January 5, 2015 [filed via www.regulations.gov]

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

Re: Chlorpyrifos; Tolerance Revocations; 80 FR 69080; November 6, 2015; Docket ID: EPA-HQ-OPP-2015-0653

Dear Ms. Friedman:

CropLife America ("CLA"), established in 1933, represents the nation's developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell, and distribute virtually all of the crop protection and biotechnology products used by American farmers. CLA members support a rigorous, science-based, and transparent process for government regulation of their products. CLA regularly engages with the Environmental Protection Agency ("EPA" or "the Agency"), as the primary federal agency responsible for the regulation of pesticides, on matters of importance to CLA's members. CLA routinely provides comments on issues of regulatory significance to CLA member companies and the broader agricultural community.

On November 6, 2015, EPA announced and opened a 60-day comment period for a proposed rule to revoke all tolerances for chlorpyrifos, 80 Fed. Reg. 69080 (Nov. 6, 2015), a pesticide active ingredient of crucial importance to American agriculture and insect pest management. CLA appreciates the opportunity to provide comments on EPA's proposal and requests that, based on these comments, EPA reevaluate its position that current tolerances for chlorpyrifos do not meet the Federal Food Drug and Cosmetic Act (FFDCA) § 408(b) safety standard. CLA focuses its comments on three primary areas: (1) concerns with EPA's approach to use of and reliance on epidemiological data; (2) concerns regarding EPA's reliance on an incomplete drinking water assessment to revoke all tolerances for a key pest management tool; and (3) concerns with EPA's administration of the rulemaking process as it relates to the proposed rule and the analyses underlying it. In addition to the information submitted here, CLA refers the Agency to its comments submitted on April 30, 2015 Docket ID: EPA-HQ-OPP-2008-0850-0831), in response to the revised human health risk assessment for the registration review of chlorpyrifos by the Agency announced on January 14, 2015. 80 Fed Reg. 1909 (Docket ID: EPA-HQ-OPP-2008-0850).

A. Introduction

At the outset, CLA notes that the Agency's activities and decision-making with respect to chlorpyrifos appear to evidence a worrying shift in Agency regulatory policy away from the objective, well-understood concepts of risk assessment that have long guided the Agency's pesticide decision-making toward an approach that more closely aligns with the precautionary principle. CLA and its members are deeply concerned about a shift to an unjustified, unexplained, and more precautionary approach to the regulation of pesticides and ask that the Agency, at its earliest opportunity, confirm that its regulatory process remains grounded in science-based risk assessment.

Further, while CLA is cognizant of the court-imposed timing pressures under which EPA is conducting its review, we note that EPA must adhere to its obligations with respect to its substantive review of the available science pertaining to the regulatory decision at issue and to the statutorily mandated administrative process.

B. Epidemiological data.

Of primary concern to CLA's members is EPA's novel approach to the use of epidemiological studies in the regulation of chlorpyrifos and the potential impact of that approach on EPA's risk assessment process and regulation of pesticides generally. It is of critical importance to all stakeholders that EPA's risk assessment process be based on well-understood, and broadly accepted scientific concepts of risk assessment. EPA's reliance here on epidemiological studies of questionable validity and relevance, while minimizing and/or excluding a vast body of toxicological and other valid and relevant data seems to signal a departure from the scientific concepts of risk assessment on which EPA has relied (and must rely) for its regulatory determinations, and a movement toward an unnecessarily more precautionary approach.

This shift is particularly troubling, given that EPA itself has acknowledged the risks and limitations in relying on epidemiological studies for regulatory decision-making. It has spent time and resources creating a draft framework to guide its use of epidemiological data in assessing risk, including that such data must be used in "the most … transparent way." *See* Draft Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment, Office of Pesticide Programs, U.S. Environmental Protection Agency, January 10, 2007 at 6 ("Draft Framework").

The Agency announced in its November 6 proposal that it would increase the Food Quality Protection Act ("FQPA") safety factor for chlorpyrifos from 1x to 10x. 80 Fed. Reg. 69080 at 69095. It based that decision on analysis contained in a "Revised Human Health Risk Assessment" ("RHHRA") completed in December 2014 and made available for comment in January 2015. As part of its analysis, EPA claims to have identified "uncertainty" regarding its risk assessment approach to chlorpyrifos and reaches that conclusion based on a narrow set of three epidemiologic studies (referred to here as the "Studies"), 80 Fed. Reg. 69090. The Agency has not conducted a full systematic review of the literature.

CLA understands that the underlying data for those Studies have never been disclosed to the Agency. In relying on those Studies, the Agency has departed from its historical approach and elevated the importance of epidemiology, despite all of its acknowledged limitations, above the extensive, robust toxicological database for chlorpyrifos. The weight given by EPA to the three epidemiological Studies is inconsistent with the Agency's statutory mandate to assess risk and make regulatory

decisions based on valid, complete, and reliable scientific data. EPA's weighting of the Studies also is inconsistent with the Agency's own Draft Framework. CLA encourages the Agency to carefully consider its approach to epidemiologic studies with respect to chlorpyrifos specifically and the potential impact on its regulatory process for pesticides in general.

Our members also take issue with the Agency's characterization of its approach to the epidemiological data as "stepwise, objective and transparent," as EPA appears to have ignored the standards it imposes on registrants in accepting and relying on the Studies.

CLA's pesticide registrant members routinely provide extensive scientific data to the Agency in support of registration submissions; these submissions must meet rigorous standards relating to study conduct and data evaluation. *See, generally,* 40 C.F.R. Part 158. Of particular relevance here, EPA's pesticide regulations require that "[r]ecords containing research relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof … be retained as long as the registration is valid and the producer is in business." 40 C.F.R. § 169.2(k) (emphasis in original). EPA's regulations also describe detailed laboratory practices "intended to assure the quality and integrity of data submitted" pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 40 C.F.R. § 160.1, including a requirement that "raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study *shall be* retained." 40 C.F.R. § 160.190 (emphasis added); *see also* 40 C.F.R. §§ 160.33(f) (requiring that raw data be archived), 160.51 (requiring facilities for the storage of raw data), 160.130(e) (requiring that study data be recorded during conduct of the study), 160.195(b) (establishing retention periods for raw data). Pesticide applicants must adhere to these standards when conducting studies for registration purposes. 40 C.F.R. § 158.70(b).

These regulations and standards underscore the value of studies whose underlying raw data is available to the Agency for review. Inexplicably and notwithstanding these requirements, EPA has based its decision to revoke all tolerances for chlorpyrifos on three studies for which raw data have never been made available to EPA. And not only does EPA's reliance on the unverifiable, unreplicable epidemiological data upon which the Studies are based run afoul of the requirements that CLA's members must follow and the Agency's own guidance on epidemiological data (requiring that it be used in "the most … transparent way"), EPA also proposes to rely on the Studies to the exclusion of the extensive body of contrary evidence.

EPA's failure to obtain and review the raw data upon which the Studies are presumably based is not only arbitrary, but also evidences a troubling lack of commitment to the robust, science-based regulatory process that Congress has established for regulating pesticides, and calls into question the credibility of EPA's decision-making process and whether its decisions are supported by substantial evidence on the record. As FIFRA's standard for registration makes clear, EPA's proposed revocation of the chlorpyrifos tolerances represents a *de facto* cancellation of the registered food uses supported by those tolerances. *See* FIFRA § 2(bb), 7 U.S.C. 136(bb). Yet EPA proposes to take this action without the required "validated test or other significant evidence raising prudent concerns" that the standard for registration has not been met, a threshold set by FIFRA for the initiation of an administrative review process that would *precede* a cancellation action. *See* FIFRA § 3(c) (8), 7 U.S.C. 136a(c) (8).

Practically, the absence of raw data prevents EPA and its stakeholders, including the chlorpyrifos registrants, from testing the Studies' results or cross-checking any of the factors EPA itself identified as key to evaluation of epidemiological data, *i.e.*, the reliability and validity of exposure estimates, appropriate consideration of confounding factors, verification of the study's statistical analysis, evaluation of potential bias in observational research, and external validity and generalizability, among others. *See* Draft Framework at 15-20.

CLA's members therefore ask that the Agency: (1) hold itself to the data standards to which it holds registrants, including requiring access to raw data as a prerequisite to relying on any study to support regulatory decisions; (2) ensure that reliance on epidemiological data, if at all, at least conforms to EPA's own Draft Framework and other procedures and policies, such as transparency in EPA decision-making; and, most importantly, (3) ensure that its regulatory process is grounded in evaluation of sound science, rather than unfounded presumption of harm.

C. Drinking Water Modeling Assessment.

CLA also is concerned about EPA's decision to base a proposed revocation of all tolerances for a crucial pest management tool based on a drinking water modeling assessment the Agency acknowledges is incomplete (see CLA comments on drinking water modeling, December 24, 2015, on 80 Fed. Reg. 57812; EPA-HQ-2015-0386). It is also important to note that the EPA method of estimating pesticide concentrations in drinking water is highly conservative. Oftentimes, the model over-predicts pesticide levels in drinking water up to many orders of magnitude above highest observed monitoring results. That the Agency has been equivocal regarding future opportunities for notice and comment on the drinking water modeling assessment, as outlined in the next section, compounds CLA's concerns.

The Agency makes clear in the proposed rule that drinking water concerns are *the* key factor in its revocation decision. 80 Fed. Reg. 69082. The Agency has begun work on a "refined drinking water assessment that might allow EPA to identify" geographical areas that are purportedly at "high risk" where "label mitigation could be put into place to address drinking water concerns." 80 Fed. Reg. 69083. EPA states that it "has not been able to complete" the refined assessment "[b]ecause of the [Ninth Circuit's] *PANNA* decision on August 10, 2015 compelling EPA to respond to the PANNA-NRDC decision by October 31, 2015." 80 Fed. Reg. 69085. Basing a regulatory decision on incomplete science is arbitrary.

Moreover, EPA's approach is an expression of the precautionary principle. Because the Agency has focused its refined drinking water assessment on identifying regions or watersheds where Estimated Drinking Water Concentrations *may* exceed the Drinking Water Level of Comparison, 80 Fed. Reg. 69105, it has relied on an as-yet unsubstantiated risk ("we are not currently able to determine with any great specificity which uses in which areas of the country do or do not present a risk concern"), 80 Fed. Reg. 69083, to take the significant step of revoking all tolerances ("the agency is unable to conclude that the risk from aggregate exposure meets" the FFDCA safety standard). 80 Fed. Reg. 69080. Again, CLA encourages the Agency to adhere to its risk-based decision-making model.

D. EPA's Implementation of Rulemaking.

In addition to its concerns regarding EPA's substantive conclusions, CLA also has concerns regarding EPA's exercise of the rulemaking process. As an initial matter, the court-ordered timeline does not justify or provide any authority for the Agency to avoid its statutory obligations to engage in a careful, comprehensive, science-based risk assessment to form the basis of its regulatory decision on chlorpyrifos. These obligations include consideration of and response to comments on EPA's analyses forming the basis of its regulatory decision.

EPA completed the Revised Human Health Risk Assessment on which it bases its proposed rule in December 2014, *see* 80 Fed. Reg. at 69082, and opened a comment period from January through April 2015. More than 6 months later, EPA published its proposed rule on November 6, 2015. Despite that timeline, and pointing to a court-imposed deadline as a basis for its failure, the Agency posits that it "has had insufficient time to address comments received on the RHHRA," including significant comments from the registrants and other stakeholders who will be directly affected by the course of action EPA has proposed.

EPA's failure to address comments on the RHHRA is problematic from a rulemaking perspective. As a threshold matter, any decision reached by EPA without an appropriate review of and response to comments is invalid and subject to challenge as arbitrary and capricious under the Administrative Procedure Act. *See Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C.Cir. 1977) ("[T]he opportunity to comment is meaningless unless the agency responds to significant points raised by the public."); *id.* at 36 ("… these procedural requirements are intended to assist judicial review as well as to provide fair treatment for persons affected by a rule"); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, (1971) (an agency must respond to comments so that a "reviewing court" may "assure itself that all relevant factors have been considered by the agency"). Moreover, to the extent EPA has reviewed and addressed comments on the RHHRA, the precursor to the proposed rule, which review appears to be arbitrary. EPA acknowledges its review of comments, including extensive science-based comments from registrants, is incomplete, but in the same document expressly relies on other comments. *See* 80 Fed. Reg. 69095. EPA's failure to marshal the appropriate resources to address the significant, scientific issues raised in the comments before proposing revocation of all tolerances raises serious concerns. EPA's regulatory decisions are better supported through considering and appropriately weighing the available scientific evidence.

Also concerning is EPA's denial of a number of requests to extend the current comment period on the proposed rule. This denial, coupled with EPA's novel requirement that parties having submitted comments on the RHHRA must re-submit comments to the current docket or face waiver, suggests that EPA may be seeking to "speed through" rulemaking in an effort to meet court-imposed timelines. *See* 80 Fed. Reg. 69081 ["Persons wishing to have EPA consider previously submitted comments on the RHHRA in connection with this proposal should submit a comment indicating that intention and identifying their earlier comments on the RHHRA. EPA will *treat as waived* any issue not raised or referenced in comments submitted on this proposal." (emphasis added This approach is flawed. EPA should apply the same "stepwise, objective and transparent" approach to the rulemaking process, including the public's comments that it claims to have applied to its own scientific analysis. 80 Fed. Reg. 60990.)]. In order to ensure that important comments are not excluded from review of this docket, we provide a listing of earlier provided comments, with docket numbers in Appendix 1; CLA contents that these comments are relevant to the scientific review of the body of science that does not support the revocation of chlorpyrifos tolerances.

Relatedly, CLA notes that the Agency is taking a "wait and see" approach to providing additional opportunities for notice and comment on the numerous issues raised by EPA's tolerance revocation rule. At various points in its Federal Register notice, EPA indicates that it will seek public comment on or otherwise update its risk assessment analysis only under certain circumstances:

- "EPA intends to update this action, *as warranted*, with any significant refinements to its drinking water assessment, and intends, *to the extent practicable*, to provide the public an opportunity to comment on the refined drinking water assessment prior to a final rule." 80 Fed. Reg. 69083 (emphasis added).

- "As a result, EPA *may* update this action with new or modified analyses as EPA completes additional work after this proposal. *For any significant new or modified analyses, to the extent practicable, EPA intends to provide the public an opportunity to comment on that work prior to issuing a final rule*." 80 Fed. Reg. 69083 (emphasis added).

- "For any significant new or modified drinking water analyses, *to the extent practicable*, EPA intends to provide the public an opportunity to comment on the work prior to issuing a final rule." 80 Fed. Reg. 69085 (emphasis added).

- "EPA is currently in the process of evaluating the available biomonitoring; however, in light of the August 10, 2015 PANNA decision that orders EPA to respond to the PANNA-NRDC Petition not later than October 31, 2015, EPA has not been able to complete that evaluation in advance of this proposal. EPA is continuing its evaluation of the available biomonitoring and *will update this action to reflect the results of that review, if warranted*." 80 Fed. Reg. 69095 (emphasis added).

- "While, as noted, that assessment is still not complete, because EPA is proposing to revoke all tolerances in this proposed rule based on its concern regarding AChE inhibition, it is unnecessary for EPA to determine at this time whether its current PADs bound the chlorpyrifos exposures measured in the epidemiology studies. In any case, *as EPA completes its further evaluation it will update this action, as warranted*." 80 Fed. Reg. 69095 (emphasis added).

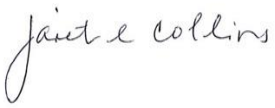
CLA asks that the Agency strongly reconsider its approach and to provide all stakeholders, including CLA's members, with notice, opportunity to comment, and substantive responses on *all* significant issues raised during this rulemaking process. All stakeholders benefit from a careful, comprehensive administrative process.

* * *

CLA appreciates the pressure facing EPA in light of the court-imposed timelines. However, EPA's rush-to-judgment approach appears poised to result in a truncated administrative process and a regulatory decision based on data and analyses that are unsound, incomplete, or both. Neither EPA, the public, growers, nor registrants are best served under these circumstances.

We look forward to continuing to work with you on these issues. Please direct any questions for CropLife America to me at jcollins@croplifeamerica.org.

Best regards,



Janet E. Collins, Ph.D., R.D.
Senior Vice President, Science and Regulatory Affairs
CropLife America
1156 15th Street, NW
Suite 400
Washington, DC 20005
+1-202-833-4474

cc: Jack Housenger, Director of the Office of Pesticide Programs, EPA
The Honorable Avi Garbow, General Counsel, EPA

APPENDIX 1

We ask EPA to consider all of the following 36 comments submitted to the docket for the chlorpyrifos Revised Human Health Risk Assessment (Docket No. EPA-HQ-OPP-2008-0850) in evaluation of the proposed revocation of chlorpyrifos tolerances (80 FR 69080; 11/6/2015).

	Document Title	**Document ID**
1	Comment submitted by Luis Gomez, Dow AgroSciences	EPA-HQ-OPP-2008-0850-0016
2	Comment submitted by Craig Barrow, Craig Barrow Consulting	EPA-HQ-OPP-2008-0850-0078
3	Comment submitted by Cindy Baker Smith, Senior Vice President and Director of Global Regulatory and Product Development, AMVAC Chemical Corporation (AMVAC)	EPA-HQ-OPP-2008-0850-0393
4	Comment submitted by Rudy Xue, Director, Anastasia Mosquito Control District, St. Augustine, Florida	EPA-HQ-OPP-2008-0850-0455
5	Comment submitted by Gowan Company	EPA-HQ-OPP-2008-0850-0507
6	Comment submitted by Julie E. Goodman, Gradient	EPA-HQ-OPP-2008-0850-0508
7	Comment submitted by Julie E. Goodman, Gradient	EPA-HQ-OPP-2008-0850-0509
8	Comment submitted by Bruce Houtman, Leader, U.S. Regulatory & Government Affairs - Crop Protection, Dow AgroSciences	EPA-HQ-OPP-2008-0850-0511
9	Comment submitted by Phillip J. Korson II, President, The Cherry Marketing Institute	EPA-HQ-OPP-2008-0850-0512
10	Comment submitted by Jennifer Henke, Environmental Biologist, Coachella Valley Mosquito and Vector Control District, California	EPA-HQ-OPP-2008-0850-0513
11	Comment submitted by Summit Toxicology, L.L.P.	EPA-HQ-OPP-2008-0850-0514
12	Comment submitted by Paul Mosquin, and Jeremy Aldworth, RTI International	EPA-HQ-OPP-2008-0850-0551
13	Anonymous public comment	EPA-HQ-OPP-2008-0850-0738
14	Comment submitted by Heather Hansen, Executive Director, Washington Friends of Farms & Forests	EPA-HQ-OPP-2008-0850-0765
15	Comment submitted by R. Schilling	EPA-HQ-OPP-2008-0850-0786
16	Comment submitted by Joseph M. Conlon, Technical Advisor, American Mosquito Control Association (AMCA)	EPA-HQ-OPP-2008-0850-0791
17	Comment submitted by Rick Reiss, Exponent, Inc.	EPA-HQ-OPP-2008-0850-0792
18	Comment submitted by Rick Reiss, Exponent, Inc.	EPA-HQ-OPP-2008-0850-0793
19	Comment submitted by California Alfalfa & Forage Association	EPA-HQ-OPP-2008-0850-0794
20	Comment submitted by Philip Bowles, Vice-Chair and Jane Townsend, Executive Director, California Alfalfa & Forage Association (CAFA)	EPA-HQ-OPP-2008-0850-0795

	Document Title	**Document ID**
21	Comment submitted by Christopher Valadez, Director, Environmental & Regulatory Affairs, California Fresh Fruit Association	EPA-HQ-OPP-2008-0850-0796
22	Comment submitted by Reece Langley, Vice President, Washington Operations, National Cotton Council (NCC)	EPA-HQ-OPP-2008-0850-0797
23	Comment submitted by Phillip Arnold, President, New Mexico Pecan Growers Association	EPA-HQ-OPP-2008-0850-0798
24	Comment submitted by Bob Blakely, Vice President, California Citrus Mutual (CCM)	EPA-HQ-OPP-2008-0850-0799
25	Comment submitted by Andrew D. Moore, Executive Director, National Agricultural Aviation Association (NAAA)	EPA-HQ-OPP-2008-0850-0801
26	Comment submitted by Jodi Raley, Director, Regulatory Affairs, California Cotton Ginners and Growers Associations (CCGGA)	EPA-HQ-OPP-2008-0850-0802
27	Comment submitted by Jodi Raley, Directory of Regulatory Affairs, Western Agricultural Processors Association (WAPA)	EPA-HQ-OPP-2008-0850-0803
28	Comment submitted by Gary W. Van Sickle, Executive Director, California Specialty Crops Council (CSCC)	EPA-HQ-OPP-2008-0850-0804
29	Comment submitted by Laura Grunenfelder, Technical Issues Manager, Northwest Horticultural Council (NHC)	EPA-HQ-OPP-2008-0850-0825
30	Comment submitted by Gabriele Ludwig, Consultant, Almond Hullers & Processors Association (AHPA)	EPA-HQ-OPP-2008-0850-0827
31	Comment submitted by James R. Cranney, President, California Citrus Quality Council (CCQC)	EPA-HQ-OPP-2008-0850-0828
32	Comment submitted by California Citrus Quality Council	EPA-HQ-OPP-2008-0850-0830
33	Comment submitted by Clare Thorp, Senior Director, Human Health Policy, CropLife America	EPA-HQ-OPP-2008-0850-0831
34	Comment submitted by Sheryl H. Kunickis, Director, Office of Pest Management Policy, Agricultural Research Service, United States Department of Agriculture	EPA-HQ-OPP-2008-0850-0833
35	Comment submitted by Kevin Robson, Horticulture Specialist, Michigan Farm Bureau (MFB)	EPA-HQ-OPP-2008-0850-0837
36	Comment submitted by Henry (Hank) Giclas, Senior Vice President, Science, Technology & Strategic Planning, Western Growers	EPA-HQ-OPP-2008-0850-0838