December 13, 2017

Ms. Wilhelmena Livingston
Office of Pesticide Programs Docket
Environmental Protection Agency (EPA/DC)
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Submitted via Regulations.gov Docket ID No. EPA-HQ-OPP-2010-0479-0045

Re: Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides; Notice of Availability; Docket ID No. EPA–HQ–OPP–2010–0479-0045 82 FR 43006 (September 13, 2017).

Dear Ms. Livingston:

CropLife America (CLA) appreciates the opportunity to review and provide comment to the Environmental Protection Agency (EPA or the Agency), on the subject notice Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides [EPA-HQ-OPP-2010-0479-0045] with specific reference to "gamma-cyhalothrin" [EPA-HQ-OPP-2010-0479]." CLA's comments also are applicable to lambda-cyhalothrin [EPA-HQ-OPP-2010-0480].

Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. 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.

CLA strongly supports the comments submitted by FMC Corporation (FMC) on lambda-cyhalothrin and gamma-cyhalothrin. CLA also incorporates, by reference, all comments and corresponding citations and references to CropLife America's historic submissions to EPA on applying and retaining traditional uncertainty factors, and specifically with respect to EPA's continued use of the Food Quality Protection Act (FQPA) Uncertainty Factor applied to children under the age of six years.

EPA Used Uncertainty Factors Instead of More Appropriate CAPHRA (Council for the Advancement of Pyrethroid Human Risk Assessment) Pharmacokinetic (PK) Modeling

Lambda- and gamma-cyhalothrin are pyrethroid insecticides that provide unique benefits for pest control. Gamma-cyhalothrin has the lowest use rate of any pyrethroid; both active ingredients have a variety of agricultural and non-agricultural uses. The cyhalothrin PK models are accompanied by an extensive body of scientific literature related to pharmacokinetics and pharmacodynamics of this class of chemicals. Within the Human Health Risk Assessment (HHRA), the Agency stated that "The agency has determined that the important PK properties relevant to the metabolism and distribution of pyrethroids in the body are sufficiently similar for members of this class such that using a 'generic' or family model structure for this class is scientifically appropriate. In other words, because of the similarities in the PK profiles of pyrethroids, a single model structure can predict the tissue dose based on the PK of every member of the class," and that the extensive research will be evaluated in the proposed October 2017 SAP (Subsequently Cancelled).

We support FMC Corporation's (FMC) statement that the CAPHRA modeling for the cyhalothrins will enable the reduction or elimination of uncertainty factors and needs to be considered in a refined human health risk assessment. It is reasonable to assume that by using these models, the acute risk estimates could be further evaluated, the acute population adjusted dose (aPAD) estimations could be changed, and thereby the resulting risk level for these compounds could be refined to reduce overstated risk. Eliminating or reducing the unnecessary intraspecies factor by use of CAPHRA modeling would greatly reduce the aPAD presented in the cyhalothrin risk assessments to a level that is more predictive of true risk.

Conclusion

CLA supports a risk-based regulatory decision-making process that includes robust risk assessments for human health and the environment. CLA supports the use of PK modeling for refinement of the risk assessment, where data are available. The use of such models to ascertain exposure scenarios more specifically derives risk values for the acute dietary risk assessment, and gravitates away from broad-use, undefined uncertainty factors. Further, the use of Data-Derived Extrapolation Factors (DDEF's), such as the CAPHRA modeling, demonstrates the extent to which rodent studies provide human-relevant data. This is a significant improvement for pesticide reviews in extrapolating true risk, since the Agency is precluded from conducting human trials.

According to the document, the risk assessment does not provide enough data to discern differences between juveniles' and adults' abilities to metabolize pyrethroids. The risk assessment goes on to determine that the uncertainty factors would be applied as such, and references a memo supporting the use of FQPA factors in pyrethroid risk assessments from 2011

(D381210, E. Scollon, 6/27/2011)[1]. There has been substantial work in the area of pyrethroid PBPK modeling, including a well-developed model that was discussed during the 2015 Scientific Advisory Panel (May, 2015)[2]. Given the timeline from the memo, as well as the advancements within the model itself, we support FMC's position that models developed by CAPHRA can better be used to predict relative tissue levels in young children and adults.

We encourage the Agency to continue to incorporate PBPK modeling in this and future assessments. Thank you for your consideration of these comments. Should you have any questions, please contact me by email (bstahl@croplifeamerica.org) or telephone (202-872-3866).

Respectfully submitted,

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[1] US EPA, 2011, Memorándum D381210. "Re-Evaluation of the FQPA Safety Factor for Pyrethroid Pesticides." June 27, 2011 (E. Scollon).
[2] US EPA, 2015, FIFRA SAP Meeting held to consider the "Research to Evaluate the Potential for Juvenile Sensitivity to Pyrethroids." May 19-21, 2015.