June 12, 2018

Mr. Garland Waleko  
Chemical Review Manager  
Pesticide Re-Evaluation Division  
Office of Pesticide Programs

via email:  Waleko.garland@epa.gov


Dear Mr. Waleko:

CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) appreciate this opportunity to comment on the Environmental Protection Agency (EPA or “Agency”) Draft for Public Comment, “Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing [EPA-HQ-OPP-2016-0093; April 8, 2018], EPA’s Office of Chemical Safety and Pollution Prevention: Office of Pesticide Programs, Office of Pollution Prevention and Toxics.

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA’s member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber, and fuel. RISE is a national trade association representing producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

Both CLA and RISE support the mission of EPA to protect public health and the environment from potential risks due to pesticide exposure, including requirements for the conduct of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-listed 40 CFR part 158 laboratory testing that supports registration of pesticides in the United States.
We support the EPA Office of Pesticides Programs’ (OPP) strategic vision for developing and implementing modeling approaches and in vitro techniques to supplement or replace existing in vivo testing currently required in support of pesticide registration. CLA and RISE member companies have worked cooperatively with EPA and other stakeholders who are committed to significantly reducing the number of animals used in acute oral, dermal, and inhalation lethality toxicity testing, along with skin and eye irritation, and skin sensitization testing (collectively the “6-pack”) required under 40 CFR part 158.

CLA and RISE member companies strongly support the ongoing work of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP (National Toxicology Program) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) that engages collaboration among global regulators to work toward global harmonization of alternative approaches to replace laboratory animal testing.

The approaches defined (DA) for acceptance of submissions of single chemicals (e.g., pesticide active or pesticide inert ingredients) that can be tested under a DA are identified in the Interim Science Policy; formulations presently will not be accepted although EPA anticipates expansion of this Interim Science Policy to include some pesticide formulations, upon completions of ongoing testing of >20 pesticide formulations products. We look forward to collaborative engagement to expand the acceptances to include pesticide formulations.

We applaud EPA for its Interim Science Policy of acceptance of alternative (in vitro, in silico, in chemico) approaches for identifying skin sensitization hazard which are to be accepted in lieu of laboratory animal studies; and for the EPA (OPP) immediate acceptance of these approaches under conditions provided in the “Interim Science Policy.”

Thank you for your consideration of these comments. Should you have any questions or wish to discuss these comments, please contact either of us directly by email or telephone.

Sincerely,

Janet E. Collins, Ph.D., RD, CFS
Executive Vice President, Science and Regulatory Affairs

Stephanie Binns
Regulatory Affairs Manager

Cc: Dr. Anna Lowit