January 12, 2017

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator McCarthy:

In the Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment[1] published in the Federal Register November 17, 2016, and accompanying assessments, specifically: Chlorpyrifos Revised Human Health Risk Assessment for Registration Review ("RHHRA")[2] and Chlorpyrifos Drinking Water Assessment for Registration Review[3], **EPA has proposed new, precedent-setting changes in how the risks for pesticides are assessed and then used for decision-making**.

EPA's proposed regulatory action relies on methodologies that are not scientifically supported and that warrant further independent peer review. In the RHHRA, EPA continues to rely upon an epidemiology study conducted by researchers at Columbia University (the "Columbia study") that has been repeatedly challenged by experts and EPA's own FIFRA Scientific Advisory Panel(s) (SAP). To date, three SAPs have reviewed EPA's proposed approach for chlorpyrifos human health assessment, including findings of the Columbia study. The SAP experts have expressed frustration that the Columbia study researchers have withheld all raw data from the public and even from EPA for many years, frustrating any attempt to verify the researchers' claims. Overall, the SAP reports from these meetings do not support the position that the Columbia study justifies disregarding over forty years of toxicological data that demonstrate the adequacy and protectiveness of the current regulatory standard.

Yet, despite these and other criticisms (or perhaps because of them), the Agency proposed in the RHHRA a brand new hypothesis (without factual support) as to how the subjects of the Columbia Study may have been exposed to just the right amount of chlorpyrifos in their homes to have resulted in the very low doses that allegedly caused neurodevelopmental effects that just a few months ago the Agency was attempting to support by reference to cord blood data. The RHHRA also suddenly lacks any definition of the neurodevelopmental effects allegedly caused by these theoretical exposures and to be used as the new benchmark health effect. No SAP ever considered this approach.

EPA's proposed regulatory action also relies on an unrefined drinking water assessment that is still based on screening-level modeling, is not adequately refined and far over-estimates levels found in the real world. EPA's drinking water assessment ignores important, science-based refinements provided by Dow AgroSciences (DAS) in a study submitted in February 2016 and in comments submitted to previous dockets by DAS and other experts.

[1] EPA-HQ-OPP-2015-0653-0402
[2] Nov. 3, 2016; EPA-HQ-OPP-2015-0653-0454
[3] April 14, 2016; EPA-HQ-OPP-0653-0437

In short, EPA now proposes to take regulatory action on the basis of significant changes in established scientific methods for setting a regulatory Point of Departure (PoD), for determining the need for a 10x safety factor, and for estimating drinking water risk, without having subjected these proposals to adequate, qualified independent review. **Therefore, we request that EPA convene FIFRA SAPs, as required by law, to address (1) EPA's reliance on the Columbia study in this manner and the proposed PoD and (2) EPA's assessment of drinking water exposures through modeling under the circumstances related to chlorpyrifos.**

1. EPA's Use of the Columbia Study and Questionable Assumptions About Chlorpyrifos Use to Establish a New PoD Are Not Scientifically Supported and Warrant Further SAP Review

EPA previously proposed setting a new PoD for chlorpyrifos based on cord blood data from the Columbia study. EPA sought guidance on its proposal from the SAP in April 2016. The Panel raised numerous and significant concerns with EPA's use of the Columbia study to inform regulatory action, consistent with those of prior SAPs, including the use of a single cord blood measurement to estimate exposure; the withholding by the researchers of all of the raw data, making the quality of the study difficult to assess; the lack of validation and replication of study results; the fact that Good Laboratory Practices were not in place to ensure the credibility of the research; and questionable approaches in the analyses of the data. The Panel strongly discouraged EPA from using the Columbia study to set a PoD in light of the magnitude of EPA's proposed action:

> " [T]he majority of the Panel considers the Agency's use of the results from a single longitudinal study to make a decision with immense ramifications based on the use of cord blood measures of chlorpyrifos as a PoD for risk assessment as premature and possibly inappropriate." Transmittal of Meeting Minutes of the April 19-21 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with "Chlorpyrifos Analysis of Biomonitoring Data," July 20, 2016 at 25.

Prior SAPs expressed similar concerns. For example, the 2008 SAP said that:

> "[a]ll three cohort studies [including the Columbia study] have limitations that include multiple chemical exposures and exposure to other organophosphates [and] should not be used quantitatively for PoDs. . . ." EPA's 2011 Preliminary Human Health Risk Assessment for Chlorpyrifos at 32-33.

The 2012 SAP said:

> "[t]he studies [including the Columbia study] entail a multi-chemical exposure spanning a multi-year period that encompasses an important period of sequential development processes necessary for brain maturation. Thus, panel members caution that it is very difficult to attribute the independent physiological effects to a single chemical in this type of multi-chemical exposure scenario. . . . [I]t cannot be stated that chlorpyrifos is the sole contributor to the observed outcomes." EPA Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held April 10-12, 2012 on "Chlorpyrifos Health Effects" at 17, 45 (July 11, 2012).

The 2016 SAP members also challenged EPA's proposal to use 2% reduction in working memory as the benchmark health effect for setting a PoD. Panel members raised serious concerns regarding the lack of biological plausibility for how low cord blood (low parts per trillion) concentrations of chlorpyrifos can alter working memory and produce neurodevelopmental impairment and concluded that the Agency provided insufficient justification to utilize this methodology. While EPA has moved away from reduction in working memory, the benchmark effect now used in the RHHRA is not defined at all. Since the 2016 SAP recognized the importance of the validity of the benchmark health effect, EPA should define the exact health effect and submit it to an SAP for review and comment.

In addition, the RHHRA fails to address the concerns raised by the 2016 SAP and prior SAPs about the generalizability, replicability, and validity of the Columbia study; EPA's use of the study without the underlying raw data; and EPA's use of the study quantitatively to derive a PoD. These concerns go to the fundamental question of reliability of the Columbia study and call into question EPA's use of any results from the study in setting a new PoD.

While EPA cites additional epidemiology studies, specifically Mt. Sinai and CHAMACOS, when the results are compared across these studies, the epidemiology data are clearly inconsistent regarding chlorpyrifos exposure and neurodevelopmental toxicity. The meaning and implications of these inconsistencies should be addressed by a SAP before deciding they are truly supportive of the Columbia study.

In addition to the need for further review of the scientific validity of the Agency's continued reliance on the results from the Columbia study, EPA's proposed approach to setting a new PoD contains several other significant issues that have not been validated and that represent new, significant changes that were not addressed in previous SAPs and merit additional review by an SAP.

To address concerns about using a single cord blood measurement, EPA has undertaken a totally new and equally questionable approach in estimating exposures. EPA contacted technical pest advisors for New York City's housing authority to determine the type of application method used at the time of the Columbia study nearly two decades ago. Using generic exposure studies conducted through phone and email surveys for that type of application, without confirming that actual exposure scenarios reported in the Columbia study reflected the generic exposures, and applying questionable assumptions about chlorpyrifos use, EPA estimated a theoretical time-weighted average exposure. Using PBPK modeling, EPA then estimated an equivalent internal dose. This sudden shift from reliance on precisely measured exposure doses in animal toxicology studies conducted under Good Laboratory Practices and required for registration, to speculative exposures, demands SAP review, particularly before being used for such a significant decision as tolerance revocation. Similarly requiring SAP review is EPA's unprecedented use of the chlorpyrifos application method to base a lowest-observed-adverse effect level ("LOAEL") in order to support a 10X safety factor under the Food Quality Protection Act.

Moreover, EPA's analysis is premised on its fundamentally inaccurate assumption that, based on the Columbia study, there is a causal linkage between chlorpyrifos exposures below the current regulatory level and effects claimed in the Columbia study. EPA's use of the Columbia study in

this manner, in light of the numerous deficiencies and limitations in the study raised by prior SAPs that EPA has not addressed, also warrants further independent SAP review.

2. EPA's Drinking Water Assessment Is Not Scientifically Robust and Development of Options for Further Refinement Warrants SAP Review

EPA has described its updated drinking water assessment as "highly refined". This description is inaccurate, as the assessment has not considered many options for refinement that have not only been proposed specifically for chlorpyrifos by Dow AgroSciences, but also generally at the industry level, through scientific conferences, Environmental Modeling Public Meeting presentations and through CropLife America.

The current assessment is based upon the Agency's standard Index Reservoir (IR) formulation, which has been in use as a screening-level tool since the late 1980s, and which has not been reviewed by a SAP since 1988. EPA has allowed more than 18 years to pass without further peer and scientific review and guidance on developing better refinement approaches.

EPA attempts to make the current assessment appear probabilistic in nature by simulating different crops; however, the results are all considered to be equally probable and cases that "could happen" by assuming that an entire drinking water source watershed contains the crop (100% Percent Cropped Area (PCA)) and that the entire area is treated on a single day at worst-case application rates and timings. Indeed, within the IR methodology, a PCA of <100% is recommended as a refinement and EPA has published guidance on developing PCAs for major crops and some common combinations of two crops[4]. However, for a product such as chlorpyrifos, with many crop uses potentially occurring in the same watershed but with different cropping management practices and applications rates and timing, the PCA methodology in the EPA's 2014 guidance is insufficient; it is necessary to bring more detailed and available cropping intensity data into the analysis to truly refine the assessment. This point was noted in the 2014 PCA guidance that recommended the use of the USDA National Agricultural Statistics Service Cropland Data Layer (CDL) as a data source. Such an approach was submitted by Dow AgroSciences in February 2016 following discussions with the Agency in a meeting with EFED in September 2015 (registration.gov docket reference EPA-HQ-OPP-2008-0850-0853). The DAS submission offered a pragmatic and still conservative consideration of PCA that resulted in a significant refinement of modeled drinking water estimates. The Agency has not addressed any of these approaches, nor any of the recommendations of DAS and others that have been submitted in previous comment periods in its current assessment.

In addition, EPA performed some preliminary analysis of a nationwide (but not publically-available) database of validated drinking water watershed and intakes that could aid in identifying drinking water sources at potential risk from pesticides. However, the Agency did not apply any results of the analysis in the current assessment, because of perceived incompleteness or uncertainties in that database.

[4] Environmental Fate and Effect Division, OPPTS, USEPA (2014). *Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update* URL: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-community-water-system-drinking-water

EPA's failure to consider these approaches to refinement warrants further peer review. EPA should bring these refinement techniques to a SAP and seek guidance on how to make its assessments reflect the best available science before using an approach that was last reviewed 18 years ago.

When combined or even considered individually, we believe the issues with the incompleteness and lack of refinement of the current EPA drinking water assessment raised above justify the need for a current, independent consideration and peer review. SAP review is a needed step before the current methodology is used for influencing a regulatory decision of the magnitude under consideration for chlorpyrifos.

* * * *

Given the unprecedented regulatory action that EPA is proposing to undertake, and the immense ramifications of that action, EPA must convene an additional SAP(s) to conduct external peer review before making its regulatory decisions regarding chlorpyrifos. As the Agency has stated, "FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists." 81 Fed. Reg. 12099, 12101 (March 8, 2016). Moreover, under FIFRA, "[t]he Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 136d(b) of this title and of the proposed and final form of regulations issued under subsection (a) of this section. . . ." 7 U.S.C. § 136w(d). This section is certainly relevant given that, as a practical matter, the proposed revocation of tolerances for chlorpyrifos is tantamount to issuance of a notice of intent to cancel the underlying registrations under FIFRA Section 6. *See, e.g.*, 40 C.F.R. 152.112(g) (requiring all necessary tolerances to be issued under FFDCA § 408 as a condition of registration under FIFRA). In addition, EPA's Peer Review Handbook provides that "[f]or highly influential scientific assessments, external peer review is the expected procedure." EPA Peer Review Handbook (4th Ed. 2015), Appendix A at A-4. Nothing could be more influential, and therefore in need of SAP review, than assessments, like the RHHRA and drinking water assessment, that propose to upend decades of regulatory decision-making. Independent peer review is also warranted by EPA's Science Advisory Board. 42 U.S.C. § 4365.

The Ninth Circuit's order that EPA rule on the pending petition to revoke tolerances does not justify a failure to conduct thorough, science-based SAP reviews of EPA's unprecedented methodologies. We urge EPA to convene SAPs on these topics as soon as possible and well before formulating any final decisions regarding the health and safety of chlorpyrifos and revocation of tolerances.

Sincerely,

Agricultural Retailers Association
Almond Alliance of California
American Farm Bureau Federation
AmericanHort
American Seed Trade Association

American Soybean Association
American Sugarbeet Growers Association
Beet Sugar Development Foundation
California Citrus Mutual
California Citrus Quality Council
California Dried Plum Board
California Fresh Fruit Association
California Walnut Commission
Cherry Marketing Institute
California Cotton Ginners and Growers Association
California Specialty Crops Council
Cranberry Institute
CropLife America
Florida Fruit and Vegetable Association
National Agricultural Aviation Association
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Potato Council
National Sorghum Producers
Northwest Horticultural Council
Oregonians for Food & Shelter
United Fresh Produce Association
US Apple Association
Washington Friends of Farms & Forests
Western Agricultural Processors Association
Western Growers Association
Western Plant Health Association

Cc:
Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Jack Housenger, Director, Office of Pesticide Programs
Ron Carleton, Counselor to the Administrator on Agricultural Policy