May 13, 2016

Integrated Approaches to Testing and Assessment Docket
Environmental Protection Agency Docket Center (EPA/DC)
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Regulations.gov

Re: Memorandum to Open Docket for Meeting Minutes, Documents, and Proposals Related to Integrated Approaches to Testing and Assessment (IATA); EPA-HQ-OPP-2016-0093 (March 16, 2016).

Dear Sir or Madam:

CropLife America (CLA) appreciates the opportunity to provide comment on the recent posting (Docket ID No. EPA-HQ-OPP-2016-0093) by the U.S. Environmental Protection Agency (EPA or the Agency) of its Memorandum to Open Docket for Meeting Minutes, Documents, and Proposals Related to Integrated Approaches to Testing and Assessment (IATA) activities in the Office of Pesticide Programs (OPP). Specifically, CLA directs these comments towards the supporting document (EPA-HQ-OPP-2016-0093-0007) entitled Retrospective Analysis & Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations (Retrospective Analysis).

Established in 1933, 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 of the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners. CLA is committed to working with EPA, as the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members’ products.

In Retrospective Analysis section 4.0 Waiver Guidance, EPA concludes that the Retrospective Analysis “fully supports a conclusion that waivers can be granted of acute dermal toxicity studies for formulations,” and that registrants may begin submitting waiver requests through existing processes. We support EPA’s conclusion and ask that the Agency provide guidance to registrants on the processes for seeking a waiver.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to register pesticides and require supporting studies to meet statutory safety standards as stipulated under 40 Code of Federal Regulations (CFR) Part 158. Flexibility exists, however, in implementing 40
CFR Part 158; EPA can require additional data (§158.75), can accept alternative approaches (§158.70), and/or can waive studies (§158.45). Under this flexibility, OPP’s strategic vision includes seeking improved approaches to more traditional toxicity tests found in the regulations in order to minimize the number of animals used while expanding the amount of information obtained. OPP’s document, “Guiding Principles for Data Requirements” notes the importance of only requiring data that inform regulatory decision making and that avoid unnecessary use of time and resources, data generation costs, and animal testing. Waiving studies, when such data offer little or no additional scientific information or public health protection is an important component of the Guiding Principles. For example, in 2012, OPP published “Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides and Pesticide Products (Acute Oral, Acute Dermal, Acute Inhalation, Primary Eye, Primary Dermal, and Dermal Sensitization,” which consolidated previously existing guidance on waivers for acute toxicity tests.

CLA members support science-based regulation and are strongly committed to the reducing, refining, and replacing test animals. The EPA Retrospective Analysis is clear, and we agree that there is an extensive body of evidence that supports waiving acute dermal toxicity studies for pesticide formulations. EPA’s conclusions agree with published data, which demonstrate that the acute dermal study does not provide essential information from the perspectives of hazard identification or communication, since the acute oral endpoint usually determines the label statements.

We note, however, that while EPA’s waiving of these studies will reduce the number of animals used to support the pesticide registration process in the United States, the impact will not be fully realized if other regulatory authorities outside the United States continue to require acute dermal toxicity studies. We encourage the EPA to reach out to other country regulatory agencies to encourage broad regulatory harmonization in waiving this data requirement. Until harmonization is achieved, EPA should recognize that in instances where a particular formulation will be registered in additional countries around the world, a dermal toxicity study will still be needed. This should be recognized as a reflection of the need to comply with global data requirements; not the lack of commitment by CLA member companies to reduce animal usage.

We also ask that EPA clarify the process for requesting and granting waivers. For example, it is unclear whether a registrant must submit a formal written waiver request to EPA for the acute

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dermal toxicity study. If a formal written waiver is required, EPA should clarify whether the waiver will be reviewed in the same timeframe as the other studies that constitute an acute toxicity package, thus meeting the overall PRIA timeline for registration of a formulation. The Agency should also make clear what particular data or information, if any, must accompany a waiver request.

In sum, CLA applauds EPA for taking this step to reduce animal testing for acute toxicity data requirements. It is encouraging to note that significant progress is being made to identify suitable alternative approaches for all six acute-toxicity endpoints. In particular, calculation-based methods (i.e., additivity) for acute oral and inhalation toxicity data on individual formulation components are highly promising to replace stand-alone studies on complete formulations. We look forward to working with EPA and the broader scientific community to advance this effort. Should you have any questions or wish to discuss any of the statements specifically, please contact me directly (jcollins@croplifeamerica.org) or (202) 833-4474.

Thank you for your consideration of these comments.

Respectfully,

Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President, Science and Regulatory Affairs