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.

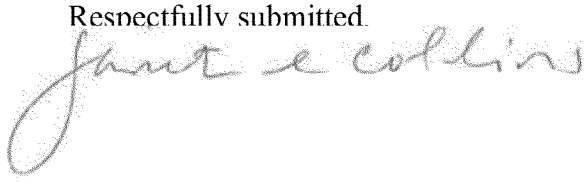
For all of these reasons, CLA respectfully requests that Dr. Infante be excluded from participation in the glyphosate SAP.

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.