August 24, 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: 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 supports a rigorous, science-based, and transparent process for government regulation of their member companies' 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 and the agricultural community.

On July 26, 2016, EPA published a notice [Federal Register (2016-17707)] of its intent to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("SAP") [EPA-HQ-OPP-2016-0385] 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] CLA members have significant concerns about the convening of the SAP on glyphosate given the extensive, scientifically-based risk assessments of the herbicide undertaken by regulators around the globe beginning with the EPA review and registration of glyphosate in 1974.

[1] 81 Fed. Reg. 48,794 (July 26, 2016).

A. Convening a Meeting of the FIFRA SAP to Review the Carcinogenicity of Glyphosate is Unnecessary and an Inappropriate Use of EPA Resources

For over 40 years, the EPA—and all other regulatory and scientific agencies worldwide that have reviewed glyphosate —have concluded that glyphosate does not pose a cancer risk to humans. This includes the European Commission, the Joint WHO/Food Agricultural Organization, Japan, and Australia.[2] In March 2015, however, after review of only a subset of the glyphosate data previously reviewed by these entities, the International Agency for Research on Cancer (IARC) concluded differently—finding that glyphosate is "probably carcinogenic to humans."[3] That conclusion spurred significant criticism from national regulators who responded that the evidence *did not* support IARC's conclusion. *See, e.g.*, European Food Safety Auth. (EFSA), *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 13 EFSA J. 4302 (Nov. 12, 2015) ("[G]lyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential . . . .").[4]

Moreover, within the past few months, two additional and significant reports have been published that provide the scientifically appropriate and valid rationale for immediate cancellation of the scheduled SAP. The most recent report of the FAO/WHO Special Session of the JMPR, "Pesticides in Food 2016," in its in-depth review found that glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.[5] This expert meeting was called specifically to assess the differences in reported human health effects (carcinogenicity,

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2 *See, e.g.*, 78 Fed. Reg. 25,396 (May 1, 2013); Scitox Assessment Servs., *A Review of the Eart Open Source (EOS) Report "Roundup and Birth Defects: Is the Public Being Kept in the Dark?"* (July 2013), http://archive.apvma.gov.au/news_media/docs/glyphosate_scitox_review_july_2013.pdf; European Comm'n, Directive 6511/VI/99, *Report for the Active Substance Glyphosate* (Jan. 21, 2002), http://ec.europa.eu/food/fs/ph_ps/pro/eva/existing/list1_glyphosate_en.pdf; *Report of Evaluation by Food Sanitation Council Agricultural Chemicals Residue Committee*, 50 Shokuhin Eisei Kenkyu, No. 8 (2000); WHO/FAO, *Pesticides Residues in Food* 145 (2011), http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report11/Glyphosate.pdf.

3 Int'l Agency for Research on Cancer, WHO, *Glyphosate*, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 112 (2015), http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf .

4 *See also* Pest Mgmt. Regulatory Agency, Health Canada, *Proposed Re-evaluation Decision PRVD2015-01, Glyphosate* (Apr. 13, 2015), http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2015-01/prvd2015-01-eng.php (overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk); Ger. Fed. Inst. for Risk Assessment, *Does Glyphosate Cause Cancer?* (Mar. 23, 2015), http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf. ("[T]he Federal Institute for Risk Assessment (BfR) was responsible for the human health risk assessment and *has assessed glyphosate as non-carcinogenic*. This was supported by competent national, European and other international institutions for health assessment including the WHO/FAO Joint Meeting on Pesticide Residues (JMPR).)"; New Zealand Environmental Protection Agency, *Review of the Evidence Relating to Glyphosate and Carcinogenicity* (Aug. 11, 2016), http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf (overall weight of evidence indicates that glyphosate is unlikely to be carcinogenic); Japanese Food Safety Comm'n, http://www.fsc.go.jp/fsciis/meetingMaterial/show/kai20160324no1.

5 FAO/WHO. *Pesticides in Food 2016: Special session of the Joint FAO/WHO meeting on pesticide residues*. FAO Plant Production and Protection Paper: 227. Rome, August 2016.

genotoxicity, and mutagenicity) between historic JMPR expert assessments of glyphosate and those reported by the WHO International Agency for Research on Cancer (IARC) in 2015.[6] The experts reporting in the global report determined that glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.

Even more recently, regulators of the Environmental Protection Authority of New Zealand concluded, "based on a weight of evidence approach, taking into account the quality and reliability of the available data, glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification under HNSO as a carcinogen or mutagen."[7]

The rationale for convening this FIFRA SAP is not the need for more or better data; nor is it the submission of a greater set of animal and *in vitro* data from Part 158-required analyses. In fact, it is clear from the 2015 report of the EPA Cancer Assessment Review Committee (CARC) Report that EPA has no further questions as to the carcinogenicity of glyphosate.[8] EPA rationale for convening the SAP is that it contends there is a need for review of new data that was not available during its previous reviews of glyphosate safety data, and that based on the conclusions of the IARC 2015 glyphosate Monograph 112, more careful review of existing epidemiologic data is needed. However, as recently as October 2015 (months following the publication of the IARC Monograph), the CARC reported, "the epidemiological studies in humans showed no association between glyphosate exposure and cancer of the following: oral cavity, esophagus, stomach, colon, rectum, colorectum, lung, pancreas, kidney, bladder, prostate, brain (gliomas), soft-tissue sarcoma, leukemia or multiple myelomas." What is new for EPA consideration from what was concluded by EPA's own CARC in October 2015?

There is no scientific justification for another EPA review of glyphosate for carcinogenicity when the EPA CARC report of October 2015 found no concerns as to potential carcinogenicity. The EPA must be clear about any further study- and specific about its hypothesis as to what might be an impact that is yet to be considered. The absence of the usual precedent step to convening an SAP—an EPA CARC finding of some concern—raises questions as to the motivation undergirding EPA's intent to reconsider (once again) its previous findings and conclusions.

What's more, the ability of EPA to gather scientists more qualified than those engaged by FAO/WHO and the JMPR to once again review the scientific literature is unlikely. The Notice to convene the FIFRA SAP on glyphosate invites nominations of candidates to serve as *ad hoc* members of FIFRA SAP, which is to convene October 18, 2016 through October 21, 2016 (the "October 2016 meeting").

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6 World Health Organization. 2015. International Agency for Research on Cancer, Monograph on Glyphosate. Volume 112. Geneva Switzerland.

7 New Zealand Environmental Protection Agency, *Review of the Evidence Relating to Glyphosate and Carcinogenicity* (Aug. 11, 2016), http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf (overall weight of evidence indicates that glyphosate is unlikely to be carcinogenic).

8 EPA. Office of Chemical Safety and Pollution Prevention 2015. Glyphosate: Report of the Cancer Assessment Review Committee. October 1 2015, Washington DC.

EPA is legally obligated to exclude industry members whose conflicts of interest and established biases preclude their ability to impartially contribute to the panel's final report, conclusions of which likely will inform regulatory determinations in the near term. CLA therefore opposes the selection of any *ad hoc* members who have already made a determination regarding the carcinogenic potential of glyphosate.

B. 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.[9] EPA must ensure that the FIFRA SAP acts "in the public interest,"[10] and does not contain members with inappropriate special interests.[11] 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."[12]

Historically, EPA has placed a premium on expertise, knowledge and experience in the field when selecting members for its advisory committees.[13] The EPA SAP office has adopted conflict of interest 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."[14] If a conflict exists between a panel candidate's private financial interests and duties as a panel member, EPA will, as a rule, seek to appoint another candidate instead.[15] Grounds for exclusion from a committee include performing consulting activities or providing expert testimony regarding an issue relating to that presented before the SAP.[16] Potential ad hoc members may also be excluded based on, *inter alia*, experience with the topic under consideration that suggests an established position or implicates an inability to render

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9 *See* 5 U.S.C. App. II, § 3(2).

10 S*ee id*. App. II, § 9(a)(2).

11 *See id.* § 5(b)(3).

12 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 [hereinafter "*Overview of Panel Formation*"]; *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).

13 *Overview of Panel Formation*, *supra* note 12, at 9 (listing "[e]xpertise, knowledge, and experience" as "primary factors that determine whether an individual is invited to serve on an SAB Panel").

14 *See* EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* (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.

15 *See Overview of the Panel Formation*, *supra* note 12, at 9-10.

16 *See Panel Formation Process for the EPA FIFRA SAP*, *supra* note 14, at 5-8.

impartial advice; evidence of partial "public statements on the issue"; and, evidence of financial conflicts of interest.[17]

The inclusion of scientists who are not impartial—or who have lost their appearance of impartiality—is counter to EPA's goal of assembling a panel of experts to provide sound, independent, and useful scientific and technical advice.[18] EPA therefore should not appoint to the FIFRA SAP any person who has publicly expressed an opinion regarding the carcinogenicity of glyphosate.

C. Representatives Who Are Not Impartial Must Not Participate as Ad Hoc Members of the FIFRA SAP

The IARC process and subsequent events revealed the pre-formed conclusions and conflicts of interest of several scientists with respect to the evaluation of the carcinogenic potential of glyphosate. By way of example, 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.[19] Dr. Christopher Portier served as the "technical advisor" to the IARC glyphosate review panel, and following publication of the IARC monograph, sought to induce regulatory agencies worldwide to adopt IARC's conclusions by undertaking a publicity campaign using letter-writing initiatives, articles and publications, and direct advocacy before regulatory bodies.[20] Dr. Portier has regularly engaged in policy advocacy against glyphosate since IARC's findings were published.[21]

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17 *See id.* at 5-8, 10-14.

18 *See* EPA Sci. Advisory Bd., *supra* note 12, at 9.

19 *See, e.g.*, David Zaruck & Julie Kelly, *'The Facebook Age of Science' at the World Health Organization*, Nat'l Review (May 3, 2016), http://www.nationalreview.com/article/434845/WHO-cancer-agency-bad-science-labels-glyphosate-probably-carcinogenic.

20 As one example, Mr. Portier pleaded with the European Food Safety Authority ("EFSA") to rethink their own findings that glyphosate does not "pose a carcinogenic hazard to humans." Christopher Portier et al., *Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR*, (Nov. 27, 2015) *available at* http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf [hereinafter "*Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR*"]. *See also* Christopher Portier et al., *Difference in the Carcinogenic Evaluation of Glyphosate Between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, J. Epidemiol Community Health (2016) [hereinafter "*Differences Study*"].

21 In speaking to the Soil Association, for instance, Mr. Portier exaggerated the findings of the IARC report, stating that "Glyphosate is definitely genotoxic. *There is no doubt in my mind*." Curt DellaValle, *Monsanto's GMO Weed Killer Damages DNA*, AgMag (July 17, 2015), http://www.ewg.org/agmag/2015/07/monsanto-s-gmo-weed-killer-damages-dna; *see also* Sustainable Pulse, *WHO Cancer Expert: Glyphosate is Definitely Genotoxic* (July 15, 2015) http://sustainablepulse.com/2015/07/15/who-cancer-expert-glyphosate-is-definitely-genotoxic/. Tellingly, Mr. Portier himself questioned his impartiality with respect to the matter in question. In response to a question about his work with EDF and his research into glyphosate, Mr. Portier responded, "I agree that this has the appearance of being a conflict of interest." Kate Kelland, *How the World Health Organization's Cancer Agency Confuses Consumers*, Reuters (Apr. 18, 2016), http://www.reuters.com/investigates/special-report/health-who-iarc/.

Drs. Guyton and Portier serve as only two examples of scientists with disqualifying biases for the purposes of appointment to the FIFRA SAP October panel. No scientist who has authored or contributed to the IARC monograph or who has advocated to the European Union that IARC's review is superior to that of other regulatory bodies[22] should participate in EPA's upcoming review of glyphosate's carcinogenicity.

Nor should the FIFRA SAP include those individuals who have made "written or oral public statements indicating the candidate has already formed a position on the topic."[23] Such individuals include signatories to the "Stop Glifosate" initiative[24] and authors of "Concerns Over Use of Glyphosate-based Herbicides and Risks Associated with Exposures: A Consensus Statement."[25] The bias born of expressing a public conclusion on a scientific topic compromises the ability of these individuals to deliver dispassionate, determinative scientific analysis and advice to EPA.

Finally, the FIFRA SAP should also exclude scientists who have a direct stake in final determinations of the FIFRA SAP on this issue.[26] Scientists with a profit motivation that could be affected by the outcome of this process may seek to downplay the toxic effects of glyphosate on human health and well-being, or conversely, overemphasize or focus solely upon the benefits of glyphosate, consistent with the well-being of an employer. For example, Dr. Portier serves as an expert in litigation on behalf of plaintiffs who argue that glyphosate causes cancer.[27] Dr. Portier therefore has a direct profit motivation in the outcome of the FIFRA SAP deliberations.

It is EPA's charge to ensure the credibility of its determinations, particularly where the question regards a topic of great interest to the public health and environmental community. The work of the ad hoc panel members in this October 2016 meeting of the FIFRA SAP will be critical to the determinations of the panel. Accordingly, EPA should reject any nominees who have any direct or potential conflicts of interest or industry bias, or offer the appearance of partiality, on the question of the carcinogenicity of glyphosate.

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22 *See, e.g., Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR, supra* note 20.

23 *See Panel Formation Process for the EPA FIFRA SAP, supra* note 14, at 16.

24 *See Stop Glifosato*, http://www.stopglifosato.it/ (last visited Aug. 11, 2016). The StopGlifosate campaign began in 2015. The campaign's signatories and supporters, such as Italy's Ramazzini Institute, publically endorse the IARC's challenged classification of glyphosate as "likely carcinogenic" to humans. *Id.*

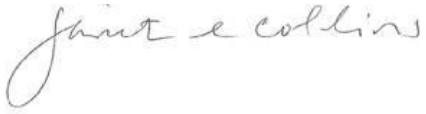
25 Myers et al. "Concerns Over Use of Glyphosate-based Herbicides and risks Associated with Exposures: A Consensus Statement," 15 Envtl. Health, no. 19 (2016).

26 This is consistent with the advice of the National Academies, which has stated "it is essential that the work of committees … not be compromised by issues of bias and lack of objectivity … . Questions of lack of objectivity and bias ordinarily relate to views, statements, or positions taken that are largely individual with a particular point of view or the positions or perspectives of a particular group." Nat'l Acad. of Scis., *Policy on Committee Composition and Balance and Conflicts of Interest* 4 (2003).

27 *See Differences Study, supra* note 20, at p. 4 ("Competing interests").

Thank you for your consideration of these comments.

Respectfully submitted,



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Cc: Mr. Steven Knott