



# WPHA

Western Plant Health Association

December 11, 2012

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-19B  
Sacramento, California 95812-4010

Re: OEHHA's selection process of chemicals including deltamethrin (52918-63-5) for the DARTIC's review and possible listing under Proposition 65

Dear Ms. Oshita:

On behalf of the Western Plant Health Association (WPHA), I would like to express our concerns regarding the selection process that OEHHA is utilizing that will impact chemicals whose registrants are WPHA members. WPHA appreciates your consideration of our concerns and suggestions presented below on the process for chemicals being considered by the Developmental and Reproductive Toxicant Identification Committee (DART IC) for review. WPHA represents the interests of crop protection and fertilizer manufacturers, agricultural biotechnology providers, and agricultural retailers in California, Arizona, and Hawaii.

The DART Criteria specify that a listing can be based solely on "sufficient evidence in experimental animals (mammals), such that extrapolation to humans is appropriate, According to the current process for identifying candidates for consideration whether to list for developmental or reproductive toxicity under Proposition 65, candidate chemicals are identified as having some relevant DART data and some potential for exposure in California. If exposure potential is confirmed and a total of  $\geq 15$  reports of relevant DART endpoints or a total of  $\geq 10$  reports of any single relevant DART endpoint exist, then the chemical is subjected to a preliminary review by the DART IC. However, this preliminary review involves only consideration of study abstracts, with no details available for Committee members to assess the credibility of the reported effects, which can lead to a decision being made that enough relevant evidence exists to require a consideration for listing even though studies may be of questionable study design and quality.

WPHA is concerned that this process seems to lack a certainty that reports that are released are truly relevant to the selection process. WPHA supports the comments posted to OEHHA's website on March 12, 2012 by Bayer CropScience, the principle registrant of deltamethrin, that researchers do perform studies on a substance that are not necessarily hazard or risk driven, and that many of these studies may not be appropriate for consideration in the listing process due to limitations in scientific robustness when measured against the DART Criteria defined in 1993 for determining the scientific validity of animal studies.

We believe that the selection process would be improved if a greater level of check were made by OEHHA to assess the robustness of published experiments before recommending a DARTIC review. Because of the economic damage that can result in the listing of a chemical, we believe this is vital for this process to move forward. Growers in CA (and even sometimes other States) will avoid when possible prop 65 products because of potential negative reaction by customers, posing questions, etc. Foreign countries are resistant to products containing prop 65 listed actives either because of lack of knowledge of what the listing means, or as an opportunity to utilize the listing for trade advantage. In addition, these chemicals can have important roles to assure the health and safety of the public as well as the economic viability of sectors of the economy dependent on their use.

Pesticides are already evaluated for developmental and reproductive toxicity in accordance with Good Laboratory Practice (GLP) studies performed with laboratory animals in accordance with U.S. (EPA) and international (O.E.C.D.) test guideline requirements. These studies should serve as the basis against which published scientifically valid studies are measured in a properly conducted and transparent Weight of Evidence determination, also required by the DART Criteria.

WPHA asks that OEHHA reconsiders its current list of chemicals to be proposed for DARTIC review until it has re-evaluated whether there is a sufficient body of studies that are appropriate to the question of real chemical hazard. We also believe that studies required for registration for pesticide products that are required as part of the California registration process be considered prior to that chemical being submitted for DARTIC review. WPHA appreciates your consideration of our comments on this process, and looks forward to working with OEHHA in addressing this issue further.

Sincerely,



Renee Pinel  
President/CEO