

March 6, 2021

Ms. Patricia Biggio  
Chemical Review Manager  
Pesticide Re-Evaluation Division  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

*Submitted electronically via Federal eRulemaking Portal*

**RE: Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (EPA-HQ-OPP-2008-0850-0964), Revised Draft Human Health Risk Assessment (EPA-HQ-OPP-2008-0850-0944), and Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (EPA-HQ-OPP-2008-0850-0941)**

Dear Ms. Biggio,

We represent a broad group of agricultural stakeholders, including growers, retailers, applicators, distributors, manufacturers, and crop consultants. We strongly support the re-registration of chlorpyrifos for its currently registered uses, as well as retention of the initially established 1x FQPA safety factor for the final registration decision, and strongly oppose cancellation of the registration for chlorpyrifos. Failing to renew the registration of chlorpyrifos could lead to catastrophic yield losses for many of the growers we represent or our customers, as often inadequate or no viable insect management alternatives to chlorpyrifos exist. While we acknowledge some epidemiological data has emerged that raises questions concerning potential neurodevelopmental risks – and we support EPA’s further review of the science on this question – we are gravely concerned overreliance on this data that EPA has acknowledged has shortcomings and limited value for risk assessment purposes will result in significant damage to U.S. users of this tool.

We also would like to acknowledge and applaud President Biden’s recent memo to the heads of executive departments and agencies reaffirming the commitment to scientific integrity and evidence-based policy making.<sup>1</sup> We appreciate that EPA has long strived for this principle, however the timing of this announcement is a keen reminder how critically important it is that our regulatory decisions are based in the strongest science and evidence available. As we discuss below, we believe the current body of available evidence demonstrates an inconclusive and tenuous link to neurodevelopmental risks beyond known acetylcholinesterase (AChE) inhibition, and it certainly does not warrant restricting or cancelling agricultural uses of chlorpyrifos.

*Economic Assessment*

Chlorpyrifos is a critically important insecticide for the U.S. agriculture community and is registered to protect 50 different crop types. Due to its effectiveness against a broad spectrum of insect pests and its ability to manage pests that have developed resistance to other classes of insecticides, chlorpyrifos remains one of the most popular and effective tools for agricultural producers in the United States. In its

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<sup>1</sup> Biden Jr., Joseph R. The White House. January 27, 2021. “Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.” <https://bit.ly/3cVMeT>

most recent memo on the *Revised Uses of Agricultural Benefits of Chlorpyrifos* (hereafter *Benefits Assessment*) dated November 18, 2020, EPA estimates the value of chlorpyrifos for U.S. agriculture at a range of \$19 million to \$130 million. This range was also incorporated into the benefits assessment of the proposed interim decision (PID). We feel this range is low for several resistance-related reasons that EPA discusses in the *Benefits Assessment* but are not factored into this value assessment. As EPA states in the *Benefits Assessment*, the economic value was assessed using historic data where chlorpyrifos was currently available and used on a variety of crops. The *Benefits Assessment* acknowledges:

*Most of EPA's cost estimates are based on reported use of chlorpyrifos against specific pests using market research data (Kynetec, 2016) from 2010 – 2014. However, if growers of a crop face relatively new pests or pest problems that are growing in intensity, using historical data on chlorpyrifos use will underestimate any estimate of the cost of alternatives or yield loss at an aggregate level.... In addition, in some crop systems that have only one or two pesticide modes of action registered, the loss of chlorpyrifos may accelerate the evolution of pest resistance against whatever alternative modes of action remain. This could be a result of growers no longer being able to rotate pesticides with different modes of action during seasonal pest management, which is a fundamental resistance management strategy. If resistance develops, unless additional modes of action are registered, the cost impact of chlorpyrifos loss will be higher.*

The *Benefits Assessment* does not venture a cost estimate to these predictive scenarios where chlorpyrifos is not available and as a result, crops facing pests where no management alternatives exist would suffer catastrophic yield losses. However, this scenario is a very real threat that we believe is likely to occur should a final registration decision significantly reduce or discontinue the use of chlorpyrifos. A recent example of this scenario is seen in the 2018 prohibition of neonicotinoids in the European Union – the only effective tool available to French sugarbeet producers to control aphid populations, which are vectors of the devastating beet yellow virus (BYV). The neonicotinoid prohibition led to widespread aphid infestations and a BYV epidemic that resulted in a 30-50 percent yield reduction for the French sugarbeet industry, with some producers reporting yield losses as high as 70 or 80 percent.<sup>2</sup> To exemplify how misplaced we feel EPA's valuation of chlorpyrifos is, this one outbreak in just one French crop is estimated to have inflicted at least \$113 million in yield loss damages – nearly exceeding EPA's top range estimate for the value of chlorpyrifos for all U.S. crops.<sup>3</sup>

There are several U.S. crops that would likely face a similar scenario with the loss of chlorpyrifos. Michigan cherry producers have no other effective management options for several pests, such as borer and mite species.<sup>4</sup> Cabbage maggots affecting several *Brassica* and other root crops in multiple states also have no other effective registered control options.<sup>5</sup> Pyrethroid-resistant aphid populations, which can also transmit soybean mosaic virus (SMV) and Alfalfa mosaic virus (AMV) in soybeans, often have no other effective management option than chlorpyrifos.<sup>6</sup> U.S. sugarbeet producers are uniquely vulnerable. Not only do they contend with sugarbeet root maggots (SRM), a pest for which chlorpyrifos is the most effective remaining management tool. Yet, due to a short post-emergence management window, growers require access to aerial applications in the event the soil conditions are too wet for

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<sup>2</sup>U.S. Department of Agriculture. Foreign Agricultural Service. Audran, Xavier. *France's Sugar Beet Crop Devastated by Disease - Sugar Industry's Viability Threatened*. August 12, 2020. <https://bit.ly/3j054Th>

<sup>3</sup>Jha, Manisha. July 8, 2020. "New Virus Hits Europe, This One Threatens Sugar Crops." *Bloomberg*. <https://bloom.bg/3oz6c1k>

<sup>4</sup>Alston, Diane, Jim Bardenhagen, David Epstein, Gene Garthe, Ben LaCross, Jim Laubach, Larry Gut, et. al. 2006. *Tart Cherry Pest Management in the Future: Development of a Strategic Plan*. <https://bit.ly/3teAcmv>

<sup>5</sup>Oregon State University. N.D. "Cabbage Maggot." Accessed January 28, 2021. <https://bit.ly/3rbfyCb>

<sup>6</sup>Potter, Bruce, Robert Koch, Phil Glogoza, Ian MacRae, and Janet Knodel. University of Minnesota-Extension. July 31, 2017. "Pyrethroid resistant soybean aphids: What are your control options?" <https://bit.ly/3j4eJLl>

ground applicators at the time of application.<sup>7</sup> Citrus, strawberries, asparagus, wheat, cotton, alfalfa, onions, and other crops all face similar threats from one or more pests. These are a just a few examples of U.S. crops that, like their French counterparts, would be left defenseless against devastating insects and secondary pests should chlorpyrifos become unavailable.

Numerous other crops that use chlorpyrifos – including many that would have their uses discontinued if a 10x FQPA safety factor is adopted – would have limited alternative options for insect management available. However, by losing access to chlorpyrifos, it is very likely the efficacy of these other existing management options would quickly erode. One of the benefits of chlorpyrifos is its mix and rotational potential, allowing growers to apply multiple layers of insect protection through various modes of action (MOA), minimizing the risk of selection pressures that result in new resistant-insect populations. These features make chlorpyrifos a vital tool in insect resistance management strategies (IRMS) for many crops. If chlorpyrifos use were to be significantly or entirely discontinued, many of these crops would have very few or, in many cases, only one other management option, allowing for insect populations to quickly select for resistance to remaining tools. The *Benefits Assessment* and the PID neglect to consider in their economic assessments the costs of these likely predictive scenarios that would greatly harm dozens of U.S. crops, resulting in staggering economic losses much higher than the value benefit range EPA assigns to chlorpyrifos.

#### *Draft Health Risk Assessment*

As stated, chlorpyrifos is a vitally important insect management tool that results in significant direct pest control benefits, as well as many secondary benefits, such as preventing the emergence of resistant-insect populations as well as preserving the efficacy of other insect control tools. EPA should consider carefully and establish with a strong level of confidence any genuine risks before considering any actions that might result in growers losing access to this critical tool. A concern we have is that the evidence of alleged neurodevelopmental risks beyond the known AChE inhibition MOA – perceived risks which EPA acknowledges were a strong motivation for pivoting to the 10x FQPA safety factor for this registration review – seem tenuous and at odds with a robust set of additional human and animal toxicological and epidemiological data on this matter. While we support EPA continuing to research these potential risks, we do not believe the evidence currently exists to justify adopting safety factors or a final registration decision that would result in significantly limiting or entirely discontinuing currently approved agricultural uses of chlorpyrifos.

As EPA has attested now in multiple draft human health risk assessments conducted as part of this registration review, the findings of the Columbia Center for Children’s Environmental Health (CCCEH) epidemiological study have been a primary driver for linking potential neurodevelopmental risks to chlorpyrifos exposure. EPA also acknowledged that this study was a significant motivation for adjusting the FQPA safety factor from 1x in its June 2011 Preliminary Human Health Risk Assessment to 10x in subsequent draft health risk assessments. We continue to have concerns about this study and how heavily EPA relied on it for conducting its draft risk assessments, as discussed further below.

We appreciate that EPA is seeking to corroborate the findings of CCCEH through supplemental research and literature reviews. However, it seems this additional research refutes the findings of the Columbia study and points to an inconclusive or tenuous link between neurodevelopmental risks beyond known

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<sup>7</sup> Khan, Mohamed, David Franzen, Mark Boetel, Ashok Chanda, Albert Sims, and Thomas Peters. University of North Dakota. January 2020. “2020 Sugarbeet Production Guide.” <https://bit.ly/3ana6Fg>

AChE inhibition and chlorpyrifos exposure. For example, in EPA's December 2016 literature review<sup>8</sup>, two studies conducted in Cincinnati, Ohio associated with the Health Outcomes and Measures of the Environment (HOME) cohort observed children at birth through early childhood. Neither study observed an association between organophosphate exposure during pregnancy and neurodevelopmental effects in children. A study in France also found no evidence of prenatal organophosphate exposure and decreased cognitive function in the children at six years of age. These are just a few examples of epidemiological studies conducted since CCCEH – in addition to the thousands of animal toxicology studies conducted over the years – that seem to point to little or no correlation between neurodevelopmental disorders and chlorpyrifos or organophosphate exposure.

It also is worth noting that at this point we are not aware of any data that identifies a different MOA for chlorpyrifos beyond the known AChE inhibition MOA that would result in neurodevelopmental effects. Given this lack of an alternative, identifiable MOA – if one exists – any action taken by EPA to mitigate this hypothetical risk would be precautionary and not data-driven. EPA should seek to establish if a risk truly exists before proposing steps to counteract it.

Another reason we have significant concern with the CCCEH study and its effect of causing EPA to resort to a 10x FQPA safety factor is the basis of the availability of raw data related to the study. Given that there are numerous other studies that suggest little to no link between organophosphate exposure and neurodevelopmental effects, there exists a strong burden for the CCCEH researchers to validate these alarming results, especially when hundreds of millions of dollars of annual agricultural use benefits hang in the balance. Another important reason this raw data would be valuable is it could point to other confounding factors, unique exposures, or other variables that might explain CCCEH's findings and why its conclusions are at odds with numerous other studies on this matter. As agricultural stakeholders, we are particularly interested in post-study determinations that chlorpyrifos metabolites in cohort participants supposedly decreased significantly following an agreement by manufacturers to voluntarily discontinue residential chlorpyrifos product sales in 2001.<sup>9</sup> This would seem to point to agricultural uses posing very little risk – certainly not a risk warranting the adoption of a 10x FQPA safety factor or discontinuing agricultural uses – compared to the now largely eliminated residential exposure risks. However, without the raw data from CCCEH's study, it is impossible to ascertain where any exposures occurred with certainty.

We applaud EPA's diligence in repeatedly seeking out the raw data of the CCCEH study on numerous occasions in the last several years.<sup>10</sup> It is regrettable, given the enormous agricultural benefits that may be impacted, that the CCCEH researchers could not meet EPA's transparency needs and agree to one of the Agency's offers to anonymize the study data. However, this apparent inability to cooperate and provide raw data which could elucidate CCCEH's findings presents another reason why EPA should not be adopting a 10x FQPA safety factor and basing its risk assessments on this study. In fact, due to numerous uncertainties and limitations with this study, EPA's FIFRA Scientific Advisory Panel (SAP) advised against using it as a basis for drawing a definitive link between chlorpyrifos and neurodevelopmental effects, or using it to establish new toxicological points of departure (POD) for

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<sup>8</sup> U.S. Environmental Protection Agency. Office of Chemical Safety and Pollution Prevention. Aldridge, Ashlee. December 28, 2016. "Summary Reviews for Additional Epidemiological Literature Studies on Organophosphates."

<sup>9</sup> Rauh, Virginia, Srikesh Arunajadai, Megan Horton, Frederica Perera, Lori Hoepner, Dana B. Barr, and Robin Whyatt. August 1, 2011. "Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide." *Environmental Health Perspectives*. <https://bit.ly/3r1K9li>

<sup>10</sup> U.S. Environmental Protection Agency. Teleconference meeting agenda and minutes. August 1, 2016. "Chlorpyrifos Dataset Discussion: Columbia Center for Children's Environmental Health Mothers and Newborns Study."

exposures.<sup>11</sup> Again, we encourage EPA to continue reviewing data on this matter, but this line of evidence suggests it would be irresponsible to discontinue registered uses on chlorpyrifos based on conflicting, tenuous epidemiological data.

An additional concern is the use of a 10x safety factor in conducting the occupational risk assessments, which EPA links to the 10x FQPA safety factor. The PID states that “chlorpyrifos poses potential dietary and aggregate risks associated with drinking water exposure for currently labelled uses with and without the 10X FQPA safety factor.” The PID goes on to state that to be consistent with the 10x FQPA safety factor, “EPA has also applied an additional 10X database uncertainty factor (UFDB) in its assessment of occupational risks.” The use of a 10X safety factor for estimating risks to mixers and loaders based on dietary and drinking water risks is not appropriate. Moreover, the purposes of FQPA safety factors are to reasonably ensure no harm will occur to infants and children. However, EPA’s worker protection standards already prohibit anyone under the age of 18 from being a pesticide handler, further questioning the logic and appropriateness of using a 10X factor for occupational risk assessments stemming from a FQPA safety factor.

#### *Draft Drinking Water Risk Assessment*

Finally, we wanted to briefly discuss EPA’s most recent draft drinking water risk assessment. In this assessment, EPA makes numerous assumptions and relies significantly on modeling that may not reflect actual conditions, especially related to drinking water exposure to chlorpyrifos oxon. For example, in the assessment, EPA assumes that due to chlorination at water treatment facilities, 100 percent of all chlorpyrifos in the water will be converted to more concerning chlorpyrifos oxon degradates. Moreover, EPA assumes 100 percent of the oxon will result in drinking water exposures and that there are no other factors that would result in degradation of the oxon before it is consumed. So far as we can tell, EPA has not empirically verified this assumption – an assumption which plays an enormous role determining drinking water exposure risks.

There are other assumptions EPA does not appear to have validated in chlorpyrifos applications. In its previous draft drinking water risk assessment, EPA stated that soils have a binding factor that may result in preventing or delaying applied chlorpyrifos from entering watersheds. We imagine this binding impact would be even greater with spray zone buffers that exist in the current registration. This would potentially have a significant mitigating effect on the volume of active ingredient (a.i.) entering watersheds and would likely result in additional volumes of a.i. degrading prior to entering water supplies. These mitigating factors would significantly reduce drinking water exposure risks. We strongly encourage EPA to validate these assumptions with real-world data prior to taking any action that would result in damaging restrictions to registered agricultural uses.

#### *Conclusion*

FIFRA is a risk-benefit statute that requires EPA to base its regulatory decisions on the benefits of an action compared to its risks. It is well established that chlorpyrifos is a remarkably valuable chemistry to U.S. agricultural producers (not to mention other vital uses, such as mosquito control) that we contend results in an even greater economic benefit than EPA has suggested in the PID. Moreover, the risks and alleged risks that EPA has based much of this registration review around are in many instances inconclusive and tenuous. The body of evidence regarding these risks does not at this time warrant

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<sup>11</sup> U.S. Environmental Protection Agency. Bradbury, Steven. July 11, 2012. “Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held on April 10-12, 2012 on ‘Chlorpyrifos Health Effects.’” 19, 28, 48.  
<https://bit.ly/3j1AEzU>

pivoting to a 10x FQPA safety factor from 1x, as EPA has proposed in previous draft risk assessments, nor does it currently warrant restricting, discontinuing grower access to, or canceling the registration of this vital chemistry. While we do encourage EPA to continue to research the validity of these potential risks, we strongly support the re-registration of chlorpyrifos using a 1x FQPA safety factor, and in a way that preserves existing uses for agricultural producers. We thank you for the opportunity to comment and stand ready to assist EPA in this important registration review effort.

Sincerely,

Agricultural Retailers Association  
American Farm Bureau Federation  
AmericanHort  
American Seed Trade Association  
American Soybean Association  
American Sugarbeet Growers Association  
Colorado Potato Administrative Committee  
Council of Producers and Distributors of Agrotechnology  
Empire State Potato Growers  
Idaho Potato Commission  
Maine Potato Board  
Minnesota Area II Potato Council  
National Agricultural Aviation Association  
National Alliance of Independent Crop Consultants  
National Association of Wheat Growers  
National Christmas Tree Association  
National Corn Growers Association  
National Cotton Council  
National Onion Association  
National Potato Council  
National Sorghum Producers  
National Sunflower Association  
North Carolina Potato Association  
North Dakota Grain Growers Association  
North Dakota Soybean Growers Association  
Northern Plains Potato Growers Association  
Oregon Potato Commission  
Pennsylvania Co-operative Potato Growers  
Potato Growers of Michigan  
Puget Sound Seed Growers Association  
Texas Citrus Mutual  
U.S. Apple Association  
USA Rice  
Virginia Potato & Vegetable Growers Association  
Washington Friends of Farms & Forests  
Washington State Potato Commission  
Wisconsin Potato & Vegetable Growers Association