

Comments by CropLife America on NMFS Biological Opinions on Chlorpyrifos, Diazinon, and Malathion¹ Docket identification number EPA–HQ–OPP–2018–0141

1 BACKGROUND

The Environmental Protection Agency (EPA or the Agency) put forth a request for public comment on the final Organophosphate Biological Opinion (BiOp, or NMFS BiOp) issued under the Endangered Species Act (ESA) by the National Marine Fisheries Service (NMFS). This BiOp considers the potential effects of FIFRA-registered uses of chlorpyrifos, malathion, and diazinon (collectively organophosphates or OPs) on federally listed threatened or endangered species (listed species) and their designated critical habitats. The NMFS BiOp and EPA’s Biological Evaluations (BEs) emerged from an inefficient process, provided conclusions and assumptions that greatly overstate actual exposure and risk potentials, and resulted, in the BiOp, in unworkable, unsupported recommendations for mitigations on use. Absent from both the BEs and BiOp is information critical to understanding how the OPs are used: where, how, and to what degree exposure to listed species may occur; and why these OP products are critical to the production of certain crops and protection of human health.

CropLife America (CLA) has commented on EPA’s BEs and other FIFRA/ESA documents arising from the consultation process, with a common and continuing theme.^{2,3} Even though CLA and many others in agriculture have presented detailed comments, we now see that in the repeated BEs and BiOps not only are flaws pointed out previously not corrected, they are magnified. Rather than repeat comments made in response to earlier versions of consultation documents, CLA has used this comment opportunity to address EPA’s broad questions with general responses supporting the many rounds of detailed comments previously submitted. EPA listed three general comment topics in the request for public input on the NMFS BiOp. We have organized our comments on these issues within the three comment topics identified by EPA and provided specific examples to illustrate how application of current data at a finer scale (*i.e.*, county, and river system) would improve the technical validity of and context for endangered species assessment relative to pesticide use.

We demonstrate by examples herein the extent of technical detail overlooked in the BiOp to also focus attention on the inadequacy and inefficiency of the ESA process demonstrated to date. Much of the technical information missing from the BEs and BiOp was overlooked because it encompasses a broad array of agricultural realities that are outside of the areas of expertise expected to exist within EPA and NMFS. Consideration of this array of information can be brought into the process by including stakeholders such as the US Department of Agriculture (USDA), which in turn gathers information from

¹ Covered by January 23, 2018 letter from Janet E. Collins, Ph.D., R.D., CFS, Executive Vice President, Science and Regulatory Affairs, CropLife America, “CropLife America Comments to the U.S. Environmental Protection Agency on the ‘Biological Opinions for Pesticides Issued Under the Endangered Species Act;’ EPA-HQ-OPP-2018-0141” (CLA Cover Letter).

² CLA submitted detailed comments on the deficiencies in the BEs to the EPA OP docket, “Comments by CropLife America on EPA OPP draft biological evaluations of chlorpyrifos, diazinon, and malathion.” Docket identification number EPA–HQ–OPP–2016–0167, 81 fed. Reg. 21341 (April 11, 2016). Prior to that, CLA also submitted comments on the flawed 2008 NMFS BiOp, “CropLife America’s Comments on the National Marine Fisheries Draft Biological Opinion on The Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon and Malathion September 15, 2008.”

³ Of note, EPA also completed a series of OP effects determinations in 2002-2003. These were not taken into account in the 2008 BiOp.

state departments of agriculture and local (county level) agricultural organizations and programs, and the pesticide registrants and other stakeholders. The BiOp also demonstrates the challenges posed by NMFS conducting exposure and risk assessment without appropriate coordination with EPA. These functions are the expertise of the EPA and expertise should be leveraged in the ESA review process to allow NMFS and USDA to focus on their relative areas of expertise as well.

2 RESPONSES TO EPA COMMENT TOPICS

2.1 EPA Comment Topic #1: Seeking information on the scientific approaches and data sources used to support the BiOp and reach determinations for the listed species and critical habitat.

One of the primary information sources initially used by NMFS in preparing the BiOp were the EPA 2016 BEs (USEPA, 2016a; USEPA, 2016b; USEPA, 2016c), which provided an overstated worst-case scenario of listed species exposure to the three OPs and potential effects of this exposure. The risk concerns presented in the BEs were based on a deterministic assessment approach rather than a probabilistic approach, and thus provided no means by which EPA or NMFS could systematically rank the presumed risk to individual listed species into low, medium and high categories to narrow the focus to species truly in jeopardy due to current uses of the three OPs. NMFS then developed its own assessment of risk (“likelihood of adverse effects” to animals and habitat) using a new and untested approach based primarily on personal judgement, without consideration of concise, local habitat, and OP use delineation. This effort, in addition to lacking transparency, concluded that all those species for which EPA determined exposure are in jeopardy, without clearly quantifying the extent and likelihood of exposure and thus actual jeopardy. These procedural duplication deviations, based on non-standard and generalized methodologies, resulted in an ultraconservative, overstated assumption of risk to growth, reproduction and/or survival of listed species.

2.1.1 The NMFS BiOp does not accurately portray species locations.

The BiOp’s failure to use best available data on topics such as species locations, barriers to fish passage, and population data in its depiction of species ranges led to inaccurate and overestimated ranges portrayed for each species. For example, within Whatcom County, WA alone, the Washington Department of Fish and Wildlife (WDFW) Fish Passage Barrier Screening Inventory (FPBSI) includes 660 partial or seasonal and 229 total fish passage barriers due to road crossings or culverts, and 33 partial and 53 total passage barriers represented by diverse types of dams and water diversion mechanisms (WDFW, 2018). Limited “Historical Watersheds – Anthropogenically Blocked” areas were identified on range maps by NMFS in the BiOp but these areas are nowhere near the scale of the fish passage barrier information from WDFW. Having not considered this information, the species range maps in the NMFS BiOp include areas that are not accessible to the species and should therefore not be considered part of the current range.

There are discrepancies, inconsistencies, and non-transparencies, as detailed in comments submitted by other stakeholders in the portrayal of species ranges in the NMFS BiOp. These discrepancies do not allow the replication of NMFS’s depiction of species range and, therefore, informed comments about NMFS species range depiction cannot be made. Species ranges used by NMFS should be further documented, corrected where needed, and supported by current, accuracy-verified ranges that are publicly available, in a comprehensive and consistent format. Where state agencies, such as the WDFW, the Oregon Department of Fish and Wildlife (ODFW), and tribal fisheries programs, have the best available data on species and habitat information such as fish passages and population counts, NMFS should use them to accurately depict species ranges.

2.1.2 The NMFS BiOp fails to estimate exposure using accurate, verified models, with output compared to extensive available monitoring data.

The BiOp uses exposure estimates taken from EPA’s BEs, which are based on multiple conservative assumptions that are carried over in the BiOp, but which, due to their overly conservative nature, do not accurately reflect species’ exposure to pesticide residue. In particular, EPA’s exposure models fail to

simulate hydrologic processes (such as dilution and tidal flushing) that significantly reduce pesticide residue exposure to aquatic organisms. Even EPA's basic edge-of-field exposure modeling is overly conservative. For example, EPA's standard aquatic exposure modeling⁴ assumes there is no buffer area (including riparian habitat) between the treated area and the receiving water body, thereby ignoring the mitigating effects of distance and intervening vegetation on off-site spray drift and surface run-off. The Agency assumed maximum use scenarios in the BEs (e.g., maximum application rate, maximum number of applications, minimum interval between applications, wind always blowing toward the receiving water body) although these use scenarios are seldom representative of how a pesticide product is actually used. NMFS failed to do its job of determining whether EPA's assumption of the "worst case" risk even occurred in the real world. Even when NMFS's subjective evaluation indicated low confidence in the exposure estimates, in most cases, overall risk was classified as medium or high.

The process for evaluating exposure should also consider the most recent residue monitoring data for individual river systems, but this was not evident in the BiOp. For example, more current surface water monitoring data for the Yakima River and other river systems are available from the Washington State Department of Agriculture (WSDA) Surface Water Monitoring Program (WSDA, 2018); the US Geological Survey (USGS) North American Water Quality Assessment (NAWQA) database contains surface water sampling information for Marion County, OR (Willamette River system) up to 2017 (USGS, 2018).

2.1.3 It is unclear how population status is determined.

NMFS mentions in the BiOp that salmon population models were used to determine population status. However, the models used were inadequately described and have not undergone any external peer review, quality assurance or controls. Moreover, results from their use were seemingly used only as a confirmation of the screening-level R-Plot risk quotient analysis. There was no clear indication that the results of this modeling effort figured into the jeopardy/no jeopardy decisions in any way.

2.1.4 Risk determinations are not derived by using a transparent process structured around defensible criteria.

NMFS's determinations of "overall risk" were based on a cascade of arbitrary criteria for effects, likelihood of exposure, "risk," and confidence, defined in such a way that most species were determined to be at risk based on very weak evidence. While the process included effects endpoints and exposure estimates provided by EPA's BEs, the outcomes (i.e., the overall risk ranking of low, medium, or high for each species) were largely determined by seemingly arbitrary criteria for categorizing effects, exposure, risk, and confidence.

For example, NMFS categorized the likelihood of exposure associated with a given species and use site as medium or high if more than 1% of the species range occurred in the same HUC-12 watershed as the use site, or if any part of the species range is less than 300-m from the use site. NMFS provided no justification for the 1% threshold or the 300-m proximity criterion. When these criteria led to categorization of likelihood of exposure as medium or high, risk was also categorized as medium or high even if the estimated exposure (from EPA's highly conservative exposure modeling) was below the effect threshold. Following this process, any species whose range exceeds the 1% overlap threshold for any use site will almost inevitably be assigned a medium or high overall risk, regardless of the species' sensitivity to the pesticide.

Similar examples of arbitrary criteria leading to overly conservative risk determinations abound in NMFS's process. Moreover, the process itself is extremely complex and virtually impossible to reconstruct for any particular species or OP use, despite the voluminous (and repetitious) documentation. As a result, the basis for NMFS's specific conclusions was not transparent, and the final risk and jeopardy

⁴ More information is available at <https://www.epa.gov/homeland-security-research/sam>.

determinations were far removed from the underlying data. The net effect was that the BiOp was largely based on “judgment calls disguised as indisputable science” (Kelly, 2010).

2.2 EPA Comment Topic #2: The RPAs and RPMs. Can they be reasonably implemented? If not, describe why not? Are there different measures that may provide equivalent protection to those in the BiOp but result in less impact to pesticide users?

Because of the underlying failure of the BiOp to comply with applicable law, EPA should reject the BiOp’s RPAs and RPMs. Further, ESA regulations require RPAs to be economically and technically feasible.⁵ The RPAs and RPMs are impossible to connect back to a risk-based conclusion and are based on a “points system” adopted from the European Union without regard to their applicability to US agriculture and pesticide use. This is further complicated by NMFS having had no apparent input from experts who understand US agriculture and pesticide use. Additionally, as proposed, they will potentially 1) have national level impacts on food prices for consumers; 2) put an unjustified burden on certain crop producers due to the regional production of crops treated with the OPs; and 3) be impossible to implement at the national level. The first step of understanding whether RPAs and RPMs are even required is to understand what conservation and production measures are currently being utilized/adopted by growers across the US.

2.2.1 The BiOp proposes RPAs and RPMs without appropriate context, and fails to evaluate external, controlling regulation or the benefits of voluntary conservation.

The BiOp appears to treat the label as the only regulatory and instructive mechanism used in complex agricultural systems for environmental protection that could benefit listed species and their habitat.⁶ Ignoring other such existing factors in the Environmental Baseline results in greatly overstating the potential impact of the OPs on listed species. There are many conservation practices and pesticide education, use and reduction programs that would be expected to reduce the potential effects assumed by the BiOp. Some of these measures are mandatory or are included as best management practices in integrated pest management plans developed by university researchers and extension personnel, and directly or indirectly benefit many of the species for which NMFS concluded registration of the OPs is likely to jeopardize species or distinct population segments and/or adversely modify designated critical habitats. These are marginally addressed in the BiOp (p. 10-34), but these programs were incompletely researched and not considered at all in the development of the Environmental Baseline or the eventual jeopardy/adverse modification opinions. By engaging USDA and other non-NMFS experts in the review process, programs like this, and their influence, would be more realistically applied to the derivation of any additional restrictive requirements – if additional burdens on the end users were needed.

For example, conservation practices and easements, where low to no agricultural land use or pesticide application will occur, mitigate chemical entry into salmon habitat. Across the US, conservation easements are funded through USDA, non-governmental organizations, and other groups. The Conservation Reserve Program, administered by the USDA Farm Service Agency, provides financial assistance to growers for various conservation practices utilized in agricultural areas, including riparian buffers, non-floodplain wetlands, utilizing marginal pasture as wetland and run-off filters, hardy grass erosion control plantings, setting aside grassland filter and sediment control areas, and reserving land for wildlife habitat. These areas are set aside as low or no-pesticide use areas and help control run-off and drift.

⁵ 50 C.F.R. § 402.02 (defining RPAs as “economically and technologically feasible” alternative actions).

⁶ For example, the California Strawberry Commission notes that “California strawberry farmers comply with more than 70 rules and regulations to deliver safe and wholesome berries to market.” More information is available at <http://www.calstrawberry.com/en-us/advisories>.

Pesticide reduction programs are selectively and incompletely reviewed in the BiOp (starting on p. 10-34), but apparently only to provide an “example” of what could go into the proposed mitigation “points system.” There are hundreds of additional conservation programs that benefit listed species either directly or indirectly. LandScope America⁷, a website project of NatureServe and the National Geographic Society, catalogs more than 41,000 conservation projects in the US, and includes an interactive map and detailed information about each effort.

Without a clear understanding of the baseline (the quantity of these measures already adopted or installed by growers), it is difficult to estimate the additional benefits that would accrue from a points system, or any RPA/RPM. As discussed above, many producers have already adopted no-spray buffers (as required on the current labels or in specific states) and spray drift reduction technology, as well as installed filter strips and riparian buffers through voluntary conservation programs at the local, state, and federal level. The BiOp should account for programs, activities and measures that have already been adopted or installed before considering its own; however, this is not clearly addressed in the BiOp. The vast array of environmental conservation and protection work currently undertaken by growers and other pesticide users should be more closely considered, particularly with the benefit of closer engagement by USDA, grower and other user groups, and pesticide registrants. CLA supports the integration of this work into the ESA process both to provide greater understanding of the current exposure of pesticides to listed species and their habitat, as well as to form the basis for potential RPAs and RPMs that may, in some circumstances, be required.

2.2.2 The practical and economic consequences to growers and consumers of restricting the OPs as NMFS suggests is unanswered.

It is important to understand regional and crop-specific pest pressures to fully recognize and consider the use patterns and need for the OPs, or any pesticide for that matter. Due to the location of listed species addressed by NMFS in the BiOp, a total of 17 states, mostly coastal, are impacted by the BiOp. At least 70% of bearing or harvested acres of approximately 50 crops for which OPs are labeled are located in 12 of the states impacted by the BiOp, which means significant agricultural impact from the BiOps in those areas. The majority of these crops are grown primarily in California, Florida, Oregon, and Washington, with a few exceptions, such as sweet corn. California growers control over 50% of the bearing and harvested acres of approximately 40 of the crops for which at least one of the OPs is labeled. When the majority of a crop is produced in a specific state or region (i.e., caneberries), any change in production, such as yield loss or acreage shifts, is likely to impact the price paid to growers and the price paid by consumers across the US. Many of the crops produced within the BiOp footprint, such as orchard and ground fruit crops, take years to reach full production and require specific growing conditions that are only found in certain regions of the country. To minimize the impact on consumers from a decline in production due to pesticide restrictions related to the RPAs and RPMs, other regions of the US and/or foreign markets would need to quickly and efficiently increase production of the impacted crops, which is unlikely.

To capture the aggregate economic impact of restricted use of the OPs on selected specialty crops, we used AGSIM (Taylor, 1993) here to estimate changes to grower income and impact on consumers, for both domestic and foreign producers and consumers. AGSIM (Taylor, 1993) is a multi-crop aggregate economic model of supply and demand for crop production in the US.⁸ Taylor (1993) provides a detailed description of the basic structure of AGSIM. Parameters and elasticities for the model are regularly updated to examine new issues, and to incorporate recent baseline data acreage, yield, prices, costs and other factors. It includes data for the following OP-labeled crops (“AGSIM crops”): apples, blueberries,

⁷ More information can be obtained at <http://www.landscape.org/connect/conservation-projects/>.

⁸ This simulation model of the aggregate economic impact of regulatory or other pressures on agriculture is validated by EPA and USDA and regularly used for such evaluations. See Mitchell, 2014; Osteen and Kuchler, 1986; Osteen and Kuchler, 1987; Taylor et al., 1991; Taylor et al., 1994.

broccoli, caneberries, celery, cherries (sweet), grapefruit, oranges, strawberries, sweet corn, and tomatoes (processing).

The most restrictive RPA, Element 1(a), as written, removes label authorization for chlorpyrifos, diazinon, and malathion for all designated high-risk uses within the BiOp footprint. The majority of impacted cropland is in California, Oregon, and Washington; however, our analysis considers all counties within the footprint where crops listed for the OPs have historically been grown. Evaluating the practical consequences of adopting the RPAs and RPMs requires a robust economic analysis, designed to address the regional nature of crops and species as well as the availability of supporting data. The percent area treated estimates input into AGSIM and the yield/variable cost impacts produced as a result of the analysis are considered conservative due to the additional unknown impact on food quality and variable costs, as well as the importance of these chemicals to resistance management in all crops. Additionally, the threat of new pests, as well as year-to-year environmental changes, adds uncertainty to the estimated impact of use restrictions. Assumptions used in the AGSIM model and further details for crops addressed in the assessment are summarized in Attachment 1. In this analysis, based on the assumptions discussed above and in Attachment 1, over 50% of caneberry and strawberry acres would be impacted by removal of label authorization of the OPs. Yields for blueberries, broccoli, and caneberries are most at risk of declining due to two main pests, cabbage maggot in broccoli and spotted winged drosophila (SWD) in blueberries and caneberries that are primarily treated with at least one of the OPs. The acres treated, percent change in yield, and percent change in variable costs presented in Attachment 1 are used to estimate economic impact using AGSIM.

Without access to the OPs, the total annual economic loss for the listed AGSIM crops is estimated at over 143 million US\$ (

Table 1). Table 1 presents the estimated change in price, production, and acreage for the listed crops, as well as the total annual economic impact to domestic and foreign producers and consumers, impact to US grower income, and impact on US consumers. A negative value represents a negative change (decrease) and a positive value represents a positive change (increase). For example, without access to the OPs, caneberry production decreases by 5.6% leading to a 5.3% increase in price and a slight decrease in acreage. This results in a total annual economic loss of over 21.5 million US\$ for both domestic and foreign producers and consumers. Even with the price increase, US caneberry growers face an estimated reduction in profit of over 2.1 million US\$; however, consumers face the greatest impact due to higher prices, with a loss of over 23.5 million US\$.

Table 1. Estimated annual percentage change in price, US production and acreage, and estimated annual total economic impact, and annual impact on net US grower income and consumers due to removal of label authorization of chlorpyrifos, diazinon, and malathion for high risk uses.

AGSIM Crop	Price	Production	Acreage	Total Economic Impact ¹	Impact on US Grower Income	Impact on US Consumers
	% Change					
Apples	+0.44%	-0.32%	+0.10%	-\$13,251	+\$1,880	-\$13,202
Blueberries	+1.45%	-3.71%	-1.22%	-\$31,191	-\$16,433	-\$20,216
Broccoli	+1.09%	-0.66%	+0.06%	-\$2,143	+\$7,510	-\$13,748
Caneberries	+5.29%	-5.64%	-0.11%	-\$21,523	-\$2,188	-\$23,512
Celery	+1.28%	-0.27%	+0.30%	-\$1,846	+\$3,101	-\$4,588
Cherries, Sweet	+0.84%	-2.91%	-1.30%	-\$19,217	-\$12,310	-\$5,566
Grapefruit	+0.14%	-0.06%	+0.06%	-\$460	-\$33	-\$374
Oranges	+1.00%	-0.29%	+0.48%	-\$18,526	-\$561	-\$16,849
Strawberries	+1.30%	-1.00%	+0.14%	-\$31,026	+\$1,343	-\$33,023
Sweet Corn	+0.06%	-0.04%	+0.00%	-\$480	+\$182	-\$585
Tomatoes, Processing	+0.23%	-0.26%	-0.01%	-\$3,508	-\$599	-\$2,243
Total Impact				-\$143,171	-\$18,109	-\$133,904

¹ This includes the total economic impact to both domestic and foreign growers and consumers.

Yield loss from insect pressure results in lower production for all AGSIM crops and higher prices paid to growers and by consumers for the crops. The magnitude of change in price and production is dependent on the percent of acres treated with at least one OP and the estimated change in acreage. When prices increase by more than production declines (in percent change), more acres will come into production. For some crops, such as oranges, higher prices received by US growers encourage growers inside and outside the BiOp footprint to increase production; however, due to the regional nature of these crops, the capability to increase production may be limited. For many of these crops, such as orchard crops, it takes years to reach harvestability and bring them into full production.

The total annual economic impact assessed by AGSIM includes impacts to both domestic and foreign growers and consumers. When domestic production declines, imports will increase to cover domestic consumption, which benefits foreign growers. Both domestic and foreign consumers are negatively impacted by higher consumer prices. Crops with a higher proportion of OP-treated acres (caneberries, sweet cherries, and strawberries) and greater yield reductions due to OP restrictions (blueberries and caneberries) are impacted the most by restrictions on OP use. Based on these assumptions, the estimated negative impact on growers and consumers is greatest for blueberries, caneberries, sweet cherries, oranges, processing tomatoes, and grapefruit. With changes in pest pressure, introduction of new pests, increases in resistance, and weather changes, it is possible that the impact could be much greater than estimated in this analysis. Furthermore, this analysis assumes that the export market would remain open to growers and that is dependent on the alternatives used to replace the OPs.

2.2.3 Important considerations related to the economic analysis

Chlorpyrifos, diazinon, and malathion are effective options in US cropping systems and provide an important mode of action for pest management plans where product rotation among pesticide modes of action is key to pest resistance management. Resistance management is the practice of rotating chemical classes in treatment programs in order to avoid the buildup of pests that are resistant to any given chemical or chemical class. For example, the OPs are sub-group 1B (assigned by the Insect Resistance

Action Committee [IRAC]; IRAC International MoA Working Group, 2018). Therefore, 1B chemicals should be alternated with chemicals that have a different group/sub-group number, such as alternating malathion with zeta-cypermethrin (Sub-group 3A, Pyrethroids/Pyrethrins) or oxamyl (Sub-group 1A, Carbamates) to treat lygus bug in celery (Godfrey and Trumble, 2008). The loss of the OPs would have a negative impact on growers' ability to manage the development of target pest resistance to other insecticides that remain on the market, which will be used more often due to restrictions of the OPs. There is direct economic impact related to resistance, but this cost is not included in the analysis. However, there is little doubt that when insects develop resistance, there is the potential for yield declines and increases in variable costs.

Additionally, growers must consider their markets, both domestic and foreign, including maximum residue levels (MRLs) for residues on the crops. MRL's are harmonized international levels of residues that are acceptable on exported/imported crops. Development of harmonized international MRLs, which allows for ease of US exports to foreign markets, often takes years once a product is registered in any given geography. Chlorpyrifos, diazinon, and malathion have well-established MRLs across the world, while other newer products may not. Numerous crops impacted by the BiOp, such as almonds, apples, and oranges, have high export demand. Reducing availability of these insecticides can have substantial economic consequences for growers that export a large portion of their production.

With increased pest pressure, there may be a reduction in quality making the crop unsellable on the fresh market; therefore, production of some crops may shift from the fresh market to the frozen or processed markets (such as strawberries). However, growers may receive a lower price, negatively impacting net returns. The impact of shifts in production are not captured in this analysis but should be considered when evaluating the aggregate impact of proposed restrictions.

2.2.4 Important considerations related to the RPAs and RPMs

While the above analysis applies to RPA Element 1(a) for chlorpyrifos, diazinon, and malathion, the other proposed RPAs (RPA Elements 1(b), 1(c), 2, 3, 4, and 5) and RPMs as outlined in Chapter 26 of the BiOp also have the potential to negatively impact US growers and consumers. For example, the BiOp does not provide any basis to support its recommendation of a 300-m no-spray buffer nor a clear definition of which areas are "adjacent to, or that drain to listed species aquatic habitats" so it is not possible to know where to implement the RPAs and RPMs. Requiring no-spray buffers in excess of what is necessary places a burden on growers that is costly and management intensive. Additionally, while the proposed points system appears to allow flexibility in how producers address drift and runoff/drainage on their operations, there are substantial administrative costs that would be incurred to implement, manage, and verify compliance. For this type of system to be successful there must be input from USDA, EPA, state agencies, growers, and the registrants to determine relevance and feasibility for US agriculture.

If growers find the RPAs and RPMs to be unworkable because they do not fit American agricultural practices and conditions or because they are too expensive, producers may choose to abandon the use of the OPs to avoid these restrictions (i.e., excessive no-spray buffers) and requirements (i.e., points system), change cropping systems, or take land out of production. Impractical and overly protective no-spray buffers will impact the insecticides used to control pests and may result in yield loss and variable cost increases similar to removing label authorization. Filter strips and riparian forest buffers require land to be taken out of production and additional consideration given to managing crops. Furthermore, vegetated buffers may not be a practical alternative in arid western growing areas.

Agriculture is not one-size-fits-all, and ease of implementation of any restriction is region, crop, and operation specific. This is the primary reason why pesticide labeling, at the national level, must allow flexibility. The RPAs and RPMs, as written, bring unnecessary, unworkable complexity to an already complex industry that is faced with increasing pest pressure and volatile market conditions.

2.3 EPA Comment Topic #3: National- and state-level use and usage data and information, particularly, 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 for data that should be considered.

2.3.1 It is imperative to assess risk using typical use rates.

EPA's exposure assessments in the BEs focus on maximum use scenarios for products (maximum allowable application rate, and number of applications, and minimum allowable interval between applications). While this approach is highly conservative, and addresses maximum potential exposures, it does not reflect how products are commonly used. Under risk assessment principles, if a risk assessment conducted for a maximum use scenario does not indicate unacceptable risks, the analysis can stop at that point. However, if the risks are unacceptable (above a defined level of concern) under these very conservative assumptions, then further analyses of more representative use scenarios are warranted. Pesticide labels generally contain a range of application rates for the applicator, with instructions indicating that the rate selected should be appropriate for the pest being controlled (rates may vary for different pests) and the amount of pest pressure. Generally, labels indicate that lower label rates and frequencies should be used for lower pest pressure and environmental conditions where degradation is reduced, while the upper-end rates and frequencies should be reserved for heavy pest pressure and environmental circumstances that maximize degradation. In practice, economic or pest damage thresholds dictate these choices.

Additionally, although labels often indicate that applications can be made every so many days, growers rarely, if ever, apply the same product repeatedly for the full permitted time because of resistance concerns. Product labels recommend alternating several types of chemistry to reduce the potential for resistance developing among pests; EPA has implemented robust resistance management policies. Therefore, having a variety of products available with different modes of action is crucial to resistance management efforts. In this sense, then, the BiOp's recommendations—based on faulty interpretation of OP use and risk—to address what the BiOp characterizes as “high risk uses” conflict with resistance management needs.

In addition to not considering typical use rates, the BiOp does not consider available OP usage data in characterizing potential risk, which results in further overestimates of potential exposure. For example, the California Department of Pesticide Regulation (CA PUR, 2017) data provides information on the amounts of a product applied, crops that the product is applied to, and where the product is applied.⁹ Similarly, field-level pesticide usage data are available from WSDA. These data, along with USDA-NASS data, confirm that the maximum use scenarios EPA and NMFS relied on for characterizing potential risks overstate the amount of product applied, which then results in overestimates of potential exposure and potential risks to the species assessed in the BiOp. The BiOp assumes maximum use on all potential crops, which is clearly an unrealistic portrayal of actual events.

⁹ Data obtained from <http://www.cdpr.ca.gov/docs/pur/purmain.htm>.

3 CONCLUDING THOUGHTS

In addition to the legal flaws stated in the CLA Cover Letter, the NMFS BiOp emerged from an inefficient process, and includes conclusions and assumptions that greatly overstate actual exposure and risk potential. Its flaws clearly illustrate the need for an efficient and reliable regulatory process for aligning registration decisions under FIFRA with the requirements of the ESA. The expertise needed to complete robust pesticide consultations already exists within government agencies and should be leveraged to its fullest extent. Review of the current NMFS BiOp makes it obvious that the expertise of each agency is not being tapped to build an accurate, transparent, and defensible analysis. EPA has expertise in ecological risk assessments for pesticides, including risk assessment methods needed to evaluate the potential risks of pesticides to non-target wildlife, such as exposure modeling and probabilistic tools. This requires significant amounts of data for pesticide registrations. Unfortunately, through the processes developed under the Interim Approach (USEPA, 2015), this expertise was not maximized. The U.S. Fish and Wildlife Service (FWS) and NMFS (collectively, the Services) have substantial expertise on threatened and endangered species, including species biology, distribution, threats, and recovery needs. USDA has expertise on how pesticides are used in agriculture, including the timing and location of pesticide applications, as well as experience in conservation practices and pesticide education, use and reduction programs. Leveraging each agency's expertise and developing a more streamlined process would allow relevance and the best available science to drive risk evaluation and species effects determinations.

As set forth in the CLA Cover Letter, NMFS should withdraw the BiOp, and, even if NMFS does not, EPA should set it aside as fatally flawed. EPA and NMFS should then work together, in coordination with FWS and USDA, as set forth in the *Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review* (USEPA, 2018), to consider the comments received on the BiOp and its supporting BEs, and to use the learnings of this attempt to improve the processes under which the BEs and BiOp were developed to reflect the best available science and to meet the requirements of both FIFRA and the ESA. CLA and its member companies are committed to working with the US government and all interested stakeholders to develop a process that protects listed species and their habitat while recognizing the important role that pesticides play in agriculture, and in the protection and enhancement of property, homes, and human health.

Attachment 1: Assumption, Pest and Production Information for Each Crop in the AGSIM Analysis

Assumptions:¹ To account for the regional nature of the species in the BiOp and the potential for overlap in OP use (double counting), the percent treated area is estimated using the acres of AGSIM crops within the BiOp footprint multiplied by the percent of acres treated with one or more of the three OPs from the 2015 USDA-NASS Chemical Survey (USDA-NASS, 2018) for all states except California. For California, percent of acres treated with the three OPs is adapted from California Pesticide Use Report (CA PUR) data for 2015 (CA DPR, 2017). Where available, yield and/or cost impacts due to restrictions on the use of OPs are from previous research, extension publications, EPA benefit assessments, and/or public comments provided on prior assessments (**Error! Reference source not found.**). To account for the use rate of the OPs, yield and variable cost changes are adjusted downward by the estimated percent treated area for each crop as described above (also shown in **Error! Reference source not found.**).

Table A1. Assumptions used in the AGSIM analysis for % of US acres treated with at least one organophosphate (OP) and % change in yield and variable costs of AGSIM crops

<u>AGSIM Crop</u>	<u>% of US Acres Treated with at Least One OP</u>	<u>% Change in Yield</u>	<u>% Change in Variable Costs</u>
<u>Apples</u>	<u>20.66%</u>	<u>-2.00%</u>	<u>0.00%</u>
<u>Blueberries</u>	<u>25.20%</u>	<u>-10.00%</u>	<u>0.00%</u>
<u>Broccoli</u>	<u>7.18%</u>	<u>-10.00%</u>	<u>-7.40%</u>
<u>Caneberries</u>	<u>55.30%</u>	<u>-10.00%</u>	<u>0.00%</u>
<u>Celery</u>	<u>28.28%</u>	<u>-2.00%</u>	<u>0.00%</u>
<u>Cherries, Sweet</u>	<u>32.55%</u>	<u>-5.00%</u>	<u>+0.70%</u>
<u>Grapefruit</u>	<u>6.41%</u>	<u>-2.00%</u>	<u>+1.00%</u>
<u>Oranges</u>	<u>15.34%</u>	<u>-5.00%</u>	<u>+2.00%</u>
<u>Strawberries</u>	<u>57.11%</u>	<u>-2.00%</u>	<u>+0.30%</u>
<u>Sweet Corn</u>	<u>2.24%</u>	<u>-2.00%</u>	<u>0.00%</u>
<u>Tomatoes, Processing</u>	<u>5.26%</u>	<u>-5.00%</u>	<u>+0.20%</u>

Crop Specific Assumptions

Apples: Chlorpyrifos is an important part of pest management in apple production, and is used to control San Jose scale, leafrollers, and aphids. At least 40% of apple acres were treated with chlorpyrifos in 2015 in New York, North Carolina, Pennsylvania, and Washington (USDA-NASS, 2018). Diazinon is also applied to apples in California (28% treated), Pennsylvania (13% treated), and Washington (5% treated; USDA-NASS, 2018).

San Jose scale may cause yield loss and ultimately destroy trees if not treated, and outbreaks are likely treated by chlorpyrifos or diazinon (Hollingsworth, 2018; Tary et al., 2018). These pesticides provide broad spectrum insect control with one application, instead of multiple applications of different insecticides to control different pests. In the Southeast, diazinon is one of the most effective options for controlling rosy apple aphid, Comstock mealybug, and wooly apple aphid. Chlorpyrifos is one of the most effective options for controlling dogwood borer and improving scale control (Tary et al., 2018). EPA estimated that growers would lose less than 1% of gross revenues due to revoking the chlorpyrifos tolerances; however, growers and USDA both identify chlorpyrifos as necessary for the control of tree-boring insects, where yield loss and tree damage can be severe (Atwood et al., 2015; Chlorpyrifos Protects, 2018; Kunickis, 2016). Growers also identified chlorpyrifos use for control of wooly apple aphid. Contrary to EPA's estimates for diazinon alone, Knutson and Smith (1999) estimated that eliminating all organophosphates and carbamates would reduce apple yields by 38% and increase variable costs by 66%.

Blueberries and Caneberries: Since EPA completed the *Benefits Assessment for Diazinon Use in Lowbush and Highbush Blueberries* (Mallampalli et al., 2002), pest pressure and distribution of acres have changed in blueberries. Production in the Pacific Northwest (PNW) has increased over the last 20 years. One of the primary pests in blueberry production is spotted wing drosophila (SWD), first found on the west coast in 2008 and on the east coast in 2011.¹⁰ Depending on the region, malathion and diazinon are both excellent options for SWD control. Additionally, in the PNW, malathion and/or diazinon are listed as options for control of seven of 11 identified blueberry pests. Malathion is one of only two chemicals for controlling obscure root weevil in the PNW. In New Jersey, diazinon protects blueberries from leaf hoppers, plum curculio, and scales, while malathion is listed as a good option for blueberry maggot control.

Caneberries are primarily grown in the PNW and California. Diazinon and malathion are options for controlling 16 out of 27 identified caneberry insect pests. Malathion has seen increased use in Washington to control SWD. Without treatment, yield loss of up to 50% is possible due to SWD. Additionally, malathion is one of two options to treat insect contaminants at harvest. Diazinon is the only listed option for strawberry crown moth, which can cause yield losses as high as 50% (Chism and Smearman, 2002). Yield losses can also be substantial due to raspberry crown borer (up to 50%) and raspberry beetle (up to 10%), if they are not controlled. Diazinon is a treatment option for both pests. Bolda et al. (2010) estimated the economic impact of SWD infestations on US production of blueberries and caneberries in California, Oregon, and Washington using assumed yield reductions of 10%, 20%, 30%, 40%, and 50%. They did not consider the impact to variable costs and quality, nor the potential impact on exports given the use of products with more restrictive maximum residue levels (MRLs). They estimated that revenue losses due to SWD as a function of a 20% yield loss for blueberries, raspberries, and blackberries would total 91.1 million US\$ based on 2008 value of production for California, Oregon, and Washington.

Broccoli: Over 90% of US broccoli is grown in California. At least 10% of broccoli acres were treated with a combination of chlorpyrifos, diazinon, and/or malathion in 2015 (CA PUR, 2017). Chlorpyrifos and diazinon are only options for controlling cabbage maggot, and among the top three options for controlling cutworms, flea beetles, and garden symphylans. In EPA's *Biological and Economic Analysis*

¹⁰ Additional information is available at <https://ag.umass.edu/fruit/resources/spotted-wing-drosophila>.

of *Diazinon on Cole Crops* (Cook and Wyatt, 2002a), the Agency assumed a 10% yield loss and a reduction in variable costs of 7.4%. In EPA's *Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances* (Atwood et al., 2015), the Agency based its assumptions of yield loss (48%) on research from 1982.

Celery: Celery is grown primarily in California; approximately 31% of celery acres were treated with malathion in 2015 (CA DPR, 2017). In California's pest management guidelines for celery, malathion is listed as a treatment option for lygus bug, and, while not listed in the California guidelines, malathion can also be used to treat aphids. The lygus bug has long been a major pest in strawberries, but emerged as a major pest in celery in 2015,¹¹ and caused significant yield loss. There is limited data available on the potential yield loss due to use restrictions on malathion and diazinon.

Cherries, Sweet: In its *Biological and Economic Analysis of Diazinon on Sweet Cherries: Impacts of Cancellation* (Cook and Wyatt, 2002b), EPA identified four individual pest scenarios (San Jose scale, black cherry aphid, boring beetles, and fruit flies) and one scenario where all four pests occur simultaneously where diazinon is used in sweet cherries. For San Jose scale, chlorpyrifos is an option for dormant-season spray and diazinon is an option for growing-season spray. For black cherry aphid, chlorpyrifos and diazinon are two of the three options for dormant-season and delayed-dormant sprays. The alternative (dimethoate) has a longer re-entry interval (REI) and cannot be used on cherries exported to Japan. Diazinon and malathion are two of seven options for spring and summer sprays for black cherry aphid. Malathion has a 12-hour REI and a 3-day preharvest interval (PHI), which is the shortest among all of the alternatives. For control of boring beetles (Pacific flatheaded borer, peachtree borer, and shothole borer), chlorpyrifos is the only dormant-season spray option (Hollingsworth, 2018). Removing infested wood is the only option for some producers. Diazinon and malathion are both options for controlling western cherry fruit fly. Malathion ULV has the shortest PHI of all the options (one day). The EPA analysis (Cook and Wyatt, 2002b) was completed prior to the introduction of SWD (as discussed earlier), but malathion is an effective option for SWD control. EPA estimated yield loss up to 25% and variable cost changes ranging from a decrease of 13.90% to an increase of 2.40% depending on pest and location (Cook and Wyatt, 2002b).

Citrus (Grapefruit and Oranges): Citrus crops are grown primarily in California and Florida; however, slightly more citrus acres in California would be impacted by the BiOp than in Florida. The University of California Agriculture and Natural Resources Statewide IPM (UC IPM) Program identified control of 14 pests as the most important uses of chlorpyrifos in California, with two pests having few or no alternative products and 12 having available alternatives (UC IPM, 2014). Chlorpyrifos is an important control option in California and Florida for pests such as scale insects, mealybugs, orangedog, katydid, grasshoppers, aphids, crickets, and thrips. Chlorpyrifos is the only pest control option listed for mealybug and Asian cockroach control in Florida citrus production (UF/IFAS Citrus Extension, 2018). Malathion is also used to control scale insects, plant bugs, and crickets, and is the only listed option for plant bug control in Florida (UF/IFAS Citrus Extension, 2018). In California and Florida, chlorpyrifos is used in season for Asian Citrus Psyllid (ACP) control as part of a chemical rotation. ACP is the vector for the bacterium that causes citrus greening disease (Huanglongbing disease) which has the potential to cause high yield loss by killing trees. While some pests, such as the fuller rose beetle, may not cause yield damage, there may be export restrictions if eggs are present on the fruit. Rejections of shipments from foreign markets can cause substantial loss to producers.

Chlorpyrifos is central to the control of liquid sugar feeding ants. There are no other modes of action or alternative practices available to control this pest. While there are bait products, chlorpyrifos is the only broad spectrum sprayable insecticide available to treat these ant pests. According to the California IPM, ant species feed on honeydew from soft scales, mealybugs, cottony cushion scales, whiteflies, psyllids, and aphids, protecting these pests and some non-honeydew-producing pests from their natural enemies.

¹¹ More information is available at <http://ucanr.edu/blogs/blogcore/postdetail.cfm?postnum=19221>.

Some ant species aggressively protect pest insects and can even plug irrigation sprinklers. They damage citrus by feeding on flowers and young fruit. They can kill newly planted trees and are a hazard to orchard workers. Previous research estimated that, if red imported fire ants were established in California, the cost would be between 387 and 989 million US\$ annually (Jetter et al., 2002). This included impacts to households, agriculture, and wildlife. EPA estimated that revoking chlorpyrifos tolerances would reduce per acre gross revenues by 5% for oranges and 1.4% for grapefruit (Atwood et al., 2015). This did not include restrictions on malathion. They only included the impact on scale and katydids and did not include ACP control nor ant control.

Strawberries: Malathion is the most common of the three OPs used in strawberry production in CA (CA DPR, 2017). In CA, malathion is the recommended treatment for cutworms (followed by diazinon) and vinegar fly. At least one of the three OPs is listed as a treatment option for 12 out of 18 listed strawberry insect and mite pests. The OPs play a vital role in strawberry production particularly related to resistance management. Strawberries are also susceptible to SWD but on a very limited basis. In EPA's *Biological and Economic Analysis of Diazinon on Strawberries: Impacts of Cancellation* (Mallampalli and Wyatt, 2002), they estimated that variable costs could increase or decrease depending on type of pest and location; however, they did not estimate a yield loss. In California, for lygus bug and aphid control, they estimated that variable costs would increase by 0.4%. Since Mallampalli and Wyatt (2002) only considered diazinon and almost 90% of strawberry acres in California were treated with malathion in 2015 (CA DPR, 2017), it is assumed that there would be a yield consequence to use restrictions. Bolda et al. (2010) estimated the economic impact of SWD infestations on US production of strawberries in California using assumed yield reductions of 1%, 2%, 5%, 10%, and 20%. As with blueberries and caneberries, they did not consider the impact to variable costs and quality, nor the potential impact on exports given the use of products with more restrictive maximum residue levels (MRLs). They estimated that revenue loss due to SWD as a function of a 20% yield loss for strawberries would total 314.3 million US\$ based on 2008 value of production for California, Oregon, and Washington.

Sweet Corn: As of 2015, 21% of sweet corn acres in California were treated with chlorpyrifos as compared to 8% in Oregon and Pennsylvania (CA DPR, 2017; USDA-NASS, 2018). While major pest pressure varies by location, chlorpyrifos and/or diazinon are options for controlling pests such as aphids, corn silk fly, cutworm, corn earworm, lesser cornstalk borer, and fall armyworm. In Florida, chlorpyrifos is one of five active ingredients for controlling lesser cornstalk borer in sweet corn¹². Chlorpyrifos provides broad spectrum insect control and reduces the number of insecticide applications needed by growers (Nelson and Schneider, 2016).

Tomatoes, Processing: When compared to other specialty crops, processing tomatoes receive minimal applications of diazinon and malathion. It is important to note that California is the primary producer of processing tomatoes in the US, and any interruption in production has the potential to negatively impact growers, processors, and consumers. EPA estimated that restricting diazinon use in processing tomatoes would reduce yields by 5% (primarily due to wireworm) and increase variable operating costs by 0.2% (Atwood and Gilbert, 2002). Knutson and Smith (1999) estimated that eliminating organophosphates and carbamates in tomatoes would reduce yields by 15% and increase variable costs by 13%. Diazinon is an option for treating garden symphylans: however, there are other alternatives. Diazinon is the primary option for pre-plant wireworm control in California. Malathion is an option for green peach aphid and other early-season aphids.

¹² More information is available at <https://erec.ifas.ufl.edu/fciig/framain.htm>.

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