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Arlington, VA 22205-2413
March 22, 2014

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

Re: Comments in Opposition to Potential Listing of Triazine Compounds as Reproductive or Developmental Toxicants Under Proposition 65

Dear Dr. Zeise:

OEHHA has issued a Notice of Intent to List (NOIL) atrazine, simazine, propazine and certain of their chlorometabolites (triazine compounds) as developmental and reproductive toxicants on the basis 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 in certain EPA documents dated from 2002 to 2006, which OEHHA has listed and selectively quoted in the NOIL. I do not believe EPA has concluded that these compounds cause developmental or reproductive effects in humans.

I am well qualified to speak with authority on the subject of how EPA evaluates the human health effects of pesticides. I spent 31 years working as a toxicologist at the Environmental Protection Agency, the last 26 in the Office of Pesticide Programs. From 2005-2011, I was the Director of the Health Effects Division (HED), responsible for human health risk assessments for all conventional pesticides. Therefore, I oversaw, at the executive level, the development of many of the triazine documents referenced in the NOIL. In addition, for several years before becoming the Director of HED, I served on the Hazard Identification Assessment Review Committee, HIARC, which was responsible for overseeing endpoint selection for HED’s risk assessments.

EPA/OPP is not required to “formally identify” hazards as part of its regulatory process. Rather, it must make a finding of “reasonable certainty of no harm” in order to establish tolerances for residues of pesticides on food. To do so, a highly protective risk-based approach to regulating pesticides has been developed, very different from a simple

identification of hazard. The routine approach to pesticide risk assessments involves the evaluation of animal toxicity studies. There is an assumption that these studies indicate what could possibly happen in humans. Without this assumption, there would be no way to do the risk assessment and make the finding of “reasonable certainty of no harm.” However, the risk assessment only evaluates a potential risk. No final determination of risk or hazard is implied by the process.

Hazard identification has long been considered the first step in risk assessment, hence the name of the HIARC committee. But as practiced in HED, hazard identification is really endpoint selection, as opposed to a definitive identification of hazard. The use of a NOAEL from a study that found an effect at some higher dose does not constitute a determination that the chemical poses a hazard of a particular type to humans. Many pesticides show little mammalian toxicity in their database, but endpoints are chosen and a risk assessment is done based on NOAELs.

The risk assessment process follows a classic series of steps: all the toxicity studies are reviewed, exposure pathways are articulated, the endpoints from the various studies that fit the exposure scenarios are evaluated and the most protective endpoints are chosen to form the basis of the risk assessment. The exposures are calculated and compared to the doses determined to be acceptable. Frequently, expected exposures are acceptable despite protective endpoints and exposure assumptions, and no further work is needed. If problems are identified, there can be refinement of the risk assessment and this is where there are sometimes considerations of Modes or Mechanisms of Action and relevance to humans. But on a routine basis, the process is protective and without deep judgment as to whether the study is relevant to humans, is truly adverse, etc. This was certainly true during the heavy workload leading to meeting the deadline for reregistration under the Food Quality Protection Act of 1996 (FQPA), when the cited documents were developed. While sometimes frustrating to registrants, this process is highly protective of human health and is generally considered the best use of Agency resources.

The language EPA uses in its regulatory documents is assertive. The documents are written as if the effects seen in animals will occur in humans. That is the nature of regulatory language. Taken at face value they appear to denote a certainty that is not necessary for the regulatory process to go forward. For EPA, it is enough that there is potential risk for the risk assessment and regulatory action to be justified. No definitive formal assessment of the hazard is required.

The documents cited in the OEHHA listing are relatively old. The HIARC document on atrazine/DACT was written in 2002. Unlike most pesticide risk assessments, the triazine assessments looked at much non-standard laboratory data on purported precursor endocrine disrupting events as the basis for the risk assessment. There continues to be

much data generation and review activity surrounding these data. While I was the HED Division Director there were several Scientific Advisory Panel meetings to discuss these data. At that time, the conclusion of these meetings was that the current risk assessment was protective. However, the review of the triazines is continuing through the Registration Review process, the periodic reevaluation of pesticides every 15 years mandated by FQPA. The triazines are scheduled for registration review in 2015. Clearly, no final determination of hazard or risk around these chemicals has been made.

Sincerely yours,

A handwritten signature in cursive script that reads "Tina E. Levine". The signature is written in black ink and is positioned below the "Sincerely yours," text.

Tina E. Levine, Ph.D.