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.

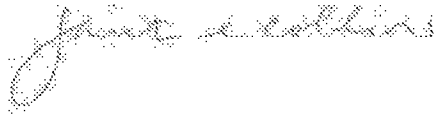
would the Agency insert leading questions about potential carcinogenicity of an ingredient in a formulation apart from the active ingredient?

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.