CENTER FOR FOOD SAFETY

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1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: EPA-HQ-OPP-2021-0231

Comments on the U.S. Fish and Wildlife Service's Draft Biological Opinion on Malathion

Center for Food Safety (CFS), on behalf of itself and its 970,000 members and supporters, submits these comments on the U.S. Fish and Wildlife Service's draft biological opinion on malathion. CFS is a public interest, nonprofit membership organization with offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and a health environment.

Introduction

The U.S. Environmental Protection Agency (EPA) issued its biological evaluation of malathion in January 2017, in which it determined that malathion was likely to adversely affect 1,778 species (97% of those listed) and 784 critical habitats (98% of the same).[1] Just months later, the U.S. Fish and Wildlife Service (henceforth, "Service") conveyed the conclusions of its draft biological opinion (BiOp) for malathion, in which jeopardy determinations were made for 1,284 (81%) of species and adverse modification determinations for 163 (22%) of critical habitats.[2]

In a breathtaking reversal, this BiOp finds that malathion jeopardizes the continued existence of just 78 species and will likely destroy or adversely modify just 23 critical habitats. The wholesale transfer of over 1,000 species from jeopardy to no jeopardy from malathion and corresponding demotion of 140 critical habitats naturally raises grave questions as to what has so radically changed over the past 3-4 years. As it turns out, the Service has introduced entirely unjustified methodological innovations into its assessment that were clearly aimed at "clearing

[1] U.S. EPA, Biological Evaluation for Malathion ESA Assessment, January 2017, Executive Summary. https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment.
[2] U.S. Fish and Wildlife Service, Overview of the National Pesticide Biological Opinions on Chlorpyrifos, Malathion and Diazinon, PowerPoint presentation, October 2017.

the decks" of as many jeopardy and adverse modification calls as possible, thereby putting numerous threatened and endangered species at risk of extinction – species and habitats that the Service until a few short years ago recognized required ESA protections from this highly toxic insecticide.

Below, we discuss two key innovations that led to this outcome, with limited examples from the chapters of the massive draft BiOp and its numerous appendices.

I. Improper and Illegal Reliance on Unreliable Malathion "Usage Data" to Inform Exposure Assessments

In a sharp departure from long-standing practice, the Service has made extensive use of average malathion usage data based primarily on surveys of farmers and other pesticide applicators – rather than label use parameters – in making jeopardy determinations for listed species exposed to malathion.[3]

This novel approach clearly violates the Endangered Species Act mandates to make determinations "solely on the basis of the best scientific and commercial data available…" and to "give the species the benefit of the doubt," thereby putting at risk of extinction hundreds of endangered species. As discussed below, label use parameters clearly represent the "best scientific and commercial data available," while the malathion usage data employed by the Service are both unreliable, and will in many cases dramatically underestimate the actual exposure of listed species to this highly toxic pesticide.

A. Usage data is unreliable, particularly at state and sub-state levels

Usage data for a particular pesticide in a given region are based on a survey of a tiny fraction of the farmers/applicators in that region. Their responses – as to rate of application, frequency of use, etc. – are assumed to be accurate, and also to represent the usage of all farmers in that region. If the sample size is too small, or unrepresentative in some way, the survey results may well be misleading, skewing substantially higher or lower than the actual usage of the applicators they are presumed to represent. One must fully understand the survey methodology in order to properly assess the validity of the survey and the usage data derived from it.

The Service obtained agricultural usage data for malathion from EPA, which collected it from the U.S. Department of Agriculture (USDA), the state of California and Kynetec, a commercial firm that supplied "[t]he majority of the data provided for the states outside of California."[4] Kynetec data are wholly inappropriate for use in the Service's ESA assessments for several reasons.

First, the company's data are "designed to address market questions asked most often by senior executives, and those involved in product development, sales and marketing" in the

[3] US Fish and Wildlife Service, Draft Malathion Biological Opinion (henceforth, "BiOp"), February 2021, Chapt. 1, p. 22.

[4] BiOp, Chapt. 2, p. 259 ff.

seed-pesticide industry, not to assess ecological impacts of pesticides.[5] Second, the surveys Kynetec conducts to collect usage data are "designed to reach a particular percentage of the total crop grown at a national level," and so at best can only be regarded as providing an accurate reflection of ***average*** usage per crop at the ***national*** level.[6] Average national usage fails to account for the localized use of relevance to listed species, which by definition (of average) will in many cases be higher than the national average. Third, while Kynetec sometimes reports statistics "at the state and Crop Reporting District (CRD) level," this can only be done "when sample size [number of farmers surveyed] is adequate."[7] Fourth, the Service freely admits that it has absolutely no basis for assessing the validity of Kynetec's methodology or the accuracy of the malathion data it generates at the state or sub-state level:

> "The data provided to the Service is lacking the statistical foundation to understand the robustness at the state level or any geographic specificity at the sub-state level. Neither EPA nor Kynetec was able to provide us with this information (e.g. how many applicators responded to the survey, how many acres are represented by the survey at the state level), nor any standards used to determine an adequate sample size at these levels, nor the minimum threshold required for reporting these values. Our understanding is that this varied on a case-by-case basis, according to the surveyor, crop, and state."[8]

This is a remarkable admission. The BiOp is largely based on data the quality and accuracy of which the Service itself has no way of vetting. Data from an impenetrable black box. Trust Kynetec, they're the experts.

But it is not surprising. Kynetec's apparent refusal to share methodological information with the Service mirrors long-standing practices of other pesticide usage collection firms, such as Doane's Marketing Research. The following statement from a USDA Advisory Committee on Agricultural Statistics closely resembles the Service's admission regarding Kynetec:

> "The proprietary agreements entered into by Doane subscribers extend well beyond prohibitions on data disclosure, to embargo revelation of the sampling and analytical procedures used to generate their data. Thus, it may be that a

[5] Id., pp. 259-260. Note that major seed-pesticide firms contract with firms like Kynetec to supply them with pesticide usage data so they can keep tabs on how their competitors' products are faring in the marketplace in relation to their own. As indicated, these data are collected to inform decisions about pesticide product development and marketing.
[6] Id., p. 260.
[7] Id., p. 260.
[8] Id., p. 260.

large number of the area wide estimates included in the Doane system are based on individual or statistically unrepresentative observations."[9]

In short, the Kynetec usage data on malathion that underlies much of the Service's BiOp is far too unreliable to utilize for the BiOp. It meets neither the ESA's "best scientific and commercial data" mandate nor the Data Quality Act or Office of Management and Budget guidelines on information quality.[10]

B. National Research Council – and formerly the Service itself – rejected usage data in favor of label use parameters

Even if malathion usage data were not unreliable, they would still be entirely unsuitable for use in making jeopardy determinations for listed species.

The Service lamely attempts to justify its usage data approach by noting that "malathion will not be used everywhere, applied at the highest allowable frequency at each site, or applied at the highest application rates each time it is used (which would likely comprise more product than it is currently manufactured or distributed)…"[11] Translation: Because malathion will not ***always*** and ***everywhere*** be used at the label maximum use parameters, the Service need not assess the impacts of such use legally sanctioned use on ***any*** listed species, ***anywhere*** or ***ever***. It is hard to imagine a more flagrant departure from the Supreme Court's interpretation of the Endangered Species Act as representing "the institutionalization of caution."

This average usage data approach is contradicted by the National Research Council, an arm of the National Academy of Sciences, whose 2013 report, at least until now, served as the touchstone for methodology and interagency coordination in ESA consultations:

"Compliance with the ESA in the context of pesticide registration requires EPA and the Services to determine the probability of adverse effects on listed species and their critical habitat ***when a pesticide is used according to its label requirements.***"[12]

[9] "Meeting of the Advisory Committee on Agriculture Statistics (ACAS): Summary and Recommendations," February 14-15, 2006, USDA NASS, Appendix III, at: http://www.nass.usda.gov/About_NASS/Advisory_Committee_on_Agriculture_Statistics/advisory-es021406.pdf.

[10] 67 Fed. Reg. 8452-8460, Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies; republication (Feb. 22, 2002), defining objectivity in part as: "the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods."

[11] BiOp, Chapt. 1, p. 22.

[12] National Research Council 2013. *Assessing Risks to Endangered and Threatened Species from Pesticides*. Washington, DC: The National Academies Press, p. 4.

> "In the context of this report, risk is defined as the probability of adverse effects on listed species or their critical habitats due to anticipated pesticide use that is ***consistent with label requirements***."[13]

In developing Interim Approaches to begin implementing the National Research Council's recommendations, the EPA, USDA, National Marine Fisheries Service as well as the Fish and Wildlife Service itself likewise all agreed that pesticide label use parameters were the appropriate input for assessing exposure in ESA consultations, from Steps 1 through 3.[14] They had sound reasons for doing so.

C. The label is the law

First and most obviously, "the label is the law," and maximum label use parameters (e.g. rates and frequencies) are not pulled out of a magician's hat, but are grounded in crop- and pest-specific considerations, and the understanding that pest infestations are episodic in nature, absent or insignificant in some years and highly damaging in others. While one may not necessarily agree with them, there are presumably agronomic reasons for permitting up to six applications of malathion per year to cabbage, at up to 1.25 lbs./acre per application, while citrus can only be sprayed once per year, but at up to 7.5 lbs/acre in California or 4.5 lbs/acre elsewhere.[15] Thus, it is only reasonable to assume that some growers will spray as intensively and frequently as permitted under pest-promoting conditions in her/her region in certain years. Indeed, for some crops it appears that average past usage closely approaches the maximum permitted by malathion labels.[16]

Second, as the Service stated in October 2017 regarding its (former) draft biological opinions for malathion, chlorpyrifos and diazinon, there are "few limits on labels for when and where these pesticides can be used so exposure can be widespread."[17] Indeed, some malathion product labels shockingly lack key maximum use parameters for a substantial minority of crops. For instance, there is apparently no limit to the number of malathion applications that can be made per season, at least with certain products, to alfalfa, blueberries, clover, trefoil, vetch, beans, grasses and lentils.[18] Relying on average usage over some arbitrary

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[13] Id., p. 37.

[14] *Interagency Approach for Implementation of National Academy of Sciences Report: Assessing Risks to Endangered and Threatened Species from Pesticides*, December 5, 2013. https://archive.epa.gov/epa/sites/production/files/2014-05/documents/session2-esa.pdf.

[15] BiOp, Chapt. 1, Table 3, pp. 14-17.

[16] USDA NASS estimated average use of malathion on blueberries as 3.6 lbs/acre/year (2009, 2011), which is quite close to the maximum annual use permitted by the label of 3.75 lbs/acre. Compare EPA, Biological Evaluation for Malathion ESA Assessment, Appendix 1-8 for USDA NASS figures, and BiOp, Chapt. 1, Table 1 for label use parameters. For other crops and time periods, past usage of malathion falls short of label permissible amounts.

[17] U.S. Fish and Wildlife Service, Overview of the National Pesticide Biological Opinions on Chlorpyrifos, Malathion and Diazinon, PowerPoint presentation, October 2017.

[18] BiOp, Chapt. 1, Table 3; see also EPA, Biological Evaluation for Malathion ESA Assessment, Appendix 1-3.

past period is highly irresponsible in these situations, where even certain malathion product labels lack clear checks in the form of maximum usage limits.

D. Average use at national/state levels underestimates exposures to many listed species

Geographically speaking, average usage of malathion for particular crops at the national or state level by definition (of average) overstates actual use in some locations and understates it in others. There is substantial geographical variability in usage, dependent on local pest pressures, environmental conditions, pesticide marketing practices, and individual farmer decision-making. For listed species, which by definition have small numbers and often quite limited geographical ranges, average-based usage estimates will gravely underestimate exposures of listed species in situations where high usage coincides with the listed species' tiny range or critical habitat, with potentially catastrophic consequences.

This is well illustrated by Hawaii and other Pacific Islands, which have a large number of endangered and threatened species. While the BiOp makes a number of jeopardy calls for listed species in Hawaii, not all that deserve protection were granted it. Malathion labels permit extraordinarily high use of this insecticide on semi-tropical fruits grown solely or primarily in Hawaii. Papaya and passion fruit can be sprayed with malathion up to 8 times per season; mango as many as 10 times (annual use up to 9.4 lbs/acre), and guava an incredible 13 times per season (annual use up to 16.25 lbs/acre).[19] This is particularly concerning because malathion as well as chlorpyrifos "[c]an remain in the environment for weeks to months after application, resulting in potential effects to species after application."[20] Moreover, because malathion labels permit repeat applications at extremely short intervals (retreatment intervals of just 3 to 7 days for these semi-tropical fruits[21]), there is a clear potential for rising environmental levels of and exposure to malathion and its degradates over the course of weeks to months.

This retreatment issue is not unique to Hawaii. Malathion labels permit repeat applications to many different crops, often at short intervals. Some labels permit malathion to be applied "as needed" with no apparent limit on the number of applications or the total per acre use per year.[22]

E. Past usage a poor guide for the future

The BiOp relies heavily on past usage of malathion, averaged over relatively short time periods of several to five years (e.g. 2008-2012),[23] as the basis for assessing future exposure of

[19] BiOp, Chapt. 1, Table 3.
[20] U.S. Fish and Wildlife Service, Overview of the National Pesticide Biological Opinions on Chlorpyrifos, Malathion and Diazinon, PowerPoint presentation, October 2017.
[21] BiOp, Chapt. 1, Table 3.
[22] EPA, Biological Evaluation for Malathion ESA Assessment, Appendix 1-3.
[23] BiOp, Appendix G.

listed species to the insecticide over the 15 years of this Action. Yet the past is often a poor predictor of the future in the world of pesticides. Fluctuating pest pressures as well as changes in the availability of pesticides similar to malathion over time could well make past usage an entirely unreliable guide.

One example is malathion use in the orange orchards of Florida. Malathion is not even cited in USDA data for malathion use on oranges in Florida from 1991 to 2005. It first appears in 2009, when usage was too low to register, and then explodes in the subsequent survey years (2011, 2015, 2017 and 2019), rising from 91,300 lbs. in 2011 to 185,600 lbs. in 2019, with percent area of bearing orange trees treated rising from 16% to 45% over the same period.[24] This sharp rise in use was apparently driven by emergence of citrus greening disease in Florida, in an attempt to control the Asian citrus psyllid, the insect vector of this disease. This illustrates how unpredictable pest pressures can make past usage an entirely unreliable guide for the future.

Malathion use on oranges in California illustrates a somewhat different point. The percent of bearing orange tree acreage treated with malathion in the state has fluctuated considerably, with no trend over time, since 1997. Percent area treated ranges from negligible (2001, 2009), to a few percent in 1997, 2003, 2005, 2017, then spiking in 2011 to 21%.[25] This variability likely reflects irregular, episodic emergence of lesser pests in different regions, rather than, like the Asian citrus psyllid in Florida, the gradual establishment and spread of a major citrus disease and its vector. (While Asian citrus psyllid is found parts of southern California, it has not become nearly as prevalent there as in Florida).

Future malathion usage will also be influenced by the future availability of comparable insecticides, another unpredictable factor. For instance, malathion usage might well increase dramatically as more states prohibit the use of the brain-damaging organophosphate insecticide chlorpyrifos, and/or EPA revokes registrations of chlorpyrifos products on a national basis. California banned chlorpyrifos in 2021, and malathion is a frequently cited substitute for it.[26] We would note that this same Work Group has identified a plethora of biopesticides far less toxic than either chlorpyrifos or malathion as substitutes for the former,[27] while biocontrol methods involving introduction of natural predators of Asian citrus psyllid are also being tested.[28] In fact, restrictions or bans of extremely toxic pesticides often serve the beneficial end of stimulating research on and implementation of much safer alternatives.

One example of how reliance on past usage data can pervert jeopardy determinations is provided by the Perdido Key beach mouse – one of six listed beach mice endemic to parts of

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[24] USDA Quick Stats. https://quickstats.nass.usda.gov, data downloaded 6/19/21.
[25] Id.
[26] Towards Safer and More Sustainable Alternatives to Chlorpyrifos: An Action Plan for California, Alternatives to Chlorpyrifos Work Group, May 2020.
https://www.cdpr.ca.gov/docs/chlorpyrifos/pdf/chlorpyrifos_action_plan.pdf.
[27] Id., e.g. Table 1A.
[28] R. Lopez, Citrus growers use predator wasp to fight disease threat. Los Angeles Times, August 4, 2013.
https://www.latimes.com/business/la-fi-predator-wasp-20130804-dto-htmlstory.html.

the Gulf Coast of Alabama and Florida – all of them declining in population. All six have nearly identical habitat and similar levels of exposure to malathion from agricultural and possible mosquito control applications. Yet the BiOp made jeopardy calls for only three of these six mice (all subspecies of *Peromyscus polionotus*). While the BiOp made a jeopardy call for the Alabama beach mouse, the Perdido Key beach mouse rated a No Jeopardy determination, despite the fact that both were rated as highly vulnerable with high exposure to malathion. The key difference, apparently, that the mosquito control district where the Key Perdido beach mouse is endemic has not reported past malathion use, although its use is legally permitted, and malathion may very well be used in the future for mosquito control.

F. Timing of malathion usage in relation to lifecycle and windows of vulnerability of listed species

Usage data also entirely fail to account for the seasonal timing of malathion's use, and potential overlaps between seasonal pulses of malathion applications in particular regions and the presence or absence of listed species with complex lifecycles. The National Research Council highlighted this important issue in the context of Pacific salmonids, and sublethal effects of organophosphate exposure on their sensory capacity, reaction, swimming ability and other performance characteristics vital to survival.[29] (NAS 2013 at 96-98, Box 4-1).

The Service has not paid sufficient attention to this issue in the BiOp. For instance, the rabbitsfoot mussel is found in Midwestern states like Indiana and Ohio that have high levels of malathion use. Mussels can be directly and indirectly harmed if their host fish are not present during their glochidia phase. While the BiOp maintains that host fish are not anticipated to be present when most malathion is sprayed, it provides no information regarding when the host fish spawn or whether this overlaps with periods of malathion usage. Spring applications of malathion might well coincide with spawning, with adverse impacts on host fish and the mussels that depend on them that are not accounted for in the BiOp.

More generally, low overall usage of malathion, averaged over diverse habitats and past time periods of a few years, may obscure harms ensuing from exposure at sensitive periods in the lifecycle of listed species themselves or others they rely upon.

For these many reasons, malathion usage data based on surveys of average use over snapshots of the past, and over broad geographic areas, provide no reliable guide to the threats this highly toxic pesticide poses to listed species in the 15 years covered by this Action.

Instead, the Service should heed the recommendations of the National Research Council and return to past practice by utilizing label use parameters as the best scientific and commercial data available to assess exposure of listed species to malathion.

[29] NRC 2013, op. cit., pp. 96-98, Box 4-1.

II. Vastly Inflated Range Estimates and Failure to Supply Accurate Range Maps

Another serious methodological error that contributed substantially to unjustified "no jeopardy" calls from malathion exposure is the Service's blatant and vast overstatement of listed species' ranges. This in turn led to minimization of the percentage overlap between those inflated ranges and areas of malathion use, lent the false impression that many listed species are exposed to malathion in only a tiny fraction of their ranges, and hence would not be jeopardized.

One example is provided by the Miami Blue Butterfly. Although this butterfly is restricted "to a few, small insular areas in the extreme southern portion of its historical range" and has undergone "an estimated >99% decline in area occupied," the Service assumes the Miami Blue's range is an absurd 3,947,862 acres.

A second example is the Houston toad, whose range the BiOp pegs at 4,976,348 acres. However, this is simply the summed acreage of nine counties that encompass the toad's habitat, and the Service well knows this endangered amphibian occupies only a small portion of this "range." Although the Service did make a jeopardy call for the Houston toad, the imputation of an inflated range does not serve the interests of conserving this species.

The Valley Elderberry Longhorn Beetle supposedly has a range of nearly 9.5 million acres in California's Central Valley, an area equivalent to 10% of the entire state that includes numerous metropolitan areas that are decidedly not habitat. Indeed, the 2019 Recovery Plan for this beetle documents only 102,000 acres of riparian forest left in the Central Valley by 1984, begging the question of how it's range could be nearly two orders of magnitude larger than the riparian forest habitat it requires.

The BiOp similarly inflates the ranges of other species, for instant Lange's Metalmark, a butterfly that at last count numbered only 10 individuals whose only habitat is the Antioch Dunes National Wildlife Refuge. The BiOp assigns an absurdly large range of 37,612 acres, whose provenance is mysterious. The best approximation of the species range dates to the 1984 Recovery Plan, where the original dune area it once occupied was as little as 190 acres.

Inflated range estimates have the effect of both reducing percent overlap with areas of malathion use and diluting the species' predicted exposure to malathion. As discussed above, what counts for listed species with low numbers and limited ranges is exposure they may credibly experience in the next 15 years in the specific, often tiny slivers of habitat they actually inhabit. Inflated range estimates that include mostly non-habitat can only dilute exposure estimates, underestimating harm from malathion and tipping what would otherwise be jeopardy to no jeopardy determinations.

The Service must also develop refined range maps for the listed species considered in this Action, and make them available to the public for analysis and comment.

III. Prudent and Reasonable Alternatives and Measures, Incidental Take Statements

The BiOp entirely fails to discuss incidental take, and lacks any meaningful discussion of Reasonable and Prudent Alternatives (RPAs), Reasonable and Prudent Measures (RPMs) or

Incidental Take Statements (ITSs). Even if these are fleshed out in the final BiOp, the Service simply cannot assume EPA will implement them, and in fact must assume the opposite given a clear pattern of non-compliance by EPA.

Since 2009, the National Marine Fisheries Service has issued a number of biological opinions on the effects of various pesticides on Pacific Northwest salmonid. These BiOps made both jeopardy calls with RPAs, and no jeopardy determinations with RPMs. EPA has systematically refused to implement any of these RPAs or RPMs for many of the affected pesticides. For instance, EPA has refused to implement the simplest of RPMs – inclusion of Endangered Species Protection Requirements language on many pertinent labels – despite acknowledging the necessity of doing so even to comply with FIFRA in 2005.[30]

This systematic refusal to comply with the Endangered Species Act precludes granting EPA the "presumption of regularity" that is normally accorded to federal agencies when it comes to their compliance with general legal mandates. Thus, in our view the Service *cannot* issue an ITS in this BiOp until EPA demonstrates some signs of compliance with the ESA, such as voluntary label changes to include *Bulletins Live*.

IV. Conclusion

The Service's draft BiOp for malathion represents a clear step backward in efforts to protect threatened and endangered species from potential extinction ensuing from malathion use. These comments have only addressed a small subset of its objectionable aspects. Center for Food Safety encourages the Service to also give serious consideration to additional issues raised by other public commenters, such as those submitted by the Center for Biological Diversity.

We strongly urge the Service to correct the many methodological errors in this BiOp, and on that basis to reconsider the 1,000+ no jeopardy determinations it made for listed species it formerly, just a few years ago, found jeopardized by malathion.

In addition, this BiOp must not be permitted to set a precedent for future assessments of the jeopardy posed by other pesticides to threatened and endangered species. We urge the Service to abandon the unreliable and hazardous innovations it employed in this BiOp, and to return to sound scientific procedures, in line with National Research Council guidance, for the final BiOp on malathion and likewise for future BiOps on other pesticides.

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[30] 70 Fed. Reg. 66392, *Endangered Species Protection Program Field Implementation* (Nov. 2, 2005).