July 24 2017

OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Avenue NW.
Washington DC 20460-0001

Submitted via Regulations.gov [Docket ID No. EPA-HQ-OPP-2010-0119]

Registration Review Proposed Interim Decisions for Aldicarb, Azoxystrobin, Bifenazate, Chlorpyrifos-methyl, Ethalfluralin, and Pirimiphos-methyl; Notice of Availability [EPA–HQ–OPP–2016–0729 (82 FR 24112) May 25, 2017]

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comment on the Environmental Protection Agency ([EPA] or the Agency)'s recent Notice of Availability, and Comment on the Proposed Interim Decisions for Aldicarb, Azoxystrobin, Bifenazate, Chlorpyrifos-methyl, Ethalfluralin, and Pirimiphos-methyl [82 FR 24112]. CLA comments will focus on the Registration Review for Chlorpyrifos-methyl [EPA-HQ-OPP-2010-0119].[1]

Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners. CLA is committed to working with EPA, as the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

EPA's Approach to Risk Assessment for Organophosphates Lacks Scientific Support

CLA has commented extensively about its continued concerns with the human health risk assessments conducted for the organophosphate pesticides (OP). In particular, the lack of consideration for scientific differences of opinion raised during the review and risk assessment for the organophosphates generally, and chlorpyrifos-methyl in particular. This lack of consideration of the fundamental lack of underlying support for the basis upon which EPA is asserting risk, has resulted in cumulative assessments not supported by a robust set of data, or an approach that has been the subject of verified review and replication. EPA's approach has taken one direction since it began its chlorpyrifos human health assessments over 20 years ago- it needs a fundamental shift, including robust scientific scrutiny and debate, to be scientifically

[1] We note that the Docket ID No. for Chlorpyrifos-methyl in the Federal Register Notice is not correct. It should be EPA-HQ-OPP-2010-0119, rather than EPA-HQ-OPP-2010-0199 as provided in the Docket.

sound, using a risk-based system rather than one that approaches human health assessments as though a hazard already has been established.

EPA has noted in the Chlorpyrifos-methyl Proposed Interim Registration Review Decision (Case Number 8011), December 2016 (page 4), CLA has petitioned the Agency [CLA Petition (EPA-HQ-OPP-2010-0119-0058)] to "halt regulatory decisions that are highly influenced/determined by results of epidemiological studies that do not meet well-defined data quality standards, and that are not integrated into the health risk assessment in a transparent, well-defined manner." As EPA notes, consideration of the epidemiological studies identified in the CLA Petition could potentially impact the interim or final registration decision for chlorpyrifos-methyl. We agree.

In fact, we continue to strongly object to this approach by EPA, particularly when the EPA Administrator, in his March 31 2017 "Order," *Chlorpyrifos: Order Denying PANNA and NRDC's Petition to Revoke Tolerances* [EPA-HQ-OPP-2007-1005; FRL-9960-77] stated, "…*that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA's risk assessment… and in light of the significant uncertainty that exists regarding the potential for chlorpyrifos to cause adverse neurodevelopmental effects, EPA's preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA's risk assessment prior to finalizing any regulatory action in the course of registration review.*

We strongly agree that further exploration of the use of epidemiologic study outcomes needs further consideration before those outcomes can be part of a regulatory decision.

EPA Lack of Acceptance of Comments from FIFRA SAP in Development of Important Documents Limits Their Usefulness

The Agency continues to use the same epidemiological studies named in the CLA Petition for its regulatory decision making. CLA is specifically concerned that supporting documents in the docket for the Chlorpyrifos-Methyl Proposed Interim Registration Review Decision have not made use of the significant amount of input from numerous FIFRA SAP, other regulatory agencies, and a recent National Academy of Sciences Report (2017).

CLA has included in this Comment to the Docket, substantial scientific and technical input as to why the supporting documents posted by EPA do not meet the scientific standard for data quality, biological plausibility in describing an MOA for all organophosphates, and the disregard for the Congressional intent, and the technical meaning of 'uncertainty' about retention of an FQPA 10X Safety Factor in regulatory decision making.

Specifically, we object to the following listed documents used in support of the regulatory decisions (interim decisions) made for organophosphates generally, and chlorpyrifos methyl, specifically. Studies used for regulatory decision making must be held to the same data quality standards as those used for GLP toxicological and developmental studies required under 40 CFR

Part 158- Studies required of registrants for demonstration of lack of unreasonable risk in pesticide human health risk assessments.

- Despite significant public comment and concern regarding the inconsistency of process and approach used by EPA in its Chlorpyrifos Revised Human Health Risk Assessment [EPA-HQ-OPP-2008-0850], when EPA published its 2015 "Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides," comments were largely ignored. EPA completed and signed its "*Updated 2016 Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides,"* here - EPA-HQ-OPP-2010-0119-0060, in December 2016, with little regard for comments received or concerns expressed about how EPA intended to use epidemiological studies in its risk assessment, and specifically, how those studies would be weighed against existing studies under CFR 40 Part 158, specifically designed to address health risk, and required for pesticide registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Significant deficiencies in the approach EPA has taken in its consideration of epidemiological studies to support its use of the Food Quality Protection Act (FQPA) 10X Safety Factor. Such deficiencies are highlighted in the comment documents embedded in this document and submitted to this Docket with CLA comments.

- EPA has responded to thousands of submitted comments to a number of dockets over the past two years, including the above-detailed "Literature Review." Scientific concerns were respectfully submitted in dockets and were followed by no response. As with the document above, in December 2016, EPA completed a response to the myriad comments it had received. The responses were not objective and were directed at one specific researcher, and the United States Department of Agriculture. Comments submitted by other Federal Agencies deserve more than a response of disagreement, and rather should be respectfully considered. Further, to cast the majority of other submitted comments (including those of CLA) as repeated comments made by one identified researcher, EPA did not take the time to respond thoughtfully, scientifically or technically. Instead, EPA chose to disparage the comments and diminish the considerations and recommendations made in those comments. The EPA "*Response to Comments for Public Comments Related to Applying the FQPA10X Safety Factor for the Organophosphate Pesticides*," here – EPA-HQ-OPP-2010-0119-0055 does not reflect well on the Agency and appears short sighted. CLA has provided a review of the Response document as an embedded document here, and as an attachment to these comments.

- In the same way that EPA dismissed legitimate scientific and technical concerns raised by several FIFRA SAP, and also by thousands of commenters, EPA largely did not deviate from its 2015 Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides, when it published its "*Updated 2016 Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides,"* here- EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf. We believe this shortsighted approach to integration of epidemiological study outcomes diminishes EPA's ability to credibly engage technical experts and epidemiologists in its development of an approach to appropriate integration of such data with the required GLP studies required of registrants under 40 CFR Part 158. We strongly believe this to be a missed opportunity, and have repeatedly requested that EPA engage stakeholders as it proceeds to use such epidemiological study outcomes in regulatory decision making.

EPA Must Consider the Quality of Data and the Biological Plausibility of Potential Associated Factors in its Risk Assessments

CLA reviews and critiques which provide the scientific basis for our members' concerns about the current EPA approach to human health risk assessment, and its lack of consistency in requirements for objective and scientifically defensible studies and study quality (including study design) in its risk assessments are embedded in the footnotes, and will be attached to our comments to this docket. These independent reviews call into question EPA use of technical and scientific information[2,3,4] and expert recommendations from FIFRA SAP (2008, 2010, 2012, 2016) to support its positions, while very different conclusions are drawn through approaches taken by other regulatory bodies, including the European Food Safety Authority[5], and the Australian Pesticides and Veterinary Medicines Authority (as noted in the embedded documents).

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[2] Exponent Critique of 2016 Updated Literature Review

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[3] Burns Critique of 2016 Updated Literature Review

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[4] Gradient Critique of EPA Response to Comments on FQPA 10X

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[5] Gradient Overview of EFSA 2017 Scientific Opinion

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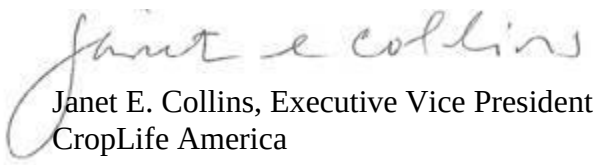
CLA does not support the approach taken by EPA to integration of epidemiologic study outcomes in its regulatory decision making. EPA support documents must be subjected to peer review. While we agree that such guidance as described in the various documents could be useful to development of an overarching approach to use of epidemiologic study outcomes in regulatory decision making, these documents must be subject to review by objective and independent scientific experts.

We welcome the opportunity to work with EPA and other Federal Agencies in pursuit of scientifically balanced approaches to human health risk assessment. We further welcome the opportunity to work with EPA to correct some of the missteps that we believe have occurred and that have negatively impacted our members' registration timelines and outcomes.

Should you have any questions or wish to discuss this matter further, please contact me directly by email ([jcollins@croplifeamerica.org]) or telephone [+1-202-833-4474].

Thank you for your consideration of these comments.

Respectfully,



Janet E. Collins, Executive Vice President
CropLife America