



February 23, 2018

Tamue L. Gibson, Designated Federal Official
Office of Science Coordination and Policy (7201M)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Submitted via Electronic Mail to gibson.tamue@epa.gov and via Regulations.gov; Docket ID: EPA-HQ-OPP-2017-0602

RE: Nominations: FIFRA Scientific Advisory Panel; Nominations to the FIFRA Scientific Panel; Request for Comments; Notice; Docket ID No. EPA-HQ-OPP-2017-0602; 83 FR 3702; Jan. 26, 2018.

Dear Ms. Gibson:

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 action, and litigation that impact 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 January 26, 2018, EPA published notice in the federal register nominating 17 individuals for potential selection for a three-year term on the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) Scientific Advisory Panel (“SAP”).¹ The notice invites public comments on the 17 individuals currently nominated, which the Agency stated will “be used to assist the Agency in selecting the new chartered Panel members.” CLA appreciates the opportunity to comment on this process.

Under FIFRA, the SAP serves in an advisory role and provides “comments on the impact of pesticides on human health and the environment” of registrations being considered by EPA.² All final decision-making authority under FIFRA rests with EPA. EPA is legally obligated to exclude scientists from the SAP whose conflicts of interest or established biases would preclude

¹ FIFRA Scientific Advisory Panel; Nominations to the FIFRA Scientific Advisory Panel; Request for Comments, 83 Fed. Reg. 3702 (Jan. 26, 2018); FIFRA § 25(d).

² *Id.*

their ability to act impartially.³ CLA therefore respectfully opposes the nomination of Dr. Beate Ritz, who is currently serving as plaintiffs' expert in the *In re Roundup Products Liability Litigation*, 16-md-02741-VC (hereinafter "Roundup[®]/glyphosate litigation") and thus has a direct substantial disqualifying financial bias, as well as Dr. Weihseh Chiu, whose patent biases should disqualify him from service on the SAP.

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

The Federal Advisory Committee Act ("FACA") imposes strict conflict of interest requirements on the SAP selection process. EPA must ensure that the SAP acts "in the public interest," and does not contain members with inappropriate special interests. To meet the requirements established by FACA, the SAP shall be composed of impartial experts capable of providing independent review. 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."⁴

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.⁵ Grounds for exclusion include performing consulting activities or providing expert testimony regarding an issue relating to that presented before the SAP.⁶ Members may also be excluded if they have taken a position that suggests an established position or implicates an inability to render impartial advice such as public statements on the issue and evidence of financial conflicts of interest.⁷

Dr. Ritz's Biases Should Disqualify Her from Being Selected to Serve on the SAP

EPA's ethical rules should preclude Dr. Ritz from being one of the nominees selected to the SAP, which has three-year terms for each of the panelists. Dr. Ritz is currently serving as one of plaintiffs' epidemiology experts in the Roundup[®]/glyphosate litigation. Dr. Ritz was retained as an expert by plaintiffs at least by August 2016 and has been serving as their expert ever since. In the Roundup[®]/glyphosate litigation, the plaintiffs allege that glyphosate-based

³ 5 C.F.R. § 2635. See also FIFRA Scientific Advisory Panel, 83 Fed. Reg. at 3703 (stating that "[p]anel members are subject to the provisions of 5 CFR part 2635, Standards of Ethical Conduct for Employees of the Executive Branch, which include rules regarding conflicts of interest.").

⁴ 5 C.F.R. § 2635.501(a)(2016); see also EPA Science Advisory Board, Office of the Administrator, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* at 9-10 (Sept. 2002) ("EPA Overview"), [https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/\\$File/ec02010.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf).

⁵ EPA Overview at 9-10, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/\\$File/ec02010.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf).

⁶ EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* at 5-8 (Sept. 16, 2004), https://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf.

⁷ *Id.* at 10-14 ("Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias.").

herbicides (“GBHs”) caused them to develop non-Hodgkin’s lymphoma (“NHL”). Glyphosate is a broad-based herbicide and is regulated by FIFRA. Glyphosate is also currently undergoing re-registration review by the EPA and the interim registration review decision for glyphosate is expected to be published in 2019.⁸ To date, Dr. Ritz has made over \$90,000 serving as an expert in the Roundup®/glyphosate litigation, an amount that will increase as the litigation moves forward. The financial benefit alone that Dr. Ritz is currently receiving by serving as an expert for the plaintiffs in the Roundup®/glyphosate litigation should preclude Dr. Ritz from serving as a panel member of the SAP as she has a direct profit motivation regarding at least one herbicide that is regulated by FIFRA.⁹

In addition to Dr. Ritz’s considerable financial bias from serving as plaintiffs’ expert in the Roundup®/glyphosate litigation, Dr. Ritz would be severely conflicted in any future analysis of glyphosate by the SAP because her decisions on such issues would have a direct impact on her clients in the ongoing litigation. Moreover, because many of the epidemiologic studies Dr. Ritz is addressing in her role as a plaintiffs’ expert – such as the Agricultural Health Study – present analyses as well on a large number of other pesticides regulated under FIFRA, this conflict would extend well beyond GBHs and preclude her from providing unbiased opinions on virtually any pesticide epidemiology. Dr. Ritz is also a member of Collegium Ramazzini,¹⁰ which has taken radical anti-pesticide positions, such as calling for 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. Ritz’s participation on the SAP would be a direct conflict of interest due to her serving as plaintiffs’ expert in the Roundup®/glyphosate litigation.

For these reasons, CLA respectfully requests that Dr. Ritz not be selected to serve on the SAP for a three-year term.

Dr. Chiu’s Biases Should Disqualify Him from Being Selected to Serve on the SAP

EPA’s ethical rules should also preclude Dr. Chiu from being one of the nominees selected to the SAP. Although the evidence of bias is not as clear for Dr. Chiu as it is for Dr. Ritz, Dr. Chiu has several ties that suggest he may already have pre-formed conclusions with respect to the agents regulated by FIFRA. Dr. Chiu has served as a member of several International Agency for Research on Cancer (“IARC”) panels, including IARC monograph 113 evaluating 2,4-D (currently undergoing re-registration review),¹² lindane, and DDT.

⁸ EPA, *EPA Releases Draft Risk Assessments for Glyphosate* (Dec. 18, 2017), <https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate>.

⁹ 5 C.F.R. § 2635.402.

¹⁰ See *Fellows*, Collegium Ramazzini, <http://www.collegiumramazzini.org/fellows.asp>.

¹¹ See Collegium Ramazzini Statement, *The Control of Pesticides in the European Union: A Call for Action to Protect Human Health at 2* (2008), [http://www.collegiumramazzini.org/download/13_thirteenthcrstatement\(2008\).pdf](http://www.collegiumramazzini.org/download/13_thirteenthcrstatement(2008).pdf).

¹² IARC’s classification of 2,4-D overall was 2B, possibly carcinogenic to humans. Subgroup 4 on mechanisms, of which Dr. Chiu was subgroup chair, found there was strong evidence that 2,4-D induces oxidative stress, a mechanism that can operate in humans, and moderate evidence that 2,4-D causes immunosuppression, based on *in*

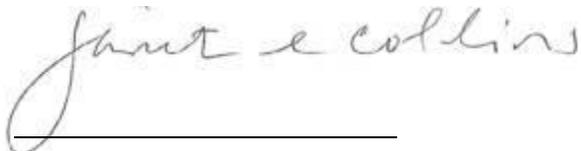
Accordingly, Dr. Chiu may be called upon to make decisions as a member of the SAP that would require him to assess the validity or correctness of decisions he previously reached for IARC. Dr. Chiu also has close professional ties to Dr. Kathryn Guyton, Dr. Ivan Rusyn, Dr. Lauren Zeise, and Dr. Vince Cogliano, listing these scientists as professional references.¹³ CLA previously wrote to the SAP about Dr. Guyton's anti-glyphosate position in August 2016.¹⁴

In addition to including several individuals who have taken anti-glyphosate positions as professional references, Dr. Chiu has published extensively with Dr. Guyton, Dr. Rusyn, and Dr. Martin (each of whom served on the IARC working group that reached carcinogenicity classifications for glyphosate, malathion, diazinon, parathion, and tetrachlorvinphos).¹⁵ Many of these papers involve using short-term mechanistic data to reach risk assessment conclusions.¹⁶ Finally, Dr. Chiu chaired a National Toxicology Program panel on perfluorooctanoic acid ("PFOA") or perfluorooctane sulfonate ("PFOS"), which found that "PFOA and PFOS are . . . an immune hazard to humans based on a high level of evidence from animal studies that PFOA and PFOS suppressed the antibody response and a moderate level of evidence from studies in humans."¹⁷ Again, these previously announced positions would create an intractable appearance of impropriety and would present unavoidable conflicts of interest in future work as a member of the SAP.

For these reasons, CLA respectfully requests that Dr. Chiu not be selected to serve on the SAP for a three-year term.

Thank you for your consideration of these comments. Should you have specific questions regarding the comments, please contact me directly by email (jcollins@croplifeamerica.org) or by telephone 202.833.4474).

Respectfully submitted,



vivo and *in vitro* studies. IARC, *IARC Monographs Evaluate DDT, Lindane, and 2,4-D*, https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr236_E.pdf.

¹³ Curriculum Vitae of Weihsueh A. Chiu (Nov. 2016) ("Chiu CV"), available at: <https://vetmed.tamu.edu/common/directory/CV/WChiu.pdf>.

¹⁴ Letter from Janet E. Collins, Senior Vice President, Science and Regulatory Affairs, to Steven Knott, Designated Federal Official, EPA Office of Science Coordination and Policy (Aug. 24, 2016) (Docket ID No. EPA-HQ-OPP-2016-0385).

¹⁵ See IARC, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, List of Participants*, <https://monographs.iarc.fr/ENG/Meetings/vol112-participants.pdf>. Dr. Rusyn and Dr. Zeise served as members of the working group and Dr. Guyton was one of the IARC Secretariats for Working Group 112.

¹⁶ See Chiu CV, *supra* note 13.

¹⁷ National Toxicology Program, *Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid (PFOA) or Perfluorooctane Sulfonate (PFOS)*, <https://ntp.niehs.nih.gov/pubhealth/hat/noms/pfoa/index.html>.

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cc: Mr. Steven Knott