To: Perron, Monique[Perron.Monique@epa.gov]; Dunbar, Anwar[Dunbar.Anwar@epa.gov]; Bloem, Thomas[Bloem.Thomas@epa.gov]; Akerman, Gregory[Akerman.Gregory@epa.gov]; Lowe, Kelly[Lowe.Kelly@epa.gov]
Cc: Moriarty, Thomas[Moriarty.Thomas@epa.gov]; Anderson, Neil[Anderson.Neil@epa.gov]
From: Nguyen, Khue
Sent: Tue 10/25/2016 9:33:54 PM
Subject: comments of interest in glyphosate SAP docket
Comment from dr weisenburger re NHL latency.pdf
Comment from CLA re charge questions.pdf
Comment from CLA re dr infante on panel.pdf
Comment from IARC.pdf

Hi all,

I was looking through comments in the glyphosate SAP docket today, and saw comments from the usual players: Monsanto, Dow, CLA, RISE, National cotton council, grower groups, CBD and other enviros, Zen, Anthony Samsel, Stephanie Seneff, etc.

This comment from Dr. Weisenburger struck out at me and was wondering if you guys saw it (see attached). **He/she thinks we misinterpreted one of her studies with respect to NHL latency.**

Also, I'm attaching other comments that might be of interest:

From CLA, re the charge questions

From IARC, in response to CLA claims of conflicts of interest among IARC's group (kind of funny!)

Extensive comment from Intertek, link here: https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0338

Lastly—see comment from CLA re Dr. Infante's participation on the panel—I might give one of you guys a call and get the scoop on this.

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

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Nguyen.khue@epa.gov

CropLife ☆AMERICA☆

October 4, 2016

Steven Knott, Designated Federal Official
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Regulations.gov Docket ID No. EPA-HQ-OPP-2016-0385-0001

Re: FIFRA SAP: Glyphosate [Docket ID: EPA-HQ-OPP-2016-0385-0001] (referring to Docket ID EPA-HQ-OPP-2016-0385-0093; and Docket ID EPA-HQ-OPP-2016-0385-0094)

Dear Mr. Knott:

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 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 represents the interests of its member companies by monitoring legislation, federal agency regulations and actions, and litigation that impacts the crop protection and pest control industries; and by participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency ("EPA" or "the Agency"), as the federal agency responsible for the regulation of pesticides, on matters of importance to CLA member companies and the agricultural community.

On July 26, 2016, EPA published a notice [81 Fed. Reg. 48794 (July 26, 2016)] of its intent to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("SAP") [EPA-HQ-OPP-2016-0385-0001] to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.[1]

On September 16, 2016, EPA posted its Federal Insecticide Fungicide and Rodenticide Act ("FIFRA") SAP ("Scientific Advisory Panel") Charge [EPA-HQ-OPP-2016-0385-0093] in which it provided background on its collection and analysis of data informing the carcinogenic potential of glyphosate. The introduction of the "Charge" memo states that available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate. EPA

[1] 81 FR 48794; FIFRA Scientific Advisory Panel: Public Meeting (July 26, 2016).

specifically states, "Although there are studies available on glyphosate-based pesticide formulations, the agency is soliciting advice from the FIFRA Scientific Advisory Panel (SAP) on this evaluation of human carcinogenic potential for the active ingredient only at this time." EPA repeats this statement verbatim in its "Glyphosate Issue Paper: Evaluation of Carcinogenic Potential" [EPA-HQ-OPP-2016-0385-0094]. EPA further describes the Issue Paper as being organized by sections to include, "Systematic Review and Data Collection"; "Data Evaluation of Epidemiology"; "Data Evaluation of Animal Carcinogenicity"; "Data Evaluation of Genetic Toxicity"; "Data Integration and Weight of Evidence Analysis Across Multiple Lines of Evidence"; and, "Collaborative Research Plan for Glyphosate and Glyphosate Formulations."

The stated purpose of the Collaborative Research Plan (Section 7 of the Glyphosate Issue Paper) is, "to evaluate the role of glyphosate in product formulations and the differences in formulation toxicity." EPA has introduced potential future research areas into its 'comprehensive analysis of available data from submitted guideline studies and the open literature,' and its weight of evidence analysis.

On page 141/227 of the Glyphosate Issue Paper, EPA says (middle of page 141) that the Agency is soliciting advice from the FIFRA SAP on the evaluation and interpretation of the available data for each line of evidence for the active ingredient glyphosate and the weight-of-evidence analysis. It is troubling that on the same page [141/227], EPA raises the potential for further research to determine whether formulation components, such as surfactants, influence the toxicity of the glyphosate formulations. EPA also comments on its plans to initiate research given these identified data gaps (which plans are described in Section 7.0). Inclusion of consideration of future research and glyphosate formulations is out of scope for this SAP.

We strongly object to inclusion of Section 7 in the FIFRA SAP Glyphosate Issue Paper, as it initiates dialogue on two subjects not relevant to this FIFRA SAP. In its statement of intent of the FIFRA SAP, EPA reports that it is asking the SAP, "to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings." [2] It is unnecessary and inappropriate to include a section for consideration that relates to potential future research that EPA might conduct. It also is inappropriate to raise for question and consideration the issue of any formulation of glyphosate when EPA has specifically stated that it is "soliciting advice from the FIFRA Scientific Advisory Panel (SAP) on this evaluation of human carcinogenic potential for the active ingredient only at this time."

We question why EPA has added Section 7: Collaborative Research Plan for Glyphosate and Glyphosate Formulations. The entirety of Section 7 is not germane to the charge of this FIFRA SAP. Consideration of what future research might be conducted, and what active and other ingredients might be assessed is not relevant to the work of this FIFRA SAP. Why would EPA question glyphosate formulations when they are not in the scope of work provided by the Charge Questions for this FIFRA SAP? Why would EPA state that, "…some have believed that glyphosate formulations may be more toxic than glyphosate alone?" This is again irrelevant to the charge of this FIFRA SAP, and suggests that there is some doubt that must be considered. At this time when EPA has clearly stated its intent to evaluate the active ingredient, glyphosate, why

[2] Id.

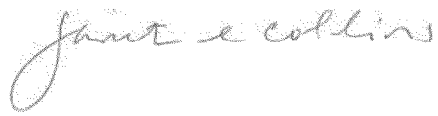
would the Agency insert leading questions about potential carcinogenicity of an ingredient in a formulation apart from the active ingredient?

We also question why EPA would collaborate and develop a research program with the National Toxicology Program (NTP) without input from the registrant. Under FIFRA § 4, as detailed in CFR 40 § 158.3, EPA could request of the registrant submission of additional data required in conjunction with reregistration of a currently registered product; or as a data call in under FIFRA § 3(c)(2)(B). Should data be required to address specific questions relevant to the registration or reregistration of a product, the registrant would be the appropriate source of those data. Indeed, EPA already reviews the toxicity of "inerts" within all pesticide formulations, including glyphosate-based formulations.[3]

We believe that the Glyphosate Issue Paper, Section 7: Collaborative Research Plan for Glyphosate and Glyphosate Formulations, as a subject of discussion for this FIFRA SAP, should be removed from the Glyphosate Issue Paper and eliminated from any consideration for discussion by the FIFRA SAP.

Thank you for your consideration of these comments.

Respectfully submitted,



Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President, Science and Regulatory Affairs

[3] *See, e.g.*, U.S. Environmental Protection Agency (EPA) (2009). Alkyl amine polyalkoxylates (JITF CST 4 insert ingredients). Human health risk assessment to support proposed exemption from the requirement of a tolerance when used as inert ingredients in pesticide formulations. DP Barcode D360944. *See also* U.S. Environmental Protection Agency (EPA), Inert Ingredients - Reassessment Decision Documents, *available at* https://www.epa.gov/ingredients-used-pesticide-products/inert-ingredients-reassessment-decision-documents.

October 12, 2016

Steven Knott, Designated Federal Official
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Electronic Mail to Knott.Steven@epa.gov and via Regulations.gov; Docket ID: EPA-HQ-OPP-2016-0385

Re: FIFRA Scientific Advisory Panel; Notice of Public Meeting: EPA's evaluation of the carcinogenic potential of Glyphosate; Request for Information and Comments; Docket ID No. EPA-HQ-OPP-2016-0385 (July 26, 2016)

Dear Mr. Knott:

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 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, representing the interests of its member companies by monitoring legislation, federal agency regulations and actions, and litigation that impacts the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency ("EPA" or "the Agency"), as the federal agency responsible for the regulation of pesticides, on matters of importance to CLA member companies, the agricultural community and the general public.

On July 26, 2016, EPA published notice in the federal register of its intention to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("FIFRA SAP") to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.[1] The notice invites nominations of candidates to serve as ad hoc members of the FIFRA SAP, which is to convene October 18, 2016 through October 21, 2016 (the "October 2016 meeting").

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[1] FIFRA, Scientific Advisory Panel 81 Fed. Reg. 48,794 (Meeting July 26, 2016).

Under FIFRA, the SAP serves in an advisory role and provides "comment[s] as to the impact on health and the environment" of registrations being considered by EPA.[2] All final decision-making authority under FIFRA rests with EPA. Pursuant to its authority under FIFRA, EPA has previously concluded that glyphosate is "not likely to be carcinogenic to humans."[3]

As CLA explained in its August 17, 2016 letter ("Conflicts Letter"), EPA is legally obligated to exclude scientists from the SAP whose conflicts of interest or established biases preclude their ability to contribute impartially to the panel's final report. CLA therefore respectfully opposes the selection of Dr. Peter Infante, whose patent biases should disqualify him from service on the SAP. CLA also asks EPA to take note of certain information regarding Dr. Kenneth Portier and confirm his ability to participate without any pre-formed conclusions, although it does not seek his disqualification.

The EPA Has an Obligation to Ensure the Impartiality of the FIFRA SAP

The Federal Advisory Committee Act (FACA) imposes strict conflict of interest requirements on the FIFRA SAP selection process.[4] As explained in greater detail in CLA's Conflicts Letter, EPA must ensure that the FIFRA SAP acts "in the public interest,"[5] and does not contain members with inappropriate special interests.[6] To meet the requirements established by FACA, the FIFRA SAP shall be comprised of impartial experts capable of providing an independent review of data on the carcinogenic potential of glyphosate. Indeed, the Office of Government Ethics advises against the participation of SAP panel members whose participation will create even the "appearance of loss of impartiality."[7]

To implement FACA's mandate, the EPA SAP office has adopted conflict-of-interest and bias rules for the selection of committee members, which aim to exclude those who "might be unable to provide impartial advice or [whose] impartiality in the particular matter might be questioned."[8] Among other requirements, "appearance of lack of impartiality, lack of independence, and bias may result in disqualification."[9]

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[2] 7 U.S.C. § 136w

[3] *See*, EPA's Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (2016).

[4] *See* 5 U.S.C. App. II, § 3(2).

[5] *See id.* App. II, § 9(a)(2).

[6] *See id.* § 5(b)(3).

[7] 5 C.F.R. § 2635.501(a) (2016); *see also* Sci. Advisory Bd., EPA, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* 9-10 (Sept. 2002), https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf; *see also* 18 U.S.C. §202(a); Sci. Advisory Bd., EPA, *Ethics for Advisory Committee Members*, https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument (last updated May 3, 2016).

[8] *See* EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* 16 (Sept. 16, 2004), http://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf [hereinafter "Panel Formation Process for the EPA FIFRA SAP"]; 81 Fed. Reg. at 48,795.

[9] *See id.* at 5-8, 10-14.

Dr. Infante's Biases Should Disqualify Him From Service on the Glyphosate SAP

EPA's ethical rules should preclude Dr. Infante's participation in the glyphosate SAP. Dr. Infante is a member of Collegium Ramazzini,[10] which has taken radical anti-pesticide positions, such as calling for a prohibition on all "pesticide use in all public areas, including residential areas and recreation grounds," even if regulatory agencies have concluded such uses were safe.[11] Dr. Infante has also repeatedly testified—exclusively for plaintiffs—in chemical exposure cases against Monsanto Company, the original registrant of glyphosate, and its affiliated entities.[12]

Even more troubling, federal courts have concluded that Dr. Infante has engaged in a pattern of biased, results-oriented analysis that disqualified consideration of his opinions. Of particular note is a decision of the Eastern District of Louisiana, which struck his testimony in a thoughtful and comprehensive opinion. *See Burst v. Shell Oil Co.,* No. 14-109, 2015 WL 3755953 (E.D. La. June 16, 2015). Judge Vance's *Burst* decision leaves little doubt that Dr. Infante is all-too-willing to manipulate scientific analysis to reach pre-determined outcomes (*i.e.*, invariably concluding a chemical is unsafe). In *Burst*, she explained that Dr. Infante's analysis "suggest[ed] a methodology driven by an attempt to achieve a particular result," *id.* at *14, which was apparent in several respects:

- "[I]n several instances, ***Dr. Infante cherry-picked data*** from studies that did not otherwise support his conclusion, ***failed to explain contrary results***, ***reached conclusions the authors of the study did not themselves make***, and ***manipulated data*** without providing any evidence of his work." *Id.* at 10 (emphasis added).

- "Dr. Infante cherry-picks data from studies in several significant instances and fails to explain contrary results in a manner that belies the reliability of his methodology." *Id.* at *13.

- The court dryly observed that: "Absent from Dr. Infante's report is any acknowledgment that this study separately examined the risk for [the specific cancer at issue] and did not find a statistically significant increased risk. The Court can only speculate as to why Dr. Infante neglected to discuss this pertinent finding in his report." *Id.* at *13.

- "[I]t is clear that Dr. Infante relied on a universe of divergent studies that either did not examine the substance at issue, did not examine the disease at issue, or did not exhibit statistically significant results. Moreover, ***Dr. Infante exhibited a willingness to ignore***

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[10] *See* http://www.collegiumramazzini.org/fellows1.asp?id=82

[11] *See* Collegium Ramazzini Statement, The Control of Pesticides in the European Union: A Call for Action to Protect Human Health (2008) available at http://www.collegiumramazzini.org/download/13_ThirteenthCRStatement(2008).pdf

[12] *See* Roney v. GenCorp, et. al., No. 05-cv-788 (S.D.W. Va. 2005); Taylor v. Airco, Inc., et. al., No. 02-30014-MAP (D. Mass. 2002); Lewis v. Airco, Inc., et. al., No. L-10503-02 (N.J. Civ. Div., Essex County 2002); Skeen, et. al. v. Monsanto Company, No. G-82-468 (S.D. Tex. 1982).

or disregard contrary results, and to manipulate data in a manner not supported by any evidence of his work or independent justification and, in one instance, inconsistent with the authors' own discussion." *Id.* at *16 (emphasis added).

Judge Vance also cast doubt on Dr. Infante's scientific rigor. In response to the court's question about an obvious gap in his analysis, the court noted: "At the hearing, Dr. Infante explained that he *performed the [relevant] calculation on a 'sticky note.'*" *Id.* at *14 (emphasis added).

Burst is not an outlier. The Eastern District of Washington has similarly struck Dr. Infante's testimony and noted his obvious willingness to disregard studies that contradicted his opinions. *See Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1168–77 (E.D.Wa. 2009) ("[T]here is simply too great an analytical gap between the data presented and the opinions offered … such that it renders the expert testimony too speculative as a matter of law.; *id.* at 1172 (noting important study supporting contrary conclusion was conspicuously "not cited by Dr. Infante"); *id.* at 1174 (noting that while study at issue was updated "notably, Dr. Infante did not cite [the update] in his report").

Dr. Infante's public—and colorful— statements also indicate he will reflexively discount any and all industry-sponsored studies and lacks the temperament for unbiased analysis of glyphosate. Dr. Infante notably contributed to a 2014 book titled: *Our Daily Poison: From Pesticides to Packaging, How Chemicals Have Contaminated the Food Chain and Are Making Us Sick*, authored by Marie-Monique Robin (who also authored the anti-Monsanto book *The World According to Monsanto*). In *Our Daily Poison*, Dr. Infante:

- Expressed his disdain for all industry-sponsored studies, stating: "How does industry find scientists to do this kind of task? It buys them, that's all! Let's be clear—***it's what I call 'prostituted science.***'" *Id.* at 144 (emphasis added).

- Expressed his view that regulatory agencies are chronically incapable of evaluating industry-sponsored studies properly: "***The problem is that biased studies are then sent to regulatory agencies, who take them at face value***. That's how highly toxic substances have been contaminating our environment, our food, our fields or our factories, for decades." *Id.* (emphasis added).

- "Generally, studies sponsored by industry have been designed in such a way that it is nearly impossible to find harmful effects. The consequence is ***that the scientific literature is regularly polluted by worthless studies***. It's pathetic." *Id.* at 141 (emphasis added).

The glyphosate SAP is certain to consider industry-sponsored studies as part of its proceedings and there is no reason to believe that Dr. Infante will consider such studies as anything other than "prostituted science" and "worthless," as he has in the past. Dr. Infante's incendiary statements manifestly demonstrate that his "impartiality in the particular matter might be questioned."

The prejudice from Dr. Infante's bias is particularly acute because he is currently the only epidemiologist on the glyphosate SAP, potentially enhancing his ability to influence the SAP proceedings improperly. Because of the potential importance of epidemiological data, EPA should replace Dr. Infante with an epidemiologist without such patent bias.

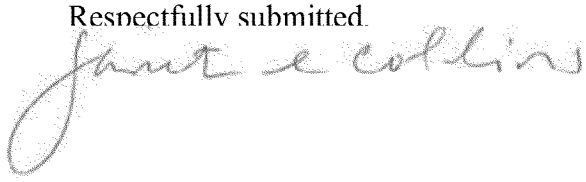
For all of these reasons, CLA respectfully requests that Dr. Infante be excluded from participation in the glyphosate SAP.

EPA Should Confirm That Dr. Kenneth Portier Will Participate Without Any Pre-Formed Conclusions.

Although he has not previously testified against or otherwise expressed the patent bias against pesticide manufacturers or the science upon which they and/or regulatory bodies rely, Dr. Portier has expressed opinions about glyphosate that suggest he may already have pre-formed conclusions as to glyphosate's safety. For example, Dr. Portier has stated that "glyphosate needs to go on the California Prop. 65 database" of chemicals that may cause cancer or have reproductive toxicity.[13] Dr. Portier has also urged "manufacturers to come up with alternative products" to glyphosate because, in his view, "We don't like to see man-made carcinogens freely circulating in the environment."[14]

Dr. Portier is also the brother of Dr. Christopher J. Portier, a noted and vehement anti-glyphosate activist. CLA requests that EPA confirm that his brother's views will not affect Dr. Portier's ability to evaluate the relevant evidence objectively and that he has not already formed a conclusion regarding the carcinogenicity of glyphosate.

Respectfully submitted,



Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President
Science and Regulatory Affairs

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[13] *See* Interview with Dr. Kenneth Portier on Smart Health Talk (Oct. 27, 2015) *available at* http://www.smarthealthtalk.com.

[14] *See* Dennis Thompson, *Genetically Modified Foods, Herbicides and Human Safety*, HealthDay (Aug. 19, 2015) *available at* https://consumer.healthday.com/vitamins-and-nutrition-information-27/food-and-nutrition-news-316/herbicides-and-gmos-702482.html.

City of Hope

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March 29, 2016

Steven Knott, MS
US Environmental Protection Agency
Office of Science Coordination and Policy
FIFRA Scientific Advisory Panel
EPA East Building, MC 7201M
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Comments to the EPA Issue Paper on Glyphosate dated September 12, 2016

Dear Mr. Knott:

I am providing the following comments to the EPA regarding the above cited document. On page 67 of this document, it states that the latency period for non-Hodgkin's lymphoma (NHL) in general is unknown and that estimates range from 1-25 years with a citation to my 1992 paper *[Weisenburger DD, Pathological classification of NHL for epidemiological studies, Cancer Research 52: 5456s-5464s, 1992]*. This statement in the EPA document implies that the range of latency periods for glyphosate exposure and the potential development NHL is likely to be within the range. Such an interpretation from my 1992 paper is incorrect. As stated in the paper, the latency period for NHL would be short following cancer treatment with chemotherapy and/or radiation, e.g. 5-6 years, and for atomic bomb survivors about 9 years, with a longer latency for those receiving smaller doses. I further stated that long-term, low-level exposure would be expected to result in a long latency period. For example, the average latency period for the development of NHL due to long-term, low-level exposure to organic solvents is about 20 years. Since exposure to glyphosate would be expected to be long-term, low-level exposure, the citation of my paper for the proposition that a latency period for glyphosate exposure in relation to NHL can range from 1-25 years would contradict the conclusion of my 1992 paper. I would expect the average latency period for glyphosate exposure in relation to potential NHL to be at the upper end of this range, most likely 20 or more years from initial exposure.

Sincerely,

Dennis D. Weisenburger, MD
Professor and Chair
Department of Pathology

International Agency for Research on Cancer

World Health Organization

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Ms Gina McCarthy
Administrator
US Environmental Protection Agency (EPA)
William Jefferson Clinton Bldg
1200 Pennsylvania Av. NW, Mail code 1101A
Washington, DC 20460, USA

E-mail: mccarthy.gina@epa.gov

Ref.: IMO/75/2-112
CPW/mg

4 October 2016

Dear Ms McCarthy,

The International Agency for Research on Cancer (IARC) is the cancer agency of the World Health Organization (WHO). Through its Monographs Programme, IARC assembles Working Groups of international experts, free from conflicts of interest, to evaluate the available scientific evidence as to whether a particular agent presents a carcinogenic hazard to humans.

Crop Life America, which represents the crop protection industry, makes two false statements relating to IARC in a letter about glyphosate from its Senior Vice President, Dr Janet E. Collins, to the EPA and posted as a "comment" in relation to Docket ID: EPA-HQ-OPP-2016-0385.

The first statement is: "In March 2015, however, after review of only a subset of the glyphosate data previously reviewed by these entities [referring to the European Commission, the Joint WHO/Food Agricultural Organization, Japan and Australia], the International Agency for Research on Cancer (IARC) concluded differently – finding that glyphosate is "probably carcinogenic to humans."

In fact the previous reports Dr Collins refers to were published up to 15 years before the IARC report. IARC was able to include the science unavailable to the previous reviews. Furthermore, IARC examines only scientific reports available in the public domain, adhering to the principle that the basis of the IARC evaluations should be open to scrutiny by others. We presume in stating a "subset" of data Dr Collins makes reference to IARC not considering those studies conducted by the industry and which are not in the public domain.

The second statement relates to the view that "several" scientists involved in the evaluation of glyphosate by the IARC Working Group had pre-formed conclusions and conflicts of interest. Dr Collins goes on to cite two examples, one concerning Dr Kathryn Guyton, an IARC staff member. Dr Collins writes: "…Dr Kathryn Guyton, one of the lead IARC scientists presented speeches to NGO groups both before and upon completion of the IARC review in which she stated that glyphosate is linked to breast cancer".

IARC absolutely rejects the false statements that Dr Guyton had either pre-formed conclusions or conflicts of interest in relation to the glyphosate evaluation. The flimsy reference by Crop Life America to statements about Dr Guyton's presentation are also false. The presentation in question noted that many studies had examined a link to breast cancer with some pesticides (not herbicides in particular), a quite different statement to the one ascribed by an unsubstantiated article in the National Review and drawn upon as supporting evidence by the Senior Vice President of Crop Life America.

Yours sincerely,

Christopher P. Wild, PhD
Director

From: Keigwin, Richard
Location: Studio E, The Renaissance Arlington Capital View, 2800 S. Potomac Avenue, Arlington, VA
Importance: Normal
Subject: CropLife America Board of Directors Visit to EPA
Start Date/Time: Mon 2/27/2017 8:00:00 PM
End Date/Time: Mon 2/27/2017 10:00:00 PM
EPA Agenda 02.22.17.pdf

CLA is making plans for their Winter Board of Directors Meeting on February 27, 2017, and they would like to visit OPP to discuss current and emerging topics of the day. Division directors and deputy office directors are asked to attend the meeting.

Draft Agenda Topics—Monday 2/27/17; 3 to 5 PM; **CLA-OPP Leadership Meeting**; Renaissance Hotel, Crystal City, VA

1. Welcome/Overview-- Diane Allemang & Rick Keigwin

2. Communications Outreach-- what are new ideas for communicating to key audiences about the rigor of the science reviews by EPA of pesticides

3. Resources-- what's likely to be new and improved in PRIA 4 and how are the real resources fitting together (aka approps)

4. Water modeling -- progress we've made together (EPA and CLA) and what's next?

5. Synergy patents-- a surprise new issue and how we (EPA and CLA) have made progress

6. What does the farmer need? Possible remarks by one of our CLA Farmer Advisory Panel members

7. How can we make the EPA staff's learning experience even better from the RISE CLA April Regulatory Conference ?

8. ESA and Pesticide Policy—are we finally at a point of regulator and/or legislative resolve ahead?

9. Adjourn meeting

AGENDA

Prepared by:	CropLife America Senior Management Team
Date:	February 22, 2017
Reviewed by:	Jay Vroom
Status:	DRAFT
To:	CLA Board of Directors and Strategic Oversight Council

Title: **CLA Meeting with EPA OPP Staff**
Date: **Monday, February 27, 3:00 – 5:00 PM**
Venue: **Renaissance Arlington Capital View – *Studio E Room***
2800 S. Potomac Avenue
Arlington, VA

	Lead	Time (mins)
1. Welcome / Overview	Allemang, Keigwin	20
2. Communications Outreach – What are new ideas for communicating to key audiences about the rigor of the pesticide science reviews by EPA?	Vroom	15
3. Resources a. What is likely to be new and improved in PRIA 4? b. How are the real resources fitting together (aka approps)?	Goldberg, Greenwood	15
4. Water Modelling a. Progress of collaboration between EPA and CLA b. What's next?	Collins	10
5. Synergy Patents a. Unexpected new issue b. Progress of collaboration between EPA and CLA	Saab	10
6. What does the farmer need?	Tom	10
7. How can we maximize benefits to EPA via CLA and RISE regulatory conference?	Collins, Reardon	15
8. Endangered Species Issues	Tamichi, Lattimore	15
9. Any other business / Adjourn		10

Participants:

CLA Board of Directors
Diane Allemang, FMC Corporation, ***Chair***
Jim Blome, Bayer CropScience, ***Vice-Chair***
Dave Tretter, Crop Production Services, ***Vice Chair***
Susanne Wasson, Dow AgroSciences, ***Vice Chair and Treasurer***
Jon Akins, TKI
Milton Allen, Helena Chemical
Jeff Bunting, GROWMARK
Don Chew, PBI/Gordon
Rico Christensen, Arysta LifeScience

EPA-HQ 2017-003964_0000014

Bill Culpepper, SePRO
Brendan Deck, Nufarm Americas
Vicente Gongora, UPI
Jim Hay, DuPont Crop Protection
Jeff Johnson, Nichino America
Andy Lee, Valent USA Corporation
Chris Payne, CNI
Steve Petersen, Gowan Company LLC
Paul Rea, BASF
Mark Ripato, Tenkoz
Dave Rummel, ADAMA
Mike Steffeck, Pinnacle Ag Holdings
Eric Wintemute, AMVAC Chemical Corporation

Strategic Oversight Council
Michael Parrish, Monsanto, ***Chair***
Eric Tamichi, Valent USA, ***Co-Chair***
Cindy Baker-Smith, Gowan
Jeff Cassady, SCPA
John Cummings, FMC
Steve Goldberg, BASF
Scott Rawlins, Wilbur-Ellis
Mark Trostle, Crop Production Services
Jake Vukich, DuPont Crop Protection

Guests
Daren Coppock, Ag Retailers Association
David Crow, DCLRS
Janis McFarland, Syngenta
Lisa Nichols, Loveland Products
Laura Peterson, Syngenta
Megan Provost, Dow
Scott Schertz, Schertz Aerial
Mike Seyfert, FMC
Chuck Spencer, GROWMARK
Kip Tom, Tom Farms

CropLife America and RISE Staff
Jay Vroom, President & CEO
Janet Collins, Executive Vice President, Science & Regulatory Affairs
Beau Greenwood, Executive Vice President, Government Relations & Public Affairs
Bill Kuckuck, Executive Vice President and Chief Operating Officer
Rachel Lattimore, Senior Vice President and General Counsel
Ray McAllister, Senior Director, Regulatory Policy
Imad Saab, Senior Director, Environmental Policy
Rebeckah Adcock, Senior Director, Government Affairs
Kellie Bray, Senior Director, Government Affairs
Jeff Case, Senior Director, Government Affairs
Kristin Landis, Deputy General Counsel
Laisha Dismuke, AVP & HR Director
Karen Reardon, Vice President, Public Affair, RISE

EPA-HQ 2017-003964_0000015

From: Dawson, Jeffrey
Location: my office
Importance: Normal
Subject: call Janet Collins re. epi workshop
Start Date/Time: Wed 2/8/2017 2:30:00 PM
End Date/Time: Wed 2/8/2017 3:30:00 PM

From: Janet Collins
Location: Teleconference
Importance: Normal
Subject: FW: Updates on epidemiology
Start Date/Time: Wed 8/10/2016 4:00:00 PM
End Date/Time: Wed 8/10/2016 4:30:00 PM

-----Original Message-----

Ex. 6 - Personal Privacy

From: Dawson, Jeffrey
Location: CLA HQ - 15th st DC
Importance: Normal
Subject: CLA Oversight Committee
Start Date/Time: Thur 6/23/2016 12:30:00 PM
End Date/Time: Thur 6/23/2016 4:30:00 PM

Here is the info... for tomorrow AM

Starts at 9

Janet E Collins, Ph.D., R.D.
Senior Vice President, Science and Regulatory Affairs
CropLife America
1156 15th Street, NW; Suite 400
Washington DC 20001

+1-202-833-4474 (direct)
+1-703-868-3280 (mobile)

To: Janet Collins[jcollins@croplifeamerica.org]; Lowit, Anna[Lowit.Anna@epa.gov]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Wed 2/8/2017 1:46:53 PM
Subject: RE: Please call my cell

Sounds good.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, February 08, 2017 8:40 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Please call my cell

I will head over to my meeting here…and will plan for 9:40 your time (8:40 my time in Des Moines).

Do all agree?

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Wednesday, February 8, 2017 8:39 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Please call my cell

Can we start at 9:40?

Sent from my iPhone

On Feb 8, 2017, at 8:34 AM, Janet Collins <jcollins@croplifeamerica.org> wrote:

I am traveling.

Janet

+1-703-868-3280 (mobile)

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
From: Lowit, Anna
Sent: Wed 2/8/2017 1:39:23 PM
Subject: Re: Please call my cell

Can we start at 9:40?

Sent from my iPhone

On Feb 8, 2017, at 8:34 AM, Janet Collins <jcollins@croplifeamerica.org> wrote:

I am traveling.

Janet

+1-703-868-3280 (mobile)

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Keigwin, Richard
Sent: Wed 2/8/2017 12:14:53 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

FYI

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Keigwin, Richard
Sent: Wed 2/8/2017 12:14:14 PM
Subject: FW: DDL 9/27, Crop Life America Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

FYI

From: Sisco, Debby
Sent: Monday, September 26, 2016 3:46 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: FW: DDL 9/27, Crop Life America Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

Heads up… expect CSB will be working on this.

Debby Sisco

Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: Milbourn, Cathy
Sent: Monday, September 26, 2016 2:40 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Keltz, Colleen <Keltz.Colleen@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>
Cc: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Subject: DDL 9/27, Crop Life America Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

Steve Davies asking-- How close is EPA to publishing the draft framework and/or does EPA have a specific date/timeline for doing so?

For Immediate Release: September 26, 2016
Contact: Genevieve O'Sullivan
Phone: (202) 731-1812
Email: gosullivan@croplifeamerica.org

CLA Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

Publication Delayed More than Five Years

WASHINGTON, DC – On September 22, 2016, CropLife America (CLA) submitted a letter to U.S. Environmental Protection Agency (EPA) Administrator Regina McCarthy requesting that the Agency publish for public comment in the Federal Register its proposed framework for the use of epidemiological studies in human health risk assessments for the regulation of crop protection products. The letter is a follow-up to a 2010 CLA petition to EPA asking that the Agency "promulgate a rule establishing clear and scientifically-sound criteria for selection of epidemiological studies to be incorporated into the Office of Pesticide Programs ("OPP") risk assessment for a given pesticide product."

EPA denied the 2010 petition in April of 2011, stating that the Agency "plans to release a revised version of [draft guidelines] for public comment this year." One month prior to EPA's response to CLA's petition, the White House issued a "Memorandum for the Heads of Executive Departments and Agencies" addressing Principles for Regulation and Oversight for Emerging Technologies, which specifically directed agencies to use the "best available scientific evidence"; develop "ample opportunities for stakeholder involvement and public participation"; and recognize benefits and costs of oversight and regulation. Yet, EPA has yet to release the draft guidelines, which puts into question its support of the use of sound scientific data in the regulation of crop protection products.

In the letter sent to Administrator McCarthy last week, Jay Vroom, president and CEO of CLA, writes, "As we look back at the landscape of the past 6-plus years since our petition and EPA's denial of that petition, it is our belief that much, much more has been said about the use of epi data, how it is evaluated for scientific veracity, and whether epidemiological information has had consistent and meaningful impacts on risk assessments. In fact, looking at two recent EPA risk assessment approaches on two different chemicals, it seems there is significant inconsistency in the EPA approach."

Vroom continues, "Based on need for consistency, and to account for all the new and deliberative discussions [in which EPA] has taken part related to epidemiological data in the last 6 years — and to follow the 2011 White House directive – CLA is asking that EPA at minimum publish for public comment in the Federal Register [its] proposed Epidemiological Framework."

"The memo from the White House in 2011 was clear about the importance of sound science and public participation in the rulemaking process," stated Dr. Janet E. Collins, SVP of science and regulatory affairs at CLA. "We are in urgent need of guidance on the use of epidemiological studies in risk assessments. The crop protection industry must be able to develop the most precise and scientifically studied products possible; our nation's farmers depend on the continual advancement of crop protection technology to get high quality and nutritious produce to consumers."

-xxx-

Established in 1933, CropLife America (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 of the vital

and necessary crop protection and biotechnology products used by American farmers. CLA can be found on Twitter at @CropLifeAmerica. CLA supports CropLife StewardshipFirst.

This email was sent to steve@agri-pulse.com
CropLife America, 1156 15th Street, NW Suite 400, Suite 400, Washington, DC 20005, United States
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Catherine C. Milbourn

U.S. EPA HQ

Office of the Administrator

Office of Media Relations

202-564-7849 (office)

202-420-8648 (mobile)

Milbourn.cathy@epa.gov

From: Steve Davies [mailto:steve@agri-pulse.com]
Sent: Monday, September 26, 2016 2:00 PM
To: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Subject: Fwd: CLA Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

would it be possible to get a comment on this by tomorrow? Thanks. Questions would be: how close is epa to publishing the draft framework and/or does epa have a specific date/timeline for doing so?

Thanks

Steve Davies

Associate Editor
202-716-8005
steve@agri-pulse.com

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---------- Forwarded message ----------
From: **Steve Davies** <steve@agri-pulse.com>
Date: Mon, Sep 26, 2016 at 1:53 PM
Subject: Fwd: CLA Asks EPA to Publish for Public Comment Proposed Epidemiological Framework
To: Daniel Enoch <daniel@agri-pulse.com>

I can do a brief on this.

Steve Davies
Associate Editor
202-716-8005
steve@agri-pulse.com

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---------- Forwarded message ----------
From: **Genevieve O'Sullivan** <gosullivan@croplifeamerica.org>
Date: Mon, Sep 26, 2016 at 12:44 PM
Subject: CLA Asks EPA to Publish for Public Comment Proposed Epidemiological Framework
To: steve@agri-pulse.com

For Immediate Release: September 26, 2016
Contact: Genevieve O'Sullivan

Phone: (202) 731-1812
Email: gosullivan@croplifeamerica.org

CLA Asks EPA to Publish for Public Comment Proposed Epidemiological Framework

Publication Delayed More than Five Years

WASHINGTON, DC – On September 22, 2016, CropLife America (CLA) submitted a letter to U.S. Environmental Protection Agency (EPA) Administrator Regina McCarthy requesting that the Agency publish for public comment in the Federal Register its proposed framework for the use of epidemiological studies in human health risk assessments for the regulation of crop protection products. The letter is a follow-up to a 2010 CLA petition to EPA asking that the Agency "promulgate a rule establishing clear and scientifically-sound criteria for selection of epidemiological studies to be incorporated into the Office of Pesticide Programs ("OPP") risk assessment for a given pesticide product."

EPA denied the 2010 petition in April of 2011, stating that the Agency "plans to release a revised version of [draft guidelines] for public comment this year." One month prior to EPA's response to CLA's petition, the White House issued a "Memorandum for the Heads of Executive Departments and Agencies" addressing Principles for Regulation and Oversight for Emerging Technologies, which specifically directed agencies to use the "best available scientific evidence"; develop "ample opportunities for stakeholder involvement and public participation"; and recognize benefits and costs of oversight and regulation. Yet, EPA has yet to release the draft guidelines, which puts into question its support of the use of sound scientific data in the regulation of crop protection products.

In the letter sent to Administrator McCarthy last week, Jay Vroom, president and CEO of CLA, writes, "As we look back at the landscape of the past 6-plus years since our petition and EPA's denial of that petition, it is our belief that much, much more has been said about the use of epi data, how it is evaluated for scientific veracity, and whether epidemiological information has had consistent and meaningful impacts on risk assessments. In fact, looking at two recent EPA risk assessment approaches on two different chemicals, it seems there is significant inconsistency in the EPA approach."

Vroom continues, "Based on need for consistency, and to account for all the new and deliberative discussions [in which EPA] has taken part related to epidemiological data in the last 6 years — and to follow the 2011 White House directive – CLA is asking that EPA at minimum publish for public comment in the Federal Register [its] proposed Epidemiological Framework."

"The memo from the White House in 2011 was clear about the importance of sound science and public participation in the rulemaking process," stated Dr. Janet E. Collins, SVP of science and regulatory affairs at CLA. "We are in urgent need of guidance on the use of epidemiological studies in risk assessments. The crop protection industry must be able to develop the most precise and scientifically studied products possible; our nation's farmers depend on the continual advancement of crop protection technology to get high quality and nutritious produce to consumers."

-xxx-

Established in 1933, CropLife America (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 of the vital and necessary crop protection and biotechnology products used by American farmers. CLA can be found on Twitter at @CropLifeAmerica. CLA supports CropLife StewardshipFirst.

This email was sent to steve@agri-pulse.com

CropLife America, 1156 15th Street, NW Suite 400, Suite 400, Washington, DC 20005, United States
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To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Janet Collins
Sent: Tue 2/7/2017 7:10:37 PM
Subject: Re: Potential meeting with CLA leaders

That's fine- any time in the morning would be good.

If you give me a time and number I can phone you.

Thank you

On Feb 7, 2017, at 1:07 PM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

I got your voicemail. I have a full day today so I probably can't call and have any significant time. Do you have a good time tomorrow? I'd also like to have Anna and Dana on… just so we are all on the same page if that works for you.

If not, please let me know.

Thanks!

Jeff

Jeffrey L Dawson

Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, June 23, 2016 8:53 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thanks Jeff- we will see you soon. Be safe

Sent from my iPhone

On Jun 23, 2016, at 8:33 AM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

We are in a cab but traffic is bad.

Thanks

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/22/2016 12:02 PM
To: Dawson, Jeffrey
Cc: Smith, Charles
Subject: RE: Potential meeting with CLA leaders

We would welcome it.

Thank you

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 11:49 AM

To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Janet,

Do you have any issues with Anna Lowit coming with us as well. She can really add a lot to the discussion.

Here is her info:

Anna Lowit– Senior Science Advisor For OPP since May 2016, before that senior scientist in for several years in HED.

Main areas of focus: all issues associated with toxicology, implementation of Tox 21, PBPK, use of epidemiology in risk assessment.

Thanks

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:52 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks very much Jeff.

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 8:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks Janet…

Info for us…

Jeff Dawson – Acting Deputy Director of HED since October 2015, before that senior scientist for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with chlorpyrifos effort. Been at EPA since 1997. Also have worked at contract lab doing GLP pesticide studies.

Billy Smith– Acting Associate Director of HED since April 2016, before that branch chief for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with glyphosate effort.

[Billy – if you see this please modify as needed. I took a shot since you aren't here today.]

Please let me know if you need more.

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:40 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders
Importance: High

Jeff – thanks for the brief discussion this morning. We would like to ask that you and Billy come to meet with our Strategic Oversight Council around 9:00 tomorrow morning. Our address is listed below—we are close to McPherson Square Metro—take the exit for Vermont Avenue and then head away from the White House. We are on the corner of 15th and M Streets NW.

Thanks very much for your willingness to speak about the use of epidemiologic data and considerations for weighing evidence from tox studies and that from the epi work. I am certain SOC members will have questions for you both!

Could you please provide me with your titles and a bit about your work at EPA?

Please call me on my cell if you need further instructions on your way to the offices tomorrow.

My best,

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

From: Vogel, Dana [mailto:Vogel.Dana@epa.gov]
Sent: Tuesday, June 21, 2016 1:48 PM
To: Janet Collins <jcollins@croplifeamerica.org>

Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Hi Janet,

My acting Deputy and Associate Directors (Jeff Dawson and Billy Smith) can attend. I have cc'd them on this email so please feel free to work directly with them on scheduling.

Thanks,

Dana

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

Hi Janet,

Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM

To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: OPP HED Managers[OPP_HED_Managers@epa.gov]
From: Davis, Donna
Sent: Wed 11/30/2016 2:12:08 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>

Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

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+1-703-868-3280 (mobile)

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Housenger, Jack[Housenger.Jack@epa.gov]; Lydon, Maureen[Lydon.Maureen@epa.gov]; Arling, Michelle[Arling.Michelle@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]; Lowit, Anna[Lowit.Anna@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Dawson, Jeffrey[Dawson.Jeff@epa.gov]
Cc: Dyner, Mark[dyner.mark@epa.gov]; Barber, Delores[barber.delores@epa.gov]
From: Ingram, Earl
Sent: Mon 11/28/2016 1:48:04 PM
Subject: FW: EPA-HQ-2017-000960 - CLA Request Columbia University Chlorpyrifos study
EPA-HQ-2017-000960 CLA FOIA Human Sujects Request 16.pdf

Jack,

Please Mark Dyner's comments below.

Earl Ingram, Chief

Public Information & Records Integrity Branch

Information Technology & Resources Management Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

(703) 305-5456

ITRMD…Where every customer is a VIP!

From: Dyner, Mark
Sent: Friday, November 25, 2016 4:44 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>

Cc: Huskey, Angela <Huskey.Angela@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>
Subject: FW: EPA-HQ-2017-000960 - CLA Request Columbia University Chlorpyrifos study

Earl,

Ex. 5 - Attorney Client

Mark

From: Ingram, Earl
Sent: Friday, November 25, 2016 3:19 PM
To: Dyner, Mark <dyner.mark@epa.gov>
Cc: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: FW: EPA-HQ-2017-000960 - CLA Request Columbia University Chlorpyrifos study

I forgot to include Mark.

From: Ingram, Earl
Sent: Friday, November 25, 2016 3:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: EPA-HQ-2017-000960 - CLA Request Columbia University Chlorpyrifos study

Hello Ana,

CropLife America has submitted a FOIA request for records concerning the compliance policy in regards to protecting human subjects used in the Columbia Study. The request is rather broad in scope but it only involves records concerning compliance with human subject rule. I was wondering do you to have the names of the staff that would potentially have responsible records? Do you know if OPP was in charge this grant or was ORD? I have attached the full request. Please feel free to call me if you have any questions.

FOIA request for documents supportive of EPA compliance with requirements for human studies protections by EPA under studies supported with federal government funds- in particular the Columbia Center for Children's Environmental Health (Columbia University) epidemiology cohort studies of inner-city mothers and children concerning pre- and post-natal pesticide exposure to chlorpyrifos and other organophosphate pesticides (hereinafter, the Columbia Study) complies with the Agency's policy for protection of human subjects, 40 C.F.R. § 26.101, et. seq.

Earl Ingram, Chief

Public Information & Records Integrity Branch

Information Technology & Resources Management Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

(703) 305-5456

ITRMD…Where every customer is a VIP!

November 3, 2016

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: FOIA Request, Protection of Human Subjects

Dear EPA FOIA Officer,

Under the federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, CropLife America (CLA) requests all reasonably segregable, nonexempt portions of "documents" that the Environmental Protection Agency (EPA or the Agency) has in its possession or control relating to any determination by the Agency that the Columbia Center for Children's Environmental Health (Columbia University) epidemiology cohort studies of inner-city mothers and children concerning pre- and post-natal pesticide exposure to chlorpyrifos and other organophosphate pesticides (hereinafter, the Columbia Study) complies with the Agency's policy for protection of human subjects, 40 C.F.R. § 26.101, *et. seq.*

According to EPA's own regulations, the use of human subjects in EPA-funded studies must meet strict protective standards, especially with regard to pregnant women and children. *Id.* In fact, EPA has instituted additional protections, beyond those agreed upon by the various federal agencies, for pregnant women and children used as subjects in EPA observational research. EPA has stated that it is committed to using those studies done in reliance on scientifically sound research that is ethically conducted. *See* https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/protections-subjects-human-research-pesticides. This request seeks information to assure the public that EPA has held itself to this high standard in funding and using the Columbia Study in pesticide risk assessments.

For purposes of this FOIA request, the term "documents" means all written, typed or otherwise preserved materials or "communications," including any letter, facsimile, email, text message, note, book, pamphlet, article, bulletin, directive, review, publication, memorandum, presentation, diary, log, test analysis, study, sample, schematic, contract, agreement, work paper, calendar, envelope, telephone message and all other writings. For purposes of this request, "communications" means any oral, written or electronic transmission of information without limitation. Examples of communications include, but are not limited to meetings, discussions, conversations, telephone calls, memoranda, letters, email messages, text messages, conferences, seminars, or notes. Communications include transmission of information via personal or unofficial email accounts and other C communication mediums.

The timeframe for documents and communications responsive to this request is from January 1, 2004 through the present.

1. All documents and communications between current or former EPA staff and any current or former Columbia University staff pertaining to Columbia University's application for research grants and other funding for the Columbia Study.

2. All documents and communications between current or former EPA staff and the following individuals (hereinafter, the Columbia Study Authors) pertaining to the protection of human subjects used in the Columbia Study:
    a. Virginia Rauh
    b. Robin Whyatt
    c. David E. Camann
    d. Frederica P. Perera
    e. Deliang Tang
    f. Howard Andrews
    g. Robin S. Garfinkel
    h. Srikesh Arunajadai
    i. Megan Horton
    j. Lori Hoepner
    k. Dana B. Barr
    l. Ralph Whitehead
    m. Diurka Diaz
    n. Jessica Dietrich
    o. Andria Reyes
    p. Patrick L. Kinney

3. All documents and communications regarding any determination by EPA that the Columbia Study complied with the Agency's requirements under 40 C.F.R. § 26.101, *et.seq.*, for the protection of human subjects for research supported by the Agency.

4. All documents and communications pertaining to any determination by EPA that the Columbia Study was "observational research," defined in EPA Order 100.17A as involving "neither the deliberate exposure of participants nor the control of environmental conditions in a way that impacts the participants' naturally occurring exposures."

5. All documents and communications between current and former EPA staff and the Columbia Study Authors (see 2, above) pertaining to:
    a. Whether pesticide exposure experienced by the human subjects participating in the Columbia Study would not have occurred but for the human subject's participation in the study;
    b. The pesticides to which the human subjects were exposed; and
    c. Dates and locations of any and all pesticide applications relevant to the Columbia Study.

6. All documents and communications pertaining to records submitted by the Columbia Study Authors (see 2, above) to the Agency under 40 C.F.R. § 26.103, *et. seq.*, including:
   - A statement of principles governing Columbia University in assuring the protection of human subjects participating in the Columbia Study;
   - The designation of one or more Institutional Review Boards (IRBs);
   - A list of IRB members including education, area of expertise, any potential conflicts of interest and any prior relationships between any member of the IRB and Columbia University;
   - Written procedures for the IRB;
   - Written procedures for ensuring prompt reporting to the IRB and EPA of any unanticipated problems involving risk to subjects or others or any serious or continuing noncompliance with 40 C.F.R. § 26.103;
   - Written determination that the collection of maternal blood or cord blood at delivery involved the least possible risk for achieving the objectives of the study;
   - Written determination that the risk of invasive blood collection was justified; and
   - Written determination that the collection of cord blood at delivery did not produce greater than minimal risk.

CLA is willing to pay fees for this request up to a maximum of $1000. If you estimate that the fees will exceed this limit, please inform me before processing this request. We prefer to receive the information electronically in PDF file format if possible, and request that any responsive materials be released to CLA on a rolling basis. CLA reserves its right to appeal any denial of this request.

If you have any questions regarding this request, please contact me at 202-833-4474 or jcollins@croplifeamerica.org. I look forward to receiving your response within the twenty-day statutory time period. Thank you for your assistance with this matter.

Sincerely,

J

Janet E. Collins, Ph.D.
Senior Vice President, Science &
Regulatory Affairs
CropLife America

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Wed 7/13/2016 6:20:52 PM
Subject: RE: Workshop

Can u write up a couple sentences to summarize it? I just sent my info on the one pager but can add this if you send me a couple sentences.

From: Dawson, Jeffrey
Sent: Wednesday, July 13, 2016 2:19 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Workshop

Yes it would be all encompassing. That was the first ground rule we discussed

Sent from my Windows Phone

From: Vogel, Dana
Sent: 7/13/2016 2:15 PM
To: Dawson, Jeffrey
Subject: RE: Workshop

Ok, what exactly did we agree to do? Does it include other stakeholder groups beside registrants?

From: Dawson, Jeffrey
Sent: Wednesday, July 13, 2016 1:52 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Workshop

Yes, this is the epi workshop I believe... From when Anna, Billy and I went over there.

We should let jim know that on his 1 pager and the workshop concept.

Sent from my Windows Phone

From: Vogel, Dana
Sent: 7/13/2016 1:34 PM

To: Dawson, Jeffrey
Subject: FW: Workshop

Any idea on what this is about?
-----Original Message-----
From: Janet Collins [Ex. 6 - Personal Privacy
Sent: Wednesday, July 13, 2016 1:33 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Workshop

Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

Janet E Collins
CropLife America

+1-202-833-4474

Sent from my iPhone

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Wed 7/13/2016 6:15:08 PM
Subject: RE: Workshop

Ok, what exactly did we agree to do? Does it include other stakeholder groups beside registrants?

From: Dawson, Jeffrey
Sent: Wednesday, July 13, 2016 1:52 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Workshop

Yes, this is the epi workshop I believe... From when Anna, Billy and I went over there.

We should let jim know that on his 1 pager and the workshop concept.

Sent from my Windows Phone

From: Vogel, Dana
Sent: 7/13/2016 1:34 PM
To: Dawson, Jeffrey
Subject: FW: Workshop

Any idea on what this is about?
-----Original Message-----
From: Janet Collins [**Ex. 6 - Personal Privacy**
Sent: Wednesday, July 13, 2016 1:33 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Workshop

Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

Janet E Collins
CropLife America

+1-202-833-4474

Sent from my iPhone

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Wed 7/13/2016 5:34:09 PM
Subject: FW: Workshop

Any idea on what this is about?
-----Original Message-----
From: Janet Collins **Ex. 6 - Personal Privacy**
Sent: Wednesday, July 13, 2016 1:33 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Workshop

Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

Janet E Collins
CropLife America

+1-202-833-4474

Sent from my iPhone

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Curt Lunchick
Sent: Thur 6/23/2016 1:00:21 PM
Subject: Re: muffin

Offer him a tooth pick. Thanks

Sent from my iPhone

On Jun 23, 2016, at 08:15, Janet Collins <jcollins@croplifeamerica.org> wrote:

> Had to get lemon poppyseed! Blueberry not happening around our office!
>
> Sent from my iPhone
>
> On Jun 23, 2016, at 7:38 AM, Curt Lunchick <curt.lunchick@bayer.com> wrote:
>
> > Don't forget a blueberry muffin for Billy.
> >
> > Best regards,
> >
> > Curt Lunchick
> >
> > Human Safety
> >
> > <image001.png>
> >
> > Crop Science Division — Tel: +1 919 549 2986
> > Bayer CropScience LP — Fax:
> > BCS-RD-DEVE-PROD, Human Safety — Mobile: +1 919 3688940
> > Building Research Triangle Park NC, Some Stall — E-mail: curt.lunchick@bayer.com
> > Zip-code City, Country — Web: http://www.bayer.com

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To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Janet Collins
Sent: Thur 6/23/2016 12:52:41 PM
Subject: Re: Potential meeting with CLA leaders

Thanks Jeff- we will see you soon. Be safe

Sent from my iPhone

On Jun 23, 2016, at 8:33 AM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

We are in a cab but traffic is bad.

Thanks

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/22/2016 12:02 PM
To: Dawson, Jeffrey
Cc: Smith, Charles
Subject: RE: Potential meeting with CLA leaders

We would welcome it.

Thank you

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 11:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Janet,

Do you have any issues with Anna Lowit coming with us as well. She can really add a lot to the discussion.

Here is her info:

Anna Lowit– Senior Science Advisor For OPP since May 2016, before that senior scientist in for several years in HED.

Main areas of focus: all issues associated with toxicology, implementation of Tox 21, PBPK, use of epidemiology in risk assessment.

Thanks

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:52 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks very much Jeff.

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 8:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks Janet…

Info for us…

Jeff Dawson – Acting Deputy Director of HED since October 2015, before that senior scientist for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with chlorpyrifos effort. Been at EPA since 1997. Also have worked at contract lab doing GLP pesticide studies.

Billy Smith– Acting Associate Director of HED since April 2016, before that branch chief for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with glyphosate effort.

[Billy – if you see this please modify as needed. I took a shot since you aren't here today.]

Please let me know if you need more.

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:40 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders
Importance: High

Jeff – thanks for the brief discussion this morning. We would like to ask that you and Billy come to meet with our Strategic Oversight Council around 9:00 tomorrow morning. Our address is listed below—we are close to McPherson Square Metro—take the exit for Vermont Avenue and then head away from the White House. We are on the corner of 15th and M Streets NW.

Thanks very much for your willingness to speak about the use of epidemiologic data and considerations for weighing evidence from tox studies and that from the epi work. I am certain SOC members will have questions for you both!

Could you please provide me with your titles and a bit about your work at EPA?

Please call me on my cell if you need further instructions on your way to the offices tomorrow.

My best,

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

From: Vogel, Dana [mailto:Vogel.Dana@epa.gov]
Sent: Tuesday, June 21, 2016 1:48 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Hi Janet,

My acting Deputy and Associate Directors (Jeff Dawson and Billy Smith) can attend. I have cc'd them on this email so please feel free to work directly with them on scheduling.

Thanks,

Dana

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

Hi Janet,

Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
Cc: Smith, Charles[Smith.Charles@epa.gov]
From: Janet Collins
Sent: Wed 6/22/2016 4:01:58 PM
Subject: RE: Potential meeting with CLA leaders

We would welcome it.

Thank you

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 11:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Janet,

Do you have any issues with Anna Lowit coming with us as well. She can really add a lot to the discussion.

Here is her info:

Anna Lowit– Senior Science Advisor For OPP since May 2016, before that senior scientist in for several years in HED.

Main areas of focus: all issues associated with toxicology, implementation of Tox 21, PBPK, use of epidemiology in risk assessment.

Thanks

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:52 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks very much Jeff.

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 8:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks Janet…

Info for us…

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Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

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Sent: Wednesday, June 22, 2016 8:40 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders
Importance: High

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1156 15th Street, NW; Suite 400

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Sent from Mail for Windows 10

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
Cc: Smith, Charles[Smith.Charles@epa.gov]
From: Janet Collins
Sent: Wed 6/22/2016 12:51:48 PM
Subject: RE: Potential meeting with CLA leaders

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From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 8:49 AM
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From: Janet Collins
Sent: Wed 6/22/2016 12:40:17 PM
Subject: RE: Potential meeting with CLA leaders

Thank you again Dana. We have agreed on a time tomorrow morning (working through Jeff today).

My best

Janet

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Cc: Smith, Charles[Smith.Charles@epa.gov]
From: Janet Collins
Sent: Tue 6/21/2016 8:35:18 PM
Subject: RE: Potential meeting with CLA leaders

Please set the time and I will send a call in number.

Thanks very much.

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Tuesday, June 21, 2016 4:35 PM
To: Janet Collins <jcollins@croplifeamerica.org>; Vogel, Dana <Vogel.Dana@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Janet,

Early tomorrow would be best.

Thanks!

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/21/2016 4:33 PM
To: Vogel, Dana
Cc: Dawson, Jeffrey; Smith, Charles
Subject: RE: Potential meeting with CLA leaders

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From: Vogel, Dana
Sent: Tue 6/21/2016 5:37:10 PM
Subject: FW: Potential meeting with CLA leaders

From: Housenger, Jack
Sent: Tuesday, June 21, 2016 1:37 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Yes

They can go

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:20 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Huh?

From: Housenger, Jack
Sent: Tuesday, June 21, 2016 1:13 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Hestitant?

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:06 PM

To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: FW: Potential meeting with CLA leaders

Are you ok with Jeff and/or Billy going to this? Given the topics, (b)(5)

Dv

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Smith, Charles[Smith.Charles@epa.gov]; Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Tue 6/21/2016 5:07:00 PM
Subject: RE: Potential meeting with CLA leaders

Checking with jack now

From: Smith, Charles
Sent: Tuesday, June 21, 2016 1:06 PM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Its up to Dana. If you want me to go I'll go. This seems more like an Anna thing and a rehash of a bunch of previous stuff…

Charles " Billy" Smith

Acting Associate Division Director

Health Effects Division

Office of Pesticide Programs

703-305-0291

From: Dawson, Jeffrey
Sent: Tuesday, June 21, 2016 12:20 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

I think we both should go – more eyes and ears and all that – but Thursday morning is best

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 11:36 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: FW: Potential meeting with CLA leaders

Interested? Let me know.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

Hi Janet,

Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
From: Smith, Charles
Sent: Tue 6/21/2016 5:05:58 PM
Subject: RE: Potential meeting with CLA leaders

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Health Effects Division

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Phone: 703-305-7329

Email: dawson.jeff@epa.gov

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]; Smith, Charles[Smith.Charles@epa.gov]
From: Vogel, Dana
Sent: Tue 6/21/2016 3:36:08 PM
Subject: FW: Potential meeting with CLA leaders

Interested? Let me know.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Thur 1/28/2016 8:27:18 PM
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ok, I'll
Wait to reply to patty.
Thanks

Dana Vogel
Sent from my iPhone

On Jan 28, 2016, at 3:26 PM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

I'm working on this too… I'll send my comments tomorrow morning.

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana
Sent: Thursday, January 28, 2016 3:23 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Middleton, Karlyn <Middleton.Karlyn@epa.gov>; Mendez, Elizabeth <Mendez.Elizabeth@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Yes I'll

Send them to patty. Thanks!

Dana Vogel

Sent from my iPhone

On Jan 28, 2016, at 2:19 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Here is the compiled set of comments Liz, Karlyn & I developed. We had made comments about the classification system but that's already in the letter, so I deleted our comments.

Do these go to FEAD?

Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Vogel, Dana
Sent: Wednesday, January 27, 2016 11:27 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
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Please let me know what you think.

We will

Probably need to

Do the response

Dana Vogel

Sent from my iPhone

Begin forwarded message:

From: "Parrott, Patricia" <parrott.patricia@epa.gov>
Date: January 27, 2016 at 11:22:38 AM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dana: Brazil has proposed using the hazard based approach to pesticide registration (the English version is attached). We have been asked to comment on the draft US response (attached file dated 12-8-15).

With Bill gone and Daniella recused, I am trying to determine if we had provided comments previously or if we are OK with the response. If no one in HED has reviewed it, could someone look it over to see if we need any changes? From my non-technical perspective it looks OK, but there may be a technical perspective missing--?

The problem is that we are overdue, and they are asking for us to concur or provide changes by this Friday, 29 Jan. Is there anyone who could look it over –focusing on the response (not the entire Brazilian proposal). Pls let me know. Thanks.

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Sanchez, Becxi - FAS [mailto:Becxi.Sanchez@fas.usda.gov]
Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

Thank you, Marielsie, Patricia et al,

Here are the draft comments currently in interagency review.

We look forward to receiving any edits you may have.

Cheers,

Becxi

From: Avila, Marielsie - FAS
Sent: Wednesday, January 27, 2016 8:27 AM
To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise

Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Patricia,

I don't have the requested comments. I was adding Becxi to the previous messsage so she can send them to you. Becxi is the coordinator for TBT measures.

Thanks,

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Parrott, Patricia [mailto:parrott.patricia@epa.gov]
Sent: Wednesday, January 27, 2016 8:24 AM
To: Avila, Marielsie - FAS; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Marielsie: There was no attachment. Would you pls resend. Thanks.

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Avila, Marielsie - FAS [mailto:Marielsie.Avila@fas.usda.gov]
Sent: Wednesday, January 27, 2016 7:41 AM
To: Taveau, Daniella <Taveau.Daniella@epa.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Sanchez, Becxi - FAS <Becxi.Sanchez@fas.usda.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

+Becxi Sanchez

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Taveau, Daniella [mailto:Taveau.Daniella@epa.gov]
Sent: Tuesday, January 26, 2016 5:11 PM
To: Parrott, Patricia
Cc: Keigwin, Richard; Avila, Marielsie - FAS; Wise, Louise
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Of course. Marielsie-- can you please send Patty the latest version of the U.S. comments on the Brazil pesticide measure when you are back in the office?

Daniella

On Jan 26, 2016, at 3:14 PM, Parrott, Patricia <parrott.patricia@epa.gov> wrote:

> I understand. Would you pls resend me the comments to ensure I have the correct document. With Bill Jordan gone and you sidelined I want to ensure we follow through appropriately. Thanks
>
> Sent from my iPhone
>
> On Jan 26, 2016, at 3:05 PM, Taveau, Daniella <Taveau.Daniella@epa.gov> wrote:
>
>> Patty,
>>
>> I am recused and cannot follow up with Janet. However, we asked for an extension of 60 days which was granted. We also drafted comments which were circulated to OPP approximately a month ago. We have not submitted them as we are still within our deadline for comments. If OPP has comments, please send them to Marielsie on cc. I wish I could be more helpful, but I am very limited on what I am allowed to do right now.
>>
>> Daniella
>>
>> On Jan 26, 2016, at 1:40 PM, Parrott, Patricia <parrott.patricia@epa.gov> wrote:
>>
>>> Daniella. Was FAS going to provide comments from the US govt on this? Not sure what the expectation was for further input or if anything else is needed from OPP. Do we have some standard language that we have used in the past to express our concerns with the hazard approach when this has come up previously?
>>>
>>> We are reaching out to our NAFTA colleagues in Mexico to see if they have had any interaction with Brazil on this proposal.

Also, Janet Collins from CLA called me to ask what we have done in response to this. Are you following up w CLA, as you had initially spoken to them about this? Pls let me know. Thanks

Sent from my iPhone

Begin forwarded message:

From: "Jordan, William" <Jordan.William@epa.gov>
Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Here is the information from Brazil.

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:	Courier Address:
USEPA Headquarters	Potomac Yards South
Clinton Building	2777 Crystal Drive
1200 Pennsylvania Ave., NW	Room 12-235

Mail Code (7501P) Arlington, VA

Washington, DC 20460

From: Taveau, Daniella
Sent: Monday, November 09, 2015 2:53 PM
To: Jordan, William <Jordan.William@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Helfgott, Daniel <Helfgott.Daniel@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Bill,

I just met with CLA and we discussed several issues.

First, are you familiar with concerns about Brazil adopting a hazard-based toxicological approach to pesticide management? I had not seen this but am looking into it.

Second, I would like to set up a meeting with OPP and CLA to discuss this, NAFTA, and Codex among other things. Are there dates that work for OPP?

Daniella

Begin forwarded message:

> **From:** "Ray McAllister" <RMcAllister@croplifeamerica.org>
> **To:** "Taveau, Daniella" <Taveau.Daniella@epa.gov>
> **Cc:** "Janet Collins" <jcollins@croplifeamerica.org>

Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

I've also attached the translation of the Brazilian proposed regulation that we have been working from. I still haven't figured out who did the translation (industry or Brazilian government). I need to do a bit more ch3ecking before sharing the CropLife draft comments to Brazil with you.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

This is the notification that was received by our European colleagues.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dear Euros and Joan,

We have just received a new WTO TBT notification from Brazil (see enclosed). According to the short content description, this concerns the following:

Draft Technical Resolution nº 87, 2 October 2015, regarding the pesticides' toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration.

This Resolution establishes the requirements and criteria to toxicological evaluation and classification, risk evaluation, the toxicological information in labels and leaflets, besides the procedures of pesticides' post-register alteration, its components and wood preservers in ANVISA's regulation.

Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

More on EU trade policy

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More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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http://www.symanteccloud.com

<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

<Comments on Brazil Anvisa tox requirements_draft_compiled.docx>

To: Lowit, Anna[Lowit.Anna@epa.gov]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]; Middleton, Karlyn[Middleton.Karlyn@epa.gov]; Mendez, Elizabeth[Mendez.Elizabeth@epa.gov]
From: Vogel, Dana
Sent: Thur 1/28/2016 8:22:44 PM
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Send them to patty. Thanks!

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Sent from my iPhone

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Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

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w: 703-308-4135

c: 703-258-4209

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Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

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Sent: Wednesday, January 27, 2016 10:48 AM
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Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

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International Trade Specialist

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From: Avila, Marielsie - FAS [mailto:Marielsie.Avila@fas.usda.gov]
Sent: Wednesday, January 27, 2016 7:41 AM
To: Taveau, Daniella <Taveau.Daniella@epa.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Sanchez, Becxi - FAS <Becxi.Sanchez@fas.usda.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

+Becxi Sanchez

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Taveau, Daniella [mailto:Taveau.Daniella@epa.gov]
Sent: Tuesday, January 26, 2016 5:11 PM
To: Parrott, Patricia
Cc: Keigwin, Richard; Avila, Marielsie - FAS; Wise, Louise
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Of course. Marielsie-- can you please send Patty the latest version of the U.S. comments on the Brazil pesticide measure when you are back in the office?

Daniella

On Jan 26, 2016, at 3:14 PM, Parrott, Patricia <parrott.patricia@epa.gov> wrote:

> I understand. Would you pls resend me the comments to ensure I have the correct document. With Bill Jordan gone and you sidelined I want to ensure we follow through appropriately. Thanks
>
> Sent from my iPhone
>
> On Jan 26, 2016, at 3:05 PM, Taveau, Daniella <Taveau.Daniella@epa.gov> wrote:
>
>> Patty,
>>
>> I am recused and cannot follow up with Janet. However, we asked for an extension of 60 days which was granted. We also drafted comments which were circulated to OPP approximately a month ago. We have not submitted them as we are still within our deadline for comments. If OPP has comments, please send them to Marielsie on cc. I wish I could be more helpful, but I am very limited on what I am allowed to do right now.
>>
>> Daniella
>>
>> On Jan 26, 2016, at 1:40 PM, Parrott, Patricia <parrott.patricia@epa.gov> wrote:
>>
>>> Daniella. Was FAS going to provide comments from the US govt on this? Not sure what the expectation was for further input or if anything else is needed from OPP. Do we have some standard language that we have used in the past to express our concerns with the hazard approach when this has come up previously?
>>>
>>> We are reaching out to our NAFTA colleagues in Mexico to see if they have had any interaction with Brazil on this proposal.

Also, Janet Collins from CLA called me to ask what we have done in response to this. Are you following up w CLA, as you had initially spoken to them about this? Pls let me know. Thanks

Sent from my iPhone

Begin forwarded message:

From: "Jordan, William" <Jordan.William@epa.gov>
Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Here is the information from Brazil.

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:	Courier Address:
USEPA Headquarters	Potomac Yards South
Clinton Building	2777 Crystal Drive
1200 Pennsylvania Ave., NW	Room 12-235

Mail Code (7501P) Arlington, VA

Washington, DC 20460

From: Taveau, Daniella
Sent: Monday, November 09, 2015 2:53 PM
To: Jordan, William <Jordan.William@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Helfgott, Daniel <Helfgott.Daniel@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Bill,

I just met with CLA and we discussed several issues.

First, are you familiar with concerns about Brazil adopting a hazard-based toxicological approach to pesticide management? I had not seen this but am looking into it.

Second, I would like to set up a meeting with OPP and CLA to discuss this, NAFTA, and Codex among other things. Are there dates that work for OPP?

Daniella

Begin forwarded message:

From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 -

pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

I've also attached the translation of the Brazilian proposed regulation that we have been working from. I still haven't figured out who did the translation (industry or Brazilian government). I need to do a bit more ch3ecking before sharing the CropLife draft comments to Brazil with you.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

This is the notification that was received by our European colleagues.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dear Euros and Joan,

We have just received a new WTO TBT notification from Brazil (see enclosed). According to the short content description, this concerns the following:

Draft Technical Resolution nº 87, 2 October 2015, regarding the pesticides' toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration.

This Resolution establishes the requirements and criteria to toxicological evaluation and classification, risk evaluation, the toxicological information in labels and leaflets, besides the procedures of pesticides' post-register alteration, its components and wood preservers in ANVISA's regulation.

Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

More on EU trade policy

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More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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http://www.symanteccloud.com

<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

<Comments on Brazil Anvisa tox requirements_draft_compiled.docx>

To: Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Lowit, Anna
Sent: Wed 1/27/2016 4:33:59 PM
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

I didn't know that something had already been started but Liz, Karlyn and I had put together some comments that we were going to submit via the anvisa website next week. we could pull those together tomorrow?

Sent from my Windows Phone

From: Vogel, Dana
Sent: 1/27/2016 11:27 AM
To: Lowit, Anna
Cc: Dawson, Jeffrey
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Please let me know what you think.
We will
Probably need to
Do the response

Dana Vogel
Sent from my iPhone

Begin forwarded message:

From: "Parrott, Patricia" <parrott.patricia@epa.gov>
Date: January 27, 2016 at 11:22:38 AM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dana: Brazil has proposed using the hazard based approach to pesticide registration (the English version is attached). We have been asked to comment on the draft US response (attached file dated 12-8-15).

With Bill gone and Daniella recused, I am trying to determine if we had provided comments previously or if we are OK with the response. If no one in HED has reviewed it, could

someone look it over to see if we need any changes? From my non-technical perspective it looks OK, but there may be a technical perspective missing--?

The problem is that we are overdue, and they are asking for us to concur or provide changes by this Friday, 29 Jan. Is there anyone who could look it over –focusing on the response (not the entire Brazilian proposal). Pls let me know. Thanks.

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Sanchez, Becxi - FAS [mailto:Becxi.Sanchez@fas.usda.gov]
Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

Thank you, Marielsie, Patricia et al,

Here are the draft comments currently in interagency review.

We look forward to receiving any edits you may have.

Cheers,

Becxi

From: Avila, Marielsie - FAS
Sent: Wednesday, January 27, 2016 8:27 AM
To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Patricia,

I don't have the requested comments. I was adding Becxi to the previous messsage so she can send them to you. Becxi is the coordinator for TBT measures.

Thanks,

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Parrott, Patricia [mailto:parrott.patricia@epa.gov]
Sent: Wednesday, January 27, 2016 8:24 AM
To: Avila, Marielsie - FAS; Taveau, Daniella; Sanchez, Becxi - FAS

Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Marielsie: There was no attachment. Would you pls resend. Thanks.

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

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Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

+Becxi Sanchez

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

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Of course. Marielsie-- can you please send Patty the latest version of the U.S. comments on the Brazil pesticide measure when you are back in the office?

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Sent from my iPhone

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Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Here is the information from Brazil.

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:

USEPA Headquarters

Clinton Building

1200 Pennsylvania Ave., NW

Mail Code (7501P)

Washington, DC 20460

Courier Address:

Potomac Yards South

2777 Crystal Drive

Room 12-235

Arlington, VA

From: Taveau, Daniella
Sent: Monday, November 09, 2015 2:53 PM
To: Jordan, William <Jordan.William@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Helfgott, Daniel <Helfgott.Daniel@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Bill,

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Second, I would like to set up a meeting with OPP and CLA to discuss this, NAFTA, and Codex among other things. Are there dates that work for OPP?

Daniella

Begin forwarded message:

From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

This is the notification that was received by our European colleagues.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

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More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

To: Janet Collins[jcollins@croplifeamerica.org]
From: Dawson, Jeffrey
Sent: Tue 2/7/2017 8:51:28 PM
Subject: Re: Potential meeting with CLA leaders

Janet

I will also call you tonight on my way home.

Thanks

Jeff

Sent from my iPhone

On Feb 7, 2017, at 2:10 PM, Janet Collins <jcollins@croplifeamerica.org> wrote:

> That's fine- any time in the morning would be good.
>
> If you give me a time and number I can phone you.
>
> Thank you
>
>
> On Feb 7, 2017, at 1:07 PM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:
>
>> Janet,
>>
>> I got your voicemail. I have a full day today so I probably can't call and have any significant time. Do you have a good time tomorrow? I'd also like to have Anna and Dana on… just so we are all on the same page if that works for you.
>>
>> If not, please let me know.
>>
>> Thanks!

Jeff

Jeffrey L Dawson

Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, June 23, 2016 8:53 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thanks Jeff- we will see you soon. Be safe

Sent from my iPhone

On Jun 23, 2016, at 8:33 AM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

We are in a cab but traffic is bad.

Thanks

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/22/2016 12:02 PM
To: Dawson, Jeffrey

Cc: Smith, Charles
Subject: RE: Potential meeting with CLA leaders

We would welcome it.

Thank you

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 11:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Janet,

Do you have any issues with Anna Lowit coming with us as well. She can really add a lot to the discussion.

Here is her info:

Anna Lowit– Senior Science Advisor For OPP since May 2016, before that senior scientist in for several years in HED.

Main areas of focus: all issues associated with toxicology, implementation of Tox 21, PBPK, use of epidemiology in risk assessment.

Thanks

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:52 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks very much Jeff.

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 8:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Thanks Janet…

Info for us…

Jeff Dawson – Acting Deputy Director of HED since October 2015, before that senior scientist for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk

assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with chlorpyrifos effort. Been at EPA since 1997. Also have worked at contract lab doing GLP pesticide studies.

Billy Smith– Acting Associate Director of HED since April 2016, before that branch chief for several years in HED.

Main areas of focus: occupational and residential exposure assessment, risk assessment, fumigants, development of exposure assessment tools and data (e.g., Res. SOPs, AHETF, etc.), heavily involved with glyphosate effort.

[Billy – if you see this please modify as needed. I took a shot since you aren't here today.]

Please let me know if you need more.

Jeff

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, June 22, 2016 8:40 AM

To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders
Importance: High

Jeff – thanks for the brief discussion this morning. We would like to ask that you and Billy come to meet with our Strategic Oversight Council around 9:00 tomorrow morning. Our address is listed below—we are close to McPherson Square Metro—take the exit for Vermont Avenue and then head away from the White House. We are on the corner of 15th and M Streets NW.

Thanks very much for your willingness to speak about the use of epidemiologic data and considerations for weighing evidence from tox studies and that from the epi work. I am certain SOC members will have questions for you both!

Could you please provide me with your titles and a bit about your work at EPA?

Please call me on my cell if you need further instructions on your way to the offices tomorrow.

My best,

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

From: Vogel, Dana [mailto:Vogel.Dana@epa.gov]
Sent: Tuesday, June 21, 2016 1:48 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Hi Janet,

My acting Deputy and Associate Directors (Jeff Dawson and Billy Smith) can attend. I have cc'd them on this email so please feel free to work directly with them on scheduling.

Thanks,

Dana

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic

study data into risk assessment, and perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

> Hi Janet,
>
> Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be

useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

From: Dawson, Jeffrey
Location: my office
Importance: Normal
Subject: FW: call Janet Collins re. epi workshop
Start Date/Time: Wed 2/8/2017 2:30:00 PM
End Date/Time: Wed 2/8/2017 3:30:00 PM

Janet –

Can we meet from 930 – 1030?

I will call your cell **Ex. 6 - Personal Privacy**

Thanks

Jeff

-----Original Appointment-----
From: Dawson, Jeffrey
Sent: Tuesday, February 07, 2017 2:29 PM
To: Dawson, Jeffrey; Vogel, Dana; Lowit, Anna
Subject: call Janet Collins re. epi workshop
When: Wednesday, February 08, 2017 9:30 AM-10:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: my office

To: Janet Collins[jcollins@croplifeamerica.org]
From: Dawson, Jeffrey
Sent: Tue 2/7/2017 7:24:26 PM
Subject: RE: Potential meeting with CLA leaders

Great, thanks!

Jeffrey L Dawson

Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, February 07, 2017 2:11 PM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: Potential meeting with CLA leaders

That's fine- any time in the morning would be good.

If you give me a time and number I can phone you.

Thank you

On Feb 7, 2017, at 1:07 PM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

I got your voicemail. I have a full day today so I probably can't call and have any significant time. Do you have a good time tomorrow? I'd also like to have Anna and Dana on… just so we are all on the same page if that works for you.

If not, please let me know.

Thanks!

Jeff

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Deputy Director

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Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, June 23, 2016 8:53 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thanks Jeff- we will see you soon. Be safe

Sent from my iPhone

On Jun 23, 2016, at 8:33 AM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Janet,

We are in a cab but traffic is bad.

Thanks

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/22/2016 12:02 PM
To: Dawson, Jeffrey
Cc: Smith, Charles
Subject: RE: Potential meeting with CLA leaders

We would welcome it.

Thank you

From: Dawson, Jeffrey [mailto:Dawson.Jeff@epa.gov]
Sent: Wednesday, June 22, 2016 11:49 AM
To: Janet Collins <jcollins@croplifeamerica.org>
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Subject: RE: Potential meeting with CLA leaders

Janet,

Do you have any issues with Anna Lowit coming with us as well. She can really add a lot to the discussion.

Here is her info:

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Main areas of focus: all issues associated with toxicology, implementation of Tox 21, PBPK, use of epidemiology in risk assessment.

Thanks

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Acting Deputy Director

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Phone: 703-305-7329

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Info for us…

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[Billy – if you see this please modify as needed. I took a shot since you aren't here today.]

Please let me know if you need more.

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Health Effects Division

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Phone: 703-305-7329

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To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
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Subject: RE: Potential meeting with CLA leaders
Importance: High

Jeff – thanks for the brief discussion this morning. We would like to ask that you and Billy come to meet with our Strategic Oversight Council around 9:00 tomorrow morning. Our address is listed below—we are close to McPherson Square Metro—take the exit for Vermont Avenue and then head away from the White House. We are on the corner of 15th and M Streets NW.

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Please call me on my cell if you need further instructions on your way to the offices tomorrow.

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Many thanks.

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To: Vogel, Dana <Vogel.Dana@epa.gov>
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I am doing further checking with my CEO but have not yet heard from him.

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Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Dawson, Jeffrey
Sent: Wed 11/30/2016 4:21:58 PM
Subject: Fwd: CLA Petition

I'm surprised it took them this long

Sent from my iPhone

Begin forwarded message:

From: "Davis, Donna" <Davis.Donna@epa.gov>
To: "OPP HED Managers" <OPP_HED_Managers@epa.gov>
Subject: FW: CLA Petition

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov<mailto:Zinn.Nicole@epa.gov>>; Moriarty, Thomas <Moriarty.Thomas@epa.gov<mailto:Moriarty.Thomas@epa.gov>>; Grable, Melissa <Grable.Melissa@epa.gov<mailto:Grable.Melissa@epa.gov>>; Nguyen, Khue <Nguyen.Khue@epa.gov<mailto:Nguyen.Khue@epa.gov>>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov<mailto:Newcamp.Caitlin@epa.gov>>; Parker, James <Parker.James@epa.gov<mailto:Parker.James@epa.gov>>; Jones, Ricardo <Jones.Ricardo@epa.gov<mailto:Jones.Ricardo@epa.gov>>; Jones, RDavid <Jones.Rdavid@epa.gov<mailto:Jones.Rdavid@epa.gov>>; Motilall, Christina <Motilall.Christina@epa.gov<mailto:Motilall.Christina@epa.gov>>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov<mailto:OPP_PRD_Managers@epa.gov>>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.
Director

Pesticide Re-evaluation Division (PRD)
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
(tel) 703 308 0052
(fax)703 308 8005
Mail code 7508P
Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov<mailto:Mosby.Jackie@epa.gov>>; Herndon, George <Herndon.George@epa.gov<mailto:Herndon.George@epa.gov>>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov<mailto:Guilaran.Yu-Ting@epa.gov>>; Keigwin, Richard <Keigwin.Richard@epa.gov<mailto:Keigwin.Richard@epa.gov>>; Layne, Arnold <Layne.Arnold@epa.gov<mailto:Layne.Arnold@epa.gov>>; Goodis, Michael <Goodis.Michael@epa.gov<mailto:Goodis.Michael@epa.gov>>; Perlis, Robert <Perlis.Robert@epa.gov<mailto:Perlis.Robert@epa.gov>>; Dyner, Mark <dyner.mark@epa.gov<mailto:dyner.mark@epa.gov>>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov<mailto:Housenger.Jack@epa.gov>>
Cc: Jay Vroom <JVroom@croplifeamerica.org<mailto:JVroom@croplifeamerica.org>>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.
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<FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf>

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Dawson, Jeffrey
Sent: Wed 7/13/2016 6:19:06 PM
Subject: RE: Workshop

Yes it would be all encompassing. That was the first ground rule we discussed

Sent from my Windows Phone

From: Vogel, Dana
Sent: 7/13/2016 2:15 PM
To: Dawson, Jeffrey
Subject: RE: Workshop

Ok, what exactly did we agree to do? Does it include other stakeholder groups beside registrants?

From: Dawson, Jeffrey
Sent: Wednesday, July 13, 2016 1:52 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Workshop

Yes, this is the epi workshop I believe... From when Anna, Billy and I went over there.

We should let jim know that on his 1 pager and the workshop concept.

Sent from my Windows Phone

From: Vogel, Dana
Sent: 7/13/2016 1:34 PM
To: Dawson, Jeffrey
Subject: FW: Workshop

Any idea on what this is about?
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Sent: Wednesday, July 13, 2016 1:33 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
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Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

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CropLife America

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Sent from my iPhone

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Dawson, Jeffrey
Sent: Wed 7/13/2016 5:52:09 PM
Subject: RE: Workshop

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CropLife America

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Sent from my iPhone

To: Curt Lunchick[curt.lunchick@bayer.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Dawson, Jeffrey
Sent: Thur 6/23/2016 3:16:28 PM
Subject: RE: muffin

funny

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Curt Lunchick [mailto:curt.lunchick@bayer.com]
Sent: Thursday, June 23, 2016 9:00 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: muffin

Offer him a tooth pick. Thanks

Sent from my iPhone

On Jun 23, 2016, at 08:15, Janet Collins <jcollins@croplifeamerica.org> wrote:

> Had to get lemon poppyseed! Blueberry not happening around our office!
>
> Sent from my iPhone
>
> On Jun 23, 2016, at 7:38 AM, Curt Lunchick <curt.lunchick@bayer.com> wrote:
>
> > Don't forget a blueberry muffin for Billy.

Best regards,

Curt Lunchick

Human Safety

<image001.png>

Crop Science Division	Tel: +1 919 549 2986
Bayer CropScience LP	Fax:
BCS-RD-DEVE-PROD, Human Safety	Mobile: +1 919 3688940
Building Research Triangle Park NC, Some Stall	E-mail: curt.lunchick@bayer.com
Zip-code City, Country	Web: http://www.bayer.com

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For alternate languages please go to http://bayerdisclaimer.bayerweb.com

To: Janet Collins[jcollins@croplifeamerica.org]
From: Dawson, Jeffrey
Sent: Thur 6/23/2016 12:33:39 PM
Subject: RE: Potential meeting with CLA leaders

Janet,

We are in a cab but traffic is bad.

Thanks

Jeff

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To: Lowit, Anna[Lowit.Anna@epa.gov]
From: Dawson, Jeffrey
Sent: Thur 6/23/2016 11:22:57 AM
Subject: logistics

Given the rain etc…

Probably head out to grab a cab at 820 or so.

Here is contact info:

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My cell is Ex. 6 - Personal Privacy

Let me know….

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Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

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Sent: Wednesday, June 15, 2016 8:23 AM
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Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Janet Collins[jcollins@croplifeamerica.org]; Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Smith, Charles[Smith.Charles@epa.gov]
From: Dawson, Jeffrey
Sent: Tue 6/21/2016 8:34:36 PM
Subject: RE: Potential meeting with CLA leaders

Janet,

Early tomorrow would be best.

Thanks!

Jeff

Sent from my Windows Phone

From: Janet Collins
Sent: 6/21/2016 4:33 PM
To: Vogel, Dana
Cc: Dawson, Jeffrey; Smith, Charles
Subject: RE: Potential meeting with CLA leaders

Thank you Dana.

Jeff and Billy- could we have a brief discussion this afternoon or early tomorrow (at your convenience)?

Thanks.

From: Vogel, Dana [mailto:Vogel.Dana@epa.gov]
Sent: Tuesday, June 21, 2016 1:48 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Hi Janet,

My acting Deputy and Associate Directors (Jeff Dawson and Billy Smith) can attend. I have cc'd them on this email so please feel free to work directly with them on scheduling.

Thanks,

Dana

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Smith, Charles[Smith.Charles@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
From: Dawson, Jeffrey
Sent: Tue 6/21/2016 5:06:55 PM
Subject: RE: Potential meeting with CLA leaders

I just thought it would be interesting for you since you hadn't seen them in this forum.

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Smith, Charles
Sent: Tuesday, June 21, 2016 1:06 PM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Its up to Dana. If you want me to go I'll go. This seems more like an Anna thing and a rehash of a bunch of previous stuff…

Charles " Billy" Smith

Acting Associate Division Director

Health Effects Division

Office of Pesticide Programs

703-305-0291

From: Dawson, Jeffrey
Sent: Tuesday, June 21, 2016 12:20 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: RE: Potential meeting with CLA leaders

I think we both should go – more eyes and ears and all that – but Thursday morning is best

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 11:36 AM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>
Subject: FW: Potential meeting with CLA leaders

Interested? Let me know.

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Health Effects Division

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CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Hrdy, David[Hrdy.David@epa.gov]
From: Schneider, Bernard - ARS
Sent: Fri 12/2/2016 3:14:50 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

Slap to epidemiologists

From: Schneider, Bernard A. [mailto:Schneider.Bernard@epa.gov]
Sent: Friday, December 02, 2016 9:52 AM
To: Schneider, Bernard - ARS
Subject: FW: CLA Petition

From: Miller, David
Sent: Friday, December 2, 2016 9:51:34 AM (UTC-05:00) Eastern Time (US & Canada)
To: OPP HED CEB; OPP HED TEB
Subject: FW: CLA Petition

CLA's petition on the 10x and epi studies.

Ashlee and Stacy – I've left hard copies on your respective chairs.

David

From: Davis, Donna
Sent: Wednesday, November 30, 2016 9:12 AM
To: OPP HED Managers <OPP_HED_Managers@epa.gov>
Subject: FW: CLA Petition

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

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November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: OPP HED CEB[OPP_HED_CEB@epa.gov]; OPP HED TEB[OPP_HED_TEB@epa.gov]
From: Miller, David
Sent: Fri 12/2/2016 2:51:34 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

CLA's petition on the 10x and epi studies.

Ashlee and Stacy – I've left hard copies on your respective chairs.

David

From: Davis, Donna
Sent: Wednesday, November 30, 2016 9:12 AM
To: OPP HED Managers <OPP_HED_Managers@epa.gov>
Subject: FW: CLA Petition

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall,

Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

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Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

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CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

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- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

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2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

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Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: OPP HED CEB[OPP_HED_CEB@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
From: Miller, David
Sent: Sun 7/17/2016 10:01:51 PM
Subject: FW: REWG meeting, August 16

FYI – Below looks to be in addition to the CARES session later that week. I am not sure I understand what "DER forms, volumes, seasonality" . Perhaps this relates to seasonality of consumption which I believe JMPR is working on. Specifically, Philip Verger sent out he following message a few weeks ago which I understand you all received:

Dear David, dear EPA Colleagues,

I would like to inform you the FAO and WHO just launch a call for expression of interest regarding possible approach (es) to estimate chronic dietary exposure for compounds used both at pesticides and veterinary drugs.

You will find the details in: http://www.who.int/entity/foodsafety/RequestForExpressionOfInterest.pdf

We hope you will be able to participate.

Best regards,

Philippe

Mike – since you are the rep to JMPR and this seems to be a JMPR thing, we should probably discuss what if anything you want to do. Do we want a coordinated US response among FDA, EPA, and USDA that basically says "currently, we're uncoordinated"? Or just one from EPA. It seems like FDA may be doing different things even within themselves. IARC is currently looking at this (but I don't think the FDA JEFCA rep (Mike DeNovi) is on this).

What more do you know about this? Note - too -the 30 July deadline and the current work being done by CEB with respect to "longer than a day" assessments as per Jim Jones earlier "the average doesn't sound like 'reasonable certainty of no harm' to me" statement.

I note that Phillippe approached me about this during CCPR48, and mentioned that Mike DiNovi from the US FDA was the rep (I think he is on JEFCA).

David

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Friday, July 15, 2016 5:06 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Reshma Arrington <rarrington@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: REWG meeting, August 16

David:

We would like to invite you to attend the REWG meeting on Tuesday afternoon, August 16. We have a slot reserved for your discussion at 1:30 p.m. to discuss "… ongoing & new joint projects with CLA-REWG - zoning, groups, DER forms, volumes, seasonality, etc." This is planned as a joint session with our Registration Committee. We are also extending an invitation to an FDA representative to attend that session – still to be identified.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Crowley, Matthew[Crowley.Matthew@epa.gov]; Hrdy, David[Hrdy.David@epa.gov]
Cc: Williams, Connor[Williams.Connor@epa.gov]
From: Miller, David
Sent: Wed 2/17/2016 3:14:11 PM
Subject: Fw: CLA Residue Experts Work Group meets on February 17

fYI - Mike D. and Jeff H. will be covering topics and they know I will be out. And I briefed Carmen on zoning. So CEB has not presentation responsiblities here.

Feel free to join call for pertinent issues if you like.

On a separate topic, we need to get prepared for the honey/glyphosate dicussion with FDA next week -specifically, one of the things is a risk back calculation that I asked Connor to do, working with David H - along the lines of tea.

david.

From: Tiu, Carmen (C) <tcarmen@dow.com>
Sent: Wednesday, February 17, 2016 9:52 AM
To: Sack, Chris A
Cc: Miller, David; Ray McAllister; Rasmussen, Mark - FAS; Herndon, George; Diana.Haynes@ams.usda.gov; Caldera, Mayra - FAS; Pat.Basu@fsis.usda.gov; Irrig Heidi USGR; Philip A Brindle; Reshma Arrington; Cheryl Cleveland (cheryl.cleveland@basf.com); Janet Collins
Subject: Re: CLA Residue Experts Work Group meets on February 17

Thanks, Chris!
Best regards,
Carmen

On Feb 17, 2016, at 8:54 AM, Sack, Chris A <Chris.Sack@fda.hhs.gov> wrote:

Everyone,

Been so busy, I just noticed we are meeting today. I will join the call around 2 to catch the discussion of honey and be available during the next session on enforcement. I don't have anything prepared to present, but glad to listen and provide input, as necessary.

Looking forward to hearing from you,

Chris

Ph: 240-402-2464

From: Tiu, Carmen (C) [mailto:tcarmen@dow.com]
Sent: Saturday, February 06, 2016 10:43 AM
To: Miller, David; Ray McAllister; Rasmussen, Mark - FAS; Herndon, George; Sack, Chris A; Diana.Haynes@ams.usda.gov; Caldera, Mayra - FAS; Pat.Basu@fsis.usda.gov
Cc: Irrig Heidi USGR; Philip A Brindle; Reshma Arrington; Cheryl Cleveland (cheryl.cleveland@basf.com); Janet Collins
Subject: RE: CLA Residue Experts Work Group meets on February 17

Many thanks David for continuing to provide support to our work-group. I am available next week to get in-sync on the Zoning and any other validation projects.

With best regards,

Carmen Tiu

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Friday, February 05, 2016 5:33 PM
To: Ray McAllister; Rasmussen, Mark - FAS; Herndon, George; Chris.Sack@fda.hhs.gov; Diana.Haynes@ams.usda.gov; Caldera, Mayra - FAS; Pat.Basu@fsis.usda.gov
Cc: Irrig Heidi USGR; Philip A Brindle; Tiu, Carmen (C); Reshma Arrington; Cheryl Cleveland (cheryl.cleveland@basf.com); Janet Collins
Subject: RE: CLA Residue Experts Work Group meets on February 17

Hello all,

I will be on annual leave during the date of the CLA meeting, but have spoken to Mike Doherty who has agreed to be available to cover the material. In any case, he would know more about the IESTI topic (1:00 to 1:30) (he attended the Geneva EFSA/WHO meeting last September) and is more in tune with the NAFTA Field Trial Requirements and Reduced Residue Field Trial Requirements.

A number of us (CLA + EPA) spoke a couple of weeks ago on the status of Global Zoning . I can bring Carmen up to date next week on the recent happenings since we met a couple of weeks ago.

Finally, we've alerted Jeff Herndon to the honey conversations we had during that CLA + EPA meeting a few weeks ago, and has the material provided.

1:00 to 1:30 pm	Codex needs/issues (IESTI)	Ray/David Miller
1:30 to 1:45 pm	Global support for Zoning Project	Carmen/D. Miller
1:45 to 2:15pm	NAFTA Field Trial Requirements – Draft Guidelines for Reduced Residue Field Trial Requirements	A. Chen, D. Miller

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, February 04, 2016 3:05 PM
To: Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Chris.Sack@fda.hhs.gov; Diana.Haynes@ams.usda.gov; Caldera, Mayra - FAS <Mayra.Caldera@fas.usda.gov>; Pat.Basu@fsis.usda.gov
Cc: Irrig Heidi USGR <heidi.irrig@syngenta.com>; Philip A Brindle <philip.brindle@basf.com>; tcarmen@dow.com; Reshma Arrington <rarrington@croplifeamerica.org>; Cheryl Cleveland (cheryl.cleveland@basf.com) <cheryl.cleveland@basf.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: CLA Residue Experts Work Group meets on February 17
Importance: High

Dear Colleagues:

We would like to invite you to meet with CLA's Residue Experts Work Group on February 17 to discuss the topics from the table below. We hope you can attend in person (see the address at the bottom of the message); conference call participation will also be available (877-304-4558 passcode 1775330125#). Please let me know:

- Do the times suggested here work well for you? Our meeting runs the afternoon of the 17th and morning of the 18th, so there is some flexibility in our scheduling. If necessary, the topics could be split up, not all kept together.

- Will other colleagues accompany you?

- Would you like to use presentation materials (PowerPoint)?

- Is there additional background we can provide in advance of the meeting?

- If you have any other questions.

Please note, there is strong interest and concern among several grower groups regarding the IESTI topic. We plan to invite them to participate in that specific discussion via conference call. We'll keep you apprised of which of them we anticipate will be calling in.

Time	Topic	Speaker
12:30 to 1:00pm	Import MRL FAS efforts/plans	Mark Rasmussen; Mayra Caldera
1:00 to 1:30 pm	Codex needs/issues (IESTI)	Ray/David Miller
1:30 to 1:45 pm	Global support for Zoning Project	Carmen/D. Miller
1:45 to 2:15pm	NAFTA Field Trial Requirements – Draft Guidelines for Reduced Residue Field Trial Requirements	A. Chen, D. Miller
2:15 to 3pm	CLA Paper MRLs for Honey to EPA, PMRA & USDA	J. Stewart, J.Herndon
3:00 to 3:45 pm	MRL Enforcement Methods & Analytical further harmonization needs	Pat Basu, D.Hanes, C.Sacks

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

1156 15th St NW

Washington, DC 20005

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Herndon, George[Herndon.George@epa.gov]
Cc: Hrdy, David[Hrdy.David@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Reshma Arrington[rarrington@croplifeamerica.org]; Miller, David[Miller.DavidJ@epa.gov]
From: Ray McAllister
Sent: Mon 2/8/2016 10:04:25 PM
Subject: Honey MRL ideas
CLA Proposal for setting MRLs in honey_EPA.PPTX
CLA Paper on Pesticide Residues in Honey_EPA rsm.pdf

Jeff:

The attached proposal and presentation are what we shared with David Miller, David Hrdy, and a few others a few weeks ago. This is what we would like to discuss in our Residue Experts Work Group meeting on the 17th. Note that these proposals are still in the formative stages, not fully developed yet.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

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202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Tuesday, January 26, 2016 3:46 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: RE: Meeting on Wednesday?

Attached is the draft paper on honey MRLs and a slide presentation explaining the approach, for

discussion tomorrow. These are not ready for sharing widely.

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To: Nako, Steve[Nako.Steve@epa.gov]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Hrdy, David[Hrdy.David@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]
From: Miller, David
Sent: Wed 1/27/2016 2:38:46 PM
Subject: RE: Meeting on Wednesday?

Cheryl,

This got ahead of me and I am just seeing this now. Tx Steve,

So we are indeed making arrangements to call you.

David

From: Nako, Steve
Sent: Wednesday, January 27, 2016 9:08 AM
To: Cheryl Cleveland <cheryl.cleveland@basf.com>; Ray McAllister <RMcAllister@croplifeamerica.org>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: RE: Meeting on Wednesday?

We can call you….at 1 919 547-2407.

From: Cheryl Cleveland [mailto:cheryl.cleveland@basf.com]
Sent: Wednesday, January 27, 2016 9:05 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>

Subject: RE: Meeting on Wednesday?

I will join by phone from RPT. I think I am the only one joining by phone so I don't necessarily need a conference line, but I do need a number to call into the conference room or I could just call Ray's mobile?

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

BASF
We create chemistry

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, January 27, 2016 9:02 AM
To: Nako, Steve <Nako.Steve@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: RE: Meeting on Wednesday?

I will arrive shortly before 10 a.m.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

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202-577-6657 (cell)

ray@croplife.us

From: Nako, Steve [mailto:Nako.Steve@epa.gov]
Sent: Wednesday, January 27, 2016 8:34 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: RE: Meeting on Wednesday?

I am here.

Call if you are coming and need to get upstairs.

-Steve

Office: 703.308.8092

Cell: 703.609.9357

From: Miller, David
Sent: Wednesday, January 27, 2016 7:56 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: Re: Meeting on Wednesday?

James and I will be there. I don't know about David Hrdy.

david.

From: Ray McAllister <RMcAllister@croplifeamerica.org>
Sent: Wednesday, January 27, 2016 6:07 AM
To: Miller, David
Cc: Hrdy, David; Jane M Stewart; Tiu, Carmen (C); Philip A Brindle; Cheryl Cleveland; Nguyen, James; Reshma Arrington; Nako, Steve
Subject: Re: Meeting on Wednesday?

David & David:

With the federal government opening 3 hours late today, will we still be able to meet at 10 a.m. at your offices?

On Jan 26, 2016, at 3:45 PM, Ray McAllister <RMcAllister@croplifeamerica.org> wrote:

Attached is the draft paper on honey MRLs and a slide presentation explaining the approach, for discussion tomorrow. These are not ready for sharing widely.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Tuesday, January 26, 2016 3:04 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: Re: Meeting on Wednesday?

David & David:

I'm working on a background paper and slide presentation to share with you for tomorrow's meeting. If my computer will cooperate from home, I'll get it to you in the next half hour.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

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ray@croplife.us

On Jan 25, 2016, at 5:28 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 4:16 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I will reserve a room at CLA as a backup, in case there is not a room available at Potomac Yards.

On Jan 25, 2016, at 3:43 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Re: Meeting on Wednesday?

Thanks. We'll plan on it.

On Jan 25, 2016, at 1:15 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

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ray@croplife.is

<CLA Paper on Pesticide Residues in Honey_EPA rsm.pdf>

<CLA Proposal for setting MRLs in honey_EPA.PPTX>

To: Hrdy, David[Hrdy.David@epa.gov]
Cc: Nako, Steve[Nako.Steve@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]
From: Ray McAllister
Sent: Wed 1/27/2016 2:18:27 PM
Subject: Re: Meeting on Wednesday?

I have paper copies of the two documents.

On Jan 27, 2016, at 9:13 AM, Hrdy, David <Hrdy.David@epa.gov> wrote:

Ray,

Look forward to seeing then!

David

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David E. Hrdy
Senior Scientist
CEB/HED/OPP/OCSPP
US EPA www.epa.gov/pesticides
Mailcode 7509P
Telephone: **703.305.6990**
Fax: 703.305.5147
OFFICE 10248 Potomac Yard 1 (South)
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Arrington <rarrington@croplifeamerica.org>
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From: Nako, Steve
Sent: Wed 1/27/2016 1:34:12 PM
Subject: RE: Meeting on Wednesday?

I am here.

Call if you are coming and need to get upstairs.

-Steve

Office: 703.308.8092

Cell: 703.609.9357

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To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Hrdy, David[Hrdy.David@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]; Nako, Steve[Nako.Steve@epa.gov]
From: Miller, David
Sent: Mon 1/25/2016 10:28:37 PM
Subject: RE: Meeting on Wednesday?

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

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To: Miller, David <Miller.DavidJ@epa.gov>
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David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
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Visit www.epa.gov/pesticides

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From: Miller, David
Sent: Mon 1/25/2016 8:43:03 PM
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Cc: Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]
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From: Ray McAllister
Sent: Fri 1/22/2016 2:46:03 PM
Subject: Re: Meet to discuss a few residue issues

A couple of us will plan to come to your office, and a few more might be on the phone.

The honey tolerance issue is a general approach, not chemical specific, and I don't believe it would involve EFED. I hope David Hrdy can join us.

Ray S. McAllister, PhD
Senior Director, Regulatory Policy
CropLife America
+1-202-872-3874 (office)
+1-202-577-6657 (cell)
ray@croplife.us

On Jan 21, 2016, at 7:50 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Ray,

Steve Nako and left you a voice mail message earlier today on this, suggesting you contact David Hrdy on this with respect to the MRLs/tolerances in honey. I have no idea what his is about. To the extent that this involves EFED or bee issues or a specific chemical, CEB would not likely be the appropriate place to talk about this.

With respect to discussions regarding zoning/exchangeability, that would be fine. James and I will both be here.

Sometime in the morning would be fine and we can give you an update. I presume that this meeting would be either by phone or you folks would come here.

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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, January 21, 2016 10:08 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Philip A Brindle <philip.brindle@basf.com>; Jane M Stewart <jane.stewart@basf.com>; Cheryl Cleveland (cheryl.cleveland@basf.com) <cheryl.cleveland@basf.com>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Meet to discuss a few residue issues
Importance: High

David:

A few folks from our Residue Experts Work Group could be in town next Wednesday the 27th, and we are wondering if you and your staff could make time in the morning (suggest 10 or 10:30 a.m.) to discuss a few projects. Please let me know right away, as they would need to make travel arrangements today.

- Preliminary ideas and proposal for MRLs/tolerances in honey;

- Progress on the zoning / exchangeability project.

Ray S. McAllister, PhD

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From: Miller, David
Sent: Fri 1/22/2016 12:50:04 AM
Subject: RE: Meet to discuss a few residue issues

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Cc: tcarmen@dow.com; Philip A Brindle <philip.brindle@basf.com>; Jane M Stewart <jane.stewart@basf.com>; Cheryl Cleveland (cheryl.cleveland@basf.com) <cheryl.cleveland@basf.com>; Reshma Arrington <rarrington@croplifeamerica.org>
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ray@croplife.us

To: OPP HED CEB[OPP_HED_CEB@epa.gov]; OPP HED TEB[OPP_HED_TEB@epa.gov]
From: Miller, David
Sent: Tue 1/12/2016 1:10:31 PM
Subject: FW: CLA Spring Conference

Any topics that you might be interested in…

David.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, January 12, 2016 7:58 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Reshma Arrington <rarrington@croplifeamerica.org>
Subject: CLA Spring Conference
Importance: High

Good morning David- and happy new year.

As I believe I mentioned previously, the CLA Spring Conference is scheduled for April 12-14 at the Renaissance Hotel in Crystal City. I wanted to ask if you or your colleagues have any specific topics that you would like to see on the program. I am certain that we will identify several in which you will have interest- and hopefully will be able to participate.

Thanks very much.

Janet E. Collins, Ph.D., R.D., CFS

Sr. Vice President Science and Regulatory Affairs

CropLife America

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Washington, DC 20005

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+1 (703) 868-3280 (mobile)

Fellow and Past President, Institute of Food Technologists

President, Phi Tau Sigma

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Nako, Steve[Nako.Steve@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]
Cc: Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]
From: Hrdy, David
Sent: Wed 1/27/2016 2:13:00 PM
Subject: RE: Meeting on Wednesday?

Ray,

Look forward to seeing then!

David

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David E. Hrdy
Senior Scientist
CEB/HED/OPP/OCSPP
US EPA www.epa.gov/pesticides
Mailcode 7509P
Telephone: **703.305.6990**
Fax: 703.305.5147
OFFICE 10248 Potomac Yard 1 (South)
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Sent: Wednesday, January 27, 2016 9:02 AM
To: Nako, Steve <Nako.Steve@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
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I will arrive shortly before 10 a.m.
~~~

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Subject: RE: Meeting on Wednesday?

I am here.

Call if you are coming and need to get upstairs.

-Steve

Office: 703.308.8092

Cell: 703.609.9357

From: Miller, David
Sent: Wednesday, January 27, 2016 7:56 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
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david.

From: Ray McAllister <RMcAllister@croplifeamerica.org>
Sent: Wednesday, January 27, 2016 6:07 AM
To: Miller, David
Cc: Hrdy, David; Jane M Stewart; Tiu, Carmen (C); Philip A Brindle; Cheryl Cleveland; Nguyen, James; Reshma Arrington; Nako, Steve
Subject: Re: Meeting on Wednesday?

David & David:

With the federal government opening 3 hours late today, will we still be able to meet at 10 a.m. at your offices?

On Jan 26, 2016, at 3:45 PM, Ray McAllister <RMcAllister@croplifeamerica.org> wrote:

Attached is the draft paper on honey MRLs and a slide presentation explaining the approach, for discussion tomorrow. These are not ready for sharing widely.

Ray S. McAllister, PhD

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David & David:

I'm working on a background paper and slide presentation to share with you for tomorrow's meeting. If my computer will cooperate from home, I'll get it to you in the next half hour.

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Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

<CLA Paper on Pesticide Residues in Honey_EPA rsm.pdf>

<CLA Proposal for setting MRLs in honey_EPA.PPTX>

Cc: Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]
To: Miller, David[Miller.DavidJ@epa.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
From: Hrdy, David
Sent: Mon 1/25/2016 9:11:25 PM
Subject: Re: Meeting on Wednesday?

Sounds great.

My meeting is a standing monthly meeting, Interagency Residue Control Group meeting with FSIS, that is not likely to take place this month. If the other meeting does take place, I will have a proxy sit in for HED.

I look forward to meeting with you on Wednesday. Rooms should not be too difficult, thank you for trying though David.

Best,

David

From: Miller, David
Sent: Monday, January 25, 2016 3:43 PM
To: Ray McAllister
Cc: Hrdy, David; Jane M Stewart; Tiu, Carmen (C); Philip A Brindle; Cheryl Cleveland; Nguyen, James
Subject: RE: Meeting on Wednesday?

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

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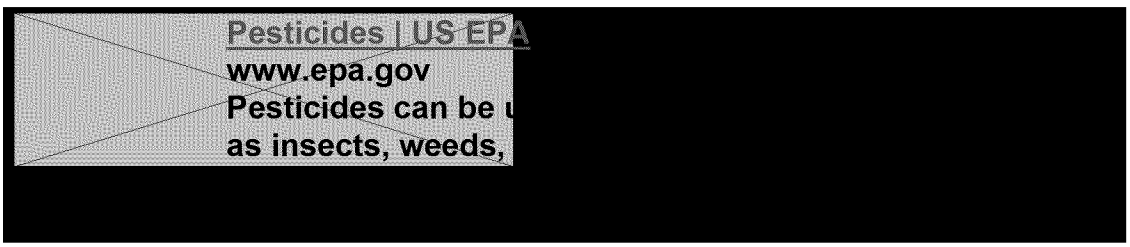

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

To: Jones, Jim[Jones.Jim@epa.gov]; Wise, Louise[Wise.Louise@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
Cc: Strauss, Linda[Strauss.Linda@epa.gov]
From: Mojica, Andrea
Sent: Mon 12/5/2016 4:11:19 PM
Subject: New CLA petition to halt chlorpyrifos decision
Lipsum - FINAL-CLA-Petition-Regulatory-Decision-Making-11-29-16.pdf

All,

Not sure if you have seen the latest CLA petition. The letter (attached) to Jack was dated last week, November 29, 2016. It asks that we halt regulatory decisions for organophosphates, chlorpyrifos specifically, that are "highly influenced/determined by result of epidemiological studies" that are not of high data quality and are not integrated into the risk assessment in a transparent manner.

Andrea

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Representing the Crop Protection Industry
1156 15th St. N.W., Suite 400 Washington, D.C. 20005 · 202.296.1585 phone 202.463.0474 fax www.croplifeamerica.org

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386 available at: https://www.regulations.gov/searchResults?pp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.
[3] See Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372 ; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.
[4] See EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment." [5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-02802016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id*. at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id*. at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Jones, Jim[Jones.Jim@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]; Strauss, Linda[Strauss.Linda@epa.gov]; Mojica, Andrea[Mojica.andrea@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]; Wise, Louise[Wise.Louise@epa.gov]; Layne, Arnold[Layne.Arnold@epa.gov]
From: Housenger, Jack
Sent: Sat 12/3/2016 10:38:42 PM
Subject: Fwd: politico on stakeholder meeting animal testing

Sent from my iPhone

Begin forwarded message:

From: Janet Collins <jcollins@croplifeamerica.org>
Date: December 3, 2016 at 5:35:45 PM EST
To: "Housenger, Jack" <Housenger.Jack@epa.gov>
Cc: "Lowit, Anna" <Lowit.Anna@epa.gov>, Jay Vroom <JVroom@croplifeamerica.org>
Subject: Re: politico on stakeholder meeting animal testing

Fair enough. What we convened Jack was a meeting of the human health risk assessment committee- our chair invited PETA and IIVCAM (?) to give their yearly updates. We did not draft this press release and had no part in its development- I believe it is PETA reaching out.

However, I take your point about EPA inclusion because after they left we had a significant discussion among CLA members about the need for US to REACH OUT TO YOU about next chapters in the in vitro space. I have strongly encouraged a collaboration and have suggested that WE need to make the invite to have the discussion about what can we do in this space that would be useful to our registrants as well as to EPA.

I regret that this work was positioned as it was- but, it is Politico. Please know that at every turn I am attempting to encourage our members to work collaboratively with EPA to ensure that the work that is supported through CLA is useful for registrations- and also to address specific questions that you have.

On behalf of CLA I can tell you that we welcome an opportunity to have a meaningful discussion about in vitro testing alternatives- Anna has repeatedly invited that and I regret that we have not taken full advantage. I will commit to that and reach out to Anna in the next weeks to try to schedule at least a preliminary discussion with her.

Thank you for your note- this type of communication is helpful and constructive.

My best

Janet

Sent from my iPad

On Dec 3, 2016, at 5:26 PM, Housenger, Jack <Housenger.Jack@epa.gov> wrote:

Janet, I was intrigued by the article below. Especially the part at the end which makes it seems as if CLA was somewhat responsible for this. I also heard that prior to our stakeholder meeting the other day CLA held a meeting on no animal testing with many of the participants that attended our meeting; however, we weren't invited. Just wondering about these given the apparent silence to date by CLA regarding this effort.

Subject: politico on stakeholder meeting animal testing

PETA, CROPLIFE HAPPY TOGETHER: It's not everyday that both People for the Ethical Treatment of Animals and CropLife America are both happy about a new EPA issuance. But that's the case with a final guidance issued Tuesday by the agency's Office of Pesticide Programs. It gives pesticide manufacturers the ability to forego the use of skin tests on animals when seeking approval for new formulations, and "has the potential to save 2,500 or more animals from being killed in pesticide tests each year," PETA says.

The guidance, which remains largely unchanged from a document issued by the agency in March, comes after OPP took a look at its testing procedures and concluded that, "for formulations, if oral data are available, then dermal data provide no added value to regulatory decision-making," PETA explains. "...By OPP's own count, the agency receives 200-300 dermal toxicity tests for formulations annually, which use about 10 animals per test," PETA notes.

CropLife, the trade association that represents pesticide manufacturers, says it worked closely with EPA and others over five years to assess the usefulness of the agency's testing requirements. "We welcome the move by EPA to focus its resources on those tests that inform the human health risk assessment," says Janet Collins, CropLife's executive VP for science and regulatory affairs.

To: Jones, Jim[Jones.Jim@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]; Wise, Louise[Wise.Louise@epa.gov]; Mojica, Andrea[Mojica.andrea@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]; Sisco, Debby[Sisco.Debby@epa.gov]; Dinkins, Darlene[Dinkins.Darlene@epa.gov]; Overstreet, Anne[overstreet.anne@epa.gov]; Keltz, Colleen[Keltz.Colleen@epa.gov]; Lowit, Anna[Lowit.Anna@epa.gov]; Dunton, Cheryl[Dunton.Cheryl@epa.gov]
From: Strauss, Linda
Sent: Fri 12/2/2016 5:05:23 PM
Subject: politico on stakeholder meeting animal testing

PETA, CROPLIFE HAPPY TOGETHER: It's not everyday that both People for the Ethical Treatment of Animals and CropLife America are both happy about a new EPA issuance. But that's the case with a final guidance issued Tuesday by the agency's Office of Pesticide Programs. It gives pesticide manufacturers the ability to forego the use of skin tests on animals when seeking approval for new formulations, and "has the potential to save 2,500 or more animals from being killed in pesticide tests each year," PETA says.

The guidance, which remains largely unchanged from a document issued by the agency in March, comes after OPP took a look at its testing procedures and concluded that, "for formulations, if oral data are available, then dermal data provide no added value to regulatory decision-making," PETA explains. "...By OPP's own count, the agency receives 200-300 dermal toxicity tests for formulations annually, which use about 10 animals per test," PETA notes.

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To: Jones, Jim[Jones.Jim@epa.gov]
From: Housenger, Jack
Sent: Fri 2/19/2016 7:10:23 PM
Subject: Fwd: DRAFT Meeting Agenda and Attendee List
Meeting Materials.pdf
ATT00001.htm

This is the agenda for our cla meeting on Monday. They wanted only a few topics to have a more in depth conversation.

Sent from my iPhone

Begin forwarded message:

From: Mary Jo Tomalewski <mjtomalewski@croplifeamerica.org>
Date: February 19, 2016 at 11:27:19 AM EST
To: "Housenger, Jack (Housenger.Jack@epa.gov)" <Housenger.Jack@epa.gov>
Cc: "Dinkins, Darlene" <Dinkins.Darlene@epa.gov>, "sisco.debby@epa.gov" <sisco.debby@epa.gov>, "Mack, Doris" <Mack.Doris@epa.gov>
Subject: DRAFT Meeting Agenda and Attendee List

Hi, Jack,

Attached is a draft agenda for our meeting with EPA on Monday, February 22 at 3:00p. Please review and let us know if you have any edits or suggestions.

Also attached is the attendee list. We are a large group this year, and I believe the room that we have reserved at the hotel can accommodate up to 60 people. Please let me know how many EPA staff will be present, so we can confirm space availability.

Thanks!

MJ

Mary Jo Tomalewski

Executive Assistant to the President & CEO

CropLife America

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Washington, DC 20005

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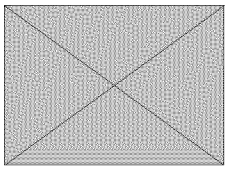

How can I serve you today?

EPA Office of Pesticides Meeting with
CropLife America (CLA) Leadership
Renaissance Arlington Capital View, *Studio C Room*
2800 S Potomac Avenue
Arlington, VA
Monday, February 22, 2016
3-5:00 p.m.

Agenda

A. **Welcome and Introductions** – Jay Vroom and Jack Housenger (**10 min**)

B. **Industry Overview Update** – Diane Allemang, FMC Corporation and CLA Board Chair (**20 min**)
   1. Agricultural economy and crop protection industry
   2. Preview: New CLA and European Crop Protection Association (ECPA) Study on Industry Research and Development
   3. Shared values and objectives – Industry and regulators
   4. RISE and CLA Spring Regulatory Conference – April 12-14, 2016

C. **Regulatory Issues Dialogue** – All (**75 min total**)
   1. Process and Consistency (**25 min**)
      (CLA discussion started by Jim Blome and Dana Sargent, Bayer CropScience)
   2. Information Transparency, Quality, Consistency (**25 min**)
      (CLA discussion started by Susanne Wasson and Constance Cullman, Dow AgroSciences)
   3. Fundamental Shift in the Regulatory Decisions (**25 min**)
      (CLA discussion started by Eric Wintemute and Cindy Baker Smith, AMVAC)

D. **General Discussion** – All (**15 min**)

E. **Adjourn**

DRAFT

EPA Office of Pesticides Meeting with
CropLife America (CLA) Leadership
Renaissance Arlington Capital View, *Studio C Room*
2800 S Potomac Avenue
Arlington, VA
Monday, February 22, 2016
3-5:00 p.m.

Attendee list

Board of Directors

Diane Allemang, **FMC Corporation, *Chair***
Milton Allen, **Helena Chemical Company**
Andrew Bodane, **Sipcam Advan**
Jeff Bunting, **GROWMARK, Inc**
Don Chew, **PBI/Gordon Corporation**
Rico Christenson, **Arysta LifeSciences**
William Culpepper, **SePRO Corporation**
Brendan Deck, **Nufarm Americas, Inc.**
Vern Hawkins, **Syngenta Crop Protection**
Jim Hay, **DuPont Crop Protection**
Jeff Johnson, **Nichino America**
Ted Ramirez, **Lonza**
Paul Rea, **BASF**
Mark Ripato, **Tenkoz, Inc.**
Mike Steffeck, **Pinnacle Ag Holdings**
Mike Vande Logt, **Winfield Solutions, LLC**
Eric Wintemute, **AMVAC Chemical Corporation**

Other CLA Members, Guests

Mike Allen, **Isagro USA**
Ed Barron, **Bayer CropScience**
Joe Bischoff, **Cornerstone Government Affairs**
Wesley Bolsen, **Cool Planet**
Heiri Gugger, **Kincannon & Reed**
Jim McVaney, **Bayer Corporation**
Lisa Nichols, **Crop Production Services**
Matt Perrin, **Bayer CropScience**
Mike Seyfert, **FMC Corporation**
Chuck Spencer, **GROWMARK**
Katie Zenk, **Land O'Lakes**

Strategic Oversight Council Members

John Cummings, **FMC, *Chair***
Jon Akins, **TKI**
Cindy Baker Smith, **AMVAC Chemical**
Constance Cullman, **Dow AgroSciences, LLC**
Steve Goldberg, **BASF**
Eric McEwen, **Gowan`**
Janis McFarland, **Syngenta**
Scott Rawlins, **Wilbur-Ellis**
Dana Sargent, **Bayer CropScience**
Scott Schertz, **Schertz Aerial**
Eric Tamichi, **Valent USA**
Mark Trostle, **Crop Production Services**

CLA Staff

Jay Vroom, President and CEO
Beau Greenwood, EVP Government Relations
Bill Kuckuck, EVP and Chief Executive Officer
Janet Collins, SVP, Science & Regulatory Affairs
Rachel Lattimore, SVP, General Counsel
Jeff Case, Senior Director, GR
Kristin Landis, Staff Attorney
Imad Saab, Director, Sci/Reg
Tamika Sims, Director, Sci/Reg
Aaron Hobbs, RISE

To: Jones, Jim[Jones.Jim@epa.gov]
Cc: Mary Jo Tomalewski[mjtomalewski@croplifeamerica.org]; Beau Greenwood[BGreenwood@croplifeamerica.org]
From: Jay Vroom
Sent: Tue 7/26/2016 10:27:19 PM
Subject: FQPA anniversary

Jim--

Wanted you to see the event invite-- hope you can come!

Jay

20th Anniversary of the Signing of the Food Quality Protection Act (FQPA)

Organized by the Pesticide Policy Coalition, American Farm Bureau Federation and CropLife America

Wednesday August 3, 2016

Offices of the American Farm Bureau Federation, 600 Maryland Avenue, SW, Suite 1000W, Washington, DC 20024

Roundtable discussion to feature opening remarks by **Senator Pat Roberts (KS)** and **former Congressman Charlie Stenholm (TX)**

Roundtable Discussion – 4:00p

Celebration Reception – 5:30 – 7:00p

Please RSVP by Monday, August 1 to Mary Jo Tomalewski (mjtomalewski@croplifeamerica.org, 202.872.3849)

__**Yes**! I plan to be at both the Roundtable and Reception

__**Yes**! I plan to be at the reception only

__**Regrets** – I am unable to join you August 3

Sent from my iPhone

To: Jones, Jim[Jones.Jim@epa.gov]; Pease, Anita[Pease.Anita@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Cowles, James[Cowles.James@epa.gov]; Goodis, Michael[Goodis.Michael@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]; Anderson, Neil[Anderson.Neil@epa.gov]; Sherman, Kelly[Sherman.Kelly@epa.gov]; Costello, Kevin[Costello.Kevin@epa.gov]; Friedman, Dana[Friedman.Dana@epa.gov]; Nguyen, Khue[Nguyen.Khue@epa.gov]; Snyderman, Steven[Snyderman.Steven@epa.gov]; Perlis, Robert[Perlis.Robert@epa.gov]; craig_aubrey@fws.gov[craig_aubrey@fws.gov]; cathy.tortorici@noaa.gov[cathy.tortorici@noaa.gov]; patrice_ashfield@fws.gov[patrice_ashfield@fws.gov]
Cc: Imad Saab[isaab@croplifeamerica.org]
From: Imad Saab
Sent: Mon 6/27/2016 10:57:14 AM
Subject: CropLife America comments on Draft Biological Evaluations of Chlorpyrifos, Diazinon, and Malathion
CLA OP BE Docket Cover Letter and Comments (final).pdf

;;;
TO: Jim Jones, Jack Housenger, Anita Pease, Jim Cowles, Michael Goods, Rick Keigwin, Neil Anderson, Kelly Sherman, Kevin Costello, Dana Friedman, Khue Nguyen, Steven Snyderman, Robert Perlis, Patrice Ashfield, Craig Aubrey, Cathy Tororici

FROM: Imad Saab

CropLife America

RE: EPA OPP Draft Biological Evaluations of Chlorpyrifos, Diazinon, and Malathion Docket identification numbers EPA-HQ-OPP-2008-0850, EPA-HQ-OPP-2008-0351, EPA-HQ-OPP-2009-0317 and EPA–HQ–OPP–2016–0167, 81 Fed. Reg. 21341 (April 11, 2016).

Attached please find CropLife America's comments on the three draft Biological Evaluations referenced above. These were submitted June 10, 2016 via Regulations.gov

Sincerely,

Imad Saab, Ph.D.

Sr. Director, Environmental Policy

CropLife America

515-344-7568

isaab@croplifeamerica.org

June 10, 2016

Mr. Michael Goodis
Acting Director, Pesticide Re-Evaluation Division
Office of Pesticides Programs
United States Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Submitted via Regulations.gov

Re: EPA OPP Draft Biological Evaluations of Chlorpyrifos, Diazinon, and Malathion, Docket identification numbers EPA-HQ-OPP-2008-0850, EPA-HQ-OPP-2008-0351, EPA-HQ-OPP-2009-0317 and EPA–HQ–OPP–2016–0167, 81 Fed. Reg. 21341 (April 11, 2016).

Dear Mr. Goodis:

CropLife America (CLA) appreciates the opportunity to comment on three draft Biological Evaluations (draft BEs) referenced above and to address the "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments" (Interim Approaches), released by the Environmental Protection Agency (EPA or the Agency) and the U.S. Fish & Wildlife Service and the National Marine Fisheries Service (the latter two collectively, the Services) on November 13, 2013. 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 of the vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners. CLA is committed to working with EPA to encourage practical, science-based regulation of its members' products.

While CLA recognizes the time and effort that went into the development of these draft BEs and the Interim Approaches, the draft BEs reflect seriously erroneous conclusions. These errors arise from flaws in EPA's current methods used to conduct an Endangered Species Act (ESA) assessment and demonstrate that the Interim Approaches are unsustainable and do not meet the goals that the National Academy of Sciences (NAS) proposed for a streamlined Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)/ESA consultation process. The Interim Approaches, as reflected in the draft BEs and related documents, is EPA's and the Services' first multi-agency attempt at an evaluation process responsive to the 2013 NAS Report.[1] While we recognize that the Agency attempted to post some documents in advance of the comment period opening, we note that these draft BEs provide the first opportunity for stakeholders to have access to the complete files and formally comment on the Interim Approaches. Given the gaps in the record[2] and EPA's refusal to extend the comment period, these comments only highlight the most striking scientific and procedural

[1] Nat'l Academy of Sciences, *Assessing Risks to Endangered and Threatened Species from Pesticides* (2013).
[2] Docket EPA–HQ–OPP–2016–0167, 81 Fed. Reg. 21341 (April 11, 2016) was published for public comment containing many instances of erroneous, incomplete and incorrect data and information.

shortcomings of the draft BEs, Interim Approaches and their related documents.[3] Nevertheless, CLA's necessarily limited review reveals that the draft BEs have not established appropriate data quality standards or meaningful tiered evaluations. In describing assumed chemical/species interactions, the draft BEs are filled with serious data errors, omissions and technical problems brought about by approaches that did not successfully address the NAS Panel's successive, tiered risk assessment goals.

THE NAS PANEL'S INTENT OF A TIERED PROCESS FOR RISK ASSESSMENT IS NOT ACHIEVED BY THE INTERIM APPROACHES

One common purpose of both FIFRA and the ESA is to assess foreseeable adverse impacts of regulatory actions. As such, both statutes are grounded in measuring ecological risk, including species and habitat. The Interim Approaches, as demonstrated here, have struggled with but failed to meet basic scientific standards for a tiered risk assessment. Due to unrealistic scientific assumptions, flawed models and missing or inappropriate applications of data and analyses, crucial steps in the assessment process that were envisioned by the Interim Approaches to screen out species do not do so.

In envisioning and now initially implementing the Interim Approaches, EPA and the Services seem to have missed a key point made by the NAS panel:

> The committee views coordination among EPA and the Services as a collegial exchange of technical and scientific information for the purpose of producing a more complete and representative assessment of risk, including the types and depths of analyses to be conducted at each step in the process. Such coordination would allow EPA's expertise in pesticides to be effectively combined with t he Services' expertise in life histories of listed species and in abiotic and biotic stressors of the species. . . . *The agencies can use Steps 1 -3 as a framework for such discussions but need not be constrained by them… .*[4]

Contrary to this advice, the draft BEs use an unnecessarily rigid, overly expanded and complex approach to the reevaluation of the effects of long-registered pesticide products on threatened and endangered species and their critical habitat. Although the Interim Approaches have adopted elements of the procedures and models from the Agency's FIFRA screening-level risk assessment process, EPA's assembly and application of those pieces is not transparent. The manner in which EPA has interpreted and implemented processes and models under the Interim Approaches disregards accepted and proven risk assessment processes and has lessened the certainty and reliability of results. In many cases, the Interim Approaches add unnecessarily conservative assumptions to already unrealistically conservative screening-level risk assessments, making them even less realistic, and thereby less relevant to meaningful risk assessment and screening. Additionally, the draft BEs are based on modeling that does not simulate pesticide exposures that are likely to occur in real-world environments, and use pathways or exposure scenarios that are

---

[3] More detailed and technical CLA comments are presented as an attachment to this letter and respond to EPA's April 5, 2016 instructions for commenting on the draft BEs (Instruction Letter).*See, e.g.*, EPA-HQ-OPP-2008-0351-0032, EPA Office of Chemical Safety and Pollution Prevention, "Instructions for Commenting on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion," (April 5, 2016).

[4] NAS Report at 35 (emphasis added).

EPA-HQ 2017-003964_0000418

either speculative or physically impossible, or both. As a result of these unrealistic assumptions,[5] the Interim Approaches have failed to provide evidence supporting the NAS Panel's goal of screening chemical and species interactions to successively eliminate risk presumptions and avoid wasting resources on multiple rounds of scrutiny of "what if" scenarios that are unlikely to exist.

Determining the impact of well-established farming practices on endangered species and their critical habitats, in accordance with the mandates EPA and the Services have been given by Congress, requires a much more reasonable focus that should include at least:

- Substantial synthesis of existing data on land use, land cover and species attributes, which is not currently undertaken in the Interim Approaches;
- Identification, qualification and use of data that are relevant, robust, reliable, and qualified for their fitness in risk assessment;
- Improved modeling and model parameters that are realistic, validated and representative of probable field conditions and interactions;
- Reasonable and representative scenarios; and
- To the extent the existing Services' "no effect/may affect" approach is retained, findings based upon factors more refined than simply co-occurrence.

THE BEs LARGELY IGNORE ESTABLISHED PRINCIPLES OF RISK ASSESSMENT

As the Agency is well aware, its regulatory actions must comply with its statutory obligations, which these draft BEs do not. The ESA requires that ESA assessments be based on the "best available scientific and commercial data," and neither FIFRA nor the ESA authorize EPA to use an overly precautionary approach.[6] The draft BEs clearly demonstrate that EPA not only did not use the best available science, but also improperly applied unrealistic and overly precautionary assumptions and principles. Indeed, each of the draft BE terrestrial and aquatic determinations and accompanying appendices, attachments and modeling tools suffers from a number of serious shortcomings that result in unreasonable overestimates of exposure and risk to endangered species from the OPs at issue. The shortcomings include:

- Use of unrealistic assumptions;
- Incorrect or irrelevant endpoints;
- Modeling design and errors;
- Failing to take advantage of best available biological information that would produce more realistic exposure estimates that are relevant to the species being assessed;
- Numerous examples of insufficient information; and
- Lack of support to enable reviewers to understand how model input values were selected.

---

[5] For example, the draft BEs assume the organophosphates at issue affect listed species if there is any overlap between pesticide use and a species' geographic range. The draft BEs ignore available temporal, agronomic, and geographical circumstances that eliminate the possibility of exposure.

[6] In addition to the ESA's mandate that EPA make decisions based on "available" information – not speculation – it also mandates avoidance of "needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives." *Bennett v. Spear,* 520 U.S. 154, 176-177 (1997.)

In short, the draft BEs are deficient in data quality and use of accepted risk assessment practices, and demonstrate serious technical flaws and unrealistic assumptions and judgments, resulting in an overly precautionary approach to risk assessment. Instead of moving forward with what is an unworkable process, the Agencies should agree that the draft BEs should be used as a learning exercise and, further, that future time and resources be spent on more effective and productive means of pesticide regulation coupled with species protection.

THE INTERIM APPROACHES WILL NOT ALLOW THE AGENCIES TO MEET STATUTORY TIMELINES

Both the ESA and FIFRA include specific mandates for timely action. FIFRA requires EPA to review every registered pesticide every fifteen years. Currently, EPA intends to complete ESA assessments and consultations as part of registration review. At the current rate that EPA and the Services are working, as evidenced by the BEs, there is simply no way that EPA can complete registration review within statutory timelines. With regard to the statutory timelines set out in the ESA, these draft BEs make it abundantly clear that EPA and the Services cannot conclude any formal consultation within 150 days from initiation of formal consultation, as is required by the ESA.[7]

EPA and the Services should consider procedural steps towards simplifying and streamlining the consultation process, including immediately implementing the Department of Interior's Counterpart Regulations for optional formal consultation procedures, as well as exploring the potential to address groupings or categories of species or habitats.[8] Consultation procedures that streamline the process will be far more protective of listed species and habitat and will fully comply with the Agencies' statutory FIFRA and ESA obligations. The Agencies should also explore opportunities for creative approaches to mitigation, including through conservation actions.

* * *

In sum, the draft BEs demonstrate that the Interim Approaches have failed as a predictive screening tool. Their use has led to "Likely to Adversely Affect" decisions for assumed interactions of species with chemicals that have been used safely across the country for 40 plus years. For example, the draft BEs show that the OPs are likely adversely affecting the Kirtland Warbler, a species well-documented as on the road to recovery. The Interim Approaches have therefore failed to provide a meaningful path towards a tiered risk assessment that will lead to an efficient, effective means to fulfill EPA's FIFRA and ESA obligations. Instead, they have created a process that does not screen and does not meaningfully assess risk, but instead threatens to remove from use valuable tools needed for production agriculture and public health, all while diverting resources away from more meaningful efforts towards species protection. CLA and its member companies continue to advocate for an ESA review process that works towards protecting species from potential adverse effects of agricultural operations.

[7] 16 U.S.C. § 1536(b)(1)(B).
[8] *See* 50 CFR §§ 402.46, 402.47.

CLA promotes reasonably characterizing use and exposure in a way that encourages more efficient and sustainable use of government, registrant and grower resources to continue to support species protection and, where possible, species recovery.

Sincerely,

Imad Saab, Ph.D.

Senior Director, Environmental Policy

Attachment: COMMENTS BY CROPLIFE AMERICA ON EPA OPP DRAFT BIOLOGICAL EVALUATIONS OF CHLORPYRIFOS, DIAZINON, AND MALATHION

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)

June 10, 2016

CropLife America
1156 15th Street NW
Washington, DC 20005
www.CropLifeAmerica.org

128 Pages

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1.0 INTRODUCTION

CropLife America (CLA) has called upon its member companies' scientific and regulatory professionals, as well as consultants to them, to compile as comprehensive a response as possible to the topics that EPA has listed in its April 5, 2016 instructions for commenting on the draft Biological Evaluations ("Instruction Letter"),[1] given the time available. CLA does not endorse the interim process nor the methods being, by EPA's own admission at various public meetings, "invented along the way" as a FIFRA/ESA process is experimentally applied, automated beyond the ability to produce meaningful results, and put forth as "best available science," something that the contents of the dockets definitely do not support or embrace. However, CropLife understands the monumental task before the Agencies, given the manner in which they have decided to address it. We therefore seek to provide meaningful, constructive comments on the draft Biological Evaluations ("BEs") and their supporting documents and have made every effort to organize this response in the manner requested by the Instruction Letter.

The Instruction Letter identified twelve topics for consideration (under the Instruction Letter's section entitled "Topics for Consideration and Comment" and comment and 7 grouped items to be addressed in a preferred outline (in the Instruction Letter as "How to Group Comments")). However, not all of the topics for consideration are included in the outline for grouping comments. Therefore, we have used the outline where it covers the topics EPA identified, and added a section that completes the coverage of the topics EPA identified as of interest. In this way, CLA has given a comprehensive response organized in the manner EPA requested.

1.1 Participants in this Commenting Effort

Participants in the production of these comments include those individuals listed in Figure 1.

[1] USEPA Office of Chemical Safety and Pollution Prevention letter from Neil Anderson, Kelly Sherman, and Kevin Costello to the Chlorpyrifos, Diazinon and Malathion Registration Review Dockets (EPA-HQ-OPP-2008-0850, EPA-HQ-OPP-2008-0351 and EPA-HQ-OPP-2009-0317, respectively) dated April 5, 2016 and titled "Instructions for Commenting on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion"

Figure 1. Individuals Contributing to these Comments

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1.2 Summary of Key Points and Recommendations

Key observations and recommendations in the sections of this comment document include but are not limited to:

- The hurried reaction pace driven by litigation deadlines has caused a leap into the use of the NAS Panel document as a policy guidance source for the procedural steps in a risk assessment. That transfer of authority is incorrect and confuses the exercise of FIFRA pesticide environmental risk assessment with the legal requirements for making no effect, may affect (NLAA/LAA) and jeopardy decisions under ESA. Incorrectly, flawed risk assessment procedures are being forced into the three decisional procedures of ESA, and in doing so, established FIFRA policy and environmental risk assessment policy have been ignored.
- The risk hypotheses as currently proposed are not set up to address the key factor/question in determining the risk to listed species. As written, there is an inherent assumption that exposure will occur, when one of the first questions that should be asked is whether or not there is a likelihood of exposure. It is only after it is determined that there is reasonable likelihood of exposure that the magnitude of exposure and potential effects should be addressed.
- The terrestrial and aquatic effects characterizations and the exposure assessments and their accompanying appendices, attachments and modeling tools suffer from a number of serious shortcomings that led to unreasonable overestimates of exposure and risk to endangered species for the 3 OPs. The shortcomings included use of unrealistic assumptions, incorrect or non-relevant endpoints, modeling errors, and failures to take advantage of best available biological information that would produce more realistic exposure estimates that are relevant to the species being assessed.
- The aquatic modeling was focused on defined aquatic Bins with a fixed set of dimensions (size and flowrate). The land area contributing to the fixed dimension Bin was modified by region of the country (defined by 2-digit hydrologic unit) following a complex, but not species specific analysis. The resulting aquatic exposure modeling presented in the BEs included some astronomically high EECs. The Agency has, in several public meetings, directly asked for help on aquatic modeling and has acknowledged that the methods envisioned for the Interim Approach are not providing output that is reasonable with respect to predicted concentrations, particularly in flowing water. CLA recommends that the Agencies reflect on the improvements we suggest here and rethink their approaches to modeling and the underlying aggregation methods (HUC units and bins).
    - The largest static bin, "Bin 7," was described as a "High-volume static," but is the standard 1 ha pond used in prior FIFRA assessments, not a new category representative of larger waterbodies as the name would indicate. Consequently, all static bins of smaller size are modeled using assumptions that go unrealistically and unjustifiably beyond the already conservative farm pond model. The biological evaluations fall short of using best data available. For example, the assessments include descriptions of aquatic species habitat and in many cases, actual waterbody names, but there is no use or synthesis of such data.
- For mosquitocide and other non-crop uses, there are ways to more accurately determine spatial distribution even in the absence of land cover and land use datasets. We have discussed an example of this in our discussion of ULV treatments of mosquitocides. We also observe that the

method the Agency used to portray nursery uses severely overstates use for many reasons, one of which is it combines pass-through "nurseries" with production and rearing locations.

- Little additional refinement was done in the iteration of Step 2, again resulting in missed opportunities to determine NE or NLAA outcomes that would simplify the overall process and conserve precious resources, particularly in the Services. Another difficulty with Step 2 is improper application of the weight of evidence process, so that any one of the lines of evidence can result in a LAA determination regardless of the weights of the other lines. Such improper application results in species not being screened out that are not at risk and that should be removed from further evaluation.
- Any additional non-fundamental attribute change such as altered behavior should be considered only when it can be linked to the three fundamental ones (survival, growth and reproduction) with exposure-response evidence that would reasonably be expected to occur and measurable in the environment. EPA has relied on the fundamental endpoints for decades when conducting appropriate risk assessments and this follows the recommendations in the 1998 Agency-wide (not just OPP) Risk Assessment Guidelines.
- EECs are estimated by predictive models and applied to the overstated spatial extent. The predictive models have both extreme conservativeness in model and scenario assumptions and large uncertainties in model accuracy and scenario relevance for listed species and their habitat requirements. Finally, none of this construct has undergone peer review or a validation process to insure the predicted exposures are fit for purpose, as described in the 2009 Guidance on the Development, Evaluation, and Application of Environmental Models, EPA/100/K-09/003 [2009 Guidance]).
- Rather than use grossly overstated predicted exposure values from faulty models as a line of evidence in the risk characterization, this portion of the analysis should instead rely on environmental monitoring data, when available, for chemicals like these that have been in use for many decades. Bringing in model predictions as a line of evidence should be deferred to the future when adequate models are available. EPA acknowledged that monitoring data is available and provides information that could be included, qualitatively, in the weight-of-evidence approach to support potential exposure pathways and exposure concentrations. However, monitoring data were not included as a line of evidence in the assessments.
- EPA's assessments use generalized opinions of "possible" (but unlikely) exposures exceeding "possible" (but not probable) effects thresholds expressed by using terms such as "could," "might," or "is possibly." These loose definitions all then combine with consistent EPA conclusions: that any level of exposure exceeding a threshold results in ecological adversity, and risk is claimed even when a particular assessment has great acknowledged uncertainty.
- Ranges of values are used instead of distributions and associated probabilities. The conclusions are not predictive, and are only precautionary, with no probability framework, as recommended in the 1998 Guidelines and the 2013 NAS report. The most useful risk hypotheses are those expressed in the form: "an exposure (x) to stressor (y) could, with probability (p), cause an

adverse response (z) of magnitude (m) in receptor (q)". Unfortunately, the BEs do not contain such useful risk hypotheses using quantitative risk characterization described in this manner.

- To establish relationships that are relevant to a valid risk assessment, the Agency should
  - (1) use taxonomic association between the listed species and laboratory species for appropriate effects thresholds,
  - (2) organize listed species by habitat type and apply appropriate exposure analysis based on these habitats,
  - (3) apply probabilities to risk analysis to get a better view of risk,
  - (4) consider effects endpoints against the frequency, magnitude and duration of exposure potential.

  This range of information provides a good relative range of risk. Otherwise all combinations are lumped together and a poor risk analysis is the result.

- The biological evaluation should exclude inflammatory and irrelevant discussions in incident reports regarding illegal (or unknown) product applications. Further, only the association between current use patterns and confirmed incident reports should be considered.
- The Interim Approach document, published in advance of Agency BE discussions, and CLA concur on sublethal effects: they are relevant only when associated with growth, reproduction and survival and reproduction. The BE spends a considerable amount of time collecting sublethal data, arraying the range of information, and then assuming that the lowest effects values for these measurements translate into whole organism and species effects, with little explanation or justification of how this is related to growth and survival of the species.
- The Agency's "lines of evidence for risk hypotheses" are actually assessment endpoints, not lines of evidence, and this is more than a matter of terminology. "Lines of evidence" and assessment endpoints are two related but very different things. The Agency gives no indication of criteria for weighing lines of evidence, or criteria for making decisions based on overall weight of evidence.
- There is just one line of evidence (for toxicity) being applied to several different attributes for a given assessment entity. "Chemical stressors" is a variation on toxicity involving environmental mixtures or the parent a.i. alone. "Abiotic stressors" are measures of characteristics (such as temperature, bacterial/viral prevalence, or environmental pH) that could enhance an assessment entity's susceptibility to the toxicity of the parent compound. Thus this WOE analysis comes down to just the basic exposure vs. toxicity comparison approach expanded to include a larger number of assessment entities and their attributes. While there may be useful information about toxicity to be gleaned from such an expansion, it does not constitute a WOE analysis that weighs a number of truly different types of evidence (i.e., that beyond just exposure/toxicity) to support conclusions about whether a pesticide may or may not pose a threat to a given assessment entity.

- Use of open literature data is appropriate only if properly screened for scientific method and completeness of documentation. Studies that fail distinctive, clear objective evaluation criteria should be given little or no weight in the weight-of-evidence process.
- Since many open literature studies use non-standard test designs, relevance is also an issue for consideration before incorporating data into the risk assessment. Therefore greater transparency is needed with regard to data reliability and relevance of the data used in the assessment.
- Much data selected for use, often including those data values identified as defining the most sensitive species, are of questionable value and acceptability. In addition, since many of the endpoints are not from standardized studies, the hazard values are not consistent and are generally not correlated to duration of environmental exposures. We recommend that Agencies use standardized GLP studies in the identification of the most sensitive species. For other consolidation purposes (*e.g.* SSDs) in higher tiers of risk assessment, additional studies of confirmed scientific rigor may be helpful.
- The lowest effects values were used across studies to calculate thresholds and construct SSDs, without respect to the relevance and reliability of the endpoint, the underlying quality of the study, or the relevance of the study to the species of concern. A functional weight of evidence approach and adequate effects characterization of species sensitivity is lost with this approach.
- The Agencies address using separate thresholds from studies conducted with the technical grade and formulated product when available. Toxicity values are used from the lowest toxicity threshold if they are from studies with the formulated product. What is missing, however, is a discussion of the relevance of the formulated products to the uses they are labeled for and their behavior from an environmental fate and relevance perspective.
- The main deficiency in the lines of evidence used in the BEs is the reality that, in effect, only a single line of evidence is brought into the analysis: toxicity. As pointed out above, this is made clear on page A9 (PF)-9, where risk is determined only by comparison of a point estimate of exposure to a variety of toxicity thresholds.
- There is no justification for the conservatism in the threshold for indirect effects based on mortality. The current approach sets the threshold at the concentrations/dose estimated to cause 10% effect on to the most sensitive species, or 5th percentile most sensitive depending on data availability, of the taxa that are relevant to the specific species being assessed. This value implies that the assessed species fitness depends on 90% survival of the most sensitive relevant species, which infers an obligate relationship between the assessed species and the relevant species which is not the purpose of this threshold. Further, this approach neither considers the duration of effects and recovery potential of the relevant species nor the diversity of the diet or habitat of the assessed species.
- Temporal scale is particularly important for interpreting ecological adverse outcome, and since the OP insecticides assessed in the BEs have been used for more than 50 years, the entire approach of the predictive analysis (that assumes this Agency action involves release of a new toxic chemical into the environment) is conceptually unsound. If one considers a listed species

to be challenged by multiple stressors limiting recovery, and a specific chemical stressor (for example, chlorpyrifos) is evaluated in a predictive assessment for its marginal contribution to possible extirpation and found to greatly impact the fitness of individuals of populations for 99.9% of the species, then it is reasonable to ask the question why this predicted mass extirpation has not occurred after decades of potential exposure. This question is not found in the BE analysis but should be considered.

- Regarding indirect effects thresholds for listed species that consume organisms that are dietary items, there is no practical relationship stated or justified between the thresholds used and their actual relationship to indirect effects. Indirect effects thresholds should be stated, or dealt with qualitatively as the Panel suggested.

2.0 ENVIRONMENTAL MODELS USED IN THE DRAFT BEs – TERRESTRIAL EXPOSURE

2.1 Overview

For terrestrial modeling, EFED briefly described the tools used to estimate exposure of birds, mammals, herptiles, terrestrial plants and terrestrial invertebrates to the 3 organophosphate compounds. For Tier I, EFED primarily relied on the TED tool which integrates T-REX for birds and mammals, T-HERPS for herptiles, the earthworm fugacity model, and TERRPLANT for terrestrial plants. EFED estimated exposure to terrestrial invertebrates via several methods (e.g., diet, dose, soil) and KABAM or empirical BCFs to estimate exposure to aquatic prey consumed by wildlife. AgDRIFT was used to estimate the distance from treated areas at which exposure due to spray drift is no longer a concern for receptors. EFED conducted higher tier probabilistic risk assessments for 13 listed bird species using TIM to estimate acute risk and MCnest to estimate chronic risk.

The terrestrial and aquatic effects characterization portion of Chapter 2 and the exposure portion of chapter 3 and their accompanying appendices, attachments and modeling tools suffer from a number of serious shortcomings that led to unreasonable overestimates of exposure and risk to endangered species for the 3 OPs. The shortcomings included use of hyper-conservative assumptions, incorrect or non-relevant endpoints, modeling errors, and failures to take advantage of best available biological information that would produce more realistic exposure estimates that are relevant to the species being assessed. In addition, there are numerous examples of EFED not providing sufficient information and support to enable reviewers to understand how model input values were selected. We discuss some of the major issues below. Given the short timeframe for review, however, there are almost certainly more issues that will be found in the future.

2.2 Missing Information

2.2.1 Information Contained in the Biological Evaluation Dockets

Insufficient information was provided in the BE dockets for reviewers to critically evaluate or replicate terrestrial exposure analyses. There are numerous examples of this issue for both the screening-level and refined terrestrial exposure analyses. Because of space considerations, we provide only two examples here.

Example 1: EFED considered potential indirect effects on terrestrial organisms by examining, among other things, effects on their food sources. Aquatic prey organisms, if affected by the OPs, were considered to contribute to an indirect effect on the listed species consuming these dietary items. EFED stated that concentrations in aquatic prey were estimated using empirical Bioconcentration Factors ("BCFs"), the Pesticide Root Zone Model (PRZM5), and the Variable Volume Water Model (VVWM) (Section 6 of Attachment 1-7). The Agency does not describe, however, how the water concentration estimates were derived using PRZM5/VVWM.[2] For example, they do not specify what assumptions were made regarding model scenarios (e.g., which aquatic bin or bins?) and parameters, nor do they specify an averaging period, or whether a mean or selected percentile was used to derive the exposure concentrations for risk assessment.

Example 2: The method for estimating EECs for listed terrestrial invertebrate species is not described in the BEs, nor are EECs presented for listed terrestrial invertebrate species. This comment was also made in the letter from the OP registrants requesting extension of the comment period.[3] EPA responded to this comment stating, *"Three types of EECs are calculated for terrestrial invertebrates: dietary based (mg a.i./kg-food), dose based (mg a.i./kg-bw) and in soil (mg a.i./kg-soil). EECs for different food items consumed by terrestrial invertebrates (e.g., broad leaves) are calculated in the same manner as described in Attachment 1-7 (see section 4). Dose-based EECs for terrestrial invertebrates that are above ground or soil-dwelling are also described in Attachment 1-7 (see section 4). The method for calculating exposures in soil is described in section 5 of Attachment 1-7. EECs are provided in the TED tools parameterized for each chemical (see response to previous comment for information on accessing this file) in the worksheets titled 'Min rate concentrations' and 'Max rate concentrations.'"* However, there are no dose-based EECs in the TED tool for terrestrial invertebrates. Moreover, to estimate dose, species body weight and food intake rate are required. No such information was provided in Chapter 3, Attachment 1-7 or in the TED tool.

[2] For more discussion of PRZM/VVWM, see Section 10.4 Evaluation of Exposure in Flowing Water Bodies and Non-Freshwater Habitats

[3] Weinberg (Weiley Rein) and Menotti (Crowell & Moring) to Goodis, April 29, 2016.

2.2.2 Use of Best Available Data

Repeatedly, EFED failed to use the best available data throughout the assessments. In many cases, EFED defaulted to out-of-date and now invalid input values, and thus did not apply the best available information in parameterizing their terrestrial exposure models. Several examples are presented below.

Example 1: Numerous field studies have been conducted with flowable chlorpyrifos (as well as the other OPs in the assessments) and these should be used to determine chemical-specific residue unit doses (RUDs). Instead of using these relevant and best available data, however, EFED relied on the generic RUDs that were calculated by Fletcher et al.[4] for all pesticides. The differences between chemical-specific and generic RUDs can be profound, because the properties of the product, the manner and setting in which it is used, and the application rates – as well as various other environmental factors – vary. For example, the generic mean and upper bound RUDs for above ground terrestrial invertebrates in T-REX and the TED tool are 65 and 94 mg ai/kg ww/lb ai/A (Table 3-17 in chlorpyrifos Biological Evaluation although units not specified there). Based on a comprehensive review of the available literature, however, Moore et al. (Section 1.2 of Appendix SI-3)[5] determined mean RUDs of 1.58 and 14.6 mg ai/kg ww/lb ai/A for soil surface invertebrates and foliage-dwelling invertebrates, respectively, in orchards. The corresponding values in field and row crops are 4.16 and 13.7 mg ai/kg ww/lb ai/A. These best available data should be applied to refine the screening- level generic assumptions. Use of the chemical-specific RUDs would lower exposure estimates to realistic levels for listed insectivorous bird, mammal, and herptile species as well as many listed terrestrial invertebrate species.

Example 2: In Section 3.2 of the chlorpyrifos Biological Evaluation, EFED stated that a foliar dissipation half-life of 4 days was used "based on data reported by Willis and McDowell (1987)"[6] to account for dissipation of pesticide residues on food items. This approach ignores more recently published information on foliar dissipation that would have enabled calculation of a dissipation half-life for each food item. As described in detail in Section 1.2 of Appendix SI-3 of Moore et al. ,[7]several high quality field dissipation studies are available that can be used to estimate half-lives for dietary items: below-ground invertebrates, foliage-dwelling invertebrates, and grass and broadleaf forage. The resulting mean half-lives (DT50s) of residue estimates for each food item are 3.12, 2.35, 2.92 and 2.09 days, respectively, which collectively indicate that EFED was overly conservative in assuming a foliar dissipation half-life of 4 days for every item of food.

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[4] Fletcher, J.S., J.E. Nellesson and T. G. Pfleeger. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environmental Toxicology and Chemistry 13:1383-1391.
[5] Moore, D.R.J., R.S. Teed, C.D. Greer, K.R. Solomon and J.P. Giesy. 2014. Refined avian risk assessment for chlorpyrifos. Reviews of Environmental Contamination and Toxicology 231:163-217.
[6] Willis G.H. and L.L. McDowell. 1987. Pesticide persistence on foliage. Reviews of Environmental Contamination and Toxicology 100:23-73.
[7] Moore, D.R.J., R.S. Teed, C.D. Greer, K.R. Solomon and J.P. Giesy. 2014. Refined avian risk assessment for chlorpyrifos. Reviews of Environmental Contamination and Toxicology 231:163-217.

Example 3: The food ingestion rate models used by EFED in the TED tool and TIM are based on a data review conducted by Nagy in 1987,[8] which is now considerably out of date. Food ingestion rate models have been updated and revised at least twice since the original publication (see Nagy et al., 1999,[9] Nagy, 2005[10]). The first and most extensive update (Nagy et al., 1999) involved the addition of data for 12 eutherian mammal species (increasing the eutherian mammal dataset by 26%), 45 bird species (nearly doubling the avian dataset), and 20 reptile species (which increased the reptilian dataset by almost 60%). The updates are in readily available peer-reviewed publications and thus there is no reason for EFED to have not identified and used these newer and best available data.

2.3 Corrections to Errors in EFED Models

For the Biological Evaluations, EFED developed several new risk assessment tools, applied untested automation routines, and extensively modified some existing models. These tools contain thousands of calculation cells and lines of code and it was thus impossible to carefully and methodically run a quality assurance (QA) evaluation of each new or modified tool under the time constraint for comment response – an exercise which should be completed thoroughly when any model is developed, merged with another, or modified. In a random exercise conducted for testing the validity of the models, several lines of code were pulled from the methods and spot-checked with respect to some of the calculations they produce. In making this incomplete but telling random check, closer examination uncovered troubling errors. A few examples are described below, and it is certain that more will be found with the complete QA evaluation that is required to ensure that these tools are reliable, relevant and correct.

Example 1: In their worksheets "min and max rate – dietary concentration results" of the TED tool, EFED estimates the "Number of exceedances of thresholds and endpoints for upper bound and mean EECs." These estimates are counts of the number of days that dietary EECs exceed threshold values per year. However, for terrestrial invertebrates consuming arthropods, the dietary EECs (i.e., mg a.i./kg diet) were compared to the dose-based thresholds (i.e., mg a.i./kg bw). This is an incorrect approach because dietary-based EECs, derived from dietary toxicity studies, cannot be compared to dose-based effects metrics, which are derived from single oral –gavage doses.

Example 2: In the TED tool, the Agency erroneously calculated the dermal route equivalency factor (F_{red}) as the oral LD50 divided by the log(dermal LD50) in column O of the "Min rate doses" and "Max rate dose" worksheets. Specifically, EFED neglected to raise the estimated log(dermal dose) to the power of

[8] Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monographs 57:11-128.
[9] Nagy, K.A., I.A. Girard and T.K. Brown. 1999. Energetics of free-ranging mammals, reptiles, and birds. Annual Review of Nutrition 19:247-277.
[10] Nagy, K.A. 2005. Field metabolic rate and body size. Journal of Experimental Biology 208:1621-1625.

ten to obtain the correct estimate for F_{red} (i.e., oral LD50 divided by dermal LD50). An example used in the spot-checking QA exercise conducted in response to the BEs demonstrates the implication for the avian exposure estimates and illustrates that this error in the TED tool *overestimates the dermal contact dose by 200 fold*.[11]

Example 3: In estimating exposure to listed wildlife predator species in the TED tool, EFED erroneously assumed that when a predator ingests vertebrate prey, it consumes their total daily intake, rather than their body burden. Prey body burden can be quite different from total daily intake for a variety of reasons but primarily because rates of uptake across the gut lining differ from rates of metabolism and excretion.

Example 4: The food ingestion rate parameters identified as applying to "mammals not in the Rodentia order" in the TED tool are incorrect and, in fact, apply to "all eutherians" assessed in Nagy (1987). The analysis that produced these parameter estimates was actually based primarily on rodent data (33 of 46 data points). Parameters for eutherians not in the Rodentia order were not reported for food intake rate by Nagy when he did his work in 1987.[12] Even in applying the older data to the model, it was done so incorrectly.

Example 5: In the TED tool, upper bound dietary EECs are incorrect for any listed species having large mammals as a dietary item (e.g., Florida panther with white-tailed deer and feral hog as primary prey). In the "min rate doses" and "max rate doses" worksheets, the cells in the "Upper bound Conc. in diet (mg/kg)" column for large mammal dietary items incorrectly reference the upper bound broadleaf plant EECs and not the correct "Large Mammals (1000g, short grass diet)" EECs. In short, EFED referenced the wrong cells, which results in the calculations that produce an incorrect value for all listed species having diets that contain large mammals.

2.4 EFED was Unreasonably Conservative in Selecting Exposure Scenarios and Input Values

Although it is appropriate to be conservative in the application of Tier 1 screening models, there are numerous instances of EFED being far too conservative, particularly when the best available data

[11] Consider the dermal contact exposure for the northern aplomado falcon (*Falco femoralis septentrionalis*) following a single application rate of 5.1 lb a.i./A of malathion. EPA estimated a dermal contact doseof 14,858 mg ai/kg bw. The upper bound dietary dose for a diet of arthropods was 110.3 mg a.i./kg bw. The estimated body weight for the falcon is 325 g. The surface area based on the equation provided in the TED tool is 473.6 cm^2. According to the Agency, F_{red} is 62.9, based on an estimated dermal LD50 of 2.16 mg ai/kg bw, which supposedly corresponded to an oral LD50 of 136 mg ai/kg bw. However, using the correct equation (i.e., log(dermal dose) raised to the power of ten), the dermal LD50 estimate shouldhave been 145 mg ai/kg bw and resulting in a F_{red} of 0.94. When the correct parameter values are used, the dermal contact dose for the northern aplomado falcon is 74.4 mg ai/kg bw, which is 200 fold lower than the EFED estimated dose of 14,858 mg ai/kg bw

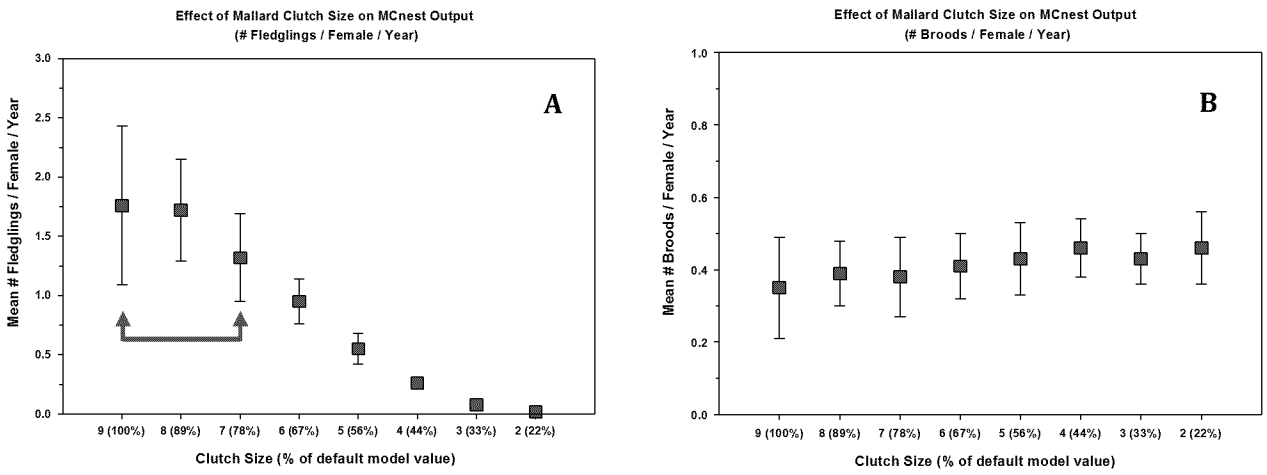
[12] Ibid

supported less conservative values. By introducing such unnecessary conservatism, the results of the Tier 1 screening process have little value. Further, the refined avian models, TIM and MCnest, are probabilistic models and therefore should have explicitly incorporated variability and uncertainty parameters rather than conservatively biased assumptions. In many aspects of these models, the recommendation of the National Academy of Sciences Panel ("Panel") to use uncertainty analysis and probabilistic methods was ignored. The following examples illustrate the hyper-conservativism in EFED's terrestrial exposure modeling.

Example 1: Exceedance of the reproductive toxicity threshold triggers a complete nest failure in MCnest. This assumption is overly conservative. For malathion, the reproductive toxicity threshold used in MCnest simulations was the NOEC for number of eggs laid, meaning that in laboratory studies, this is the level at which there were no observed effects on the number of eggs laid. To assess the biological and ecological significance of using percent reduction in egg production instead of assuming total nest failure, MCnest simulations were run using EFED's assumptions and results from control or untreated groups of mallards. Using the model in this fashion, adjusting the data from untreated (unexposed) animals, we demonstrate the flaw in nest failure predictions over time. For a specific example, baseline or control conditions for mallard (i.e., no exposure) with default life-history parameters from the EPA's mallard life-history library were used for subsequent model simulations, and were run reducing clutch size in a step-wise fashion. Fledglings per successful nest were reduced proportional to the clutch size reduction.

All other life history parameters remained constant at default values (i.e., baseline). MCnest output was

Figure 2. Effect of mallard clutch size on MCnest output under control (i.e., no exposure) conditions



compared across clutch size by visually inspecting 95% confidence intervals for Fledglings/Female/Year and Broods/Female/Year (see Figure 2).

Clutch size reduction to 78% of baseline resulted in a mean # Fledglings/Female/Year with substantial overlap of 95% confidence intervals with the baseline 95% confidence intervals (green arrow in Figure 2 above). Figure 2 (A) above demonstrates that if the percent reduction in eggs observed from an avian reproduction study is less than 22%, modeled fecundity responses from MCnest would be very similar to the baseline (i.e., clutch size = 9). However, in the refined avian analyses described in the OP Biological Evaluations, effects to 1 or 2 of 9 mallard eggs resulted in total reproductive failure. For the other OPs, the toxicity thresholds used in MCnest were different. For example, NOECs from avian reproduction studies based on a reduction in 14-d old nestling weight, an endpoint used in the other assessments, is highly unlikely to lead to the entire nest failure that EFED predicted. The assumption in MCnest that modeled doses above a selected reproductive toxicity threshold result in complete nest failure is overly conservative for a refined effects assessment because it is without scientific support and the degree of relevance of the endpoint to complete nest failure is not addressed or established in any way.

Example 2: To estimate inhalation dose to wildlife in treated areas, EFED assumed that all volatilized pesticide will be trapped beneath the crop canopy (see Section 7d in Attachment 1-7). This is obviously unrealistic and counterintuitive assumption. If a pesticide is sprayed downward, as in ground and aerial applications to field and row crops, interception will be greatest at the top of the canopy, which is exposed to the atmosphere. Thus, when intercepted pesticide volatilizes, much of it will diffuse into the open atmosphere, as opposed to an illusory closed system beneath the canopy. In scenarios in which the crop does not cover the ground entirely (e.g., orchards, early season field and row crops), there is little constraint on airflow below the canopy, particularly at the time scales of hours and days. Thus, the Agency's approach is overly conservative and not responsive to the portrayal of relevant physical processes. To make matters worse, the air concentration and respective volume of air respired were multiplied by 24 by EFED to estimate dose over a 24 hour period. This assumption is hyper-conservative because it does not account for any degradation or dissipation of the pesticide that would occur over a full day.

Example 3: In TIM and the combined TIM/MCnest, frequency on field (FOF) is the amount of time in a simulation that a bird spends on the treated field. TIM requires input values for mean, minimum and maximum FOF values to generate a beta-pert distribution of FOF values for the simulated species of birds. For agricultural fields, listed species that build their nests on the ground in grassland areas are defined as field residents, whereas other species are edge residents. For orchards and vineyards, field residents are those that build their nests on the ground in grasslands and woodlands as well as those that build their nests in the mid-story and canopy, whereas other species are edge residents. Mean FOF values for field residents and edge species are conservatively defined by EFED to be 97% and 69%, respectively, in agricultural fields and 87% for both field residents and edge species in orchards and vineyards. This generic approach to estimating mean FOF ignores a wealth of information available for nearly all listed bird species that should be used to derive much more scientifically defensible FOF distributions relevant to listed species. For example, the Kirtland's warbler exclusively forages in 5-23

year old jack pine forests at least 30 acres in size during the breeding season.[13] They have never been observed foraging in pastures or other habitats resembling field and row crops, yet EFED assumed that they were an edge species and thus obtained 69% of their diet from treated fields. Even during migration, over 80% of documented migrant warblers (n=184) were found in shrub/scrub habitat, which is characterized as habitat dominated by woody plants ≤20 feet in height and similar in structure to their breeding habitat (Petrucha et al., 2013).[14] An additional 10% of individuals were found in residential areas dominated by private yards.[15] Less than 4% of migrating individuals were found in each of parks, woodlands (closed canopy forest), and orchards (fruit tree plantations; spring only). Thus, EFED was hyper-conservative in characterizing the proportion of the diet that Kirtland's warbler obtains from treated pastures during the breeding season.

As an aside, the fact that (1) populations of this bird are rising, (2) one of its main stressors is cow bird nest parasitism, and (3) its recovery is being used as an example of landscape scale, ecosystem-services-based management should be taken into account at some point. Significantly, most of its breeding habitat is protected and managed using clear-cut logging and controlled burns and/or herbicides conditions that give the warbler the nesting conditions it requires and also allow sustainable forest product harvest.

Example 4: EFED used the TED tool to estimate exposure for insect pollinators rather than using the Bee-REX model. This is inconsistent with the Agency's policy to use exposure estimates from Bee-REX to assess the risk of pesticides to all pollinator species, a fact has been vetted by their Scientific Advisory Panel. Predicted contact exposure using T-REX (TED tool) is approximately 50 fold higher than the corresponding estimates from Bee-REX, thus resulting in highly exaggerated exposure and risk estimates for listed insect pollinator species and listed species that prey upon them or listed plant species that are reliant on them for pollination.

2.5 Necessary Terrestrial Modeling Improvements

The shortcomings in the BE terrestrial modeling must be improved before such exercises provide relevant, reliable and reproducible results. The Agency is not using best available data and realistic assumptions in the exposure and risk characterizations. They are also inappropriately using exposure tools in risk assessment before they have been fully evaluated, quality tested and peer reviewed. At this point in the interim process, EPA has not provided the technical details needed for a critical evaluation of the terrestrial exposure assessment methodology.

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[13] Donner, D.M., J.R. Probst and C.A. Ribic. 2008. Influence of habitat amount, arrangement, and use on population trend estimates of male Kirtland's warblers. Landscape Ecology 23:467-480.
[14] Petrucha, M.E., P.W. Sykes, Jr., P.W. Huber and W.W. Duncan. 2013. Spring and fall migrations of Kirtland's warblers (*Setophaga kirtlandii*). North American Birds 66:382-427.
[15] Ibid

3.0 COMMENTS ADDRESSING AQUATIC MODELS

The Agency has, in several public meetings, directly asked for help on aquatic modeling and has acknowledged that the methods envisioned for the Interim Approach are not providing output that is reasonable with respect to predicted concentrations, particularly in flowing water. In this section we address aquatic model inputs, models and their parameterization and spray drift, and in particular spray drift and mosquitocide use assessment. The appropriateness of model selection and the importance of model parameterization in various settings are also discussed.

3.1 Model Inputs

Some of the exposure model inputs are derived from interpretation of the (1) pesticide label's Direction for Use; (2) properties of the compound that affect its environmental fate and transport; and (3) drift estimates from drift modeling. Appropriate model input is critical to accurate estimates of exposure. However, the best science and relevant data have not been used to establish these values. Examples of shortcomings regarding EPA's selection are discussed below.

3.1.1 Pesticide Application Methods:

The BEs for chlorpyrifos and diazinon describe that selecting application dates, "considers a number of factors including label directions, timing of pest pressure, meteorological conditions, and pre-harvest restriction intervals." However, this has not been done. In the case of both of these pesticides, application timing appears to have only been based on the selection of the wettest month. The MAL assessment appears to be the only one that incorporated pest pressure information into application date selection. Although the pest pressure information for MAL was provided, it was not clear how and for which scenarios this additional information influenced the final selection of application dates.

EPA acknowledges that "efforts may be made to avoid pesticide application right before precipitation events," and that "usage data are available showing that pesticide applications commonly occur a few days before the day of precipitation events." However, it does not appear that use patterns and geographical variations are considered in any way, and that is extremely important because species do occur with regional and seasonal specificity. Considering only a worst case to represent all uses and all locations deprives the assessment of the opportunity to eliminate species from concern in cases where application timing is different from seasonal species presence. There is no reference provided for the usage data EPA mentions, which prevents determining whether the usage data is representative of all use patterns and all geographical areas where the pesticide is applied. Additionally, if usage information are not based on long term trends, then the selected application date likely will not be a "reasonable estimate."

3.1.2 Environmental Fate and Transport:

The interpretation of the environmental half-life of a product is critical to its proper selection as an input to modeling. However, the BEs do not include any details about kinetic modeling to determine DT50s (Disappearance Time 50, the time required for the concentration of the test substance to decline by 50% of the initial value). The Agency states in the BEs that theDT50s are based on revised kinetic analyses using recent NAFTA guidance. However, detailed inputs and outputs from the revised analyses are not included, thus it is not possible to determine if the environmental half-lives are correctly derived and reproducible.

Additional environmental fate parameters are listed as ranges and do not detail individual values. Sources for the data are not always included. The BEs state that literature values were included in the environmental fate dataset; however, there is no mention of a process in which the literature data was deemed acceptable. Without confidence in the appropriateness of these parameters, their use as inputs to models cannot be validated.

3.1.3 Drift Estimates:

The drift methods followed standard practice for Tier2 FIFRA risk assessment and thus greatly overstate potential exposure. Each assessment assumed that the wind was blowing in the direction of the receiving water body at ~10mph for every application of the 30-year simulation and that drift reduction technology, which may be specified on the label or in best management practices, was not taken into account. The probability of applications actually occurring when the wind is blowing toward the water body should be stated to put data into context. Including probability in the assessment process was an explicit recommendation of the NAS Panel. Reflecting the label language and best management practices is also in concurrence with the Panel's recommendation to use best available data and science.

The drift values used are upper end estimates and do not reflect of realistic environmental exposure conditions. Adjusting the prediction by including variable wind speed, equipment factors, and wind direction over the course of a simulation would produce more realistic loadings.

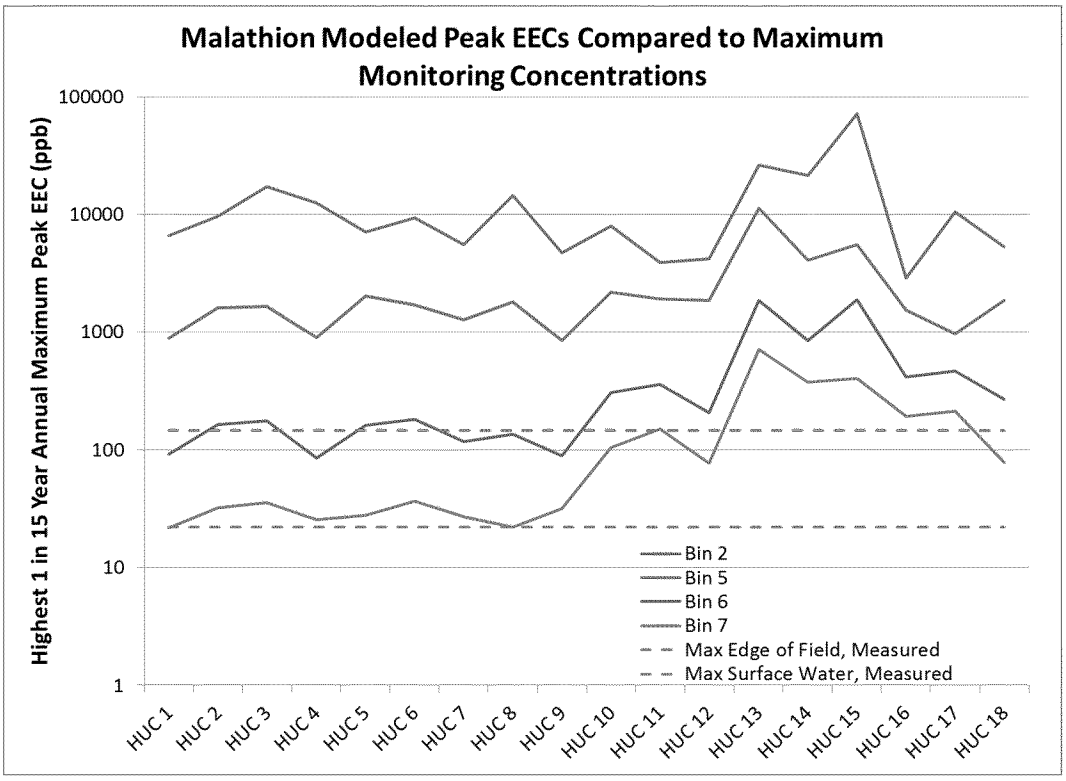
3.2 Aquatic Models

3.2 Aquatic Exposure Modeling

The aquatic modeling was focused on defined aquatic Bins with a fixed set of dimensions (size and flowrate). The land area contributing to the fixed dimension Bin was modified by region of the country (defined by 2-digit hydrologic unit) following a complex, but not species specific analysis. The resulting aquatic exposure modeling presented in the BEs included some astronomically high EECs. The modeled peak EECs reported in the BEs includes values as high as 71,800 ppb for malathion, 65,500 ppb for

diazinon, and 69,900 for chlorpyrifos (final EECs reported for chlorpyrifos were capped at its assumed solubility of 2,000 ppb). These EECs do not include the modeled values for Bin 3 and Bin 4, which were reported in the BEs to be as high as 393,000 for malathion, 2,730,000 ppb for diazinon, and 121,000,000 ppb for chlorpyrifos! The BEs acknowledged problems with this original set of modeled EECs for Bin 3 and Bin 4, and presented an evaluation of potential refinement approaches to improve the modeling results. Because the refinement approaches explored were not successful for all 3 OPs, the final approach used to arrive at EECs for Bin 3 and Bin 4 was to scale them from Bin 2 EECs by factors of 5x and 10x respectively. This resulted in predicted concentrations as high as 6,550 - 7,180 ppb in flowing water habitats representing major watersheds of main-stem rivers with average flow rates of 100 m^3/s or greater. The highest concentrations ever measured for these three OPs in any surface water body are in the range of 15 ppb – 62 ppb, more than two orders of magnitude lower than some of the predicted concentrations in major rivers. The peak EECs predicted for in the BEs were up to several orders of magnitude higher than maximum measured concentrations across all the aquatic habitat bins, flowing and static. Furthermore, these peak receiving water EECs were several orders of magnitude higher than peak measured edge of field concentrations. Figure 3 below shows this comparison for Bins 2, 5, 6, 7 and 7 for malathion. These predicted exposure concentrations are not conservative or protective, rather they are implausible and uninformative for use in the endangered species risk assessment process.

Figure 3. Malathion Modeled Peak EECs Compared to Maximum Monitoring Concentrations



Further evidence of the errors in the predicted peak EECs in reported in the BEs can be shown by comparing the modeled edge of field concentrations to the peak EECs in the receiving water bodies. This analysis was conducted by re-running the BE scenarios with drift set down to a negligible value (0.001) so that a direct comparison could be made between runoff concentrations and the resulting receiving water concentrations. Figure 4 below is an example for chlorpyrifos and Bin 2 EECs. Both dissolved and total (dissolved plus sorbed) concentrations are shown. The exposure results shown are from 1,247 agricultural and broad area use non-seed scenarios that were run for chlorpyrifos BE. The dissolved edge of field concentrations are 1 to 2 orders of magnitude lower than the receiving water EECs across all of the scenarios. The total edge of field concentrations, much higher than we would expect to be relative to dissolved water body concentration, are still often an order of magnitude lower than the receiving water concentrations. This is physically impossible to achieve in reality and is evidence that the methods and assumptions that went into generating these exposure predictions contain fundamental errors.

The anomaly of receiving water EECs being higher than edge of field EECs is not limited to Bin 2. It occurs for some of the ESA scenarios across all of the four habitat bins modeled. Figure 5 shows the ratio of 1 in 15 year annual maximum peak receiving water EEC to the 1 in 15 year annual maximum peak edge of field EEC. Values of greater than 1.0 indicate receiving water concentrations greater than edge of field concentration. While in reality, we would expect receiving waters to provide, sometimes substantial, diluting effects, the predicted receiving water peak EECs often show the opposite.

Figure 4. Chlorpyrifos Bin 2 Peak EECs Compared to Peak Edge of Field EECs

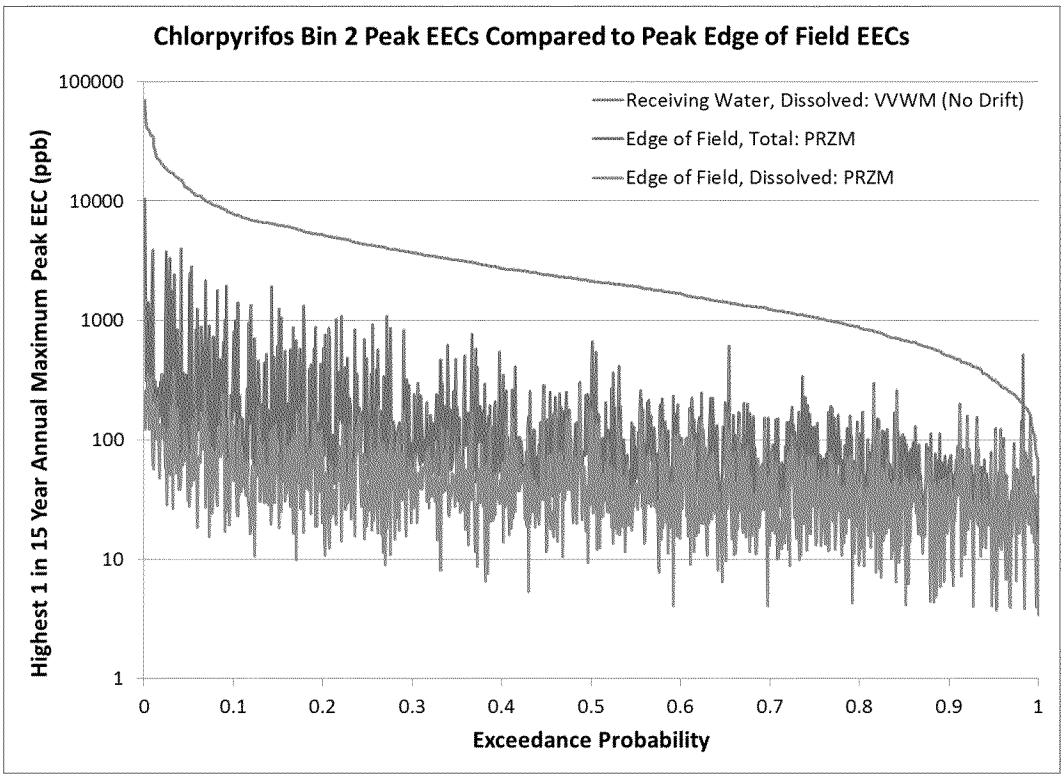
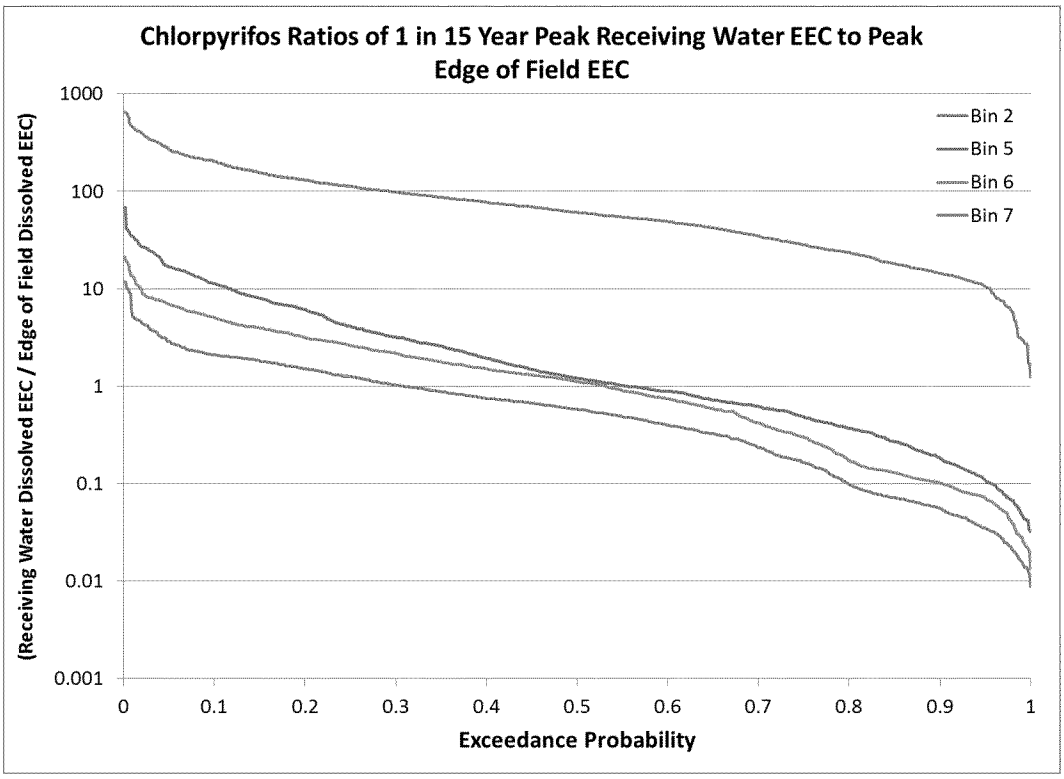


Figure 5. Chlorpyrifos Ratios of 1 in 15 Year Peak Receiving Water EEC to Peak Edge of Field EEC



CLA has provided comments on many aspects of the BE aquatic exposure modeling throughout this document. Many of these comments are directed towards very specific aspects of scenario selection, model selection, and model parametrization. While the hope is that these specific comments will lead to an improved overall modeling approach, they should not be received without also addressing the most significant issue that must be dealt with is the erroneously high EECs predicted for many of the scenarios resulting from large relative watershed sizes and the implausible assumption of instantaneous pesticide loading to a receiving water with no dilution from runoff water. Additionally, the biological information included in the BEs were not utilized to create species relevant exposure values or even provide at a minimum a confirmation of the weather, soil, or receiving waterbody appropriateness to specific species.

3.2.1 Scenario Development for the Agricultural Environment

The aquatic exposure methods relied heavily on models and tools available and validated for FIFRA assessments, including a suite of scenarios that have been developed under FIFRA and through peer

review. Those models over-predict actual environmental concentrations of pesticide residues in water.[16] However, in the BEs, the existing models were modified and catchment descriptions altered in a way that introduced even more unrealistic characteristics and over-prediction in the model outputs. The existing scenarios for crops and soils were modified selectively, without a logical and defensible derivation of a new "scenario." Instead, the crop-representative scenario was moved to a watershed/waterbody "scenario" by introducing selective changes that have not been validated for relevancy or realism. For example, modifications to account for a watershed-based approach were made by arbitrary changes to the assigned weather station(s) that would have been used in the existing crop-based scenarios. In existing scenarios, a fixed 10 ha treated area to 1 ha standard pond has been used to represent the "worst case" runoff situation. In the modified scenarios, the standard pond in the middle of the field was replaced with multiple fixed receiving water bodies and an elaborate method of changing the contributing area size, without justification of how these changes were relevant to the actual dynamics of an agricultural watershed area. Furthermore, suites of actual conditions surrounding listed species were not developed and evaluated, and new and relevant scenarios were not created. The scale of the watershed scenario is so large that the localized conditions that are specifically important to characterize species exposure are lost. For example, the watershed selected to represent the Pacific Northwest covers 177,523,042 acres and encompasses everything from temperate rain forest to arid desert conditions. Although the changes EPA has introduced appear to lead to a complex screening-level tier, they actually remove refinements and understandings that have been built up over the many years of FIFRA risk assessment and eliminate many species-relevant exposure values.

The arbitrary, broad brush approach described above is unresponsive to the Panel's recommendations to use best available data, including data and expertise available from the USDA. Beginning in 2007, USDA's National Agricultural Statistics Service (NASS) published census data by watershed.[17] In contrast to EPA's use of only 19 regions to represent the entire US, data from the Census of Agriculture are available for 38 individual land characteristics at the 6-digit Hydrologic Unit Code (HUC) level. To explain this further, EPA has represented their scenarios at the 2-digit HUC level, which for the Pacific Northwest spans 177,523,042 acres – only 27% or less of which is in farms. To better account for species and farm distribution, EPA should subdivide these regions using more refined USGS subregions. The HUC 2 region is divided by USGS into 221 subregions (4-digit HUC level) based on water flow patterns from the major rivers within the region. The subregions are further divided into 376 basins (6-digit HUC level). Even at this level of refinement, there remain an average of over 472,000 acres in a 6-digit HUC unit, much larger than the actual critical habitat and the contributing areas to many species found in very limited and defined locations.

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[16] Multiple presentations on this topic from task forces (FESTF, PWG for example) and registrants are available from EPA Public Workshop presentations, SETAC, ACS and CLA conferences and we will gladly provide specific copies to further support the details discussed here

[17] USDA Census of Agriculture 2012 Census by Watershed. https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Watersheds/

3.2.2 Aquatic Exposure Modeling Tools

The Pesticide Water Calculator (PWC, running PRZM5 and VVWM) model is adequately documented and is a continuation of established exposure methodologies used in EPA FIFRA tiered assessment approaches. The assumptions and limitations are well known. The simple application of this tool with generic scenarios may be appropriate as a screening-level assessment, but these screening-level assessments do not provide species-specific results. This tool is inadequate for representing more complex landscape elements that are necessary to put species-specific exposure in context.

The model PFAM is used to represent exposure resulting from applications to cranberries, a "worst case" setting for aquatic exposure. The cranberry aquatic exposure setting is used to represent all crops and species aquatic exposure assumptions. Depending upon the BE, PFAM version 1.0 or 1.104 was used. Version 1.104 is not available on the EPA Pesticide models webpage, only version 1.0 is available. Furthermore, documentation, descriptions of crop scenarios used, and model output details are lacking and the results reported by EPA cannot be verified or duplicated.

Although PFAM can be used to simulate concentrations in a receiving water body, a conceptual model has not been developed and was not included in the ESA modeling effort... This method assumes species are exposed to in-paddy/bog concentrations because concentrations in flood water releases are used without considering the nature of the receiving area. This is inappropriate for organisms like fish, living in existing receiving waters in which dilution occurs, or for flood releases or overflows spilling into a dry environment (no dilution) where fish would not be present in what was a previously dry environment.

The specific details of the cranberry simulations were not provided, but in rice scenarios that have been provided by EPA, water levels and weir heights were set to the same height. In practice there would be room for paddies/bogs to have some rain without causing overflows/runoff. However, all rice scenarios are set up such that any rain amount greater than the evaporation on that day will cause overflow. Also, since the water level is maintained daily at that level in the scenarios, daily irrigation is triggered and the water levels never go down. These two factors are significant because exposure is based on overflow concentrations. Due to this set-up, overflows will happen much more frequently than in reality and will not allow degradation in water/sediment phases and photolysis to occur before overflows, as it would in a reasonable portrayal of a field setting.

As presented, the EPA Downstream Dilution tool (Appendix 3-5) has documentation of limited detail related to the actual methods, assumptions, inputs, and history of regulatory use. It is important to understand how the tool estimates a "distance" downstream that in turn predicts which concentrations are high enough to cause potential effects, or low enough to be below a level of concern. Explanation on these aspects is completely missing from the documents. Before using a new tool, EPA is obligated to provide source information, detailed methodology, QA/QC procedures and adequate documentation so that the public can verify their assumptions and repeat the analyses.

3.2.3 Parameterization of the Various Aquatic Bins

EPA's aquatic bins are defined based on a fixed, limited set of dimensions applied uniformly across the country. Although this was an attempt to move away from use of the single "farm pond" model, the bin dimensions are not based on best available science and the bins overlook species- and geographically-specific factors. The assumption that all aquatic endangered species can be represented appropriately by waterbodies with dimensions fixed to 9 options is flawed and a severe limitation of the assessment. For example, the biological evaluations include descriptions of widely diverse environments that are represented by a single bin, such as the description for "Bin 5, low volume" which is intended to represent "vernal pools, small ponds, floodplain habitats that are cut off from main channel flows, underground pools, and seasonal wetlands." Furthermore, the largest static bin, "Bin 7," was described as a "High-volume static," but is the standard 1 ha pond used in prior FIFRA assessments, not a new category representative of larger waterbodies as the name would indicate. Consequently, all static bins of smaller size are modeled using assumptions that go unrealistically and unjustifiably beyond the already conservative farm pond model. The biological evaluations fall short of using best data available. For example, the assessments include descriptions of aquatic species habitat and in many cases, actual waterbody names, but there is no use or synthesis of such data. These factual details need to be more than just mentioned in passing; the data can and should be applied to (1) customize model environments, (2) make landscape inputs representative of the known areas of species occurrence, (3) adjust bin standardization for important geographic specifics, and (4) determine if the assigned bin is representative of the described water body that is inhabited by listed species of concern. The current oversimplification of the tiered screening process results in exposure values that are not relevant or meaningful to species-specific conclusions...

3.2.3 Urban Use Scenarios

A new conceptual model for exposure in urban environments was presented. The new conceptual model was not backed up with data to show that they are realistic and representative of actual urban environments. Some specific aspects of the urban conceptual model scenarios that could use some further justification or help in understanding the assumptions made include the following:

- The neighborhood consists of ¼ acre lots with 1000 ft^2 building footprints. How was this lot size and house size arrived at and how does it compare to neighborhoods throughout the US?
- It appears that the neighborhood only consists of ¼ acre house lots, and does not include additional roadway areas as previous EPA residential conceptual models have (EPA, 2010[18]). The residential conceptual model description should include whether other impervious and pervious areas, not specifically part of house lots, make up a portion of a residential watershed.

[18]EPA (United States Environmental Protection Agency). 2010. Environmental Fate and Ecological Risk Assessment for the Registration of Indaziflam. Office of Pesticide Programs, Environmental Fate and Effects Division. June 1, 2010.

- The fence use site leads to a very large application area (especially for CPY). In addition, it is unrealistic to have these fences surrounding every lot in a neighborhood.
- Patios and other treated areas are not to scale on map (MAL scenario). 1,000 ft^2 would be the same size as the house footprint and nearly as large as the garden area. Given that this is a significant area, it should be better justified and represented to actual scale on the diagram to provide a better sense of the proportion of the lot these use sites occupy.
- The presence of a utility easement use site (CPY) across the back of every hose lot in a neighborhood does not seem realistic. Are there examples of data to support this? This could be refined by an adjustment for probability or a percentage for expected incidence.

New conceptual models for urban exposure modeling were introduced for the CPY and MAL assessments. It is necessary that a conceptual model for urban pesticide use assessment should be consistently applied to all pesticides, even if some uses do not apply for some pesticides. In the current assessments, there are important differences in the conceptual models used for each compound, including:

- Presence of a utility easement impacting a conceptual house lot for CPY but not MAL
- Presence of a large trash storage area for CPY but not for MAL
- The size and extent of a fence assumed in each conceptual model
- Garden area and patio/garbage cans/shrubs/firewood/ornamentals were present in MAL but not CPY

The conceptual model for urban pesticide use should be consistent across all pesticides, even if some uses do not apply for some pesticides.

Many aspects of the conceptual urban model and its associated supporting assumptions have led to unrealistically high screening level EECs, generated without benefit of model validation. For example:

- Much of the pervious (porous) area use sites used the "Right of Way" scenario, which has a very high curve number (92). This curve number approaches the runoff rate of an impervious surface. The "Right of Way" scenario should be replaced with a more appropriately conservative pervious scenario, such as the "Residential" scenario. Use rates for some uses were outside the realm of reasonable worst case scenarios, and Directions for Use, such as the fence treatment for CPY that resulted in 15.5 lb/ac over the entire pervious portion of the lot and 1.2 lb/ac over the entire impervious portion.
- Assumption of a large impervious trash storage area use site (MAL scenario) equal to the size of the driveway represents an unreasonable large, high runoff use site area for a ¼ acre lot.
- The percent treated areas for the CPY and MAL scenarios were unrealistically high. For CPY, 100% of the residential neighborhood was effectively treated, while for MAL, 39% was treated. Both of these values are erroneously high, especially considering that neither of the two AIs have lawns on the label as a potential use site.

- The residential modeling approach does not account for run-on from rights of way into lawn, where infiltration would occur and reduce exposure potential. Models that are designed to simulate hydrologic transport in residential and urban environments, such as SWMM, account for this process and would be appropriate. Work conducted by the Pyrethroid Working Group (PWG) has demonstrated the use of SWMM in a refined residential pesticide exposure modeling assessment (Winchell et al., 2014[19]).
- Extrapolating the single lot conceptual model to watersheds of the size associated with Bin 3, Bin 4, and many Bin 2, Bin 6, and bin 7 scenarios greatly exaggerates the density and percent treated area. This is because the approach does not account for the vast areas of the urban landscape that are not house lots (parks, shopping centers, major roadways, industrial parks) and that medium to larger watersheds will have many different types of land uses throughout them.

3.3 Spray Drift Parameterization

3.3.1 Spray Drift Exposure Modeling

For ESA/FIFRA regulation, two models are currently used to predict deposition, AgDRIFT®,[20] based on data generated by the Spray Drift Task Force, and AGDISP.[21] Spray drift exposure estimates based on ground applicationswere derived from models of empirical data which were obtained from field studies designed to determine deposition of drift under circumstances prevailing at the time of the study. Additional empirical data may be found in the model used by the Pesticide Management Regulatory Agency (PMRA) that is responsible for pesticide evaluations in Canada. In Canada, PMRA uses the Agricultural Buffer Zone Workbook[22] for estimating drift deposition based on data generated by Agriculture and Agri-Food Canada (AAFC).[23] Additionally, the RegDISP model uses the empirical deposition curves from the Spray Drift Task Force, and the Canadian Agricultural and Agri Food Canada studies (2000, 2004, and 2011) and represents the most complete collection of North American drift data for ground applications. The parameters can be varied to estimate drift deposition using available ground data that in turn depend on the variables monitored and controlled for in the underlying data.

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[19] Winchell M, Padilla L, Jackson S. 2014. Development and application of a higher tier urban modeling approach for estimating pyrethroid concentrations in static water bodies using SWMM and AGRO-2014. PWG Report - PWG-ERA-11. MRID 49327502. Stone Environmental Inc. Montpelier, VT

[20] AgDRIFT® Spray Drift Taskforce software, Version 2.0. http://www.agdrift.com/AgDRIFt2/DownloadAgDrift2_0.htm

[21] US Department of Agriculture Forest Service. 2006. AGDISP US Forest Service spray modeling software. http://www.continuum-dynamics.com/pr-agdisp.html

[22] Health Canada. 2005. Agricultural Buffer Zone Workbook, http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_pro2005-06/index-eng.php

[23] Wolf, T, and B.C. Cladwell. 2001. Development of a Canadian spray drift model for the determination of buffer zone distances. In Expert Committee on Weeds, Proceedings of the 2001 National Meeting, Quebec City, Sainte Anne de Bellvue, Quebec: ECW-CEM. D. Bernier, DRA Campbell, D. Cloutier, Eds

Typically, droplet spectra (VMD_{50}), release height, and wind speed can be changed. The model for aerial applications in both AgDRIFT and AGDISP is a mechanistic model that has been verified through comparison to field trials.[24]

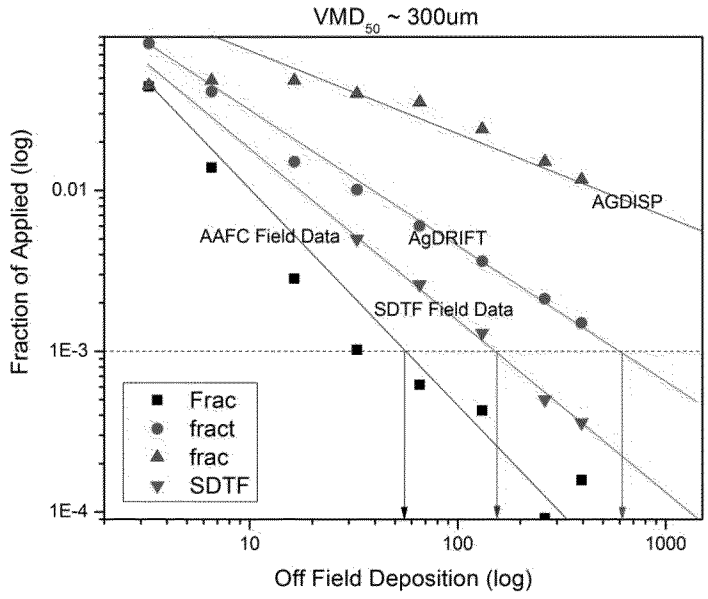
Aerial models have many other factors than can be adjusted to impact predicted spray drift. AgDrift aerial modeling is appropriate in tier III risk assessment for determination of spray buffers by air, although the default assumptions of constant meteorology, minimal surface roughness and absence of a crop canopy are likely to over-predict drift deposition at far distances downwind. For this and other reasons, AgDrift aerial modeling is not appropriate for aerial ULV modeling (see discussions for alternative approaches in the discussion of mosquitocides, below

3.3.2 Appropriateness of Model Selection

The outputs of the ground models used by North American regulatory Agencies, i.e., AgDRIFT, AGDISP, and the PMRA tool, are compared in Figure 6 below, which illustrates the magnitude of over-prediction of the two former models compared to actual field results. Both AgDRIFT and AGDISP deposition curves are for the same spray quality or VMD_{50} (or nozzle). Both the AgDRIFT and AGDISP deposition curves should be close to the AAFC (Agriculture and Agri-Food Canada) flat fan data, which is consistent with the Spray Drift Task Force Data[25,26] that the AgDrift model is based on. However, at 400 feet both models greatly over predict deposition. The PMRA model provides a good approximation of the AAFC field data assuming use of newer air induction nozzle technology. We can see from this evaluation that both AgDRIFT and AGDISP are not representative of currently used nozzles and drift reduction best management practices, while the PMRA tool provides a much better fit.

[24] Bird, S, S,G, Perry, S. L. Ray, and M. E. Teske. 2002. Environmental Toxicology and Chemistry, 21, pp.672
[25] Johnson, David. 1992. Ground Field Study in Texas. Spray Drift Task Force, Sponsor study number F92-009, MRID No. 43493801 McKenna & Cuneo, 1900 K Street, N.W. Washington, D.C. 20006, Subdivision R- USEPA Pesticide Assessment Guidelines Pesticide Spray Drift Evaluation Guideline 202- 1
[26] Johnson, David. 1994. Ground Field Study in Texas Spray Drift Task Force, Sponsor studynumber F93-016 McKenna & Cuneo, 1900 K Street, N.W. Washington, D.C. 20006, Subdivision R- USEPA Pesticide Assessment Guidelines Pesticide Spray Drift Evaluation Guideline 202- 1

Figure 6. Deposition Curves from Models and Field Data



3.3.3 Current State of the Art for Ground Modeling - RegDisp

RegDisp predicts spray drift deposition from ground application of pesticides based upon regression equations constructed from data reported by Wolf and Caldwell (2001 and 2004), Wolf (2011), and the Spray Drift Task Force (1992 and 1993). The user can choose from these established deposition datasets by selecting study year, nozzle, boom height, sprayer speed, and wind speed. RegDisp also includes functionality that allows users to input equations constructed from their own data sets. The user chooses the form of equation and the required parameters and then saves their equation with a name to the RegDisp database. Once an established or custom deposition equation is selected, RegDisp estimates deposition as the fraction applied. Existing tools developed as part of the AGDISP interface allow the user to run the deposition and stream assessment tools. RegDisp is a modification of AGDISP 8.26, a tool developed by the USDA Forest Service to predict spray drift from aerial applications of pesticides. RegDisp has been integrated with AGDISP so that the user can choose whether to run AGDISP or RegDisp, and would be the more current and appropriate model to use in the assessment process.

3.4 Spray Drift and Mosquitocide Use Assessment

General Comments on ULV Applications

As noted above, the ULV mosquito adulticide use of malathion is unique compared to the other agricultural and non-agricultural uses, even other ULV agricultural and non-agricultural uses. For typical

agricultural or non-agricultural uses, the aim is to achieve deposition on the plant surface to be protected. As such, spray droplet distributions for these applications aim to maximize deposition and coverage, and applications are made in conditions that do not favor drift. In contrast, ULV mosquito adulticide applications aim to produce a cloud of droplets that remains suspended and moves through a zone where adult mosquitoes are flying. Thus spray droplet distributions have much smaller Volume Median Diameters (VMD or Dv0.5 are much smaller), and ideal meteorological conditions for applications promote drift. Due to the diurnal activity of flying adult mosquitoes, applications are typically made in the morning and evening crepuscules.

The second major difference between ULV mosquito adulticide treatments and other agricultural and non-agricultural applications is that ULV mosquito adulticide applications are made by Mosquito Abatement Districts or other governmental departments of public health. EPA (September 23, 2009 – Draft (2009b)) estimated that there are 1200 such entities: 400 Mosquito Abatement Districts and 800 other public Agencies. ULV mosquito adulticide applications require specialized equipment to generate the aerosols for optimal mosquito control. Thus, applications are made by highly trained applicators whose aim is to maximize the concentration in the air and to minimize deposition (Mark Latham, Manatee County Mosquito Control District, personal communication). These state and local professionals are necessarily very familiar with listed species in their districts. They are also very likely to follow the ULV adulticide label as written. In the following sections, we explain an approach to mosquitocide evaluation that reflects both spatial distribution of applications and the directions for use that are on mosquito adulticide labeling.

Modeling Approach

For drift estimates, EPA has used the AGDISP model. However, there are few data available for reliable parameterization of this model of malathion ULV adulticide applications. One excellent study by Mickle et al. (2005) is available, we recommend that these empirical data be used instead of a model run. Drift predictions using AgDrift do not produce valid data for ULV applications.

Scope of Usage for Adult Mosquito Control

The footprint for mosquito control derived by EPA was based on the somewhat trivial observation that mosquitoes are widely distributed across the coterminous US, so the footprint is all of the US. This selection ignores the well-established fact that mosquito adulticides are applied by Mosquito Abatement Districts. A detailed analysis, based on actual use information, was performed as follows.

Assembling ULV Adulticide Usage Information

For the purposes of this assessment, usage information is defined as the application rate, timing, interval, and frequency for a specific geographic location. For mosquitocide and other non-crop uses, there are ways to determine spatial distribution even in the absence of land cover and land use

datasets. The approach that is described here is relevant to other uses that are not associated with a geographic land or use attribute.

Usage information for some agricultural uses is tracked by the GfK Kynentech – AgroTrak® database. This information can be matched with the geographic footprint for a specific crop from USDA, to evaluate the extent, timing, and intensity of pesticide use on that crop. For non-agricultural uses, including mosquito adulticide uses, Kline Inc. does make some market surveys, but their typical surveys provide limited information about timing, application rate, frequency, or intervals. Furthermore, because mosquito adulticides are applied to a wide variety of locations, such as urban or suburban residential areas, their environs, rangeland, pastures, or other uncultivated non-agricultural areas, such as wastelands and roadsides, there is no simple USDA location classification that can be used to show the geographic footprint of ULV mosquito adulticide use.

However, ULV mosquito adulticide applications are very specialized in that they must be made by certified applicators, using very specialized equipment. Indeed, ULV mosquito adulticide applications are typically made within specific boundaries by dedicated Mosquito Abatement Districts and other state or local departments of public health. Applications are based on monitoring of mosquito populations, complaint calls, or may arise from an emergency situation (e.g., hurricane), or public health threat (e.g. Zika virus).

To define the geographic scope of ULV mosquito adulticide use, 4 sources of information were summarized. The first was a survey conducted by Angela Beehler of the Benton County WA Mosquito Control District, for the American Mosquito Control Association (AMCA). The second was a survey of sales and distributors conducted by Cheminova/FMC Inc. The third was from publicly available usage information from Florida, and the fourth was from publicly available usage information from California. The methods used to develop these 4 datasets are described in turn.

The usage information from the American Mosquito Control Association is based on a series of surveys that covered the United States (Angela Beehler personal communication 2015). First, all members of the American Mosquito Control Association were emailed and asked if they use malathion, and if so, how many applications they make per year. This information was combined with the list of all AMCA members to cast a broad net as to the universe of potential users. This list of potential users includes organized mosquito control districts that did not answer the email survey, but that would be capable of making ULV mosquito adulticide applications. To supplement this list, entities that reported use in the California and Florida pesticide databases were added. Then, based on information from the basic producer of malathion, a list of entities that purchased malathion in the last 3 years was obtained. Finally, regional and state vector control associations were asked to provide their member lists and malathion users. We believe that these various "slices" of the universe of entities that use ULV malathion as a mosquito adulticide provide comprehensive coverage of the entities that have recently applied malathion as a ULV mosquito adulticide in the conterminous 48 states. The level of resolution of

the results is application at the county level. Information on application rates, timing, and intervals is not available from this survey. These data were previously provided to the EPA.

To obtain malathion ULV sales data, Cheminova/FMC tabulated all sales locations of its ULV mosquito adulticide products, for Cheminova/FMC and its major distributor, for the years 2011 to 2014. These sales locations were either assigned to states and counties directly, or assigned to cities or ULV applicators. The level of resolution of the results is application at the county level. Information on application rates, timing, and intervals is not available from this survey. This sales information is claimed as confidential business information.

In addition to these broad county level tabulations of potential ULV mosquito adulticide use sites, data were also obtained for the last 10 years from 2 states, California and Florida. The purpose of this exercise was to attempt to gauge the use rates, numbers of applications, and application intervals of ULV mosquito adulticide applications for these states, if possible. These factors were not covered by the AMCA or Cheminova surveys.

The Florida data were obtained from the website: http://www.freshfromflorida.com/Divisions-Offices/Agricultural-Environmental-Services/Consumer-Resources/Mosquito-Control/Reports

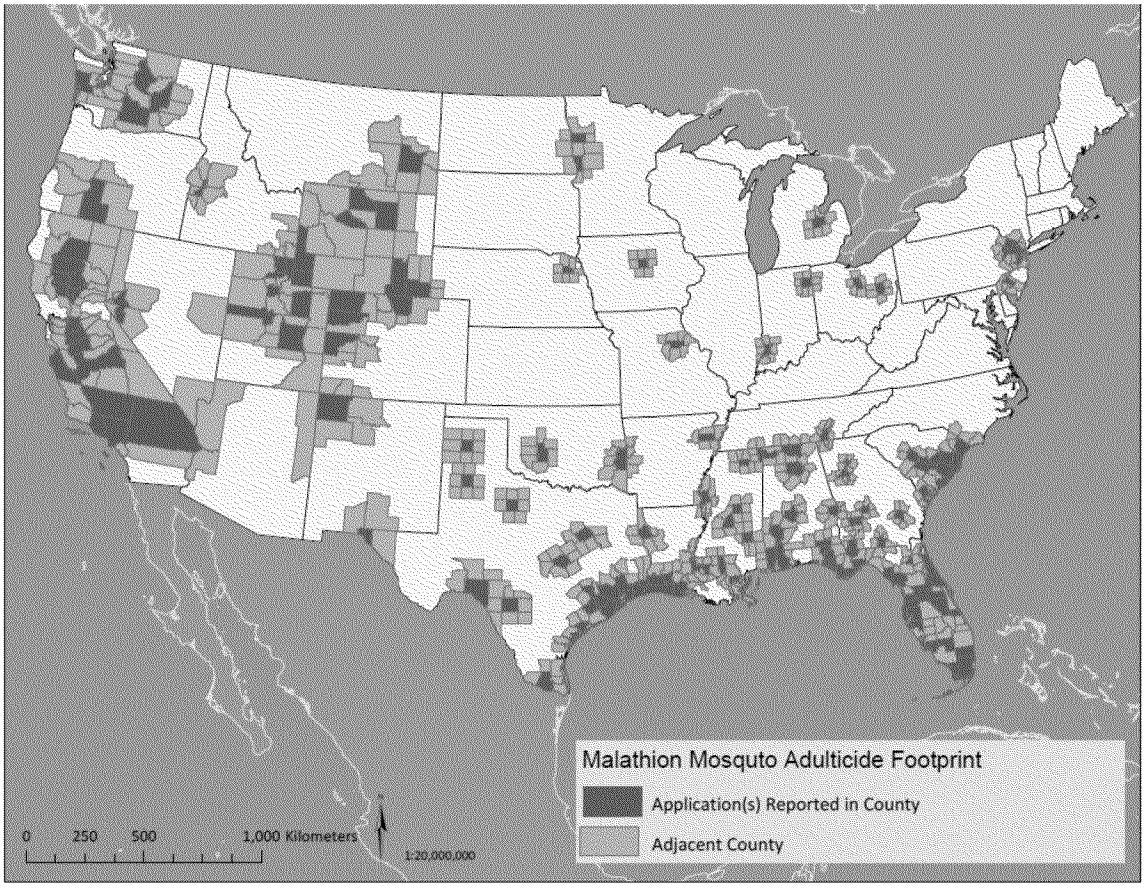
The dataset covers the years 2003 to 2014. Florida mosquito control data are summarized by active ingredient and county. Gallons of product, pounds of active ingredient, and acres treated are generally available for each county-year combination. Application methods are broken out by aerial and ground. Unfortunately, this Florida database does not provide the timing of applications, the number of applications, or the interval between applications. To estimate the intensity of usage in a particular county, the total county acreages were obtained, and then the total number of acres treated by air or ground were divided by the county acreage. This measure provides a crude estimate of the intensity of air or ground applications in each county.

The California data cover the years 2004 to 2013, and were obtained from the website: http://calpip.cdpr.ca.gov/main.cfm

Only data for non-agricultural applications were summarized. There is a category called Public Health Applications that relates most closely to the ULV mosquito adulticide uses. Data were obtained by county for each year. Timing of applications was included in the database. However, unfortunately, there were several pieces of missing data, including whether the application was made by air or ground and the application rate per acre. As had been done for the Florida data, county acreages were obtained. To estimate the number of acres that could be treated, the total pounds of malathion applied was divided by the maximum ground application rate. This estimated number of acres treated was then divided by the total acreage in the county to arrive at an index of use intensity for that county.

The 4 datasets were combined to generate a list of counties where ULV malathion mosquito adulticide applications have been made. To conservatively ensure that the potential for drift was taken into account, all counties adjacent to the counties where malathion ULV applications were reported to have been made were also included. The results of this tabulation are shown in Figure 7. ULV malathion applications have been made in 159 counties, and there are 514 adjacent counties for a total of 573 counties with potential for exposure, as opposed to EFED's assumption that use is in all US counties.

Figure 7. Counties where ULV Malathion Mosquito Adulticide Applications have been made, and Adjacent Counties



The business confidential nature of the usage information assembled by Cheminova/FMC precludes its detailed discussion here. However, two key points can still be made without compromising data confidentiality. These points are: (a) Scope of use -- although pest mosquitoes are widely distributed throughout the conterminous 48 states, actual ULV applications for adult mosquito control have been made in about half of the states and 159 counties; (b) Volume of use – Malathion usage has dropped considerably since 2004.

The relatively restricted geographic extent of use is a direct result of the fact that most ultra low volume applications to control adult mosquitoes are made by Mosquito Abatement Districts or other local, state, or federal entities in response to a direct threat to human health. The reduction in ULV malathion adulticide use is due to increasing preference for other organophosphates or for pyrethroids, but with the reservation that prevention of resistance build-up by chemical class rotation is very important to continuing to be able to control outbreaks of disease-carrying mosquitoes.

Finally, it is important to note that the Consultation Handbook specifically notes "Under no circumstances should a Services representative obstruct an emergency response decision made by the action Agency where human life is at stake."

4.0 COMMENTS ON THE APPROACH USED FOR STEP 1 [MAKING MAY AFFECT [MA] OR NO EFFECT [NE] DETERMINATIONS]

4.1 General Comments

The Step 1 framework used in the draft BEs is unnecessarily conservative in that actual exposure potential is ignored. Instead, the spatial extent of use sites for both crop and non-crop uses is greatly overstated so that the co-occurrence (overlap) analysis for a potential MA determination is applied in a precautionary, not predictive, manner. Further, the exposure assessment tools used to estimate EECs have both extreme conservativeness in model and scenario assumptions and large uncertainties in model accuracy and scenario relevance for listed species and their habitat requirements. Finally, none of this construct has undergone peer review or a validation process to ensure the decision criteria are fit for purpose. In particular, there are serious errors with the approaches used to define spatial extent of use sites, model aquatic and terrestrial exposure, establish relevance of aquatic habitat bins, and relate effects thresholds to assessment endpoints. A true screening step could have been included in the analysis plan to eliminate species from further consideration. The use and validity of this approach has been demonstrated in three prior EPA endangered species case studies submitted to EPA by registrants (on atrazine[27]) or FESTF (on 2,4-D[28] and clomazone[29]).

[27] MRID 46078601. Overview; MRID 46078602. Summary of EPA-EFED Ecological Risk Assessment; MRID 46078603. National Risk Assessment for Aquatic Organisms and Critical Habitat; MRID 46078604. National Risk Analysis for Terrestrial Organisms and Critical Habitat; MRID 46078605. National Risk Analysis Summary of Results; MRID 46078606. Spatial Scoping Analysis for All Uses; MRID 46078607. Agricultural Usage Data Analysis; MRID 46078608. Site Specific Analysis; MRID 46078609. Taxonomic Specific Analysis.

[28] MRID 46535401. Endangered Species Assessment on Non-Target Plants Potentially at Risk from Use of 2,4-Dichlorophenoxyacetic Acid in Almonds, Rice, Strawberries, and Wheat.

[29] MRID 47647401. Frank, A.R. Clomazone: Analysis of Potential Direct and Indirect Effects on Threatened and Endangered Species. January 13, 2009. FIFRA Endangered Species Task Force (FESTF), Washington, DC and FMC Corporation, Princeton, NJ.

The hurried reaction pace driven by litigation deadlines has caused a leap into the use of the NAS Panel document as a policy guidance source for the procedural steps in a risk assessment. That transfer of authority is incorrect and confuses the exercise of FIFRA pesticide environmental risk assessment with the legal requirements for making no effect, may affect (NLAA/LAA) and jeopardy decisions under ESA. Incorrectly, flawed risk assessment procedures are being forced into the three decisional procedures of ESA, and in doing so, established FIFRA policy and environmental risk assessment policy have been ignored.

In 2003, OPP and the Services jointly published an advanced notice of public rulemaking on joint counterpart ESA Section 7 regulations ("Counterpart Regulations").[30] These changes were proposed to better integrate the consultation process between the Agencies and increase its efficiency and effectiveness. While a portion of these regulations has been stricken, language survives that allows EPA to determine if an action is likely or not likely to cause an adverse effect ("LAA" or "NLAA" decisions). Given an agreed alternative consultation approach (an Alternative Consultation Agreement between OPP and the Services, which was adopted) and a scientific review of the adequacy of OPP's program by the Services, now embodied in a letter from the Services to EPA, the Counterpart Regulations provide endorsement that OPP's pesticide review and evaluation process can stand in for the Services except when a jeopardy determination is required. The important documents that brought the Counterpart Regulations into effect are:

- The proposed and final joint Counterpart Regulations[31,32]
- The draft and final Alternative Consultation Agreement[33,34]
- OPP's "Overview Document"[35]
- The Services' evaluation of the Overview Document[36]

It is important to note that the Overview Document was very much an integral part of the overall response to improving FIFRA/ESA consultation, and it documents OPP's framework for risk assessment, which the Services' evaluation endorsed. Following the Counterpart Regulations, in 2005, OPP published its final revised ESPP field procedures.[37] Notably, this document envisions a very interactive state involvement and a heavy dependence on monitoring data from terrestrial field studies and aquatic

[30] FR 68:3786 (January 24, 2003)
[31] FR 69:4465 (January 30, 2004)
[32] FR 69:47732 (August 5, 2004)
[33] Draft Alternative Consultation Agreement for Implementation of Optional Alternative Consultation Procedures. EPA, FWS and NMFS, January 2004
[34] Final Alternative Consultation Agreement for Implementation of Optional Alternative Consultation Procedures. EPA, FWS and NMFS, August 26, 2004
[35] Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs: Endangered and Threatened Species Effects Determinations. USEPA January 23, 2004.
[36] Williams and Hogarth to Hazen: Evaluation of EPA Overview Document. FWS/NMFS January 26, 2004
[37] Federal Register 67 (231): 71549. Notice: Endangered Species Protection Program Field Implementation. November 2, 2005

systems, as well as a monitoring program to determine whether county bulletins are effective in protecting listed species and critical habitat. Services have agreed not only in the Counterpart Regulation process, but also historically, in the establishment of environmental risk assessment policy, that the criteria set by EPA for making risk determinations by the risk evaluation procedures they have established through policy are adequate to protect listed species.[38]

4.2 Management of Data

In the draft BEs, EPA has substituted their reliable and proven risk assessment program with a series of automated, worst-case compilations that produce results that are impossible to follow or reproduce. For example, rather than work with a screening endpoint like a risk quotient, to establish toxicity distributions and compile available data, EPA uses a data array with all endpoints and ranges of values without apparent consideration of relevance or appropriateness in selecting relevant taxa and toxicity endpoints (the failure of this method is discussed in several sections of this comment document). With this method, species diversity and sensitivities are illustrated but not effectively used in the risk analysis. There is no anchoring policy or guidance to bring consistency to the risk assessment process, or to meaningfully put screening level data into context. If the data array and other newly introduced methods are utilized in the assessment their utility is limited to a first cut no effect/may effect determination. Subsequent validation, interpretation and relevancy of data needs to be applied, along with further quantification of other assessment parameters.

EPA states that it has followed its guidance on the use of open literature studies,[39] with modifications as described in Chapter 1, Attachment A8. EPA's guidance on the web site (hereinafter referred to as Open Literature Guidance) states that a study may be considered appropriate for "quantitative" use if it meets following:

a) is reported in, or can be converted to, environmentally-relevant exposure units;

b) the endpoint is consistent with endpoints currently used to derive risk quotients (e.g. LC50 for acute exposure in fish;

c) "sufficient information must (emphasis added) be provided in the open literature to substantiate and/or independently evaluate whether the study conclusions (i.e. dose-response) and endpoints are accurate", and

[38] Interagency Agreement between EPA/OPP. U.S. Department of Interior (USDI), Office of Protected Species (OES), and U.S. Department of Commerce (USDC), National Marine Fisheries Service (NMFS), 1980
[39] Available at http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_evaluation_open_literature.htm.

d) the endpoint from the open literature study must be lower (i.e., more sensitive) than the lowest endpoint from a comparable registrant-submitted study for all taxon with the exception of aquatic-phase and terrestrial-phase amphibians, freshwater mollusks, reptiles, and for derivations of SSDs for other groups.

Chapter 1, Attachment A8 states that EPA used ECOTOX as a first screen. Given that the criteria for inclusion in ECOTOX are very minimal, this is appropriate for casting a wide net and as an initial screen. The second level of screening was OPP's, as described above. However, the only criterion that seemed to be retained was "a", regarding the units. Data with environmentally-relevant exposure units were used to build the arrays; the other criteria were not applied. This means studies with very low reliability and relevance can become part of the arrays, essentially rendering the arrays useless. Uncertainty is supposed to be included in the effects arrays (Chapter 1, page-51 in the chlorpyrifos BE) – but how uncertainty is used is not discussed. While the concept of arrays, to allow presentation of a great deal of data visually, is appealing, by including essentially all open literature without critical evaluation, EPA has presented a meaningless compilation of data.

It is stated that the open literature studies used for development of thresholds were "intensively reviewed" and only the study providing the lowest effect information was reviewed in detail. It is further stated in Chapter 1, Attachment A8 that the studies used for thresholds had to meet the definition of "quantitative" as described in the Open Literature Guidance. This means they would have had to meet the criteria given above in "b", "c" and "d." As an example for plants, if data were insufficient to construct an SSD (as was the case for the OPs, and as mentioned previously SSDs were not even considered for plants), only studies providing lower effect levels than registrant-submitted guideline studies were even considered (criterion "d"). This ignores potentially high quality plant effects data that could constructively inform the assessment, because at best, they would only be shown in the arrays (along with data of questionable quality). Moreover, EPA does not seem to have followed criteria "b" and "c" as illustrated by the examples below. It should be mandatory that, if an open literature study is to supplant a GLP-compliant guideline study for threshold derivation, it be of high quality.

4.3 Effects Determinations in Step 1 (Aquatic Assessment)

The step 1 aquatic exposure discussion in section 1.4.1.1.c.1 indicates several overly conservative assumptions that led to an unrealistic and inaccurate portrayal of the potential overlap of pesticide exposure and species location. The smallest representative water body and the highest representative use rate are paired whether this pairing initially is accurate or not, let alone realistic for different settings. To do this, EPA uses the concentrations generated for Bin 2 from the highest use rate in a "downstream dilution tool" that, through a spatial analysis algorithm, flags "Yes" and "No" pixels for inclusion or exclusion. Because the assumed concentrations arise from an extremely small flowing system combined with the highest use pattern, the starting value is an upper end estimate. This value is then applied to all land use pixels in the landscape, incorrectly omitting conditions for different use

patterns for different land uses. Layered on top of that incorrect procedure is the assumption that every pixel of land use is adjacent to a small flowing system and contributing runoff, erosion, and drift. All of these collective assumptions led to a footprint downstream that is not representative of a given use pattern and pesticide exposure potential. To correct this:

- Do not limit values to the concentrations generated from Bin 2 (low flow habitats, flow rate = 0.001 m^3/s). The choice of bins should depend on the existence and habitat preferences of the endangered species being studied.
- Demonstrate or statistically evaluate the assumption that a 1-in-15 year exceedance of the EEC has proven ecological significance. This analysis would conform to NAS Panel recommendations to use best available science and methods as well as a probabilistic approach.
- Develop a methodology that more realistically represents entry and dilution in a flowing system. In the pilot assessments, EPA determines percent use area based on (1) an exaggerated portrayal of the chemical's use footprint and (2) the 'yes' and 'no' pixels from the binary land cover. Summing all the 'yes' and 'no' pixels within a watershed and within all such upstream watersheds grossly overstates the chemical use and potential exposure footprint.
- Modify the unrealistic assignment of EEC exceedance to achieve a more realistic portrayal of potential exposure. Assigning the 1-in-15 exceedance assumption to each of the 'yes' pixels is unrealistically conservative.

4.4 Effects Characterization for Terrestrial Plants

In the nontarget plant effects characterization, It is important to array the information appropriately for clarity on the risk characterization. All data should be used, including in field observations, etc. Integral to these assessments are the guideline required pre-emergent (seedling emergence) and post-emergent (vegetative vigor) studies that provide toxicity data for 10 species. It is well known that the results of these studies are conservative in that they are conducted in greenhouse conditions where the plants not field hardy, the soil has low organic matter, and the applications are made directly to the plants (e.g., no not mimic drift). This should be noted in the effects characterization.

Additional information is used in the effects characterization from the literature. Given that some of these studies (such as a chlopyrifos study noting reduced photosynthetic rate and stomatal conductance) are used in the effects determination, it is not clear they have undergone a thorough data reliability and relevance evaluation. For example, how does the endpoint noted above relate to the other data in the array.

In the current assessments, the nontarget plant data (Chapter 2) is presented in many ways, and hence can be a bit confusing. For example, sublethal effects are discussed for pre-emergence and post-emergence studies first; subsequently, these effects are discussed again but considered first for monocots and then for dicots. It would also make more sense to organize the table presenting the

thresholds by first presenting the data used for Step 1 (e.g., NOAEC values) and then the data used for Step 2 (LOAEC and EC_{25} values). Another example, is in Figure 10-1 Summary of data array for chlorpyrifos. It is not clear what data are included in the array (NOEC, LOEC, EC25 etc…), and if it makes sense to combine them, and what the red dot indicates (mean or median, but should include both). It should be made clear why the data are presented in different ways and how it will be used in the risk conclusions.

Generally, there is no presentation of the effects data from Chapter 2 in the WoE tables presented in Chapter 4. It is not clear by how much does the 'exposure' exceed the NOAEC or LOAEC. The weight of evidence sections in the effect determination should refine the analyses by noting the levels of conservatism in each step of the process, and beginning to integrate species biology into the conclusions. Using the *Pritchardia remota* example, the "high risk" direct effect to growth is determined based on a threshold value NOEC being exceeded for the minimum and maximum application rates at the site of a pre-emergent application, however, for post-emergence application, the LOEC value is not exceeded for the upper bound rate (4 lb a.i./A). Based on *Pritchardia remota* habitat being located in scattered, small groves in two valleys with elevations of 50 to 800 feet (information from WoE Appendix 4-3aa), actual in field or edge of field exposure would be rare at most. It is not evident that this WoE document included overlap in critical habitat from the CDLs, or the TED tool analysis for distance that risk extends from edge of field.

SSDs are proposed to be constructed "for direct effects to animals with robust data sets." What is the definition of sufficient data for an SSD? Why are SSDs precluded from being constructed for plants (assuming there are sufficient data)? For example, for chlorpyrifos there are data for 14 species of monocots and 31 species of dicots, yet the risk characterization only uses data for lowest endpoints. It is stated that "because of the variability in study designs and endpoints, it was not possible to derive an SSD with the available plant data" (page 215, Chapter 2 for chlorpyrifos – *check to see for other compounds*). It would seem that, at least considering the typical Tier II registrant-submitted studies, the data would be suitable,e.g., have similar study designs and endpoints, for at least 10 species.

2). For Step 1, the text on page A4(PF)-2 states the following:

- For <u>direct effects to all taxa</u> - sublethal endpoints (NOAEC, NOAEL, or EC_x):

For plants, the level corresponding to a reproduction/growth no observed adverse effect concentration or level (i.e., NOAEC or NOAEL) for the most sensitive species is used.

Then in Table A 1-4.1, it is stated to use the concentration equal to the lowest value among the available NOAEC and EC_{05} values, implying an equivalence between the NOAEC and the EC_{05}. There is no published justification that the EC_{05} represents a meaningful endpoint for a toxicity test with either

aquatic or terrestrial plants, from either a statistical or biological basis. [To the contrary, recent investigations have determined that a 5% effect is within the expected control variance for both aquatic and terrestrial plant standard toxicity tests, and cannot be reliably determined statistically (Staveley et al., 2014; Staveley et al., 2015). In addition, the biological significance of a 5% effect on plant growth is questionable. The reference to EC_{05} should be deleted from Table A 1-4.1 in reflection of these considerations and to be consistent with the text.

3). In Step 2, for direct and indirect effect thresholds based on sublethal endpoints: Sublethal effects to plants are to be based on "the level that corresponds to the reproduction or growth NOAEC, NOAEL, or EC_{05} for the most appropriate surrogate species" (Chapter 1, Attachment 1-4, page A4(PF)-4)) – how is an evaluation of the "most appropriate surrogate species" made? Characteristics such as "Monocot, dicot, fern and allies, conifer, lichen" are included for each endangered plant species in the "Weight of Evidence" matrices associated with Chapter 4. Is the "appropriate surrogate species" based on this information, or merely based on aquatic vs. terrestrial? The text says that the lowest LOAEC or EC_{25} is used from available terrestrial plant studies to assess indirect effects related to terrestrial and wetland plants; Table A 1-4.2 states this as the lowest LOAEC and EC_{25} value from the available seedling emergence and vegetative vigor studies. The latter is much more specific and appears to preclude data from studies not conducted according to the standard seedling emergence and vegetative vigor guidelines. Table A 1-4.2 further states that for indirect effects related to *aquatic plants*, the lowest available LOAEC and EC_{25} for aquatic plants is used. It is noted that standard aquatic plant toxicity tests typically report the EC_{50}, not the EC_{25}. Will registrant-submitted studies need to be re-evaluated to determine the EC_{25} or does this imply that registrant studies will not be preferentially used when evaluating indirect effects related to aquatic plants?

5.0 COMMENTS ON THE APPROACH USED FOR STEP 2

5.1 Risk Characterization

The Step 1 procedure implemented in the BEs confuses the identity of the action area with the conduct of a step 1 screening level assessment to determine whether there is an effect or no effect as a consequence of the registration action. Currently, Step 1 is limited to just that: defining the action area. A missing step, whether called "Step 1" or "Step 2," based on co-occurrence analysis could have screened out more species if individual uses were considered rather than combining all label uses allowed in a specific location. In addition, the tiered framework recommendation in the 1998 Agency-wide EPA Guidelines for Risk Assessment[40] suggests that a more extensive "Step 1b" could have involved a risk-based screening step to reduce the extent of the risk assessment. This was not done, and there are important consequences related to programmatic inefficiency and inability of the Services to apply their limited resources to complete high quality biological opinions of unnecessarily great scope.

[40] FR 63(93):26846-26924 (May 14, 1998)

Similarly, little additional refinement was done in the iteration of Step 2, again resulting in missed opportunities to determine NE or NLAA outcomes that would simplify the overall process and conserve precious resources, particularly in the Services. Another difficulty with Step 2 is improper application of the weight of evidence process, so that any one of the lines of evidence can result in a LAA determination regardless of the weights of the other lines. Such improper application results in species not being screened out that are not at risk and that should be removed from further evaluation.

Using the concept of fitness of an individual in risk hypotheses unfortunately makes the hypotheses less explicit and therefore somewhat ambiguous, or, at the least, difficult to follow throughout the analysis. Reference to the fundamental attribute changes of mortality, reduced growth, and reduced reproduction would be more explicit and more directly related to lines of evidence for both direct and indirect effects. Furthermore, they are consistent with ESA's basic definitions for protection of listed species. Any additional non-fundamental attribute change such as altered behavior should be considered only when it can be linked to the three fundamental ones with exposure-response evidence that would reasonably be expected to occur and measurable in the environment. EPA has relied on the fundamental endpoints for decades when conducting appropriate risk assessments and this follows the recommendations in the 1998 Guidelines. The BE documents do not explain why the change to the concept of fitness is necessary to improve the process, and there is no underlying policy or guidance to support such a drastic and unprecedented change. Under the OPP process that is codified in Agency-wide risk assessment policy, EPA is capable to determine the likelihood of its action to affect a listed species not only under FIFRA but under many other statutes. It is inefficient, and contradictory to the Agency's approach to risk assessment, to make unneeded and untested changes to such policy at an Office level.

5.2 Decision Criteria (i.e. NLAA, EECs, RQs)

No effect ("NE"): Absence of co-occurrence alone is not the sole criterion for a no effect determination. Co-occurrence with the action area as the sole criterion for a no-effect determination requires consideration of what is meant by both the "action area" and "range/habitat." Action area attributes include site of application and off-site drift, runoff, etc. Range/habitat attributes include amount that is in protected areas (e.g., parks, refuges, preserves), buffers between fields and range/habitat, etc. A definition of "overlap" also is required at this Step, and not delayed until Step 2. As it currently is applied, the criterion is inefficient and unnecessarily sends more work to later in the process where resources are limited.

Not Likely to Adversely Affect ("NLAA"): The rationale for selecting the threshold range overlap of less than 1% is not given. Because 100% of species and Critical Habitat exceed the threshold it does not appear to be a good discriminator, probably due to the overstated spatial extent of potential use. EPA can make this decision using the guidance of the Counterpart Regulations and their supporting policy and review documents.

Estimated Environmental Concentrations ("EECs"): The Step 1 framework used in the draft BEs is unnecessarily protective in that actual exposure potential is ignored. Instead, the spatial extent of use sites for both crop and non-crop uses is greatly overstated so that the overlap analysis for a potential MA determination is applied in a precautionary, not predictive, manner. EECs are estimated by predictive models and applied to the overstated spatial extent. The predictive models have both extreme conservativeness in model and scenario assumptions and large uncertainties in model accuracy and scenario relevance for listed species and their habitat requirements. Finally, none of this construct has undergone peer review or a validation process to insure the predicted exposures are fit for purpose, as described in the 2009 Guidance on the Development, Evaluation, and Application of Environmental Models, EPA/100/K-09/003 [2009 Guidance]). In particular, there are serious acknowledged errors with the approaches used to model aquatic and terrestrial exposure. Given the recommendations in the 2009 Guidance and acknowledgment of the errors, the models applied to the BEs are not valid. Rather than use grossly overstated predicted exposure values from faulty models as a line of evidence in the risk characterization, this portion of the analysis should instead rely on environmental monitoring data, when available, for these chemicals that have been in use for many decades. Bringing in model predictions as a line of evidence should be deferred to the future when adequate models are available.

5.3 Deficiencies in the "Step 2" Approach

In Step 2, many of the deficiencies listed for Step 1 are carried over. Of particular importance are the overstated spatial use footprints and unvalidated conservative exposure predictions. Many refinements could be brought into both Steps 1 and 2 to improve exposure predictions and effects profiles and apply general aspects of biological attributes in the assessment to eliminate species from further consideration by assigning a NE determination based on low probability of occurrence of adverse effects at the appropriate spatial and temporal scales. Registrants are demonstrating this in a case study that uses an efficient, logical, reproducible, and scientifically valid processes to address a stepwise process of sorting and documenting NE/MA and LAA/NLAA findings.

EPA's assessments, on the other hand, use generalized opinions of "possible" (but unlikely) exposures exceeding "possible" (but not probable) effects thresholds expressed using terms such as "could," "might," or "is possibly." These loose definitions all then combine with consistent EPA conclusions: that any level of exposure exceeding a threshold results in ecological adversity, risk is claimed even when a particular assessment has great acknowledged uncertainty. Ranges of values are used instead of distributions and associated probabilities. The conclusions are not predictive, and are only precautionary, with no probability framework, as recommended in the 1998 Guidelines and the 2013 NAS report. The most useful risk hypotheses are those expressed in the form: "an exposure (x) to stressor (y) could, with probability (p), cause an adverse response (z) of magnitude (m) in receptor (q)".[41]

[41] Hope BK, Clarkson JR. 2014. A strategy for using weight-of-evidence methods in ecological risk assessments. HERA 20:290-315

Unfortunately, the BEs do not contain such useful risk hypotheses using quantitative risk characterization described in this manner.

Why is the absence of useful risk hypotheses important? The risk characterization for Step 2 depends upon a series of highly conservative assumptions to test the simplistic risk hypotheses. Because probabilities are multiplicative, not additive, the final result is an extremely unlikely event.[42] It may not be necessary or prudent to be so conservative throughout an assessment that even a highly unlikely event will result in a LAA determination. For example, use of a 1-in-15 years 4-day average for an estimated water concentration as an exposure value will result in much more LAA determinations than use of a 21-d, 60-d, or 90-d average (for 1-in-15 years). Because the estimation of these average concentrations includes a concatenation of multiple conservative input values, the probability that a listed species will experience such a concentration is very small. When the impact represents a sublethal or indirect effect, the probability that such an effect would occur after only 4 days of exposure is even less, and this needs to be taken into consideration with respect to determining if the effect is likely to impact survival, growth or reproduction. And finally, the probability that a sufficient number of individuals experience such an exposure by being present and exposed to the 1-in-15 year, 4-day occurrence in such a way that actually results in decreased fitness, to a level that could possibly affect the population growth, is vanishingly small.

For Step 2 (NLAA/LAA), it is very difficult to discern what effects values are being used. The species-specific summary tables in Appendix 4-3 state the types of endpoints that are available, but are not very clear about which one was used (e.g., NOAEC or LC20?) nor do they present the actual numeric value. The effects endpoint used in Step 2 should no longer be the ultra-conservative 1-in-a-million threshold, so a policy decision needs to be in place to define what level of effect will be acceptable. Policy guidance at OPP, and agreed to by the Services, is in place for this determination and should be honored conceptually (HED ERA SEP) or modified formally through FIFRA procedures for substantive policy changes. Additionally, a spreadsheet showing the effects values used for each species in Step 1 and Step 2 would be very helpful, as would including the numeric values into each of the species-specific summary files in Appendix 4-3.

The current step 2 aquatic methodology does not utilize the detailed locations and use site information in a substantive way, and thus ignores best available data. Instead, aquatic exposure was estimated using assigned bins (based loosely on assumed habitats generically) and the HUC2 location, with no further refinement to account for known habitat, known location and actual waterbodies identified as supportive of specific species.

Best available data need to be incorporated into the assessment. The NAS Panel identified what several of these (mostly government) databases are and also recognized that data developed by registrants was a potentially useful source of knowledge. Further refinement and filtering should be employed based on

[42] Hope BK. 2012. Exposure gone "wild": A call for rational exposure scenarios. HERA 18:485-487

such data, including (1) designated critical habitat, (2) land cover representative of known habitat; (3) known waterbodies in the vicinity of a given species where an aquatic input is important; (4) actual potential use sites adjacent to or up gradient from these locations; and (5) customized exposure assessment to reflect the actual conditions relevant to the species (soil type, weather, crop types, wind direction, elevation, etc.). While the use of multiple data sets may seem daunting, their aggregation and assimilation into the may affect determination can, and in several cases has, been accomplished.[43]

What are called "step 2 exposure estimates" in these assessments are not improvements on the basic crop-species action area determination that is done in Step 1. They actually backtrack from Step 1 because EPA has applied unjustified caveats, illogical areas of concern, and unproven taxonomic relationships when used as "surrogate data" in assumptions that attempt to overcome the deficiencies in the presented methodologies. The exercise is less meaningful as a screen than are the current methods in use, some of which are described in the Overview Document, and it cannot be carried forward to step 3 as if it met species specific endpoint needs. Unfortunately the conservative assumptions, noted numerical issues, assumed drainage area to receiving water ratios, and limitations of using a fixed receiving water body (regardless of actual habitat or hydrology in location of species), do not constitute a "refined analysis."

5.4 Modeling

5.4.1 Aquatic

The aquatic modeling approach followed in Step 2 remains an ultra-conservative, screening level assessment. If this approach had been followed with corrections leading to sensible inputs and models appropriate for the types of water bodies being simulated (e.g., a flowing water model for Bin 2, Bin 3, and Bin 4), then this analysis would have been reasonable for Step 1 of the assessment. The approach followed does not make use of the species critical habitat, known location, or known waterbody information appropriate for a Step 2 analysis for making LAA/NLAA determinations. Nearly all of the comments concerning the BE aquatic modeling throughout this document have been focused on the Step 2 methods, as screening level aquatic exposure modeling was omitted from Step 1. As has been discussed throughout this document, the most significant flaws in the BEs aquatic modeling approach followed in Step 2 include:

- Overly generalized scenarios assigned to represent vast HUC2 hydrologic regions with significant variability in agronomic and soil conditions.
- Minimal accounting for climate variability in regions where significant differences are found over very short distances.

[43] For example, through FESTF's Information Management System.

- Use of a single, highly conservative PRZM scenario to represent all locations of a given crop group within a HUC2, regardless of the proximity or relevance of this scenario to the range of an individual species.
- Highly conservative, screening level assumption for critical model inputs such as Percent Cropped Area (PCA) and Percent Treated Area (PTA) that are implausible for many of the aquatic habitats modeled and not relevant to the species being assessed.
- Representation of watersheds larger than a field size while maintaining a homogenous areas from both the landscape characteristics standpoint and an agronomic standpoint.
- The extrapolation of a single field and static receiving water model to scales both larger (Bin 3, Bin 4) and smaller (Bin 5) than these models were intended to represents.
- Incorporating assumptions concerning watershed drainage area and resulting drainage area to normal capacity ratios (DA/NC) that violate the conceptual model of a static water body with no overflow, and completely break physical laws by assuming massive instantaneous inputs of pesticide runoff load into a receiving water with no change in water volume.
- The inappropriate use of VVWM, a model designed to represent a static water body with overflow, to simulate open channel flowing systems.
- Uniform application timing across large watersheds oversimplifies the realism occurring at the watershed scale and species-specific level of assessment, overstating acute exposure substantially.
- The lack of a probabilistic element to the exposure modeling that accounts for variability and uncertainty in model inputs and assumption as recommended by the NAS report.
- Not utilizing actual habitat data provided in the BE to prove appropriateness of tools employed for the species being evaluated or modify assumptions to develop species relevant scenarios.

Overall, a considerably more refined, species-specific aquatic exposure modeling approach is necessary at Step 2 in order to have sufficient data required to make LAA/NLAA decisions for each species.

5.4.2 Terrestrial

For assessments of endangered birds and mammals in its biological evaluations of malathion, chlorpyrifos, and diazinon, EFED introduced the TED model. According to information provided by EFED, the TED model is a umbrella-type model that compiles several of EFED's more standard, well-known terrestrial organism exposure and risk models, such as T-REX, T-HERPS, SIP, and STIR into a single model. However, information provided in the BEs suggests that EFED has added components to the TED model that are not included in the underlying models that TED is based on, such as additional feed item categories, and a food chain biomagification component. Unfortunately, the TED model is not readily available for download and trial from EPA's pesticide website, or its pesticide models website.

Therefore, a direct evaluation of the TED model is only if the model can be verified as the intended on for use.[44]

Based on EFED's description of the TED model, this model is expected to have similar underlying assumptions and limitations as those found in the T-REX, T-HERPS, SIP, and STIR models. These assumptions include scaling factors that may inaccurately modify toxicity endpoints (LD50 and NOAEL values) of endangered species, and inaccurate assumptions concerning the daily feed ingestion rates of different sized (weight) animals. Based on EFED's description of the TED model, we presume that these same inaccuracies are included in the TED model. Key assumptions of the T-REX and T-HERPS models, which we also presume are included in TED, also include assumptions that birds and mammals ingest only a single category of feed item daily (e.g., eat 100% short grass), and that 100% of an animal's diet is consists of pesticide-treated feed. Although the T-REX and T-HERPS models include modules for evaluating both maximum estimated residues on feed items and median or typical estimated residues on feed items, in recent registration reviews EFED has based its assessments only on maximum estimated residues; therefore we presume EFED made the same assumption about endangered animals only ingesting feed items with maximum estimated residues for its TED analyses.
Another significant limitation of the T-REX and T-HERPS models, which we presume is also included in TED since TED is apparently based on these models, is that the T-REX and T-HERPS models compare both acute and chronic toxicity endpoints to a single-day, acute EEC. For chronic effects, this represents a mismatch of toxicity and exposure, particularly since the vast majority of chronic toxicity effects do not result from a single-day exposure, but rather the chronic toxicity endpoints used by EFED are based on continuous exposures of birds and mammals to a pesticide over a period of months, primarily in reproduction studies. Detailed examples are given in the terrestrial modeling sections that follow.

Also, the T-REX and T-HERPS models assume that residues from multiple applications, which EFED modeled for its malathion, diazinon, and chlorpyrifos endangered species assessments, are linearly additive on feed items. Again, based on EFED's description of TED, we presume this assumption also applies to EFED's TED model. This assumption of residues from multiple applications being linearly additive may greatly simplify the modeling exercise, but based on actual residue trials, this assumption is greatly overestimates residues on feed items and is unrepresentative of potential exposure under actual use conditions.

EFED conducted higher tier probabilistic risk assessments for 13 listed bird species using TIM to estimate acute risk, but these results are more or less presented as an "example" of what could be done - - but has not been done. Such refinement should be performed for the listed terrestrial species and, with aquatic modeling, for aquatic species, that failed in their Tier I analyses – which, as it now stands in the draft BEs, represents the vast majority of listed terrestrial species. However, prior to applying TIM to a refined assessment, the model itself requires correction of the inherent flaws that are currently in it.

[44] The TED model is available through Internet sources, but the location is obscure and the status of the model is not known.

The BE develops thresholds around the most sensitive sublethal endpoints irrespective of the demonstrated relevance of the endpoints for risk characterization (*e.g.* AChE inhibition in *H. azteca*). Sublethal thresholds should be based on growth, survival, reproduction and growth endpoints that can be used in Steps 2 and 3.

5.5 Monitoring Data

EPA acknowledged that monitoring data is available and provides information that could be included, qualitatively, in the weight-of-evidence approach to support potential exposure pathways and exposure concentrations. However, monitoring data were not included as a line of evidence in the assessments. Monitoring data should be used more explicitly in the analysis. For example, a systematic analysis of the proximity of detections to species locations should be conducted and included as a line of evidence. The highest monitoring data concentrations reported were 1 to 3 orders of magnitude lower than the modeled aquatic EECs. However, this was not accounted for to assess the realism of the new modeling scenarios and approaches. The significant discrepancy should have been reason for assigning high uncertainty to the modeled EECs and led to the development of alternative modeling approaches.

Other models also need further evaluation, validation and vetting. EPA indicates that preliminary investigation of bias factors and SEAWAVEQ is underway. These tools would enhance the ability to use general monitoring data quantitatively. Mosquin's work, published in the Journal of Environmental Quality in 2011 should be considered in developing robust bias factor approaches.[45] Additionally, the WARP model, a conservative exposure screening tool, was used to estimate concentrations of chlorpyrifos and diazinon. WARP-predicted concentrations provide valuable information about potential locations and upper bounds on the magnitude of pesticide exposure that should be considered in a weight of evidence approach. Although EPA conducted an analysis with WARP, it did not factor that analysis into LAA/NLAA determinations. WARP concentrations were orders of magnitude lower than concentrations predicted with PRZM/VVWM models. Discrepancies of this magnitude require explanation and further investigation to determine which, if either, of the models may be appropriate for exposure modeling.

[45] Estimation of Upper Centile Concentrations Using Historical Atrazine Monitoring Data from Community Water Systems. Paul Mosquin, Roy W. Whitmore and Wenlin Chen. Journal of Environmental Quality 41 (3): 834-844.

6.0 CONSIDERATION OF FURTHER REFINEMENT

6.1 Aquatic

6.1.1 Aquatic Modeling Parameterization and Species Relevance

The revised approach to modeling aquatic exposure is conceptually not different from screening level models reviewed in the Overview Document. As a screening level assessment, the use of standard scenarios is in line with typical FIFRA risk assessment methods, and standard scenarios are appropriate to use as an early screen of high-end exposure values representing a "worst case" situation, but they do not support a final determination of exposure to endangered species. The source scenarios that have been in use in screening level assessments were developed to represent major production areas, using soil with a moderate to high runoff potential and incorporating agronomics of the specific high production crop area. For the endangered species assessments, EPA made only one modification to these scenarios, and that modification is of questionable scientific relevance, and definitely not a modification that brings any specificity to endangered species assessment. Changing the standard crop scenarios to HUC2 scenarios was accomplished only by a modification of the weather station source, and it is not correct to assume the source is representative of the HUC2 area as a whole; nor does this change do anything to make the model more "specific" to endangered species. In fact the opposite is true. In many cases, only one or two scenarios are used to represent the entire country (Table A3-1.4, Attachment 3-1). It is critical to note the deficiency of this approach because the use of scenarios in this manner does not lead to a representative exposure value for soil, weather, or cropping practices in agricultural areas that may be in proximity to listed species. A focused assessment on species of concern must rely on the best available data for the location of the species of concern. While the biological evaluations espouse an extreme volume of exposure estimates, it is impossible to identify if any of these values are relevant to the unique and localized conditions where a given endangered species is found. The use of HUC2 as an organizational unit for scenarios, weather stations, and crop parameterization is not appropriate for species with known locations. For an exposure relevant to the species perspective, the core data must be better tailored to the species location.
Aquatic exposure modeling at Step 2 should move beyond simple screening level approaches that use a single conservative PRZM simulation to predict EECs in flowing water bodies draining from heterogeneous watersheds. Step 2 aquatic exposure modeling approaches should include the following:

- Representation of the heterogeneous landscape through explicit simulation of the land uses and soils that comprise a given watershed.

- Spatially explicit predictions of EECs that can be associated with species habitat locations.

- An accounting for variability in pesticide application timing that occurs at the watersheds scale. Over larger areas, it is likely that applications timing will vary over a wider window than only the

application interval, and would have significant effect on peak EECs. Accounting for application date variability should be considered in Step 2 aquatic exposure modeling.

- Both PCA and PTA should be incorporated for all 3 flowing bins, as well as the medium and large static bins. These factors are used by HED in their risk assessments for human exposure. PCAs can be calculated based on aggregate use site footprints from multiple crop groups, and PTA, while based on state-level data, can be meaningfully included in the determination of EECs at Step 2. PCAs should be determined independently for each habitat bin and be based on appropriately sized watersheds (e.g., NHDPlus catchments for Bin 2, HUC10 to HUC12 for Bin 3). The use of a state-level PTA should transfer directly to the larger Bin 4 watersheds, which are at the same scale. State-level PTA can be used in several ways for Bin 2 and Bin 3, either as multiplicative factor to PCA, or, by splitting the EECs into percentages assuming worst case 100% PTA and the remainder assuming 0% PTA (no exposure) to then determine the likelihood of exposure at the level associated with use on all labeled crops. Because PCA and PTA are so important in determining exposure concentrations, these factors should be considered rigorously at Step 2, rather than waiting until Step 3.

- Padilla et al.[46] provides a proposed methodology for using the PRZM and SWAT in refined site-specific modeling of flowing water habitat.

6.1.2 Other Observations

Data and parameters that are representative of the species' local habitat and chemical use footprint should be used. Specifically:

- Rainfall patterns across a HUC-2 significantly vary. Assigning a few SAMSON weather stations for each HUC-2 is not representative of the vast diversity it presents. For an expanded, but simple view, there are about 242 SAMSON weather stations across the Unites States[47] that represent data from 1961-1990. Gridded rainfall data from NOAA (NCEP/NCAR)[48] –available at a higher resolution of 2.5 x 2.5 degrees and covering a more recent time period (1961 – till date) and data derived from these rainfall grids closest to the use footprint area and species locations are more representative of the local area, and incorporates the most current trends in rainfall patterns in that area.

[46] Padilla, L., M. Winchell, N. Poletika, and P. Havens. 2016. A watershed-scale refined flowing water exposure modeling approach for endangered species assessments. USEPA Environmental Exposure Public Meeting, Arlington, VA. May 9, 2016
[47] https://www.epa.gov/sites/ production/files/documents/CITY_MAP.PDF
[48] http://www.esrl.noaa.gov/psd/data/reanalysis/reanalysis.shtml)

- Soils data and classification provided by SSURGO (with the most recently released gSSURGO) offers the details needed for a more robust and local scale assessment.
- Cropping patterns based on planting and harvest dates are key to identifying the chemical use footprint area. USDA's Plant Hardiness Zone (PHZ) map[49] provides sub-state level information, based on temperature, to identify areas that are most likely suited for growing crops. USDA's Field Crops Usual Planting and Harvest Dates[50] reported at the state level indicate the dates/periods in which the crops are planted and harvested in most years based on 20 years of historical crop progress estimates, as well as the knowledge of industry specialists. The above two datasets in conjunction provide a more detail assessment and local understanding of the crops to determine chemical use footprint and time of chemical application (which can be particularly important if species presence or increased vulnerability has a temporal aspect)

6.2 Endpoints and Thresholds

The results of reliable and relevant studies[51] on organism responses to target chemical exposure need to be used to set the thresholds that are then inputs for modeling. Therefore, ensuring that those threshold values are set appropriately is critical to the outcome of the risk assessment exercise. The draft BEs do not use best available data, relevant studies or valid estimates to set these thresholds, as is described in detail below.

Toxicity to taxon from exposure to other chemical stressors of concern and non-chemical stressors (*e.g.*, temperature) are discussed. However, stressors often most critical to the health and recovery of the species are not considered. Either the specific action should be considered (individual registration) or the stressors that are most likely to put species at risk should be mentioned and added into the effects determination (e.g. habitat loss, urbanization, weather events, invasive species etc.). This is critical to understanding if the action has an impact on the baseline for the species of concern. For example, if a Registration Review action is to specify the number of treatments that can be made per season, and an added buffer to prevent soil erosion, when before that action, use was unlimited and there was no buffer, then the Registration action improves the baseline rather than further degrades it.

It is stated that the EPA does not typically request toxicity studies for amphibians from pesticide registrants, but rather uses data on freshwater fish to represent potential effects to amphibians in the

[49] http://planthardiness.ars.usda.gov/PHZMWeb/
[50] http://usda.mannlib.cornell.edu/usda/current/planting/planting-10-29-2010.pdf
[51] The validity or adequacy of a study is often thought of as having 2 components: reliability and relevance. Reliability is "the inherent quality of a test relating to test methodology and the way that the performance and the results of the test are described." Relevance is "the extent to which a test is appropriate for a particular hazard or risk assessment." (Technical Guidance Document on Risk Assessment, European Commission, 2003; Klimisch et al., 1997)

aquatic phase. If amphibian data is available and sufficiently relevant and reliable it should be used as surrogate information for listed amphibians.

Questions or uncertainties can occur related to using surrogates to represent potential effects to individual listed species. However, a penalty should not be imposed for having effects data of increased relevance. If data is available for a species more taxonomically similar than other laboratory species tested then this data should be used if of sufficient quality.

7.0 COMMENTS ON THE USE/USAGE OF CHLORPYRIFOS, DIAZINON, OR MALATHION

EPA has adopted a *"weight-of-evidence approach to risk assessment when making determinations (for listed species and designated critical habitats) for the three pilot ESA pesticides (chlorpyrifos, diazinon, malathion)."* In implementing this approach, EPA assumes that a given compound is used on every acre of crop, every year, for the maximum number of applications permitted on the label at the maximum rate. Yet, compelling evidence, readily available and previously used by EPA, disproves these assumptions.

As shown in Figure 8, the U.S. Census of Agriculture shows that a total of 100.7 million acres of agricultural land were treated by **any** means to control **all** insects in 2012, which is 25.8% of cropland and 11.0% of the land in farms. The same Census information is available for each of the 386 6-digit HUC watershed basins.

USDA has extensive pesticide use survey data, including acres treated, application rates, and number of applications per treated acre. USDA data are available for individual pesticides for crop and state combinations where pesticides are typically used. Private survey data are also available, such as that collected annually by GfK.[52]

Major field crops account for much of the total usage of the three pilot pesticides, chlorpyrifos, diazinon, malathion (CDM), but the percentage of acreage of major field crops treated is small. Survey statistics reveal that CDM was used on 2%, 14%, 0.9%, and 0.3% of the U.S. acreage of wheat, hay, cotton and rice, respectively. Acreage treated is higher for specialty crops such as oranges, strawberries, cherries and apples, averaging 92%, 94%, 27% and 32%. Percentage of acreage treated with CDM is lower, in some instances much lower, than the above numbers, to the extent that individual pesticides are used on the same land and to the extent that multiple treatments are made.

[52] The only major data gap is the extent of usage of individual pesticides on the same acre, but this gap could be closed in future USDA/EPA/NASS surveys.

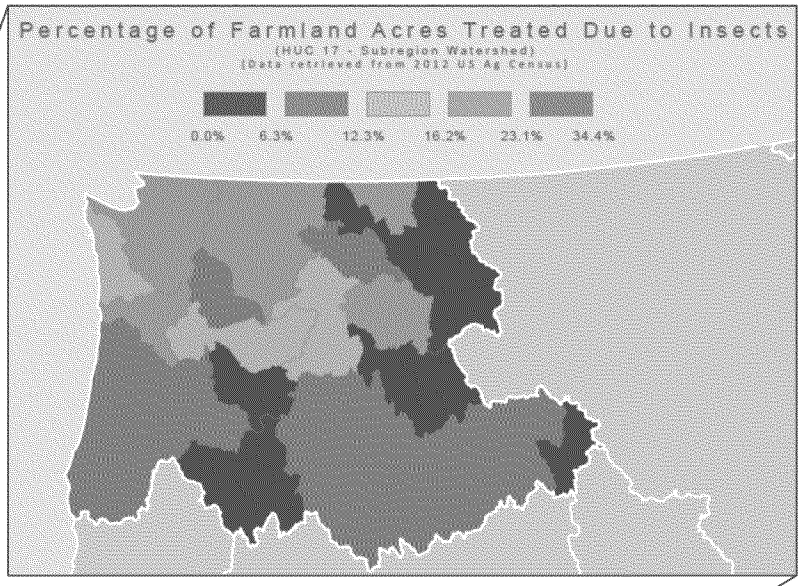
Regional percentages vary considerably by crop. For example, in Michigan in 2011, chlorpyrifos was used on 67% of the apple bearing acreage, but only 9% of cherry acreage.

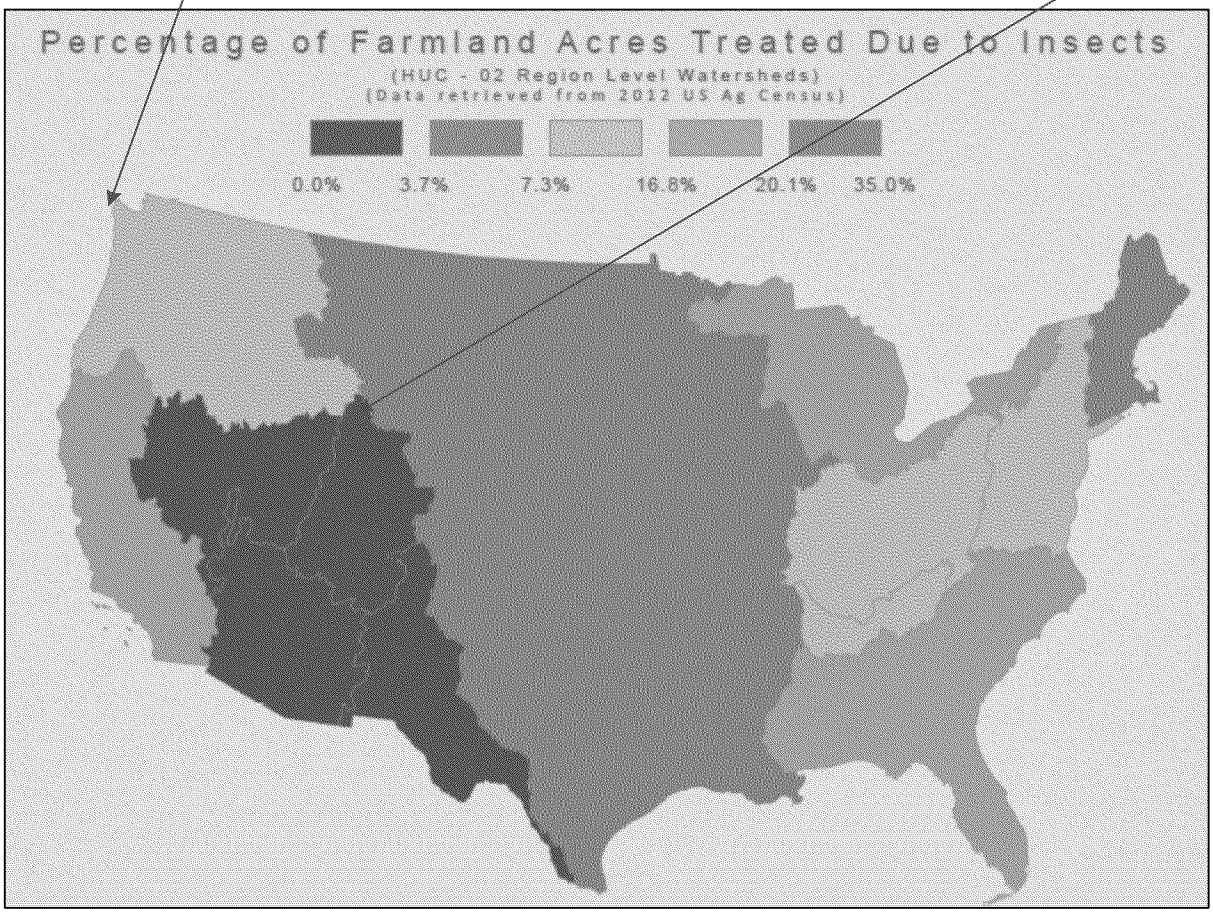
USDA survey data reveal that the average number of applications of pesticides is generally below the permitted maximum. For example, in recent years the average number of applications of Malathion on winter wheat was 1.1 with 2 permitted, on alfalfa 1.4 actual and 6 permitted, on strawberries 2.5 actual and 4 permitted, and on oranges 1.3 actual and 3 permitted.

Applying EPA's usage assumptions to all permitted crops at maximum rates at maximum number of applications gives total A.I. numbers that are orders of magnitude higher than actual use. For example, Malathion usage under the EPA assumptions would total 1,042 times actual agricultural use of it in recent years.

EPA recently used publicly available data to profile usage of individual pesticides, including chlorpyrifos, diazinon, malathion. Yet, they have not incorporated this data into ESA risk evaluation. By assuming that a given compound is used on every acre of crop, every year, for the maximum number of applications permitted on the label they have placed an elephant on the "weight of evidence" scales.

Figure 8. Percentage of Farmland Acres Treated Due to Insects According to 2012 Census of Agriculture


Percentage of Farmland Acres Treated Due to Insects
(HUC 17 - Subregion Watershed)
(Data retrieved from 2012 US Ag Census)
0.0%
6.3%
12.3%
16.2%
23.1%
34.4%


Percentage of Farmland Acres Treated Due to Insects
(HUC - 02 Region Level Watersheds)
(Data retrieved from 2012 US Ag Census)
0.0%
3.7%
7.3%
16.8%
20.1%
35.0%

8.0 NON-TECHNICAL COMMENTS OF A BROADER REGULATORY NATURE CONCERNING THE REGISTRATION REVIEW PROGRAM OR THE ENDANGERED SPECIES PROGRAM

In its Instruction letter, EPA notes, "The interim scientific methods used in these draft BEs were developed collaboratively with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS), hereafter referred to as the Services, based on recommendations from the April 2013 National Academy of Sciences." EPA goes on to state, "As part of this effort, the U.S. Department of Agriculture has provided information on crop production and pesticide uses." The Panel released its report to the Agencies in April 2013 and to the public in May 2013. In August of 2012, OPP called for public comment on Registration Review and the ESA consultation process,[53] an exercise that resulted in a final guidance document issued on March 19, 2013[54], just a little over a month before the NAS Panel report was issued. In light of the developments since the publication of the Panel report, commitments made in this document are very important to revisit when addressing what is needed in policy development. A few points that EPA made that have either not been followed up on, or that are yet to be addressed are:

- A greater role for USDA
- Earlier involvement of stakeholders in the review process, to include
  - Use patterns defined by the registrant in advance of risk assessment by the Agencies
  - Clarifying product use and use practices through additional meetings with states, USDA and commodity groups
  - Consideration of early risk reduction, including key efficacious rates, existing conservation practices
- Consideration of pesticide use and usage data, solicited from USDA and grower groups
- Increased use of the informal consultation process

OPP notes that these changes and the involvement of growers and state lead Agencies "*will also ensure that the protection measures are economically and technologically feasible*."[55] In discussing consultation, OPP notes, "*in developing draft RPAs and RPMs, the Services should include only those risk reduction measures that EPA has the authority to impose and should then defer to EPA to implement these measures using its existing statutory authorities. For example, the Services might identify a level of exposure below which jeopardy would not occur. In response, EPA will implement changes to the pesticide registration that will reasonably ensure that the specified level of exposure is not exceeded.*"[56]

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[53] FR 77: 49792 (August 17, 2012)
[54] Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives. EPA (March 19, 2013)
[55] Ibid, page 8.
[56] Ibid, page 11.

For efficiency and regulatory compatibility, an agreement on negligible risk for pesticide assessment could define both "acceptable risk" under FIFRA and "no jeopardy" under ESA.
Thence came the "NAS Panel report," Assessing Risks to Endangered and Threatened Species from Pesticides.[57] During the interim since the issuance of this report, CLA has been dealing mainly with the science of ecological risk assessment in response to the findings of the Panel and the developments at the Agencies in light of it. That is a correct response, because the Panel was instructed, and repeatedly reminded report readers, that their mission was "science only" and not to address policy. However, in absence of addressing policy needs in response to the Panel report, by default the report becomes a policy guidance document – a role for which it was not intended nor for which it is fit. That has become quite clear in the 3 years of operations under OPP's "Interim Approach"[58] to Registration Review.

9.0 DOCUMENT ERRORS AND TECHNICAL CORRECTIONS

It appears that EPA and the Services worked together to attempt to improve risk assessment efficiencies through automation and aggregation of resources. However, this relegated the biological evaluation to a database exercise without the usual thoughtful and meaningful application of scientific process and a subsequent evaluation in a tiered framework. The biological evaluation included an impressive amount of effects data and species data. However, this detailed level of information and species scale resolution is lost when endpoints across species, within a taxonomic group, assigned as mean and worst case values regardless of species attributes or sensitivity. The attempted efficiencies instead cause the biological evaluations to suffer scientifically by merging species endpoints, focusing only on worst case exposure values across use patterns, not sufficiently conducting spatial analysis, and only focusing on an individual scale views. To use the data and resources effectively, species must be well represented and specifically addressed so that there is not a subsequent high "failure rate" that defeats the intent of the NAS Panel's tiered risk assessment process.

The biological evaluations need to improve in their establishment of a relationship between effects data and relevance to individuals and species at representative environmental exposure concentrations. It is not established in the biological evaluations how thresholds used in the assessment translate into a likely or not likely effects determination (i.e. ecological consequence is not established). Units are often missing in tables and graphs in the effects section. Additionally, the biological evaluations do not appreciate the wealth of data on many species that is available for the OPs. Rather than rely on effects data for the best taxonomic surrogate for the listed species, the BEs rely on the lowest effect value for a taxonomic group. This increases the uncertainly and reduces the value of the assessment.

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[57] NRC NAS Committee on Ecological Risk Assessment under FIFRA and ESA, "Assessing Risks to Endangered and Threatened Species from Pesticides

[58] Interim approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report. EPA, November 15, 2013.

CLA's chapter-by-chapter comments in this section have iterated needed biological evaluation improvement recommendations, such as:

- Use taxonomic association between the listed species and laboratory species for appropriate effects thresholds, organize listed species by habitat type and apply appropriate exposure analysis based on these habitats, apply probabilities to risk analysis to get a better view of risk, consider effects endpoints against the frequency, magnitude and duration of exposure potential. This range of information provides a good relative range of risk. Otherwise all combinations are lumped together and a poor risk analysis is the result.
- The biological evaluation should exclude inflammatory and irrelevant discussions regarding illegal (or unknown) product applications relative to incident reports. Further, only the association between current use patterns and confirmed incident reports should be considered.
- The Interim Approach document and CLA concur on sublethal effects: they are relevant only when associated with growth, survival and reproduction. The BE spends a considerable amount of time collecting such information, arraying the range of information, and then assuming that the lowest effects values for these measurements translates into whole organism and species effects, with little explanation or justification of how this is related to growth and survival of the species.

Overall, the biological evaluations lack consideration for causal linkage between effects, exposures and risk to individuals or species as a whole. This lack of analysis has resulted in a process that is highly ineffectual in reaching what could be interim no effect/NLAA decisions. This is especially concerning as the analysis now, presumably, moves to the Services with little progress or certainty on how the remaining analysis can be conducted effectively. The conclusion that a pesticide is likely to impact all taxonomic groups and nearly all species within those groups defeats the value of the tiered approach that the NAS Panel recommended, and ultimately provides a disservice by putting undue burden on the Services and communicating to stakeholders an unrealistic and incomplete view of risk. Chapter by chapter examples of specific observations follow. These are complete because time and the nature of the documents did not allow a thorough review and findings reported by EPA could not be tracked back to specific data and references in many cases. We provide these comments in addition to those that the individual registrants may observe and report.

9.1 Chapter 1 and its Attachments and Appendices

9.1.1 Chapter 1 Body

- Section 1.2.1 and Fig. 1-2: AOP shows potential pathway from AChE inhibition to individual mortality, but is entirely qualitative. Has there been any quantitative analysis to relate AChE inhibition to assessment endpoints?

- Section 1.2.2, p. 23, paragraph on bioconcentration: based on log Kow, possible bioconcentration; but rapidly metabolized, so bioconcentration limited; how will this inconsistency be accounted for in the weight of evidence?
- Fig 1-3, p. 25: "Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk." Exposure by ingestion of contaminated food is one such exposure pathway. But effects on aquatic plants leading to "reduction in algae and aquatic plants" and "Reduction in primary productivity" would also seem to have a low likelihood of contributing to risk, and should be shown with dotted lines. (Same comment applies to terrestrial conceptual model in Fig 1-4, p. 26.
- Risk hypotheses "link directly to the protection goals of Step 2" (p. 27). These are phrased qualitatively: "reduces the fitness of an individual" based on direct or indirect effects, or "adversely impacts PCEs" for designed critical habitat. Quantitative criteria are needed: reduced fitness by how much? With what likelihood? How frequently? Where?
- Fig 1-5, p. 28: The 3-step process is a logical decision tree but the figure doesn't indicate the criteria for "yes" and "no" findings at each step. P. 29: Step 1 is the process leading to a No Effect/May Affect decision. There are several pathways to a No Effect finding: e.g. no county-level co-occurrence, no action area co-occurrence, not toxic on or beyond treated field, habitat preferences preclude exposure, species is already subject to a protection program. It is unfortunate that the BE takes only one of these pathways – action area co-occurrence – as the sole indicator of No Effect.
- The BE says (p. 29) "Step 1 does not identify the degree of effect that would be anticipated (e.g., an insignificant effect), or whether the risk of exposure of [sic] adverse effects is unlikely to occur (e.g., a discountable effect), where the action area overlaps with listed resources." But this is not in fact the case. The degree of effect is indeed identified: a 1-in-a-million likelihood of individual mortality, or no observable chronic effect. And the risk of exposure is presumed, based on EFED modeling practices: 1 year in 10 (or 15) in a worst-1-in-10 watershed under worst case assumptions (e.g. percent treated area), though the assumptions are mostly implicit and are rarely mentioned. Without such comparisons of assumed effect and exposure, how can the off-site extent of the action area be determined? And if the assumed effect and exposure metrics are available, why not use them directly as part of the Step 1 process (e.g., as described in the Overview Document)?
- What are the criteria for effect magnitude and exposure probability that would result in a finding of no co-occurrence with the action area? And for species that move to Step 2, what are the criteria for NLAA vs LAA?
- Section 1.4.1.1: "Information on effects thresholds and results from offsite transport models will be used to establish the spatial extent of the action area." So effects thresholds and exposure modeling <u>are</u> involved in Step 1.
- Section 1.4.1.1.a, p. 31: Using 5-year aggregation from CDL, will move to 10-year as data become available. Are 5- to 10-year-old data applicable to current crop distributions?

- Section 1.4.1.1.a, p. 31: If NASS acreage exceeds CDL, expand CDL until it equals NASS. "This reduces land cover mapping errors by adjusting the extent of each category to the best available census values." What is the evidence that NASS is more accurate than CDL? How much does this add to the action area, fractionally?
- Boundary of action area is based on lowest exposure concentration found to be toxic. What is the allowable exceedance frequency of this exposure concentration? What is the implicit exceedance frequency, given the model assumptions?
- Where is the Downstream Dilution Tool presented?
- "The 1-in-15-year EEC is the maximum annual, daily aquatic concentration, developed from the 30-year distribution of maximum annual daily environmental concentrations, which, on average, will be exceeded only once every 15 years. It is important to note that for any single 15-year period, the 1-in-15 year value may be exceeded more than once, or not at all." It is also important to note that the EECs are based on conservative, multiplicative assumptions and are much higher than nearly all measured concentrations in the environment.
- The most sensitive taxon for spray drift, terrestrial invertebrates, was the basis for the spray drift action area for all taxa (p. 35). The spray drift action area therefore overestimated the area where other, less sensitive taxa would be at risk.
- p. 36, last paragraph: "This process is iterative [i.e., if additional information becomes available during the course of conducting Step 2 that indicates that the action area is not adequate for the action(s) being assessed, the action area can be revisited]." If such additional information indicated that the action area had been overestimated, it is possible that a species finding would need to be changed to No Effect (no co-occurrence with the action area) in Step 2.
- Section 1.4.2, p. 37: "Exposure values are based primarily on fate and transport model results that assess the range of labeled uses of the pesticide (rates, methods)." EECs from EFED are taken without a discussion of what they represent – i.e., high-end estimates under worst-case assumptions.
- Section 1.4.2.1, Table 1-7, Lines of evidence for risk hypotheses: The phrases in the column headed "Line of Evidence" are actually assessment endpoints, not lines of evidence, and are more than a matter of terminology. "Lines of evidence" and assessment endpoints are two related but very different things. There is no indication in this table about criteria for weighing lines of evidence, or criteria for making decisions based on overall weight of evidence. (Repeated on p. 45-46)
- Section 1.4.2.2, WoE: Approach begins with risk hypotheses "that link directly to the protection goals of Step 2." Nothing about the protection goals of Step 2 appears to be in this chapter, nor in Attachment 1-9. (See separate comments on Attachment 1-9.) The elements of the WoE are plausible risk hypotheses (A/B/C as presented on p. 45-46) and the criteria for expressing "confidence" as "relevance" and "robustness" are reasonable in principle. The key to the success of the WoE will be setting appropriate criteria for relevance and robustness such that they discriminate between species at greatest risk (LAA) and species at less risk (NLAA) or no risk (No Effect). If the criteria in Table 1-8 are set in such a way that the great majority of species fall

into the highest risk category, the criteria are in need of adjustment because they fail to adequately discriminate the degree of risk to different species. What is needed here are meaningful criteria and a clearly defined way to weight them.

- Section 1.4.2.2.a.1, p. 49: What is the scientific basis for the 1-in-15 year EECs? What is the scientific basis for this exposure criterion? How many receiving water sites are presumed to receive this amount of exposure with this frequency, and how many are acceptable?
- Section 1.4.2.2.a.1, p. 50: "Since general monitoring studies are not coordinated with specific applications of pesticides, it is unlikely that they capture the maximum concentrations that exist in the environment." There is no logical connection between coordinating monitoring with specific applications, and capturing the maximum concentrations. Given sufficient numbers of samples, there is a finite probability of including some that are near the upper end of the distribution, and this probability is increased by monitoring programs that target locations and times where pesticide concentrations are likely to be greatest.
- Section 1.4.2.2.a.1, p. 51: If monitoring data exceed effects thresholds, confidence is increased that the chemical poses a risk. But the opposite should also be the case: if a substantial amount of monitoring data, representing a wide range of potential exposure conditions including high-exposure situations, indicate that concentrations are far below the model predictions (EECs), confidence should be increased that the chemical poses no risk (or confidence in the exposure estimate should be decreased). It is true, as stated at the end of this section, that "risk cannot necessarily be precluded," but that is not the appropriate criterion in this case – not that risk can ever be precluded, but that it can be kept within acceptable levels.
- Section 1.4.2.2.b.1, p. 53: Use of open literature data is appropriate if properly screened for scientific method and completeness of documentation. Studies that fail objective evaluation criteria should be given little or no weight in the WoE process. Since many open literature studies use non-standard test designs, relevance is also an issue for consideration before incorporating data into the risk assessment. Therefore greater transparency is needed with regard to data reliability and relevance of the data used in the assessment (see section 10.8).
- Section 1.4.2.1.b.1.2, p. 53: The threshold for indirect effects is 10% effect (EC10 or LC10) for the 5th percentile species (or the most sensitive species). This is an extremely conservative threshold except for listed species with obligate dependencies on other species. Most predators are unlikely to be affected by a 10% reduction in 5% of their prey species, and habitat is unlikely to be affected by a 10% reduction in 5% of the plant species.
- Section 1.4.2.1.b.1.2, p. 54: The threshold for sublethal effects is the lowest available NOAEC that can be "quantitatively or qualitatively linked" to survival and reproduction. A plausible AOP can be constructed for AChE inhibition, or many other sublethal effects, but these do not generally account for the degree of actual linkage to the assessment endpoints of growth, survival and reproduction. Thus this threshold essentially becomes the lowest concentration causing any measurable effect on any parameter in any study. As such, this line of evidence should be rated low for relevance.

Comments on Attachment 1-9, Weight of Evidence Approach

p. 2: The "lines of evidence" (A1 through A5, etc.) are actually risk hypotheses or assessment endpoints, not lines of evidence. The individual lines of evidence are more or less the rows in Table 1-7 of Chapter 1. Each line of evidence can be evaluated for relevance/robustness of EECs and effect thresholds.

p. 3: Under exposure relevance, a bullet should be added to address confidence in model accuracy and realism, and the need to quantify the inherent bias resulting from conservative assumptions. Based on the two bullets now under exposure relevance, essentially any SWC output is considered High Relevance by default, regardless of the implicit and explicit assumptions. Likewise, "robustness" would be high for any compound with a complete set of efate data; very few compounds would have field-scale monitoring data so this robustness criterion is unlikely to come into play.

p. 4: AOP and other approaches to linking measured effects to assessment endpoints are more relevant when quantitative linkages are known; this implies that such approaches are less relevant when quantitative linkages not known, and should not be rated high for relevance in that case.

9.1.2 Chapter 1 Attachments

Attachment 1-12:

Attachment 12 references 'Supplemental Information 3" as an excel file "Compiled Aquatic Invertabrates.xlsx" which appears to have the information that led to the assignment of bins. This file does not seem to be available with the other documentation. An attachment 1-12 Supplement "Supplemental Information 1: Federally Listed Aquatic Invertebrate Database (XLSX) is provided which we assume to be the same document and the reference needs to be corrected.

The background information included batch run control files, for example "1. Chlorpyrifos Aquatic Modeling Batch Input File (ES)111615.csv" and they were sufficient to replicate USEPA output. The xlsx version of the inputs were not included in documentation. Based on the example provided on the provisional models web page, the xlsx version contains additional functionality for creating run rows and it would be desirable to have the XLSX version as well as the CSV:

- Aquatic bin information (field size, waterbody area, depths, etc.) are auto-populated with a lookup function from a tables found in a hidden tab.
- Guidance for choosing inputs is provided in row 1
- A read me tab is provided with directions for creating input sheets and running batch files in PWC.

Rice scenarios are not publically available (although available by request). Cranberry scenarios are not available publically and should be released thru typical EFED channels.

9.2 Chapter 2 and its Attachments and Appendices

2.1 Introduction to Fish and Aquatic-Phase Amphibian Toxicity:

It is stated that the EPA does not typically request toxicity studies for amphibians from pesticide registrants, but rather uses data on freshwater fish to represent potential effects to amphibians in the aquatic phase. If amphibian data is available and sufficiently relevant and reliable it should be used as surrogate information for listed amphibians.

Issues or uncertainties exist related to using surrogates to represent potential effects to individual listed species. However, a penalty should not be imposed for having effects data of increased relevance. If data is available for a species more taxonomic similar than other laboratory species tested then this data should be used if of sufficient quality.

2.2 Threshold Values for Fish and Aquatic-Phase Amphibians

This section discusses using separate thresholds from studies conducted with the technical grade and formulated product when available. Toxicity values are used from the lowest toxicity threshold if they are from studies with the formulated product. What is missing is a discussion of the relevance of the formulated products when environmental fate and dissipation are considered.

Regarding indirect effects thresholds for listed species that consume fish and aquatic-phase amphibians, there is no practical relationship stated or justified between the thresholds used and their actual relationship on indirect effects. Indirect effects thresholds should be stated.

Summary arrays of effects data are grouped by the type of effect (*e.g.,* behavior, reproduction, mortality), and present the range of values for each effect type. The square symbols represent mean endpoint values and the bars represent the data range. The decision to combine data in this way results in losing the detail and resolution needed to advance the risk assessment in a pragmatic way. By combining data (all fish for example) into such arrays the ability to associate the data between appropriate surrogate species (lab to listed species) is lost. The mean values from all studies are assumed to be more relevant otherwise. Further, the relevance of each endpoint group is lost when all fish species are combined together in this way.

2.3 Summary Data Arrays for Fish and Aquatic-Phase Amphibians

Inter-laboratory variability in effects data can result in a range of responses for the same species tested. These difference can be accounted for by using a geometric mean of the values from the distribution.

The toxicity data for each taxon are generally presented as summary data arrays developed using the Data Array Builder v.1.0. This array does little more than illustrate the range of effects responses. It would be appropriate to use this range in sensitivities to characterize the range of risk across listed species of interest and not assume worst-case values are representative (e.g. class, order, family) associations.

Data in these arrays are grouped by the type of effect (*e.g.,* behavior, reproduction, mortality), and present the range of LOAECs and NOAECs (NOAECs must have a corresponding LOAEC to be represented in array) for each effect type. The relevance of behavior responses are not related to whole organism responses and thus species and population level responses. Further the distribution of effects is necessary to later understand the impacts at the population level. It is not clear how this detail will be appropriately translated for use in STEP 3.

There is much discussion regarding impacts of effects such as AChE inhibition, effects to sensory systems, and impacts on behavior. This include references to BCM=Biochemical, CEL=Cellular, PHY=Physiological, BEH=Behavioral and POP=Population responses. The linkage of this to survival and reproduction is not established and it is unclear how population responses could be determined based on this information or how these observations can be related to species populations. This appears to be mostly a database exercise without a critical technical review of the effects characterization.

2.3, paragraph 1: Every data point from every study is presented in the data array summaries. How is this information useful? How does inclusion of all this data alter the conclusion of the mean toxicity value for each effect?

2.4 Lines of Evidence for Fish and Aquatic-Phase Amphibians

Acute mortality (LC_{50}) data for chlorpyrifos are available for 40 fish species and 8 amphibian species based on studies submitted by the registrant or identified in the ECOTOX database. However, the value of this data is lost when these studies are lumped together because the understanding of sensitivity ranges within a taxonomic group is not possible. Therefore, the compiled data do not allow for appropriate association between relevant mortality data and a given listed species. The ultimate loss is the level of resolution needed for risk characterization and, if necessary, risk mitigations that may be needed for a species of concern.

Species effects data and endpoints from studies ranging in exposure durations were considered (e.g. 96 hours up to 10 days) and were included but it is not clear how the differing exposure durations may be translated into comparisons to exposure modeling and risk analysis.

The mortality thresholds for Freshwater and Estuarine/Marine Fish (E/M) fish are based on the 1-in-a million of the HC_{05} based on the Species Sensitivity Distribution (SSD). Again, compiling data into an SSD and calculated HC05 causes the resolution of the species to species level comparison to be lost. This is

especially problematic when there is a wide range of sensitivities across taxonomic groups. In effect, what the SSD would allow you to do is assign species to those data on the distribution and using exposure it would be a way to group species for further analysis but not to stop fully.

Using the lowest value from the distribution for indirect effects builds unrealistic conservatism into the assessment. The assumption here is the amphibian prey base is uniformly sensitive at lowest concentrations resulting in a much more significant impact to prey base. This conservative view should be corrected for (or captured) in the risk characterization.

Data arrays in some cases focus on the sensitive end of the toxicity spectrum. Some of these data may be relevant to some listed species but the selection for the most sensitive end of the distribution for all listed species does not make scientific sense.

Section 2.4.1, Amphibians: How are these studies weighted, if at all? It's difficult to place much confidence in 2 LC50 values where the variance is larger than the LC50 itself (LC50 = 121.87 µg/L ± 346.68; LC50 = 205.24 µg/L ± 543.75). This is likely due to the large spacing in the dose concentrations (50, 500, 5000 µg/L), so it's not clear why these studies are considered the most reliable data.

2.4.2.2 Effects on Reproduction of Fish and Aquatic-Phase Amphibians

Similar to other sections, a data array is presented with endpoints and ranges. Species sensitivities are illustrated but not effectively used in the risk analysis. This makes sense from a "may effect" analysis stand point at the taxonomic level but not in a "likely to adversely affect" sub taxonomic scale analysis.

2.4.2.3 Effects on Behavior of Fish and Aquatic-Phase Amphibians

Lowest toxicity values for behavior impacts are presented with no reference to how these translate to actual whole organisms (individual effects). Even if these were translated into whole organism (then species to populations) they would not expected to be representative to all species. A relationship between behavioral effects across a range of exposure values varied with time is also not established. The Interim Approach states that relevance of sublethal effects (e.g. behavior) is limited to whether or not they can specifically be linked to impacts on individual survival and reproduction. Not making an association between sublethal effects and impacts on growth, survival and reproduction clearly does allow for the assessment of these sublethal effects later to the population level.

Section 2.4.2.3: A behavioral LOEC of 625 µg/L is given for 'the number of movements in the Zebrafish.' What does this mean, and how is this interpreted as a behavioral effect? And how is this correlated to a whole organism effect?

Section 2.4, page 2-18

The chlorpyrifos BE bases hazard values and thresholds for estuarine/marine fish on values collected for freshwater fish, even when marine fish toxicity values are available.

Section 2, page 2-27 and elsewhere

As acknowledged in the chlorpyrifos BE (page 2.51), aquatic phase amphibians may be less sensitive than fish. Despite this, fish hazard values are used when more sensitive, even when amphibian values are available. This is inappropriate for risk assessment and we recommend that the BE be modified to use relevant hazard data for amphibians.

Section 2, page 2-35

The behavioral endpoints identified, *e.g*. spontaneous swimming and feeding behaviors, are of questionable value for risk assessment. The selection of these inappropriate values is propagated to the marine environment as there are no similar studies with E/M species. We recommend that ESA assessments be based on conventional endpoints at screening-level Steps 1 and 2. Step 3 should incorporate higher-tier methods including probabilistic estimates and population models.

Section 2, page 2-38

Cholinesterase inhibition is a highly sensitive biomarker of exposure and is the mode of action of the OPs. However, ChE inhibition should not be used as an effect measure in the place of conventional endpoints, particularly at Steps 1 and 2.

Section 2.5, page 2-46

The BE effects table eliminates some studies that are not reported in units other than µg/L, mg/L, *etc*. It appears that some of these could be converted to µg/L in order to expand the database for use in risk assessment.

2.6 Concentrations Where No Effects Were Observed in Fish and Aquatic-Phase Amphibian Studies

This section illustrates a wide range of values across species where effects were not noted in studies with constant exposures (unlike field conditions). However, the conservative nature of these effects data are not adequately used and expressed in the risk assessment towards discussion of risk probability.

2.7 Incident Reports for Fish and Aquatic-Phase Amphibians

This section as a whole is highly speculative, misleading, inflammatory and without adequate context. The section mentions that some incidents were attributed to compound uses but highlights clear cases

of illegal or undetermined uses. This is inappropriate in that illegal uses are not supported by the label and therefore not appropriate for the risk characterization. The section does not provide context as to the relevance of the uses to current labeled uses.

Section 2.7, page 2-49

In reviewing the incident database, the BE concludes that "exposure pathways for chlorpyrifos are complete and that exposure levels are sufficient to result in field-observable effects." In fact, the reporting of 110 incidents over a 35-year period (1974 – 2009) represents a very small proportion of the applications of chlorpyrifos that have been made. All of the specific use examples described in the BE were of uncertain legality and/or could not be conclusively attributed to chlorpyrifos. The low number of incidents, especially in recent years, brings into question how approved uses of chlorpyrifos are related to the dramatic environmental effects portrayed by the BEs.

Tables 2-1, 2-2 and throughout

The data selected for use, often including those identified as the most sensitive species, may be of questionable value and acceptability. In addition, as many of the endpoints are not from standardized studies, the hazard values are not consistent and are generally not correlated to duration of environmental exposures. We recommend that the EPA and Services use standardized GLP studies in the identification of most sensitive species. For other consolidation purposes (*e.g.* SSDs) in higher tiers of risk assessment, additional studies of confirmed scientific rigor may be helpful.

Table 2-3: How are these studies weighted? Are guideline studies given more weight than ECOTOX studies?

3.0 Effects Characterization for Aquatic Invertebrates

Section 3, page 2-52 and throughout - The BE develops thresholds around the most sensitive sublethal endpoints for invertebrates irrespective of the demonstrated relevance of the endpoints for risk assessment (*e.g.* AChE inhibition in *H. azteca*). Sublethal thresholds should be based on growth, survival and reproduction endpoints that can be used in Steps 2 and 3.

3.1 Introduction to Aquatic Invertebrate Toxicity

Much like other effects sections it is stated that the data is used for weight-of-evidence approach. However, this approach is no more than completing data arrays which illustrate the range of sensitivities but then only calculates or pulls from the lowest end of the spectrum. It appears that the weight-of-evidence approach is only showing the range of potential effects from various endpoints.

3.2 Threshold Values for Aquatic Invertebrates

Lethal thresholds are derived from SSDs of survival from aquatic invertebrate acute toxicity studies, while sublethal thresholds are based on the most sensitive sublethal effects identified among registrant-submitted studies and open literature in the ECOTOX database. This section states that the lowest effects values were used across studies to calculate thresholds and construct SSDs, without respect to the relevance and reliability of the endpoint, the underlying quality of the study, or the relevance of the study to the species of concern. A weight of evidence approach and adequate effects characterization of species sensitivity is lost with this approach.

3.3 Summary Data Arrays for Aquatic Invertebrates

The presented data arrays contain a wide range of endpoint and ECx values. The section does not include a discussion of statistical quality of these extrapolated values (especially those at the low end or beyond the data). This evaluation and associated use of these data are paramount regarding the relevance and reliability of the data and thus the assessment as a whole.

The data arrays do not provide an association between the actual data use and what is plotted. Units are often missing from figures and tables.

3.4.1 Effects on Mortality of Aquatic Invertebrates

The mortality thresholds for freshwater and E/M aquatic invertebrates are based on the 1-in a million of the HC05 based on the SSD. This approach is highly conservative and inappropriate as it does not effectively characterize the sensitivity of many of the species for which data is provided. A threshold calculation for sensitive species should only represent a threshold for species more closely associated to them taxonomically at the screening scale.

Similar to fish, there is an extensive range in species sensitivity across invertebrates. This range is illustrated but not effectively used in the risk characterization.

Section 3.4.1, Mollusks: Shell deposition studies are designed to monitor for shell growth. EC50 values derived from these studies are effects thresholds, and are not intended to be used as a proxy for mortality. Also, it was mentioned that this study did not meet validity criteria for control shell growth.

Section 3.4.2 and throughout

The chlorpyrifos BE incorporates isolated results from qualitative studies into the analysis and weight-of-evidence assessments, without consideration of their relevance or reliability. The conclusions of the BE should be based on high-quality, quantitative studies that are reliable and relevant to the assessment and species of interest.

Section 3.4.2.1: It's interesting that data based on mosquito testing is included, given that chlorpyrifos is used as a mosquito adulticide. Does inclusion of this data skew the overall species sensitivity analysis?

Section 3.4.2.2: A *Daphnia* reproduction LOEC based on reduced offspring in the 1st brood doesn't mean much. Neonate production in the 1st brood in cladocerans is variable, therefore a longer-term study is recommended to allow for 3-4 total broods. Based on what is summarized in this paragraph, there were no differences in reproduction in subsequent broods. This is a good example of why all data requires a critical technical review and understanding of life history patterns before it can be used quantitatively in the BE.

Section 3.4.2.2: The third paragraph in the chlorpyrifos document discusses a marine 35d early life stage toxicity study, but never mentions the species.

3.8 Summary of Effects to Aquatic Invertebrates

It is stated that chlorpyrifos is highly toxic to aquatic invertebrates with less sensitivity exhibited in the mollusk group. Again, there is a range of sensitivity and this statement and the overall analysis loses this resolution.

Figure 3-1: What does NOC stand for?

Table 3 -5: This table is very difficult to interpret and should be better portrayed.

Section 3, Page 4-3

EPA discusses species range geospatial files that were provided by USFWS and NMFS. Could these files please be made publicly available for comment by stakeholders, and so that entities outside of EPA and the Services can conduct the same type of assessment?

Section 2, Page 4-2 and throughout

EPA makes numerous highly conservative assumptions and decisions in arriving at step three as illustrated by the fact that 97% of species for chlorpyrifos are judged "Likely to Adversely Affect" even when the assessment is refined in step 2. The combinations of conservative assumptions and estimates used by EPA regarding potential effects and modeled exposures will result in theoretical scenarios that are far in excess of reasonable environmental exposure and risk. We recommend that EPA and the Services reconsider their ESA methodologies to incorporate additional tools to be able to arrive and environmental realistic and scientifically defensible conclusions around ESA.

Section 4, Page 4-5

The BEs state that an NLAA determination is made for those species and/or designated critical habitats for which the use site (including off-site transport) and range overlap at 1% or more after rounding for significant digits. This approach is very simple and expeditious and relies on little species information. However, (1) the scientific basis for the 1% overlap is unclear, appears to be arbitrary, and needs to be improved, and (2) exceeds the accuracy of the underlying data. This value should be adjusted by species, by the size of the action area, and the location, characteristics and area of the critical habitat. An approach involving such species-specific information would introduce a level of realism, and result in more scientifically-based decision at the Step 1/Step 2 stage. We request that such methods be incorporated into the ESA process at Step 1 and Step 2.

Section 4.4: In other sections of these comments, we have noted how no qualifying evaluation of literature was made. This specific example demonstrates that:

Threshold for aquatic vascular plants, chlorpyrifos: this was based on an open literature study "Removal of chlorpyrifos by water lettuce (*Pistia stratiotes* L.) and duckweed (*Lemna minor L.*)" published in the International Journal of Phytoremediation (study ID 155150, Prasertsup and Ariyakanon, 2011). Based on the information available in ECOTOX, and the information provided in Chapter 2 (page 96-97), this study does not meet many of the factors that "should be considered as important in determining the utility of an open literature study" (page 23 of the Open Literature Guidance), as follows:

Open Literature Guidance	**Study ID 155150**
Nature of the test substance – must indicate exact nature	Not clear if TGAI or formulated product, % a.i. not reported.
Species age, sex, size, life stage, and source reported	Chapter 2, Table 4-1 says the species are from Thailand. No other information given.
Number of organisms tested per concentration and number of concentrations tested	No information
Exposure method, route, frequency and duration	7 day duration, no other information. Analytical verification of exposure apparently not done
Suitable number of controls	A control is reported to be included, but no other information
Performance of test species was typical	No information
Observations (nature, time, of occurrence, severity, etc.)	Relative growth rate was based on wet weight and dry weight; frequency of measurement not provided.
Husbandry conditions	No information. Test apparently conducted in water, not growth medium, so plants may have been under sub-optimal conditions with respect to nutrients
Statistical methods	NOEC for population growth rate reported at

	level of significance <0.05. No further information.
Complete and accurate description of procedures and evaluation of results	ECOTOX record provides limited information. Some additional information in Chapter 2.
Important information missing	Yes
Other useful information: test chemical properties, water quality, negative and solvent control performance, endpoint selection	Temperature, pH, conductivity and dissolved oxygen are reported (single values only). Dissolved oxygen is not a relevant water quality parameter for aquatic plant toxicity studies.

It is noted that this was the only study providing quantitative endpoints for vascular aquatic plants and chlorpyrifos. Nevertheless, due to the weaknesses in this study, it should not be used to make conclusions of "high risk with medium confidence" to most of the listed aquatic plants.

Example 2: Threshold value for terrestrial plants, chlorpyrifos. The selected threshold for Step 2 for post-emergent exposure to monocots was based on an open literature study which reported effects on reduced photosynthetic rate and reduced stomatal conductance in corn at 0.999 lb a.i./A (Study ID E064451, Godfrey and Holtzer, 1992). It is not clear how these endpoints are translated into the assessment endpoint of growth and reproduction. Also, based on the information available in ECOTOX, and the information provided in Chapter 2 (pages 224-225), this study does not meet many of the factors that "should be considered as important in determining the utility of an open literature study" (page 23 of the Open Literature Guidance), as follows:

Open Literature Guidance	**Study ID E064451**
Nature of the test substance – must indicate exact nature	Lorsban 4E, % a.i. not reported.
Species age, sex, size, life stage, and source reported	*Zea mays*, Pioneer 3377, 58 days post planting
Number of organisms tested per concentration and number of concentrations tested	No information on replication. Only one treatment rate tested.
Exposure method, route, frequency and duration	Dosed by ground spray 2 times during a 14-day period. Study done in 2 different years. No analytical verification of exposure.
Suitable number of controls	No information
Performance of test species was typical	No information
Observations (nature, time, of occurrence, severity, etc.)	Physiologic parameters measured with a portable photosynthesis system at 2 or 3 time points after treatment.
Husbandry conditions	No information.

Open Literature Guidance	Study ID E064451
Nature of the test substance – must indicate exact nature	Lorsban 4E, % a.i. not reported.
Species age, sex, size, life stage, and source reported	*Zea mays*, Pioneer 3377, 58 days post planting
Number of organisms tested per concentration and number of concentrations tested	No information on replication. Only one treatment rate tested.
Statistical methods	LOAEC reported at level of significance <0.05, ANOVA (general linear models). No further information.
Complete and accurate description of procedures and evaluation of results	ECOTOX record provides limited information. Some additional information in Chapter 2.
Important information missing	Yes
Other useful information: test chemical properties, water quality, negative and solvent control performance, endpoint selection	"Silty clay loam soil" but no details; pH, organic matter, moisture, etc. not reported.

Given that this study is deficient in a number of the criteria, that it reports physiologic measurements not correlated to the standard measurements of growth (dry weight and shoot height), and that post-emergence data for monocots are available from standard guideline studies (MRID 49307201), this study is inappropriate for selection as a threshold. The guideline studies show that chlorpyrifos does not affect monocot vegetative vigor with IC25 values >5.7 lb. a.i./acre. Note that the full MRID citations are stated to be given in Appendix X, but Appendix X was not provided.

Other examples of studies that were used by EFED without providing detail on the robustness of the study:

- Malathion (aquatic plants)– Chapter 2, Page 109 – direct effect evaluating dissolved oxygen production and cell density in green algae; EFED indicated this study would be used to represent all aquatic plants. This effect is not related to effects related to growth, reproduction or survival.
- Chlorpyrifos (aquatic plant)–Chapter 2, page 89 – the most sensitive threshold value for "all aquatic plants," for direct effects, is based on decreased photosynthesis in a nonstandard species of marine diatom. This effect is not related to effects related to growth, reproduction or survival.

9.3 Chapter 3 and its Appendices

Chapter 3, Section 3.4.2.2: The third paragraph discusses a marine 35d early life stage toxicity study, but never mentions the species.

Chapter 3, Figure 3-1: What does NOC stand for?
Chapter 3, Table 3 -5: This table is difficult to interpret and needs to be better organized and portrayed.

Chapter 3, Section 2.8: Aquatic Modeling Results, CPY

- Issue: EECs regularly exceed the solubility limits
  - BE Statement: "While EECs would not normally be expected to exceed the water solubility limit, variations in waterbody conditions (e.g., pH, temperature, turbidity, hardness) could be different than those used to determine the solubility, such that EECs could be above the water solubility limit; however, concentrations are not expected to be orders of magnitude higher than the solubility reported for laboratory studies."
    CLA Comment: This is overall an inappropriate justification for EECs being higher than laboratory solubility. Note that in case of CPY, the solubility values used were already on the very high end of laboratory results (see Giesy & Solomon for additional solubility values[59]).
  - BE Statement: "EECs derived using the PRZM5/VVWM for Bin 3 (moderate flow aquatic bin) and Bin 4 (high flow aquatic bin) exceeded the solubility of chlorpyrifos by several orders of magnitude for some modeled use scenarios and Bin 4 EECs are greater than Bin 3 EECs which are greater than Bin 2 EECs."
    CLA Comment: This indicates towards a flaw in the overall flowing water modeling approach. A given screening level flowing modeling approach should be appropriate for a range of watershed and water body sizes. The fact that Bin 3 and Bin 4 EECs were determined to be unreasonable point towards the broader limitations and inappropriateness of the flowing water modeling approach that was followed.
  - BE Statement: "Moreover, the concentrations for these flowing bins are several orders of magnitude higher than that derived for the statics bins which have no outlet for the release of pesticide."
    CLA Comment: This should be true for Bin 2 as well. EECs in the small static habitat (Bin5) should be higher than Bin 2. This is not the case in the BEs, which is an indication of the unreliability of the flowing water EECs, including Bin 2.
  - BE Statement: "Limited data are available for edge of field concentrations and should not be used to characterize an upper bound exposure estimate."
    CLA Comment: While limited monitoring data is available for edge of field concentrations, modeled edge of field concentrations are available for every PRZM5 simulation that was run. These values provide an extremely conservative upper limit for every flowing water simulation that was run. These modeled edge of field dissolved concentrations were often 2 orders of magnitude lower than the Bin 2 peak EECs that ranged from 17 ppb to 69,900 ppb (for chlorpyrifos).

[59] Giesy J, Solomon K. 2014. Ecological Risk Assessment of Chlorpyrifos in Terrestrial and Aquatic Systems in the United States. New York, NY: Springer International Publishing.

- BE Statement: "Use of solubility is more appropriate for defining an upper bound exposure estimate."
  CLA Response: The need to use solubility as an upper bound exposure estimate demonstrates the flaws in the modeling approach. Modeled edge of field concentrations (from a conservatively parameterized model) serve as better upper bound for a low flow water body.
- BE Statement: "Existing atrazine monitoring data sets are used to evaluate the relative magnitude in EECs as a chemical moves successively from Bin 2 to Bin 4".
  CLA Comment: There is no data presented to support that the relationship between atrazine from small headwater streams to larger rivers would apply directly to the 3 OPs. Atrazine's environmental fate properties differ from the 3 OP, including solubility, adsorption to sediment, and degradation rates, all of which impact the fate of the pesticide over time in a flowing water system. For the monitoring datasets assessed (AEMP and Heidelberg University), atrazine is used on crops with very high PCA (corn/sorghum) and is very widely used on those crops (a high PTA). These differences in use pattern between atrazine in the watersheds evaluated and the 3 OPs make the transfer of conclusions on atrazine to the 3 OPs unsubstantiated.
- BE Statement: "As such, a qualitative approach is being considered where Bin 2 EECs are generated using the PRZM5/VVWM".
  CLA Comment: An appropriate quantitative approach, that accounts for pesticide environmental fate properties, should be applied to arrive at EECs more relevant to specific pesticide chemistry. Furthermore, the use of erroneously high EECs for Bin 2 to derive Bin 3 and Bin 4 EECs further propagates this error to additional species that are found in these habitats.
- BE Statement: "Bin3 EECs are characterized as being conservatively 5 and 10 times lower than the Bin 2 EECs, and the Bin 4 EECs are characterized as being conservatively 5 and 10 times lower than the Bin 3 EECs."
  CLA Comment: This statement is unclear as written. Based on review of the detailed model results in Appendix 3-4f, it appears that EECs for bin 3 are 5 times lower than Bin 2 and that EECs for Bin 4 are 10 times lower than Bin 2. This needs to be clarified.

Chapter 3, Section 2.9: Aquatic Modeling Sensitivity Analysis

- The aquatic exposure sensitivity analysis was only conducted for environmental fate parameters and application dates only. Given that the flowing water scenarios and modeling approaches are brand new, a sensitivity analysis that included the following parameters would have been more useful:
  - Water body dimensions
  - Water body flow rates within the range of the Bin
  - Watershed area
  - Flow-through options

Chapter 3, Section 2.13.1: Uncertainties in Aquatic Modeling and Monitoring Estimates, Surface Water Aquatic Modeling

- One source of uncertainty described for static water modeling was the effects of increase or decreases in pond levels. Significant increases in levels occurred for many of the static bin scenarios as a result of the very large watersheds. This source of uncertainty should be quantified.
- For flowing water bodies, changes in volume were only associated with surface runoff, and did not account for shallow subsurface flow (interflow) or groundwater contributions (baseflow). These components of streamflow are accounts for more than 50% of total stream flow in many regions of the country and should be accounted for.
- Multiple conservative assumptions for spray drift modeling were described, including the constant 10 mph wind speed, always blowing from the treated field to the receiving water body, no interception of drift on vegetation or other barriers, or BMPs followed by applicators. While these conservative assumptions are appropriate for Step 1 modeling, Step 2 modeling should incorporate more realistic assumptions through a probabilistic analysis of the likelihood of a range of spray drift conditions.
- EECs were shown to be very sensitive to application dates. The uncertainty in application dates should be accounted for in Step 2 modeling in order to achieve a more comprehensive probability distribution of annual maximum EECs to compare against species end points.

Chapter 3, Section 2.6.1: Urban Exposure Model (Chlorpyrifos))

- The neighborhood conceptual model:
  - A large trash storage area (a use site for CPY) equal to the size of a driveway is part pf the conceptual model. Are there examples available of such large trash storage areas on these sized lots? The size seems like an unreasonably large area to devote to trash storage.
  - The fence in this scenario leads to a very large application area. It is unclear what the 6 ft represents, and it is unrealistic to have these fences surrounding every lot in a neighborhood. The applications to the wood fence are treated as impervious surface applications. There is no evidence that PRZM simulations using an impervious curve number value produce predictions of pesticide transport from wooden surface with an acceptable degree of accuracy. The application to the wooden fence is at a rate equivalent to 72.5 lb/acre, which seems extreme.
  - A utility easement is present on a portion of every house lot, which does not seem possible for an entire neighborhood of ¼ acre lots.
  - All the uses of CPY modeled result in effective treated area assumption of 100% of every house lot. There is a 0% likelihood of this assumption happening in reality. Additional data concerning urban outdoor pesticide use should be considered in order to estimate an upper bound on the percent treated area for the urban scenarios.

Chapter 3, Section 2.6.1: Urban Exposure Model (Malathion)

- The neighborhood conceptual model:
  - Patios and other treated areas are not to scale on map. 1,000 ft2 would be the same size as the house footprint and nearly as large as the garden area. Given that this is a significant area, it should be better justified and represented to actual scale on the diagram to provide a better sense of the proportion of the lot these use sites occupy.
  - Dimensions of important features would be helpful
  - Total percent treated area with malathion is equivalent to 38.8% of the neighborhood. What is the likelihood that a residential watershed (of any size) would be 38.8% treated with malathion? Based on our understanding of malathion sales and residential use, this likelihood would be close to 0%. Is this an appropriate screening level scenario assumption?

Attachment 3-1, Background Document: Aquatic Exposure Estimation for Endangered Species, Section: 3.1.3.3.3 Estuarine and Marine

- EPA approximated pesticide exposure in offshore (bin 9) and tide pool (bin 8) marine environments using pesticide concentrations calculated for large stream/riverine-type habitats (bin 4, 7) and smaller stream/pond-type habitats (bin 2, 3, 5), respectively. Neither tidal pools nor offshore marine environments can be modeled appropriately with existing habitat scenarios which represent homogenous watershed areas draining into pond-like receiving waters that are either static or allow for steady inflow/overflow. In addition, the EPA standard scenarios defining weather, crop, and soil characteristics for each HUC2 are based on inland environmental conditions and therefore are not representative of coastal environments.
- Tidal pools by definition are filled with seawater by tidal flushing and wave activity during high wind/storm conditions. The ratio between tidal pool volume and watershed area is not determined by rainfall/runoff. Therefore the watershed sizes from the surrogate habitats, determined through regression of flow rate with drainage area (flowing bins) or precipitation/evaporation/runoff balance to maintain a specific normal capacity (static bins), are not relevant for modeling pesticide exposure in tidal pools and are not related to tidal pool capacity. Tide pools, which vary in volume and may be completely submerged during high tide, do not experience runoff loadings from a fixed-size watershed into a fixed-volume receiving body in the way that classical ponds and streams do. In addition to having inappropriate watershed areas for tide pools, the habitat surrogates have inappropriate flow regimes for tidal pools. The rate, magnitude, and frequency of tidal flushing cannot be approximated by the steady stream inflow/outflow rates used in the surrogates. Tides will have a leading order impact on dilution of any pesticide residues present in the pool via partial or total exchange of the tide pool water with seawater every 12 hours. This is fundamentally different and requires a different modeling approach from the continual, constant baseflow assumed for flowing habitat bins. The watershed areas and flow rates are critical parameters influencing pesticide loadings and dilution in receiving waters. The values of these parameters determined for the static and flowing habitat bins that were used as surrogates for tidal pool habitats are not representative

of tidal pools and require a different modeling approach. Both watershed area and diluting flow/exchange rates for tidal pools are not determined by the same factors used to define these values for the surrogates. In addition, for tidal pools these values are highly variable over the course of one day and these variations are not captured with the surrogates.

- Like tidal pools, the dimensions of offshore marine environments and their drainage areas are not determined by regional variations in precipitation/evaporation/runoff balances or typical stream baseflow rates. Offshore marine habitats are tidally influenced and therefore vary in volume due to twice daily mixing and flushing of the tides. Their volumes and the related dilution of any pesticide residues are determined more by their connection to bays, seas, and oceans (large reservoirs of residue-free seawater) than runoff from upland drainage areas. For offshore marine environments, the drainage areas contributing pesticide loadings will vary for each receiving water body based on local geography and elevation. There is not a generalized relationship between the volume of the marine environment and the contributing coastal watershed area. Specific offshore habitats of interest need to be modeled with spatially explicit characteristics by water models capable of simulating tidal effects.

9.4 Chapter 4 and its Appendices

This chapter of the BE is titled "Effects Determination," although it is, in reality, the Risk Characterization section. It is understandable that such a title was selected if one is to assume the objective of the work is to determine if there is No Effect/May Effect (Step 1) or NLAA/LAA (Step 2); however, it creates confusion with Section 2 (Effects Characterization). Therefore, it is recommended that the section be renamed "Rick Characterization" to be in keeping with the Agency's *Guidelines for Ecological Risk Assessments.* Note that section 8 of this chapter is already titled "Risk Analysis" so it makes sense to realign the name of the Section as well.

The Risk Characterization for Step 2 depends upon a series of highly conservative assumptions. Because probabilities are multiplicative, not additive, the final result is an extremely unlikely event.[60] It may not be necessary or prudent to be so conservative throughout as a highly unlikely event will result in a LAA determination. For example, use of a 1-in-15 years 4-day average for an estimated water concentration as an exposure value will result in much more LAA determinations than use of a 21-d, 60-d, or 90-d average (for 1-in-15 years). Because the estimation of these average concentrations includes a concatenation of multiple conservative input values, the probability that a listed species will experience such a concentration is very small. When this represents a sublethal effect, the probability that such an effect would occur after only 4 days of exposure is even less. And finally, the probability that a sufficient number of individuals experience such an exposure that actually

[60] Hope BK. 2012. Exposure gone "wild": A call for rational exposure scenarios. HERA 18:485-487

results in decreased fitness to a level that could possibly affect the population growth is vanishingly small.

Step 1 No Effect/May Effect determinations are based on the overlap between the crop "action area" and the species range/habitat. While considerable information is provided about how the crop "action area" is determined, less information is available about species range/habitat and what is meant by "overlap."

The term "habitat" is not described. Perhaps the ESA definitions of "habitat" and "critical habitat" can be incorporated into this document.

A definition of "overlap" is needed for Step 1 – Does the "action area" have to overlap all of the species range/habitat or just a portion of it? If a portion, how much? What if they are contiguous (i.e., share a boundary but there is no overlap)? Note that this is defined later in Step 2 as a minimum of 1% overlap, but there is no such definition provided for the initial, Step 1 analysis.

It is surprising that the degree of overlap between the "action area" and the range/habitat is not considered until Step 2 (Section 4 of Chapter 4). This should be part of Step 1.

There is no rationale presented for why 1% overlap was chosen as the minimum required overlap for inclusion as "May Effect". The 1% value seems to be highly conservative, as most of the species do not utilize 100% of their range/habitat 100% of the time. An argument could be made for considering 5% as the *de minimus* amount as well. Please provide a rationale for why such a conservative value was chosen, and include this in the Step 1 analysis.

Attachment 1-6 provides the information about "Action Area" and "Overlap." In the malathion and diazinon documents, this is an EXCEL File (same file in both documents); it has not been incorporated into the chlorpyrifos document although all the information is in the file.

The tab "RangeOverlap" is exactly the same in the malathion and diazinon files. Is this correct? If not, which chemical are these numbers referencing?

Why does the "Species percent overlap with each use site" on the "RangeOverlap" or CHOverlap" tabs not include offsite transport? Therefore, how is the "site" defined? Is the "action area" (= site + off-site transport) defined somewhere else (it does not appear to be available in an EXCEL format).

Section 4 of Chapter 4 says "see **ATTACHMENT 1-6** for results of the Step 1 and Step 2 analysis." This is not an accurate statement as the overlap does not include the entire "action area."

Since **ATTACHMENT 1-6** incorporates the RESULTS of the analysis (i.e., overlap of species range/habitat with chemical use areas), it should be in Section 4 not in Section 1 (Problem Formulation). These data provide the basis for the No Effect/May Effect determination (assuming that "site" and "action area" are the same).

While the **ATTACHMENT 1-6** EXCEL file is helpful in displaying the percent overlap between use area and range/habitat (although it should be "action area" not "use area" and incorporate the calculated off-site movement), presentation of the data via maps would be very helpful, particularly if landcover were included as a filter (e.g., one could then see how agricultural fields might be overlapping with salt marshes).

Chlorpyrifos is assumed to be used in 100% of the US and all its territories for mosquito control and "wide area use." This seems like an oversimplification, particularly since "wide area use" is defined as "*e.g.*, for ants and other misc. pests." It calls into question whether one should really assume that 100% of the range/habitat of species such as the polar bear and the grizzly bear should be considered at risk, as substantial portions of their habitats are not associated with areas of intensive human use. Similarly, the short-tailed albatross only occasionally nests on Midway Island in areas protected for bird nesting, where mosquito control and "wide area use" are unlikely (major nesting colonies are outside the U.S., in Japan). Another example is the band-rumped storm petrel that is a pelagic forager and nests on steep cliffs on volcanic islands; these will not be subject to spraying for control of mosquitoes, ants, or other misc. pests. A Step 1 No Effect/May Effect analysis should encompass more in-depth thinking about the actual locations/ecology of each of the species.

A list of the species for which a "not toxic" conclusion can be made should be included. These species will obviously not need to be carried through the risk assessment so a "NLAA" determination can be made early in Step 2. This should be its own Section in Chapter 4. If the chemical is toxic to all species, then the Section will simply state that fact and move on. "Not toxic" is as defined by EPA (i.e., no effects at the upper testing limit).

For Step 2 (NLAA/LAA), it is very difficult to discern what effects values are being used. The species-specific summary tables in Appendix 4-3 state the types of endpoints that are available, but are not very clear about which one was used (e.g., NOAEC or LC20?) nor do they present the actual numeric value. The effects endpoint used in Step 2 should no longer be the ultra-conservative 1-in-a-million threshold, so an argument needs to be presented as to which level of effect will be acceptable. A spreadsheet showing the effects values used for each species in Step 1 and Step 2 would be very helpful, as would including the numeric values into each of the species-specific summary files in Appendix 4-3.

Similarly, there is no indication of what risk quotient is considered "high," "medium," or "low" so it is impossible to determine if there is consistency in assignment of these values across all lines of evidence for all species, routes of exposure, etc. How large of an effect is needed and how much of an exceedance of the EEC is required to place the risk in each of these risk categories?

Section 4 – this sentence is confusing: "*An effects determination of "Not Likely to Adversely Affect" is reached for 14 species that were "presumed extinct" based on information gathered in review of the 5 year status review but did not meet the additional criteria to receive a no effect detemination*." What are the "additional criteria" that need to be met to receive a "no effect" determination?

Section 4 – it is not clear why exposure is not discountable for Midway Islands, the pacific island coral atolls, and Mona Island of Puerto Rico, all of which have less than 150 people living on them. Midway Islands, in particular, are primarily protected wildlife refuges so assumption of exposure to any of these pesticides is not warranted, or the separate ESA analysis that is conducted through wildlife refuge management procedures should be considered.

The granular exposure analysis for Step 2 (**Appendix 4-6**) for diazinon uses a toxicity threshold for birds set at 1-in-a-million. This is highly conservative and should only be applied in Step 1, not here in Step 2.

Sublethal effects such as behavioral changes, cholinesterase depression, etc. are deemed "relevant to species fitness." However, the degree of relevance can vary as there are thresholds of change below which the organism can adapt. These thresholds have not been identified in Section 2; rather, the value selected appears to be the lowest value where there was a significant difference from control values. This is a large uncertainty for most of the sublethal endpoints (although there are some studies for cholinesterase effects in fish that could be referenced to determine the appropriate behavior-associated threshold, for example) and should be included where determining the weight to put on the "relevancy" criterion in the WoE approach.

We are unable to find the location where the EEC is compared to the toxicity threshold value for each of the endpoints being considered (mortality, cholinesterase, behavior, etc.), so it is not clear how a "high," "medium," or "low" risk categorization is determined. It would be very helpful to have these values and the associated risk ratio presented in the species-specific tables in **Appendix 4-3**. A large amount of information is presented in Sections 2 and 3 from which these values are derived, but it is nearly impossible to correctly attribute the numbers from those tables to the rows in the species-specific tables in Appendix 4-3.

Example 1: Diazinon Appendix 4-3q. Plant*: Asplenium diellaciniatum* (10586), has a "high risk" determination. There is no way to understand why – perhaps because the LOAEC is exceeded for post-emergent or for "alternate rate" applications? But by how much is it exceeded – 2X, 10X,

100X? And how much of a growth reduction does this represent (10%, 50%)? What are the NOAEC and LOAEC values that were used?

Example 2: Chlorpyrifos Appendix 4-3aa) - "*Pritchardia remota*", a growth direct effect was identified as a "high risk", with "low confidence". While it is not clear in the biological evaluation chapters how a "low" confidence rating impacts the weight of a risk conclusion, the "high risk" conclusions are overly conservative based on multiple lines of evidence that should have been included as well as made transparent in the risk determination. This overly conservative approach was a contributing factor that resulted in nearly all listed species resulting in a "likely to adversely affect" call in each of these insecticides' assessments.

To refine this analysis, the levels of conservatism in each of these WoE documents should be defined. Using the *Pritchardia remota* example, the "high risk" direct effect to growth is determined based on a threshold value NOEC being exceeded for the minimum and maximum application rates at the site of a pre-emergent application, however, for post-emergence application, the LOEC value is not exceeded for the upper bound rate (4 lb a.i./A). Based on *Pritchardia remota* habitat being located in scattered, small groves in two valleys with elevations of 50 to 800 feet (information from WoE Appendix 4-3aa), actual in field or edge of field exposure would be rare at most. It is not evident that this WoE document included overlap in critical habitat from the CDLs, or the TED tool analysis for distance that risk extends from edge of field.

*For pre-emergent exposure at the site of application, the NOAEC is **not** exceeded for the minimum application rate of 0.5 lb a.i/A and the NOEC is **not** exceeded for the upper bound rate of 3 lb a.i./A. The LOAEC is not exceeded for the minimum application rate and the LOAEC is not exceeded for the upper bound rate.....For post-emergent exposure, the NOAEC **is** exceeded for the minimum application rate of 0.5 lb a.i/A and the NOAEC **is** exceeded for the upper bound rate of 3 lb a.i./A. The LOAEC **is** exceeded for the minimum application rate and the LOAEC **is** exceeded for the upper bound rate....Considering alternate rate: etc with various scenarios either exceeding or not exceeding NOAEC and LOAEC values.*

The **sea turtle** analysis (Section 7.1) has multiple assumptions that result in an unrealistic conclusion of risk for these species and misses some key issues to consider when assessing exposure potential:

Exposure to bird eggs is used as a surrogate for exposure to turtle eggs, although there is no mention of the fact that birds have hard, calcified shells while turtle eggs are covered in a leathery membrane with no outer shell. Although it is known that bird eggshells are permeable, the degree of permeability likely differs significantly between bird and turtle eggs. This area of uncertainty should be acknowledged.

Extrapolation of dermal exposure estimates between birds and turtles should not be done. Bird skin is very thin without much fat in the dermis whereas turtle skin is more leathery and has greater

amounts of subcutaneous fat. The permeability of the skin likely differs significantly (although turtle skin may be similar to the skin on bird legs/feet). Additionally, the percent of the turtle's body where chemical may come in contact with skin is significantly different than that of birds.

Estimation of uptake of chemical into the near-shore diet significantly overestimates turtle exposures. There is a large uncertainty in the KABAM estimate of the BCF for uptake into plants and the result is a highly conservative (i.e., high) value.

The estimate of the amount of chemical likely to be in near-shore waters is also highly uncertain. This is acknowledged in the following paragraph (emphasis added):

It should be noted that these estimates of exposure are highly conservative, since they represent the highest 4-day and 21-day average concentrations estimated in a 15 year period. *They do not necessarily represent concentrations that would be considered likely in estuary and near shore areas.* In addition, there is a high degree of uncertainty related to the representativeness of bins 2, 3 and 5 for estuaries. *It is questionable whether bin 2, which is a small water body has sufficient volume to hold an adult sea turtle*.

Furthermore, as stated in the diazinon Chapter 4 (emphasis added):
The EECs for these bins reflect contributions from both runoff and spray drift from treated areas adjacent to the waterbodies, which may not typically occur for intertidal and subtidal nearshore waterbodies *which have beaches between the treated area and the leading edge of the water*....[and for bins 2 and 3} there is uncertainty in how well these bins reflect the *turbulent, mixing nature of the 12-hour tidal cycle* and the EECs that may be present. ... it is uncertain if these surrogate bins could hold sufficient volume to contain adult sea turtles."

It is important to note that juvenile **turtles** are <u>not</u> reared in near-shore tidal pools as stated in the document. The hatchlings move into the open ocean waters and juveniles float with the currents for 1+ years, returning to near-shore habitats as subadults.

In **Section 7**, the malathion and diazinon documents say to See Table 2-6.1 of Chapter 2 for the avian dietary thresholds for mortality and sublethal effects; the chlorpyrifos document says to see Table 2-5.2 in Chapter 2 for these values. These tables do not appear in Chapter 2.
In **the sea turtle** analysis, EPA dismisses the monitoring data that show low concentrations of chemical in estuaries. However, these comprise a valid line of evidence and should be considered as part of the estimation of risk to chronic exposure (peak exposures may not have been captured). The measured values are significantly lower than the modeled values.

In the malathion document, the only exposure route where toxicity thresholds are exceeded for **sea turtles** is for uptake into fish in areas where the Rio Grande empties into the Gulf of Mexico (because of

the assumption of high use on cotton crops). Only the loggerhead and olive ridley turtles are known to consume fish, so an assumption of risk is made because the EECs will exceed a sublethal threshold toxicity value. However, there are two reasons to discount this finding:

i. Fish is a minor dietary component of the diet of both these species who prefer to forage on shrimp, mollusks, crabs, and jellyfish. Therefore, it should not be assumed that fish comprise 100% of the diet so the total exposure will be significantly less [It is worth noting that the Stellar sea lion risk analysis in Section 7.3 did take into account the fact that fish are only one of a variety of organisms that comprise their diet, and assumed 100% fish consumption is inappropriate].

ii. Secondly, the loggerhead and olive ridley turtles do not forage in the area where the Rio Grande discharges into the Gulf of Mexico. In fact, the olive ridley is not found in the Gulf of Mexico. U.S. foraging areas are along the California coast, where cotton cultivation does not occur. The loggerhead turtle forages along the U.S. Gulf Coast, but is found primarily *east* of the Mississippi delta.

iii. Furthermore, the analysis shows that any direct effect via spray drift is discountable more than approximately 30 m from the application site, and most coastlines do not have agriculture that close to the shore (see above comment).

Green **sea turtles** are found only in southern Florida, so direct effects via uptake to plants should be represented only by HUC 3 – the highest calculated value for HUC 3 is less than that of HUC 13 which provided the high value used in the analysis. Furthermore, the 21-d, 60-d, and 90-d average peak values for 1-in-15 years are much, much lower than the 4-d average peak value. Therefore, the conclusion for direct effects for all species for all three chemicals should be "low risk" and NLAA.

A similar argument can be made for the **manatee**, which is found only in HUC 3. Potential for freshwater exposure should be based on the values from this HUC alone. Again, the 4-d average value for 1-in-15 years may be overly conservative for this analysis and a more realistic value of 21-d, 60-d, or 90-d average should be chosen.

Dermal exposure in pinnipeds (**Section 7.3**) should not be comparable to terrestrial species due to the subcutaneous blubber layer. Similarly, polar bears and otters have different fur properties to reduce water penetration and therefore reduce the amount of contact of the chemical with the skin. This uncertainty, combined with the uncertainty of exposure potential, is sufficiently great that the dermal exposure route should not contribute to an LAA conclusion for marine mammals.

Inhalation exposure for marine mammals **(Section 7.3)** has an additional level of uncertainty than what was mentioned in the text. Because most marine mammals make protracted dives underwater, they have mechanisms for reducing blood flow to extremities and differing breathing patterns when surfacing. This likely will change the metabolism and distribution of chemical through the

body, making extrapolations of toxic effects highly uncertain. The inhalation exposure route should not contribute to an LAA conclusion for marine mammals.

The analyses for the cave-dwelling terrestrial invertebrates **(Section 7.4)** are identical for all three chemicals. They are all based on assumptions of exposure of dietary items occurring outside the caves and then being washed into the cave or moving into the cave after exposure and prior to death. There is no quantification of this probability, and the statement is made that "there is a potential for effects if exposure occurs, but it's not clear what effects would occur at the exposure concentrations." The probability that is not addressed is the frequency with which prey items might be exposed to lethal concentrations of the pesticides sufficiently close to the cave mouth that they would be transported into the cave, with the exception of documenting that leaf litter could have lethal concentrations for several days. Mapping the overlap of the "action area" with the species habitat should be based on the location of cave mouths, not on the general area within which caves occur (e.g., karst formations of west Texas). This will narrow the area of overlap and help identify the type of agricultural activity that is most likely to result in pesticide use near/around cave mouths. The distance from an agricultural field to a cave mouth should be included in the analysis. Given all the assumptions and qualitative nature of the assessment, the Confidence for direct effects should be "low," not "medium" as shown in **Table 4-21**.

Section 8 of Chapter 4 (Refined Risk Analysis for Bird Species) is an excellent example of how the Step 2 analysis should be approached for all species, data and resources permitting. It provides a probabilistic analysis that is much more informative than the simple deterministic risk ratio and follows the recommendation of the NAS report. Unfortunately, there are deficiencies in model implementation and parameterization.

The Refined Risk Analysis in **Section 8** of Chapter 4 highlights the importance of the selection of the level of effect, e.g., HC05 versus HC50. More information needs to be provided in the prior sections about why particular thresholds are selected.

The Refined Risk Analysis in **Section 8** also provides information about risk of mortality versus risk of reproductive effects, and how these relate to timing of the pesticide applications. These are extremely useful pieces of information as they can be brought to bear on the LAA/NLAA determination for each typical enduse product (which may have different application times) and for each species life history (i.e., some species are more affected by increased mortality and others by reduced reproduction).

For example, the red-cockaded woodpecker is not particularly vulnerable to mortality of individuals, but reproductive effects on the small breeding populations could be significant.[61] So a determination of a low risk of mortality may result in a NLAA while a similar level of risk of reproductive effects might constitute a LAA determination.

Chapter 4 Page-Specific Comments:

Section 3, Page 4-3

EPA discusses species range geospatial files that were provided by USFWS and NMFS. Could these files please be made publically available for comment by stakeholders, and so that entities outside of EPA and the Services can conduct the same type of assessment?

Section 2, Page 4-2 and throughout

EPA makes numerous highly conservative assumptions and decision in arriving at step three as illustrated by the fact that 97% of species for chlorpyrifos are judged "Likely to Adversely Affect" even when the assessment is refined in step 2. The combinations of conservative assumptions and estimates used by EPA regarding potential effects and modeled exposures that will result in theoretical scenarios that are far in excess of reasonable environmental exposure and risk, even if some of the individual estimates alone are scientifically defensible. We recommend that EPA and the Services reconsider their ESA methodologies to incorporate additional tools to be able to arrive and environmental realistic and scientifically defensible conclusions around ESA.

Section 4, Page 4-5

A "Not Likely to Adversely Affect" determination is made for those species and/or designated critical habitats for which the use site (including off-site transport) and range overlap is less than 1% after rounding for significant digits. This approach is very simple and expeditious and relies on little species information. However, the scientific basis for the 1% overlap is unclear, appears to be arbitrary, and could be improved. This value should be adjusted by species, by the size of the action area, and the location, characteristics and area of the critical habitat. An approach involving such species-specific information would introduce a level of realism, and result in more scientifically-based decision at the Step 1/Step 2 stage. We request that such methods be incorporated into the ESA process at Step 1 and Step 2.

[61] *See*: US Fish and Wildlife Service. Red-cockaded woodpecker recovery. Updated November 17, 2015. http://www.fws.gov/rcwrecovery/files/RecoveryPlan/executive_summary.pdf.

10.0 TOPICS FOR CONSIDERATION AND COMMENT

10.1 Identification of "Best Available" Spatial Data to Represent Potential Pesticide Use Sites and Species Locations (Attachments 1-2 and 1-3)

Comment 1: Species location data

Section 1.4.1.2 states that species ranges used in the co-occurrence analysis were provided to EPA in the form of Geographic Information System (GIS) spatial files by the FWS and NMFS. However, the spatial data files used to assign "May Affect" determinations were not made available in the documents posted by EPA. As such, a thorough analysis of these files as "best available" is not possible. EPA has released neither a subset of their data nor a summary file indicating species presence at even the county level for all species. Attachment 1-6 contains a "SpeciesRegions_DraftBE" worksheet but very broad region-presence information is provided. State and county presence is provided for some, but not all of the species addressed in this assessment, in the biological information attachments (Attachments 1-11 through Attachment 1-21), but it is not clear how this geographic range information relates to the species location files received from the Services and used in the overlap analysis in Section 1.4.1.3. Additionally, the co-occurrence analysis should consider temporal aspects as migratory species are only present in a given area for a limited duration and thus may not overlap with the action area when a pesticide is applied.

Species presence by Hydrologic Unit Code region (HUC 2) is provided in Attachment 1-10 but the rationale behind using this very large unit and the methodology supporting these pairings is not provided. Presumably a county or sub-county GIS overlay of HUC regional boundaries against species range was performed, but this is not stated. Section 1.4.1.2 in Chapter 1 states that "FWS requested from the species experts in their Regional and Field Offices the most refined range data (*e.g., sub-county level where possible)* for all listed species under their jurisdiction." Based on the information provided in Attachment 1-10, less than 10% of the species range files used to assign HUCs were refined beyond county. Using county-level range data for over 90% of the species analyzed dramatically over-estimates extent and results in inaccurate and unrealistic HUC assignments (e.g., Sei Whale in HUC 11). The highest resolution data available should be used to represent species range; county-level range data is not considered the "best available". As requested by EPA and USFWS for this pilot, the FIFRA Endangered Species Task Force (FESTF) generated and provided species range maps for each listed species[62]. These range maps included location data refined to the sub-county level obtained from NatureServe and other sources.

Comment 2: Potential pesticide use sites - Agricultural

[62] See MRID 49515201. FESTF Species Maps – Phase 1; MRID 49643401. FESTF Species Maps – Phase 2; MRID 49880801. FESTF Species Maps – Phase 3.

The use of the Cropland Data Layer (CDL) to represent potential pesticide use in agriculture is generally considered the best available at the national level. However, there are other datasets, from the Washington State Department of Agriculture and the California Farmland Mapping & Monitoring Program, for example, which would provide more accurate data at the state, regional, or local level.

Also, it is commonly known that each CDL dataset contains "data errors" and varying degrees of data accuracy[63]. Of note are "spurious pixels," or small areas that are misclassified as agricultural land. These are individual or a few pixels assigned a land use that is inconsistent with their location (such as one pixel on the shore of a pond that is classified as a particular crop). When multiple CDL datasets are aggregated, the spurious pixels (which are typically in different places for each dataset) can artificially expand the use site footprint and result in use site areas outside the true agricultural land footprint. Attachment 1-3 notes that "several methods have been employed to minimize data errors within the CDL" but according to the process definition, the CDL 2014 Cultivated Layer contains all the misclassified pixels (spurious pixels) for the 2014 data year, without any refinement or validation for actual true crop use areas. Therefore, using the CDL 2014 Cultivated Layer as a cultivated land mask to adjust for land cover mapping errors clearly includes known errors in the resulting adjusted land use areas. When "refining" a dataset, the same dataset containing known errors should not be used as mask; this process inherently propagates known data errors. A more suitable dataset to use for the cultivated mask would be the high-quality National Land Cover Dataset (NLCD) 2011, in which land use data have been validated, and spurious pixels removed from areas that cannot support agriculture. The NLCD 2011 has been relied upon for non-agricultural land use types in these evaluations, so the use of this dataset should be acceptable as an alternative data source. Further, if the NLCD 2011 Cultivated Crops (Class 82) and Pasture/Hay (Class 81) could be used as a general refinement for the aggregated CDL for crops and hay/forage production, then the spurious pixel problems within the CDL datasets may be greatly reduced, resulting in a use site footprint that is more consistent with actual land use.

Comment 3: Potential pesticide use sites - Agricultural

Appendix 1-6 describes that label limitations and geographic use restrictions (e.g., many diazinon uses are only allowed in Texas) were taken under consideration when modeling HUC 2 regions but there is no indication that these limitations and restrictions were considered when developing crop footprints. To incorporate the "best available" data, crop footprints should be limited to registered uses and incorporate geographic use restrictions to accurately reflect the extent of potential pesticide use.

Comment 4: Potential pesticide use sites – Non-agricultural

- The potential use site footprint for mosquito control was not spatially defined and assumed to be in every HUC and every watershed. However, data available from the American Mosquito Control Association, registrants, and mosquito control districts indicate at the county and sub-

[63] https://www.nass.usda.gov/Research_and_Science/Cropland/metadata/meta.php

county level where applications for mosquito control take place. This would be a much more realistic spatial footprint representing mosquito control use.

- Appendix 1-6 notes via table footnote that the land cover class "other trees" includes only Christmas trees (with possible misclassification). It is not clear if the land cover class "other trees" was actually utilized to represent the extent of Christmas trees and how the "possible misclassification" was resolved.
- Golf course is listed as a use in the chlorpyrifos master use table, but the dataset representing the spatial extent of this use is not included in Attachment 1-3 with the other non-agricultural uses. Therefore, it is not possible to comment on this dataset as "best available" to represent this use.
- Attachment 1-3 notes that NLCD Developed or Open Space Developed land use categories were used to spatially represent certain non-agricultural label uses, but it is not clear which non-agricultural label uses are represented by which land use category. Details should be provided for these non-agricultural uses.
- The use site footprints for nursery uses were derived using a proprietary business database, Dun and Bradstreet. It is difficult to evaluate its use and conclusions drawn from the data without the knowledge of what the data looks like or the metadata associated with the dataset. Efforts should be made to make this data publicly available. Additionally, the description for this footprint notes that SIC codes "018" and "526" from Dun and Bradstreet were buffered by their facility size. Despite efforts to map production facilities only, this method overstates potential use in nurseries because it includes businesses with no nursery facilities, such as those that are strictly lawn supplies stores, and nursery facilities that do not use pesticides at all.
- Spatially mapped rangeland is the best characterization of the Cattle Ear Tag use. However, tags are used only when pest pressures are high and very minimal off-target exposure is expected. It is suggested the spatial extent of this use be refined with cattle density information from USDA or the Census of Agriculture Farm Survey to determine the presence of cattle and potential exposure.

10.2 Methods Used to Identify Potential Overlaps (and Extent) of Species Locations and Potential Use Sites and their Applications in Effects Determinations Made in Steps 1 and 2 (Attachment 1-6)

This section reviews the details of the use of spatial datasets, methods, and tools to determine the co-occurrence of the Action Area and species locations. The evaluation focuses on the general approach and is generic to all three OPs. However, because the total use site footprints for malathion and chlorpyrifos were considered to be the entire US, the methods presented for the more limited use site footprint of diazinon served as a better example for review. The primary document considered in this evaluation included:

1.) Chapter 1, Section 1.4.1.1: Action Area
2.) Attachment 1-4: Process for Determining Effects Thresholds
3.) Attachment 1-6: Co-Occurrence Analysis
4.) Appendix 3-5: Downstream Dilution Tool Results

Comment 1

Document 1: Chapter 1, Problem Formulation, Section 1.4.1.1c: Action Area, Off-site transport area; Document 2: Attachment 1-4: Process for Determining Effects Thresholds, Section 1: Effects Thresholds for the Action Area (Step 1)

The determination of the spray drift off-site transport distance component of the Action Area was based on spray drift modeling results and effects end points for the most sensitive aquatic or terrestrial species. For the aquatic species, the Expected Environmental Concentrations (EECs), due to spray drift, for the most sensitive aquatic habitat bin (Bin 5) was compared against the end point for the most sensitive taxa (aquatic invertebrates) to determine the spatial extent of the off-site transport distance. The use of both the most sensitive aquatic habitat, which many aquatic species do not occupy as habitat, and the effect endpoint that is several orders of magnitude lower than is appropriate for many taxa, results in an Action Area that is scientifically inaccurate for many taxa and species. The extent of the spray drift based off-site transport zone and associated Action Area needs to be specific to the aquatic habitat characteristics a species occupies and based on relevant conservative effects end points.

Comment 2

Document: Appendix 3-5: Downstream Dilution Tool Results, Section: Use of Downstream Dilution Tool in Step 1

The downstream dilution approach is a simplified method to estimate pesticide concentrations in flowing water bodies downstream of potential use sites. The method assumes that conservative estimates of pesticide concentrations in small high vulnerability water bodies occur on all potential use site areas across the landscape, and that all non-potential use site areas of the landscape would generate pesticide concentration of 0. From this simple perspective, the "Percent Treated Area" (PTA) upstream of any point along a stream network can be used to estimate the pesticide concentration by diluting the estimated concentration from the use site areas by the contributions from the areas with no pesticide use. Implicit in this approach is the notion that all land uses, soils, and slopes within a watershed generate runoff and baseflow contributions to streamflow at the same rate. The approach also does not account for any environmental fate processes of the pesticide during its travel downstream. The EPA recognizes these simplifying assumptions in the BE documents, however it should be emphasized that the downstream dilution methodology is not a substitute for a processes-based watershed hydrologic model which is necessary to achieve more accurate estimates of pesticide concentrations in flowing water bodies.

Comment 3

Document: Appendix 3-5: Downstream Dilution Tool Results, Section: Use of Downstream Dilution Tool in Step 1

In determining the downstream dilution component of the Action Area, EPA assumed "the rights-of-way scenario (a protective scenario utilizing a high curve number)" to generate an EEC that was assumed to reflect the entire use site footprint of the active ingredient (AI). A "right-of-way" use is an off-label use pattern for the AI for which this scenario was applied, and as such is not relevant to the labeled use patterns for the AI (limited to orchards/vineyards, vegetables and ground fruit, nurseries, and cattle ear tags). The determination of EECs for use in the Step 1 downstream dilution analysis should be based upon EECs associated with scenarios for labeled uses of the AI being assessed.

Comment 4

Document: Appendix 3-5: Downstream Dilution Tool Results (Diazinon), Section: Use of Downstream Dilution Tool in Step 1

In determining the downstream dilution component of the Action Area, EPA assumed the single highest EEC simulated for Bin 2 from all HUC2 watersheds and the worst case use pattern (239,000 µg/L) represented potential EECs from the entire use site footprint. Had this EEC been generated from a specific PRZM scenario associated with one of the diazinon labeled uses (see comment 1 above), it should not have been extrapolated to crop group footprints and HUC2 for which it is not relevant. At the Step 1 downstream dilution analysis, EECs relevant to specific crop groups and HUC2 watersheds should be used in the analysis. The screening level aquatic exposure modeling for individual crop groups and HUC2s has been designed to be extremely conservative, so to select a single EEC that is the highest EEC generated nationally (from an irrelevant scenario) and apply it universally across the entire use site footprint is not scientifically valid. Conservative screening level EECs that are crop group and HUC2 specific should be used in defining the downstream dilution component of the Action Area.

Comment 5

Document: Appendix 3-5: Downstream Dilution Tool Results (Diazinon), Section: Use of Downstream Dilution Tool in Step 1, Use of Downstream Dilution Tool in Step 2

The use site footprint used in the Step 1 downstream dilution analysis included uses that do not pose a runoff exposure potential issue. In the diazinon BE, a use site footprint for Cattle Ear Tags was included for downstream dilution concentration calculations, yet the Cattle Ear Tag use was later acknowledged not to pose a runoff risk (Section "Use of Downstream Dilution Tool in Step 2)". Downstream dilution concentrations can only be based upon uses that have the potential to contribute to flowing water exposure resulting from runoff. Uses that do not contribute to runoff should be excluded from the site footprint use in downstream dilution.

Comment 6

Document: Appendix 3-5: Downstream Dilution Tool Results (Diazinon); Section: Use of Downstream Dilution Tool in Step 1

The Step 1 downstream dilution analysis used the "lowest aquatic endpoint" to calculate the dilution factor (DF) in determining the Action Area for all species. This lowest aquatic endpoint based on the most sensitive species taxa can be significantly different from end points for the remaining taxa and species. The use of an end point for an aquatic invertebrate (the most sensitive taxa for the OP pesticides) to determine a downstream dilution factor for aquatic plants (with endpoints several orders of magnitude higher than aquatic invertebrates) is not scientifically justifiable. The determination of downstream dilution Action Area extent should be relevant to the species being assessed, and should be minimally based on effects end points related to the taxa to which the species belongs. Not accounting for the wide range in species sensitivities to exposure results in inappropriate "May Effect" determinations for species that are insensitive to the pesticide exposure.

Comment 7

Document: Appendix 3-5: Downstream Dilution Tool Results (Diazinon), Section: Use of Downstream Dilution Tool in Step 2

The Step 2 downstream dilution approach followed in the EPA BE is a refinement of the Step 1 downstream dilution, and is similar to the recommended process for Step 1. It is unclear from the BE description of how EECs used in the downstream dilution analysis are determined for areas where multiple crop group footprints overlap. A conservative approach would be to take the EEC from the crop group with the highest EEC. A more realistic approach would be to take the average of the EECs for the crop groups that overlap at each pixel, accounting for the variability and uncertainty of the crop group footprints.

Comment 8

Document: Appendix 3-5: Downstream Dilution Tool Results (Diazinon); Section: Use of Downstream Dilution Tool in Step 2

The Step 2 (and Step 1) downstream dilution approach followed in the EPA BEs used a worst case 1-in-15-year annual maximum instantaneous peak concentrations from Bin 2 simulations with PWC as the basis for calculating downstream EEC dilution factors. The instantaneous peak concentrations from the PWC model can be several orders of magnitude higher than the daily average concentrations and are based on a physically impossible conceptual model of exposure in flowing water bodies (see comments on aquatic exposure modeling). The use of instantaneous peak EECs in the downstream dilution analysis is conceptually incorrect, because a nominal amount of travel time is required for landscape-generated pesticide loads to reach downstream locations. In addition, given that the landscape model (PRZM) used

to generate the pesticide and runoff loads operates on a daily time step, daily average pesticide concentrations should be used as the basis for downstream dilution calculations.

Comment 9

Document: Appendix 3-5: Downstream Dilution Tool Results (Chlorpyrifos), Section: Use of Downstream Dilution Tool in Step 2

Downstream dilution was not conducted for chlorpyrifos "because of the widespread use of chlorpyrifos and the uncertainty with where the adulticide, wide area, and non-agricultural uses could occur, the entire United States is considered the action area for chlorpyrifos for Step I." (Appendix 3-5) The same rationale was applied for Step 2. However, the tables in Appendix 1.6 and I .7 indicate that developed uses (which include mosquito control) are separate from agricultural uses and there are certain agricultural use sites that are not applicable across all HUCs (e.g., rice and grassland). If applications are excluded for rice and grassland in some HUCs then it would not be valid to assume use on these sites for any purposes, including mosquito control. Some agricultural crop groups, where use is restricted, should not be assumed to allow a non-Ag, wide area use in Action Area delineation and co-occurrence analysis.

Comment 10

Document: Chapter 4 Effects Determinations, Section 4: Effects Determinations of NLAA - No overlap

A NLAA is determined in Step 2 for all species and/or designated critical habitats with less than 1% co-occurrence with use sites (including off-site transport). There is no information provided for the basis of the 1% cut-off. It is unclear whether the 1% co-occurrence represents a level of co-occurrence determined to be ecologically significant, of if these is other justification in the selection of 1% as opposed to a different nominal threshold (e.g., 0.5%, 2%, 5%). In addition, this implementation of a co-occurrence threshold does not account for uncertainty in the CDL pixel classifications. Recent approaches for developing probabilistic crop footprints using the CDL would help quantify the likelihood of co-occurrence while accounting for dataset uncertainty (see Budreski at al., 2015).[64]

[64] Budreski, K., M. Winchell, L. Padilla, J. Bang, and R. A. Brain. 2015. A Probabilistic Approach for Estimating the Spatial Extent of Pesticide Agricultural Use Sites and Potential Co-Occurrence with Listed Species for Use in Ecological Risk Assessments. Integr Environ Assess Manag. doi: 10.1002/ieam.1677.

10.3 Estimation of Exposure in Various Aquatic Environments (Bins) that have been Regionally Delineated and the Parameterization of Bins and their Relevance across the Landscape

10.3.1 Static Waterbody Parameterization and Methodologies

The reliance on a fixed volume waterbody led the Agency to make other adjustments (DA/NC/watershed size) that introduced extreme concentration predictions. For static bins specifically, the approach of calculating a large watershed to support a static environment introduces errors and led to clearly higher predicted concentrations in dry climates (Table 3-7 chlorpyrifos). The assumption that a large land area could drain to a single puddle, pool, or pond is not documented and their existence supporting endangered species is not documented or justified. One approach would be to start the assessment where the species exist and guide the tools and assessment to look up gradient from there, rather than adjusting watersheds to support an environment that may not exist. More specifically:

- The documentation notes that watershed (and therefore) DA/NC are set to achieve a DA/NC around 15 m^2/m^3 for Bin 5 and a D/ANC "around" 12 and 5 m^2/m^3 for Bin 6 and 7, respectively. There is limited discussion of the source or meaning of these values and no discussion as to how an endangered species habitat is represented by the waterbody or these back calculated "watersheds" to support the static waterbody.
- Evaluating the supplemental information reveals a large range of predicted field sizes/watershed derived from the 242 meteorological station simulations (using the single high runoff soil scenarios, MSCorn). The data was organized by HUC2 and a selection of the 10-25% result for Bin 5 or 75% result for Bin 6 and 7 within each HUC was made, to achieve the desired outcome (it appears achieving the desired final median value was the goal, how these different percentiles were selected is unclear). The data reveals a large range of calculated DA/NC within and across HUC2 areas and highlights that as an organizational unit, the HUC2 is not correct when the goal is predicted concentrations in a localized hydrologic feature.
- Table A 3-1.8 summarizes the selection of Watershed/DA/NC for each HUC2 which is the percentile result within the HUC2 region. Furthermore, describing the results based on the median value simplifies the range and actual impact of the values in the assessment. A more accurate description of the DA/NC values being used in the assessment can be found in the table below, and it is important to note that the HUC2 areas with the larger defined watersheds (drier climates) also resulted in higher predicted concentrations.

DANC (m^2/m^3)	Bin 5	Bin 6	Bin 7
Median	14.9	11.0	5.7
Average	154.7	44.2	18.3
Max	1255.0	204.0	78.8
Min	0.8	0.6	0.3
StdDev	311.4	66.9	25.7

10.3.2 Regional Aquatic Modeling Parameterization and Species Relevance

HUC-2 is too large an area and any single representation derived from it unrealistic. A HUC-2 represents a drainage basin and has no commonality with rainfall, soils, or crop patterns, it simply identifies which major river or coastal water the land area eventually drains to.

10.4 Evaluations of Exposures in Flowing Water Bodies and in Non-Freshwater Habitats

10.4.1 Flowing Water Systems

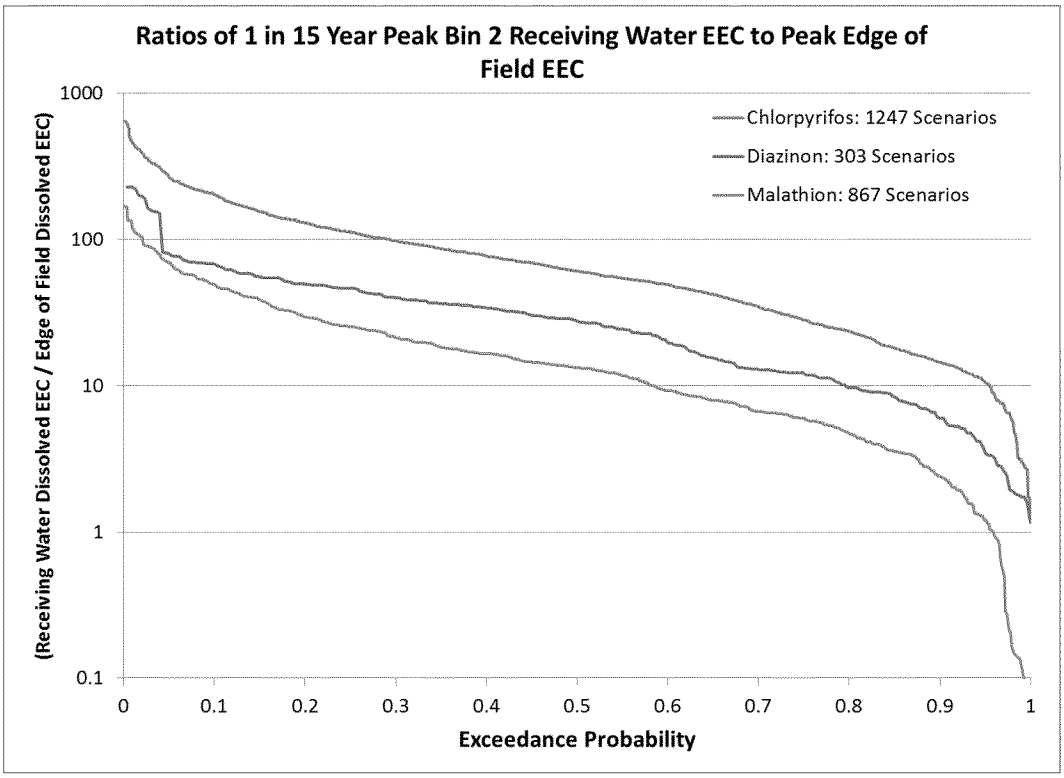
The Bin 2 flowing water Peak EECs are impossibly high (and admittedly so per EPA public statements) due to flaws in the modeling design and assumptions. This is readily demonstrated by comparing the model-simulated 1-in-15-year edge-of-field concentrations to the receiving water concentrations generated by flawed flowing water modeling. The edge-of-field concentrations produced by model simulations that have been described in the Overview Document and vetted through the Science Advisory Panel are several orders of magnitude lower than the resulting peak receiving water concentrations for all scenarios. This is an impossible situation: that the dilution process produces receiving water levels of pesticide residues several orders of magnitude higher than edge of field levels. Dilution physically cannot result in concentration and it is inappropriate to put forth values generated by these untested models as meaningful.

As a way of evaluating model output using results from the chlorpyrifos assessment, the distribution of EECs generated are shown for a population of 1,056 chlorpyrifos scenarios (excluding seeds and urban uses) in Figure 9 below. These results are compared in the figure to both dissolved and total edge of field concentrations.

As a way of quantifying the degree of the over-prediction of Bin 2 EECs, the ESA PRZM/VVWM scenarios were re-run for each of the 3 OPs with drift set to a negligible amount (drift fraction of 0.001), thus ensuring that 1 in 15 year annual maximum peaks would be runoff driven rather than drift driven. These Bin 2 receiving water EECs were then compared against the matching 1 in 15 year edge of field concentrations. For a pair of EECs associated with a single ESA scenario, the ratio of the receiving water 1 in 15 year peak EEC to the edge of field 1 in 15 year EEC was calculated. Any ratio with a value of

greater than 1 indicated a receiving water EEC higher than the edge of field EEC. The results of this analysis are summarized in the figure below for all chlorpyrifos, diazinon, and malathion. Receiving water concentrations are 10x or more higher than edge of field concentrations for 95% of chlorpyrifos scenarios, 80% of diazinon scenarios, and 58% of malathion scenarios To have receiving water concentrations of a diluent several orders of magnitude higher than the contributing source of the diluent is physically impossible and does not comply with logic or the conventional understanding of the dilution process. A more credible expectation is for dissolved receiving water EECs to be lower than edge of field dissolved EECs. Deriving EECs for larger flowing water bodies (Bin 3 and Bin 4) from these erroneous Bin 2 EECs propagates this error to affect a greater number of species than need be included in the assessments. The flaws in this modeling must be corrected.

Figure 9. Ratios of 1 in 15 Year Peak Bin 2 Receiving Water EEC to Peak Edge of Field EEC



The errors in the screening level flowing water EECs can be addressed by taking the following steps:

- Replacing VVWM with a receiving water model designed to simulate pesticide fate and transport in a flowing channel. The Soil and Water Assessment Tool (SWAT) has this capability and has been shown to produce realistic peak exposure values for small, medium, and large flowing water bodies.

- Incorporating a baseflow rate equal to the minimum of the flow range associated with each habitat bin. Bin 2 baseflow = 0.001 (m^3/s); Bin 3 baseflow = 1 (m^3/s); Bin 4 baseflow = 100 (m^3/s)
- Constraining the watershed areas to that which can drain into a main channel within 1 day.
- Applying Percent Cropped Area (PCA) adjustments at a minimum to Bin 3 and Bin 4
- Winchell et al.[65] provides a proposed methodology for using the SWAT in screening level modeling of generic flowing water bins.

Aquatic exposure modeling at Step 2 should move beyond simple screening level approaches that use a single conservative PRZM simulation to predict EECs in flowing water bodies draining heterogeneous watersheds. Step 2 aquatic exposure modeling approaches should include the following:

- Representation of the heterogeneous landscape through explicit simulation of the land uses and soils that comprise a given watershed.
- Spatially explicit predictions of EECs that can be associated with species habitat locations.
- An accounting for variability in pesticide application timing that occurs at the watershed scale.
- Incorporation of Percent Treated Area (PTA) that acknowledges that 100% of potential use sites do not get treated with a given pesticide.

Additional comments on the specific aspects of the flowing water conceptual model and parameterization are provided below.

1. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.2: Revised Conceptual Model and Approach for ESA

- Figure A 3-1.1: The conceptual model for flowing water habitat exposure assumes that the treated field (a square the size of the entire watershed) is adjacent to the water body across the watershed's entire length. As watersheds become large (Bin 3 and Bin 4), this conceptual model of a watershed deviates more significantly from reality. This is in part what led to increasingly higher and more extreme EECs for the modeled Bin 3 and Bin 4. The watershed conceptual model should be reconsidered to better reflect actual watershed characteristics at Step 2 modeling.

2. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.3.2: Aquatic Habitat Bins

[65] Winchell, M., L. Padilla, N. Pai, N. Poletika, P. Whatling and P. Havens. 2016. Development and evaluation of a screening level flowing water exposure modeling approach for endangered species assessments. USEPA Environmental Exposure Public Meeting, Arlington, VA. May 9, 2016.

- The Bin 2 parameters do not represent the vast majority of low flow habitats. The Bin 2 description is as follows, "Some examples of low flow habitats include springs, seeps, brooks, small streams, floodplain habitats (oxbows, side channels, alcoves, etc.), dendritic channels that occur within exposed intertidal areas, and distributary channels in estuaries on the incoming and slack tides." The assumed velocity, of 1 foot per minute, is indicative of an extremely slow moving, essentially stagnant, waterbody, and does not reflect the vast majority of types of habitat listed that Bin 2 represents. Hydraulic calculations using Manning's equations and a very high roughness value of 0.125 result in a channel slope of 0.00001, which is not typical of headwater streams across the US.
- Flowing Bin Flow Rates. The flow rate characteristics of each Bin were given a range (e.g., Bin 2 = 0.001 – 1 m3/s). In each of the 3 flowing bins, the lowest flow rate was assumed when parameterizing the models. While this is conservative, given that the flow rates vary over 3 orders of magnitude within a single Bin, it would be good to evaluate the effects of higher flow rate assumptions when modeling in Step 2.

3. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.3.3: Watershed Sizes

- Watershed areas for the flowing bins were estimated using a regression of area versus average annual flow from the USGS NHDPlus dataset. The watershed sizes estimated, while accurately representative of the targeted flow rates of the three bins (0.001, 1, and 100 m3/s) are not appropriate sized drainage areas for use with the VVWM model.
    - VVWM received runoff and pesticide loads from PRZM on a daily time step. The watershed areas derived based on the NHDPlus regression equations result in watershed areas that exceed a 1-day unit hydrograph base time for Bin 4 scenarios. Watershed areas need to be constrained to areas that can fully drain into a main channel within 1 day.
    - The watershed areas for the flowing bins resulted in drainage area to normal capacity ratios (DA/NC) of 1.) Bin 2: 334 – 7725, 2.) Bin 3: 604 – 11218, 3.) Bin 4: 739 – 35614. The EXAMS/VVWM model has long been used to simulate receiving waterbody pesticide concentrations from much smaller watersheds, with DA/NC of 5 (EPA farm pond). The use of VVWM for scenarios with such extremely different ratios of drainage area to water body size needs to be validated to ensure that results are appropriate for such a different hydrologic scenario.

4. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.4.2.1: Issues Modeling Medium- and High-Flowing Waterbodies, Modifications Considered But Not Incorporated

The following improvements for Bin 3 and Bin 4 modeling were explored but not considered:

- **Incorporation of Base Flow:** This section discussed approaches to incorporating baseflow into the model parameterization for Bin 3 and Bin 4. Several methods for estimating baseflow rates were presented, however no conclusions were presented as to a preferred approach to estimate baseflow. Estimation of baseflow for Bin 2 was not mentioned in this discussion. Baseflow occurs for all sized streams across much of central, eastern, and more humid parts of the western US. If there were no baseflow, we would not have a flowing aquatic habitat, with the exception of storm events. For screening level flowing water modeling, a nominal baseflow rate should be set for each of the 3 flowing habitat bins. Given that the flow rates that define each bin span a range (e.g., 1 to 100 m3/s for Bin 3), the lowest flow of the range should be assumed to represent the baseflow condition. Flows below this amount do not define the bin of the species that inhabit that class of waterbody. During storm events, the flow rates will increase to levels above the minimum defined for the bin.
- **Percent Use Area and Percent Use Treatment Adjustment Factors:** The concept of using Percent Crop Areas (PCA), Percent Use Areas (PUA) or Percent Treated Areas (PTA) was proposed. It was noted that these factors are used by HED in their risk assessments for human exposure. Both PCA and PTA should be incorporated for all 3 flowing bins. PCAs can be calculated based on aggregate use site footprints from multiple crop groups, and PTA, while based on state-level data, can be meaningfully included in the determination of EECs at Step 2. PCAs should be determined independently for each habitat bin and be based on appropriately sized watersheds (e.g., NHDPlus catchments for Bin 2, HUC10 to HUC12 for Bin 3). The use of a state-level PTA should transfer directly to the larger Bin 4 watersheds, which are at the same scale. State-level PTA can be used in several ways for Bin 2 and Bin 3, either as multiplicative factor to PCA, or, by splitting the EECs into percentages assuming worst case 100% PTA and the remainder assuming 0% PTA (no exposure) to then determine the likelihood of exposure at the level associated with use on all labeled crops. Because PCA and PTA are very important in determining exposure concentrations, these factors should be considered rigorously at Step 2, rather than waiting until Step 3.
- **Adjustment of Water Body Length:** It was suggested that increasing the water body length, accounting for a meandering stream, would increase the water body volume and thereby reduce the DA/NC ratios lowering the EECs to more realistic levels. Given the current use of VVWM, this effect would be true, but it is the underlying use of the VVWM to model a flowing channel that leads to the problems of unrealistically high EECs with large DA/NC ratios. The extreme EECs with higher DA/NC ratios do not occur with models designed to simulate channel flow, such as SWAT (see Winchell et al., 2016[66]). We suggest that water body length is not the main issue to address for the flowing scenarios.
- **Spreading Out Applications:** Based on testing with diazinon, it was determined that spreading out applications across a window equivalent to a retreatment interval, did not have a significant

[66] Winchell, M., L. Padilla, N. Pai, N. Poletika, P. Whatling and P. Havens. 2016. Development and evaluation of a screening level flowing water exposure modeling approach for endangered species assessments. USEPA Environmental Exposure Public Meeting, Arlington, VA. May 9, 2016.

effects on peak EECs. Over larger areas, it is likely that applications timing will vary over a wider window than only the application interval, and would have significant effect on peak EECs. Accounting for application date variability should be considered in Step 2 aquatic exposure modeling.

5. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.4.2.2: Issues Modeling Medium- and High-Flowing Waterbodies, Modifications Explored and Incorporated into Modeling

The following improvements for Bin 3 and Bin 4 modeling were explored and incorporated into a case study:

- **Curve Number Adjustment:** An area weighted CN value at the HUC12 level was calculated and used to select a 90th percentile CN value for each HUC2 and used as the representative CN value for Bin 3 and Bin 4. This is a very sound approach to obtain appropriately conservative CN values. A suggestion would be that for Bin 4, a larger watershed (say HUC8 or HUC6) 90th percentile CN value be used to more appropriately represent that Bin. In addition, this approach should be applied for Bin 2 as well, using NHDPlus catchments as the watershed units from which to select a 90th percentile CN value for each HUC2.
- **Daily Flow Averaging:** The option of using daily flow averaging (instead of 30-year flow averaging) in VVWM was evaluated. It was mentioned that the SAM model was used for daily flows, but it is very unclear how this was done. It is assumed that simply the VVWM flow averaging period was simply changed from 30 years to 1 day to implement this option, and that SAM was not required. Nevertheless, the daily flow averaging option should be a requirement for modeling of all flowing bins (2, 3, and 4).
- **Adjustment of Water Body Dimensions:** This option used a "representative length" of 40 m to represent that water body length (as opposed to the full watershed length) and adjusted the volume accordingly. This "representative length" has been proposed for use in SAM. While this option may be effective at lowering EECs closer to realistic levels, it is conceptually inaccurate, and would not be necessary if an appropriate flowing water receiving model were used to route the flows (such as SWAT).
- **Use of Daily Average EECs:** The use of daily average EECs instead of peaks was proposed. One argument was that typical toxicological studies have a 48-hour duration. For this reason, daily average or 48-hour average EECs should be used instead of peak EECs for all aquatic habitat bins. There are no toxicological tests that measure effects of instantaneous exposure.

6. Attachment 3-1: Background Document: Aquatic Exposure Estimation for Endangered Species, Section 3.1.4.4: Modifications Evaluation, Pilot Chemicals, Final Approach

- The alternative modeling approaches for Bin 3 and Bin 4 modeling were evaluated for atrazine and compared against monitoring data. The proposed approaches resulted in the most refined EECs comparing relatively favorably with atrazine monitoring data, so the refinement approaches were tested for the 3 OPs.
- Based on testing with the 3 OPs, the alternative modeling approaches produced similar results for some cases. . Values higher than solubility were still noted and cases of Bin 4 and Bin 3 EECs higher than Bin 2 were also noted. The lack or improvement in EECs is being driven by the limitations in receiving water model (VVWM). Several of the alternative modeling approaches considered (CN, daily average EECs) are good ideas for refinement and should be pursued in conjunction with a more appropriate receiving water model.
- Final Approach to Calculating Bin 3 and Bin 4 EECs: Based on review of atrazine monitoring data, scaling factors were derived to estimate Bin 3 and Bin 4 EECs from the model-simulated Bin 2 EECs. While these values are more appropriate than the modeled values that had been calculated, there are limitations to this approach:
    - There is no data presented to support that the relationship between atrazine from small headwater streams to larger rivers would apply directly to the 3 OPs. Atrazine's environmental fate properties differ from the 3 OP, including solubility, adsorption to sediment, and degradation rates, all of which impact the fate of the pesticide over time in a flowing water system.
    - For the monitoring datasets assessed (AEMP and Heidelberg University), atrazine is used on crops with very high PCA (corn/sorghum) and is very widely used on those crops (a high PTA). These differences in use pattern between atrazine in the watersheds evaluated and the 3 OPs make the transfer of conclusions on atrazine to the 3 OPs inappropriate.

10.4.2 Appropriateness of Marine Bin Surrogates

Neither tidal pools nor offshore marine environments can be modeled appropriately with existing habitat scenarios which represent homogenous watershed areas draining into pond-like receiving waters that are either static or allow for steady inflow/overflow. In addition, the EPA standard scenarios defining weather, crop, and soil characteristics for each HUC2 are based on inland environmental conditions and therefore are not representative of coastal environments.

Watershed areas assumed for the marine scenarios (based on their surrogate freshwater scenarios) are not relevant to these habitats. The watershed sizes from the surrogate habitats, determined through regression of flow rate with drainage area (flowing bins) or precipitation/evaporation/runoff balance to maintain a specific normal capacity (static bins), are not relevant for modeling pesticide exposure in marine habitats and are not related to their capacity.

The habitat surrogates have inappropriate flow regimes for the marine bins. The rate, magnitude, and frequency of tidal flushing and currents cannot be approximated by the steady stream inflow/outflow rates used in the surrogates freshwater bins. For tidal pools, tidal action will have a major impact on dilution of any pesticide residues present in the pool via partial or total exchange of the tide pool water with seawater every 12 hours. This is fundamentally different and requires a different modeling approach from the freshwater bins.

10.5 Evaluation of Exposure to Terrestrial Organisms, including Dietary and Non-Dietary Routes of Exposure

It is unclear what ecotoxicological endpoints were used in the risk assessments for terrestrial invertebrates (i.e., what specific toxicity test results were used to assess the risk for each listed species). There appears to be no foundation for the conclusions reached. Given these examples of uncertainties, it is surprising that the Agency concluded that there is a high degree of certainty in their risk predictions.

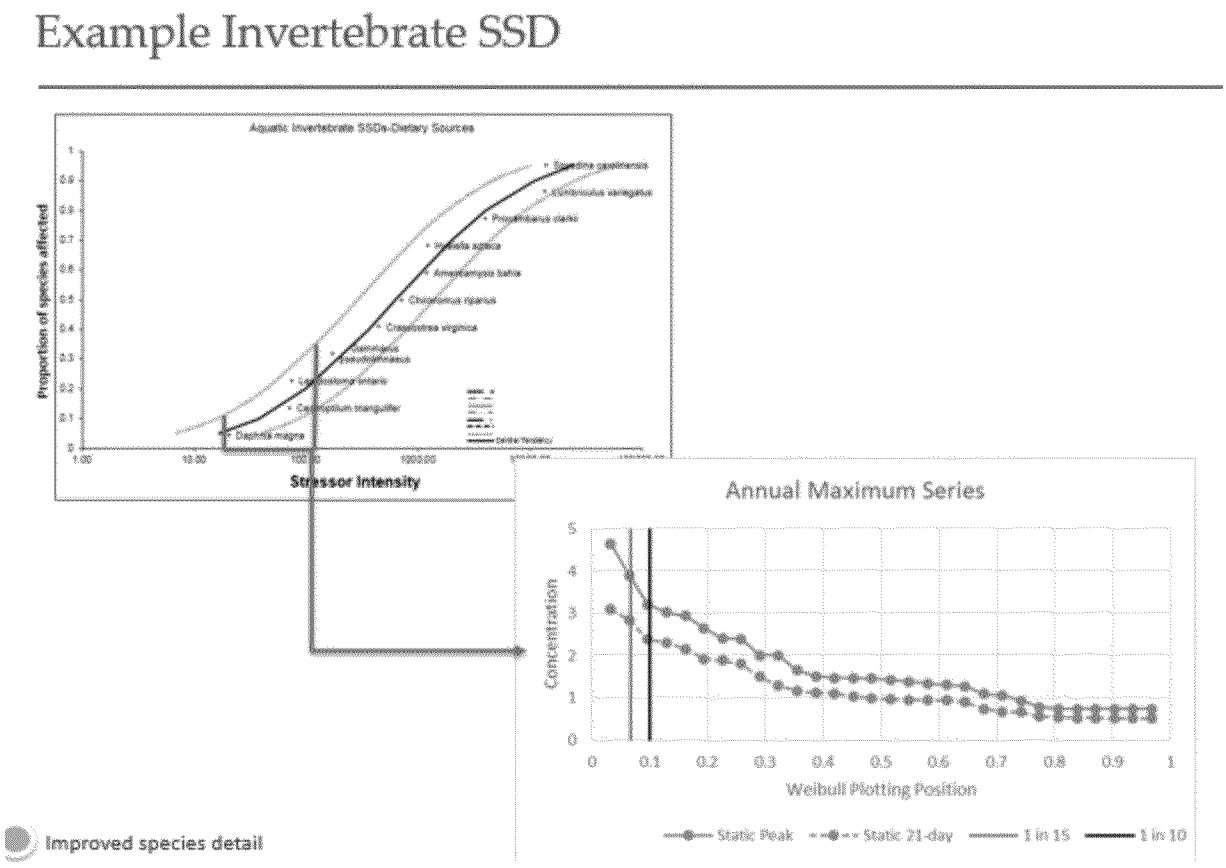
The statement is made "T*here are currently no toxicity data available for terrestrial plants and chlorpyrifos that have mortality as an endpoint.*" This is a false statement, there is data from the pre-emergent and post-emergent studies. If mortality occurred it would be noted. A more accurate statement would be that no mortality occurred in these studies at the rates tested.

The information in the weight of evidence tables for the different species indicates that there is information available for a given number of species, but does not state what the endpoints were or how they were used. This makes it impossible to validate the application of data for terrestrial invertebrates. Therefore, a thorough scientific analysis that ties assigned values to species is required. Evaluation of results based on currently available information is otherwise impossible. It is also unclear what toxicity information was used to predict the sensitivity of snails.

10.6 Use of Species Sensitivity Distributions to Evaluate Effects (Attachment 1-5)

When developing the SSD for avian acute oral toxicity, page 2 of Attachment 1-5 describes that acute oral LD50 endpoints are normalized to represent birds with a body weight of 100g prior to curve fitting. This normalizing step is not necessary since each endpoint is reported in dimensions (mg/kg bw) that are normalized for body weight. The question of relevant exposures (perhaps conservative to start) and impacts to a subset of the prey based (ecological meaningful) have to be addressed.

Figure 10. Example Invertebrate SSD



If there are enough data points to construct a reliable SSD (the number varies depending on reference sources, ranging from about 5 to 8) then a point estimate from the SSD (perhaps the HC5) can be used as the basis for the ES effect threshold, as an alternative to using the most sensitive species. If there are fewer than 20 species in the SSD, chances are the HC5 is slightly lower than the LC50 for the most sensitive species. Sublethal endpoints observed in LC50 studies (e.g. lethargy, disorientation, agitation, pilation) should not be used for any purpose. In the past, EPA has used the HC10, at least for plants and within the Office of Water. They have also used the HC10 for indirect effects.

SSD is normally used as a higher tier assessment approach for ecological risk assessment. The assessment factor (AF) applied to the HC_x (either lower limit or median) should be reduced. In the non-listed non-target organism ecological risk assessment, according to the practical guidance published by

EFSA,[67] the AF is reduced from 100 (for acute) and 10 (for chronic) to 3-6 (the selection of the AF depends on the data set size and the distribution of the data along the SSD curve). Since it has been shown (and would be expected) that listed species are not inherently more sensitive to chemicals than non-listed species, application of the SSD approach in the listed non-target organisms would be expected to have a similar reduction of the AF from one-in-a-million. How much it needs to be reduced to will require further understanding of how much the uncertainty plays in the data extrapolation.

SSDs have been used in chemical risk assessment for at least 20 years as an improvement over basing risk characterization on the most sensitive species. Theoretically, an SSD depicts the fraction of species in a community that would be affected (by a specified amount, e.g. 50% mortality) at a given exposure concentration, and the HCx represents the concentration causing a certain magnitude of community effect. EFED uses SSDs in this way for assessment of indirect effects (e.g. indirect effect on fish diet due to direct effect on invertebrate community). Ecologists have supported the use of SSDs for this purpose, with certain qualifications. The big question, of course, is relating overall community impact to the fraction of species affected, something that has not been done in the Agencies' evaluation of indirect effects.

In the BEs, the SSD is also being used for a different purpose, namely, to make an assumption that an untested listed species is equal in sensitivity to the xth percentile of tested species. This seems sensible, in principle, and when enough data are included in the SSD it avoids the assumption that the listed species is as sensitive as the most sensitive tested species (which may be an outlier). One can argue about what percentile is appropriate to assume – 5th percentile (HC5) seems highly conservative, since it has been shown (and would be expected) that listed species are not inherently more sensitive to chemicals than non-listed species. Theoretically, the SSD describes an underlying distribution of species sensitivities, and only makes sense if species are compared using similar endpoints. There is no point comparing an NOEC for lethargy for Species A with an LC50 for Species B – the comparison doesn't yield anything about which species is more sensitive. Lethal and sublethal endpoints cannot be mixed and endpoints measured at different life stages (e.g., time-wise) should not be mixed as well. It is clear that only the same set of the endpoints from different species can be used to generate a valid SSD. The protection level on which the assessment relies determines what endpoints need to be focused on for the SSD to reduce the uncertainty in data extrapolation. The same group of endpoints (survival; growth; reproduction; off-spring survival, etc.) that are used for the SSD will be helpful in determining a reliable HCx that is relative to the protection level.

The data set that can be used for SSD is in general from the standard studies with a range of species that are tested. There are two factors that should be considered for the data quality in regard to the usage in SSD.

[67] EFSA Journal 2013; 11(7):3290

1) Whether the group of the non-target organisms tested are sensitive to the product (depends on the mode of action).

For these three biological evaluations, the most useful/sensitive groups of non-target organism are recognized as arthropods (by literature). If the SSD approach is applied to non-target plants, its use should be evaluated with respect to bringing more certainty to the risk assessment.

2) The quality of the data set that is used in the SSD also depends on the selection of the data, and the process of the data within the same species.

Following the Agency test guideline that is designed for generating pesticide endpoints, and, where used, having assurance that published data are reliable and relevant, are crucial steps to ensuring whether the data generated are reliable or reproducible. A consistent set of toxicological endpoints needs to be used in a given set of SSDs in order to reduce the uncertainty. If there are several qualified studies available for the same species, a geometric mean approach should be used to reduce the inter-lab and inter-study variation of the endpoints, which ultimately helps reduce uncertainty.

3) The number of data points that are used for SSD are very crucial to the meaning of an SSD as well. At least 5 data points are needed for vertebrates, and 8 data points are needed for invertebrates according to the practical guidance published by EFSA.[68]

Specifically:

- Conceptually, it is more relevant to use the SSD in a higher tier assessment and not as the source for the one-in-a-million value. The one-in-a-million value would be more appropriate as a tier 1 assessment using the lowest endpoint, if relying on one data point only for a specific taxa (fish, aquatic invertebrates, etc.). In this scenario, the uncertainty would be higher than using data from multiple sources. With the SSD, the uncertainty level is significantly lower because many species are used to generate the regression curve to calculate HCx values. Since the uncertainty is much lower when using an SSD, it is proposed that the level of uncertainty (i.e., one-in-a-million) should be adjusted to reflect this decrease in uncertainty. The uncertainty level should be based on the life history patterns of each listed species; a cookie cutter approach would not be applicable.

- The quality of the SSD is only as good as the quality of the data used to construct the regression line. Data quality has been extensively discussed in previous sections. This includes the selection of test organisms tested once by one author (e.g., snake-head catfish, rainbowfish, etc.) and/or sublethal effects that cannot be correlated to whole organism response (survival, growth, reproduction).

[68] Ibid

- The authors are trying to do too much with the SSDs. That is, the significance of a specific point of interest is diluted or lost because the authors include all data in the SSDs (i.e., horizontal lines) that are of questionable quality at best. It would be more reasonable to apply a set of criteria to all data for a single species/AI (things like flow-through vs static, measured vs nominal, etc.) and identify the most reliable endpoint, and if there are multiple equally reliable endpoints for a particular species/AI, take the geometric mean to use for that species in the SSD. It is also possible to generate SSDs using Oracle Crystal Ball software to select an endpoint for each species from the range of available endpoints, or from the confidence interval around an individual value, as one way to incorporate the uncertainty around individual data points into the SSD.

- Each SSD should be constructed with similar endpoints. That is, sublethal endpoints should not be mixed with survival (or immobility) endpoints; it is also not advisable to combine survival endpoints from different study times (i.e., 24 hr, 48 hrs, etc.). Likewise, it is not advisable to construct SSDs consisting of different sublethal effects. There is obvious biasing (either direction) when obvious sublethal effects (i.e., lethargy) are mixed with less obvious and less proved/replicated/relevant sublethal effects (PAM fluoresence for aquatic plants).

- SSD summary statistics do not provide units.

10.7 Characterization of Toxicity Data from Registrant Submitted Toxicity Data and Literature, and Utility of Sublethal Effects Data

Crucial to any risk assessment are the underlying data for the effects and exposure characterization, which are then used in the risk characterization and weight of evidence approaches. The data used must be robust in both its reliability and relevance to the risk assessment paradigm and its associated assessment endpoints, attributes and risk hypotheses. The Numerous papers have provided examples of such an evaluation process (Klimisch et al. 1997,[69] Durda and Preziosi 2000,[70] Hobbs et al. 2005,[71] Schneider et al. 2009,[72] Breton et al. 2009,[73] Hall et al., 2012,[74] Van Der Kraak et al. 2014,[75] Beasley et al.

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[69] Klimisch H-J, Andreae M, Tillmann U. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Regulatory Toxicology and Pharmacology* 25:1-5.
[70] Durda JL, Preziosi DV. 2000. Data quality evaluation of toxicological studies used to derive ecotoxicological benchmarks. *Human and Ecological Risk Assessment* 6:747-765.
[71] Hobbs DA, Warne MSJ, Markich SJ. 2005. Evaluation of criteria used to assess the quality of aquatic toxicity data. *Integrated Environmental Assessment and Management* 1:174-180.
[72] Schneider K, Schwarz M, Burkholder I, Kopp-Schneider A, Edler L, Kinsner-Ovaskainen A, Hartung T, Hoffmann S. 2009. ToxRTool, a new tool to assess the reliability of toxicological data. Toxicology Letters (Amsterdam) 189:138-144.
[73] Breton RL, Gilron G, Thompson R, Rodney S, Teed S. 2009. *A new quality assurance system for the evaluation of ecotoxicity studies submitted under the new substances notification regulations in Canada*. Integrated Environmental Assessment and Management 5:127-137.

2015,[76] Moermond et al. 2015[77]). What is common in nearly all of these schemes is a thorough evaluation of study with a clear documentation on the evaluation of each study.

In general, there is concern for the lack of completeness and transparency in the evaluation of the data use dint he risk assessment. Comments on the reliability and relevance of the underlying data in the assessment and how it can be used are found throughout this document. Some examples of sections where more information can be found are:

- Section 9: Documentation errors and technical correction – provide examples of where a more thorough review of the data is needed and where the relevance of the data needs to be better established or explained.
- Section 10.7: Use of SSD
- The following sections to 10.8 reviewing published literature, incident data, and sublethal effects.
- Section 10.9: Use of mortality effects thresholds based on chance effects – discussed the transparency needed in grouping of the data and establishing thresholds
- Section 10.11: Weight of evidence – discusses the importance of an *a priori* approach to the risk assessment paradigm and the weighing of the data.

10.7.1 Submitted and Published Literature Data

The results of data characterization as described in BE Appendix 1-4 and 2-3 cannot be evaluated. The utility of the data array builder is questionable because the open literature review summaries (Appendix 2-3) are incomplete and cannot be linked to data in the "array." The data array builder is questionable because many studies have either not been reviewed or have not been included in the review summary and the reason for doing such is not explained. For studies included in the review and used quantitatively in the BEs, Appendix 2-3 contains the following warning (in capital letters), "some of the 'quantitative' studies still need to go through secondary review." It is very concerning that endpoints used in the BEs have been selected from studies that have not undergone thorough review. Data from these studies should not be relied upon until the study results are evaluated.

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[74] Hall, A.T., B.D. McGaughey and J.A. Gagne. 2012. *Data Quality, Reliability, and Relevance Standards for Ecological Risk Assessment: Recommendations for improvements to pesticide regulation in compliance with the Endangered Species Act*. In K.D. Racke, BD. McGaughey, J.L Cowles, AT Hall, SH Jacksons, JJ Jenkins and JJ Johnson (Eds), Pesticide Regulation and the Endangered Species Act. American Chemical Society, Washington DC.
[75] Van Der Kraak GJ, Hosmer AJ, Hanson ML, Kloas W, Solomon KR. 2014. Effects of atrazine in fish, amphibians, and reptiles: An analysis based on quantitative weight of evidence. Critical Reviews in Toxicology 44(S5):1-66.
[76] Beasley A, Belanger SE, Otter RR. 2015. Stepwise Information-Filtering Tool (SIFT): A method for using risk assessment metadata in a nontraditional way. *Environmental Toxicology and Chemistry* 34:1436-1442.
[77] Moermond C, Kase R, Korkaric M, Agerstrand M. 2015. CRED: Criteria for reporting and evaluating ecotoxicity data. *Environmental Toxicology and Chemistry* DOI:10.1002/etc.3259.

EPA states that it has followed its guidance on the use of open literature studies,[78] with modifications as described in Chapter 1, Attachment A-8. EPA's guidance on the web site (hereinafter referred to as Open Literature Guidance) states that a study may be considered appropriate for "quantitative" use if it meets following:

a) is reported in, or can be converted to, environmentally-relevant exposure units;

b) the endpoint is consistent with endpoints currently used to derive risk quotients (e.g. LC50 for acute exposure in fish;

c) "sufficient information *must* (emphasis added) be provided in the open literature to substantiate and/or independently evaluate whether the study conclusions (i.e. dose-response) and endpoints are accurate", and

d) the endpoint from the open literature study must be lower (i.e., more sensitive) than the lowest endpoint from a comparable registrant-submitted study for all taxon with the exception of aquatic-phase and terrestrial-phase amphibians, freshwater mollusks, reptiles, and for derivations of SSDs for other groups.

Chapter 1, Attachment A8 states that EPA used ECOTOX as a first screen. Given that the criteria for inclusion in ECOTOX are very minimal, this is appropriate for casting a wide net and as an initial screen.

The second level of screening should have been OPP's evaluation of the appropriateness of a study's use in the assessment, as described above. However, the only criterion that seemed to be retained was item (a), regarding the units. Data with environmentally-relevant exposure units were used to build the arrays; the other criteria were not applied. This means that studies with very low reliability and relevance can become part of the arrays, essentially rendering the arrays useless. Uncertainty is supposed to be included in the effects arrays (Chapter 1, page 51 in the chlorpyrifos BE) – but how uncertainty is used is not discussed. While the concept of arrays, to allow presentation of a lot of data visually, is appealing, by including essentially all open literature without critical evaluation, EPA has presented a meaningless compilation of data.

Returning to discussion of the open literature studies that EPA used for development of thresholds, it is stated that these were "intensively reviewed" and only the study providing the lowest effect information was reviewed in detail. It is further stated in Chapter 1, Attachment A8 that the studies used for thresholds had to meet the definition of "quantitative" as described in the Open Literature Guidance. This means they would have had to meet the criteria given above in "b", "c" and "d." For plants, if data were insufficient to construct an SSD (as was the case for the OPs, and as mentioned

[78] http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_evaluation_open_literature.htm

previously SSDs were not even considered for plants), only studies providing lower effect levels than registrant-submitted guideline studies were even considered (criterion "d"). This ignores potentially high quality plant effects data that could constructively inform the assessment, because at best, they would only be shown in the arrays (along with data of questionable quality). Moreover, EPA does not seem to have followed criteria "b" and "c" as illustrated by the examples provided in Section 9.0 (Document Errors and Technical Corrections, review of BE section 4.4).

The presented data arrays contain a wide range of endpoint and ECx values, in absence of a discussion of statistical quality of these extrapolated values (especially those at the low end or beyond the power of the data). This type of evaluation is paramount to subsequent use of these data, regarding the relevance and reliability of the data and thus the assessment as a whole. In fact, the data arrays do not provide an association between the actual data used for assessment and what is plotted in the array. Units, source and other critical items of data integrity are often missing from figures and tables.

Effects data considered in the BEs, or any risk assessment, should be relevant to the assessed organism(s) and robust (reliable). Therefore, effects data should only be considered if: (1) studies are on test organisms that are relevant to the organism(s) being assessed; (2) it is representative of effects from environmentally relevant exposure routes and durations; (3) data are produced from a suitable test system with appropriate test conditions; (4) results are reproducible; and (5) the study produces endpoints that can be quantitatively or qualitatively linked to survival, growth, or reproduction. Not all effects data considered in the draft BEs meet these criteria. As stated on pp. 2 of Attachment 1-4, *"Endpoints generally are: a) from in vivo studies that are conducted with whole organisms; b) representative of environmentally relevant exposures routes, and c) able to be quantitatively or qualitatively linked to effects on survival, growth or reproduction."* However, some endpoints (e.g., plasma acetylcholine levels) are not linked to toxicological effects, yet are still considered as an adverse effect in the evaluations. Effects data should be re-evaluated, with additional scrutiny, for its relevance and utility in the final BEs.

Page 4 of Attachment 1-4 states, *"For deriving a threshold based on sublethal direct effects to listed animals, the lowest available NOAEC or NOAEL or other scientifically defensible effect threshold (ECx) that can be quantitatively or qualitatively linked to survival or reproduction of a listed individual is used,"* however, the draft BEs rely on sublethal endpoints such as plasma cholinesterase which have no link to growth, survival and reproduction or toxicological relevance in general.

When assessing the indirect effects to endangered birds and mammals by compound related mortality of prey items, the use of an LC50 is more appropriate than the LD50. Using the LC50 does not require the toxicity thresholds to be scaled to different size classes to accommodate a unit-to-body weight adjustment, nor is it then necessary to add the assumption that uptake and absorption kinetics of a gavage toxicity study approximate the absorption associated with uptake from a dietary matrix. Further, the assessment should more accurately portray individual species diets by assigning prey to the

appropriate size class based on the best available species information. Using only the default assumption that a 20g bird or 15g mammal feeds only on treated short grass will grossly overstate assumed exposure when compared to exposures calculated from actual dietary composition.

10.7.2 Use of Incident Data

The use and interpretation of incident data is highly speculative, misleading, inflammatory and without adequate context. It also does not follow the policy document it references.[79] Variously in the three assessments, EFED mentions that some incidents, while strongly linked to compound uses, were clear cases of illegal application or undetermined sources or rates. Yet, an incident like this was used to support a risk assumption as if it were a labeled, legal use. Illegal uses are not supported by the label and therefore not appropriate for use objectively or subjectively in risk characterization. Any use of incident data needs to provide context as to the relevance of the reported event to current labeled uses and the likelihood that it was from a labeled, legal application, or if not, what kind of evidence it supplies should be described.

Foreign incident reports should not be used to supplement the available U.S. incidents. Foreign incidents may not represent U.S. agronomic practices, products, uses, or exposures given differences in environmental conditions and therefore do not benefit the characterization of potential effects to species in the U.S.

10.7.3 Sublethal Effects Data - Animals

Sublethal endpoints in the BEs should be limited to effects with a direct link to survival, growth, or reproduction and should exclude effects that are markers for exposure with no direct link to apical adverse effects (e.g., plasma cholinesterase inhibition). Endpoints should be weighted with direct measures of survival, growth, and reproduction, receiving the highest weight depending, in part, on the level of biological organization at which the endpoint was measured. For non-apical sublethal endpoints that are part of an Adverse Outcome Pathway ("AOP") (e.g., acetylcholinesterase inhibition), weighting should in part be influenced by the number of key events identified in the study.

In the BEs, available effects data for cholinesterase inhibition are considered in the mortality and behavioral lines of evidence and in some cases may be used to define the lowest effects threshold in the assessment. Chapter 2 explains the use of cholinesterase inhibition data in this way is justified based on the AChE AOP. AChE AOPs include the key event of acetylcholine accumulation at the neuromuscular junctions of skeletal muscle or synapses in cardiac tissue. Some endpoints considered in the BEs, including plasma cholinesterase inhibition, do not inform whether this key event has been triggered. Therefore, plasma cholinesterase inhibition and other values not directly related to an event should not

[79] Policy Memo from Don Brady to Managers and Staff of EFED. Guidance for Using Incident Data in Evaluating Listed and Non-listed Species under Registration Review. October 13, 2011

be used in the assessment as values that trigger an "effect."

The uncertainty regarding the ability to accurately predict apical outcomes from biochemical or behavioral measures must be considered based on the current quantitative understanding, and the reliance of these endpoints in the BEs must be weighted based on the uncertainties associated with them.

Controlled laboratory studies and the conditions under which they are conducted influence the outcome of a study. Confinement under laboratory conditions may alter the behavior, physical condition, and even biochemical levels in some species. The potential impact of test conditions must be intensely scrutinized when evaluating studies for sublethal effects such as predatory behavior, because captivity itself can bring on stress that results in exaggerated behavior. Thus, any stress-related indications should be validated in the field or considered in light of the stress presented by the testing environment.

10.7.4 Sublethal Effects Data – Plants

Figure 1-8.1 in Chapter 1, Attachment A8 shows a flow diagram that was used on the studies appearing in ECOTOX. This figure echoes the AOP concept, which is an attractive unifying concept but has not been worked out for many chemicals. Interestingly, the AOP is known for the organophosphate pesticides, and based on the AOP, effects on plants would be eliminated from further consideration as plants do not have acetylcholine. However, plants were not eliminated. More generically, it is not clear just how effects at the biochemical, cellular, or organ levels are to be demonstrated to be relatable to survival or reproduction, and therefore allowed to be considered further for development of thresholds.

10.7.5 Interpretation of "Sublethal" in Context of the Assessment

Sublethal effects, as recommended by the NAS Panel, will most likely require the subjective interpretation of whether these types of effects are possible and detectable in the natural environment. However, EFED instead attempted to make this a quantitative evaluation regardless of the fact that no context for environmental expression of an indirect effect actually has potential to adversely impact an individual or the population of organisms. For example, EFED used the lowest toxicity values for behavioral impacts with no reference as to how these translate to actual whole organisms (individual effects). Even if these were translated into whole organisms and then then species to populations, they would not be expected to be representative of all species and all settings. A relationship between behavioral effects across a range of exposure values which vary with time is also not established. The Interim Approach states that relevance of sublethal effects (e.g. behavior) needs to relate to the impacts on individual survival and reproduction. Making an association between sublethal effects and impacts on growth, survival and reproduction, if such a link can be made, clearly does allow for the assessment

of these sublethal effects at the population level. If the link cannot clearly be made, then the mere existence of a sublethal effect is not evidence of a likely effect on species survival and reproduction.

10.8 Use of Mortality Effects Thresholds Based on Chance Effects

10.8.1 General Issues

This section discusses using separate thresholds from studies conducted with the technical grade and formulated product when available. Toxicity values are used from the lowest toxicity threshold if they are from studies with the formulated product. What is missing is a discussion of the relevance of the formulated products from an environmental fate and relevance perspective.

Regarding indirect effects thresholds for listed species that consume fish and aquatic-phase amphibians, there is no practical relationship stated or justified between the thresholds used and their actual relationship on indirect effects. Indirect effects thresholds should be stated.

There is no justification for the conservatism in the threshold for indirect effects based on mortality. The current approach sets the threshold at the concentrations/dose estimated to cause 10% effect on to the most sensitive species, or 5th percentile most sensitive depending on data availability, of the taxa that are relevant to the specific species being assessed. This value implies that the assessed species fitness depends on 90% survival of the most sensitive relevant species, which infers an obligate relationship between the assessed species and the relevant species which is not the purpose of this threshold. Further, this approach neither considers the duration of effects and recovery potential of the relevant species nor the diversity of the diet or habitat of the assessed species.

10.8.2 Summary Data Arrays for Fish and Aquatic-Phase Amphibians

Inter-laboratory variability in effects data can result in a range of responses for the same species tested. These differences can be accounted for by using a geometric mean of the values from the distribution.

The toxicity data for each taxon are generally presented as summary data arrays developed using the Data Array Builder v.1.0. This array does little more than illustrate the range of effects responses. It would be appropriate to use this range in sensitivities to characterize the range of risk across listed species of interest and not assume worst-case values are representative (e.g. class, order, family) associations.

Data in these arrays are grouped by the type of effect (*e.g.,* behavior, reproduction, mortality), and present the range of LOAECs and NOAECs (NOAECs must have a corresponding LOAEC to be represented in array) for each effect type. The relevance of behavior responses are not related to whole organism responses and thus species and population level responses. Further, clarifying the distribution of effects

is necessary to later understanding of the impacts at the population level. It is not clear if this detail will be appropriately translated for use in STEP 3.

The mortality thresholds for freshwater and estuarine/marine fish are based on the 1-in-a million of the HC_{05} based on the Species Sensitivity Distribution (SSD). Again, compiling data into an SSD and calculated HC_{05} causes the resolution of the species-to-species level comparisons to be lost. The overly conservative selection of thresholds is especially problematic when there is a wide range of sensitivities across taxonomic groups. Instead, the SSD should be utilized to assign listed species to those data on the distribution that are as closely taxonomically related as possible, then threshold exposure values could provide a mechanism to group species for further analysis but not to end the assessment and "risk conclusion" at that point. For example, in fish and invertebrates there is an extensive range in species sensitivity across species in each taxonomic group. While the range is illustrated in data arrays, it is not effectively used in the risk characterization. For example, it is stated that chlorpyrifos is highly toxic to aquatic invertebrates, but that less sensitivity is exhibited in the mollusk group. While this acknowledges the fact that sensitivity ranges are different, this fact is not applied to the overall analysis of aquatic invertebrates.

Using the lowest value from the EFED compiled distribution for indirect effects builds unrealistic conservatism into the assessment. For example, this assumption for amphibian food items would mean that the amphibian prey base is interpreted as being uniformly sensitive at the lowest concentrations in the distribution curve, resulting in a much more significant impact to prey base than if only certain prey organisms are sensitive (which is normally the case). This incorrect application of data needs to be corrected in the risk characterization.

There is much discussion regarding impacts to things such as AChE inhibition, effects to sensory systems, and impacts on behavior. This include references to BCM=Biochemical, CEL=Cellular, PHY=Physiological, BEH=Behavioral and POP=Population responses. The linkage of these responses to survival and reproduction are not established, and it is unclear how population responses are actually determined or translated to species populations. This appears to be mostly a database exercise without characterization.

10.9 Weight of Evidence Approach Used, including the High, Medium, and Low Weighting Assignments to the Various Lines of Evidence to Evaluate Risk and Make Effects Determinations

Consistently throughout the assessments, it is stated that data are used for weight-of-evidence approach. However, this approach is no more than auto-generating data arrays which compile the range of sensitivities reported in available and often unqualified studies. The "weight" is limited to again automatically extracting the lowest value from the lowest end of the data array – in many cases this value either cannot be linked to its original source, or can be demonstrated to be from a source not

validated, not relevant, or not reliable. It appears that the weight-of-evidence approach merely shows the range of potential values from various endpoints, with no scientifically defensible, robust determination of what the lowest value actually means or how it was derived.

10.9.1 A Solid Approach to Considering the Weight of the Evidence Begins with a Well Designed Problem Formulation

The overall structure of the assessment, with multiple files, makes it extremely difficult to evaluate and exactly understand what data, input, and assumptions were used in the evaluations. One coherent formulating document is needed. Usage information should be given greater weight for compounds such as these, which have been on the market for so long. The usage maps presented by EPA do not appear to show wide spread uses; in fact great stretches of the county appear to have minimal use, which does not support the Agency's assertion that the whole county is the action area. While clearly available to the Agency, the best commercial data was not used. This coupled with the fact that very different uses were combined into one "use classification" further confounds the problem formulation. The lumping of all uses together seems to be counterproductive – if there is a no overlap between a specific use and a listed species, then registration of that use should be considered to have no effect on listed species.

Furthermore, there is nothing in the problem formulation that considers mitigations already in place. Before the current "Bulletins Live" process, several hundred county bulletins had been developed by EPA in a voluntary endangered species protection program, and these carried mitigations that evolved through early OPP-Services consultation as well as subsequent interactions with field biologists and local knowledgeable experts. To completely disregard these in the assessment as existing tools that can be used to mitigate exposure fails to take advantage of much work and communication that resulted in an accumulation of knowledge that is still useful.

The risk hypotheses as currently proposed (section 1.3.2) are not set up to address the key factor/question in determining the risk to listed species. As written, there is an inherent assumption that exposure will occur, when one of the first questions that should be asked is whether or not there is a likelihood of exposure. It is only after it is determined that there is reasonable likelihood of exposure that the magnitude of exposure and potential effects should be addressed. Analysis Plan – 3 step approach, figure 1-5.

It is important to realize that the 3 step approach is not an analysis plan or risk assessment scheme, it is simply a schematic of questions that must be answered under the current regulatory scheme to meet the mandates of ESA. It is appropriate in describing the regulatory process, but is not particularly helpful in terms of planning the details of the risk assessment. The schematic also implies that risk assessment is separate for each question being answered, which is inefficient and counterproductive. In fact, the figure is opposite what the process really should be. The three "steps" or regulatory questions

should feed into a single problem formulation from which an analysis plan would then be developed to address the protection goals. A tiered risk assessment process, without the artificial limits currently being imposed, could then be applied to efficiently address all assessment parameters.

In setting up the evaluation of weight of the evidence, lines of evidence should be independent, relevant to the nature of the data under evaluation and transparent. However, the lines described are artificially inflated and for most part are not independent of each other, and therefore a weighting scheme should be defined accordingly.

10.9.2 EPA's Current Method on Weight of the Evidence Ignores Scientifically Established Approaches to this Exercise

Use of weighting in incorporating lines of evidence into risk assessment is not explicitly recommended in the 1998 Guidelines, but the three categories suggested for consideration when evaluating lines of evidence can be implemented in a weighting scheme. These categories are: (1) adequacy and quality of data, (2) degree and type of uncertainty associated with the evidence, and (3) relationship of the evidence to the risk assessment questions, There is a substantial literature on the use of weight of evidence in risk assessment, yet the BE authors referenced none of these published papers, and therefore there is no means of understanding how the apparently novel approaches in the BE relate to prior work meeting the standards of scientific peer review. Concern over addressing adequacy and quality of data (1) is mentioned above. Uncertainty (2) is expressed throughout the BEs as qualitative confidence levels of low, medium, and high. It is not clear how these levels were assigned or the method used to insure consistency of application. In other sections of these comments we point out the difficulties with the confusion between toxicity thresholds, assessment endpoints, risk hypotheses, and lines of evidence. This confusion certainly complicates item (3) in the weighting scheme. The flaws in the WOE method, and solutions to them follow.

10.9.2.1 No References to the WOE Literature (Chapter 1, Attachment 1-9)

Although WOE methods figure prominently in the draft Biological Evaluation (BE), there are no references to the existing – and not insubstantial – WOE literature in either Chapter 1 or Attachment 1-9. Thus there is no way to easily determine whether the WOE method outlined in these locations builds on (or is even cognizant of) prior research or whether it is a *de novo* approach unique to this evaluation. The latter appears to be the case here and it seems ill-advised to have embarked on a significant WOE analysis for a major biological evaluation without first having consulted the literature.

10.9.2.2 Assessment Endpoints Not Clearly Defined (Chapter 1)

It is more likely that the purpose of a WOE will be achieved when it is deployed within the context of EPA's existing – and now long established – process for conducting useful ecological risk assessments (USEPA, 1998). A key first step in this process is, as stated above, Problem Formulation, and a key

component within that is the specification of assessment endpoints. An assessment endpoint is an expression of the environmental value (species, ecological resource, or habitat type) that is to be protected. Useful assessment endpoints are defined by both the valued ecological entity (or resource) and an attribute of that entity (or resource) to protect. Although Chapter 1 of the BE addresses some aspects of Problem Formulation (e.g., the conceptual models and risk hypotheses) it does not clearly define (or even much discuss) the assessment endpoints on which these models and hypotheses depend. In Section 1.3.2, for example, statements such as "*...on species and assessment endpoints...*" and "*...for each species and designated critical habitat...*" incorrectly convey the idea that species or critical habitat (i.e., entities) are somehow different than assessment endpoints. They are not and this misunderstanding could contribute to disconnects within the WOE analysis. The large number of assessment endpoints inherent in this BE have to be inferred by parsing through Figures 1-3 and 1-4, whereas they should have been explicitly stated in Chapter 1. Having this many assessment endpoints, several of which would be hard to evaluate with existing or readily obtainable information, works against the usefulness of a WOE analysis. It would have been better to use the Planning & Scoping and Problem Formulation phases to drill down to a selected and limited number of assessment endpoints whose analysis would provide decision makers with focused and actionable information.

10.9.2.3 Lack of Consistency in Terminology (Chapter 1, Attachment 1-9)

The captions for Figures 1-3 and 1-4 alter the specification of attributes shown in the conceptual models ("*For 'Attribute Change', the terms 'Individual Organisms', 'Food Chain', and 'Habitat Integrity' are equivalent to 'Individual Fitness', 'Indirect Effects Related to Prey', and 'Indirect Effects Related to Physical and Biological Features of Habitat', respectively.*"). It is these altered specifications, and not those in the figures, that appear – highly abbreviated – in the risk hypotheses in Section 1.3.2. The risk hypotheses also introduce critical habitat as an entity, direct and indirect effects, and the terms PCE and PBF. These latter two terms seem consistent with the existing definition of "measures [of ecosystem and receptor] characteristics." This is not just quibbling over semantics. If one of the purposes of a WOE analysis is to bring clarity and consistency to an assessment, then not clearly defining terms, changing terms *ad libitum*, introducing old terms as new terms, or allowing seeming inconsistencies between terms used in the conceptual model and those used in the risk hypotheses only detracts from accomplishment of this purpose.

10.9.2.4 Confusion of Assessment Attributes with Lines of Evidence (LOEs) (Chapter 1, Attachment 1-9)

The assessment endpoints, and not the risk hypotheses, should be the first link to the protection goals (i.e., management goals) for Step 2. Then the assessment attribute part of the assessment endpoint is linked to one or more risk hypotheses and then each hypothesis is linked to at least one LOE (here one based on toxicity - exposure and effect). Here, however, assessment attributes are incorrectly identified as LOEs - which would result in weights being applied to an attribute and not to the evidence. For example (Attachment 1-9, page A9 (PF)-3, Bullets A & B), survival (the inverse of mortality) is an

attribute, not an LOE. The LOEs refer to whether that attribute will be affected and, if so, to what extent; for example:

> Assessment endpoint: Assessment entity + its assessment attribute(s).
> Assessment entity: An individual of Listed Species *X*.
> Assessment attributes (for *X*): Survival, growth, reproduction, behavior, sensory function, prey items, pollinators/diaspore dispersal vectors, plant habitat, obligate organisms. Note that each attribute need not (and probably should not) be weighted the same relative to the other attributes.
> Risk hypothesis: Exposure to Pesticide *Y* used according to registered labels (includes parent active ingredient, formulations, and degradates of concern) will adversely affect one or more of the attributes related to *X*.
> Line-of-Evidence: (1) Level of exposure and (2) effect on attribute associated with that level of exposure (i.e., the exposure/response function). Evidence for characteristics might also be included here (as is alluded to by Bullet C).

A distinction has been made between the effects of direct exposures (Bullet A - the individual comes into contact with the pesticide) and those from indirect exposures (Bullet B - something the individual needs - food, prey, habitat - comes into contact with the pesticide). This is a useful distinction but the evaluation of indirect effects on populations of prey or food species or habitat organisms is more difficult and uncertain than evaluation of direct effects on individuals. In addition, loss of individuals within a population of prey or food species – unless it is great enough to extirpate local populations of those species – should not be accorded the same level of concern (i.e., weight) as the loss of an individual listed species.

Bullet C implies that there could also be evidence for a suite of characteristics (factors that may influence or confound the behavior and location of an assessment entity, the distribution of a stressor, as well as the life history characteristics of the entity or its surrogate that may affect its exposure or response to a stressor). Again, a useful thought, but one that is much harder to evaluate reliably than direct effects. Thus, the information described in bullets B and C should be subjectively evaluated, as recommended by the NAS Panel, rather than given an objective "weight" and added to an actual WOE exercise. Finally, exactly how the LOEs implied by Bullet C were implemented is not clearly discussed in the text.

10.9.2.5 Unclear Ranking of Exposure LOE Criteria

The only LOE for exposure is the estimated environmental concentration (EEC), presumably based on predictive modeling (which model or models is not stated explicitly). The text states that two criteria ("relevance" and "robustness") were used to evaluate this LOE. Aside from the fact that the terms "relevance" and "robustness" have been applied contrary to mainline scientific approaches (see related

discussion of relevance and robustness in other portions of these comments), there are at least four or five, but not just two, criteria:

1) Model developed to predict exposure in relevant habitat;
2) Consistency with the species habitat (the text on page A (PF)-10 speaks of the conceptual model for the exposure scenario being consistent with the habitat; however, it's not clear whether this is the same criterion as (1), an additional criterion, or a typo (predictive, not conceptual));
3) Exposure scenarios representative of pesticide use patterns;
4) Extent of chemical-specific fate data (per Appendix 4-3, this criterion includes chemical specific foliar dissipation half-life, additional exposure routes, species-specific Mineau scaling factor, AgDRIFT deposition – all of which could be treated as separate criteria);
5) Exposure results similar across "lines of information" (e.g., field-scale monitoring data, other model predictions) - which raises the question of why these other data and predictions were not treated as criteria in their own right?

These criteria are weighted presumably with respect to a given assessment attribute for a given assessment entity – but this is not stated and may not be understood (see comments above about what constitutes an assessment endpoint). The text on page A (PF)-10 also concatenates criteria (3) and (4) into one conditionally interlocking criterion, whereas it would have been clearer to have kept them separate.

Although the text and table on page A (PF)-10 establish high (H), medium (M), and low (L) weights for these criteria, and connects these criteria to the confidence to be placed in the risk estimate, weights for each criterion do not appear in Appendices 3-6 or 4-3. Instead, the entire exposure analysis appears to be only a lengthy narrative, with no explicit weights given for individual exposure criteria, and no clear connection between a given narration and a weight. Having established criteria for and presumably weights to the exposure LOE, it seems incumbent on the analyst to provide a summary of these weights by criterion by attribute somewhere in the BE – in Chapter 3, for example – as was done for risk in Chapter 4. Ideally, each of the 4 or 5 criteria associated with exposure would be weighted individually and then those weights combined to establish the overall weight for the exposure LOE for a given assessment attribute. This would produce an objective, defensible and repeatable WOE analysis. This would also enable readers to determine the strengths and weaknesses for a given criterion for a given attribute. If these 4 or 5 criterion are, in fact, weighted somewhere within the BE where those weights might appear it is not at all obvious.

10.9.2.6 Unclear Ranking of Effect LOE Criteria

The only LOE for effect appears to be the results from toxicity studies (EC25, EC50, LC50, LOAEC, SSD, etc.). This is not evident from the discussion of the effect LOE criteria but becomes so once the criteria

for ranking risk (page A9 (PF)-9) are examined. Within this context (and also looking at Attachment 4-3), there appear to be five criteria.

1) Established relationship between measure of effect (a toxicity endpoint) and assessment attribute (not assessment endpoint as stated in Attachment 1-9) [Potential attributes include not only survival, growth, reproduction, behavior, and sensory function, but also AOP, brain AChE activity, acceleration, stamina, and olfactory recordings. Note that this list includes attributes found here and not elsewhere in the text.];
2) Representativeness of test organisms (surrogates) to listed species or critical habitat, based on phylogenetic closeness (same order) or similar life history or physiology;
3) Number of toxicity studies potentially applicable to a given listed species or critical habitat;
4) Consistency within toxicity studies potentially applicable to a given listed species or critical habitat;
5) Availability of field studies.

Here, again, weights for each of these criteria do not appear in Appendices 3-6 or 4-3. Instead, the entire effects analysis appears to be only a lengthy narrative, with no explicit rankings of these effect criteria, and no clear connection between a given narration and a weight. Having established criteria and presumably weights for the effect LOE, it seems incumbent on the analyst to provide a summary of these weights by criterion by attribute somewhere in the BE – in Chapter 4, for example. Again, ideally, each of the 5 criteria associated with effects would be weighted individually and then those weights combined to establish the overall weight for the effect LOE for a given assessment attribute.

10.9.2.7 Risk Estimate Based on Just One LOE

On page A9 (PF)-6, it is stated that risk is established by comparing the overlap of exposure and effect levels – with "consideration" given to the degree of overlap. Overlap could imply that distributions of exposure and effect are being compared to derive a probabilistic risk estimate (there are SSDs in use here but is unclear whether the probabilities this method is capable of generating were used in the WOE analysis). However, on page A9 (PF)-9, it becomes clear that here "risk" is determined simply by where exposure is relative to a variety of toxicity thresholds, with consideration of the overlap limited to: L if below the lowest threshold, H if above a threshold where effects were observed, and M in between. So, in short, this entire WOE analysis comes down to just one LOE (for toxicity), with its "risk" estimate derived solely as a point estimate of exposure relative to a point estimate of effect (i.e., with a quotient methodology). The primary concern here, which has been a long acknowledged weakness in the quotient methodology, is that a threshold exceedance (*i.e.*, a quotient >1) should not be automatically interpreted as a "high" probability of adversity. This is based on the lack of any fixed relationship between a quotient value and the probability of an adverse effect. Inferring such a probability with just a threshold is difficult at best, if not impossible. This is one key feature that argues against the use of a quotient methodology to generate a "risk" estimate in a WOE analysis. Although thresholds (quotients)

have become an established and comfortable approach to regulatory decision making, they are not risk and are not informative when one's desire is to base a decision on the probability of a future outcome – or to even know how large or small that probability might be. Decision makers with no, or only heavily biased, insights into such chances may be encouraged or required to incur or impose significant direct and indirect costs to avoid an outcome that has no real chance of ever materializing. They may also choose a risk management alternative that limits or precludes the possibility of beneficial outcomes. Having said this, however, a numerical relationship ("quotient") as a flagging criterion – but not as a basis for final decisions on risk – is a reasonable way for policy to guide a tiered risk assessment process as long as a quotient of >1 is defined as the need to apply certain additional data and processes to a refined risk assessment exercise.

The explanatory text in Attachment 4-1 for the summary sheets (e.g., Figure A 4-1.20) incorrectly identifies assessment attributes (e.g., mortality, etc.) as LOEs, thus giving the impression that multiple, different LOEs were used to assess risk. As noted above, there is just one LOE (for toxicity) being applied to several different attributes for a given assessment entity. "Chemical stressors" is a variation on toxicity involving environmental mixtures or the parent a.i. alone. "Abiotic stressors" are measures of characteristics (such as temperature, bacterial/viral prevalence, or environmental pH) that could enhance an assessment entity's susceptibility to the toxicity of the parent compound. Thus this WOE analysis comes down to just the basic exposure vs. toxicity comparison approach expanded to include a larger number of assessment entities and their attributes. While there may be useful information about toxicity to be gleaned from such an expansion, it does not constitute a WOE analysis that weighs a number of truly different types of evidence (i.e., that beyond just exposure/toxicity) to support conclusions about whether a pesticide may or may not pose a threat to a given assessment entity.

It is also not clear whether these summary sheets (e.g., Figure A 4-1.20) were intended to be the risk vs. confidence summary graphs like the one shown in Figure A 1-9.2, because what is shown in this figure could not be found in the main text.

10.9.2.8 Unclear Derivation of Confidence in the Risk Estimate

A table on page A9 (PF)-10 shows how confidence in the risk estimate is assessed on the basis of weights assigned to the LOEs for exposure and effect. Here, all of the criteria applicable to either exposure or effect are reduced to a single H, M, or L weight. Exactly how this was accomplished on a consistent basis is unclear. And (as was commented on above) while there are criteria and overall weights (ranks) for both the exposure and effects LOEs, there appears to be no summary of these rankings by individual criterion and attribute anywhere in the BE. Ideally, each of the criteria associated with both exposure and effect would be weighted individually and then those weights combined to establish the overall weight (rank) for the toxicity LOE for a given assessment attribute for a given assessment entity. The long narratives in Attachment 4-3 could serve as backup for these individual weights rather than (as they do now) the sole basis for these weights. What is also not clear here is exactly how this determination

of confidence "...may also consider other factors..." While considerations evaluated subjectively or with best professional judgment are acceptable, the introduction of a superficial, subjective conclusion called a "WOE determination" is incorrect. There needs to be greater clarity as to when and how this was done.

10.9.2.9 Effects Determination

There are policy considerations in how a risk/confidence estimate relates to an effects determination (per page A9 (PF)-8) that are beyond the scope of these comments. However, there are three technical aspects of the Effects Determination table (Table A 1-9.2) that merit comment:

1. It confusingly suggests that the risk estimate applies to a LOE. Instead, what is presented is a risk estimate and the assessor's confidence in it (both based only an LOE for toxicity (exposure and effect)) for an attribute of an entity.
2. Per Figure A 4-1.20 in Attachment 4-1, there could be as many as 10 attributes (if chemical and abiotic stressors are included as attributes rather than as factors) for any given assessment entity. An effects determination is being made on the basis of just one of these. If, to posit an extreme example, the risk/confidence for one attribute were weighted H/H and that for all the rest were weighted L/L, you'd still conclude LAA. Thus you'd reach an LAA determination by ignoring 90% of the evidence. Policy considerations aside, ignoring evidence seems to contravene the purpose of a WOE analysis, even one based on one LOE (for toxicity). Since 90% of the evidence seems to be ignored, or subsumed by aggregation, and the conclusion that over 90% of the species are at risk from the use of OPs is obviously an indication of how the assessment has been adversely impacted by the methods used.
3. As noted before, it is probably not safe to assume that each attribute is of equal weight with respect to an LAA determination. For example, it may be possible to assess a mortality attribute with greater certainty or less equivocation than a sensory or behavioral attribute. So to continue the example in (2) above, if the attribute whose risk/confidence is weighted H/H is the weakest (lowest weighted) of the 10 attributes, then not only is the assessment making an LAA determination with 10% of the available evidence but also with the weakest part of that evidence. This too seems to contravene the intent of a WOE analysis.

10.9.3 Improvements Needed

CLA provides extensive comments on the risk characterization section ("effects determination") of the assessment. We preface our comments, however, by pointing out that there is a serious lack of transparency in the section, and it is very difficult to piece together what was done. For example, there is lack of information on how "uncertainty" was defined and no references to the literature on weight of evidence approaches. These and other examples are discussed in more detail below.

The main deficiency in the lines of evidence used in the BEs is the reality that, in effect, only a single line of evidence is brought into the analysis: toxicity. As pointed out above, this is made clear on page A9 (PF)-9, where risk is determined only by comparison of a point estimate of exposure to a variety of toxicity thresholds. The analysis is therefore confounded by identifying these toxicity thresholds with attribute changes relevant to risk hypotheses for which lines of evidence are considered and evaluated (1998 Guidelines for Ecological Risk Assessment, EPA/630/R-95/002F [1998 Guidelines]). These include (1) mortality, (2) reduced growth, and (3) reduced reproduction (see, for example, chlorpyrifos Chapter1 Table 1-4 and the related Figures 1-3 and 1-4). CLA points out that in prior published examples following a generally accepted process, mortality from direct acute (short-term) exposure is evaluated by bringing into the analysis plan individual lines of evidence of exposure (modeled, monitored, evaluated in field studies) paired with exposure/response information such as dose-response results (from laboratory, semi-field, and field studies) to determine the probability of mortality. The BEs confuse attributes with lines of evidence. The lines of evidence are estimates of whether the attribute(s) will change, not the other way around. Such confusion distorts the risk assessment process and represents a radical departure from the recommendations of the 1998 Guidelines. Moreover, the remaining "lines of evidence" given in Table 1-4 represent either: a) attributes that relate to (1), mortality, (2), reduced growth, or (3), reduced reproduction (which includes EFED's item (4), impaired behavior and (5), impaired sensory function); b) independent risk hypotheses (which includes EFED's item (6), indirect effects and (7), mixture toxicity); or c) ecosystem characteristics (which includes EFED's item (8), factors independent of an OP insecticide). Of these, only item (8) can be considered amenable to evaluation with a toxicity line of evidence (exposure + effect). For this case, any example of (8) should be evaluated in a specific pairing with a line of evidence including exposure and exposure/response to determine how either is mediated by the relevant ecosystem characteristic. Due to these radical departures from the recommended risk assessment process it is difficult for a reviewer to follow the logic of the analysis plan and judge the validity of the overall BE risk characterization.

Temporal scale is particularly important for interpreting ecological adverse outcome, and since the OP insecticides assessed in the BEs have been used for more than 50 years, the entire approach of the predictive analysis (that assumes this Agency action involves release of a new toxic chemical into the environment) is conceptually unsound. If one considers a listed species to be challenged by multiple stressors limiting recovery, and a specific chemical stressor (for example, chlorpyrifos) is evaluated in a predictive assessment for its marginal contribution to possible extirpation and found to greatly impact the fitness of individuals of populations for 99.9% of the species, then it is reasonable to ask the question why this predicted mass extirpation has not occurred after decades of potential exposure. This question is not found in the BE analysis but should be considered.

Thus, the entire analysis is undermined by an unrecognized conflation of causal and predictive assessment that fails to acknowledge an environmental baseline incorporating many decades of stressor presence in the environment. Consequently, there are lines of evidence not pointing toward the same conclusion such as water quality monitoring for chemical stressors vs. exposure modeling. In addition,

whole lines of evidence are ignored: population recovery surveys taking into account natural fluctuations can be compared to predictions from effects and population models. The case of Kirtland's warbler provides such a recovery survey, which, if included in the analysis, would not point to the same conclusion as was supported by the predictions of flawed effects and population modeling.

Review of the BEs is greatly hampered by lack of understanding of the methods used for reviewing, analyzing, and summarizing the uncertainty in the "lines of evidence" supporting the risk assessment. What is missing is clarity as to the methods used to pick exposure and effect (components of a toxicity line of evidence) criteria, weight them, and combine them. A further deficiency is non-transparency in evaluation of data quality and relevance. The documents do not appear to provide an explicit systematic assignment of quality or relevance to data sources crucial to the risk characterization. Therefore, in many cases it is not possible to judge the validity of lines of evidence contributing to risk conclusions.

The line of evidence related to the possibility of exposure in specific locations suffers from a large overstatement in spatial scale of potential use sites, and this leads to overprediction of ecological adversity for both direct and indirect effects. It is difficult to accept the premise that crops not on product labels contribute to potential exposure in specific growing regions. Likewise, it is highly unlikely that wide-area uses are actually used everywhere. Instead of assuming this is the case, additional lines of evidence relevant to species and use setting – such as historical mosquito adulticide application areas – should have been considered.

10.9.4 High, Medium and Low Weighting Assignments

The **weight of evidence** approach is incomplete. The assessment identifies multiple lines of evidence, each of which has an associated qualitatively defined "high", "medium", and "low" risk value and a similar qualitative "certainty" value. However, each of the lines of evidence is then considered on its own, and there is no aggregate weighting of ALL the lines to get a final "weight of evidence" for the species/crop/chemical combination (*see*: Hope BK, Clarkson JR. 2014. A strategy for using weight-of-evidence methods in ecological risk assessments. HERA 20:290-315). In fact, if at least one of the lines of evidence has a "high risk" or "medium risk" estimation, regardless of the confidence in this result, then the species is given a "LAA" determination to be carried forward to Step 3.

The graphic that shows the relative placement of all the lines of evidence in the risk-uncertainty space is a good start. One should then give scores on a scale of 1-5 (or 1-10; or whatever is preferred) for each line. The scores are then added up and divided by the total number of lines to give an average score. This average of all the scores determines the overall conclusion for that species/crop/chemical combination. A qualitative decision is made about how high a score is required to move a species/crop/chemical to the next Step (i.e., to assume a LAA).

Example 1:

- Line 1: High Risk/Low confidence =3
- Line 2: Low Risk/High confidence = 4
- Line 3: High Risk/High confidence = 5
- Line 4: Low Risk/Low confidence = 1
- Line 5: High Risk/Low confidence = 3
- Line 6: High Risk/High confidence = 5
- Average Score: 3.5

Example 2:

- Line 1: High Risk/Low confidence =3
- Line 2: High Risk/Low confidence =3
- Line 3: Low Risk/Low confidence = 1
- Line 4: Low Risk/Low confidence = 1
- Line 5: High Risk/Low confidence = 3
- Line 6: High Risk/High confidence = 5

Average Score: 2.7

An average score of 3.5 or higher would result in LAA. So Example 1 would be LAA and Example 2 would be NLAA. Note that in Example 2, there is one line of evidence that has "high risk/high confidence" but the entire WoE shows low confidence and some aspects of low risk.

10.9.5 Other Observations

The information presented in the WoE tables for relevance, surrogacy, and robustness is very generic and it is not clear how it was used to justify decisions. For example, the evaluation of robustness of effects data for terrestrial plants does not mention anything about the number of studies supporting the assessment or the quality of the studies, let alone the degree to which the studies agree. These are the factors mentioned in the Problem Formulation chapter, Attachment 1-9, that should be considered when evaluating robustness.

In the Problem Formulation, Chapter 1, Attachment 1-9 Supplemental Information 1, the following is stated regarding establishing conclusions for high, medium and low risk, for assessing direct risks to animals and plants: "If exposure exceeds the threshold or lowest endpoint but not an endpoint where effects were observed, risk is MEDIUM." If exposure does not exceed a threshold of effect, why is there a conclusion of any risk?

For indirect effects to plants, the risk conclusion is MEDIUM "if exposure is below the lowest EC_{25} (terrestrial) or EC_{50} (aquatic) for some plant types but above for other plant types." How many are "some" plant types? Would just one below the lowest threshold qualify? How is "plant types" used here? Is it herbaceous dicot, woody dicot, etc.? Then wouldn't the question be "is exposure below the EC_{25} for some but not all species within the plant type"? It would not matter if there were effects on monocots, for example, if the assessment was for herbaceous dicots. Does the amount of exceedance matter, i.e., is a risk quotient of 2 considered the same as one of 20 or 200?

These three categories also ignore any type of probability analysis. Something that may be named as in the "high" category but composed of a combination of circumstances that is virtually impossible in the environment is an improbable event – and certainly, improbable events should fall into a low category for potential risk. For example, in addressing concentrations where no effects were observed in fish and aquatic-phase amphibian studies, a wide range of values across species where effects were not noted in studies with constant exposures (unlike field conditions) were presented. However, the nature of these effects data are not considered or applied to the risk assessment with respect to the probability of an actual "risk."

Valid data is not being used in a way that supports the development of lines of evidence. For example, acute mortality (LC_{50}) data for chlorpyrifos are available for 40 fish species and 8 amphibian species based on studies submitted by the registrant or identified in the ECOTOX database. However, the value of this data is lost by the manner in which these studies are combined together, built into an "array" without meaningful and necessary analytical thought. To understand toxicity, the sensitivity range within a taxonomic group must be understood, but is lost entirely by the BE method. This, then, does not allow for appropriate association between a laboratory study and how it might be interpreted for a listed species. The ultimate flaw is that the level of resolution required for risk characterization and possible risk mitigation is entirely missing. Additionally, Species effects data and endpoints from studies ranging in exposure durations (e.g. 96 hour up to 10 days) were compiled, but it is not clear if or how the differing exposure durations were translated into simulated exercises in exposure modeling and risk analysis.

The exposure estimates are not specified in the WoE spreadsheets for the risk conclusion. The WoE spreadsheets indicate a comparison of threshold values to potential exposure values, however, the calculation of exposure needs to be clarified. Exposure values are calculated in screening exposure modeling derived from TerrPlant and AgDrift modeling, which is compiled in TED. The default assumptions used in these models need to be defined, as potential risk is overestimated due to these conservative parameters. For example, the exposure portion of the WoE spreadsheet for listed plant species is derived from the TED tool, where the input values for terrestrial plants are the threshold values from chapter 2, identified as "indirect and direct effects, for "growth" related endpoints. The TED spreadsheet uses these "growth" based threshold values to define the distance from the edge of field

that risk extends, however, this information is not considered in the WoE risk conclusion, as the WoE often concludes that critical habitat overlaps 100% in most cases. Each of these conservative assumptions should be included in the risk conclusion before a "likely to adversely affect" call is made.

In each summary table in the Appendix of Chapter 4, virtually all of the plant species in the list have "High Risk" findings listed for mortality, growth, and indirect/pollinator. This is difficult to reconcile with the findings in individual tables where it is frequently stated that NOEC or LOEC were not expected to be exceeded.

The jump from pollinator effects to indirect plant effects is poorly elucidated. Given the range in diversity in potential pollinators, it is not obvious that effects on pollinators on a field will significantly reduce pollination services on plants that are off-field and not directly exposed. Overlap with mosquito control use areas is reported in some species, but the application rates exhibiting risk may far exceed the label rate for mosquito use.

In some cases, the statement in the appendix table is made that "Indirect effects do not extend off field based on impacts to biotic diaspore dispersal vectors." [See *Kanaloa kahoolawensis*, for example]. However, indirect risks to NTP are still given as HIGH. Only off-field effects are relevant for virtually all listed plants.

The presentation of both the NOAECs and LOAECs in the WoE tables for plants makes it unclear how they were used. According to the Problem Formulation, the NOAECs are to be used in Step 1 and the LOAECs used in Step 2.

In multiple cases for the analysis of terrestrial plant risk, for example (chlorpyrifos Appendix 4-3aa, "*Pritchardia remota*"), a growth direct effect was identified as a "high risk", with "low confidence". The "high risk" direct effect to growth is determined based on a threshold value NOEC being exceeded for the minimum and maximum application rates at the site of a pre-emergent application, however, for post-emergence application, the LOEC value is not exceeded for the upper bound rate (4 lb a.i./A). Based on *Pritchardia remota* habitat being located in scattered, small groves in two valleys with elevations of 50 to 800 feet (information from WoE Appendix 4-3aa), actual in field or edge of field exposure would be rare at most. It is not evident that this WoE included overlap in critical habitat from the CDLs, or the TED tool analysis for distance that risk extends from edge of field.

10.10 Qualitative Marine / Cave Species Assessments

The qualitative assessments for sea turtles, whales, deep sea fish, other marine mammals, cave dwelling invertebrate species, lichens, pinnipeds, and otters suffer from lack of available data and great acknowledged uncertainties. It is difficult to accept these risk characterizations as anything other than

professional opinion supported by unvalidated screening and pre-screening models employing simplifying assumptions that do not correspond to actual characteristics of agroecosystem/natural ecosystem boundaries (beaches, estuaries, caves), stressor environmental behavior, or receptor absorption and metabolism. The categories of low-medium-high risk and confidence do not appear to be based on more than non-transparent professional judgment.

10.11 Other Types of Assessments

The comprehensive assessment for cattle ear tags represents a new methodology that has not undergone peer review. It is surprising that any LAA findings can be associated with a slow-release product that is not released into the environment upon application but rather is attached to the animal requiring protection from arthropod pests.

To: Jones, Jim[Jones.Jim@epa.gov]
Cc: Mary Jo Tomalewski[mjtomalewski@croplifeamerica.org]
From: Jay Vroom
Sent: Thur 3/10/2016 8:28:47 PM
Subject: Re: Methyl bromide Idaho matter

Jim:

It¹s been over a month since I sent this message‹maybe it got held up in spam filter or otherwise diverted? I¹ll ask Mary Jo to call your office to see if we can be sure you¹ve seen this‹I have some CLA members together next week where we¹re ready to discuss this further please!

Jay

On 2/8/16, 4:33 PM, "Jay Vroom" <JVroom@croplifeamerica.org> wrote:

>Jim,
>
>Thanks for the heads up on this issue. Top sources at USDA tell us that
>they were progressing on a settlement well in excess of amount you
>mentioned when a tort action came over the top, seeking million(s) in
>damages-- and freezing the other negotiations. If a court dismisses the
>tort matter then the Department is interested in returning to the
>negotiated approach.
>
>Have you heard anything further?
>
>Jay
>
>Sent from my iPhone

To: Jones, Jim[Jones.Jim@epa.gov]
Cc: Housenger, Jack[Housenger.Jack@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]; Wise, Louise[Wise.Louise@epa.gov]
From: Barone, Stan
Sent: Thur 10/13/2016 10:04:34 AM
Subject: Fwd: CLA objection to expert panel participation
CLA Comments on SAP Disqualification 10 12 16.pdf
ATT00001.htm

Jim

We are trying to verify concerns raised about panel members.

Can we chat about the options this morning.

Sent from my iPhone

Begin forwarded message:

From: "Knott, Steven" <Knott.Steven@epa.gov>
Date: October 12, 2016 at 12:41:25 PM EDT
To: "Bailey, Laura" <Bailey.Laura@epa.gov>, "Barone, Stan" <Barone.Stan@epa.gov>
Subject: FW: CLA objection to expert panel participation

FYI – concerns raised regarding Drs. Infante and Portier.

Steve

Steven M. Knott, M.S.

Chemist and Senior Designated Federal Officer

FIFRA Scientific Advisory Panel and

Chemical Safety Advisory Committee

U.S. EPA Office of Science Coordination and Policy

Knott.steven@epa.gov

(202) 564-0103

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, October 12, 2016 12:29 PM
To: Knott, Steven <Knott.Steven@epa.gov>
Subject: CLA objection to expert panel participation
Importance: High

Dear Steven- as noted in our earlier letter, CLA has concerns about potential conflict(s) of interest by member(s) of the FIFRA SAP on glyphosate carcinogenicity. We have posted the attached letter to the docket for the SAP as well.

Please contact me directly with any questions or concerns.

Best

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

October 12, 2016

Steven Knott, Designated Federal Official
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Electronic Mail to Knott.Steven@epa.gov and via Regulations.gov; Docket ID: EPA-HQ-OPP-2016-0385

Re: FIFRA Scientific Advisory Panel; Notice of Public Meeting: EPA's evaluation of the carcinogenic potential of Glyphosate; Request for Information and Comments; Docket ID No. EPA-HQ-OPP-2016-0385 (July 26, 2016)

Dear Mr. Knott:

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 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, representing the interests of its member companies by monitoring legislation, federal agency regulations and actions, and litigation that impacts the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency ("EPA" or "the Agency"), as the federal agency responsible for the regulation of pesticides, on matters of importance to CLA member companies, the agricultural community and the general public.

On July 26, 2016, EPA published notice in the federal register of its intention to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("FIFRA SAP") to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.[1] The notice invites nominations of candidates to serve as ad hoc members of the FIFRA SAP, which is to convene October 18, 2016 through October 21, 2016 (the "October 2016 meeting").

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[1] FIFRA, Scientific Advisory Panel 81 Fed. Reg. 48,794 (Meeting July 26, 2016).

Under FIFRA, the SAP serves in an advisory role and provides "comment[s] as to the impact on health and the environment" of registrations being considered by EPA.[2] All final decision-making authority under FIFRA rests with EPA. Pursuant to its authority under FIFRA, EPA has previously concluded that glyphosate is "not likely to be carcinogenic to humans."[3]

As CLA explained in its August 17, 2016 letter ("Conflicts Letter"), EPA is legally obligated to exclude scientists from the SAP whose conflicts of interest or established biases preclude their ability to contribute impartially to the panel's final report. CLA therefore respectfully opposes the selection of Dr. Peter Infante, whose patent biases should disqualify him from service on the SAP. CLA also asks EPA to take note of certain information regarding Dr. Kenneth Portier and confirm his ability to participate without any pre-formed conclusions, although it does not seek his disqualification.

The EPA Has an Obligation to Ensure the Impartiality of the FIFRA SAP

The Federal Advisory Committee Act (FACA) imposes strict conflict of interest requirements on the FIFRA SAP selection process.[4] As explained in greater detail in CLA's Conflicts Letter, EPA must ensure that the FIFRA SAP acts "in the public interest,"[5] and does not contain members with inappropriate special interests.[6] To meet the requirements established by FACA, the FIFRA SAP shall be comprised of impartial experts capable of providing an independent review of data on the carcinogenic potential of glyphosate. Indeed, the Office of Government Ethics advises against the participation of SAP panel members whose participation will create even the "appearance of loss of impartiality."[7]

To implement FACA's mandate, the EPA SAP office has adopted conflict-of-interest and bias rules for the selection of committee members, which aim to exclude those who "might be unable to provide impartial advice or [whose] impartiality in the particular matter might be questioned."[8] Among other requirements, "appearance of lack of impartiality, lack of independence, and bias may result in disqualification."[9]

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[2] 7 U.S.C. § 136w

[3] *See*, EPA's Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (2016).

[4] *See* 5 U.S.C. App. II, § 3(2).

[5] *See id.* App. II, § 9(a)(2).

[6] *See id.* § 5(b)(3).

[7] 5 C.F.R. § 2635.501(a) (2016); *see also* Sci. Advisory Bd., EPA, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* 9-10 (Sept. 2002), https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf; *see also* 18 U.S.C. §202(a); Sci. Advisory Bd., EPA, *Ethics for Advisory Committee Members*, https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument (last updated May 3, 2016).

[8] *See* EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* 16 (Sept. 16, 2004), http://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf [hereinafter "Panel Formation Process for the EPA FIFRA SAP"]; 81 Fed. Reg. at 48,795.

[9] *See id.* at 5-8, 10-14.

Dr. Infante's Biases Should Disqualify Him From Service on the Glyphosate SAP

EPA's ethical rules should preclude Dr. Infante's participation in the glyphosate SAP. Dr. Infante is a member of Collegium Ramazzini,[10] which has taken radical anti-pesticide positions, such as calling for a prohibition on all "pesticide use in all public areas, including residential areas and recreation grounds," even if regulatory agencies have concluded such uses were safe.[11] Dr. Infante has also repeatedly testified—exclusively for plaintiffs—in chemical exposure cases against Monsanto Company, the original registrant of glyphosate, and its affiliated entities.[12]

Even more troubling, federal courts have concluded that Dr. Infante has engaged in a pattern of biased, results-oriented analysis that disqualified consideration of his opinions. Of particular note is a decision of the Eastern District of Louisiana, which struck his testimony in a thoughtful and comprehensive opinion. *See Burst v. Shell Oil Co.,* No. 14-109, 2015 WL 3755953 (E.D. La. June 16, 2015). Judge Vance's *Burst* decision leaves little doubt that Dr. Infante is all-too-willing to manipulate scientific analysis to reach pre-determined outcomes (*i.e.*, invariably concluding a chemical is unsafe). In *Burst*, she explained that Dr. Infante's analysis "suggest[ed] a methodology driven by an attempt to achieve a particular result," *id.* at *14, which was apparent in several respects:

- "[I]n several instances, ***Dr. Infante cherry-picked data*** from studies that did not otherwise support his conclusion, ***failed to explain contrary results***, ***reached conclusions the authors of the study did not themselves make***, and ***manipulated data*** without providing any evidence of his work." *Id.* at 10 (emphasis added).

- "Dr. Infante cherry-picks data from studies in several significant instances and fails to explain contrary results in a manner that belies the reliability of his methodology." *Id.* at *13.

- The court dryly observed that: "Absent from Dr. Infante's report is any acknowledgment that this study separately examined the risk for [the specific cancer at issue] and did not find a statistically significant increased risk. The Court can only speculate as to why Dr. Infante neglected to discuss this pertinent finding in his report." *Id.* at *13.

- "[I]t is clear that Dr. Infante relied on a universe of divergent studies that either did not examine the substance at issue, did not examine the disease at issue, or did not exhibit statistically significant results. Moreover, ***Dr. Infante exhibited a willingness to ignore***

[10] *See* http://www.collegiumramazzini.org/fellows1.asp?id=82
[11] *See* Collegium Ramazzini Statement, The Control of Pesticides in the European Union: A Call for Action to Protect Human Health (2008) available at http://www.collegiumramazzini.org/download/13_ThirteenthCRStatement(2008).pdf
[12] *See* Roney v. GenCorp, et. al., No. 05-cv-788 (S.D.W. Va. 2005); Taylor v. Airco, Inc., et. al., No. 02-30014-MAP (D. Mass. 2002); Lewis v. Airco, Inc., et. al., No. L-10503-02 (N.J. Civ. Div., Essex County 2002); Skeen, et. al. v. Monsanto Company, No. G-82-468 (S.D. Tex. 1982).

or disregard contrary results, and to manipulate data in a manner not supported by any evidence of his work or independent justification and, in one instance, inconsistent with the authors' own discussion." *Id.* at *16 (emphasis added).

Judge Vance also cast doubt on Dr. Infante's scientific rigor. In response to the court's question about an obvious gap in his analysis, the court noted: "At the hearing, Dr. Infante explained that he *performed the [relevant] calculation on a 'sticky note.'*" *Id.* at *14 (emphasis added).

Burst is not an outlier. The Eastern District of Washington has similarly struck Dr. Infante's testimony and noted his obvious willingness to disregard studies that contradicted his opinions. *See Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1168–77 (E.D.Wa. 2009) ("[T]here is simply too great an analytical gap between the data presented and the opinions offered … such that it renders the expert testimony too speculative as a matter of law.; *id.* at 1172 (noting important study supporting contrary conclusion was conspicuously "not cited by Dr. Infante"); *id.* at 1174 (noting that while study at issue was updated "notably, Dr. Infante did not cite [the update] in his report").

Dr. Infante's public—and colorful— statements also indicate he will reflexively discount any and all industry-sponsored studies and lacks the temperament for unbiased analysis of glyphosate. Dr. Infante notably contributed to a 2014 book titled: *Our Daily Poison: From Pesticides to Packaging, How Chemicals Have Contaminated the Food Chain and Are Making Us Sick*, authored by Marie-Monique Robin (who also authored the anti-Monsanto book *The World According to Monsanto*). In *Our Daily Poison*, Dr. Infante:

- Expressed his disdain for all industry-sponsored studies, stating: "How does industry find scientists to do this kind of task? It buys them, that's all! Let's be clear—***it's what I call 'prostituted science.***'" *Id.* at 144 (emphasis added).

- Expressed his view that regulatory agencies are chronically incapable of evaluating industry-sponsored studies properly: "***The problem is that biased studies are then sent to regulatory agencies, who take them at face value***. That's how highly toxic substances have been contaminating our environment, our food, our fields or our factories, for decades." *Id.* (emphasis added).

- "Generally, studies sponsored by industry have been designed in such a way that it is nearly impossible to find harmful effects. The consequence is ***that the scientific literature is regularly polluted by worthless studies***. It's pathetic." *Id.* at 141 (emphasis added).

The glyphosate SAP is certain to consider industry-sponsored studies as part of its proceedings and there is no reason to believe that Dr. Infante will consider such studies as anything other than "prostituted science" and "worthless," as he has in the past. Dr. Infante's incendiary statements manifestly demonstrate that his "impartiality in the particular matter might be questioned."

The prejudice from Dr. Infante's bias is particularly acute because he is currently the only epidemiologist on the glyphosate SAP, potentially enhancing his ability to influence the SAP proceedings improperly. Because of the potential importance of epidemiological data, EPA should replace Dr. Infante with an epidemiologist without such patent bias.

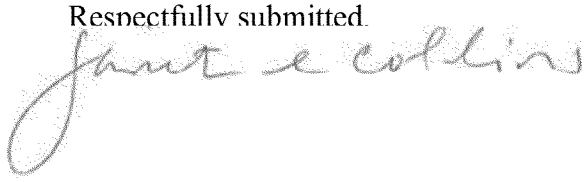
For all of these reasons, CLA respectfully requests that Dr. Infante be excluded from participation in the glyphosate SAP.

EPA Should Confirm That Dr. Kenneth Portier Will Participate Without Any Pre-Formed Conclusions.

Although he has not previously testified against or otherwise expressed the patent bias against pesticide manufacturers or the science upon which they and/or regulatory bodies rely, Dr. Portier has expressed opinions about glyphosate that suggest he may already have pre-formed conclusions as to glyphosate's safety. For example, Dr. Portier has stated that "glyphosate needs to go on the California Prop. 65 database" of chemicals that may cause cancer or have reproductive toxicity.[13] Dr. Portier has also urged "manufacturers to come up with alternative products" to glyphosate because, in his view, "We don't like to see man-made carcinogens freely circulating in the environment."[14]

Dr. Portier is also the brother of Dr. Christopher J. Portier, a noted and vehement anti-glyphosate activist. CLA requests that EPA confirm that his brother's views will not affect Dr. Portier's ability to evaluate the relevant evidence objectively and that he has not already formed a conclusion regarding the carcinogenicity of glyphosate.

Respectfully submitted,



Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President
Science and Regulatory Affairs

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[13] *See* Interview with Dr. Kenneth Portier on Smart Health Talk (Oct. 27, 2015) *available at* http://www.smarthealthtalk.com.

[14] *See* Dennis Thompson, *Genetically Modified Foods, Herbicides and Human Safety*, HealthDay (Aug. 19, 2015) *available at* https://consumer.healthday.com/vitamins-and-nutrition-information-27/food-and-nutrition-news-316/herbicides-and-gmos-702482.html.

From: Mary Jo Tomalewski
Location: American Farm Bureau Federation, 600 Maryland Avenue, SW, Suite 1000W
Importance: Normal
Subject: FQPA 20th Anniversary Commemoration and Ceremony
Start Date/Time: Wed 8/3/2016 8:00:00 PM
End Date/Time: Wed 8/3/2016 11:00:00 PM

;;;
As a follow-up to an invitation that you received last week:

20th Anniversary of the Signing of the Food Quality Protection Act (FQPA)

Organized by the Pesticide Policy Coalition, American Farm Bureau Federation and CropLife America

Wednesday August 3, 2016

Offices of the American Farm Bureau Federation, 600 Maryland Avenue, SW, Suite 1000W, Washington, DC 20024

Roundtable discussion to feature opening remarks by **Senator Pat Roberts (KS)** and **former Congressman Charlie Stenholm (TX)**

Roundtable Discussion – 4:00p

Celebration Reception – 5:30 – 7:00p

Please RSVP by Monday, August 1 to Mary Jo Tomalewski
(mjtomalewski@croplifeamerica.org, 202.872.3849)

To: Jay Vroom[JVroom@croplifeamerica.org]
From: Jones, Jim
Sent: Fri 1/29/2016 12:46:30 PM
Subject: Follow up

Jay, can we talk briefly today? I am on the road but if you send me a phone number and time I can call you. Jim

Sent from my iPhone

To: Jay Vroom[JVroom@croplifeamerica.org]
From: Jones, Jim
Sent: Thur 1/28/2016 10:14:19 PM
Subject: RE: Thanks for your time with the CLA SOC last night!

Jay, I'm glad I was able to participate. I've already debriefed Jack and we look forward to engaging with you and your members on many of the challenging issues we discussed. Thanks. Jim

-----Original Message-----
From: Jay Vroom [mailto:JVroom@croplifeamerica.org]
Sent: Wednesday, January 27, 2016 7:36 PM
To: Jones, Jim <Jones.Jim@epa.gov>
Cc: Rachel Lattimore <RLattimore@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>; Beau Greenwood <BGreenwood@croplifeamerica.org>
Subject: Thanks for your time with the CLA SOC last night!

Dear Jim,

Thanks for the long and in depth conversation with our member leaders last night. Your accessibility has always been outstanding -- and last night you even had to deal with snow impediment!

Our mutual challenges are considerable, but honest face to face engagement like you afforded us last night help everyone move forward. Sincere thanks for your hard work and the years you've invested in making EPA a premier regulator.

Best regards,

Jay

To: Jay Vroom[JVroom@croplifeamerica.org]
Cc: John Cummings[John.Cummings@fmc.com]
From: Jones, Jim
Sent: Tue 1/26/2016 4:02:07 PM
Subject: Re: Dinner with CLA SOC group tonight?

See you around 6

Sent from my iPhone

> On Jan 26, 2016, at 9:31 AM, Jay Vroom <JVroom@croplifeamerica.org> wrote:
>
> Oh yes, absolutely !!
>
> Not only appropriate attire for a day like this‹they¹re made of cotton!
> :-)
>
>> On 1/26/16, 9:28 AM, "Jones, Jim" <Jones.Jim@epa.gov> wrote:
>>
>> Can I wear blue jeans?
>>
>> Sent from my iPhone
>>
>>> On Jan 26, 2016, at 8:04 AM, Jay Vroom <JVroom@croplifeamerica.org>
>>> wrote:
>>>
>>> Jim
>>>
>>> Our meeting is still "on" even though the snow is still deep and the
>>> government is closed again today.
>>>
>>> Are you still able to join us for the dinner tonight? We have a 4
>>> wheel drive vehicle available if you need a lift...
>>>
>>> Jay
>>>
>>> Sent from my iPhone
>

To: Jay Vroom[JVroom@croplifeamerica.org]
Cc: John Cummings[John.Cummings@fmc.com]
From: Jones, Jim
Sent: Tue 1/26/2016 2:28:00 PM
Subject: Re: Dinner with CLA SOC group tonight?

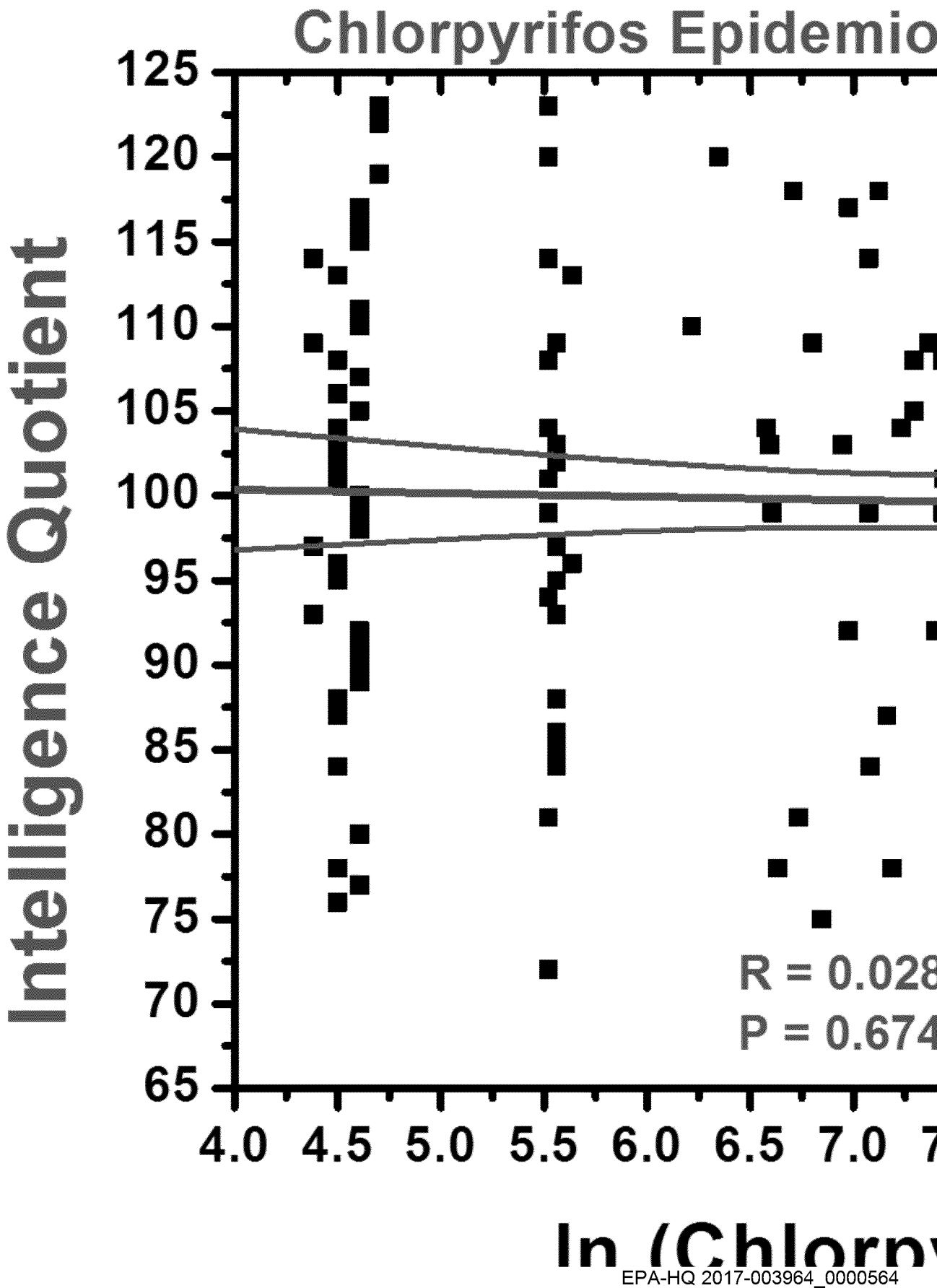
Can I wear blue jeans?

Sent from my iPhone

> On Jan 26, 2016, at 8:04 AM, Jay Vroom <JVroom@croplifeamerica.org> wrote:
>
> Jim
>
> Our meeting is still "on" even though the snow is still deep and the government is closed again today.
>
> Are you still able to join us for the dinner tonight? We have a 4 wheel drive vehicle available if you need a lift...
>
> Jay
>
> Sent from my iPhone

To: Kent, Ray[Kent.Ray@epa.gov]; Dotson, Douglas[Dotson.Douglas@epa.gov]
Cc: Daiss, Rebecca[Daiss.Rebecca@epa.gov]
From: Irwin, William
Sent: Wed 11/30/2016 6:38:45 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

EX. 5- Deliberative Process


Chlorpyrifos Epidemio
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4.5
5.0
5.5
6.0
6.5
7.0
R = 0.028
P = 0.674
In (Chlorp

From: Drew, Danette
Sent: Wednesday, November 30, 2016 10:44 AM
To: Irwin, William <Irwin.William@epa.gov>
Subject: FW: CLA Petition

From: Metzger, Michael
Sent: Wednesday, November 30, 2016 9:14 AM
To: Dobreniecki, Sarah <Dobreniecki.Sarah@epa.gov>; Donovan, William <donovan.william@epa.gov>; Drew, Danette <Drew.Danette@epa.gov>; Encarnacion, Ideliz <Encarnacion.Ideliz@epa.gov>; Habiba, Uma <Habiba.Uma@epa.gov>; Liccione, John <Liccione.John@epa.gov>; Lowe, Kelly <Lowe.Kelly@epa.gov>; Rickard, Kristin <Rickard.Kristin@epa.gov>; Savoia, Pete <Savoia.Pete@epa.gov>; Taylor, Linda <Taylor.Linda@epa.gov>
Subject: FW: CLA Petition

FYI

From: Davis, Donna
Sent: Wednesday, November 30, 2016 9:12 AM
To: OPP HED Managers <OPP_HED_Managers@epa.gov>
Subject: FW: CLA Petition

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

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Washington DC 20001

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+1-703-868-3280 (mobile)

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

From: Janet Collins
Location: DCRoomPYS11100-Potomac
Importance: Normal
Subject: IESTI in Codex
Start Date/Time: Mon 12/19/2016 8:00:00 PM
End Date/Time: Mon 12/19/2016 9:00:00 PM

All- please let me know if you need to propose a different time.

Also- should we meet in person or by conference call?

Thanks

From: Janet Collins
Location: Teleconference
Importance: Normal
Subject: Updates on epidemiology
Start Date/Time: Wed 8/10/2016 4:00:00 PM
End Date/Time: Wed 8/10/2016 4:30:00 PM

Ex. 6 - Personal Privacy

Code **Ex. 6 - Personal Privacy**

From: Janet Collins
Location: Conference call
Importance: Normal
Subject: Canceled: Epidemiology workshop
Start Date/Time: Tue 7/26/2016 7:30:00 PM
End Date/Time: Tue 7/26/2016 8:00:00 PM

Ex. 6 - Personal Privacy

Code: **Ex. 6 - Personal Privacy**

To: Jane M Stewart[jane.stewart@basf.com]; Carmen Tiu (tcarmen@dow.com)[tcarmen@dow.com]; Ray McAllister (RMcAllister@croplifeamerica.org)[RMcAllister@croplifeamerica.org]
Cc: Doherty, Michael[Doherty.Michael@epa.gov]
From: Miller, David
Sent: Wed 2/15/2017 4:11:21 PM
Subject: RE: [CLA-REWG] Agenda and Minutes - Feb Meeting

Tx. I think Carmen's out of office message said she'd be back either today or tomorrow. She wrote me from Asia last night.

Also, I am checking right now with Mike D. on good/bad times for him on those two days so we can make some suggestions to Ray McA. if the times are not yet solidified.

Finally – I always forget this - is Carmen the chair of the REWG and Cheryl Cleveland the chair of the DAWG. I also get mixed up on that. if that's wrong, my apologies to Cheryl for not keeping her in the loop on this (REWG) matter.

David.

David J. Miller CAPT | USPHS Commissioned Corps

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Jane M Stewart [mailto:jane.stewart@basf.com]
Sent: Wednesday, February 15, 2017 11:00 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Carmen Tiu (tcarmen@dow.com) <tcarmen@dow.com>; Ray McAllister (RMcAllister@croplifeamerica.org) <RMcAllister@croplifeamerica.org>
Subject: FW: [CLA-REWG] Agenda and Minutes - Feb Meeting

HI David – paper looks great.

This is the last draft agenda for next week's meeting that I have seen. I am not sure if we already have a more updated version with dates/times. Ray?

Carmen may still be traveling, so if it's ok with Ray, I will send the Global Zoning paper to him so he can circulate to the whole group today.

I have an AI-specific meeting on the 22nd at the EPA offices in Crystal City. Hopefully we will be finished by noon and then I will take the metro or a cab to the CLA offices, but may be a little late. I hope Ray saves me some lunch.

Thanks!

...Jane

Jane Stewart, PhD.
Expert, Scientist
Environmental and Residue Sciences
BASF Corporation

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From: CLA-REWG@yahoogroups.com [mailto:CLA-REWG@yahoogroups.com] **On Behalf Of** Sci Reg scireg@croplifeamerica.org [CLA-REWG]
Sent: Thursday, February 09, 2017 10:42 AM
To: CLA-REWG@yahoogroups.com
Cc: Tiu, Carmen (C) <tcarmen@dow.com>; Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: [CLA-REWG] Agenda and Minutes - Feb Meeting [1 Attachment]

REWG Members,

A few things for our upcoming meeting:

1. Our next REWG meeting will be held on February 22nd & 23rd at the CLA Headquarters (1156 15th St. NW, STE 400, Washington, DC 20005);

2. If you do not see a calendar invite on that day from me, please let me know and I will add you;

3. Find attached the November meeting minutes; and

4. We have put together a list of topics that we would like to speak on at the meeting. Please comment on the list below and address any items we did not include.

Feb-17	F&B	Interaction with GMA reps	Mano Basu-GMA, 30 minutes
Feb-17	L.Rossi	TSCA update MRL workshops Korea, Taiwan	Lois - 30 minutes
Feb-17	EPA	Updates from EPA (zoning, IESTI, OECD, etc)	D.Miller & team - 1 hour
Feb-17	USDA	Updates from USDA (Its, capacity building, events)	M.Rasmussen & team - 30 minutes
Feb-17	EPA, USDA	CCPR 49 preparation	All - 30 minutes
Feb-17	BCI	Updates from BCI on MRL & Growers Priorities	M.Lanz - 30 minutes

Feb-17	REWG	Metrics 2016 Performance, 2017 Goals	All- 1 hour
Feb-17	REWG	Residue & MRL global regulatory updates, impact on USA (OECD, EU, ARG, MEX, CHI)	All - 1 hour
Feb-17	REWG	REWG support to IESTI, Res-Def (EU, CDX)	All - 30 minutes
Feb-17	REWG	Suggestions for ACS Aug.2017	Phil, Heidi - 30 minutes
Feb-17	REWG	Codex Coalition update	Carmen & All - 30 minutes

Thank you,

Courtney DeMarco

Science and Regulatory Affairs

CropLife America

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Posted by: Sci Reg <SciReg@CropLifeAmerica.org>

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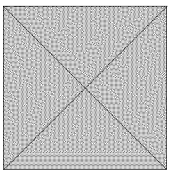

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To: cheryl.cleveland@basf.com[cheryl.cleveland@basf.com]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; RMcAllister@croplifeamerica.org[RMcAllister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; jane.stewart@basf.com[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]
Cc: Maria Maratos[Marie.Maratos@fsis.usda.gov]; Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Bacon, Laura[Bacon.Laura@epa.gov]
Sent: Mon 1/30/2017 10:25:27 PM
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

From: Miller, David
Sent: Monday, January 30, 2017 2:52 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maria Maratos' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Also -as an FYI – we will set up an IESTI conference call for some time during the latter half of February to discuss the current exploratory activities EPA is doing. As I mentioned briefly during the the Codex CCPR Interest Group meeting held on Thursday of last week here in Crystal City and on the phone, EPA mathematical statistician James Nguyen has taken some extensive crop field trial data from USA and Canada (some of you will know it as the USA-Canada Zoning Data Set assembled by PMRA) and also done some simulations to show how much the variability factor would need to go down if we use the HR instead of the MRL in the IESTI equation assuming we want to keep everything else the same. We also have an interest in (but have not started yet) looking at the WHO food consumption data on a gram/kg bw basis and seeing how this might change.

If there are any days or combination of days that definitely don't work for you during the last two full weeks of February and you are interesting in attending the call, please let me know (it is as yet unscheduled)

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Friday, January 27, 2017 3:33 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: FW: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

All,

Please find attached and below the communication that we send to the CCPR/IESTI co-chairs with the US Government response to their second round request for comments. This was sent to them on Wednesday evening of this week.

David.

From: Miller, David
Sent: Wednesday, January 25, 2017 8:14 PM
To: 'CCPR_IESTI@rivm.nl' <CCPR_IESTI@rivm.nl>
Cc: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Bernadette,

The United States appreciates the opportunity to review and comment on the revised discussion paper. We understand from your email communications that you are only seeking comments and suggested changes on topics and issues with which the U.S. absolutely disagrees, and the purpose of this second round of commenting given the very short turn-around time is not to by any means to "fine-tune" or to reach consensus on the draft document.

We further understand that -- particularly given the wide variety of reactions to the document and critiques offered during the first round of commenting -- that no decisions on changes to the IESTI equation will be made or decided upon at the coming CCPR meeting. You also state in your email communication that "[T]here will be more opportunity later on to refine wording". With respect to this latter point, we believe that the document is not yet and is not anticipated to be in the near future in a state at which only "refined wording" is necessary. There are a number of very important fundamental concepts relating to such topics as regulatory targets and goals, next steps, and continued investigational work that (understandably at this early stage) will need to be further discussed and agreed upon before we can consider the document in need of only changes to refine wording.

With the above in mind and your call for only comments on issues that member countries absolutely disagree, the U.S. offers the following limited comment set.

1. It may facilitate understanding of IESTI documents (especially when the documents are translated to other languages) to replace subjective terms such as "conservative" and "conservatism" with objective terms such as accuracy, over-estimation of exposure, increased estimates of exposure, etc.

2. Appendix 2, Table 3 (challenges that arise from the possible revision of the current IESTI equations), Line 11 – The process outlined here is of critical importance to the development of an updated IESTI equation. We feel that this statement must be retained in future versions of this document, perhaps with the following minor modification (based on the previous comment):

Reaching consensus regarding the approach to be used to evaluate ~~the level of conservatism of~~ the accuracy of exposure estimates generated with proposed IESTI equations and how these estimates compare to estimates generated with the present set of IESTI equations and state-of-the-science probabilistic methods.

3. Paragraph 7, lines 114 to 119 indicates that it is critical that the accuracy of the resulting pesticide intake estimates be evaluated and that "prior to conducting such evaluations, CCPR needs to reach consensus on the target upper percentile of intake [exposure] to be estimated by the equations. It is not clear to us that it is necessary – or even possible – for CCPR to reach consensus on the target upper percentiles of intake. Appropriate comparisons can be performed across a range of potential target percentiles to evaluate the degree to which the current and proposed IESTI equations may overstate "real world" exposures as estimated using more realistic pesticide residue concentration data reflecting more realistic percent crop treated data and using more realistic food consumption data, all evaluated probabilistically. To require that CCPR reach consensus on a target upper percentile of intake prior to conducting any evaluation of the equations will likely set back and limit any quantitative assessments and comparisons which we feel are critical to evaluate the need for or desirability of any changes to the equation.

4. Paragraph 9, lines 126-132 discusses a preliminary 5% figure as being an estimate of the number of lost MRLs based on implementation of all the recommendations made during the 2015 Geneva Workshop. We think that this number is entirely too preliminary and insufficiently supported to be placed in into present CCPR document, and simple counts of MRLs that may be lost do not necessarily appropriately reflect the trade value or other equally appropriate metrics that may be of interest. Further, the statement that the estimate of the potential loss of MRLs "may be an overestimation" seems to characterize this estimate in a way that the government of

the U.S. does not believe is necessarily accurate and can be misleading. We suggest that the 5% estimate and its characterization of it likely being an overestimate be eliminated from the document, and replaced by a statement that indicates that a thorough evaluation of the lost MRLs in terms of MRL counts, trade value, lost pest control, and other metrics be included instead. Overall, we believe the paper needs to provide greater emphasis on the necessity that any evaluation of changes to the equation also reflect trade impacts.

5. We believe the paper should emphasize and re-affirm that consideration of the proposed changes to the IESTI equation is something that needs to be done with considerable care and deliberation, and that these considerations will likely take an extended period of time and involve considerable resources as well as input from a variety of stakeholders and across a variety of viewpoints.

To facilitate your review and compilation of the above enumerated comments, we have attached these as a Word table in the format you requested.

The U.S. thanks you for allowing an extra day for us to convey these comments and also very much appreciates the significant effort that was required on your part to prepare the revised document over such a short period. We look forward to productive discussions on this issue at the CCPR meeting in April, 2017.

Regards,

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division

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703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Tuesday, January 24, 2017 11:21 AM
To: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>
Cc: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Marie,

We are happy to receive the US comments by January 25.

Kind regards,
Bernadette

From: "Maratos, Marie - FSIS" <Marie.Maratos@fsis.usda.gov>
To: "'CCPR_IESTI@rivm.nl'" <CCPR_IESTI@rivm.nl>,
Cc: "Miller.DavidJ@epa.gov" <Miller.DavidJ@epa.gov>
Date: 23-01-2017 23:02
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Bernadette,

The United States is in the process of finalizing our comments and will expect to have them to you by the morning of January 25th.

Thank you for your understanding.

Best regards,
Marie

****

Marie Maratos
International Issues Analyst
U.S. Codex Office
Room 4865 South Building
Food Safety and Inspection Service (FSIS)
U.S. Department of Agriculture (USDA)
Washington, DC, USA
Phone: +1.202.690.4795
Mobile: +1.202.412.7901
Fax: +1.202.720.3157
Email: Marie.Maratos@fsis.usda.gov

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Monday, January 23, 2017 6:18 AM
To: IESTI Participants WG; IESTI Observers WG
Subject: Fw: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

A kind reminder to last week's request to comment by 24 January at the latest on the second draft of the IESTI discussion paper.

Kind regards,
Bernadette Ossendorp

----- Forwarded by Bernadette Ossendorp/RIVM/NL on 23-01-2017 12:15 -----

From: CCPR_IESTI_cleanmail181169
To: "IESTI Participants WG" <IESTI_Participants_WG@rivm.nl>, "IESTI Observers WG" <IESTI_Observers_WG@rivm.nl>,
Date: 17-01-2017 20:29
Subject: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS
Sent by: Bernadette Ossendorp

Dear all,

Again, thank you for actively participating in improving the discussion document on the IESTI for the next CCPR.
Attached you will find the following documents:

- a pdf file in which we have compiled all your comments along the paragraphs of the discussion document, including the response of the drafting team. Comments were provided by 25 countries / organizations. The document begins with a number of responses to generic concerns raised by several contributors. Then, on page 3 follow a number of general comments that generally do not lead to adjustments in the discussion paper. Then follow from page 16 the specific comments, which refer to a particular line or paragraph in the text and suggest adjustments to the paper. On page 56 are suggestions for new items in Table 1 (advantages) and on page 58 suggestions for new items in Table 2 (challenges).

- a pdf file with version 2 of the Discussion document, accompanied by a tracked-changes Word-version of the same file, for you to see what was changed.

- The report of the 2015 Geneva workshop (as we now call it for briefness), which has as Annex A the Background document with the scientific rationale for proposing the changes. We noted that many of you had not been in the position to have a look at this earlier, and as we would prefer not to re-iterate all this text in the current document, please have a look if your comments are addressed by what was written there.

- a Word-file containing the new version of the comments table. Please use this table for providing comments to version 2.

Please note that due to the very tight timelines, our Australian co-chairs have agreed to comment on the document in parallel with the whole group.

We would like to receive your comments on version 2 by **24 January** ate the latest. Please try not to go too much into detail, only suggest changes when you absolutely disagree to a certain part of text. We would like to emphasize that surely, no decisions on changes to the IESTI (risk communication / risk management part) will be made at the coming CCPR. There will be more opportunity later on to refine wording.
Please let us know if you need any further clarifications.

Looking forward to our continued cooperation,
Kind regards,
Bernadette Ossendorp

----- Forwarded by Bernadette Ossendorp/RIVM/NL on 17-01-2017 19:53 -----

From: CCPR_IESTI_cleanmail181169

To: "IESTI Participants WG" <IESTI_Participants_WG@rivm.nl>, "IESTI Observers WG" <IESTI_Observers_WG@rivm.nl>,
Date: 12-01-2017 22:08
Subject: update on progress - version 2 of IESTI discussion paper
Sent by: Bernadette Ossendorp

Dear all,

Thank you for your active participation in the first commenting round on the draft discussion paper on IESTI. In total, we have received 38 pages of comments from 25 countries / organizations, which is very helpful for improving the discussion paper. However, this vast number has a downside too: we have not yet been able to address them all by today, as planned. We hope to send you the response to all comments and the adjusted discussion paper early next week.

FYI: we will proceed to organize a physical eWG meeting prior to or during CCPR. We'll let you know date and room when decided.

Kind regards,
Bernadette Ossendorp

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To: cheryl.cleveland@basf.com[cheryl.cleveland@basf.com]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; RMcAllister@croplifeamerica.org[RMcAllister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; jane.stewart@basf.com[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]
Cc: 'Maratos, Marie - FSIS'[Marie.Maratos@fsis.usda.gov]; 'Basu, Pat - FSIS'[Pat.Basu@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
Sent: Fri 1/27/2017 8:28:26 PM
Subject: RE: Update on IESTI comments and status of IESTI paper from NL-AUS

From: Miller, David
Sent: Friday, January 13, 2017 3:18 PM
To: cheryl.cleveland@basf.com; jcranney@calcitrusquality.org; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; RMcAllister@croplifeamerica.org; kent.rupprecht@bayer.com; jane.stewart@basf.com; bruce.young@bayer.com
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: Update on IESTI comments and status of IESTI paper from NL-AUS

All,

Just a quick update. Recall that we were supposed to receive back a second updated IESTI draft earlier this week and to allow us to submit any final second round of comments by 20 January to the co-chairs.

I received the following email yesterday from one of the IESTI co-chairs:

Dear all,

Thank you for your active participation in the first commenting round on the draft discussion paper on IESTI. In total, we have received 38 pages of comments from 25 countries / organizations, which is very helpful for improving the discussion paper.

However, this vast number has a downside too: we have not yet been able to address them all by today, as planned. We hope to send you the response to all comments and the adjusted discussion paper early next week.

FYI: we will proceed to organize a physical eWG meeting prior to or during CCPR. We'll let you know date and room when decided.

Kind regards,
Bernadette Ossendorp

Regards,

David,

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
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From: Miller, David
Sent: Thursday, December 22, 2016 2:50 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com'

<jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; 'Janet Collins' <jcollins@croplifeamerica.org>
Subject: USG comments on IESTI equation - formally submitted 12/21 evening.

All,

Please find attached a PDF of the USG comments submitted to the CCPR- IESTI mail box yesterday evening, 12/21/2017.

Happy Holidays,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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From: Miller, David
Sent: Tuesday, November 29, 2016 9:05 AM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Participants list IESTI eWG

All,

Please find attached from the NL-AUS co-chairs the list of participants in the IESTI eWG.

I have also attached an updated list of participants in the US IESTI eWG Interest Group. This has been updated to add a phone number, correct a typo, and correct an interest group designation.

David.

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Tuesday, November 29, 2016 7:21 AM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: Participants list IESTI eWG

Dear all,

On the request of the US Codex Office, please find attached a list of participants in the IESTI eWG.

Kind regards,

Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
mobile +31 6 11702050

E-mail to: CCPR_IESTI@rivm.nl

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To: Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]
Cc: cheryl.cleveland@basf.com[cheryl.cleveland@basf.com]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; rmcallister@croplifeamerica.org[rmcallister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; jane.stewart@basf.com[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]; Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
From: Miller, David
Sent: Tue 1/17/2017 9:11:29 PM
Subject: Re: Update on IESTI comments and status of IESTI paper from NL-AUS

From: Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>
Sent: Friday, January 13, 2017 3:27 PM
To: Miller, David
Cc: cheryl.cleveland@basf.com; jcranney@calcitrusquality.org; Johnston, John - FSIS; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; rmcallister@croplifeamerica.org; kent.rupprecht@bayer.com; jane.stewart@basf.com; bruce.young@bayer.com; Maratos, Marie - FSIS; Bacon, Laura; Doherty, Michael
Subject: Re: Update on IESTI comments and status of IESTI paper from NL-AUS

This is exactly what our problem was before we set up the OMB formulated system for receiving feedback that we could review and respond to in a timely manner for the CCPR eWG for methods of analysis.
In 3 years of running this WG, we never missed a deadline. Of course we had a very competent members in the US team that worked well together.
I think this IESTI group have just discovered that they have bitten off more than they can chew.
Just my thoughts.
Pat B

Dr. Pat Basu
Chief Public Health Veterinarian-FSIS
SL-Chemistry, Toxicology & Related Sciences
USDA/FSIS/OPHS
Washington, DC
Mobile: 202-251-1682

Sent from my iPhone

On Jan 13, 2017, at 2:18 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

All,

Just a quick update. Recall that we were supposed to receive back a second updated IESTI draft earlier this week and to allow us to submit any final second round of comments by 20 January to the co-chairs.

I received the following email yesterday from one of the IESTI co-chairs:

Dear all,

Thank you for your active participation in the first commenting round on the draft discussion paper on IESTI. In total, we have received 38 pages of comments from 25 countries / organizations, which is very helpful for improving the discussion paper.

However, this vast number has a downside too: we have not yet been able to address them all by today, as planned. We hope to send you the response to all comments and the adjusted discussion paper early next week.

FYI: we will proceed to organize a physical eWG meeting prior to or during CCPR. We'll let you know date and room when decided.

Kind regards,
Bernadette Ossendorp

Regards,

David,

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs

703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Thursday, December 22, 2016 2:50 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
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Subject: USG comments on IESTI equation - formally submitted 12/21 evening.

All,

Please find attached a PDF of the USG comments submitted to the CCPR- IESTI mail box yesterday evening, 12/21/2017.

Happy Holidays,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
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From: Miller, David
Sent: Tuesday, November 29, 2016 9:05 AM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
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Subject: FW: Participants list IESTI eWG

All,

Please find attached from the NL-AUS co-chairs the list of participants in the IESTI eWG.

I have also attached an updated list of participants in the US IESTI eWG Interest Group. This has been updated to add a phone number, correct a typo, and correct an interest group designation.

David.

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Sent: Tuesday, November 29, 2016 7:21 AM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
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Kind regards,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
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Sent: Fri 12/2/2016 2:49:38 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Miller, David[Miller.DavidJ@epa.gov]; Carmen Tiu (tcarmen@dow.com)[tcarmen@dow.com]; Ray McAllister (RMcAllister@croplifeamerica.org)[RMcAllister@croplifeamerica.org]
From: Jane M Stewart
Sent: Wed 2/15/2017 4:00:05 PM
Subject: FW: [CLA-REWG] Agenda and Minutes - Feb Meeting

HI David – paper looks great.

This is the last draft agenda for next week's meeting that I have seen. I am not sure if we already have a more updated version with dates/times. Ray?

Carmen may still be traveling, so if it's ok with Ray, I will send the Global Zoning paper to him so he can circulate to the whole group today.

I have an AI-specific meeting on the 22nd at the EPA offices in Crystal City. Hopefully we will be finished by noon and then I will take the metro or a cab to the CLA offices, but may be a little late. I hope Ray saves me some lunch.

Thanks!

...Jane

Jane Stewart, PhD.
Expert, Scientist
Environmental and Residue Sciences
BASF Corporation

Phone: +1 919 547-2273 Mobile: +1-973-641-2103 Fax: +1 919 547-2421 E-Mail: jane.stewart@basf.com
Postal Address: BASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709, USA

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From: CLA-REWG@yahoogroups.com [mailto:CLA-REWG@yahoogroups.com] **On Behalf Of** Sci Reg scireg@croplifeamerica.org [CLA-REWG]

Sent: Thursday, February 09, 2017 10:42 AM
To: CLA-REWG@yahoogroups.com
Cc: Tiu, Carmen (C) <tcarmen@dow.com>; Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: [CLA-REWG] Agenda and Minutes - Feb Meeting [1 Attachment]

REWG Members,

A few things for our upcoming meeting:

1. Our next REWG meeting will be held on February 22nd & 23rd at the CLA Headquarters (1156 15th St. NW, STE 400, Washington, DC 20005);

2. If you do not see a calendar invite on that day from me, please let me know and I will add you;

3. Find attached the November meeting minutes; and

4. We have put together a list of topics that we would like to speak on at the meeting. Please comment on the list below and address any items we did not include.

Feb-17	F&B	Interaction with GMA reps	Mano Basu-GMA, 30 minutes
Feb-17	L.Rossi	TSCA update MRL workshops Korea, Taiwan	Lois - 30 minutes
Feb-17	EPA	Updates from EPA (zoning, IESTI, OECD, etc)	D.Miller & team - 1 hour
Feb-17	USDA	Updates from USDA (Its, capacity building, events)	M.Rasmussen & team - 30 minutes
Feb-17	EPA, USDA	CCPR 49 preparation	All - 30 minutes
Feb-17	BCI	Updates from BCI on MRL & Growers Priorities	M.Lanz - 30 minutes
Feb-17	REWG	Metrics 2016 Performance, 2017 Goals	All- 1 hour

Feb-17	REWG	Residue & MRL global regulatory updates, impact on USA (OECD, EU, ARG, MEX, CHI)	All - 1 hour
Feb-17	REWG	REWG support to IESTI, Res-Def (EU, CDX)	All - 30 minutes
Feb-17	REWG	Suggestions for ACS Aug.2017	Phil, Heidi - 30 minutes
Feb-17	REWG	Codex Coalition update	Carmen & All - 30 minutes

Thank you,

Courtney DeMarco

Science and Regulatory Affairs

CropLife America

1156 15th Street, NW

Suite 400

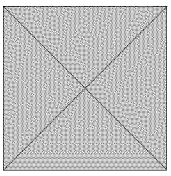
Washington, DC 20005

(202) 872-3867

View attachments on the web

Posted by: Sci Reg <SciReg@CropLifeAmerica.org>

Reply via web post • Reply to sender • Reply to group • Start a New Topic • Messages in this topic (1)



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To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Maria Maratos[Marie.Maratos@fsis.usda.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Sat 2/11/2017 11:54:00 AM
Subject: Re: final version of IESTI discussion paper

David:

Thanks for the clarification. Most of the interested observer organizations are represented in the IESTI effort by US-based affiliates or members, some of whom already participate in the IESTI US Interest Group. I'll explain to the others the conditions and possibilities for further participation.

I understand you have a workshop in Ecuador in early March where you will have an opportunity to share US positions on IESTI with Latin American Goverment participants in the IESTI eWG. I'm hoping the private interests can have a similar opportunity leading up to CCPR49. We'll work within your parameters.

Ray S. McAllister, PhD
Senior Director, Regulatory Policy
CropLife America
+1-202-872-3874 (office)
+1-202-577-6657 (cell)
ray@croplife.us

On Feb 11, 2017, at 7:29 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Hello Ray,

I've spoken to a few folks around here, and I am not comfortable at this time to opening up the US IESTI Interest Group meeting scheduled for next Thursday 16 February to observer organizations that have signed up directly with the EU-AUS co-chairs to participate on the IESTI eWG.

My hope is to discuss during the Thursday meeting thoughts regarding strategy and approach and these are only preliminary at this point and it would be premature for these to be shared widely. I also have concerns about such observer groups "dropping in" and "dropping out" of the IESTI US Interest Group on a more or less haphazard basis and the associated continuity-of-discussion issues.

We can talk about this if you like. Of course, if these are **US-based** observer groups and they'd like a more permanent place in the US Government discussions and would like to participate on a regular basis, that would likely be fine – please let me know and we can discuss. While "sign up" to the US Interest Group on IESTI was supposed to occur last fall, I wouldn't object to folks deciding they want to sign up now (even if a bit late) if they want to commit to being a member of the group.

David.

David J. Miller CAPT | USPHS Commissioned Corps

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Thursday, February 02, 2017 5:19 PM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Subject: RE: final version of IESTI discussion paper

Hello Ray,

I've not forgotten your query below, and should have an answer for you early next week on whether we'd like to limit this to the IESTI US interest group or expand it to others. I will say that I am leaning against expanding the call to other IESTI observer organizations.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, February 01, 2017 9:22 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: final version of IESTI discussion paper

David:

There are a number of other observer organizations that have signed up to participate on the IESTI eWG. Can we invite them to listen in on this call? Would it be helpful to provide a list of the groups?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Tuesday, January 31, 2017 5:17 PM
To: cheryl.cleveland@basf.com; jcranney@calcitrusquality.org; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; Ray McAllister <RMcAllister@croplifeamerica.org>; kent.rupprecht@bayer.com; jane.stewart@basf.com; bruce.young@bayer.com
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>

Subject: RE: final version of IESTI discussion paper

All,

It looks like from responses I've received that February 16 (Thursday) works for everybody (for sometime) between 2:30 and 5 pm for a phone call on IESTI with the IESTI work group.

I will go ahead and schedule this once I confirm a room – if you are not able to make this, please let me know. This is expected to be a meeting by phone, so no need for most of you to travel.

David

From: Miller, David
Sent: Monday, January 30, 2017 5:24 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maria Maratos' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: FW: final version of IESTI discussion paper

Dear US IESTI eWG Interest Group members:

Please find attached something I just received re: the IESTI document and additional information sent out by the eWG co-chairs.

This is just in, so we haven't had a chance yet to go through it. Note that there is discussion below of a physical Work Group meeting being proposed, and that the NL will possibly request that such an in-session WG meeting be considered when the provisional agenda is discussed.

As I indicated in my email of earlier today to you all, I will plan on scheduling a IESTI US Interest Group Conference call sometime during the latter half of February.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Monday, January 30, 2017 4:55 PM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: final version of IESTI discussion paper

Dear all,

Thank you once more for actively participating in improving the discussion document on the IESTI for the next CCPR. Even with the short response time this second time around, we have received input from 17 counties / organizations, which was very helpful
Attached you will find the following documents:

- a pdf file in which we have compiled all your comments along the paragraphs of the discussion document, including the response of the Dutch drafting team.

- a pdf file with the final version of the Discussion document, accompanied by a tracked-changes Word-version of the same file, for you to see what was changed. The clean discussion paper was also sent to the Codex Secretariat for translation.

Please note that the paper is not a position paper, but a discussion paper. We hope that thanks to your input, the paper is now more balanced in addressing all points of view. The conclusions and recommendations are not aimed at deciding on what to change in the IESTI equations during CCPR49 in April. They are aimed at deciding on a process by which to gather sufficient information for delegates to make an informed decision at a later session.

I have asked the Codex Secretariat whether it would be possible to have a physical meeting of our eWG before the matter is formally discussed in plenary. Gracia Brisco noted that CCPR48 did not agree on any physical meetings of the eWG prior to the session or in conjunction with the session.
There is however a possibility during the adoption of the provisional agenda (Agenda Item 1) when the lead country of the EWG could request the establishment of an in-session WG to have a live discussion in the margins of the plenary. Such in-session WG can be scheduled to take place after we finish the plenary session on Tuesday or over the lunch breaks on Tuesday or Wednesday.
The Netherlands will request to establish such an in-session WG. As many of you have indicated that a physical meeting of our eWG would be appreciated, I hope that sufficient support will be given to our request. If you are not the head of your delegation, please discuss this with him or her.

Looking forward to see you in Beijing,
Kind regards, also on behalf of the drafting team and our Australian co-chairs,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
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To: Miller, David[Miller.DavidJ@epa.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Janet Collins[jcollins@croplifeamerica.org]
From: Cindy Smith
Sent: Thur 2/9/2017 11:09:49 PM
Subject: RE: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Sorry David –I have been meaning to send you my new contact info – here it is:

Cindy Baker Smith

Gowan USA

10332 Almost Heaven Street

Las Vegas, NV 89131

Phone: 928-580-2811

Fax: 928-373-1988

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, February 09, 2017 1:31 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Janet Collins <jcollins@croplifeamerica.org>; Cindy Smith <csmith@gowanco.com>
Subject: RE: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Ok. Tx. I will update the EPA Codex interest group mailing list and re-send the email to her.

David

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, February 09, 2017 4:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Janet Collins <jcollins@croplifeamerica.org>; Cindy Smith <csmith@gowanco.com>
Subject: Re: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Cindy has returned to Gowan. (Copied here)

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.us

On Feb 10, 2017, at 4:20 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Hello Ray and Janet,

I recently send out some material re: the CCPR49 to the US Codex Interest group (different from and broader than US IESTI interest group) and got a bounce-back re: Cindy Baker from Amvac.

See the delivery failure below. Do you know Cindy's current email address?

Tx.

David

From: postmaster@Amvac.local [mailto:postmaster@Amvac.local]
Sent: Thursday, February 09, 2017 2:10 PM
To: Miller, David
Subject: Undeliverable: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Delivery has failed to these recipients or groups:

Cindys@amvac-chemical.com (Cindys@amvac-chemical.com)
The e-mail address you entered couldn't be found. Please check the recipient's e-mail address and try to resend the message. If the problem continues, please contact your helpdesk.

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Cindys@amvac-chemical.com
#550 5.1.1 RESOLVER.ADR.RecipNotFound; not found ##

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"Doherty, Michael" <Doherty.Michael@epa.gov>, "Wing.Yu@chemtura.com" <Wing.Yu@chemtura.com>, "Dougtnelson1@gmail.com" <Dougtnelson1@gmail.com>, "ronaldwilliams@coca-cola.com" <ronaldwilliams@coca-cola.com>, "Marie.Maratos@fsis.usda.gov" <Marie.Maratos@fsis.usda.gov>, "tcarmen@dow.com" <tcarmen@dow.com>, "mike@cmschofieldconsulting.com" <mike@cmschofieldconsulting.com>, "fukushimak@iskbc.com" <fukushimak@iskbc.com>, "JKozlowski@nichino.net" <JKozlowski@nichino.net>, "Robin.Charlton@valent.com" <Robin.Charlton@valent.com>, "Terry.Councell@fda.hhs.gov" <Terry.Councell@fda.hhs.gov>, "Sara.Kucenski@fas.usda.gov" <Sara.Kucenski@fas.usda.gov>, "Nguyen, Thuy" <Nguyen.Thuy@epa.gov>, "meldan@luxpam.com" <meldan@luxpam.com>, "jcollins@croplifeamerica.org" <jcollins@croplifeamerica.org>, "Wu.Li@yum.com" <Wu.Li@yum.com>, "Miller, David" <Miller.DavidJ@epa.gov>, "allen.scarborough@bayer.com" <allen.scarborough@bayer.com>, "Shah, Pv" <Shah.Pv@epa.gov>, "Vogel, Dana" <Vogel.Dana@epa.gov>, "james.m.nyangulu@monsanto.com" <james.m.nyangulu@monsanto.com>, "Ruihong.Guo@ams.usda.gov" <Ruihong.Guo@ams.usda.gov>, "Diana.Haynes@ams.usda.gov" <Diana.Haynes@ams.usda.gov>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "John.Johnston@fsis.usda.gov" <John.Johnston@fsis.usda.gov>, "charlotte.liang@fda.hhs.gov" <charlotte.liang@fda.hhs.gov>, "cheryl.cleveland@basf.com" <cheryl.cleveland@basf.com>, "aroberts@TSGUSA.com" <aroberts@TSGUSA.com>, "SSpaulding@central.com" <SSpaulding@central.com>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "Julie.Chao@fas.usda.gov" <Julie.Chao@fas.usda.gov>, "MBasu@gmaonline.org" <MBasu@gmaonline.org>, "gflanley@sherpa360.com" <gflanley@sherpa360.com>, "k-fukushima@iskweb.co.jp" <k-fukushima@iskweb.co.jp>, "leggettm@iskbc.com" <leggettm@iskbc.com>, "ya-tada@iskweb.co.jp" <ya-tada@iskweb.co.jp> Subject: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS Thread-Topic: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS Thread-Index: AdKBQsoYdPvMxoIkQeescAltq77jYQA/JGnAAA2CSeAAJEhOgA== Date: Thu, 9 Feb 2017 19:10:12 +0000 Message-ID: <BY1PR09MB0791BFFEBA633FAB6327D351F7450@BY1PR09MB0791.namprd09.prod.outlook.com> References: <VI1PR0501MB244557500771EDB76E7B57AEF1430@VI1PR0501MB2445.eurprd05.prod.outlook.com> <842b4368be0242178955435e69c6e46a@BN1PR0204MB0099.001f.mgd2.msft.net> <BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com> In-Reply-To: <BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com> Accept-Language: en-US Content-Language: en-US X-MS-Has-Attach: yes X-MS-TNEF-Correlator: x-originating-ip: [2620:117:500e:77::d00b] x-ms-office365-filtering-correlation-id: 4cb55584-8191-453d-8f6f-08d4511f4661 x-microsoft-antispam: UriScan:;BCL:0;PCL:0;RULEID:(22001);SRVR:BN1PR09MB074; x-microsoft-exchange-

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19:10:13.0014 (UTC) X-MS-Exchange-CrossTenant-fromentityheader: Hosted X-MS-
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Transport-CrossTenantHeadersStamped: BN1PR09MB074

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Janet Collins[jcollins@croplifeamerica.org]; Cindy Smith[csmith@gowanco.com]
From: Ray McAllister
Sent: Thur 2/9/2017 9:18:37 PM
Subject: Re: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Cindy has returned to Gowan. (Copied here)

Ray S. McAllister, PhD
Senior Director, Regulatory Policy
CropLife America
+1-202-872-3874 (office)
+1-202-577-6657 (cell)
ray@croplife.us

On Feb 10, 2017, at 4:20 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Hello Ray and Janet,

I recently send out some material re: the CCPR49 to the US Codex Interest group (different from and broader than US IESTI interest group) and got a bounce-back re: Cindy Baker from Amvac.

See the delivery failure below. Do you know Cindy's current email address?

Tx.

David

From: postmaster@Amvac.local [mailto:postmaster@Amvac.local]
Sent: Thursday, February 09, 2017 2:10 PM
To: Miller, David
Subject: Undeliverable: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Delivery has failed to these recipients or groups:

Cindys@amvac-chemical.com (Cindys@amvac-chemical.com)
The e-mail address you entered couldn't be found. Please check the recipient's e-mail address and try to resend the message. If the problem continues, please contact your helpdesk.

Diagnostic information for administrators:

Generating server: Amvac.local

Cindys@amvac-chemical.com
#550 5.1.1 RESOLVER.ADR.RecipNotFound; not found ##

Original message headers:

Received: from mail6.bemta8.messagelabs.com (10.40.40.220) by ex1-amvac.Amvac.local (10.40.40.221) with Microsoft SMTP Server id 14.3.248.2; Thu, 9 Feb 2017 11:09:31 -0800 Return-Path: <Miller.DavidJ@epa.gov> Received: from [216.82.241.131] by server-2.bemta-8.messagelabs.com id C6/E1-02120-D9EBC985; Thu, 09 Feb 2017 19:10:21 +0000 X-Brightmail-Tracker: H4sIAAAAAAAAA2VTa0hTYRju2znbOV6Wx3nZ27AfjcKwJooERhB
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"Doherty, Michael" <Doherty.Michael@epa.gov>, "Wing.Yu@chemtura.com" <Wing.Yu@chemtura.com>, "Dougtnelson1@gmail.com" <Dougtnelson1@gmail.com>, "ronaldwilliams@coca-cola.com" <ronaldwilliams@coca-cola.com>, "Marie.Maratos@fsis.usda.gov" <Marie.Maratos@fsis.usda.gov>, "tcarmen@dow.com" <tcarmen@dow.com>, "mike@cmschofieldconsulting.com" <mike@cmschofieldconsulting.com>, "fukushimak@iskbc.com" <fukushimak@iskbc.com>, "JKozlowski@nichino.net" <JKozlowski@nichino.net>, "Robin.Charlton@valent.com" <Robin.Charlton@valent.com>, "Terry.Councell@fda.hhs.gov" <Terry.Councell@fda.hhs.gov>, "Sara.Kucenski@fas.usda.gov" <Sara.Kucenski@fas.usda.gov>, "Nguyen, Thuy" <Nguyen.Thuy@epa.gov>, "meldan@luxpam.com" <meldan@luxpam.com>, "jcollins@croplifeamerica.org" <jcollins@croplifeamerica.org>, "Wu.Li@yum.com" <Wu.Li@yum.com>, "Miller, David" <Miller.DavidJ@epa.gov>, "allen.scarborough@bayer.com" <allen.scarborough@bayer.com>, "Shah, Pv" <Shah.Pv@epa.gov>, "Vogel, Dana" <Vogel.Dana@epa.gov>, "james.m.nyangulu@monsanto.com" <james.m.nyangulu@monsanto.com>, "Ruihong.Guo@ams.usda.gov" <Ruihong.Guo@ams.usda.gov>, "Diana.Haynes@ams.usda.gov" <Diana.Haynes@ams.usda.gov>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "John.Johnston@fsis.usda.gov" <John.Johnston@fsis.usda.gov>, "charlotte.liang@fda.hhs.gov" <charlotte.liang@fda.hhs.gov>, "cheryl.cleveland@basf.com" <cheryl.cleveland@basf.com>, "aroberts@TSGUSA.com" <aroberts@TSGUSA.com>, "SSpaulding@central.com" <SSpaulding@central.com>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "Julie.Chao@fas.usda.gov" <Julie.Chao@fas.usda.gov>, "MBasu@gmaonline.org" <MBasu@gmaonline.org>, "gflanley@sherpa360.com" <gflanley@sherpa360.com>, "k-fukushima@iskweb.co.jp" <k-fukushima@iskweb.co.jp>, "leggettm@iskbc.com" <leggettm@iskbc.com>, "ya-tada@iskweb.co.jp" <ya-tada@iskweb.co.jp> Subject: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS Thread-Topic: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS Thread-Index: AdKBQsoYdPvMxoIkQeescAltq77jYQA/JGnAAA2CSeAAJEhOgA== Date: Thu, 9 Feb 2017 19:10:12 +0000 Message-ID: <BY1PR09MB0791BFFEBA633FAB6327D351F7450@BY1PR09MB0791.namprd09.prod.outlook.com> References: <VI1PR0501MB244557500771EDB76E7B57AEF1430@VI1PR0501MB2445.eurprd05.prod.outlook.com> <842b4368be0242178955435e69c6e46a@BN1PR0204MB0099.001f.mgd2.msft.net> <BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com> In-Reply-To: <BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com> Accept-Language: en-US Content-Language: en-US X-MS-Has-Attach: yes X-MS-TNEF-Correlator: x-originating-ip: [2620:117:500e:77::d00b] x-ms-office365-filtering-correlation-id: 4cb55584-8191-453d-8f6f-08d4511f4661 x-microsoft-antispam: UriScan:;BCL:0;PCL:0;RULEID:(22001);SRVR:BN1PR09MB074; x-microsoft-exchange-

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x-microsoft-antispam-prvs:
<BN1PR09MB074BA3F64DDCF43A7E2A9AAF7450@BN1PR09MB074.namprd09.prod.outlook.com>
x-exchange-antispam-report-test:
UriScan:(84896068252459)(261320762254229)(105329927740338)(197117283949776)(12300249208716
x-exchange-antispam-report-cfa-test:
BCL:0;PCL:0;RULEID:(102415395)(6040375)(601004)(2401047)(5005006)(8121501046)(10201501046)
x-forefront-prvs: 02135EB356 x-forefront-antispam-report:
SFV:NSPM;SFS:(10019020)(7916002)(39450400003)(189002)(377454003)(30584003)(199003)(2525140
received-spf: None (protection.outlook.com: epa.gov does not designate
permitted sender hosts) spamdiagnosticoutput: 1:99 spamdiagnosticmetadata: NSPM
Content-Type: multipart/mixed;
boundary="_006_BY1PR09MB0791BFFEBA633FAB6327D351F7450BY1PR09MB0791namp_" MIME-
Version: 1.0 X-MS-Exchange-CrossTenant-originalarrivaltime: 09 Feb 2017
19:10:13.0014 (UTC) X-MS-Exchange-CrossTenant-fromentityheader: Hosted X-MS-
Exchange-CrossTenant-id: 88b378b3-6748-4867-acf9-76aacbeca6a7 X-MS-Exchange-
Transport-CrossTenantHeadersStamped: BN1PR09MB074

To: Miller, David[Miller.DavidJ@epa.gov]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; RMcAllister@croplifeamerica.org[RMcAllister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; Jane M Stewart[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]
Cc: Maria Maratos[Marie.Maratos@fsis.usda.gov]; Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Bacon, Laura[Bacon.Laura@epa.gov]
From: Cheryl Cleveland
Sent: Tue 1/31/2017 7:37:02 PM
Subject: IESTI call

Regarding call - Thursday Feb 23rd is very inconvenient for me. Afternoons are preferable.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, January 30, 2017 2:52 PM
To: Cheryl Cleveland <cheryl.cleveland@basf.com>; jcranney@calcitrusquality.org; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; RMcAllister@croplifeamerica.org; kent.rupprecht@bayer.com; Jane M Stewart <jane.stewart@basf.com>; bruce.young@bayer.com
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Also -as an FYI – we will set up an IESTI conference call for some time during the latter half of

February to discuss the current exploratory activities EPA is doing. As I mentioned briefly during the the Codex CCPR Interest Group meeting held on Thursday of last week here in Crystal City and on the phone, EPA mathematical statistician James Nguyen has taken some extensive crop field trial data from USA and Canada (some of you will know it as the USA-Canada Zoning Data Set assembled by PMRA) and also done some simulations to show how much the variability factor would need to go down if we use the HR instead of the MRL in the IESTI equation assuming we want to keep everything else the same. We also have an interest in (but have not started yet) looking at the WHO food consumption data on a gram/kg bw basis and seeing how this might change.

If there are any days or combination of days that definitely don't work for you during the last two full weeks of February and you are interesting in attending the call, please let me know (it is as yet unscheduled)

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Friday, January 27, 2017 3:33 PM

To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: FW: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

All,

Please find attached and below the communication that we send to the CCPR/IESTI co-chairs with the US Government response to their second round request for comments. This was sent to them on Wednesday evening of this week.

David.

From: Miller, David
Sent: Wednesday, January 25, 2017 8:14 PM
To: 'CCPR_IESTI@rivm.nl' <CCPR_IESTI@rivm.nl>
Cc: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Bernadette,

The United States appreciates the opportunity to review and comment on the revised discussion paper. We understand from your email communications that you are only seeking comments and suggested changes on topics and issues with which the U.S. absolutely disagrees, and the purpose of this second round of commenting given the very short turn-around time is not to by any means to "fine-tune" or to reach consensus on the draft document.

We further understand that -- particularly given the wide variety of reactions to the document and critiques offered during the first round of commenting -- that no decisions on changes to the IESTI equation will be made or decided upon at the coming CCPR meeting. You also state in your email communication that "[T]here will be more opportunity later on to refine wording". With respect to this latter point, we believe that the document is not yet and is not anticipated to be in the near future in a state at which only "refined wording" is necessary. There are a number of very important fundamental concepts relating to such topics as regulatory targets and goals, next steps, and continued investigational work that (understandably at this early stage) will need to be further discussed and agreed upon before we can consider the document in need of only changes to refine wording.

With the above in mind and your call for only comments on issues that member countries absolutely disagree, the U.S. offers the following limited comment set.

1. It may facilitate understanding of IESTI documents (especially when the documents are translated to other languages) to replace subjective terms such as "conservative" and "conservatism" with objective terms such as accuracy, over-estimation of exposure, increased estimates of exposure, etc.

2. Appendix 2, Table 3 (challenges that arise from the possible revision of the current IESTI equations), Line 11 – The process outlined here is of critical importance to the development of an updated IESTI equation. We feel that this statement must be retained in future versions of this document, perhaps with the following minor modification (based on the previous comment):

Reaching consensus regarding the approach to be used to evaluate ~~the level of conservatism of~~ the accuracy of exposure estimates generated with proposed IESTI equations and how these estimates compare to estimates generated with the present set of IESTI equations and state-of-the-science probabilistic methods.

3. Paragraph 7, lines 114 to 119 indicates that it is critical that the accuracy of the resulting pesticide intake estimates be evaluated and that "prior to conducting such evaluations, CCPR needs to reach consensus on the target upper percentile of intake [exposure] to be estimated by the equations. It is not clear to us that it is necessary – or even possible – for CCPR to reach consensus on the target upper percentiles of intake. Appropriate comparisons can be performed across a range of potential target percentiles to evaluate the degree to which the current and

proposed IESTI equations may overstate "real world" exposures as estimated using more realistic pesticide residue concentration data reflecting more realistic percent crop treated data and using more realistic food consumption data, all evaluated probabilistically. To require that CCPR reach consensus on a target upper percentile of intake prior to conducting any evaluation of the equations will likely set back and limit any quantitative assessments and comparisons which we feel are critical to evaluate the need for or desirability of any changes to the equation.

4. Paragraph 9, lines 126-132 discusses a preliminary 5% figure as being an estimate of the number of lost MRLs based on implementation of all the recommendations made during the 2015 Geneva Workshop. We think that this number is entirely too preliminary and insufficiently supported to be placed in into present CCPR document, and simple counts of MRLs that may be lost do not necessarily appropriately reflect the trade value or other equally appropriate metrics that may be of interest. Further, the statement that the estimate of the potential loss of MRLs "may be an overestimation" seems to characterize this estimate in a way that the government of the U.S. does not believe is necessarily accurate and can be misleading. We suggest that the 5% estimate and its characterization of it likely being an overestimate be eliminated from the document, and replaced by a statement that indicates that a thorough evaluation of the lost MRLs in terms of MRL counts, trade value, lost pest control, and other metrics be included instead. Overall, we believe the paper needs to provide greater emphasis on the necessity that any evaluation of changes to the equation also reflect trade impacts.

5. We believe the paper should emphasize and re-affirm that consideration of the proposed changes to the IESTI equation is something that needs to be done with considerable care and deliberation, and that these considerations will likely take an extended period of time and involve considerable resources as well as input from a variety of stakeholders and across a variety of viewpoints.

To facilitate your review and compilation of the above enumerated comments, we have attached these as a Word table in the format you requested.

The U.S. thanks you for allowing an extra day for us to convey these comments and also very much appreciates the significant effort that was required on your part to prepare the revised document over such a short period. We look forward to productive discussions on this issue at the CCPR meeting in April, 2017.

Regards,

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
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703-305-5147 (fax)

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From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Tuesday, January 24, 2017 11:21 AM
To: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>
Cc: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Marie,

We are happy to receive the US comments by January 25.

Kind regards,
Bernadette

From: "Maratos, Marie - FSIS" <Marie.Maratos@fsis.usda.gov>
To: "'CCPR_IESTI@rivm.nl'" <CCPR_IESTI@rivm.nl>,
Cc: "Miller.DavidJ@epa.gov" <Miller.DavidJ@epa.gov>
Date: 23-01-2017 23:02
Subject: RE: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

Dear Bernadette,

The United States is in the process of finalizing our comments and will expect to have them to you by the morning of January 25th.

Thank you for your understanding.

Best regards,
Marie

****

Marie Maratos
International Issues Analyst
U.S. Codex Office
Room 4865 South Building
Food Safety and Inspection Service (FSIS)
U.S. Department of Agriculture (USDA)
Washington, DC, USA
Phone: +1.202.690.4795
Mobile: +1.202.412.7901
Fax: +1.202.720.3157
Email: Marie.Maratos@fsis.usda.gov

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Monday, January 23, 2017 6:18 AM
To: IESTI Participants WG; IESTI Observers WG
Subject: Fw: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS - REMINDER

A kind reminder to last week's request to comment by 24 January at the latest on the second draft of the IESTI discussion paper.

Kind regards,
Bernadette Ossendorp

----- Forwarded by Bernadette Ossendorp/RIVM/NL on 23-01-2017 12:15 -----

From: CCPR_IESTI_cleanmail181169
To: "IESTI Participants WG" <IESTI_Participants_WG@rivm.nl>, "IESTI Observers WG" <IESTI_Observers_WG@rivm.nl>,
Date: 17-01-2017 20:29
Subject: version 2 of IESTI discussion paper - REQUEST FOR COMMENTS
Sent by: Bernadette Ossendorp

Dear all,

Again, thank you for actively participating in improving the discussion document on the IESTI for the next CCPR.
Attached you will find the following documents:

- a pdf file in which we have compiled all your comments along the paragraphs of the discussion document, including the response of the drafting team. Comments were provided by 25 countries / organizations. The document begins with a number of responses to generic concerns raised by several contributors. Then, on page 3 follow a number of general comments that generally do not lead to adjustments in the discussion paper. Then follow from page 16 the specific comments, which refer to a particular line or paragraph in the text and suggest adjustments to the paper. On page 56 are suggestions for new items in Table 1 (advantages) and on page 58 suggestions for new items in Table 2 (challenges).

- a pdf file with version 2 of the Discussion document, accompanied by a tracked-changes Word-version of the same file, for you to see what was changed.

- The report of the 2015 Geneva workshop (as we now call it for briefness), which has as Annex A the Background document with the scientific rationale for proposing the changes. We noted that many of you had not been in the position to have a look at this earlier, and as we would prefer not to re-iterate all this text in the current document, please have a look if your comments are addressed by what was written there.

- a Word-file containing the new version of the comments table. Please use this table for providing comments to version 2.

Please note that due to the very tight timelines, our Australian co-chairs have agreed to comment on the document in parallel with the whole group.

We would like to receive your comments on version 2 by **24 January** ate the latest. Please try not to go too much into detail, only suggest changes when you absolutely disagree to a certain part of text. We would like to emphasize that surely, no decisions on changes to the IESTI (risk communication / risk management part) will be made at the coming CCPR. There will be more opportunity later on to refine wording.
Please let us know if you need any further clarifications.

Looking forward to our continued cooperation,
Kind regards,
Bernadette Ossendorp

----- Forwarded by Bernadette Ossendorp/RIVM/NL on 17-01-2017 19:53 -----

From: CCPR_IESTI_cleanmail181169
To: "IESTI Participants WG" <IESTI_Participants_WG@rivm.nl>, "IESTI Observers WG" <IESTI_Observers_WG@rivm.nl>,
Date: 12-01-2017 22:08
Subject: update on progress - version 2 of IESTI discussion paper
Sent by: Bernadette Ossendorp

Dear all,

Thank you for your active participation in the first commenting round on the draft discussion paper on IESTI. In total, we have received 38 pages of comments from 25 countries / organizations, which is very helpful for improving the discussion paper. However, this vast number has a downside too: we have not yet been able to address them all by today, as planned. We hope to send you the response to all comments and the adjusted discussion paper early next week.

FYI: we will proceed to organize a physical eWG meeting prior to or during CCPR. We'll let you know date and room when decided.

Kind regards,
Bernadette Ossendorp

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To: Miller, David[Miller.DavidJ@epa.gov]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; RMcAllister@croplifeamerica.org[RMcAllister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; Jane M Stewart[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]; 'Maratos, Marie - FSIS'[Marie.Maratos@fsis.usda.gov]; 'Basu, Pat - FSIS'[Pat.Basu@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
From: Cheryl Cleveland
Sent: Tue 1/24/2017 2:33:03 PM
Subject: FW: CLI IESTI comments on 2nd round were submitted.
Jan 2017 comments table CCPR paper version 2.pdf

Hello to the US team watching the IESTI eWG. Please find attached the final comments that were submitted by CropLife last night. I have confirmation from the eWG lead that these were received by today's deadline of Jan 24th. I hope they are helpful in your US response and in the CODEX discussion scheduled tomorrow afternoon.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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	Country / Observer	Indicate text (page/line*)	Comment
1	CropLife International	Full text	CropLife International appreciates the opportunity to provide input on refinement of this draft document for the upcoming CCPR meeting. We recognize the amount of work that has already occurred and that current draft is a significant and altered version of the initial draft. **For transparency, we strongly request additional changes so that the finalized paper will better reflect the differences of opinion raised in the commenting periods by the eWG.** If differences are clearly flagged, all CCPR delegates can clearly recognize the scope of further work needed to achieve completion. The paper should **clarify that in order to address the full remit of the eWG additional work and analysis is still needed.** CropLife International welcomes opportunities to remain active in the on-going work.
2	CropLife International	Overall Document Organization and Order	The paper is currently organized along a historical timeline and thus the eWG remit is buried within the body of the paper. **Please consider moving the remit of the eWG to the beginning of the document**, before the history and the workshop equations, to better clarify the purpose of this work by the eWG. Currently the 2015 workshop equations are presented as final, rather than a starting point for the eWG. **Please clarify that listed equations were recommended during the 2015 workshop, but they are not the final product of this eWG and that there is not agreement on the case for change amongst all members of the eWG.** Finally, the work of this eWG so far has captured comments on the 2015 IESTI equations; an improved outcome would be conclusions on **a more specific workplan clarified in the document – including a List of future work for the eWG or the proposed FAO/WHO workgroup.** We are encouraged by the acknowledgement of the significant technical challenges with the inclusion of Appendix 2. We propose that **Table 3 is better placed in the body of the report and specifics are more fully discussed rather than left as an Appendix.**
3	CropLife International	Paragraph 2 Line 33-34/Page 1	It is agreed that that *dietary exposure* should not exceed a reference dose, but there is not agreement across the eWG that the proposed equations are the appropriate way to calculate that *exposure*. It it also not agreed that use of the MRL in the current equation is the only way to assess residues supporting the MRL. Please r**emove existing paragraph and replace** with the following to eliminate ambiguity and better reflect the work of the eWG. **Consumer safety as related to pesticide residues is assessed by estimating a life-time dietary exposure to the residue and comparing this with the Acceptable Daily Intake (ADI), and, in**

			case the compound has acutely toxic properties, by estimating a short-term dietary exposure and comparing this with the Acute Reference Dose (ARfD). The foundation for acceptable consumer safety from an acute intake perspective is that dietary exposure should not exceed the ARfD. The overall objective of all the work is to review in detail the existing IESTI equations and proposed updates to those equations. The outcome of this eWG indicated there is not full agreement that the 2015 proposed equations using the MRL are the best estimates of dietary exposure.
4	CropLife International	Paragraph 4 Page 2 Line 49-53,	The current statement ignores the compounded conservatism built into the full IESTI approach. **Please add**: **However, the stated concern regarding risk assessment with the HR rather than MRL level needs further discussion in the eWG**. **Additional conservatism exists in both the toxicity endpoint (with multiplied uncertainty factors for possible interspecies and intraspecies differences), and the IESTI methodology (use of large portion consumption, variability factors)**. The scenario leading to a possible consumer risk is not just a residue value above the HR (rare), but a combination of a number of rare events. For example, an individual must encounter a rare food item with residues above 3xHR (variability factor x HR), they must encounter it on a day when they are eating a particularly large portion of that food item, the pesticide in question is one in which humans are more sensitive than the most sensitive test species, and the consumer must be a member of a sensitive subpopulation. The compounded low probabilities of each of these occurrences makes the probability of them co-occurring extremely low. **Please add: The IESTI equation as it stands is quite conservative and protective of consumer safety, even when using HR/STMR. However, if the intention is to improve communicating to a lay audience, replacement of HR by MRL in the equation should be accompanied by adjustment of the other variables to provide a reasonable realistic exposure scenario.**
5	CropLife International	Paragraph 4 Page 2 Line 51	**Please add** the following to the text or as a footnote for transparency to the reader who is not familiar with the OECD MRL calculator. **When the MRL is derived with the OECD calculator, the MRL can only be much higher than the HR if it is from a small or highly variable dataset. In either case a variability estimate is included in the calculator algorithms for established MRL (mean + 4 * SD). The MRL thus incorporates the uncertainty of small or highly variable datasets. Thus use of the MRL with an extra variability factor would be an unnecessary form of double counting**.

6	CropLife International	Paragraph 4 Page 2 Line 53	**Please provide examples of the stated ARfD exceedances, and which IESTI equations were used for these assessments. If this type of this exceedance is a driving reason for change, the issue should be better illustrated with clear examples** and documented frequency of exceedance. Under what circumstances – based upon a flaw in info used, formula problem, etc.? Is this using the current JMPR equations, or the proposed equations which are not adopted yet or the EU IESTI with higher variability factors of > 3? We agree with the US delegation that "using the CXL and "v" will likely overestimate variability and overestimate pesticide intake. We expect that determining what "v" would be most appropriate to pair with the CXL will require a substantial effort, but we believe that this is an important effort"**.**
7	CropLife International	Paragraph 4 Page 2 Line 56	**Please remove** "and concerns among the general public as to whether the MRL can be considered safe". The general public is not typically not aware of the differences in the input parameters from various regions and regulatory agencies.
8	CropLife International	Paragraph 6, page 2 Lines 78	**Please add** an important clarification **These listed equations were recommended during the 2015 workshop, but they are not the final product of this eWG. Instead the work of this eWG is to use them as a starting point for additional discussion. The eWG has collected challenges to these as listed in Table 2 and 3**.
9	CropLife International	Paragraph 6, page 2 Lines 78	Please **add** a clarification that reflects the concerns raised during commenting: **Many are concerned that the proposed equations are unnecessarily conservative, especially for the cases which mathematically use the following to estimate the exposure <u>at the consumer dinner plate</u>: a) 3X the MRL, b) the MRL for a blended or c) the MRL for animal commodity.**
10	CropLife International	Paragraph 6, page 3, line 87	Instead of a general reference to the workshop report, for clarity to all readers, **this CCPR document needs to better specify the"several changes in the input parameters" expected.**
11	CropLife International	Paragraph 6, page 3, Line 92	The use of the MRL for blended commodities will inappropriately lead to failure of MRLs. Please **clarify** how the effects of bulking and blending will be addressed.
12	CropLife International	Paragraph 7, page 3, line 109	CropLife International agrees with the principle of benchmarking; **please clarify the path** to achieve a "FAO/WHO –documented probabilistic based approach". Would it be the work of the eWG to explore models? To ensure transparency, utilized probabilistic models need to be available to the public and validated. International agreement on a FAO/WHO model will require additional agreement beyond that for input to the IESTI. This appears to indicate a significant amount of work; please allocate appropriate amount of time. **Use of existing national models rather than development of a new FAO/WHO could be used in initial benchmarking**.
13	CropLife International	Paragraph 8, page 3, line	The *5% number quoted is extremely preliminary* and is *likely to be an underestimate* given that the CF factor (conversion factor

		119	for differences in residue definition) of the equation was not explored in the analysis and adjusted LP data was not available to all. **Please remove the statement that the 5% may be an overestimate. Please add: Many are concerned that incremental changes to the equation should not be considered, but rather the changed equation as a whole needs to be considered. The full impact on number of MRLs lost cannot be assessed while the inputs and equations are not finalized.**
14	CropLife International	Paragraph 8, page 3, line 119	For balance, **please add that the loss of any MRLs without a clearer and stronger justification is a concern to many serving in the EWG.**
15	CropLife International	Paragraph 8, page 3, line 119	Part of the *remit of the eWG is to assess impact on trade*. A preliminary estimate of the overall average of MRLs lost does not adequately address impact on trade. **A further analysis by crop and sector is needed to understand impact. What is planned process for impact assessment?**
16	CropLife International	Paragraph 13, page 5	**Please move the remit of the eWG to the beginning of the document**, to clarify the purpose of the paper.
17	CropLife International	Table 1 item 3	**Recommend rewording** to better reflect diversity of thought expressed on eWG. Many doubt it will improve risk communication to the public. And it is not agreed that use of MRL is the only option. **Please change to:** **When communicating about pesticide residues and dietary risk assessment, the use of the MRL instead of the HR in IESTI equations *may* be more accepting to the public in some regions**
18	CropLife International	Table 1 item 5	**Recommend rewording** to be more transparent that impact on trade has not been explored in depth by the eWG**:** **Updating the IESTI methodology, including clarification of the input parameters, *may* encourage its use by a larger number of countries thereby helping to prevent trade barriers.**
19	CropLife International	Table 1 item 7	**Recommend rewording** because full world-wide harmonization is not realistic. The exposure calculation is not the only consideration in world wide harmonisation and prevention of trade barriers. Variations in residue definition and tox endpoints will continue to drive trade mismatches even if exposure were to be universally calculated. **Please change to:** **Updating the IESTI methodology, including clarification of the input parameters, *may* encourage its use by a larger number of countries thereby helping to prevent trade barriers.**
20	CropLife International	Table 1 item 8	This is a very general statement and was not agreed at least in previous discussions at the CCPR 2016. It is confusing because MRLs can be considered as GAP specific too. The "transparency" of MRLs as international trade standards irrespective of the kind of treatment (eg application type) is not improved by a change in the IESTI equation. **Please remove.**
21	CropLife	Table 1 item	Please **consider deleting** or inserting the words ***may improve***,

	International	9	to reflect discussion at the CCPR 2016 as controversial. The topic should be highlighted as subject of future work along with improving other parameters in the equation.
22		Table 2, point 1	**Please add: a substantial effort will be required to derive scientifically based variability factors, and homogenization factors for bulk and blended commodities. The provision of the LP (g/kg) data is critical; there is no way to consider the assessment and impact of the equation changes possible until these data are available.**
23	CropLife International	Table 2	Please add: **the loss of any MRLs without a clearer justification is a concern to many serving in the eWG.**
24	CropLife International	Page 7 Paragraph 17	It is agreed quantifying the differences between the current and proposed IESTI is important, please **consider state-of-the-science probabilistic methods and monitoring data** for consumer dietary exposure as part of the comparison.
25	CropLife International	Page 7 Paragraph 18	Proposed changes need to **clearly define the level of conservativeness** based on scientifically valid and defensible data.
26	CropLife International	Page 7 Paragraph 19	Regarding the proposed FAO/WHO technical working group to encourage transparency, please consider input from stakeholders and close with the the eWG. **Regarding the proposed eWG please add 'open to members and observers…'** Also please consider OECD residue chemistry expert groups should be consulted for specific questions. It is suggested that this consultation include other residue chemistry and dietary expert groups within CropInternational, CropLife America etc. Commodity Trade associations could also provide valuable input as well.
27		Table 3, Point 5	Any increased trial # requirements for minor crops, need to consider work already agreed upon by eWG on MU.
28		Table 3, Point 8	***Strongly agree*, this is a critical point.**
29		Table 3, Point 9.	**Please delete this point. Environmental factors** only affect the measured pesticide residue at the field level. They are one of the many variabilities that are embodied in the MRL setting process & the resulting MRL reflects those additional variabilities. **Weather or wind speed should not have a further role in estimating exposure at the diet level**.
30		Table 3/ point 13	CropLife International agrees that if the MRL must be used in assessment of bulk and blended commodities, **appropriate homogenization and bulk commodity factors must be developed for specific crops and commodities to accurately reflect consumer exposure.**

Discussion paper IESTI 2017 draft version 2_comments
*Line numbers according to the .pdf version of draft 2.

To: Miller, David[Miller.DavidJ@epa.gov]
From: Bacon, Laura
Sent: Thur 1/5/2017 9:59:17 PM
Subject: RE: Participation in the CCPR Delegation

Cool- you beat me to it! ☺

Laura Bacon

Biologist, Risk Assessment Branch 3

Health Effects Division, Cube S-10315

Office of Pesticide Programs

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Phone: (703) 305-7390

From: Miller, David
Sent: Thursday, January 05, 2017 4:58 PM
To: Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Participation in the CCPR Delegation

Laura,

Just FYI --

I added these Gretchin and Manojit to the Sharepoint Codex interest list.

David

From: Miller, David
Sent: Thursday, January 05, 2017 4:52 PM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>; Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>
Cc: Gretchen Flanley <gflanley@sherpa360.com>; Basu, Manojit <MBasu@gmaonline.org>; Janet Collins <jcollins@croplifeamerica.org>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: Participation in the CCPR Delegation

Ray,

Will do for EPA's list.

Please let me know if they are also interested in also participation in any of the three eWGs: IESTI, Prioritization, and Crop Groups and being added to these lists as well.

Tx.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, January 04, 2017 4:59 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>

Cc: Gretchen Flanley <gflanley@sherpa360.com>; Basu, Manojit <MBasu@gmaonline.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Participation in the CCPR Delegation

Marie & David:

I have recommended to a couple of colleagues that they become more involved in the US delegation to the CCPR. Could you add these folks to the distribution list for meetings, announcements, and activities?

Mano Basu works for GMA, here in Washington.

Manojit Basu, PhD

Technical Lead, Consumer Product Safety & Regulatory Affairs

Grocery Manufacturers Association

1350 I Street, NW, Suite 300

Washington DC 20005

MBasu@gmaonline.org

(Ph): 202-639-5983 (C): 865-382-5121

Gretchen E. Flanley is a consultant to grain industries. Her coordinates are immediately below, and she provided the introduction appended at the bottom.

Sherpa 360 LLC

Ph: 484-851-3005

Cell: 301-233-7401

Email: gflanley@sherpa360.com

www.sherpa360.com

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

Gretchen Flanley, Introduction:

I serve as an agricultural consultant offering a variety of services including strategic planning, international negotiations, issues and project management and organizational development. With over 20 years of experience along the value chain and in federal service, I mainly focus on technical issues related to production agriculture, both domestic and international, such as biotechnology, plant breeding innovation and maximum residue levels. My clients mainly are grower organizations, and of interest here, are the US Grains Council and the US Soybean Export Council. In addition, I facilitate a group, Commodity Research & Opportunities Partnership, a group of representatives from 5 row crops (corn, soy, sorghum, wheat and cotton) to discuss and strategize on common areas of research and production.

To: Miller, David[Miller.DavidJ@epa.gov]; Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]
Cc: Gretchen Flanley[gflanley@sherpa360.com]; Basu, Manojit[MBasu@gmaonline.org]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Wed 1/4/2017 9:59:20 PM
Subject: Participation in the CCPR Delegation

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To: Miller, David[Miller.DavidJ@epa.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Marie Maratos[Marie.Maratos@fsis.usda.gov]
From: Janet Collins
Sent: Mon 12/19/2016 1:18:21 PM
Subject: RE: IESTI in Codex

Perfect. Thank you David- most appreciated.

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, December 19, 2016 7:59 AM
To: Janet Collins <jcollins@croplifeamerica.org>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Marie Maratos <Marie.Maratos@fsis.usda.gov>
Subject: RE: IESTI in Codex

Hello Janet

This time works well. Call in seems fine. I've invited a few others as well , so we will do a call-in as follows:

Call in info is:

Ex. 6 - Personal Privacy

Then enter **Ex. 6 - Personal Privacy**

Monday 19 December from 3 to 4 pm EST

Others are John Johnston (from USDA), Pat Basu (From USDA and alternate US delegate), Marie M., and John Doherty (EPA, and JMPR rep). I've let Laura Bacon know as well that she is welcome to attend if she is able (her focus is in eWG/Priorities)

I guess I am assuming that this is about IESTI equation and the comments due to the NL-AUS co-chairs tomorrow. Is that right?

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

-----Original Appointment-----
From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, December 14, 2016 3:25 PM
To: Janet Collins; Marie Maratos; Miller, David; Ray McAllister
Subject: IESTI in Codex
When: Monday, December 19, 2016 3:00 PM-4:00 PM Customized Time Zone.
Where: DCRoomPYS11100-Potomac

All- please let me know if you need to propose a different time.

Also- should we meet in person or by conference call?

Thanks

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov)[Marie.Maratos@fsis.usda.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
From: Janet Collins
Sent: Mon 12/12/2016 9:54:00 PM
Subject: RE: US position on IESTI

David- Marie is out of the office until at least tomorrow. Let's see if she is available on the 19th- that would be ideal for us.

Thanks again.

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, December 12, 2016 3:44 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov) <Marie.Maratos@fsis.usda.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: US position on IESTI

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Also, I was going to send out a reminder to all folks earlier today -- but forgot ; -)

I think we asked for all comments on IESTI by COB tomorrow (13 December). Do you think CLA will have them ready for then.

Recall, we will need to review them here, generate an official USG response, and send this off to the NL- AUS IESTI co-chairs on the 20th.

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and Acting Chief, Toxicology & Epidemiology Branch
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From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, December 12, 2016 3:38 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov) <Marie.Maratos@fsis.usda.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: US position on IESTI

David and Marie- could we have a meeting to talk about what is the US position(s) on the IESTI work; and if the US would support an in person WG if the work proceeds? Ray and I can provide updates on the industry comments if that would be helpful.

Thanks. Might December 19 work?

Janet

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Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov)[Marie.Maratos@fsis.usda.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]; Cheryl Cleveland[cheryl.cleveland@basf.com]
From: Janet Collins
Sent: Mon 12/12/2016 8:49:48 PM
Subject: RE: US position on IESTI

David- they are near final now. We just had a call on this about an hour ago.

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, December 12, 2016 3:44 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov) <Marie.Maratos@fsis.usda.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
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From: Janet Collins
Sent: Mon 12/12/2016 8:37:48 PM
Subject: US position on IESTI

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Thanks. Might December 19 work?

Janet

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Aldridge, Ashlee[Aldridge.Ashlee@epa.gov]
From: Woods, Stacy
Sent: Fri 12/2/2016 2:59:15 PM
Subject: RE: CLA Petition

OK. It's an… interesting… read for sure!

From: Miller, David
Sent: Friday, December 02, 2016 9:58 AM
To: Woods, Stacy <woods.stacy@epa.gov>
Cc: Aldridge, Ashlee <Aldridge.Ashlee@epa.gov>
Subject: RE: CLA Petition

Good question. Certainly not at this time. So this is just an FYI.

David

From: Woods, Stacy
Sent: Friday, December 02, 2016 9:56 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Aldridge, Ashlee <Aldridge.Ashlee@epa.gov>
Subject: RE: CLA Petition

Thanks David. Would you like us to prepare anything in response?

From: Miller, David
Sent: Friday, December 02, 2016 9:52 AM
To: OPP HED CEB <OPP_HED_CEB@epa.gov>; OPP HED TEB <OPP_HED_TEB@epa.gov>

Subject: FW: CLA Petition

CLA's petition on the 10x and epi studies.

Ashlee and Stacy – I've left hard copies on your respective chairs.

David

From: Davis, Donna
Sent: Wednesday, November 30, 2016 9:12 AM
To: OPP HED Managers <OPP_HED_Managers@epa.gov>
Subject: FW: CLA Petition

FYI – a petition from CLA related to the 10x for the OPs.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack

Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Miller, David[Miller.DavidJ@epa.gov]
From: Aldridge, Ashlee
Sent: Fri 12/2/2016 2:58:14 PM
Subject: RE: CLA Petition

David,

I just read the attached. It sounds like CLA doesn't like the incorporation of our epi data. What does this mean for us going forward? How will we convince CLA that our epi data is sound?

If you could clear up my confusion, I'd appreciate it, as I'm trying to better understand ☺

Ashlee

From: Miller, David
Sent: Friday, December 02, 2016 9:52 AM
To: OPP HED CEB <OPP_HED_CEB@epa.gov>; OPP HED TEB <OPP_HED_TEB@epa.gov>
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Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

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Executive Vice President, Science and Regulatory Affairs

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To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Aldridge, Ashlee[Aldridge.Ashlee@epa.gov]
From: Woods, Stacy
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From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Ray McAllister[RMcAllister@croplifeamerica.org]
From: Janet Collins
Sent: Thur 12/1/2016 7:27:54 PM
Subject: CLA holiday party

David- hoping that you will be able to make the CLA holiday party on the 13th. We have included Codex office folks as well and would like for you to have the opportunity to meet some of our members and other colleagues during that time.

My best

Janet

To: OPP HED Managers[OPP_HED_Managers@epa.gov]
From: Davis, Donna
Sent: Wed 11/30/2016 2:12:08 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Miller, David[Miller.DavidJ@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Doherty, Michael
Sent: Tue 11/15/2016 4:58:17 PM
Subject: Re: Visit with CLA's Residue Experts Work Group

I am available at 10:00.

Mike

From: Doherty, Michael
Sent: Wednesday, November 9, 2016 12:49 PM
To: Ray McAllister; Miller, David
Cc: tcarmen@dow.com; Irrig Heidi USGR; Janet Collins
Subject: RE: Visit with CLA's Residue Experts Work Group

Maybe – Let me see if I can move a meeting and I'll get back to you.

Mike

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, November 09, 2016 12:39 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Doherty, Michael <Doherty.Michael@epa.gov>; tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Re: Visit with CLA's Residue Experts Work Group

David & Mike:

I found out there is another agenda item from 9 to 10 a.m. that we can't move. So can we have you folks come from 10 a.m. to noon?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.us

On Nov 9, 2016, at 8:55 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Would 8 am or 8:30 work out ok for everybody. Mike D. and I would presumably intend on just on going directly to CLA from home rather than going to the office first.

David.

From: Doherty, Michael
Sent: Wednesday, November 09, 2016 8:52 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Visit with CLA's Residue Experts Work Group

I am available the morning of the 17th as well.

Mike

From: Miller, David
Sent: Wednesday, November 09, 2016 7:57 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>; Doherty, Michael <Doherty.Michael@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Visit with CLA's Residue Experts Work Group

I have a meeting with FDA from 1 to 3 pm on Thursday 17th. Other than that I am free. First thing in the morning on the 17th would work well for me.

Mike D. – how does your 17th work?

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, November 08, 2016 4:34 PM
To: Doherty, Michael <Doherty.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Visit with CLA's Residue Experts Work Group

David & Mike:

Does Thursday morning (November 17) work for you to attend the Residue Experts Work Group meeting at the CLA offices? The meeting actually starts on the afternoon of the 6th (also a possibility) but we would like to coordinate with some other visitors on Thursday. What would be your schedule constraints on Thursday?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Miller, David[Miller.DavidJ@epa.gov]
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Sent: Tuesday, November 08, 2016 4:34 PM
To: Doherty, Michael <Doherty.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Visit with CLA's Residue Experts Work Group

David & Mike:

Does Thursday morning (November 17) work for you to attend the Residue Experts Work Group meeting at the CLA offices? The meeting actually starts on the afternoon of the 6th (also a possibility) but we would like to coordinate with some other visitors on Thursday. What would be your schedule constraints on Thursday?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Doherty, Michael[Doherty.Michael@epa.gov]; tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Wed 11/9/2016 5:38:57 PM
Subject: Re: Visit with CLA's Residue Experts Work Group

David & Mike:

I found out there is another agenda item from 9 to 10 a.m. that we can't move. So can we have you folks come from 10 a.m. to noon?

Ray S. McAllister, PhD
Senior Director, Regulatory Policy
CropLife America
+1-202-872-3874 (office)
+1-202-577-6657 (cell)
ray@croplife.us

On Nov 9, 2016, at 8:55 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Would 8 am or 8:30 work out ok for everybody. Mike D. and I would presumably intend on just on going directly to CLA from home rather than going to the office first.

David.

From: Doherty, Michael
Sent: Wednesday, November 09, 2016 8:52 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Visit with CLA's Residue Experts Work Group

I am available the morning of the 17th as well.

Mike

From: Miller, David
Sent: Wednesday, November 09, 2016 7:57 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>; Doherty, Michael <Doherty.Michael@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
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ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Miller, David[Miller.DavidJ@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
Cc: Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Tiu, Carmen (C)
Sent: Wed 11/9/2016 2:01:56 PM
Subject: RE: Visit with CLA's Residue Experts Work Group

Sounds good to me, we'll finish the agenda based on this starting time.

Many thanks, see you all soon.

Carmen

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, November 09, 2016 8:57 AM
To: Miller, David; Doherty, Michael
Cc: Tiu, Carmen (C); Irrig Heidi USGR; Janet Collins
Subject: RE: Visit with CLA's Residue Experts Work Group

Let's plan on 8:30 a.m. We will have breakfast here for the group.

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

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Sent: Wednesday, November 9, 2016 8:55 AM
To: Doherty, Michael <Doherty.Michael@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>

Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
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O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Wed 11/9/2016 1:57:01 PM
Subject: RE: Visit with CLA's Residue Experts Work Group

Let's plan on 8:30 a.m. We will have breakfast here for the group.

Ray S. McAllister, PhD

Senior Director Regulatory Policy

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To: Miller, David[Miller.DavidJ@epa.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Doherty, Michael
Sent: Wed 11/9/2016 1:52:16 PM
Subject: RE: Visit with CLA's Residue Experts Work Group

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Mike

From: Miller, David
Sent: Wednesday, November 09, 2016 7:57 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>; Doherty, Michael <Doherty.Michael@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
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ray@croplife.us

To: Doherty, Michael[Doherty.Michael@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Tue 11/8/2016 9:34:03 PM
Subject: Visit with CLA's Residue Experts Work Group

David & Mike:

Does Thursday morning (November 17) work for you to attend the Residue Experts Work Group meeting at the CLA offices? The meeting actually starts on the afternoon of the 6th (also a possibility) but we would like to coordinate with some other visitors on Thursday. What would be your schedule constraints on Thursday?

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Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]
From: Ray McAllister
Sent: Fri 8/5/2016 4:31:09 PM
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David, Laura, & Marie:

Should individuals who have sent you a request to participate on the "internal US-interested party group" for the various eWGs expect an acknowledging email response? A couple of folks have asked me about it, wondering about the status of their requests. I have encouraged interested folks to respond directly. I don't think you need any note from me supporting their individual requests. Is that correct?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, July 22, 2016 9:53 AM
To: 'Miller, David' <Miller.DavidJ@epa.gov>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Thanks for the clarification. We look forward to working with you on these important projects.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, July 21, 2016 5:28 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Hello Ray,

Per our phone conversation this a.m. and my offer to send you a more detailed email later today, I checked with USDA Codex Office representative Marie Maratos yesterday who indicated that it would be fine to share the invitation with others on your committees who would have interest.

There were a couple things she wanted me to remind you of but it seems -from Marie's email earlier this afternoon and your response -- that you are clear on these now. If not, feel free to email me and Marie. The bottom line is that folks who join our internal US-interested party group will assist in developing the positions as a group but these will be vetted by me (as the US delegate) and sent to the Chair of the eWG as the official USG set of comments/work product.

To the extent that a member of our internal US-interested party group wants a different opinion voiced, he or she will need to do this independently as part of another group (which would require joining each working group directly) . So if you or any of your colleagues want to join discussions as a part of Crop Life International, or any other NGO, they are welcome to do so, but they would have to register directly through the Netherlands Chair.

I also checked with Marie if it was permissible for a member of the US eWG interested party group to ALSO serve on a different group, and she indicated that this would be fine. In other words, folks can join as many groups within an eWG as they like and serve on as many eWGs as they like.

I think most of this is what you've read before from Marie's email. But I wanted to close out our phone discussion of this morning with an email, as I promised.

Marie – if there is anything incorrect or misleading about what I've said above, please feel free to send out an email correcting it.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 9:03 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu; jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu; john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com; ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
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To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Wed 8/3/2016 7:04:00 PM
Subject: RE: Epidemiology workshop

Phone meeting makes sense

Sent from my Windows Phone

From: Janet Collins
Sent: 8/3/2016 2:54 PM
To: Lowit, Anna
Cc: Vogel, Dana; Miller, David; KARIN. S. BENTLEY-1; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com); Baker-Smith, Cindy (CindyS@amvac-chemical.com)
Subject: RE: Epidemiology workshop

Anna- that would work well on the 10th. Do you prefer a teleconference for the first meeting?

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Wednesday, August 3, 2016 2:14 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Hi Janet

How about noon on the 9th or 10th?

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, August 01, 2016 1:42 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Thank you Anna. Unfortunately our Sci/Reg intern is making her final presentation to CLA- and we would normally be able to change it but we have invited a number of people for our registration committee and some stakeholders here in DC.

Can we look to next week- again, we will make that work as best we can.

Thanks again for following up on this.

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Monday, August 1, 2016 1:10 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Hi Janet

This week is tight. We can talk over lunch (noon) on Thursday.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Friday, July 29, 2016 11:10 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Anna- do you have some recommendations for dates in the coming week or 10 days?

From: Janet Collins
Sent: Tuesday, July 26, 2016 12:53 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>

Subject: Re: Epidemiology workshop

Thank you Ana-yes of course. As before, please provide a couple of times convenient for you and we will set a call.

Best

Janet

Sent from my iPhone

On Jul 26, 2016, at 10:37 AM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

> Hi everyone,
>
> We are sorry but a briefing has popped up that several of us need to attend. can we reschedule for next week?
>
> Anna
>
> Sent from my Windows Phone

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Wed 8/3/2016 6:13:55 PM
Subject: RE: Epidemiology workshop

Hi Janet

How about noon on the 9th or 10th?

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, August 01, 2016 1:42 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Thank you Anna. Unfortunately our Sci/Reg intern is making her final presentation to CLA- and we would normally be able to change it but we have invited a number of people for our registration committee and some stakeholders here in DC.

Can we look to next week- again, we will make that work as best we can.

Thanks again for following up on this.

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Monday, August 1, 2016 1:10 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Hi Janet

This week is tight. We can talk over lunch (noon) on Thursday.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]

Sent: Friday, July 29, 2016 11:10 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Anna- do you have some recommendations for dates in the coming week or 10 days?

From: Janet Collins
Sent: Tuesday, July 26, 2016 12:53 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: Re: Epidemiology workshop

Thank you Ana-yes of course. As before, please provide a couple of times convenient for you and we will set a call.

Best

Janet

Sent from my iPhone

On Jul 26, 2016, at 10:37 AM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

> Hi everyone,
>
> We are sorry but a briefing has popped up that several of us need to attend. can we reschedule for next week?
>
> Anna
>
> Sent from my Windows Phone

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Mon 8/1/2016 5:09:30 PM
Subject: RE: Epidemiology workshop

Hi Janet

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Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

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Office of Pesticide Programs, USEPA

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Sent from my iPhone

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> Anna
>
> Sent from my Windows Phone

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Irrig Heidi USGR[heidi.irrig@syngenta.com]; tcarmen@dow.com[tcarmen@dow.com]; Reshma Arrington[rarrington@croplifeamerica.org]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Tue 7/26/2016 7:37:22 PM
Subject: RE: REWG meeting, August 16

Thanks, David. We'll assemble our questions for you also.

Suzanne Fitzpatrick from FDA will attend also.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Tuesday, July 26, 2016 3:30 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: REWG meeting, August 16

Yes, I can be there, either in person or phone. I will check with Mike Doherty on his availability too.

I will list topics later, but there are several that can be covered.

Also, a number of us will be there for a CARES-NG meeting on the 18th. But I think this is CSPA, not CLA.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, July 26, 2016 3:27 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: REWG meeting, August 16

David:

Did you see my invitation, sent week before last? Are you available on the 16th?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, July 15, 2016 5:06 PM
To: 'Miller, David' <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; Reshma Arrington <rarrington@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: REWG meeting, August 16

David:

We would like to invite you to attend the REWG meeting on Tuesday afternoon, August 16. We have a slot reserved for your discussion at 1:30 p.m. to discuss "… ongoing & new joint projects with CLA-REWG - zoning, groups, DER forms, volumes, seasonality, etc." This is planned as a joint session with our Registration Committee. We are also extending an invitation to an FDA representative to attend that session – still to be identified.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]
From: Ray McAllister
Sent: Tue 7/26/2016 7:27:06 PM
Subject: RE: REWG meeting, August 16

David:

Did you see my invitation, sent week before last? Are you available on the 16th?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, July 15, 2016 5:06 PM
To: 'Miller, David' <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; Reshma Arrington <rarrington@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: REWG meeting, August 16

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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Janet Collins[jcollins@croplifeamerica.org]; Lowit, Anna[Lowit.Anna@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Tue 7/26/2016 4:37:51 PM
Subject: RE: Epidemiology workshop

Hi everyone,

We are sorry but a briefing has popped up that several of us need to attend. can we reschedule for next week?

Anna

Sent from my Windows Phone

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; DAVID A SALTMIRAS [AG/1000][david.a.saltmiras@monsanto.com]; Cindy Baker-Smith[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Fri 7/22/2016 3:47:54 PM
Subject: RE: Follow up

Hi janet

It looks like Tuesday at 3:30-4 works for us.

anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, July 21, 2016 7:39 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Thank you Anna. If you could propose two or three potential times to talk I can send an invite with call in numbers.

This is most appreciated.

Janet

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Thursday, July 21, 2016 1:04 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Hi Janet

Thanks for following up. A call next week sounds fine.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 5:36 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Anna- would it be possible to convene at least a call to discuss objectives and goals for the workshop so that the epi group can start considering input for collaboration?

Many thanks.

From: Janet Collins
Sent: Tuesday, July 19, 2016 4:11 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: Re: Follow up

Thanks Anna. I will be the contact for CLA participation

Thanks again

Janet

Sent from my iPhone

On Jul 19, 2016, at 3:07 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Hi Janet

Sorry we have not connected on the phone. I was on vacation for 2 weeks & am just catching up.

As was noted at the meeting at CLA a few weeks ago, we would be interested in dialoguing with CLA on using epidemiology in risk assessment and a workshop may be a possible venue. I talked to Karin Bentley today and my understanding is that the HARC has an epidemiology sub-team which has been discussing a possible workshop. Karin is going to get back in contact with OPP in the next couple weeks on this.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

To: rmcallister@croplifeamerica.org[rmcallister@croplifeamerica.org]; Miller, David[Miller.DavidJ@epa.gov]
From: Maratos, Marie - FSIS
Sent: Fri 7/22/2016 2:06:02 PM
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David,

I think you covered this well! But of course if there are any additional questions, I am happy to help.

Marie

****

Marie Maratos

International Issues Analyst

U.S. Codex Office

Room 4865 South Building

Food Safety and Inspection Service (FSIS)

U.S. Department of Agriculture (USDA)

Washington, DC, USA

Phone: +1.202.690.4795

Mobile: +1.202.412.7901

Fax: +1.202.720.3157

Email: Marie.Maratos@fsis.usda.gov

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Friday, July 22, 2016 9:53 AM
To: Miller, David
Cc: Maratos, Marie - FSIS
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Thanks for the clarification. We look forward to working with you on these important projects.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, July 21, 2016 5:28 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Hello Ray,

Per our phone conversation this a.m. and my offer to send you a more detailed email later today, I checked with USDA Codex Office representative Marie Maratos yesterday who indicated that it would be fine to share the invitation with others on your committees who would have interest.

There were a couple things she wanted me to remind you of but it seems -from Marie's email

earlier this afternoon and your response -- that you are clear on these now. If not, feel free to email me and Marie. The bottom line is that folks who join our internal US-interested party group will assist in developing the positions as a group but these will be vetted by me (as the US delegate) and sent to the Chair of the eWG as the official USG set of comments/work product.

To the extent that a member of our internal US-interested party group wants a different opinion voiced, he or she will need to do this independently as part of another group (which would require joining each working group directly) . So if you or any of your colleagues want to join discussions as a part of Crop Life International, or any other NGO, they are welcome to do so, but they would have to register directly through the Netherlands Chair.

I also checked with Marie if it was permissible for a member of the US eWG interested party group to ALSO serve on a different group, and she indicated that this would be fine. In other words, folks can join as many groups within an eWG as they like and serve on as many eWGs as they like.

I think most of this is what you've read before from Marie's email. But I wanted to close out our phone discussion of this morning with an email, as I promised.

Marie – if there is anything incorrect or misleading about what I've said above, please feel free to send out an email correcting it.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)

703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 9:03 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu; jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu;

john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com; ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

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To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]
From: Ray McAllister
Sent: Fri 7/22/2016 1:53:22 PM
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Thanks for the clarification. We look forward to working with you on these important projects.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

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Sent: Thursday, July 21, 2016 5:28 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

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There were a couple things she wanted me to remind you of but it seems -from Marie's email earlier this afternoon and your response -- that you are clear on these now. If not, feel free to email me and Marie. The bottom line is that folks who join our internal US-interested party group will assist in developing the positions as a group but these will be vetted by me (as the US delegate) and sent to the Chair of the eWG as the official USG set of comments/work product.

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David J. Miller CAPT | USPHS

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703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 9:03 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu; jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu; john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com;

ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; DAVID A SALTMIRAS [AG/1000][david.a.saltmiras@monsanto.com]; Cindy Baker-Smith[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Thur 7/21/2016 5:03:31 PM
Subject: RE: Follow up

Hi Janet

Thanks for following up. A call next week sounds fine.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 5:36 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Anna- would it be possible to convene at least a call to discuss objectives and goals for the workshop so that the epi group can start considering input for collaboration?

Many thanks.

From: Janet Collins
Sent: Tuesday, July 19, 2016 4:11 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: Re: Follow up

Thanks Anna. I will be the contact for CLA participation

Thanks again

Janet

Sent from my iPhone

On Jul 19, 2016, at 3:07 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Hi Janet

Sorry we have not connected on the phone. I was on vacation for 2 weeks & am just catching up.

As was noted at the meeting at CLA a few weeks ago, we would be interested in dialoguing with CLA on using epidemiology in risk assessment and a workshop may be a possible venue. I talked to Karin Bentley today and my understanding is that the HARC has an epidemiology sub-team which has been discussing a possible workshop. Karin is going to get back in contact with OPP in the next couple weeks on this.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

To: Miller, David[Miller.DavidJ@epa.gov]
From: Ray McAllister
Sent: Wed 7/20/2016 1:02:52 PM
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu; jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu; john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com; ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>;

Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

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Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Janet Collins[jcollins@croplifeamerica.org]; Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]
From: Lowit, Anna
Sent: Tue 7/19/2016 8:07:04 PM
Subject: Follow up

Hi Janet

Sorry we have not connected on the phone. I was on vacation for 2 weeks & am just catching up.

As was noted at the meeting at CLA a few weeks ago, we would be interested in dialoguing with CLA on using epidemiology in risk assessment and a workshop may be a possible venue. I talked to Karin Bentley today and my understanding is that the HARC has an epidemiology sub-team which has been discussing a possible workshop. Karin is going to get back in contact with OPP in the next couple weeks on this.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Reshma Arrington[rarrington@croplifeamerica.org]; Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Fri 7/15/2016 9:06:08 PM
Subject: REWG meeting, August 16

David:

We would like to invite you to attend the REWG meeting on Tuesday afternoon, August 16. We have a slot reserved for your discussion at 1:30 p.m. to discuss "… ongoing & new joint projects with CLA-REWG - zoning, groups, DER forms, volumes, seasonality, etc." This is planned as a joint session with our Registration Committee. We are also extending an invitation to an FDA representative to attend that session – still to be identified.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Janet Collins[jcollins@croplifeamerica.org]
From: Ray McAllister
Sent: Fri 4/15/2016 6:45:30 PM
Subject: IESTI, CCPR, EWG

David:

Thanks for taking the time to meet with our Food and Beverage Committee yesterday afternoon. Please let us know what you can, as soon as you can about the position to be taken by the US Delegation on the IESTI proposals in the coming CCPR meetings.

We would encourage EPA to take an active leadership role in the Electronic Working Group that is formed. The experience, expertise, and tools that EPA has in probabilistic risk assessment are vital to balance other perspectives and ensure that discussions are anchored in reality.

Do you know how stakeholders can participate in an Electronic Working Group? Can they nominate representatives to participate directly?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Maria Maratos[Marie.Maratos@fsis.usda.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]
From: Miller, David
Sent: Fri 2/10/2017 10:29:19 PM
Subject: RE: final version of IESTI discussion paper

Hello Ray,

I've spoken to a few folks around here, and I am not comfortable at this time to opening up the US IESTI Interest Group meeting scheduled for next Thursday 16 February to observer organizations that have signed up directly with the EU-AUS co-chairs to participate on the IESTI eWG.

My hope is to discuss during the Thursday meeting thoughts regarding strategy and approach and these are only preliminary at this point and it would be premature for these to be shared widely. I also have concerns about such observer groups "dropping in" and "dropping out" of the IESTI US Interest Group on a more or less haphazard basis and the associated continuity-of-discussion issues.

We can talk about this if you like. Of course, if these are **US-based** observer groups and they'd like a more permanent place in the US Government discussions and would like to participate on a regular basis, that would likely be fine – please let me know and we can discuss. While "sign up" to the US Interest Group on IESTI was supposed to occur last fall, I wouldn't object to folks deciding they want to sign up now (even if a bit late) if they want to commit to being a member of the group.

David.

David J. Miller CAPT | USPHS Commissioned Corps

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Thursday, February 02, 2017 5:19 PM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Subject: RE: final version of IESTI discussion paper

Hello Ray,

I've not forgotten your query below, and should have an answer for you early next week on whether we'd like to limit this to the IESTI US interest group or expand it to others. I will say that I am leaning against expanding the call to other IESTI observer organizations.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, February 01, 2017 9:22 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: final version of IESTI discussion paper

David:

There are a number of other observer organizations that have signed up to participate on the

IESTI eWG. Can we invite them to listen in on this call? Would it be helpful to provide a list of the groups?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Tuesday, January 31, 2017 5:17 PM
To: cheryl.cleveland@basf.com; jcranney@calcitrusquality.org; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; Ray McAllister <RMcAllister@croplifeamerica.org>; kent.rupprecht@bayer.com; jane.stewart@basf.com; bruce.young@bayer.com
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>
Subject: RE: final version of IESTI discussion paper

All,

It looks like from responses I've received that February 16 (Thursday) works for everybody (for sometime) between 2:30 and 5 pm for a phone call on IESTI with the IESTI work group.

I will go ahead and schedule this once I confirm a room – if you are not able to make this, please let me know. This is expected to be a meeting by phone, so no need for most of you to travel.

David

From: Miller, David
Sent: Monday, January 30, 2017 5:24 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maria Maratos' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: FW: final version of IESTI discussion paper

Dear US IESTI eWG Interest Group members:

Please find attached something I just received re: the IESTI document and additional information sent out by the eWG co-chairs.

This is just in, so we haven't had a chance yet to go through it. Note that there is discussion below of a physical Work Group meeting being proposed, and that the NL will possibly request that such an in-session WG meeting be considered when the provisional agenda is discussed.

As I indicated in my email of earlier today to you all, I will plan on scheduling a IESTI US Interest Group Conference call sometime during the latter half of February.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Monday, January 30, 2017 4:55 PM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: final version of IESTI discussion paper

Dear all,

Thank you once more for actively participating in improving the discussion document on the IESTI for the next CCPR. Even with the short response time this second time around, we have received input from 17 counties / organizations, which was very helpful
Attached you will find the following documents:

- a pdf file in which we have compiled all your comments along the paragraphs of the discussion document, including the response of the Dutch drafting team.

- a pdf file with the final version of the Discussion document, accompanied by a tracked-changes Word-version of the same file, for you to see what was changed. The clean discussion paper was also sent to the Codex Secretariat for translation.

Please note that the paper is not a position paper, but a discussion paper. We hope that thanks to your input, the paper is now more balanced in addressing all points of view. The conclusions and recommendations are not aimed at deciding on what to change in the IESTI equations during CCPR49 in April. They are aimed at deciding on a process by which to gather sufficient information for delegates to make an informed decision at a later session.

I have asked the Codex Secretariat whether it would be possible to have a physical meeting of our eWG before the matter is formally discussed in plenary. Gracia Brisco noted that CCPR48 did not agree on any physical meetings of the eWG prior to the session or in conjunction with the session.
There is however a possibility during the adoption of the provisional agenda (Agenda Item 1) when the lead country of the EWG could request the establishment of an in-session WG to have a live discussion in the margins of the plenary. Such in-session WG can be scheduled to take place after we finish the

plenary session on Tuesday or over the lunch breaks on Tuesday or Wednesday.
The Netherlands will request to establish such an in-session WG. As many of you have indicated that a physical meeting of our eWG would be appreciated, I hope that sufficient support will be given to our request. If you are not the head of your delegation, please discuss this with him or her.

Looking forward to see you in Beijing,
Kind regards, also on behalf of the drafting team and our Australian co-chairs,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
mobile +31 6 11702050
E-mail: bernadette.ossendorp@rivm.nl

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www.rivm.nl *De zorg voor morgen* begint vandaag

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To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Janet Collins[jcollins@croplifeamerica.org]; Cindy Smith[csmith@gowanco.com]
From: Miller, David
Sent: Thur 2/9/2017 9:30:53 PM
Subject: RE: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Ok. Tx. I will update the EPA Codex interest group mailing list and re-send the email to her.

David

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, February 09, 2017 4:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Janet Collins <jcollins@croplifeamerica.org>; Cindy Smith <csmith@gowanco.com>
Subject: Re: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Cindy has returned to Gowan. (Copied here)

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.us

On Feb 10, 2017, at 4:20 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Hello Ray and Janet,

I recently send out some material re: the CCPR49 to the US Codex Interest group (different from and broader than US IESTI interest group) and got a bounce-back re: Cindy Baker from Amvac.

See the delivery failure below. Do you know Cindy's current email address?

Tx.

David

From: postmaster@Amvac.local [mailto:postmaster@Amvac.local]
Sent: Thursday, February 09, 2017 2:10 PM
To: Miller, David
Subject: Undeliverable: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Delivery has failed to these recipients or groups:

Cindys@amvac-chemical.com (Cindys@amvac-chemical.com)
The e-mail address you entered couldn't be found. Please check the recipient's e-mail address and try to resend the message. If the problem continues, please contact your helpdesk.

Diagnostic information for administrators:

Generating server: Amvac.local

Cindys@amvac-chemical.com
#550 5.1.1 RESOLVER.ADR.RecipNotFound; not found ##

Original message headers:

Received: from mail6.bemta8.messagelabs.com (10.40.40.220) by ex1-amvac.Amvac.local (10.40.40.221) with Microsoft SMTP Server id 14.3.248.2; Thu, 9 Feb 2017 11:09:31 -0800Return-Path: <Miller.DavidJ@epa.gov>Received: from [216.82.241.131] by server-2.bemta-8.messagelabs.com id C6/E1-02120-D9EBC985; Thu, 09 Feb 2017 19:10:21 +0000X-Brightmail-Tracker: H4sIAAAAAAAAA2VTa0hTYRju2znbOV6Wx3nZ27AfjcKwJooERhB
RdIGMbj80WdRZnbYD25SdGQuKpkQrK9GswLVKKyTLMjWzsompUOkSMksQC0q7rHv+yJYjO2ff
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To: Ray McAllister[RMcAllister@croplifeamerica.org]; jcollins@croplifeamerica.org[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Thur 2/9/2017 7:20:46 PM
Subject: FW: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Hello Ray and Janet,

I recently send out some material re: the CCPR49 to the US Codex Interest group (different from and broader than US IESTI interest group) and got a bounce-back re: Cindy Baker from Amvac.

See the delivery failure below. Do you know Cindy's current email address?

Tx.

David

From: postmaster@Amvac.local [mailto:postmaster@Amvac.local]
Sent: Thursday, February 09, 2017 2:10 PM
To: Miller, David
Subject: Undeliverable: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUS

Delivery has failed to these recipients or groups:

Cindys@amvac-chemical.com (Cindys@amvac-chemical.com)
The e-mail address you entered couldn't be found. Please check the recipient's e-mail address and try to resend the message. If the problem continues, please contact your helpdesk.

Diagnostic information for administrators:

Generating server: Amvac.local

Cindys@amvac-chemical.com
#550 5.1.1 RESOLVER.ADR.RecipNotFound; not found ##

Original message headers:

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Thu, 9 Feb 2017 11:09:31 -0800Return-Path: <Miller.DavidJ@epa.gov>Received:
from [216.82.241.131] by server-2.bemta-8.messagelabs.com id C6/E1-02120-
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"jcranney@calcitrusquality.org" <jcranney@calcitrusquality.org>,
"Jason.Sandahl@fas.usda.gov" <Jason.Sandahl@fas.usda.gov>,

"jbaron@aesop.rutgers.edu" <jbaron@aesop.rutgers.edu>, "jessica.christiansen@monsanto.com" <jessica.christiansen@monsanto.com>, "defrancj@science.oregonstate.edu" <defrancj@science.oregonstate.edu>, "john.abbott@syngenta.com" <john.abbott@syngenta.com>, "jwilson@cranberryinstitute.org" <jwilson@cranberryinstitute.org>, "kimb@bryantchristie.com" <kimb@bryantchristie.com>, "LCox@nichino.net" <LCox@nichino.net>, "Bacon, Laura" <Bacon.Laura@epa.gov>, "Mark.Rasmussen@fas.usda.gov" <Mark.Rasmussen@fas.usda.gov>, "willett@nwhort.org" <willett@nwhort.org>, "pat.basu@fsis.usda.gov" <pat.basu@fsis.usda.gov>, "Paulo.Almeida@fsis.usda.gov" <Paulo.Almeida@fsis.usda.gov>, "klaiber@pea-lentil.com" <klaiber@pea-lentil.com>, "Peter.Horne-1@USA.dupont.com" <Peter.Horne-1@USA.dupont.com>, "philip.brindle@basf.com" <philip.brindle@basf.com>, "guerrero_raul_j@yahoo.com" <guerrero_raul_j@yahoo.com>, "rmcallister@croplifeamerica.org" <rmcallister@croplifeamerica.org>, "selen.stromgren@fda.hhs.gov" <selen.stromgren@fda.hhs.gov>, "mcgreevy@pea-lentil.com" <mcgreevy@pea-lentil.com>, "scholz@pea-lentil.com" <scholz@pea-lentil.com>, "svnielse@starbucks.com" <svnielse@starbucks.com>, "Phang, Whang" <Phang.Whang@epa.gov>, "Doherty, Michael" <Doherty.Michael@epa.gov>, "Wing.Yu@chemtura.com" <Wing.Yu@chemtura.com>, "Dougtnelson1@gmail.com" <Dougtnelson1@gmail.com>, "ronaldwilliams@coca-cola.com" <ronaldwilliams@coca-cola.com>, "Marie.Maratos@fsis.usda.gov" <Marie.Maratos@fsis.usda.gov>, "tcarmen@dow.com" <tcarmen@dow.com>, "mike@cmschofieldconsulting.com" <mike@cmschofieldconsulting.com>, "fukushimak@iskbc.com" <fukushimak@iskbc.com>, "JKozlowski@nichino.net" <JKozlowski@nichino.net>, "Robin.Charlton@valent.com" <Robin.Charlton@valent.com>, "Terry.Councell@fda.hhs.gov" <Terry.Councell@fda.hhs.gov>, "Sara.Kucenski@fas.usda.gov" <Sara.Kucenski@fas.usda.gov>, "Nguyen, Thuy" <Nguyen.Thuy@epa.gov>, "meldan@luxpam.com" <meldan@luxpam.com>, "jcollins@croplifeamerica.org" <jcollins@croplifeamerica.org>, "Wu.Li@yum.com" <Wu.Li@yum.com>, "Miller, David" <Miller.DavidJ@epa.gov>, "allen.scarborough@bayer.com" <allen.scarborough@bayer.com>, "Shah, Pv" <Shah.Pv@epa.gov>, "Vogel, Dana" <Vogel.Dana@epa.gov>, "james.m.nyangulu@monsanto.com" <james.m.nyangulu@monsanto.com>, "Ruihong.Guo@ams.usda.gov" <Ruihong.Guo@ams.usda.gov>, "Diana.Haynes@ams.usda.gov" <Diana.Haynes@ams.usda.gov>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "John.Johnston@fsis.usda.gov" <John.Johnston@fsis.usda.gov>, "charlotte.liang@fda.hhs.gov" <charlotte.liang@fda.hhs.gov>, "cheryl.cleveland@basf.com" <cheryl.cleveland@basf.com>, "aroberts@TSGUSA.com" <aroberts@TSGUSA.com>, "SSpaulding@central.com" <SSpaulding@central.com>, "amelia.elizabeth.jackson.-.gheissari@monsanto.com" <amelia.elizabeth.jackson.-.gheissari@monsanto.com>, "Julie.Chao@fas.usda.gov" <Julie.Chao@fas.usda.gov>, "MBasu@gmaonline.org" <MBasu@gmaonline.org>, "gflanley@sherpa360.com" <gflanley@sherpa360.com>, "k-fukushima@iskweb.co.jp" <k-fukushima@iskweb.co.jp>, "leggettm@iskbc.com" <leggettm@iskbc.com>, "ya-tada@iskweb.co.jp" <ya-tada@iskweb.co.jp>Subject: FW: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUSThread-Topic: CCPR49 - INVITATION AND PROVISIONAL AGENDA E/F/S - #AGFC-CODEX-ALIMENTARIUSThread-Index: AdKBQsoYdPvMxoIkQeescAltq77jYQA/JGnAAA2CSeAAJEhOgA==Date: Thu, 9 Feb 2017 19:10:12 +0000Message-ID: <BY1PR09MB0791BFFEBA633FAB6327D351F7450@BY1PR09MB0791.namprd09.prod.outlook.com>References <VI1PR0501MB244557500771EDB76E7B57AEF1430@VI1PR0501MB2445.eurprd05.prod.outlook.com> <842b4368be0242178955435e69c6e46a@BN1PR0204MB0099.001f.mgd2.msft.net>

<BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com>In-Reply-To: <BY1PR09MB079182A97E17A9F5104D15B1F7450@BY1PR09MB0791.namprd09.prod.outlook.com>Accept-Language: en-USContent-Language: en-USX-MS-Has-Attach: yesX-MS-TNEF-Correlator:x-originating-ip: [2620:117:500e:77::d00b]x-ms-office365-filtering-correlation-id: 4cb55584-8191-453d-8f6f-08d4511f4661x-microsoft-antispam: UriScan:;BCL:0;PCL:0;RULEID:(22001);SRVR:BN1PR09MB074;x-microsoft-exchange-diagnostics: 1;BN1PR09MB074;7:MP0be//8UGW8m9o1MzYKmH6ovuJ/AK6zbz6wzUJ/uWXFjG3hOIPLSXUNxETbScHvZ+4G4M138
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forefront-prvs: 02135EB356x-forefront-antispam-report: SFV:NSPM;SFS:(10019020)(7916002)(39450400003)(189002)(377454003)(30584003)(199003)(2525140
spf: None (protection.outlook.com: epa.gov does not designate permitted sender hosts)spamdiagnosticoutput: 1:99spamdiagnosticmetadata: NSPMContent-Type: multipart/mixed; boundary="_006_BY1PR09MB0791BFFEBA633FAB6327D351F7450BY1PR09MB0791namp_"MIME-Version: 1.0X-MS-Exchange-CrossTenant-originalarrivaltime: 09 Feb 2017 19:10:13.0014 (UTC)X-MS-Exchange-CrossTenant-fromentityheader: HostedX-MS-Exchange-CrossTenant-id: 88b378b3-6748-4867-acf9-76aacbeca6a7X-MS-Exchange-Transport-CrossTenantHeadersStamped: BN1PR09MB074

To: Ray McAllister[RMcAllister@croplifeamerica.org]
From: Miller, David
Sent: Thur 2/2/2017 10:18:38 PM
Subject: RE: final version of IESTI discussion paper

Hello Ray,

I've not forgotten your query below, and should have an answer for you early next week on whether we'd like to limit this to the IESTI US interest group or expand it to others. I will say that I am leaning against expanding the call to other IESTI observer organizations.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, February 01, 2017 9:22 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: final version of IESTI discussion paper

David:

There are a number of other observer organizations that have signed up to participate on the IESTI eWG. Can we invite them to listen in on this call? Would it be helpful to provide a list of the groups?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Tuesday, January 31, 2017 5:17 PM
To: cheryl.cleveland@basf.com; jcranney@calcitrusquality.org; Johnston, John - FSIS <John.Johnston@fsis.usda.gov>; Angela.S.Klemens@dupont.com; vincent.a.leopold@monsanto.com; Ray McAllister <RMcAllister@croplifeamerica.org>; kent.rupprecht@bayer.com; jane.stewart@basf.com; bruce.young@bayer.com
Cc: Maria Maratos <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>
Subject: RE: final version of IESTI discussion paper

All,

It looks like from responses I've received that February 16 (Thursday) works for everybody (for sometime) between 2:30 and 5 pm for a phone call on IESTI with the IESTI work group.

I will go ahead and schedule this once I confirm a room – if you are not able to make this, please let me know. This is expected to be a meeting by phone, so no need for most of you to travel.

David

From: Miller, David
Sent: Monday, January 30, 2017 5:24 PM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maria Maratos' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: FW: final version of IESTI discussion paper

Dear US IESTI eWG Interest Group members:

Please find attached something I just received re: the IESTI document and additional information sent out by the eWG co-chairs.

This is just in, so we haven't had a chance yet to go through it. Note that there is discussion below of a physical Work Group meeting being proposed, and that the NL will possibly request that such an in-session WG meeting be considered when the provisional agenda is discussed.

As I indicated in my email of earlier today to you all, I will plan on scheduling a IESTI US Interest Group Conference call sometime during the latter half of February.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Monday, January 30, 2017 4:55 PM

To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: final version of IESTI discussion paper

Dear all,

Thank you once more for actively participating in improving the discussion document on the IESTI for the next CCPR. Even with the short response time this second time around, we have received input from 17 counties / organizations, which was very helpful
Attached you will find the following documents:

- a pdf file in which we have compiled all your comments along the paragraphs of the discussion document, including the response of the Dutch drafting team.

- a pdf file with the final version of the Discussion document, accompanied by a tracked-changes Word-version of the same file, for you to see what was changed. The clean discussion paper was also sent to the Codex Secretariat for translation.

Please note that the paper is not a position paper, but a discussion paper. We hope that thanks to your input, the paper is now more balanced in addressing all points of view. The conclusions and recommendations are not aimed at deciding on what to change in the IESTI equations during CCPR49 in April. They are aimed at deciding on a process by which to gather sufficient information for delegates to make an informed decision at a later session.

I have asked the Codex Secretariat whether it would be possible to have a physical meeting of our eWG before the matter is formally discussed in plenary. Gracia Brisco noted that CCPR48 did not agree on any physical meetings of the eWG prior to the session or in conjunction with the session.
There is however a possibility during the adoption of the provisional agenda (Agenda Item 1) when the lead country of the EWG could request the establishment of an in-session WG to have a live discussion in the margins of the plenary. Such in-session WG can be scheduled to take place after we finish the plenary session on Tuesday or over the lunch breaks on Tuesday or Wednesday.
The Netherlands will request to establish such an in-session WG. As many of you have indicated that a physical meeting of our eWG would be appreciated, I hope that sufficient support will be given to our request. If you are not the head of your delegation, please discuss this with him or her.

Looking forward to see you in Beijing,
Kind regards, also on behalf of the drafting team and our Australian co-chairs,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
mobile +31 6 11702050
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To: Ray McAllister[RMcAllister@croplifeamerica.org]; Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]
Cc: Gretchen Flanley[gflanley@sherpa360.com]; Basu, Manojit[MBasu@gmaonline.org]; Janet Collins[jcollins@croplifeamerica.org]; Bacon, Laura[Bacon.Laura@epa.gov]
From: Miller, David
Sent: Thur 1/5/2017 9:52:04 PM
Subject: RE: Participation in the CCPR Delegation

Ray,

Will do for EPA's list.

Please let me know if they are also interested in also participation in any of the three eWGs: IESTI, Prioritization, and Crop Groups and being added to these lists as well.

Tx.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, January 04, 2017 4:59 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>
Cc: Gretchen Flanley <gflanley@sherpa360.com>; Basu, Manojit <MBasu@gmaonline.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Participation in the CCPR Delegation

Marie & David:

I have recommended to a couple of colleagues that they become more involved in the US delegation to the CCPR. Could you add these folks to the distribution list for meetings, announcements, and activities?

Mano Basu works for GMA, here in Washington.

Manojit Basu, PhD

Technical Lead, Consumer Product Safety & Regulatory Affairs

Grocery Manufacturers Association

1350 I Street, NW, Suite 300

Washington DC 20005

MBasu@gmaonline.org

(Ph): 202-639-5983 (C): 865-382-5121

Gretchen E. Flanley is a consultant to grain industries. Her coordinates are immediately below, and she provided the introduction appended at the bottom.

Sherpa 360 LLC

Ph: 484-851-3005

Cell: 301-233-7401

Email: gflanley@sherpa360.com

www.sherpa360.com

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

Gretchen Flanley, Introduction:

I serve as an agricultural consultant offering a variety of services including strategic planning, international negotiations, issues and project management and organizational development. With over 20 years of experience along the value chain and in federal service, I mainly focus on technical issues related to production agriculture, both domestic and international, such as biotechnology, plant breeding innovation and maximum residue levels. My clients mainly are grower organizations, and of interest here, are the US Grains Council and the US Soybean Export Council. In addition, I facilitate a group, Commodity Research & Opportunities Partnership, a group of representatives from 5 row crops (corn, soy, sorghum, wheat and cotton) to discuss and strategize on common areas of research and production.

To: Janet Collins[jcollins@croplifeamerica.org]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Marie Maratos[Marie.Maratos@fsis.usda.gov]
From: Miller, David
Sent: Mon 12/19/2016 12:59:18 PM
Subject: RE: IESTI in Codex

Hello Janet

This time works well. Call in seems fine. I've invited a few others as well , so we will do a call-in as follows:

Call in info is:

Ex. 6 - Personal Privacy

Then enter **Ex. 6 - Personal Privacy**

Monday 19 December from 3 to 4 pm EST

Others are John Johnston (from USDA), Pat Basu (From USDA and alternate US delegate), Marie M., and John Doherty (EPA, and JMPR rep). I've let Laura Bacon know as well that she is welcome to attend if she is able (her focus is in eWG/Priorities)

I guess I am assuming that this is about IESTI equation and the comments due to the NL-AUS co-chairs tomorrow. Is that right?

David

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

-----Original Appointment-----
From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, December 14, 2016 3:25 PM

To: Janet Collins; Marie Maratos; Miller, David; Ray McAllister
Subject: IESTI in Codex
When: Monday, December 19, 2016 3:00 PM-4:00 PM Customized Time Zone.
Where: DCRoomPYS11100-Potomac

All- please let me know if you need to propose a different time.

Also- should we meet in person or by conference call?

Thanks

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov)[Marie.Maratos@fsis.usda.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
From: Miller, David
Sent: Mon 12/12/2016 8:43:56 PM
Subject: RE: US position on IESTI

That would be fine by me.

Also, I was going to send out a reminder to all folks earlier today -- but forgot ; -)

I think we asked for all comments on IESTI by COB tomorrow (13 December). Do you think CLA will have them ready for then.

Recall, we will need to review them here, generate an official USG response, and send this off to the NL- AUS IESTI co-chairs on the 20th.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, December 12, 2016 3:38 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Marie Maratos "Maratos, Marie" "Maratos, Marie" <Marie.Maratos@fsis.usda.gov> (Marie.Maratos@fsis.usda.gov) <Marie.Maratos@fsis.usda.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: US position on IESTI

David and Marie- could we have a meeting to talk about what is the US position(s) on the IESTI work; and if the US would support an in person WG if the work proceeds? Ray and I can provide updates on the industry comments if that would be helpful.

Thanks. Might December 19 work?

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Fri 12/9/2016 5:37:33 PM
Subject: RE: Participants list IESTI eWG

Not yet officially announced yet. But -if they continue their pattern of the past with Beijing selected in alternate years - it will be Beijing.

Again, though, nothing official out yet.

David

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, December 07, 2016 6:31 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Participants list IESTI eWG

Thanks again David.

Do you have any idea where the meeting will be held in China?

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Wednesday, December 7, 2016 5:26 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Subject: FW: Participants list IESTI eWG

Here's the second email to which I referred….

From: Miller, David
Sent: Tuesday, November 29, 2016 9:05 AM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>;

'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Participants list IESTI eWG

All,

Please find attached from the NL-AUS co-chairs the list of participants in the IESTI eWG.

I have also attached an updated list of participants in the US IESTI eWG Interest Group. This has been updated to add a phone number, correct a typo, and correct an interest group designation.

David.

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Tuesday, November 29, 2016 7:21 AM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: Participants list IESTI eWG

Dear all,

On the request of the US Codex Office, please find attached a list of participants in the IESTI eWG.

Kind regards,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)

PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
mobile +31 6 11702050

E-mail to: CCPR_IESTI@rivm.nl

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To: jcollins@croplifeamerica.org[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Wed 12/7/2016 10:25:57 PM
Subject: FW: Participants list IESTI eWG
Participants eWG IESTI 29Nov2016.pdf
CCPR Interest Group_draft_send_updated 11-22-2016.xlsx

Here's the second email to which I referred....

From: Miller, David
Sent: Tuesday, November 29, 2016 9:05 AM
To: 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Johnston, John - FSIS' <John.Johnston@fsis.usda.gov>; 'Angela.S.Klemens@dupont.com' <Angela.S.Klemens@dupont.com>; 'vincent.a.leopold@monsanto.com' <vincent.a.leopold@monsanto.com>; 'RMcAllister@croplifeamerica.org' <RMcAllister@croplifeamerica.org>; 'kent.rupprecht@bayer.com' <kent.rupprecht@bayer.com>; 'jane.stewart@basf.com' <jane.stewart@basf.com>; 'bruce.young@bayer.com' <bruce.young@bayer.com>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>; 'Basu, Pat - FSIS' <Pat.Basu@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Participants list IESTI eWG

All,

Please find attached from the NL-AUS co-chairs the list of participants in the IESTI eWG.

I have also attached an updated list of participants in the US IESTI eWG Interest Group. This has been updated to add a phone number, correct a typo, and correct an interest group designation.

David.

From: CCPR_IESTI@rivm.nl [mailto:CCPR_IESTI@rivm.nl]
Sent: Tuesday, November 29, 2016 7:21 AM
To: IESTI Participants WG <IESTI_Participants_WG@rivm.nl>; IESTI Observers WG <IESTI_Observers_WG@rivm.nl>
Subject: Participants list IESTI eWG

Dear all,

On the request of the US Codex Office, please find attached a list of participants in the IESTI eWG.

Kind regards,
Bernadette Ossendorp

Dr. B.C. Ossendorp
Head Dept. Food Safety
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 274 3970, fax +31 30 274 4475
mobile +31 6 11702050

E-mail to: CCPR_IESTI@rivm.nl

DENK AAN HET MILIEU VOORDAT U DIT BERICHT PRINT
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www.rivm.nl *De zorg voor morgen* begint vandaag

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To: jcollins@croplifeamerica.org[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Wed 12/7/2016 10:23:21 PM
Subject: FW: REWG meeting today - materials from EPA
Meeting Material CLA REWG-EPA OPP meeting 11-17-2016.docx

Hello Janet,

Here's what Mike D. and I sent around in advance of the REWG meeting a few weeks ago. Note the references/links provided.

The link to the WHO/FAO document comparing DEEM probabilistic vs. IESTI equation – done more than 10 years ago – and entitled "The Probabilistic Approach to Acute Dietary Exposure Analysis and its Applicability at the International Level" is repeated here:

ftp://ftp.fao.org/codex/meetings/CCPR/CCPR34/pr0203be.pdf

I will forward to you momentarily the info on the IESTI eWG: both the US Interest Group and the actual eWG (this latter one being sent out by the NL-AUS co-chairs).

david.

From: Miller, David
Sent: Thursday, November 17, 2016 9:24 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: 'Philip.brindle@basf.com' <Philip.brindle@basf.com>; 'Tiu, Carmen (C)'

<tcarmen@dow.com>; Jane M Stewart <jane.stewart@basf.com>; Doherty, Michael <Doherty.Michael@epa.gov>
Subject: REWG meeting today - materials from EPA

Please see attached agenda topics and background material for today's meeting. Could you please forward to REWG folks that will be on the phone. I will bring about 20 hard copies to distribute.

Also, Mike at I will be leaving Crystal City at 9:30 via taxi so should be at CLA at about 9:50 or so.

See you then.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Philip.brindle@basf.com[Philip.brindle@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Jane M Stewart[jane.stewart@basf.com]; Doherty, Michael[Doherty.Michael@epa.gov]
From: Miller, David
Sent: Thur 11/17/2016 2:24:25 PM
Subject: REWG meeting today - materials from EPA
Meeting Material CLA REWG-EPA OPP meeting 11-17-2016.docx

Please see attached agenda topics and background material for today's meeting. Could you please forward to REWG folks that will be on the phone. I will bring about 20 hard copies to distribute.

Also, Mike at I will be leaving Crystal City at 9:30 via taxi so should be at CLA at about 9:50 or so.

See you then.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Doherty, Michael[Doherty.Michael@epa.gov]; Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Wed 11/9/2016 1:55:20 PM
Subject: RE: Visit with CLA's Residue Experts Work Group

Would 8 am or 8:30 work out ok for everybody. Mike D. and I would presumably intend on just on going directly to CLA from home rather than going to the office first.

David.

From: Doherty, Michael
Sent: Wednesday, November 09, 2016 8:52 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Visit with CLA's Residue Experts Work Group

I am available the morning of the 17th as well.

Mike

From: Miller, David
Sent: Wednesday, November 09, 2016 7:57 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>; Doherty, Michael <Doherty.Michael@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Visit with CLA's Residue Experts Work Group

I have a meeting with FDA from 1 to 3 pm on Thursday 17th. Other than that I am free. First thing in the morning on the 17th would work well for me.

Mike D. – how does your 17th work?

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, November 08, 2016 4:34 PM
To: Doherty, Michael <Doherty.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Visit with CLA's Residue Experts Work Group

David & Mike:

Does Thursday morning (November 17) work for you to attend the Residue Experts Work Group meeting at the CLA offices? The meeting actually starts on the afternoon of the 6th (also a possibility) but we would like to coordinate with some other visitors on Thursday. What would be your schedule constraints on Thursday?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Doherty, Michael[Doherty.Michael@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Wed 11/9/2016 12:56:35 PM
Subject: RE: Visit with CLA's Residue Experts Work Group

I have a meeting with FDA from 1 to 3 pm on Thursday 17th. Other than that I am free. First thing in the morning on the 17th would work well for me.

Mike D. – how does your 17th work?

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, November 08, 2016 4:34 PM
To: Doherty, Michael <Doherty.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Janet Collins <jcollins@croplifeamerica.org>
Subject: Visit with CLA's Residue Experts Work Group

David & Mike:

Does Thursday morning (November 17) work for you to attend the Residue Experts Work Group meeting at the CLA offices? The meeting actually starts on the afternoon of the 6th (also a possibility) but we would like to coordinate with some other visitors on Thursday. What would be your schedule constraints on Thursday?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

To: rmcallister@croplifeamerica.org[rmcallister@croplifeamerica.org]
From: Miller, David
Sent: Thur 11/3/2016 8:58:31 PM
Subject: pilot question

Ray,

Dana is out today and tomorrow. Re: your question of a "pilot", does this one sound like the one you were thinking of:

How much of a difference is needed in MRLs to say that there is a (beyond chance) difference. This effort is something that we have not yet put a lot of effort into, except for a number of computer simulations we are doing. It is attempt to broadly get at the issue of what to do if the US tolerance (based on US field trials) would be different from the PMRA MRL (based on Canadian field trials). And how one defines "different" in a more quantitative and probabilistic way.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Ray McAllister[RMcAllister@croplifeamerica.org]
From: Miller, David
Sent: Fri 10/14/2016 4:47:40 PM
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Yes, I can. Thanks for letting me know.

David

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Friday, October 14, 2016 12:10 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

I thought I had requested to participate for all three eWGs, but I don't see the X in the column for the Classification eWG. Can you still add me there?

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: 202-872-3874 C: 202-577-6657

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Friday, October 14, 2016 12:01 PM
To: barney@AESOP.Rutgers.edu; Cheryl Cleveland <cheryl.cleveland@basf.com>; martin.cole@bayer.com; jcranney@calcitrusquality.org; david.edwards@fda.hhs.gov; fukushimak@iskbc.com; diana.haynes@ams.usda.gov; John.Johnston@fsis.usda.gov; jjonker@nmpf.org; Angela Klemens <angela.s.klemens@usa.dupont.com>; kunkel@AESOP.Rutgers.edu; vincent.a.leopold@monsanto.com; Ray McAllister <RMcAllister@croplifeamerica.org>; kent.rupprecht@bayer.com; Allen Scarborough <allen.scarborough@bayer.com>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; tim.wilson@arysta.com; Bruce Young <bruce.young@bayer.com>
Cc: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>

Subject: FW: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Dear all,

In July, I sent out the following email to individuals that we have listed as having an interest in CCPR issues. In that message, I requested that folks interested in participating in US activities related to one or more of the three eWG's formed at CCPR48 in Chongqing contact me and Laura Bacon by email. A number of folks responded, and I have attached an Excel spreadsheet listing their names, affiliations, email addresses, phone numbers, sectors, and which of the three US interest groups relating to the three attached eWG calls for interest they expressed an interest in participating. The attached spreadsheet is currently draft, so if you know of others that may wish to have an interest or you not missing information or mistakes on my part, please let me know by return email.

I will note that the US government has volunteered to participate at the Codex level for all three eWGs. To date, we have not yet been contacted by the Chairs of either the Priorities List (chaired by GER and AUS) or IESTI (chaired by NL and AUS). We will certainly keep an eye on that, and let you know when they make contact.

Finally, , please keep an eye out for an invitation in the not-to-distant future for our fall 2016 planning meeting for CCPR49 /April 2017.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)

703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Sunday, July 17, 2016 3:43 PM
To: 'barney@AESOP.Rutgers.edu' <barney@AESOP.Rutgers.edu>; 'billb@bryantchristie.com' <billb@bryantchristie.com>; 'blandine.trouille@trade.gov' <blandine.trouille@trade.gov>; 'cprice@calcitrusquality.org' <cprice@calcitrusquality.org>; 'Cindys@amvac-chemical.com' <Cindys@amvac-chemical.com>; 'kunkel@AESOP.Rutgers.edu' <kunkel@AESOP.Rutgers.edu>; 'dtrinka@blueberries.com' <dtrinka@blueberries.com>; 'gludwig@almondboard.com' <gludwig@almondboard.com>; 'heidi.irrig@syngenta.com' <heidi.irrig@syngenta.com>; 'jcranney@calcitrusquality.org' <jcranney@calcitrusquality.org>; 'Jason.Sandahl@fas.usda.gov' <Jason.Sandahl@fas.usda.gov>; 'jbaron@aesop.rutgers.edu' <jbaron@aesop.rutgers.edu>; 'jessica.christiansen@monsanto.com' <jessica.christiansen@monsanto.com>; 'defrancj@science.oregonstate.edu' <defrancj@science.oregonstate.edu>; 'john.abbott@syngenta.com' <john.abbott@syngenta.com>; 'jwilson@cranberryinstitute.org' <jwilson@cranberryinstitute.org>; 'kimb@bryantchristie.com' <kimb@bryantchristie.com>; 'LCox@nichino.net' <LCox@nichino.net>; 'Nollen.Laura@epa.gov' <Nollen.Laura@epa.gov>; 'Mark.Rasmussen@fas.usda.gov' <Mark.Rasmussen@fas.usda.gov>; 'willett@nwhort.org' <willett@nwhort.org>; 'pat.basu@fsis.usda.gov' <pat.basu@fsis.usda.gov>; 'Paulo.Almeida@fsis.usda.gov' <Paulo.Almeida@fsis.usda.gov>; 'klaiber@pea-lentil.com' <klaiber@pea-lentil.com>; 'Peter.Horne-1@USA.dupont.com' <Peter.Horne-1@USA.dupont.com>; 'philip.brindle@basf.com' <philip.brindle@basf.com>; 'guerrero_raul_j@yahoo.com' <guerrero_raul_j@yahoo.com>; 'rmcallister@croplifeamerica.org' <rmcallister@croplifeamerica.org>; 'selen.stromgren@fda.hhs.gov' <selen.stromgren@fda.hhs.gov>; 'mcgreevy@pea-lentil.com' <mcgreevy@pea-lentil.com>; 'scholz@pea-lentil.com' <scholz@pea-lentil.com>; 'svnielse@starbucks.com' <svnielse@starbucks.com>; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; 'Wing.Yu@chemtura.com' <Wing.Yu@chemtura.com>; 'Dougtnelson1@gmail.com' <Dougtnelson1@gmail.com>; 'ronaldwilliams@coca-cola.com' <ronaldwilliams@coca-cola.com>; 'Marie.Maratos@fsis.usda.gov' <Marie.Maratos@fsis.usda.gov>; 'tcarmen@dow.com' <tcarmen@dow.com>; 'mike@cmschofieldconsulting.com' <mike@cmschofieldconsulting.com>; 'fukushimak@iskbc.com' <fukushimak@iskbc.com>; 'JKozlowski@nichino.net' <JKozlowski@nichino.net>; 'Robin.Charlton@valent.com' <Robin.Charlton@valent.com>; 'Terry.Councell@fda.hhs.gov' <Terry.Councell@fda.hhs.gov>; 'Sara.Kucenski@fas.usda.gov'

<Sara.Kucenski@fas.usda.gov>; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; 'meldan@luxpam.com' <meldan@luxpam.com>; 'jcollins@croplifeamerica.org' <jcollins@croplifeamerica.org>; 'Wu.Li@yum.com' <Wu.Li@yum.com>; 'molly.miller@basf.com' <molly.miller@basf.com>; 'DavidJ Miller' <Miller.DavidJ@epa.gov>; 'allen.scarborough@bayer.com' <allen.scarborough@bayer.com>; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; 'james.m.nyangulu@monsanto.com' <james.m.nyangulu@monsanto.com>; 'Ruihong.Guo@ams.usda.gov' <Ruihong.Guo@ams.usda.gov>; 'Diana.Haynes@ams.usda.gov' <Diana.Haynes@ams.usda.gov>; Olinger, Christine <Olinger.Christine@epa.gov>; 'amelia.elizabeth.jackson.-.gheissari@monsanto.com' <amelia.elizabeth.jackson.-.gheissari@monsanto.com>; 'John.Johnston@fsis.usda.gov' <John.Johnston@fsis.usda.gov>; 'charlotte.liang@fda.hhs.gov' <charlotte.liang@fda.hhs.gov>; 'cheryl.cleveland@basf.com' <cheryl.cleveland@basf.com>; 'aroberts@TSGUSA.com' <aroberts@TSGUSA.com>
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; 'Marie.Maratos@fsis.usda.gov' <Marie.Maratos@fsis.usda.gov>; 'John.Johnston@fsis.usda.gov' <John.Johnston@fsis.usda.gov>; 'pat.basu@fsis.usda.gov' <pat.basu@fsis.usda.gov>
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Karen Cain[karen.cain@bayer.com]; Hamilton, Robert[Robert.Hamilton@valent.com]; cowins, janet[Cowins.Janet@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Swartz, Christina[Swartz.Christina@epa.gov]; Philip A Brindle[philip.brindle@basf.com]
From: Miller, David
Sent: Tue 8/16/2016 10:34:35 PM
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Hello Ray,

Per today's discussion, here is the link to the USA Delegate's report for CCPR48:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/recent-delegation-reports/2016/delegate-report-48-ccpr

I tried the all the links in the 2nd to last paragraph (concerning IESTI) and they all seem to work for me. I think you said when you tried them, they seemed to be de-linked. Could you please try again and if you continue to have problems, please let me know.

Tx.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs

703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Tuesday, August 16, 2016 11:04 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: 'tcarmen@dow.com' <tcarmen@dow.com>; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; 'Karen Cain' <karen.cain@bayer.com>; 'Hamilton, Robert' <Robert.Hamilton@valent.com>; cowins, janet <Cowins.Janet@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>; 'Philip A Brindle' <philip.brindle@basf.com>
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Hello Ray,

Mike Doherty, Janet Cowins and I will be there at CLA HQ at 1pm for an hour. Janet is the HED person that will be presenting at ACS next week in Philadelphia as part of a symposium being organized by Phil B. and Carmen T. (I think)

Here's a suggested set of agenda topics for today's one-hour session at CLA for the REWG. Note that there are a lot to cover in the time, so we will likely need to move fast

I. Global Zoning – next steps and follow-on, including *Statistics and Public Policy* (see below)

II. Crop Groups and MRL-setting: status and our work with PMRA

III. Bernie Schneider's Crop Groupings – status and timeline

a. Herbs/Spices

b. Root and Tuber/Leaves

c. Legume Vegetables/Leaves

d. Cereal Grains/Forage, Fodder, Straw

e. Forage, Fodder, Grasses/Animal Feeds

f. Cucurbits

IV. Codex and Codex eWGs

a. IESTI (responses re: interest due to Codex 31 August

b. Crop Grouping (responses re: interest due to Codex 31 August)

c. Prioritization (responses re: interest were due 15 August)

d. Next Steps/prep for April 2017 meeting – late September/October time frame

V. ACS meeting/Phila. – any issues/arrangements?

VI. Other topics (CLA)

a. Seasonality

b. Volume

c. DER forms (I don't know what this is?)

From: Miller, David
Sent: Tuesday, August 16, 2016 8:40 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: 'tcarmen@dow.com' <tcarmen@dow.com>; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; 'Karen Cain' <karen.cain@bayer.com>; 'Hamilton, Robert' <Robert.Hamilton@valent.com>; cowins, janet <Cowins.Janet@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Ray –

I heard back: we can do 1 pm to 2 pm instead of the original 1:30 to 2:30.

David.

From: Miller, David
Sent: Monday, August 15, 2016 11:45 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Karen Cain <karen.cain@bayer.com>; Hamilton, Robert <Robert.Hamilton@valent.com>; cowins, janet <Cowins.Janet@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Hello Ray,

I was just about to email you.

I have us listed for 1:30 to 2:30. I understand that Janet Cowens and Mike Doherty may be coming with me. Janet will be attending ACS next week and giving a presentation as part of the symposia that Phil Bridle is leading, so we thought it might be good for folks to introduce themselves.

Here is what you said before in an earlier email to me:

We would like to invite you to attend the REWG meeting on Tuesday afternoon, August 16. We have a slot reserved for your discussion at 1:30 p.m. to discuss "… ongoing & new joint projects with CLA-REWG - zoning, groups, DER forms, volumes, seasonality, etc." This is planned as a joint session with our Registration Committee. We are also extending an invitation to an FDA representative to attend that session – still to be identified.

Mike D. and I discussed this last Friday. An update on zoning and next steps, crop grouping etc.

is fine. We will likely have a few other topics as well.

Neither he nore I were familiar with the topics "DER forms", "volumes", or "seasonality" and we assumed that this was more related to the Registration Committee. Can you clarify what you mean by these topics and confirm (if true) that these are not topics that concern Mike D. or me.

Tx.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, August 15, 2016 11:36 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Karen Cain <karen.cain@bayer.com>; Hamilton, Robert <Robert.Hamilton@valent.com>
Subject: Residue Experts Work Group meeting, Tuesday Aug 16
Importance: High

David:

We have you on the agenda for tomorrow's REWG meeting at 2:30 p.m. The FDA folks just informed me they cannot send someone to the meeting, freeing up some time earlier in the agenda. Would 1:30 or 2:00 p.m. p.m. fit your schedule just as well? It could give us a little more discussion time. Who else will be coming with you?

Tomorrow afternoon is a joint session with CLA's Registration Committee, so it will be a much

larger crowd than normal.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Irrig Heidi USGR[heidi.irrig@syngenta.com]; Karen Cain[karen.cain@bayer.com]; Hamilton, Robert[Robert.Hamilton@valent.com]; cowins, janet[Cowins.Janet@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]; Swartz, Christina[Swartz.Christina@epa.gov]; Philip A Brindle[philip.brindle@basf.com]
From: Miller, David
Sent: Tue 8/16/2016 3:03:33 PM
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Hello Ray,

Mike Doherty, Janet Cowins and I will be there at CLA HQ at 1pm for an hour. Janet is the HED person that will be presenting at ACS next week in Philadelphia as part of a symposium being organized by Phil B. and Carmen T. (I think)

Here's a suggested set of agenda topics for today's one-hour session at CLA for the REWG. Note that there are a lot to cover in the time, so we will likely need to move fast

I. Global Zoning – next steps and follow-on, including *Statistics and Public Policy* (see below)

II. Crop Groups and MRL-setting: status and our work with PMRA

III. Bernie Schneider's Crop Groupings – status and timeline

a. Herbs/Spices

b. Root and Tuber/Leaves

c. Legume Vegetables/Leaves

d. Cereal Grains/Forage, Fodder, Straw

e. Forage, Fodder, Grasses/Animal Feeds

f. Cucurbits

IV. Codex and Codex eWGs

a. IESTI (responses re: interest due to Codex 31 August

b. Crop Grouping (responses re: interest due to Codex 31 August)

c. Prioritization (responses re: interest were due 15 August)

d. Next Steps/prep for April 2017 meeting – late September/October time frame

V. ACS meeting/Phila. – any issues/arrangements?

VI. Other topics (CLA)

a. Seasonality

b. Volume

c. DER forms (I don't know what this is?)

From: Miller, David
Sent: Tuesday, August 16, 2016 8:40 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: 'tcarmen@dow.com' <tcarmen@dow.com>; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; 'Karen Cain' <karen.cain@bayer.com>; 'Hamilton, Robert' <Robert.Hamilton@valent.com>; cowins, janet <Cowins.Janet@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

Ray –

I heard back: we can do 1 pm to 2 pm instead of the original 1:30 to 2:30.

David.

From: Miller, David
Sent: Monday, August 15, 2016 11:45 AM
To: 'Ray McAllister' <RMcAllister@croplifeamerica.org>
Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Karen Cain

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Mike D. and I discussed this last Friday. An update on zoning and next steps, crop grouping etc. is fine. We will likely have a few other topics as well.

Neither he nore I were familiar with the topics "DER forms", "volumes", or "seasonality" and we assumed that this was more related to the Registration Committee. Can you clarify what you mean by these topics and confirm (if true) that these are not topics that concern Mike D. or me.

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From: Miller, David
Sent: Tue 8/16/2016 12:39:59 PM
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

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Cc: tcarmen@dow.com; Irrig Heidi USGR <heidi.irrig@syngenta.com>; Karen Cain <karen.cain@bayer.com>; Hamilton, Robert <Robert.Hamilton@valent.com>; cowins, janet <Cowins.Janet@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Swartz, Christina <Swartz.Christina@epa.gov>
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From: Miller, David
Sent: Mon 8/15/2016 3:44:59 PM
Subject: RE: Residue Experts Work Group meeting, Tuesday Aug 16

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Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; McNiff, Barbara - FSIS[Barbara.McNiff@fsis.usda.gov]
From: Miller, David
Sent: Fri 8/5/2016 4:40:02 PM
Subject: FW: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

I haven't been sending individual responses acknowledging receipt, but intend –closer to our internal deadline of mid-August - to send a general email to volunteers re: next steps.

And – no – we don't need a note from you supporting individual requests.

David

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Friday, August 05, 2016 12:31 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David, Laura, & Marie:

Should individuals who have sent you a request to participate on the "internal US-interested party group" for the various eWGs expect an acknowledging email response? A couple of folks have asked me about it, wondering about the status of their requests. I have encouraged interested folks to respond directly. I don't think you need any note from me supporting their individual requests. Is that correct?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, July 22, 2016 9:53 AM
To: 'Miller, David' <Miller.DavidJ@epa.gov>
Cc: 'Maratos, Marie - FSIS' <Marie.Maratos@fsis.usda.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Thanks for the clarification. We look forward to working with you on these important projects.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, July 21, 2016 5:28 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

Hello Ray,

Per our phone conversation this a.m. and my offer to send you a more detailed email later today, I checked with USDA Codex Office representative Marie Maratos yesterday who indicated that it would be fine to share the invitation with others on your committees who would have interest.

There were a couple things she wanted me to remind you of but it seems -from Marie's email earlier this afternoon and your response -- that you are clear on these now. If not, feel free to email me and Marie. The bottom line is that folks who join our internal US-interested party group will assist in developing the positions as a group but these will be vetted by me (as the US delegate) and sent to the Chair of the eWG as the official USG set of comments/work product.

To the extent that a member of our internal US-interested party group wants a different opinion voiced, he or she will need to do this independently as part of another group (which would require joining each working group directly) . So if you or any of your colleagues want to join discussions as a part of Crop Life International, or any other NGO, they are welcome to do so, but they would have to register directly through the Netherlands Chair.

I also checked with Marie if it was permissible for a member of the US eWG interested party group to ALSO serve on a different group, and she indicated that this would be fine. In other words, folks can join as many groups within an eWG as they like and serve on as many eWGs as they like.

I think most of this is what you've read before from Marie's email. But I wanted to close out our phone discussion of this morning with an email, as I promised.

Marie – if there is anything incorrect or misleading about what I've said above, please feel free to send out an email correcting it.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)

703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 9:03 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

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202-577-6657 (cell)

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu;

jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu; john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com; ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5352 (voice)
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To: Doherty, Michael[Doherty.Michael@epa.gov]
From: Miller, David
Sent: Tue 7/26/2016 7:51:31 PM
Subject: FW: REWG meeting, August 16

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, July 26, 2016 3:37 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Irrig Heidi USGR <heidi.irrig@syngenta.com>; tcarmen@dow.com; Reshma Arrington <rarrington@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: REWG meeting, August 16

Thanks, David. We'll assemble our questions for you also.

Suzanne Fitzpatrick from FDA will attend also.

Ray S. McAllister, PhD

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Tuesday, July 26, 2016 3:30 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: REWG meeting, August 16

Yes, I can be there, either in person or phone. I will check with Mike Doherty on his availability too.

I will list topics later, but there are several that can be covered.

Also, a number of us will be there for a CARES-NG meeting on the 18th. But I think this is CSPA, not CLA.

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Cc: tcarmen@dow.com; 'Irrig Heidi USGR' <heidi.irrig@syngenta.com>; Reshma Arrington <rarrington@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>
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To: Ray McAllister[RMcAllister@croplifeamerica.org]
From: Miller, David
Sent: Tue 7/26/2016 7:30:09 PM
Subject: RE: REWG meeting, August 16

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Per our phone conversation this a.m. and my offer to send you a more detailed email later today, I checked with USDA Codex Office representative Marie Maratos yesterday who indicated that it would be fine to share the invitation with others on your committees who would have interest.

There were a couple things she wanted me to remind you of but it seems -from Marie's email earlier this afternoon and your response -- that you are clear on these now. If not, feel free to email me and Marie. The bottom line is that folks who join our internal US-interested party group will assist in developing the positions as a group but these will be vetted by me (as the US delegate) and sent to the Chair of the eWG as the official USG set of comments/work product.

To the extent that a member of our internal US-interested party group wants a different opinion voiced, he or she will need to do this independently as part of another group (which would require joining each working group directly) . So if you or any of your colleagues want to join discussions as a part of Crop Life International, or any other NGO, they are welcome to do so, but they would have to register directly through the Netherlands Chair.

I also checked with Marie if it was permissible for a member of the US eWG interested party group to ALSO serve on a different group, and she indicated that this would be fine. In other words, folks can join as many groups within an eWG as they like and serve on as many eWGs as they like.

I think most of this is what you've read before from Marie's email. But I wanted to close out our phone discussion of this morning with an email, as I promised.

Marie – if there is anything incorrect or misleading about what I've said above, please feel free to send out an email correcting it.

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 9:03 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

David:

Is it okay to share this invitation with others on our committees who would be interested? Do you have any reason to limit the number of participants on the eWGs through the US Delegation?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, July 17, 2016 3:43 PM
To: barney@AESOP.Rutgers.edu; billb@bryantchristie.com; blandine.trouille@trade.gov; cprice@calcitrusquality.org; Cindys@amvac-chemical.com; kunkel@AESOP.Rutgers.edu; dtrinka@blueberries.com; gludwig@almondboard.com; heidi.irrig@syngenta.com; jcranney@calcitrusquality.org; Jason.Sandahl@fas.usda.gov; jbaron@aesop.rutgers.edu; jessica.christiansen@monsanto.com; defrancj@science.oregonstate.edu; john.abbott@syngenta.com; jwilson@cranberryinstitute.org; kimb@bryantchristie.com; LCox@nichino.net; Bacon, Laura <Bacon.Laura@epa.gov>; Mark.Rasmussen@fas.usda.gov; willett@nwhort.org; pat.basu@fsis.usda.gov; Paulo.Almeida@fsis.usda.gov; klaiber@pea-lentil.com; Peter.Horne-1@USA.dupont.com; philip.brindle@basf.com; guerrero_raul_j@yahoo.com; Ray McAllister <RMcAllister@croplifeamerica.org>; selen.stromgren@fda.hhs.gov; mcgreevy@pea-lentil.com; scholz@pea-lentil.com; svnielse@starbucks.com; Phang, Whang <Phang.Whang@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Wing.Yu@chemtura.com; Dougtnelson1@gmail.com; ronaldwilliams@coca-cola.com; Marie.Maratos@fsis.usda.gov; tcarmen@dow.com; mike@cmschofieldconsulting.com; fukushimak@iskbc.com; JKozlowski@nichino.net; Robin.Charlton@valent.com; Terry.Councell@fda.hhs.gov; Sara.Kucenski@fas.usda.gov; Nguyen, Thuy <Nguyen.Thuy@epa.gov>; meldan@luxpam.com; Janet Collins <jcollins@croplifeamerica.org>; Wu.Li@yum.com; molly.miller@basf.com; Miller, David <Miller.DavidJ@epa.gov>; allen.scarborough@bayer.com; Shah, Pv <Shah.Pv@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; james.m.nyangulu@monsanto.com; Ruihong.Guo@ams.usda.gov; Diana.Haynes@ams.usda.gov; Olinger, Christine <Olinger.Christine@epa.gov>; amelia.elizabeth.jackson.-.gheissari@monsanto.com; John.Johnston@fsis.usda.gov; charlotte.liang@fda.hhs.gov; cheryl.cleveland@basf.com; aroberts@TSGUSA.com
Cc: Bacon, Laura <Bacon.Laura@epa.gov>; Marie.Maratos@fsis.usda.gov; John.Johnston@fsis.usda.gov; pat.basu@fsis.usda.gov
Subject: CCPR49 (2017) - Electronic Working Group Solicitations of interest/participation

All,

Several invitations have recently been sent out by Codex as a follow-on the April 2016 CCPR48 meeting in Chongqing, China. Specifically, these relate to participation in eWGs

relating to (i) crop classification of food and feed; (ii) revisions to the IESTI equation; and (iii) Priorities. Please find these attached, noting the listed August deadlines to express interest in participation.

All who would like to participate in the US coordinated response should send their contact information to me with a cc: to Laura Nollen, using the same information in the subject line as appears in the subject line of this email. Please do this at least two weeks prior to the pertinent deadline dates listed on the attached announcement. Those who would like to participate representing other NGOs within Codex should send their contact information directly to the chairs of the WGs whose email addresses are provided in the relevant invitations.

Regards,

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Nollen, Laura[Nollen.Laura@epa.gov];
Marie.Maratos@fsis.usda.gov[Marie.Maratos@fsis.usda.gov]
From: Miller, David
Sent: Wed 4/27/2016 9:42:40 PM
Subject: Re: Visit at breakfast?

Yes. I will be down there about 645 and look for you. I am finishing up ppt deck and reviewing iesti today so won't have much time. Marie and Laura - feel free to join.

David

Sent from my iPhone

On Apr 28, 2016, at 5:33 AM, Ray McAllister <RMcAllister@croplifeamerica.org> wrote:

> David:
>
> Would you have time to visit briefly at breakfast time over a few issues?
>
> Ray S. McAllister, PhD
> Senior Director, Regulatory Policy
> CropLife America
> +1-202-872-3874 (office)
> +1-202-577-6657 (cell)
> ray@croplife.us

To: Ray McAllister[RMcAllister@croplifeamerica.org]
Cc: Janet Collins[jcollins@croplifeamerica.org]; Basu, Pat - FSIS[Pat.Basu@fsis.usda.gov]; Madden, Barbara[Madden.Barbara@epa.gov]; Nollen, Laura[Nollen.Laura@epa.gov]
From: Miller, David
Sent: Sun 4/17/2016 5:15:05 PM
Subject: RE: IESTI, CCPR, EWG

Ray,

My understanding is that any international NGO may officially join any Codex WG. However, they are never full or voting members, a status only given to member-country reps.

Since Crop Life International has representatives that participate in Codex, Crop Life America Representatives may want to ask this question about their participation and the associated details while at the Codex meeting and discuss next steps and anticipated involvement with them.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Friday, April 15, 2016 2:46 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Janet Collins <jcollins@croplifeamerica.org>
Subject: IESTI, CCPR, EWG

David:

Thanks for taking the time to meet with our Food and Beverage Committee yesterday afternoon. Please let us know what you can, as soon as you can about the position to be taken by the US Delegation on the IESTI proposals in the coming CCPR meetings.

We would encourage EPA to take an active leadership role in the Electronic Working Group that is formed. The experience, expertise, and tools that EPA has in probabilistic risk assessment are vital to balance other perspectives and ensure that discussions are anchored in reality.

Do you know how stakeholders can participate in an Electronic Working Group? Can they nominate representatives to participate directly?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Thur 4/14/2016 7:16:03 PM
Subject: RE: Are you coming over?

Coming over now…

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, April 14, 2016 2:44 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Are you coming over?

We are on the 2nd floor- we will finish by 3:45 so as early as you can would be great.

Thanks.

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, April 14, 2016 2:40 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Are you coming over?

Just got out (a bit longer than I thought) – can I do it at 3:15 instead? What room are you in on 2nd floor?

David.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, April 14, 2016 2:38 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: Are you coming over?

We are on the 2nd floor.

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Thur 4/14/2016 6:39:39 PM
Subject: RE: Are you coming over?

Just got out (a bit longer than I thought) – can I do it at 3:15 instead? What room are you in on 2nd floor?

David.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, April 14, 2016 2:38 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: Are you coming over?

We are on the 2nd floor.

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Thur 4/14/2016 12:57:43 AM
Subject: RE: Updates on CCPR

Would 3:30 to 4:00 work for you all? I do have a meeting from 3:00 to 3:30, but suspect that it won't last that long.

I may be able to do it about 2:15, if I get early from a PPDC conference call. Is that a possibility for you folks.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Miller, David
Sent: Tuesday, April 12, 2016 8:30 PM
To: 'Janet Collins' <jcollins@croplifeamerica.org>
Subject: RE: Updates on CCPR

Hello Janet,

Sometime between 12 and 4 on Thursday would work. I will get you more details on the time early tomorrow, so you can plan. I would expect it to be short.

One thing to note, if you haven't already:

The US Draft position as of 3/23 was posted on the Codex website at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings/public-meetings

I don't see it there anymore, so I have attached it here. Note Agenda Item 8e and 8f which might be of interest to the Food and Beverage Committee.

For reference the CCPR provision agenda and other material is available at:

http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, April 11, 2016 10:13 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Updates on CCPR

Thanks David! On Thursday this week in the afternoon—you could come for lunch and stay…or perhaps talk around 2:45 or as a working lunch if that is possible—then it would be 12:15ish.

Thanks again for considering this request!

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, April 11, 2016 10:07 AM
To: Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Updates on CCPR

Hello Janet,

This week? On what day?

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, April 11, 2016 7:23 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: Updates on CCPR

David- good morning! I wanted to check in to see if you might be available for a short discussion with the CLA Food and Beverage Committee to discuss CCPR and what you see as the issues for residues in food and beverages (ingredients)? Some of these members will go to CCPR and I also think it would be helpful for them to meet you if they have not already, and recognize you as the EPA delegate (and head of the US delegation) since you are new in this role.

We will be meeting at the Renaissance Crystal City so we could make it work at your

convenience. We begin with lunch at 12:00 and go to 4:00- might that timeframe work for you?

Many thanks.

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Wed 4/13/2016 12:30:06 AM
Subject: RE: Updates on CCPR
CCPR2016 US Draft Positions.final.pdf

Hello Janet,

Sometime between 12 and 4 on Thursday would work. I will get you more details on the time early tomorrow, so you can plan. I would expect it to be short.

One thing to note, if you haven't already:

The US Draft position as of 3/23 was posted on the Codex website at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings/public-meetings

I don't see it there anymore, so I have attached it here. Note Agenda Item 8e and 8f which might be of interest to the Food and Beverage Committee.

For reference the CCPR provision agenda and other material is available at:

http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48

David.

David J. Miller CAPT | USPHS

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and Acting Chief, Toxicology & Epidemiology Branch
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From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, April 11, 2016 10:13 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Updates on CCPR

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Thanks again for considering this request!

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, April 11, 2016 10:07 AM

To: Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Updates on CCPR

Hello Janet,

This week? On what day?

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, April 11, 2016 7:23 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: Updates on CCPR

David- good morning! I wanted to check in to see if you might be available for a short

discussion with the CLA Food and Beverage Committee to discuss CCPR and what you see as the issues for residues in food and beverages (ingredients)? Some of these members will go to CCPR and I also think it would be helpful for them to meet you if they have not already, and recognize you as the EPA delegate (and head of the US delegation) since you are new in this role.

We will be meeting at the Renaissance Crystal City so we could make it work at your convenience. We begin with lunch at 12:00 and go to 4:00- might that timeframe work for you?

Many thanks.

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Mon 4/11/2016 2:07:12 PM
Subject: RE: Updates on CCPR

Hello Janet,

This week? On what day?

David

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, April 11, 2016 7:23 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: Updates on CCPR

David- good morning! I wanted to check in to see if you might be available for a short

discussion with the CLA Food and Beverage Committee to discuss CCPR and what you see as the issues for residues in food and beverages (ingredients)? Some of these members will go to CCPR and I also think it would be helpful for them to meet you if they have not already, and recognize you as the EPA delegate (and head of the US delegation) since you are new in this role.

We will be meeting at the Renaissance Crystal City so we could make it work at your convenience. We begin with lunch at 12:00 and go to 4:00- might that timeframe work for you?

Many thanks.

Janet

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Ray McAllister[RMcAllister@croplifeamerica.org]
From: Cheryl Cleveland
Sent: Tue 1/26/2016 1:30:06 PM
Subject: RE: Meeting on Wednesday?

David I would like to phone in – I hope arrangements can be made for me to join.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, January 25, 2016 5:29 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: RE: Meeting on Wednesday?

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 4:16 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I will reserve a room at CLA as a backup, in case there is not a room available at Potomac Yards.

On Jan 25, 2016, at 3:43 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
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703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Re: Meeting on Wednesday?

Thanks. We'll plan on it.

On Jan 25, 2016, at 1:15 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: tcarmen@dow.com[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Jane M Stewart[jane.stewart@basf.com]; Cheryl Cleveland (cheryl.cleveland@basf.com)[cheryl.cleveland@basf.com]; Reshma Arrington[rarrington@croplifeamerica.org]
From: Ray McAllister
Sent: Thur 1/21/2016 3:08:06 PM
Subject: Meet to discuss a few residue issues

David:

A few folks from our Residue Experts Work Group could be in town next Wednesday the 27th, and we are wondering if you and your staff could make time in the morning (suggest 10 or 10:30 a.m.) to discuss a few projects. Please let me know right away, as they would need to make travel arrangements today.

- Preliminary ideas and proposal for MRLs/tolerances in honey;

- Progress on the zoning / exchangeability project.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Reshma Arrington[rarrington@croplifeamerica.org]
From: Janet Collins
Sent: Tue 1/12/2016 12:57:33 PM
Subject: CLA Spring Conference

Good morning David- and happy new year.

As I believe I mentioned previously, the CLA Spring Conference is scheduled for April 12-14 at the Renaissance Hotel in Crystal City. I wanted to ask if you or your colleagues have any specific topics that you would like to see on the program. I am certain that we will identify several in which you will have interest- and hopefully will be able to participate.

Thanks very much.

Janet E. Collins, Ph.D., R.D., CFS

Sr. Vice President Science and Regulatory Affairs

CropLife America

1156 15th Street, NW, Suite 400

Washington, DC 20005

+1 (202) 833-4474 (direct)

+1 (703) 868-3280 (mobile)

Fellow and Past President, Institute of Food Technologists

President, Phi Tau Sigma

To: Sci Reg[SciReg@CropLifeAmerica.org]; Miller, David[Miller.DavidJ@epa.gov]; Chris.Sack@fda.hhs.gov[Chris.Sack@fda.hhs.gov]; Diana.Haynes@ams.usda.gov[Diana.Haynes@ams.usda.gov]; Sitra.Abubeker@ams.usda.gov[Sitra.Abubeker@ams.usda.gov]; Tamika Sims[tsims@croplifeamerica.org]; 'cla-rewg@yahoogroups. com'[cla-rewg@yahoogroups.com]
From: Ray McAllister
Sent: Tue 11/17/2015 3:35:24 PM
Subject: REWG meeting logistics; November 17

TO: CLA Residue Experts Work Group and guests

FROM: Ray S. McAllister, PhD
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
202-577-6657 (cell)
ray@croplife.us

For the start of today's REWG meeting, we will modify our schedule to accommodate a joint session with the Registration Committee (whose meeting is in progress). David Miller and Dan Kunkel will be on the telephone at 12:15 p.m. for an update on crop grouping activities. The REWG and RC will pick up lunch and meet together in the Washington Room at noon, and eat lunch while we hear that update. Afterward, the REWG will move to the Jefferson Conference Room to continue its meeting, while the Registration Committee will stay in the Washington Room.

Conference call numbers:

- Noon Joint session for both RC and REWG: Ex. 6 - Personal Privacy pass code Ex. 6 - Personal Privacy - RC will continue using this number throughout the day.
- After the joint session, when we announce the groups are separating, REWG will use Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy passcode Ex. 6 - Personal Privacy

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Nancy_Beck@americanchemistry.com[Nancy_Beck@americanchemistry.com]
From: Miller, David
Sent: Tue 2/2/2016 5:56:48 PM
Subject: RE: IARC proposal for Tox Forum

Janet,

I am not a toxicologist so I am not sure I'd be the right person. Would Anna Lowit, Elizabeth Mendez, or somebody else perhaps be more appropriate?

If you want to talk by phone on the general idea, I could perhaps suggest others here who may be more suited. Are you available tomorrow or Thursday ?

David

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, February 02, 2016 11:43 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Nancy_Beck@americanchemistry.com
Subject: IARC proposal for Tox Forum

David- do you have a few minutes to discuss this proposal that we have developed for a session at Tox Forum in SLC in the summer?

If you could let me know your schedule I can come back to you with a specific time request.

Thanks

Janet

Cc: Ray McAllister[RMcAllister@croplifeamerica.org]
To: Cheryl Cleveland[cheryl.cleveland@basf.com]
From: Miller, David
Sent: Tue 1/26/2016 1:33:01 PM
Subject: Re: Meeting on Wednesday?

Yes, we can do that.

From: Cheryl Cleveland <cheryl.cleveland@basf.com>
Sent: Tuesday, January 26, 2016 8:30 AM
To: Miller, David
Cc: Ray McAllister
Subject: RE: Meeting on Wednesday?

David I would like to phone in – I hope arrangements can be made for me to join.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, January 25, 2016 5:29 PM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: RE: Meeting on Wednesday?

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 4:16 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I will reserve a room at CLA as a backup, in case there is not a room available at Potomac Yards.

On Jan 25, 2016, at 3:43 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Re: Meeting on Wednesday?

Thanks. We'll plan on it.

On Jan 25, 2016, at 1:15 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

To: Janet Collins[jcollins@croplifeamerica.org]
From: Miller, David
Sent: Fri 12/18/2015 11:35:26 PM
Subject: RE: CCPR question

Hello Janet,

I will be back in the office beginning Monday 28 December through the following Wednesday. Chatting during that time would be fine. Feel free to give me a call or drop me a line.

David.

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, December 16, 2015 6:01 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: CCPR question

David- do you have a few minutes over the next couple of days to discuss a potential CCPR/CCFICS project that I am thinking of that might provide guidance to the food and beverage committee?

At your convenience—after the holidays if necessary!

My best

Janet

To: Janet Collins[jcollins@croplifeamerica.org]; Marie Maratos[Marie.Maratos@fsis.usda.gov]
From: Miller, David
Sent: Thur 12/10/2015 7:35:52 PM
Subject: RE: CLA holiday party

Janet,

Thanks for the invite, but I will not be able to make it.

I thought we had a good meeting yesterday - thanks for inviting us to that.

Enjoy the holidays !

David.

-----Original Message-----
From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, December 10, 2015 2:33 AM
To: Marie Maratos <Marie.Maratos@fsis.usda.gov>; Miller, David <Miller.DavidJ@epa.gov>
Subject: CLA holiday party

Marie and David- I had hoped to catch up with you both to thank you for joining the CLA food and beverage committee meeting today- and to extend an invitation to you both to drop by the Newseum for the CLA Christmas party TONIGHT.

The time is 5:30 to 7:30- please do come by to 'make merry' with colleagues and friends!

My best

Janet

Sent from my iPhone

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Tiu, Carmen (C)[tcarmen@dow.com]
Cc: Rutgers[kunkel@AESOP.Rutgers.edu]
From: Miller, David
Sent: Tue 11/17/2015 5:20:20 PM
Subject: RE: REWG meeting logistics; November 17

Hello Ray and Carmen,

•□□□□□□□ I am on the line at: Ex. 6 - Personal Privacy passcode 4 Ex. 6 - Personal Privacy for the

Whenever you ready.

If you are and for some reason I am on the wrong line, please call me at the number below:

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Tuesday, November 17, 2015 10:35 AM
To: Sci Reg <SciReg@CropLifeAmerica.org>; Miller, David <Miller.DavidJ@epa.gov>;

Chris.Sack@fda.hhs.gov; Diana.Haynes@ams.usda.gov; Sitra.Abubeker@ams.usda.gov; Tamika Sims <tsims@croplifeamerica.org>; 'cla-rewg@yahoogroups. com' <cla-rewg@yahoogroups.com>
Subject: REWG meeting logistics; November 17
Importance: High

TO: CLA Residue Experts Work Group and guests

FROM: Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

For the start of today's REWG meeting, we will modify our schedule to accommodate a joint session with the Registration Committee (whose meeting is in progress). David Miller and Dan Kunkel will be on the telephone at 12:15 p.m. for an update on crop grouping activities. The REWG and RC will pick up lunch and meet together in the Washington Room at noon, and eat lunch while we hear that update. Afterward, the REWG will move to the Jefferson Conference Room to continue its meeting, while the Registration Committee will stay in the Washington Room.

Conference call numbers:

•□□□□□□□ Noon Joint session for both RC and REWG: Ex. 6 - Personal Privacy pass code Ex. 6 - Personal Privacy RC will continue using this number throughout the day.

•□□□□□□□ After the joint session, when we announce the groups are separating, REWG will use Ex. 6 - Personal Privacy passcode Ex. 6 - Personal Privacy

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Nollen, Laura[Nollen.Laura@epa.gov]; Pat.Basu@fsis.usda.gov[Pat.Basu@fsis.usda.gov]; Ray McAllister[rmcallister@croplifeamerica.org]; Maratos, Marie - FSIS[Marie.Maratos@fsis.usda.gov]
From: Cheryl Cleveland
Sent: Mon 3/14/2016 7:17:07 PM
Subject: RE: Public meeting, CCPR Delegation, 3/23/2016

Hello David,

I was curious if an agenda has been set for the March 23rd meeting. As you know, the IESTI equation as it relates to dietary exposure is of particular interest to several of us within the CLA Dietary Working Group. I would like to attend the March 23rd meeting in person and share a bit of our concerns over the proposed IESTI changes to be discussed at the CCPR meeting in April, if there is an opportunity. So I am curious if the suggestion of the IESTI topic which Ray raised had made it onto the March 23rd meeting agenda? This would allow me to make appropriate travel arrangements.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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From: CLA-REWG@yahoogroups.com [mailto:CLA-REWG@yahoogroups.com] **On Behalf Of** Ray McAllister rmcallister@croplifeamerica.org [CLA-REWG]
Sent: Wednesday, March 02, 2016 5:20 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Maratos, Marie - FSIS <Marie.Maratos@fsis.usda.gov>
Cc: Nollen, Laura <Nollen.Laura@epa.gov>; Pat.Basu@fsis.usda.gov
Subject: [CLA-REWG] Public meeting, CCPR Delegation, 3/23/2016
Importance: High

TO: David Miller and Marie Maratos

FROM: Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

At the March 23 public meeting of the US CCPR Delegation, we would request that the delegation discuss changes to the JMPR version of the International Estimate of Short Term Intake (IESTI), actively being promoted by EFSA, WHO and FAO. We believe the issue is of high importance and interest to US growers as well as CLA members. The proposed changes will ultimately and adversely **impact trade** for key crops and agricultural commodities, due to elimination of CODEX MRLs available to cover exports for US growers. The proposed changes **increase the conservatism of dietary exposure assessment, disproportionate to any risk involved; they are not warranted** based on food safety concerns, or based on the practical and realistic US approach to dietary exposures. Since this topic will be raised in the approaching CCPR meetings in China, US growers and the crop protection industry need a thorough understanding of the proposed changes; the implications for international agricultural trade; the timelines for potential consideration, adoption and implementation of the changes; and positions that will be taken by the US Delegation in this international discussion.

This discussion on March 23 could easily occupy 30 minutes (or more) on the agenda, though we recognize the other business that must be conducted at this meeting. I could foresee strong interest among grower groups to call in for the discussion, even if they haven't previously participated in activities of the delegation.

We would urge you to share this request with others invited to the March 23 meeting.

Posted by: Ray McAllister <RMcAllister@croplifeamerica.org>

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From: Janet Collins
Location: Conference call
Importance: Normal
Subject: Canceled: Epidemiology workshop
Start Date/Time: Tue 7/26/2016 7:30:00 PM
End Date/Time: Tue 7/26/2016 8:00:00 PM

Ex. 6 - Personal Privacy

To: Janet Collins[jcollins@croplifeamerica.org]; Pease, Anita[Pease.Anita@epa.gov]; Cowles, James[Cowles.James@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
From: Lowit, Anna
Sent: Thur 12/1/2016 8:21:30 PM
Subject: RE: CLA holiday party

Thanks Janet. I did receive it but won't be able to make it.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, December 01, 2016 2:33 PM
To: Pease, Anita <Pease.Anita@epa.gov>; Cowles, James <Cowles.James@epa.gov>; Housenger, Jack <Housenger.Jack@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Subject: CLA holiday party

All- hoping that you will be able to join us for the CLA holiday party this year (December 13th). You should all have received an invitation- please let me know if you have not. Great opportunity to meet in a less formal environment- many colleagues from government, academia and industry will join.

My best

Janet

To: Vogel, Dana[Vogel.Dana@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]
From: Lowit, Anna
Sent: Wed 11/30/2016 3:56:48 PM
Subject: FW: CLA Petition
FINAL CLA Petition Regulatory Decision Making 11 29 16.pdf

We are not planning a long, exhaustive response to the comments document on the epi issues, just concise, thematic, using the SAP reports as much as possible. Does this petition change that approach (and if so, we can't make the current timeframe)?

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Davis, Donna
Sent: Wednesday, November 30, 2016 9:12 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Rickard, Kristin <Rickard.Kristin@epa.gov>
Subject: FW: CLA Petition

I assume you all already know about this/have this. It was shared with me with the statement that the no directional change is signaled yet, but this might have an impact on the response to comment for the 10x/epi so the team should know about it. I haven't shared it beyond the managers and the 10X team. Please let me know if you think it would wise to do so.

From: Zinn, Nicole
Sent: Wednesday, November 30, 2016 8:59 AM
To: Davis, Donna <Davis.Donna@epa.gov>
Subject: FW: CLA Petition

FYI

From: Anderson, Neil
Sent: Tuesday, November 29, 2016 2:43 PM
To: Zinn, Nicole <Zinn.Nicole@epa.gov>; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Parker, James <Parker.James@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: CLA Petition

FYI – petition from CLA to stop decision-making on OPs with the epi 10x. I have no idea at this point on what this means for us in regards to upcoming decisions for various OPs.

From: Guilaran, Yu-Ting
Sent: Tuesday, November 29, 2016 2:25 PM
To: OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: FW: CLA Petition

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Housenger, Jack
Sent: Tuesday, November 29, 2016 2:19 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: FW: CLA Petition

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, November 29, 2016 2:12 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Cc: Jay Vroom <JVroom@croplifeamerica.org>
Subject: CLA Petition

Dear Jack- attached please find a CLA Petition to EPA for the suspension of regulatory decision making for organophosphate pesticides based on human health assessments using epidemiologic study outcomes from studies that do not meet the EPA data quality standards published in EPA guidance.

Should you have questions, please feel free to contact me directly.

Thank you.

Janet E Collins, Ph.D., R.D.

Executive Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

November 29, 2016

Dr. Jack Housenger
United States Environmental Protection Agency
Director, Office of Pesticide Programs
2777 Crystal Drive
One Potomac Yard South
Room 12621
Arlington, VA 22202-3553

Sent via email

Re: Petition EPA 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

Dear Director Housenger:

Enclosed please find a CropLife America (CLA) Petition to the US Environmental Protection Agency (EPA) to suspend any regulatory decision making on human health risk assessment(s) for organophosphate and other pesticides, using an FQPA 10X Safety Factor supported principally by the use of epidemiologic studies that generally do not meet well-defined data quality standards, and specifically are heavily weighted on the Columbia Study outcomes.

CropLife America is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers and other consumers. We are committed to the safe and responsible use of the industry's products in order to provide safe and abundant food, as well as to control insect and plant disease vectors for the protection of human health, all providing valuable benefits to the agriculture, farmers and the consumer.

The Petition requests EPA to cease regulatory decision making, specifically with respect to the organophosphate pesticides, until EPA has transparently developed criteria for acceptance of epidemiologic studies in human health risk assessment, and guidance for integration of epidemiologic studies in pesticide risk assessment historically based on animal toxicological and *in vitro* studies.

Due to uncertainties within the regulatory environment created by the lack of such integration guidance, and the potential impact on the availability of crop protection products based on inappropriate selection and use of epidemiological studies by the EPA Office of Pesticide

Programs in its human risk assessments for pesticide registrations, CLA respectfully requests that you respond to our Petition within 45 days.

Should you have any questions regarding the CLA Petition, please contact me directly [jcollins@croplifeamerica.org (+1-202-833-4474)].

Respectfully submitted,

Janet E. Collins, Ph.D., R.D.
Executive Vice President
CropLife America

PETITION TO HALT REGULATORY DECISIONS DETERMINED BY RESULTS OF EPIDEMIOLOGICAL STUDIES THAT DO NOT MEET WELL-DEFINED DATA QUALITY STANDARDS AND THAT ARE NOT INTEGRATED INTO THE RISK ASSESSMENT IN A TRANSPARENT, WELL-DEFINED MANNER

CropLife America (CLA) petitions the Environmental Protection Agency (EPA or the Agency) to halt any regulatory decisions on any organophosphate pesticide (OP), where that action is based primarily on results from highly influential studies that do not meet well-defined data quality standards, where the use of such a study is a determinative factor, yet the public has no means of knowing how EPA is determining the data quality of such a study and how it is being integrated into the risk assessment when its conclusions are not consistent with results from more traditional, and required testing. EPA's reliance on the Columbia Center for Children's Environmental Health epidemiology cohort studies of inner-city mothers and children (the Columbia Study) concerning pre- -natal pesticide exposure to chlorpyrifos to drive regulatory decisions is an example of this.

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 farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment.

STATUTORY AND REGULATORY BACKGROUND

No pesticide product can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),

7 U.S.C. § 136 *et seq*. Through FIFRA, the EPA receives extensive hazard and exposure information that is used to evaluate the risks of pesticide products.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), requiring EPA, when setting tolerances for pesticide residues on food, to make a safety finding that the pesticide can be used with "a reasonable certainty of no harm" to human health. 21 U.S.C. § 346a(b)(2)(A). To meet this standard, EPA must consider (among other things) the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor (the Safety Factor) when setting and reassessing tolerances unless adequate data are available to support a different factor. *Id.*

EPA's human health pesticide risk assessment has traditionally relied on validated toxicological studies using laboratory animals along with data to estimate the potential exposure based on the proposed use of the pesticide product. Epidemiological studies of adverse effects in humans have not been uniformly or consistently incorporated into this quantitative risk assessment process, due to the observational nature of epidemiologic research, primarily due to questions related to study design, population studied, and lack of clear evidence of the magnitude and duration of exposure during critical phases of development and/or evidence of a dose-response relationship that would more clearly support a conclusion that exposure to a particular chemical may have caused an observable/measurable toxic effect, among other factors that would impact the use of epidemiologic study outcomes in quantitative risk assessment. While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the

information provided by epidemiological studies needs to be closely scrutinized before use in a regulatory risk assessment.

Through recent statements made by EPA in OP registration review dockets, EPA now seeks to change this process and incorporate unreliable and unverifiable epidemiological evidence directly into its pesticide risk assessment process through a framework that utilizes a weight of evidence approach, without explaining to the public how these studies, of varying quality, will be weighted when EPA does not have access to the raw data, and no criteria exist for either choice of study or integration of such data. EPA should cease further action on regulatory decision-making that finds epidemiological study results to be determinative until the Agency can establish criteria against which such study results can be evaluated, and clearly articulate how the Agency will determine the value added within the risk assessment in the context of the traditional empirical data.

EPA'S SHIFT IN APPROACH TO RISK ASSESSMENT

In January 2010, EPA published a Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (the Draft Framework). The Draft Framework declares that "[EPA] intends to employ…epidemiology studies and human health incident data in its human health risk assessment" and that its "goal is to use such information in the most scientifically robust and transparent way." Draft Framework at 6. EPA based its decision to incorporate epidemiology into the risk assessment process on two reports issued by the National Research Council for the National Academy of Sciences, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (2007) and *Science and Decisions* (2009). Per the Draft Framework, EPA expressed its intent to conduct human health risk assessments

that incorporate data from new sources, specifically information found in epidemiology studies, human incident databases, and biomonitoring studies.

In the Draft Framework, EPA sets forth a general plan for incorporating epidemiological studies into its risk assessment process and for weighing that evidence alongside traditional mechanistic and toxicological evidence in a weight of the evidence analysis. The Draft Framework describes the major types of epidemiological studies, noting the strengths and limitations of each in terms of their applicability to the risk assessment process. EPA's Draft Framework is premised on a proposed weight of the evidence evaluation that uses the modified Bradford Hill criteria as established in the Mode of Action Human Relevance Framework[1]; the framework serves as an approach for organizing and evaluating diverse types of data to determine the evidence available on the potential human health consequences of pesticide exposure.

In a critical failing, the Draft Framework did not set forth any criteria for selecting the epidemiological studies to be incorporated, or for evaluating the quality and validity of a particular epidemiological study to determine whether that study should be used in an EPA risk assessment in the first place, in spite of the fact that in its own guidance on use of open literature data for human health risk assessment, and the data quality guidance, EPA stated that it would work with the public (including the regulated community) to develop these criteria. Toxicological and exposure studies, in contrast, generally must meet strict design and "good laboratory practice" quality criteria and disclose all analyses for consideration during registration or registration review processes. *See e.g.*, 40 C.F.R. §§ 152.50, 158.80, and Part 160.

[1] A summary of EPA's Motion of Action Human Relevance Framework can be found at: https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=246035.

As discussed in more detail below, a FIFRA Scientific Advisory Panel (2010 SAP) reviewed the Draft Framework at a meeting held in February 2010. While the 2010 SAP praised EPA for its use of the Bradford Hill criteria as the basis for how to incorporate epidemiology in a weight of the evidence analysis, the SAP strongly recommended that EPA establish a stringent set of quality-based criteria to determine whether to accept a given epidemiological study for use in risk assessment. FIFRA Scientific Advisory Panel Meeting Minutes No. 2010-03 at 10 (Feb. 2-4, 2010) (2010 SAP Minutes). Since the 2010 SAP meeting, CLA and its members have repeatedly requested an opportunity for input into such criteria; the Agency has continued to deny these requests, and has not issued the 2010 SAP-recommended criteria, despite have stated that it would work with the public to develop such criteria.

On September 25, 2015, EPA made available for public comment its "Pesticide Registration: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides" (Draft Risk Assessments).[2] The Draft Risk Assessments were intended to support the registration review of (1) a group of 22 pesticides known as sulfonylureas (not at issue here) and (2) seven OPs. CLA provided comments to each of the dockets contained within the overarching docket.[3] At that time, CLA also commented on the "Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphates" (the Literature Review) that was part of each of the seven OP dockets.[4] In the Literature Review EPA stated (buried on page 80 of 101) that it will be retaining the full 10X Safety Factor for *all*

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[2] "Pesticide "Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides; Notice of Availability and Request for Comment," 80 Fed. Reg. 57812 (Sept. 25, 2015), Docket No. EPA-HQ-OPP-2015-0386, available at: https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2015-0386&fp=true&ns=true.

[3] *See* Docket No. EPA-HQ-OPP-2012-0372-0066 (Sept. 12, 2016), available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0372; Docket No. EPA-HQ-OPP-2008-0345-0046 (March 3, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0345-0046.

[4] *See* EPA-HQ-OPP-2010-0119-0039 (February 22, 2016), available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0119-0039.

OP pesticides. The Agency's stated rationale for retaining the full Safety Factor was based primarily on conclusions drawn from the Columbia Study, despite the fact that EPA has not evaluated, or even reviewed, the data underlying the Columbia Study's conclusions.

More recently, on November 10, 2016, the Agency issued a prepublication version of "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment."[5] In that document EPA states that it intends to revoke all food tolerances for the OP. That decision is based, at least in part, on applying the full 10X Safety Factor using the Columbia Study as the comparator for exposure levels considered to cause harm.

INTEGRATION OF DATA SOURCES IN HUMAN HEALTH RISK ASSESSMENT

Importance of Epidemiological Data in Risk Assessment

While EPA has stated that epidemiological evidence, generically speaking, may provide important informative data for the risk assessment process, this determination does not mean that each and every published epidemiological study will provide equally important, valid or useful information. Like all information considered in a risk assessment, the quality and validity of the information provided by epidemiological studies needs to be closely scrutinized.

Findings from properly conducted, high quality epidemiological studies may prove useful in characterizing and evaluating human health risks. But not all epidemiological evidence is created equal. Bias, confounding factors, and in particular, unreliable and invalidated exposure assessments commonly occur in epidemiological studies, limiting the value of the researchers' conclusions for quantitative risk assessments. In addition, a study's probative value varies dramatically depending on design and approach – observational studies, for instance, such as case series or ecological "cluster" analyses, do not carry the strength of association assessment

[5] https://www3.epa.gov/pesticides/PrePublicationCopy_16P-0280_2016-11-10.pdf

that prospective cohort and case control studies do and are often utilized only (if at all) for hypothesis generating purposes. *See* 2010 SAP Minutes at 20-21.

"Weight of evidence," in this context, requires more than mere consideration of "all" forms of epidemiological studies. The weight of evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. *See* U.S. Environmental Protection Agency, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, EPA 100/B-03/001 June 2003. Epidemiology studies used in risk assessments, thus, should report all analyses, negative or positive and provide all underlying data.

To date, EPA has provided no transparency regarding how it is judging the quality of epidemiological studies or weighing them against its traditional data requirements. Additional transparency and structure is needed before decisions are made based on this inscrutable evaluation.

EPA MUST ENSURE THE QUALITY OF DATA USED IN RISK ASSESSMENTS

The quality of scientific information forming the foundation for pesticide registration and use decisions is essential to all EPA risk assessments. For example, in 2002 EPA published "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," EPA/260R-02-008 (the Guidelines). EPA issued these Guidelines to formalize and maximize the quality of disseminated information, particularly with respect to the objectivity, utility, and integrity of scientific data. Under the Guidelines, information disseminated by EPA must be "presented in an accurate,

clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." *Id.* at 15. Objectivity of influential scientific information is judged against the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996 to ensure the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data). *Id.* at 22.

Moreover, "influential" information, which is information that will have a clear and substantial impact on important public policies or private sector decisions, must "adhere to a rigorous standard of quality" and "should be subject to a higher degree of quality." *Id.* at 20. As noted in the Guidelines, information that can "adversely affect in a material way the economy, productivity, competition, jobs" or that addresses "precedent-setting or controversial scientific or economic issues" is considered influential. Because the overall economic impact on a currently registered pesticide of an EPA reassessment could be substantial, scientific data used to make those decisions would be influential. Unquestionably, epidemiological studies used in these risk assessments that impact registrations thus qualify as "influential" data subject to heightened quality standards under the Guidelines.

Requirements set out in the FQPA for setting tolerances mirror these guidelines. Under the FQPA, EPA must consider, among other relevant factors, the validity, completeness, and reliability of the available data from studies of the pesticide chemical. 21 U.S.C. § 346a.

CRITERIA FOR A WELL-DESIGNED, ROBUST EPIDEMIOLOGICAL STUDY

A well-designed, robust epidemiological cohort or case control study has certain features that OPP should look for before admitting a study into a risk assessment. These include, but are not limited to:

- well-characterized, quantitative exposure assessments that minimize measurement error, evaluates exposure during an etiologically relevant period, and decrease the likelihood of inaccurate or biased information;
- well-characterized, documented identification of disease and/or health status.
- a well-defined study population that includes persons with a wide range of exposures as well as unexposed persons; and
- documented efforts to control for selection bias, information bias and confounding; and
- full disclosure of the results of all statistical analyses conducted and models evaluated.

While quantitative criteria are a critical first step in separating reliable epidemiological studies from less reliable studies, an element of scientific judgment is required to make a complete assessment. To ensure a well-informed process, EPA must utilize the expertise of qualified epidemiologists to review the body of epidemiology evidence for a given pesticide to determine whether each study satisfies quality criteria. The 2010 SAP recommended several specific questions to be asked when evaluating each specific epidemiological study for potential use in a risk assessment. Those include:

1. Was the epidemiological study conducted primarily in a hypothesis- generating or a hypothesis-testing mode? Studies with no specific *a priori* hypothesis are more likely to generate false positive results.
2. Was the method of assessing exposure reliable and adequate?

3. Were inclusion and exclusion criteria clearly stated and reasonable to provide a representative sample with regard to exposure and health outcome so as to provide a relatively unbiased and representative estimate of effect?
4. Was the method of assessing the criteria for determining health outcome clearly stated and valid and reliable; e.g. confirmed with histopathology; and were they designed to detect newly diagnosed (rather than prevalent) cases so that it was reasonably possible to determine that exposure preceded disease?
5. Was appropriate information on potentially confounding factors, such as socio-demographic, behavioral and dietary factors collected for both exposed and unexposed groups or for cases and controls in the same way, and were they appropriately controlled in the analyses of the data? Were data on co-morbid conditions collected? (i.e. factors that are associated with the health condition of interest as well as factors associated with exposure)
6. Did the study sample the population or individuals of interest? (i.e. was selection bias minimized and generalizability optimized?) How does the study population relate to the universe of potentially exposed populations?
7. Did the study examine individuals with a wide range of exposures? (i.e. ability to detect a dose-response and to generalize to other populations). Did the study include unexposed populations or individuals?
8. Did the exposures examined in the study relate to past or current situations? (i.e. acute versus chronic exposures and the target health end points)
9. Did the study have adequate statistical power to detect meaningful differences for outcomes between the different groups of exposed and unexposed or less exposed

individuals while controlling for important confounding factors? Does the sample size take into account the expected incidence of the target health effect in the study populations? Was the study powerful enough to detect statistically meaningful differences while adjusting for confounding variables and exposure measurement error that typically reduce statistical power?

See 2010 SAP Minutes at 16-17.

NECESSITY OF THIS PETITION

It is undisputed that numerous high-quality animal toxicity studies on OPs have been conducted according to scientifically validated test methods and reviewed by the Agency in support of their registrations under FIFRA. The weight of evidence from these studies currently supports a highly conservative regulatory point of departure based on replicated Good Laboratory Practice studies in multiple species, durations and routes of exposure. Furthermore, the outcomes from these animal studies are aligned with and corroborated by standard physicochemical and mechanistic principles that have withstood the test of time. Thus, based on extensive laboratory data, EPA has moved away from the full 10X Safety Factor for OPs.

EPA has made a significant and fundamental change in the way it is applying the Safety Factor. As stated in the Literature Review and evidenced in the current OP draft risk assessments, EPA now intends to apply the full 10X Safety Factor to all OP pesticides, based primarily on conclusions drawn from the Columbia Study, although neither EPA nor the registrant have access to the data upon which this decision is based. Significant data quality inadequacies in the Columbia Study 'file' exist; and there is no indication of how EPA 'weighted' the Columbia Study results in any type of weight-of-evidence process, with no criteria for such approach. EPA's reliance on this study, in spite of significant and negative

comment and direction from three separate FIFRA SAPs is without precedent. Where are the data; what is the EPA response to the three SAP reviews and recommendations; and, most importantly, what is new in assessment of the Columbia Study publications since EPA began its assessment of chlorpyrifos that would support EPA changing its approach to assessment long after the Columbia Studies were published?

Such reliance violates both FIFRA and the FQPA and flies in the face of the Guidelines and 2010 SAP recommendations, discussed above. Neither EPA nor interested stakeholders, of which OP registrants are included, have been granted access to the Columbia Study's underlying data. Thus, EPA could not have adequately evaluated the data to determine its validity, completeness, and reliability, as required by the FQPA. The Agency has not confirmed that the data meets the quality criteria as recommended by 2010 SAP and it certainly does not meet the Guidelines' standard that information disseminated by EPA be "presented in an accurate, clear, complete, and unbiased manner" with substance that "is accurate, reliable, and unbiased." Because EPA's intended use of the Columbia Study meets none of the quality criteria required for epidemiological data use in pesticide risk assessment, EPA should not be allowed to make decisions based upon it.

For the reasons set forth here, CLA petitions EPA to cease further action on any regulatory decision-making based primarily on epidemiological studies until the Agency develops, and sets forth for public comment, data quality criteria for how these study results will be evaluated, weighed and integrated into the traditional data set required for pesticide risk assessment, consistent with the quality standards required by both Congress and EPA, itself.

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]
From: Lowit, Anna
Sent: Fri 9/16/2016 5:32:19 PM
Subject: RE: NAS meeting 9/27-9/28

Hey Janet

Sorry to be slow getting back to you. I've been out of the office at an internal EPA workshop.

Here is the file I mentioned & associated SACATM meeting.

http://ntp.niehs.nih.gov/about/org/sacatm/meetings/docs/2016/september/index.html

http://ntp.niehs.nih.gov/ntp/about_ntp/sacatm/2016/september/vision20160927_508.pdf

I'm trying to get the info on the NAS meeting for you but it may not be a fully, open public meeting. (I don't even have the agenda yet, suggesting it's not a widely publicized/attended meeting---although subsequent efforts on this topics will be).

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, September 15, 2016 7:18 AM

To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: NAS meeting 9/27-9/28
Importance: High

Anna- you mentioned a 9/27 NAS meeting to which we should be alerted. Can you direct me to where I might find details of the meeting?

Thanks.

Janet

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Wed 8/3/2016 7:04:00 PM
Subject: RE: Epidemiology workshop

Phone meeting makes sense

Sent from my Windows Phone

From: Janet Collins
Sent: 8/3/2016 2:54 PM
To: Lowit, Anna
Cc: Vogel, Dana; Miller, David; KARIN. S. BENTLEY-1; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com); Baker-Smith, Cindy (CindyS@amvac-chemical.com)
Subject: RE: Epidemiology workshop

Anna- that would work well on the 10th. Do you prefer a teleconference for the first meeting?

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Wednesday, August 3, 2016 2:14 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Hi Janet

How about noon on the 9th or 10th?

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, August 01, 2016 1:42 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Thank you Anna. Unfortunately our Sci/Reg intern is making her final presentation to CLA- and we would normally be able to change it but we have invited a number of people for our registration committee and some stakeholders here in DC.

Can we look to next week- again, we will make that work as best we can.

Thanks again for following up on this.

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Monday, August 1, 2016 1:10 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Hi Janet

This week is tight. We can talk over lunch (noon) on Thursday.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

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From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Friday, July 29, 2016 11:10 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
Subject: RE: Epidemiology workshop

Anna- do you have some recommendations for dates in the coming week or 10 days?

From: Janet Collins
Sent: Tuesday, July 26, 2016 12:53 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>

Subject: Re: Epidemiology workshop

Thank you Ana-yes of course. As before, please provide a couple of times convenient for you and we will set a call.

Best

Janet

Sent from my iPhone

On Jul 26, 2016, at 10:37 AM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

> Hi everyone,
>
> We are sorry but a briefing has popped up that several of us need to attend. can we reschedule for next week?
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> Sent from my Windows Phone

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From: Lowit, Anna
Sent: Wed 8/3/2016 6:13:55 PM
Subject: RE: Epidemiology workshop

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Anna

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Senior Science Advisor

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From: Janet Collins [mailto:jcollins@croplifeamerica.org]

Sent: Friday, July 29, 2016 11:10 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com) <david.a.saltmiras@monsanto.com>; Baker-Smith, Cindy (CindyS@amvac-chemical.com) <CindyS@amvac-chemical.com>
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From: Lowit, Anna
Sent: Mon 8/1/2016 5:09:30 PM
Subject: RE: Epidemiology workshop

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To: Janet Collins[jcollins@croplifeamerica.org]; Lowit, Anna[Lowit.Anna@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; SALTMIRAS, DAVID A [AG/1000] (david.a.saltmiras@monsanto.com)[david.a.saltmiras@monsanto.com]; Baker-Smith, Cindy (CindyS@amvac-chemical.com)[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Tue 7/26/2016 4:37:51 PM
Subject: RE: Epidemiology workshop

Hi everyone,

We are sorry but a briefing has popped up that several of us need to attend. can we reschedule for next week?

Anna

Sent from my Windows Phone

To: Janet Collins[jcollins@croplifeamerica.org]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; DAVID A SALTMIRAS [AG/1000][david.a.saltmiras@monsanto.com]; Cindy Baker-Smith[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Fri 7/22/2016 3:47:54 PM
Subject: RE: Follow up

Hi janet

It looks like Tuesday at 3:30-4 works for us.

anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Thursday, July 21, 2016 7:39 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Thank you Anna. If you could propose two or three potential times to talk I can send an invite with call in numbers.

This is most appreciated.

Janet

From: Lowit, Anna [mailto:Lowit.Anna@epa.gov]
Sent: Thursday, July 21, 2016 1:04 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Hi Janet

Thanks for following up. A call next week sounds fine.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Wednesday, July 20, 2016 5:36 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: RE: Follow up

Anna- would it be possible to convene at least a call to discuss objectives and goals for the workshop so that the epi group can start considering input for collaboration?

Many thanks.

From: Janet Collins
Sent: Tuesday, July 19, 2016 4:11 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
Subject: Re: Follow up

Thanks Anna. I will be the contact for CLA participation

Thanks again

Janet

Sent from my iPhone

On Jul 19, 2016, at 3:07 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Hi Janet

Sorry we have not connected on the phone. I was on vacation for 2 weeks & am just catching up.

As was noted at the meeting at CLA a few weeks ago, we would be interested in dialoguing with CLA on using epidemiology in risk assessment and a workshop may be a possible venue. I talked to Karin Bentley today and my understanding is that the HARC has an epidemiology sub-team which has been discussing a possible workshop. Karin is going to get back in contact with OPP in the next couple weeks on this.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

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w: 703-308-4135

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Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]; KARIN. S. BENTLEY-1[KARIN.S.BENTLEY-1@dupont.com]; DAVID A SALTMIRAS [AG/1000][david.a.saltmiras@monsanto.com]; Cindy Baker-Smith[CindyS@amvac-chemical.com]
From: Lowit, Anna
Sent: Thur 7/21/2016 5:03:31 PM
Subject: RE: Follow up

Hi Janet

Thanks for following up. A call next week sounds fine.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

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To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; KARIN. S. BENTLEY-1 <KARIN.S.BENTLEY-1@dupont.com>; DAVID A SALTMIRAS [AG/1000] <david.a.saltmiras@monsanto.com>; Cindy Baker-Smith <CindyS@amvac-chemical.com>
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Thanks again

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Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

To: Janet Collins[jcollins@croplifeamerica.org]; Vogel, Dana[Vogel.Dana@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]
From: Lowit, Anna
Sent: Tue 7/19/2016 8:07:04 PM
Subject: Follow up

Hi Janet

Sorry we have not connected on the phone. I was on vacation for 2 weeks & am just catching up.

As was noted at the meeting at CLA a few weeks ago, we would be interested in dialoguing with CLA on using epidemiology in risk assessment and a workshop may be a possible venue. I talked to Karin Bentley today and my understanding is that the HARC has an epidemiology sub-team which has been discussing a possible workshop. Karin is going to get back in contact with OPP in the next couple weeks on this.

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Janet Collins
Sent: Tue 7/19/2016 11:43:13 AM
Subject: Re: Workshop

Dana- would it be possible to talk later today?

Sent from my iPhone

> On Jul 15, 2016, at 9:46 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:
>
> Hi Janet
>
> Anna is out this week but will be back on Monday. Maybe we could all do a call early next week?
>
> Dana
>
> -----Original Message-----
> From: Janet Collins [**Ex. 6 - Personal Privacy**
> Sent: Wednesday, July 13, 2016 1:33 PM
> To: Vogel, Dana <Vogel.Dana@epa.gov>
> Subject: Workshop
>
> Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?
>
> Thanks
>
> Janet E Collins
> CropLife America
>
> +1-202-833-4474
>
> Sent from my iPhone

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Janet Collins
Sent: Fri 7/15/2016 9:09:14 PM
Subject: Re: Workshop

Thanks Dana. Perhaps you and/or Anna could recommend a couple of options and I could choose one that works for me as well.

Appreciate your getting back to me!

Have a good weekend.

Sent from my iPhone

> On Jul 15, 2016, at 10:46 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:
>
> Hi Janet
>
> Anna is out this week but will be back on Monday. Maybe we could all do a call early next week?
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> Thanks
>
> Janet E Collins
> CropLife America
>
> +1-202-833-4474
>
> Sent from my iPhone

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Janet Collins
Sent: Wed 7/13/2016 5:33:05 PM
Subject: Workshop

Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

Janet E Collins
CropLife America

+1-202-833-4474

Sent from my iPhone

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Housenger, Jack
Sent: Tue 6/21/2016 5:36:49 PM
Subject: RE: Potential meeting with CLA leaders

Yes

They can go

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:20 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Huh?

From: Housenger, Jack
Sent: Tuesday, June 21, 2016 1:13 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

EX. 5- Deliberative Process

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:06 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: FW: Potential meeting with CLA leaders

EX. 5- Deliberative Process

Dv

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

Hi Janet,

Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Housenger, Jack
Sent: Tue 6/21/2016 5:13:16 PM
Subject: RE: Potential meeting with CLA leaders

EX. 5- Deliberative Process

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:06 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: FW: Potential meeting with CLA leaders

EX. 5- Deliberative Process

Dv

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Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Janet Collins
Sent: Tue 6/21/2016 3:26:52 PM
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

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Many thanks.

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Subject: Re: Potential meeting with CLA leaders

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Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: Janet Collins
Sent: Fri 6/17/2016 11:53:18 AM
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

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Sent from my iPhone

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Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Vogel, Dana[Vogel.Dana@epa.gov]
From: outlook_cd457caf49b8422f@outlook.com
Sent: Wed 6/15/2016 12:22:55 PM
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

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Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: jcollins@croplifeamerica.org[jcollins@croplifeamerica.org]
Cc: Housenger, Jack[Housenger.Jack@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]; Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Friedman, Dana[Friedman.Dana@epa.gov]; Myers, Tom[Myers.Tom@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]
From: Dinkins, Darlene
Sent: Wed 4/20/2016 4:07:48 PM
Subject: EPA response to CLA letter supporting DAS and AMVAC petitions
CropLife - Janet Collins 4-20-16 JEH.pdf

Dr. Collins,

On behalf of Jack Housenger, I am sending the attached response to CropLife America's April 6, 2016, letter supporting Dow Agricultural Sciences and AMVAC petitions.

Darlene Dinkins

Office of Pesticide Programs

U.S. Environmental Protection Agency

(703) 305-5214

To: Vogel, Dana[Vogel.Dana@epa.gov]; Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]; Costello, Kevin[Costello.Kevin@epa.gov]
From: Housenger, Jack
Sent: Mon 4/18/2016 6:23:52 PM
Subject: FW: CLA Request to Open Documents for Public Review
Final Submitted CLA Open Documents for Review 4 6 16.pdf
ATT00001.htm

This is it

From: Housenger, Jack
Sent: Thursday, April 07, 2016 10:25 PM
To: Dyner, Mark <dyner.mark@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

Begin forwarded message:

> **From:** Janet Collins <jcollins@croplifeamerica.org>
> **Date:** April 6, 2016 at 10:28:40 AM EDT
> **To:** "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
> **Subject: CLA Request to Open Documents for Public Review**
>
> Mr. Housenger, Ms. Guilaran, and Mr. Dumas- CropLife America is requesting that several of the documents posted for review of the proposed upcoming FIFRA SAP on Chlorpyrifos be reopened/opened for public review and comment. We believe that these documents are being used to serve as the foundation for charge questions being used by the SAP, and also for the renewed focus on the registrations for the organophosphates generally.
>
> Attached please find the formal request. We would appreciate hearing from you about a possible timeline for such action.
>
> My best

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]
Cc: Housenger, Jack[Housenger.Jack@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Lowit, Anna[Lowit.Anna@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]
From: Costello, Kevin
Sent: Mon 4/18/2016 5:34:22 PM
Subject: Last mention of CLA request to open documents for public review

This is the last direct mention of CLA's request that I could find. There may be additional responses, but I was not on the mailing list for this one.

From: Friedman, Dana
Sent: Friday, April 08, 2016 9:01 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Ex. 5 - Deliberative Process

Dana

Sent: Thursday, April 07, 2016 10:25 PM
To: Dyner, Mark <dyner.mark@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

Begin forwarded message:

From: Janet Collins <jcollins@croplifeamerica.org>
Date: April 6, 2016 at 10:28:40 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
Subject: CLA Request to Open Documents for Public Review

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Attached please find the formal request. We would appreciate hearing from you about a possible timeline for such action.

My best

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

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To: Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]; Friedman, Dana[Friedman.Dana@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Lowit, Anna[Lowit.Anna@epa.gov]; Costello, Kevin[Costello.Kevin@epa.gov]; Myers, Tom[Myers.Tom@epa.gov]
From: Dyner, Mark
Sent: Thur 4/14/2016 1:41:10 PM
Subject: RE: CLA Request to Open Documents for Public Review
DASresponse_040416_ytg.md.docx

Comments on Yu-Ting's version.

From: Guilaran, Yu-Ting
Sent: Thursday, April 14, 2016 7:34 AM
To: Friedman, Dana <Friedman.Dana@epa.gov>; Housenger, Jack <Housenger.Jack@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Cc: Lowit, Anna <Lowit.Anna@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Myers, Tom <Myers.Tom@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Please see attached for my comments, thanks.

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Friedman, Dana
Sent: Thursday, April 14, 2016 7:09 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Cc: Lowit, Anna <Lowit.Anna@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Myers, Tom <Myers.Tom@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Hi all,

I think it's important to turn this response around to DAS before the SAP, so Dana, Yu-Ting, if there are no additional comments, I can prepare a hard copy for signature. Please just let me know.

Thanks,

Dana

Dana L. Friedman

Pesticide Re-evaluation Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

703-347-8827

From: Friedman, Dana
Sent: Friday, April 08, 2016 9:01 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
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Ex. 5 - Deliberative Process

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To: Friedman, Dana[Friedman.Dana@epa.gov]; Housenger, Jack[Housenger.Jack@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Lowit, Anna[Lowit.Anna@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]; Costello, Kevin[Costello.Kevin@epa.gov]; Myers, Tom[Myers.Tom@epa.gov]
From: Guilaran, Yu-Ting
Sent: Thur 4/14/2016 11:34:20 AM
Subject: RE: CLA Request to Open Documents for Public Review
DASresponse_040416_ytg.docx

Please see attached for my comments, thanks.

Regards,

Yu-Ting Guilaran, P.E.

Director

Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

From: Friedman, Dana
Sent: Thursday, April 14, 2016 7:09 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>
Cc: Lowit, Anna <Lowit.Anna@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Myers, Tom <Myers.Tom@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Hi all,

I think it's important to turn this response around to DAS before the SAP, so Dana, Yu-Ting, if there are no additional comments, I can prepare a hard copy for signature. Please just let me know.

Thanks,

Dana

Dana L. Friedman

Pesticide Re-evaluation Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

703-347-8827

From: Friedman, Dana
Sent: Friday, April 08, 2016 9:01 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Dana

Sent: Thursday, April 07, 2016 10:25 PM
To: Dyner, Mark <dyner.mark@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

Begin forwarded message:

From: Janet Collins <jcollins@croplifeamerica.org>
Date: April 6, 2016 at 10:28:40 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
Subject: CLA Request to Open Documents for Public Review

Mr. Housenger, Ms. Guilaran, and Mr. Dumas- CropLife America is requesting that several of the documents posted for review of the proposed upcoming FIFRA SAP on Chlorpyrifos be reopened/opened for public review and comment. We believe that these documents are being used to serve as the foundation for charge questions being used by the SAP, and also for the renewed focus on the registrations for the organophosphates generally.

Attached please find the formal request. We would appreciate hearing from you about a possible timeline for such action.

My best

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Housenger, Jack[Housenger.Jack@epa.gov]; Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Lowit, Anna[Lowit.Anna@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]; Costello, Kevin[Costello.Kevin@epa.gov]; Myers, Tom[Myers.Tom@epa.gov]
From: Friedman, Dana
Sent: Thur 4/14/2016 11:09:00 AM
Subject: RE: CLA Request to Open Documents for Public Review
DASresponse_040416.docx

Hi all,

I think it's important to turn this response around to DAS before the SAP, so Dana, Yu-Ting, if there are no additional comments, I can prepare a hard copy for signature. Please just let me know.

Thanks,

Dana

Dana L. Friedman

Pesticide Re-evaluation Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

703-347-8827

From: Friedman, Dana
Sent: Friday, April 08, 2016 9:01 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>

Cc: Vogel, Dana <Vogel.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Ex. 5 - Deliberative Process

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Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

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From: Janet Collins <jcollins@croplifeamerica.org>
Date: April 6, 2016 at 10:28:40 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
Subject: CLA Request to Open Documents for Public Review

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Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Vogel, Dana[Vogel.Dana@epa.gov]; Keigwin, Richard[Keigwin.Richard@epa.gov]
From: Guilaran, Yu-Ting
Sent: Mon 4/11/2016 3:05:56 PM
Subject: Fwd: CLA Request to Open Documents for Public Review

FYI...

Sent from my iPhone

Begin forwarded message:

From: "Dyner, Mark" <dyner.mark@epa.gov>
Date: April 11, 2016 at 10:07:24 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Friedman, Dana" <Friedman.Dana@epa.gov>, "Guilaran, Yu-Ting" <Guilaran.Yu-Ting@epa.gov>, "Lowit, Anna" <Lowit.Anna@epa.gov>
Cc: "Perlis, Robert" <Perlis.Robert@epa.gov>, "Wakefield, Benjamin J." <wakefield.benjamin@epa.gov>
Subject: RE: CLA Request to Open Documents for Public Review

Ex. 5 - Deliberative Process

From: Housenger, Jack
Sent: Thursday, April 07, 2016 10:25 PM
To: Dyner, Mark <dyner.mark@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

Begin forwarded message:

From: Janet Collins <jcollins@croplifeamerica.org>
Date: April 6, 2016 at 10:28:40 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
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Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

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+1-202-833-4474 (direct)

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To: Housenger, Jack[Housenger.Jack@epa.gov]; Dyner, Mark[dyner.mark@epa.gov]; Guilaran, Yu-Ting[Guilaran.Yu-Ting@epa.gov]
Cc: Vogel, Dana[Vogel.Dana@epa.gov]; Lowit, Anna[Lowit.Anna@epa.gov]
From: Friedman, Dana
Sent: Fri 4/8/2016 1:00:56 PM
Subject: RE: CLA Request to Open Documents for Public Review
DASresponse_040416.docx

Ex. 5 - Deliberative Process

Dana

Sent: Thursday, April 07, 2016 10:25 PM
To: Dyner, Mark <dyner.mark@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
Subject: Fwd: CLA Request to Open Documents for Public Review

Recommendations?

Sent from my iPhone

Begin forwarded message:

From: Janet Collins <jcollins@croplifeamerica.org>
Date: April 6, 2016 at 10:28:40 AM EDT
To: "Housenger, Jack" <Housenger.Jack@epa.gov>, "Dumas, Richard" <Dumas.Richard@epa.gov>, "yu-ting.guilaran@epa.gov" <yu-ting.guilaran@epa.gov>
Subject: CLA Request to Open Documents for Public Review

Mr. Housenger, Ms. Guilaran, and Mr. Dumas- CropLife America is requesting that several of the documents posted for review of the proposed upcoming FIFRA SAP on Chlorpyrifos be reopened/opened for public review and comment. We believe that these documents are being used to serve as the foundation for charge questions being used by the SAP, and also for the renewed focus on the registrations for the organophosphates generally.

Attached please find the formal request. We would appreciate hearing from you about a possible timeline for such action.

My best

Janet E Collins, Ph.D., R.D.

Senior Vice President, Science and Regulatory Affairs

CropLife America

1156 15th Street, NW; Suite 400

Washington DC 20001

+1-202-833-4474 (direct)

+1-703-868-3280 (mobile)

To: Janet Collins[**Ex. 5 - Deliberative Process**
From: Vogel, Dana
Sent: Tue 7/19/2016 12:03:09 PM
Subject: Re: Workshop

Hi Janet
Anna and. Are pretty booked today. Does anytime Thursday work for you?

Sent from my iPhone

> On Jul 19, 2016, at 7:44 AM, Janet Collins **Ex. 5 - Deliberative Process** wrote:
>
> Dana- would it be possible to talk later today?
>
> Sent from my iPhone
>
>> On Jul 15, 2016, at 9:46 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:
>>
>> Hi Janet
>>
>> Anna is out this week but will be back on Monday. Maybe we could all do a call early next week?
>>
>> Dana
>>
>> -----Original Message-----
>> From: Janet Collins [mailto **Ex. 5 - Deliberative Process**
>> Sent: Wednesday, July 13, 2016 1:33 PM
>> To: Vogel, Dana <Vogel.Dana@epa.gov>
>> Subject: Workshop
>>
>> Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?
>>
>> Thanks
>>
>> Janet E Collins
>> CropLife America
>>
>> +1-202-833-4474
>>
>> Sent from my iPhone

To: Anna Lowit[Lowit.Anna@epa.gov]
From: Vogel, Dana
Sent: Mon 7/18/2016 12:40:37 PM
Subject: FW: Workshop

What works for you?
-----Original Message-----
From: Janet Collins [mailto: **Ex. 5 - Deliberative Process**
Sent: Friday, July 15, 2016 5:09 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Workshop

Thanks Dana. Perhaps you and/or Anna could recommend a couple of options and I could choose one that works for me as well.

Appreciate your getting back to me!

Have a good weekend.

Sent from my iPhone

> On Jul 15, 2016, at 10:46 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:
>
> Hi Janet
>
> Anna is out this week but will be back on Monday. Maybe we could all do a call early next week?
>
> Dana
>
> -----Original Message-----
> From: Janet Collins [mailto: **Ex. 5 - Deliberative Process**
> Sent: Wednesday, July 13, 2016 1:33 PM
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>
> Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?
>
> Thanks
>
> Janet E Collins
> CropLife America
>
> +1-202-833-4474
>
> Sent from my iPhone

To: Janet Collins Ex. 5 - Deliberative Process
From: Vogel, Dana
Sent: Fri 7/15/2016 2:46:26 PM
Subject: RE: Workshop

Hi Janet

Anna is out this week but will be back on Monday. Maybe we could all do a call early next week?

Dana

-----Original Message-----
From: Janet Collins [mailto: Ex. 5 - Deliberative Process
Sent: Wednesday, July 13, 2016 1:33 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Workshop

Dana- I have been trying to follow up with Ana Lowit about discussing a topic for potential future work. Do you have a few minutes to discuss a way forward?

Thanks

Janet E Collins
CropLife America

+1-202-833-4474

Sent from my iPhone

To: Housenger, Jack[Housenger.Jack@epa.gov]
From: Vogel, Dana
Sent: Tue 6/21/2016 5:20:00 PM
Subject: RE: Potential meeting with CLA leaders

Huh?

From: Housenger, Jack
Sent: Tuesday, June 21, 2016 1:13 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

EX. 5- Deliberative Process

From: Vogel, Dana
Sent: Tuesday, June 21, 2016 1:06 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: FW: Potential meeting with CLA leaders

EX. 5- Deliberative Process

Dv

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and

perhaps intention to update the Framework document.

These are ideas only- areas where we have been having discussions.

Is this possible? Tomorrow and Thursday are open—he/she could join for a discussion and stay for lunch if that would work.

Many thanks.

From: Janet Collins
Sent: Friday, June 17, 2016 7:53 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Re: Potential meeting with CLA leaders

Thank you Dana- I thought I sent you a response yesterday.

I am doing further checking with my CEO but have not yet heard from him.

Thank you

Sent from my iPhone

On Jun 15, 2016, at 9:15 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

> Hi Janet,
>
> Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: Potential meeting with CLA leaders

Dana- we often invite EPA leaders to participate in meetings of our Strategic Oversight Council. We have not invited HED in the past and would like- to invite you to participate as you are availability. The meeting is scheduled for next week (June 22 and 23). Is this possible to fit into your schedule (at the CLA offices).

Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Housenger, Jack[Housenger.Jack@epa.gov]
From: Vogel, Dana
Sent: Tue 6/21/2016 5:06:28 PM
Subject: FW: Potential meeting with CLA leaders

Are you ok with Jeff and/or Billy going to this? Given the topics, I'm a little hesitant.

Dv

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, June 21, 2016 11:27 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: RE: Potential meeting with CLA leaders

Dana- if possible, we would like to take you up on your offer of a colleague. Topics of interest are residues in drinking water, integration of epidemiologic study data into risk assessment, and perhaps intention to update the Framework document.

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Sent from my iPhone

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dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
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Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: janet collins[jcollins@croplifeamerica.org]
From: Vogel, Dana
Sent: Wed 6/15/2016 1:15:53 PM
Subject: RE: Potential meeting with CLA leaders

Hi Janet,

Unfortunately I am out of the office mo9st of next week and therefore not available to attend. Alternatively, I could have one of my HED Deputy Directors attend. Please let me know if that is something you feel would be useful.

Thanks,

dana

From: outlook_cd457caf49b8422f@outlook.com [mailto:outlook_cd457caf49b8422f@outlook.com] **On Behalf Of** janet collins
Sent: Wednesday, June 15, 2016 8:23 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
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Many thanks.

Janet E Collins, Ph.D., R.D.

CropLife America

+1-202-833-4474

Sent from Mail for Windows 10

To: Tamika Sims[tsims@croplifeamerica.org]
From: Vogel, Dana
Sent: Fri 11/6/2015 5:18:11 PM
Subject: RE: PPDC presentation question

Hi Tamika,

Thanks for your email. Great timing! We are currently in the process of putting together an OCSPP-wide document on how our office does systematic review. Once the document is approved, I am happy to share it with you and I believe the ultimate plan is to have it posted on the web. In the meantime, this document may be helpful→

The 2010 draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" includes two key components: problem formulation and use of the MOA/AOP frameworks, was reviewed favorably by the Science Advisory Panel (SAP) in 2010 (FIFRA SAP, 2010). The document was originally intended for use in human health risk assessment but the basic principles of problem formulation and MOA/AOP are also applicable to ecological risk assessment.

Thanks,

Dana

From: Tamika Sims [mailto:tsims@croplifeamerica.org]
Sent: Wednesday, November 04, 2015 2:29 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: PPDC presentation question

Hi Dana,

Hope you are well. Good to see you at the PPDC a couple of weeks ago. Even though I could not attend your presentation in person on October 21st, I was able to pick up a hard copy of the slides

while at EPA on the 22nd. I wanted to ask you about the 'Systematic Review' process employed by EPA (you reference it on slide 4), and of course we here about the Systematic Review process quite often. Could you point me in the direction of the documented methodology used by EPA?—I searched EPA website was not able to come up with it. I do see some things listed under the IRIS, but want to be sure I am reviewing the correct materials.

Thanks for any help you can provide.

Regards,

Tamika

Tamika D. Sims, PhD

Director, Human Health Policy

CropLife America

1156 15th Street N.W., Suite 400

Washington, DC 20005

Office: 202.872.3866

Cell: 404.610.6776

To: Housenger, Jack[Housenger.Jack@epa.gov]
From: Vogel, Dana
Sent: Tue 10/20/2015 11:35:58 AM
Subject: FW: Speaker for October HARC Face to Face meeting
Questions for Jim Cowles- HHRC F2F Oct 2015.docx
HHRC Agenda October 2015 F2F Meeting.doc

From: Cowles, James
Sent: Thursday, October 15, 2015 5:38 PM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Subject: FW: Speaker for October HARC Face to Face meeting

Dana-

I was invited to the CLA HHRC next week to discuss DW modeling. However, several of the questions are more HED oriented than EFED. Are you available to tag team this with me? Just want to share the fun.

Jim

From: Tamika Sims [mailto:tsims@croplifeamerica.org]
Sent: Thursday, October 15, 2015 2:59 PM
To: Cowles, James <Cowles.James@epa.gov>
Cc: Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Jim,

Thanks again for your time and agreeing to participate in our Committee meeting next week. Attached you will find the gathered questions from our CLA member company representatives

and also an agenda for the meeting.

As I mentioned, it would be good if you could come to the office by 2:50 or so. Also, will you be preparing slides for the meeting? If so, please email them to me by **Tuesday October 20, 2015** and I can have them uploaded on the meeting room laptop for an east transition into your presentation. If you will any other AV needs besides a laptop and projector, please let me know.

Please let me or Janet know if you have any questions or concerns. Looking forward to our discussions next week.

Best,

Tamika

Tamika D. Sims, PhD

Director, Human Health Policy

CropLife America

1156 15th Street N.W., Suite 400

Washington, DC 20005

Office: 202.872.3866

Cell: 404.610.6776

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Wednesday, October 14, 2015 4:50 PM
To: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Hi Tamika-

A little before 3 works. I look forward to seeing the questions.

Jim

From: Tamika Sims [mailto:tsims@croplifeamerica.org]
Sent: Wednesday, October 14, 2015 4:36 PM
To: Cowles, James <Cowles.James@epa.gov>; Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Subject: RE: Speaker for October HARC Face to Face meeting

Hello Jim,

Thanks for your flexibility. 3pm- 4pm will work fine. Can you come to the CLA office a little bit before 3 pm so we can get you settled in?

Also, I will deliver the review questions from the Committee to you early tomorrow in order for you to prepare for the meeting. Sorry for the delay.

Thanks!

Tamika

Tamika D. Sims, PhD

Director, Human Health Policy

CropLife America

1156 15th Street N.W., Suite 400

Washington, DC 20005

Office: 202.872.3866

Cell: 404.610.6776

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Tuesday, October 13, 2015 11:11 AM
To: Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Cc: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Hi Janet-

Does 3-4 pm on the 21st work for you?

Jim

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, October 05, 2015 10:47 AM
To: Cowles, James; Brady, Donald
Cc: Tamika Sims
Subject: RE: Speaker for October HARC Face to Face meeting

Jim- is there any way that we can shift this meeting with you until the afternoon? We have a conflict with another meeting going on at that time and want to have maximal attendance.

Thank you.

Janet

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Wednesday, September 30, 2015 4:40 PM
To: Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Cc: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

HI Janet-

I look forward to joining you on Oct 21. I have looked at my calendar and 11-12 works best for me. Generally when we meet with the ERAC we get specific questions ahead of time so we can better address the group. If HARC could get me specific questions by the 14th that would give me adequate time to follow-up with our staff.

Thanks

Jim

Jim Cowles, Ph.D.
Associate Director

Environmental Fate and Effects Division (EFED)

US Environmental Protection Agency
EFED
Office of Pesticide Programs
1200 Pennsylvania Ave NW,

Mail Stop: 7507P
Washington DC 20460

FedEx Only:
2777 South Crystal Drive
12th Floor

Suite S-12741
Arlington, VA 22202

P: 703-347-0285
E: cowles.james@epa.gov

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, September 29, 2015 5:47 PM
To: Brady, Donald
Cc: Tamika Sims; Cowles, James
Subject: Re: Speaker for October HARC Face to Face meeting

This is a great offer- should we connect directly with Jim?

Thank you Don (and Jim). We will set agenda according to your calendar needs.

Sent from my iPhone

On Sep 25, 2015, at 4:24 PM, "Janet Collins" <jcollins@croplifeamerica.org> wrote:

> Thanks very much Don—I will check to see what ERAC would prefer; I would like to accept your generous offer and then tap you next time.
>
> I will be back in touch asap.
>
> Have a great weekend—we are having our annual meeting here in Orlando- getting ready for afternoon showers.

Janet

From: Brady, Donald [mailto:Brady.Donald@epa.gov]
Sent: Friday, September 25, 2015 3:03 PM
To: Janet Collins <jcollins@croplifeamerica.org>
Cc: Tamika Sims <tsims@croplifeamerica.org>; Cowles, James <Cowles.James@epa.gov>
Subject: RE: Speaker for October HARC Face to Face meeting

I am traveling that week but we can get someone there, probably Jim Cowles. Sorry to be late responding, I was out of the office for 3 days. Let me know.

Director, Environmental Fate and Effects Divison

OPP, EPA

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, September 22, 2015 4:13 PM
To: Brady, Donald
Cc: Tamika Sims
Subject: Speaker for October HARC Face to Face meeting

Don- I am writing to see if you might be available to speak to the CLA Human Health Risk Assessment Committee at its upcoming meeting on October 21 in the CLA offices. The discussion would be about EPA's (EFED's) approach to drinking water assessments. As you know, we have a drinking water dietary assessment group and we also have a 'water' group in eco tox-- this would be focussing on the drinking water piece.

We have new staff person in the Human Health Policy position- Dr. Tamika Sims who joins use from the International Bottled Water Association- and I would like to introduce

you to her as well.

We can make anytime that works in your schedule fit into the agenda.

Many thanks

Janet

Sent from my iPad

To: Cowles, James[Cowles.James@epa.gov]
From: Vogel, Dana
Sent: Thur 10/15/2015 11:57:28 PM
Subject: Re: Speaker for October HARC Face to Face meeting

I think I can make it work. Just FYI I am meeting with Janet and a few others on Monday at py

Dana Vogel
Sent from my iPhone

On Oct 15, 2015, at 5:38 PM, Cowles, James <Cowles.James@epa.gov> wrote:

Dana-

I was invited to the CLA HHRC next week to discuss DW modeling. However, several of the questions are more HED oriented than EFED. Are you available to tag team this with me? Just want to share the fun.

Jim

From: Tamika Sims [mailto:tsims@croplifeamerica.org]
Sent: Thursday, October 15, 2015 2:59 PM
To: Cowles, James <Cowles.James@epa.gov>
Cc: Janet Collins <jcollins@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Jim,

Thanks again for your time and agreeing to participate in our Committee meeting next week. Attached you will find the gathered questions from our CLA member company representatives and also an agenda for the meeting.

As I mentioned, it would be good if you could come to the office by 2:50 or so. Also, will

you be preparing slides for the meeting? If so, please email them to me by **Tuesday October 20, 2015** and I can have them uploaded on the meeting room laptop for an east transition into your presentation. If you will any other AV needs besides a laptop and projector, please let me know.

Please let me or Janet know if you have any questions or concerns. Looking forward to our discussions next week.

Best,

Tamika

Tamika D. Sims, PhD

Director, Human Health Policy

CropLife America

1156 15th Street N.W., Suite 400

Washington, DC 20005

Office: 202.872.3866

Cell: 404.610.6776

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Wednesday, October 14, 2015 4:50 PM
To: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Hi Tamika-

A little before 3 works. I look forward to seeing the questions.

Jim

From: Tamika Sims [mailto:tsims@croplifeamerica.org]
Sent: Wednesday, October 14, 2015 4:36 PM
To: Cowles, James <Cowles.James@epa.gov>; Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Subject: RE: Speaker for October HARC Face to Face meeting

Hello Jim,

Thanks for your flexibility. 3pm- 4pm will work fine. Can you come to the CLA office a little bit before 3 pm so we can get you settled in?

Also, I will deliver the review questions from the Committee to you early tomorrow in order for you to prepare for the meeting. Sorry for the delay.

Thanks!

Tamika

Tamika D. Sims, PhD

Director, Human Health Policy

CropLife America

1156 15th Street N.W., Suite 400

Washington, DC 20005

Office: 202.872.3866

Cell: 404.610.6776

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Tuesday, October 13, 2015 11:11 AM
To: Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Cc: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

Hi Janet-

Does 3-4 pm on the 21st work for you?

Jim

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Monday, October 05, 2015 10:47 AM
To: Cowles, James; Brady, Donald
Cc: Tamika Sims
Subject: RE: Speaker for October HARC Face to Face meeting

Jim- is there any way that we can shift this meeting with you until the afternoon? We have a conflict with another meeting going on at that time and want to have maximal attendance.

Thank you.

Janet

From: Cowles, James [mailto:Cowles.James@epa.gov]
Sent: Wednesday, September 30, 2015 4:40 PM
To: Janet Collins <jcollins@croplifeamerica.org>; Brady, Donald <Brady.Donald@epa.gov>
Cc: Tamika Sims <tsims@croplifeamerica.org>
Subject: RE: Speaker for October HARC Face to Face meeting

HI Janet-

I look forward to joining you on Oct 21. I have looked at my calendar and 11-12 works best for me. Generally when we meet with the ERAC we get specific questions ahead of time so we can better address the group. If HARC could get me specific questions by the 14th that would give me adequate time to follow-up with our staff.

Thanks

Jim

Jim Cowles, Ph.D.
Associate Director

Environmental Fate and Effects Division (EFED)

<image001.png US Environmental Protection Agency
EFED
Office of Pesticide Programs
1200 Pennsylvania Ave NW,

Mail Stop: 7507P

FedEx Only:
2777 South Crystal Drive
12th Floor

Suite S-12741

P: 703-347-0285
E: cowles.james@epa.gov

Washington DC 20460 Arlington, VA 22202

From: Janet Collins [mailto:jcollins@croplifeamerica.org]
Sent: Tuesday, September 29, 2015 5:47 PM
To: Brady, Donald
Cc: Tamika Sims; Cowles, James
Subject: Re: Speaker for October HARC Face to Face meeting

This is a great offer- should we connect directly with Jim?

Thank you Don (and Jim). We will set agenda according to your calendar needs.

Sent from my iPhone

On Sep 25, 2015, at 4:24 PM, "Janet Collins" <jcollins@croplifeamerica.org> wrote:

> Thanks very much Don—I will check to see what ERAC would prefer; I would like to accept your generous offer and then tap you next time.
>
> I will be back in touch asap.
>
> Have a great weekend—we are having our annual meeting here in Orlando- getting ready for afternoon showers.
>
> Janet

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Director, Environmental Fate and Effects Divison

OPP, EPA

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We can make anytime that works in your schedule fit into the agenda.

Many thanks

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Sent from my iPad

<Questions for Jim Cowles- HHRC F2F Oct 2015.docx>

<HHRC Agenda October 2015 F2F Meeting.doc>