



Ms. Gina McCarthy, Administrator
Environmental Protection Agency
Docket Center (EPA/ DC), (28221)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

December 12, 2016

RE: Scientific Advisory Panel meeting on glyphosate's carcinogenic potential
Docket ID: EPA-HQ-OPP-2016-0385

Dear Administrator McCarthy,

The Center for Food Safety urges you to promptly reinstate Dr. Peter Infante to the Science Review Board of the FIFRA Scientific Advisory Panel (SAP) formed to assess the carcinogenic potential of the herbicide glyphosate. Dr. Infante is a highly regarded epidemiologist with a long record of public service, including a stint on an EPA advisory board, who possesses the technical expertise to assess glyphosate's carcinogenic potential. The EPA dismissed Dr. Infante only after duly appointing him to the SAP, in response to pressure from a special interest, the pesticide industry lobby group CropLife, in violation of the Federal Advisory Committee Act. Not only would his presence on the Panel contribute to a rigorous and high-quality evaluation of glyphosate's carcinogenic potential, his dismissal gives the appearance of a lack of impartiality, compromising the credibility of the Panel's advice and recommendations.

We applaud EPA's decision to convene a Scientific Advisory Panel to assess the carcinogenicity of glyphosate. Glyphosate was recently classified as "probably carcinogenic to humans" by the World Health Organization's International Agency for Research on Cancer (IARC),¹ the world's premier authority on carcinogenic agents. Almost 100 medical and public health scientists endorsed IARC's assessment,² while Monsanto and other pesticide companies dispute it.

Scientific Advisory Panels are groups of independent scientists the EPA convenes to provide expert advice on particular issues. EPA has a well-established protocol for appointment of Science Review Board members to SAPs to ensure that they meet high

¹ Guyton KZ et al. (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *Lancet Oncology* 16: 490-491; International Agency for Research on Cancer (2015). *Glyphosate Monograph, Volume 112*, World Health Organization, Lyon, France.

<http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf>.

² Portier CJ et al. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). *Journal of Epidemiology and Community Health* 70(8): 741-745.

NATIONAL HEADQUARTERS

660 Pennsylvania Avenue, SE, Suite 302
Washington, D.C. 20003
T: 202-547-9359 F: 202-547-9429

CALIFORNIA OFFICE

303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: 415-826-2770 F: 415-826-0507

PACIFIC NORTHWEST OFFICE

917 SW Oak Street, Suite 300
Portland, OR 97205
T: 971-271-7372 F: 971-271-7374

HAWAII OFFICE

1132 Bishop Street, Suite 2107
Honolulu, Hawaii 96813
T: 808-681-7688

standards of technical expertise, and are free from conflicts of interest.³ EPA staff determine the areas of expertise needed on the Panel; solicit nominations from the public and various stakeholders; then interview prospective members, review their CVs and published literature, and screen them for potential conflicts of interest. The glyphosate SAP roster, including Dr. Peter Infante, was announced on October 4th. On October 12th, the pesticide lobby group CropLife sent a letter to EPA requesting that Dr. Infante be dismissed. Just two days later, EPA took the unusual step of postponing the meeting, originally scheduled for October 18th to 21st.⁴ EPA announced a new Panel roster that excluded Dr. Infante on November 15th. He was the only Panel member dismissed, though five new members were appointed. The rescheduled meeting is to take place December 13th to 16th.

We protest the dismissal of Dr. Infante. An epidemiologist with extensive experience in chemical carcinogenesis, he is eminently qualified to serve on the SAP (see Appendix). In 24 years at the Occupational Safety and Health Administration (OSHA), Dr. Infante played a major role in assessing cancer risks and developing safety standards for exposure of workers to toxic substances such as asbestos, benzene and lead. His positions at OSHA included Director of the Office of Carcinogen Identification and Classification. In three years at the National Institute for Occupational Safety and Health, he conducted epidemiology studies on a number of workplace carcinogens. Dr. Infante's expertise has been recognized by the many U.S. and international bodies that have engaged his services as a cancer expert. These include the U.S. National Toxicology Program, the World Trade Organization, and the International Agency for Research on Cancer. The EPA itself previously appointed Dr. Infante to its Science Advisory Board Chemical Assessment Advisory Committee. Dr. Infante has testified before Congress many times regarding causes of cancer and chemical pollution.

EPA standards for serving as Scientific Review Board members on FIFRA Scientific Advisory Panels are quite clear. The primary selection criterion is "technical and scientific expertise and experience." The other criteria are "availability and willingness to serve," "scientific credibility and independence," and "lack or absence of conflict of interest."⁵ Dr. Infante meets these criteria, as demonstrated by EPA's initial appointment of him. EPA has not provided any explanation for its dismissal of Dr. Infante, and refused to respond to a press inquiry on the matter,⁶ despite its avowed commitment "to have the panel formation process transparent to the public so they can understand and participate in the process."⁷

³ EPA (2004). Information on the Panel Formation Process for the EPA FIFRA Scientific Advisory Panel. Environmental Protection Agency, revised 9/16/04. https://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf.

⁴ Gillam C (2016). EPA bows to chemical industry in delay of glyphosate cancer review. Huffington Post, 10/19/16. http://www.huffingtonpost.com/carey-gillam/epa-bows-to-chemical-indu_b_12563438.html.

⁵ EPA (2004), op. cit., p. 4.

⁶ Martyn A (2016). Pesticide industry blackballs leading researcher from safety review panel. Consumer Affairs, 11/21/16. <https://www.consumeraffairs.com/news/pesticide-industry-blackballs-leading-researcher-from-safety-review-panel-112116.html>.

⁷ EPA (2004), op. cit., p. 2.

CropLife raised several objections to Dr. Infante's appointment in its October 12th letter,⁸ to which Dr. Infante ably responded.⁹ These include criticisms of Dr. Infante's expert testimony in a case involving an association between a worker's exposure to benzene and development of acute myeloid leukemia. The scientific community has reached consensus on benzene exposure as a cause of acute myeloid leukemia.¹⁰ This is evidenced by an amicus brief to the court, authored by 60 scientists, in support of Dr. Infante's testimony.¹¹ CropLife also objects to Dr. Infante's expert testimony in several cases involving vinyl chloride exposure and liver and biliary cancer that happened to involve Monsanto as a defendant. Vinyl chloride has been known to induce angiosarcoma of the liver since 1974, and like benzene is classified as carcinogenic to humans (Group 1) by IARC.¹² Dr. Infante's testimony in past cases is clearly not a conflict of interest and does not compromise his fitness to serve on this SAP.

CropLife also attempts to discredit Dr. Infante for his membership in an independent international scientific association (Collegium Ramazzini) that issued a statement calling on the European Union to control pesticides to better protect human health. The statement included a call for legislation to prohibit pesticide use in public areas, hospitals and health care facilities. This recommendation is in agreement with numerous other efforts by scientists and physicians to better protect people from pesticidal harms. For instance, fifteen state and federal public health scientists reported on illnesses from exposure to registered pesticides at schools, and called for a prohibition on pesticide spraying in buffer zones around schools, among other exposure reduction measures.¹³ In 2012, the American Academy of Pediatrics issued a statement on Pesticide Exposure in Children that describes numerous pesticide-related health risks and called for "regulatory action on pesticides" to "reduc[e] problematic exposures."¹⁴ In any case, Dr. Infante was not involved in any of the Collegium's discussions of or positions on pesticide issues.

CropLife's major objection appears to be Dr. Infante's skepticism with regard to the quality and objectivity of industry-sponsored studies, as expressed in statements he was quoted as

⁸ Letter from Janet E. Collins, Senior Vice President of Science and Regulatory Affairs, CropLife, to Steven M. Knott, Designated Federal Official, Office of Science and Coordination Policy, EPA, October 12, 2016.

⁹ Letter from Dr. Peter Infante to Steven Knott, Designated Federal Official, Office of Science and Coordination Policy, EPA, October 21, 2016. <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0439>.

¹⁰ Benzene has been classified by IARC as carcinogenic to humans (Group 1) since at least 1987, see: <http://www.inchem.org/documents/iarc/suppl7/benzene.html>.

¹¹ See Amicus Brief in Burst Case 11/15/2015, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0439>.

¹² Wagoner JK (1983). Toxicity of vinyl chloride and poly(vinyl chloride): a critical review. *Environmental Health Perspectives* 52: 61-66; for IARC's classification, see Baan R et al. (2009). A review of human carcinogens – Part F: Chemical agents and related occupations. *Lancet Oncology* 10: 1143-1144.

¹³ Alarcon WA et al. (2005). Acute illnesses associated with pesticide exposure at schools. *JAMA* 294: 455-465.

¹⁴ American Academy of Pediatrics. Policy Statement: Pesticide Exposure in Children. *Pediatrics* 130(6): e1757-e1763. <http://pediatrics.aappublications.org/content/early/2012/11/21/peds.2012-2757>.

making in a book. CropLife maintains that these statements demonstrate that Dr. Infante is not capable of impartially assessing the evidence of glyphosate's carcinogenicity. We strongly disagree.

First, CropLife presents no evidence that Dr. Infante has "stated a position on the particular matter being reviewed" – the carcinogenicity of glyphosate – which would be grounds for disqualification.¹⁵ Dr. Infante likewise states unequivocally that he has no special interest in and has not formed any opinion on the health effects of glyphosate. Nor has he testified in any legal or regulatory proceedings, nor worked on behalf of industry, regarding glyphosate.

Second, skepticism with regard to industry-sponsored studies falls under the head of a "point of view" – and EPA does not choose or exclude SAP candidates based on their viewpoints, but rather on their technical expertise.¹⁶ In any case, most independent scientists who have studied the potential harms and regulation of chemicals would agree that one should view industry-sponsored studies with considerable skepticism, given inherent conflicts of interest. There is abundant evidence to support Dr. Infante's skeptical viewpoint in this regard.¹⁷

Third, Dr. Infante's expertise is in human epidemiology, and all of the epidemiology studies of glyphosate to be evaluated by this SAP were conducted by government or university scientists, not by or for pesticide firms. Thus, even if one were to regard Dr. Infante's skeptical point of view regarding industry studies as problematic, it would have no bearing on the objectivity of his technical evaluation of human epidemiology on glyphosate. Any

¹⁵ See EPA (2004), op. cit., p. 2: "Board members offer technically and scientifically sound, independent peer review, and have not previously ... stated a position on the particular matter being reviewed."

¹⁶ See EPA (2004), op. cit., p. 2: "The FIFRA SAP is chartered to provide expert scientific advice. This charter distinguishes the FIFRA SAP from representative advisory committees that exist to provide advice related to stakeholder viewpoints. Thus, *FIFRA SAP participation is balanced based on the function of the technical expertise required, not by various stakeholders' points of view.*" (italics added for emphasis)

¹⁷ There is a vast literature on and innumerable examples of industrial concerns conducting fraudulent science, and/or sponsoring campaigns to undermine independent science that reflects adversely on their products. For tobacco industry misinformation as the model for subsequent industry obfuscation efforts, see Michaels D (2008). *Doubt is Their Product*. Oxford University Press, 2008. Concerning how industry funding of studies on atrazine and bisphenol A correlates with "no adverse effects" findings where independent science finds harms, see Rohr & McCoy (2010). Preserving environmental health and scientific credibility: a practical guide to reducing conflicts of interest. *Conservation Letters* 3: 143-150, and vom Saal and Hughes (2005). An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment. *Environmental Health Perspectives* 113(8): 926-933. Regarding the falsification of over 1,000 animal studies conducted by Industrial Bio-Test Laboratories under contract with Monsanto and other companies that were submitted to EPA and FDA in support of pesticide and drug product "safety," see Schneider K (1983). *Faking It: The Case Against Industrial Bio-Test Laboratories and IBT – Guilty: How Many Studies are No Good? Originally published in The Amicus Journal (1983), now available at http://planetwaves.net/contents/faking_it.html and http://planetwaves.net/contents/ibt_guilty.html. In short, there are strong, evidence-based reasons for approaching industry-conducted or -funded studies on their products with skepticism.*

residual concerns on this point could be addressed by recusing Dr. Infante from participation in assessment of the industry-sponsored animal studies.¹⁸

Finally, EPA is obligated by the Federal Advisory Committee Act (FACA) to ensure that this FIFRA Scientific Advisory Panel serves “the public interest”.¹⁹ Further, Congress mandated that federal agencies follow the guideline that such advisory groups shall not be “inappropriately influenced by any special interest...”.²⁰ EPA’s dismissal of Dr. Infante at the behest of CropLife, a special interest representing pesticide manufacturers generally and in particular the Monsanto Company, chief manufacturer of glyphosate, is a clear violation of that Congressional guideline and thus violates FACA. It also gives a strong “appearance of lack of impartiality”²¹ with respect to the SAP as a whole.

For these reasons, we urge the EPA to reinstate Dr. Infante to the Scientific Advisory Panel. Not only would his presence on the Panel help ensure a rigorous and high-quality evaluation of glyphosate’s carcinogenic potential, his removal compromises the credibility of the SAP’s advice and recommendations.

We thank you for your consideration of this letter.

Respectfully submitted,

Bill Freese, Science Policy Analyst, Center for Food Safety

cc:

Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Steven Knott, Designated Federal Official, Office of Science Coordination and Policy

¹⁸ EPA Science Advisory Board Staff: Ethics for Advisory Committee Members. “Possible remedies [to a conflict of interest or appearance of a loss of impartiality] ... include recusal from some part of the matter...” Environmental Protection Agency. Last updated 5/3/16.

<https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument>.

¹⁹ 5 U.S.C. App. § 9(a)(2).

²⁰ 5 U.S.C. App. § 5(b)(3), setting forth, in this guideline for Congress’s own review of FACA’s implementation, that it shall “(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee’s independent judgment;”. See, § 5(c), which provides: “To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.”

²¹ EPA (2004), op. cit., p. 13.

Appendix: Biosketch of Dr. Peter Infante

Excerpted from “Biosketches for FQPA Science Review Board Members”
FIFRA Scientific Advisory Panel: Review of a Set of Scientific Issues being Evaluated by the
Environmental Protection Agency (EPA) regarding EPA's Evaluation of the Carcinogenic
Potential of Glyphosate
Open Meeting October 18-21, 2016

Issued by EPA on October 4, 2016

Peter F. Infante, Dr.P.H.

Dr. Infante is currently the Managing Member of Peter F. Infante Consulting, LLC, an organization dedicated to research and analysis of occupational and environmental health issues. Between 2002 and 2011, he was Adjunct Professor, and Professorial Lecturer, of Environmental and Occupational Health at the George Washington University, School of Public Health, Washington. He was previously the Director, Office of Standards Review, Health Standards Program and Director of the Office of Carcinogen Identification and Classification at OSHA. During his 24 years in OSHA, he played a major role in determining cancer and other risks to workers during the development of standards for a number of toxic substances, including asbestos, arsenic, benzene, cadmium, ethylene oxide, formaldehyde, lead and MDA. Prior to working at OSHA, he was employed by the National Institute for Occupational Safety and Health (NIOSH) where he conducted epidemiological studies related to a number of carcinogens found in the workplace including, benzene, beryllium and vinyl chloride. He has served as an expert consultant in epidemiology for: the National Toxicology Program's (NTP) Report on Carcinogens (RoC); for Working Groups of the International Agency for Research on Cancer (IARC); the EPA Science Advisory Board (SAB) Chemical Assessment Advisory Committee; and as an expert on cancer risk from asbestos exposure for the World Trade Organization (WTO) in Geneva, Switzerland. He has testified before the U.S. Congress on numerous occasions about chemical pollution and the causes of cancer. He is a Fellow of the American College of Epidemiology and the Collegium Ramazzini. Dr. Infante received his D.D.S. degree from the Ohio State University, and his Dr.P.H. degree from the University of Michigan, School of Public Health, Department of Epidemiology.