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Subject: Comments in Opposition to Potential Listing of Atrazine, Simazine, Propazine, and Associated Metabolites as Reproductive or Developmental Toxicants under Proposition 65's Authoritative Bodies Listing Mechanism

Dear Dr. Zeise:

On February 7, 2014, California's Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Intent to List (NOIL) atrazine, simazine, propazine, and their associated chlorometabolites (triazine compounds) as developmental and reproductive toxicants on the basis that the United States Environmental Protection Agency (EPA or the Agency), an authoritative body for purposes of Proposition 65, has "formally identified" these compounds as causing developmental and reproductive toxicity in certain EPA documents dated between 2002 and 2006, which OEHHA references and selectively quotes from in the NOIL. As discussed below, **these compounds should not be listed under Proposition 65.**

PERSONAL BACKGROUND

I am a principal at Exponent and the Director of its Washington, DC office. Exponent is an engineering, scientific and regulatory consulting firm. I have more than 45 years of government and consulting experience dealing with hazard and risk assessment, and the regulation of pesticides, chemicals, foods, drugs, and consumer products. I recognize and understand the importance of using sound science to regulate risk and the need to effectively communicate potential hazards to a variety of audiences including consumers.

I spent 22 years working for three Federal agencies: The US Food and Drug Administration (FDA), the US Consumer Product Safety Commission (CPSC), and the US Environmental Protection Agency (EPA). I began my government career as a food and drug inspector with FDA. I also served as a program analyst writing compliance programs for FDA field and compliance personnel. Following my FDA experience, I worked at the CPSC in a variety of senior positions that focused primarily on injury investigation and regulatory and compliance activities related to consumer products.

At EPA, I served in three different positions. I began my EPA career as the Deputy Director of the Office of Toxic Substances. In that position, I was responsible for the implementation and management of the Toxic Substances Control Act and its supporting regulations.

Subsequently, I moved to EPA's Office of Pesticide Programs (OPP). I spent several years as the director of OPP's Registration Division. At that time, the Registration Division was responsible for three major programs: The registration of pesticide products, the reregistration (now called registration review) of pesticides, and the special review activity. I completed my time at EPA by then becoming the Director of OPP's newly created Special Review and Reregistration Division, which was responsible for those two named activities.

As a Division Director in EPA's Office of Pesticide Programs, I was responsible for making or recommending risk management (regulatory) decisions. Based on substantial amounts of data and information, OPP science divisions developed hazard and exposure assessments which were combined into risk assessments. Such risk assessments evaluated potential human, ecological and environmental risks. Risk and benefit information was then considered in order to weigh possible risks and potential benefits associated with the use of pesticides. Based on the entire body of data and assessments of those data, regulatory decisions were made. These decisions focused on whether or not to register a pesticide, whether or not to continue (reregister) a pesticide, and whether or not to conduct a special review and/or cancellation proceeding that could lead to the cancellation of a pesticide registration. As discussed below, the comprehensive assessment and decision making process was, and is, based on the consideration of potential risk rather than the formal designation of a pesticide as any sort of toxicant.

REASONS WHY THE TRIAZINE COMPOUNDS SHOULD NOT BE LISTED UNDER PROPOSITION 65

The triazine compounds should not be listed under Proposition 65 as developmental or reproductive toxicants for the following reasons:

1. EPA has no statutory or regulatory mandate or authority to formally identify pesticides as toxicants.
2. OEHHA cannot rely on EPA's hazard identification and risk assessment process.
3. OEHHA cannot rely on EPA registration review (reregistration) documents.

Each of these reasons is discussed below.

1) EPA Has No Statutory or Regulatory Mandate or Authority to Formally Identify Pesticides as Toxicants.

EPA's Office of Pesticide Programs regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). The Agency has issued regulations under each of those statutes (40 CFR 150-189). In addition, EPA provides guidance and policy documents that are available on the Agency's website.

FIFRA is a licensing statute. A registrant (holder of a pesticide registration) cannot sell or distribute a pesticide unless the product has been registered by EPA.

EPA requires that substantial amounts of data be submitted to support an application for registration. Studies include toxicology, residue and product chemistry, environmental fate, ecotoxicology, and exposure studies. Agency scientists review submitted studies and other available information, and conduct risk assessments that consider possible risk issues. If risks are acceptable, EPA grants the registration.

In addition, under the FFDCA, the Agency must establish a tolerance for any food use of a pesticide. A tolerance is the allowable level of a pesticide in or on food. EPA reviews residue data and considers potential dietary risk from the use of a pesticide. EPA cannot establish the tolerance and thus cannot grant the registration unless the use of the pesticide meets the **FFDCA statutory safety standard of a reasonable certainty of no harm**.

There are statutory mandates that require registrations and tolerances for pesticides. EPA has issued regulations covering both of these activities through notice and comment rulemaking as required by the Administrative Procedure Act. Thus, there are formal requirements, procedures and policies that govern the granting of registrations and the establishment of tolerances.

There is no statutory mandate that requires or authorizes the Agency to develop and issue a list of developmental or reproductive toxicants. There is no process for formally identifying pesticides as developmental or reproductive toxicants. Such designations are not the role of the EPA.

The EPA pesticide program is focused on the assessment of possible risk, coupled with the mitigation of such potential risk by use restrictions and safety requirements. When EPA grants a food use registration and establishes a tolerance for that use, the Agency is making a finding that, within a reasonable certainty, humans will be exposed to essentially no risk. This statutory and regulatory framework does not involve a formal and definitive identification of a pesticide as a particular kind of toxicant known to cause toxicity in humans.

2) OEHHA Cannot Rely on EPA's Hazard Identification and Risk Assessment Process.

The typical EPA pesticide risk assessment process includes hazard identification, dose-response, exposure assessment, and risk characterization phases. EPA's hazard identification process is far different than OEHHA's hazard identification activity.

OEHHA's Proposition 65 hazard identification activity involves a weight of the evidence review of available information and data targeted toward a determination of whether or not a chemical has been clearly shown to cause cancer or reproductive effects in humans. That is, is there enough evidence to determine that the chemical is known to cause such effects and should therefore be formally listed by OEHHA as a known toxicant.

EPA's hazard identification step in its risk assessment process stands in sharp contrast to the OEHHA system. EPA is not attempting to determine whether a pesticide should be listed or formally identified as being known to cause effects in humans. Rather, EPA uses the hazard identification step to review available animal toxicity studies and identify adverse effects which may present potential or possible risk in humans. Based on that review, the Agency selects an appropriate no observed adverse effect level (NOAEL) for risk assessment purposes. EPA then proceeds from the hazard identification phase through the next three phases of its risk assessment process which it must do to determine whether anticipated exposures of a food use pesticide meet the required reasonable certainty of no harm safety standard.

To determine whether or not a pesticide use meets that safety standard, the Agency utilizes each of the four steps in its risk assessment process, but is focused on the end result of the last risk characterization phase. Rather than formally identifying a pesticide as a particular kind of toxicant, EPA looks at a variety of toxicology endpoints. The Agency selects the lowest available NOAEL from the suite of NOAELs in animal toxicology studies, and uses that number for risk assessment purposes. For EPA, a risk is acceptable if potential exposure is less than a calculated reference dose (RfD), where the RfD is determined by dividing the selected NOAEL (i.e., a dose with no observed toxicity) by whatever safety or uncertainty factors (usually 100 to 1,000) are considered adequate by the Agency. Thus, the reasonable certainty of no harm standard is met if anticipated exposures are 100 to 1,000 times (two to three orders of magnitude) less than the most sensitive NOAEL in a suite of toxicology studies. If the safety standard is met, the Agency has determined there is a reasonable certainty of no risk to humans. EPA can then grant or continue a registration and can establish or continue a tolerance. If the standard is not met, the food use cannot be approved unless risk can be mitigated (e.g., reduce the application rate of the pesticide) so that the safety standard is met.

OEHHA's mandate is to use hazard identification information as the basis for providing hazard information to consumers and other stakeholders. EPA's pesticide program uses information from each of the four risk assessment steps to evaluate and respond to possible or potential risks that may be presented by pesticide products.

Different mandates and responsibilities lead OEHHA and EPA to act differently. Both OEHHA and EPA have important but very different public health roles. The focus of EPA is on risk

assessment and risk mitigation whereas OEHHA is focused on formally identifying and communicating hazards. EPA does not formally identify or list toxicants.

3) OEHHA Cannot Rely on EPA Registration Review (Reregistration) Documents.

EPA's pesticide registration review program (formerly called reregistration) has been ongoing since the 1970's. The current registration review program requires that each pesticide be reviewed every 15 years. As science evolves, new data requirements are put in place, and older studies may no longer meet current scientific standards. As a result the database supporting the use of a pesticide needs to be upgraded periodically. Once again, the focus of the Agency's registration review program is not on hazard identification and hazard communication related to the formal identification of pesticides as toxicants that are known to cause toxicity in humans. Rather, EPA requires new studies, conducts new risk assessments, and determines whether the uses of a pesticide meet the reasonable certainty of no harm standard or whether possible risks must be mitigated through cancellation or adjustments of some or all of the uses of the pesticide to achieve a reasonable certainty of no human risk.

As in the case of registration and tolerance setting, EPA conducts a registration review to ensure that the uses of a pesticide meet that safety standard. The Agency is not formally identifying any pesticide as a particular kind of toxicant known to cause toxicity to humans. EPA did not formally identify the triazine compounds as developmental or reproductive toxicants in the registration review and tolerance reassessment documents referenced by OEHHA.

CONCLUSIONS

EPA's Office of Pesticide Programs is a technically competent authoritative body that bases regulatory decisions on a rigorous assessment of possible risks. The Agency focuses on whether or not food use pesticides such as the triazine compounds meet the FFDCA safety standard of a reasonable certainty of no harm. EPA's OPP does not formally identify pesticides as developmental or reproductive toxicants. Formally identifying pesticides as particular types of toxicants is neither the mandate nor the function of EPA under either the FFDCA or FIFRA. The statutory responsibility of EPA's OPP is to make regulatory decisions based on the conservative assessment of potential risk; it is not to develop lists of toxicant pesticides.

For the reasons discussed, OEHHA cannot rely on EPA statements concerning the triazine compounds as developmental or reproductive toxicants. **While EPA is an "authoritative body", it does not formally identify pesticides as developmental or reproductive toxicants.**

Sincerely,



Edwin F. (Rick) Tinsworth