: 273-303.

Salmon Safe. 2018. Salmon-Safe Certification Standards for Farms. Located at: https://salmonsafe.org/wp-content/uploads/2018/03/Farms-Standards-Version-2.7-May-2018.pdf

Sargeant, D., E. Newell, P. Anderson, and A. Cook. 2013. Surface Water Monitoring Program for Pesticide in Salmon-Bearing Streams, 2009-2011 Triennial Report. A Cooperative Study by the Washington State Departments of Ecology and Agriculture. Publication number 13-03-002

United States Department of Agriculture (USDA). 2018. Farms and Land in Farms: 2017 Summary. National Agricultural Statistics Service. ISSN: 1995-2004. Located at: http://usda.mannlib.cornell.edu/usda/current/FarmLandIn/FarmLandIn-02-16-2018.pdf

USDA Natural Resources Conservation Service (USDA NRCS). 2018a. California Payment Schedules: Practices Scenarios. Located at: https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/financial/?cid=nrcseprd1328227

USDA Natural Resources Conservation Service (USDA NRCS). 2018b. National Conservation Practice Standards. Located at: https://www.nrcs.usda.gov/wps/portal/nrcs/main/national/technical/cp/ncps/

Whitfield Aslund, M., et al. 2017. Ecological risk assessment for Pacific salmon exposed to dimethoate in California. Environmental Toxicology and Chemistry. Vol. 36(2). Pp. 532-543 https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.3563

Winchell, M. F., N. Pai, B. H. Brayden, C. Stone, P. Whatling, J. P. Hanzas, and J. J. Stryker. 2018. Evaluation of Watershed-Scale Simulations of In-Stream Pesticide Concentrations from Off-Target Spray Drift. J. Environ. Qual. 47:79-87. doi:10.2134/jeq2017.06.0238