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March 21, 2014

Lauren Zeise, Ph.D.  
Deputy Director  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, California 95814

**Re:** *Notice of Intent to List Chlorotriazines as Reproductive Toxicants for  
Purposes of Proposition 65*

Dear Dr. Zeise:

I write in response to the February 7, 2014 Office of Environmental Health Hazard Assessment (OEHHA) Notice of Intent to List (NOIL or Notice) atrazine, simazine, propazine and certain of their chlorometabolites (triazine compounds) as developmental and reproductive toxicants for purposes of Proposition 65. In the Notice, OEHHA concludes that the United States Environmental Protection Agency (EPA), an authoritative body for purposes of Proposition 65, has "formally identified" these compounds as causing developmental and reproductive toxicity based on material from EPA documents dated from 2002 to 2006, quoted in the NOIL.

In my opinion as a former Deputy Director of the Health Effects Division of EPA's Office of Pesticide Programs (OPP), these documents do not show that EPA has concluded that these compounds cause developmental or reproductive effects in humans. Rather, they show that OPP has taken a precautionary approach in noting certain dose-related biological responses observed in laboratory animal studies, and used this information as reference points in imposing regulatory requirements to protect against the risk of potential adverse effects that might be caused in human populations by these pesticide active ingredients.

By way of background I was Deputy Director of OPP's Health Effects Division from 2009-2011, with responsibility for the efforts of the OPP health scientists preparing the risk assessments and other related evaluations conducted to inform decisions about the registration review of pesticides. During this time, OPP undertook a re-evaluation of the human health effects of atrazine. This review included three Scientific Advisory Panel (SAP) meetings in 2010 and one in 2011.

During the course of my 33 year career at EPA I served in a variety of other positions, including Acting Division Director of the Neurotoxicology Division (2007-2009) and Assistant Lab Director for Toxics & Pesticides (2002-2007) within the National Health and Environmental Effects Research Laboratory in the Office of Research and Development, as Deputy Staff Director of the Science Advisory Board (1995-2002) among other positions. I also served as Science Advisor to Senator Daniel Patrick Moynihan (1992-1994).

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During the preparation of this letter, I reviewed the pertinent portions of the Proposition 65 regulations under Title 27 of the California Code of Regulations. In particular, I have reviewed Section 25306 of that Title, which provides for listing chemicals as carcinogens or reproductive toxicants on the basis of their "formal identification" by authoritative bodies, such as EPA. Of course, I also reviewed the NOIL and the EPA statements and documents that it refers to. In addition, I have read the statements by Debra Edwards, a past Director of the OPP, and Rick Tinsworth, a former Director OPP's Special Review and Reregistration Division.

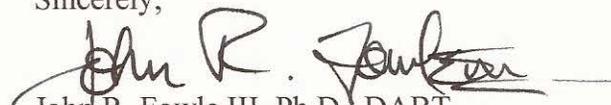
Based on this information, I agree with the opinions expressed in the statements by Drs. Edwards and Tinsworth: OEHHHA's conclusion that EPA identified triazine pesticides as causing developmental and reproductive toxicity in humans is inaccurate, and is based on a misunderstanding of OPP's approach to the regulation of pesticides; given the FQPA safety standard of "reasonable certainty of no harm," OPP's approach to regulating chemicals to ensure the safety of humans runs counter to the simplistic approach of labeling chemicals as "known to cause reproductive toxicity."

I also have noted, as Dr. Edwards observed, that the Final Workplan for the Registration Review of atrazine, published on December 31, 2013, calls for the review of atrazine to be conducted during 2014 and completed in 2015. In light of this, I believe that EPA statements and actions in 2006 should not be treated as "final." Rather, they are under re-evaluation at this very time. Accordingly, it appears inappropriate to use EPA statements and actions in 2006 as the basis for an "authoritative body" listing. As Dr. Edwards states: "...it would be highly prudent to carefully consider EPA's more recent risk assessments, based in current science, prior to assuming any "known" or "causal" relationship between exposure to triazines and reproductive or developmental effects."

These professional experiences that I referred to above have provided me with an understanding of how EPA uses data, including data from tests on laboratory animals to conduct risk evaluations to inform regulatory and other decisions, and I understand the uncertainties and other limits of such data used when assessing potential hazard and potential risk. EPA has developed policies on planning and scoping and risk characterization because environmental legislation at both the federal and state level has been drafted at different times and for different purposes. Experience has shown that risk assessments conducted for one purpose are not necessarily appropriate for other purposes.

Here, for reasons explained above, statements and observations from EPA during the EPA risk assessment process for regulating pesticides, and in particular the triazine compounds, appear to an inappropriate basis for determining that these pesticides have been "formally identified" as reproductive toxicants for purposes of Proposition 65.

Sincerely,

  
John R. Fowle III, Ph.D., DABT  
Principal  
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