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October 21, 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 Glyphosate Scientific Advisory Panel Submission by
CropLife America dated October 12, 2016

Dear Mr. Knott:

This letter is in response to the above-referenced letter from CropLife America ("CropLife"), a trade association that represents the nation's manufacturers, formulators and distributors of crop protection chemicals and pest control products. CropLife claims that I should be excluded from participation on the glyphosate scientific advisory panel ("SAP"). This letter responds to the allegations against me.

First, I would like to present you with an overview of my credentials and qualifications. As indicated in my resume previously provided to you, I have 47 years of experience as an epidemiologist. My work includes employment as a senior epidemiologist with various governmental agencies, including three years with the National Institute for Occupational Safety and Health (NIOSH) and 24 years with the Occupational Safety and Health Administration (OSHA). During my time at NIOSH, I conducted epidemiological studies related to a number of carcinogens found in the workplace, including benzene, beryllium and vinyl chloride. I was the lead author on the first cohort study to demonstrate a significant association between benzene exposure and leukemia. The findings of this study led OSHA in 1977 to promulgate an Emergency Temporary Standard (ETS) to reduce occupational exposure to benzene. During my 24 years at OSHA, I 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 methylenedianiline (MDA). I have 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. I have testified before the U.S. Congress on numerous occasions about chemical pollution and the causes of cancer. I have over 100 publications in peer reviewed scientific journals.

CropLife claims that EPA ethical rules preclude my participation in the glyphosate SAP, specifically due to my membership in the Collegium Ramazzini. Founded in 1982, by Drs. Irving Selikoff and Cesare Maltoni, the Collegium is an independent academy of 180 internationally recognized experts in the fields of occupational and environmental health. Fellows are selected for membership based upon a "clear personal distinction of integrity," and their contributions to occupational and environmental health. I was selected for membership in 2002. The mission of the Collegium is to advance the study of occupational and environmental health issues and to act on scientific evidence to protect the public health. CropLife contends that the Collegium has taken radical anti-pesticide positions such as a prohibition on pesticide use in public areas, and that this position should disqualify me from participating on the SAP. Although I have been involved in a number of scientific analyses and public health positions related to the Collegium, I have not participated in any of the discussions or positions taken by the Collegium on pesticides.

CropLife next contends that I am biased against Monsanto and its affiliated entities because of prior testimony in litigation. This is not the case. I offered epidemiological opinions about whether the scientific literature supported a causal connection between a chemical and a particular human cancer. The chemical exposure cases in which I have testified in the past 8-12 years where Monsanto happened to be a defendant were all related to vinyl chloride (VC) exposure and liver and biliary cancer--cancers recognized in the scientific literature to be caused by VC exposure. The first type of liver cancer identified in 1974 to be caused by VC, namely, angiosarcoma of the liver (ASL), is considered as a sentinel cancer related to VC exposure. In other words, when an individual is diagnosed with ASL, inquiry is made to determine if and where he or she was exposed to VC. In these cases, I was asked to opine whether or not there was an association between VC and these rare liver diseases. My testimony was not for or "against Monsanto."

Further, as indicated in my application to serve on the SAP,

I have no special interest in regard to glyphosate. I have not been involved in any litigation involving glyphosate nor have I formed any opinion regarding this issue. I have not testified in any proceedings, legal or regulatory, regarding glyphosate. I have also not worked on behalf of industry regarding glyphosate.

CropLife next contends that "federal courts have concluded" that I have "engaged in a pattern of biased, results-oriented analysis that disqualified consideration" of my opinions. Out of the many court opinions I have offered, CropLife chooses to "cherry-pick" an instance or two in which a court has (erroneously) taken issue with my methodology and scientific rigor. It cites a case from the federal district of Louisiana to support this position. CropLife, however, does not provide you with the complete account of this particular case, as well as a complete description of my history in testifying in legal proceedings. The *Burst v. Shell Oil Co.* case involved a worker who was exposed to benzene for a period of 9-10 years while working at various gasoline filling stations. He died from acute myelogenous leukemia (AML). There is no question in the scientific community (or the overwhelming majority of the legal community) that benzene is a cause of AML. I have provided expert reports in many benzene-related cases in litigation and have testified in numerous benzene-related cases as well. The ruling by this judge is an anomaly. While Judge Vance is entitled to her opinion as to the epidemiology of benzene and AML, the overwhelming majority of the judicial system does not share her opinion. Further, this particular judge is not a scientist, not an epidemiologist and has no training in epidemiology. Criticisms of scientific methodology and opinions based upon analysis of scientific data are appropriate from scientists in the same field. As a further note, subsequent to her decision, 40 occupational health physicians, epidemiologists, statisticians and others involved in occupational health from around the world signed an Amicus Brief supporting the epidemiological methodology I used in the case. The Court was asked to reverse its decision to exclude my opinions based on my methodology. See attachment.

CropLife next offers several quotes from me in the book entitled "Our Daily Poison" authored by the French journalist Marie Monique Robin. CropLife unilaterally concludes from the quotes that I will reflexively discount any industry-sponsored study on glyphosate. This is simply not the case. As an epidemiologist, it is my job and my ethical duty to consider and evaluate the aggregate of research, whether it is supported by industry, governmental agencies, academia or any other source. This research varies in quality and needs to be evaluated on an individual study basis. If this were not the reality of the situation, there would be no need for an advisory committee to

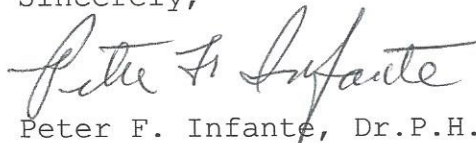
evaluate the EPA's interpretation of the "strengths and limitations of the available studies" (SAP charge question #2). Furthermore, none of the epidemiological studies related to glyphosate and cancer that were provided to me for review by EPA were funded by industry. Therefore, any potential bias with respect to my evaluating industry-sponsored epidemiological studies is a moot point.

From my specific experience as the Designated Federal Official for the Occupational Safety and Health Administration's (OSHA) Federal Advisory Committee on Metalworking Fluids, I am aware that the Federal Advisory Committee Act ("FACA") simply requires that all advisory committees be "fairly **balanced** as to function and viewpoint;" it does not require that every committee member has lived his or her life in a bubble and never expressed an opinion that might be objectionable to a particular interest. Committee members may approach their task with somewhat divergent perspectives and viewpoints. In my opinion, the claim that ethics rules would be violated through the matters raised in the CropLife letter clearly lacks foundation. On the other hand, the CropLife letter suggests that CropLife is attempting to impermissibly skew the composition of the committee in its favor, and is certainly not applying its own purported desire for unquestioned neutrality.

Finally, I have no bias against glyphosate, or pesticides in general, and CropLife's letter provides no credible evidence that I have done anything that would impede my ability to effectively evaluate the epidemiological evidence related to glyphosate exposure and potential cancer risk. As an example, in 2014 and 2015, I served on the EPA Science Advisory Board ("SAB") Chemical Assessment Augmented for Ethylene Oxide, a chemical used as a sterilizing agent in hospitals and other occupational sectors. There were no assertions by any party that I exhibited any bias in my evaluation of the epidemiological studies related to ethylene oxide, nor was this ever an issue raised by any party, including, most importantly, the manufacturers of ethylene oxide.

I believe I have properly rebutted the criticisms raised by CropLife and I look forward to my participation on the glyphosate SAP in the capacity of a qualified and ethical epidemiologist.

Sincerely,

A handwritten signature in cursive script that reads "Peter F. Infante". The signature is written in dark ink and is positioned above the printed name.

Peter F. Infante, Dr.P.H., F.A.C.E.

Attachment: