



April 30, 2018

Environmental Protection Agency  
Office of Pesticide Programs  
EPA Docket Center (EPA/DC) (28221T)  
1200 Pennsylvania Avenue NW  
Washington DC 20460-0001

via Regulations.gov: **EPA-HQ-OPP-2009-0361**

**Re: Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides; Notice of Availability; Docket ID No. EPA-HQ-OPP-2017-0720; 83 FR 8476; Feb. 27, 2018.**

Dear Sirs:

Established in 1933, CropLife America (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's member companies produce, sell and distribute virtually all crop protection and biotechnology products used by American farmers. CLA is committed to working with the U.S. Environmental Protection Agency (EPA or "Agency"), as the primary federal agency responsible for the regulation of pesticides, to encourage practical, risk-based regulation of its members' products.

On February 27, 2018, EPA made available, for a 60-day public comment period, 11 separate dockets under its "Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides; Notice of Availability;" [EPA-HQ-OPP-2017-0720]. Within separate dockets were draft human health and/or ecological risk assessments for 11 pesticides, including the "Glyphosate. Draft Human Health Risk Assessment in Support of Registration Review" [EPA-HQ-OPP-2009-0361]. CLA appreciates the opportunity to comment on components of the glyphosate human health and preliminary ecological risk assessment.

CLA's comments will largely refer to pesticide industry concerns about the approaches used by EPA in its risk assessments rather than specific technical issues on glyphosate. Several CLA member companies will provide specific technical details regarding the glyphosate risk assessments. CLA supports its member companies' and the Joint Glyphosate Task Force's comments, as well as those from RISE (Responsible Industry for a Sound Environment) by reference herein.

Glyphosate is a nonselective Group 9 herbicide currently registered for pre-emergence and post-emergence application to a variety of fruit, vegetable, and field crops, as well as turf (golf courses and residential lawns) and aquatic application scenarios. Glyphosate is well known to have low toxicity across species, durations, life stages, and routes of exposure.

**Representing the Crop Protection Industry**

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## **The Preliminary Ecological Risk Assessment for Glyphosate and its Salts Requires Refinement**

EPA's preliminary ecological risk assessment for glyphosate considers ecological toxicity studies from registrants' submissions to EPA, and studies from the open literature, largely not quantitatively assessed. EPA also has included a preliminary screening level assessment for endangered species; a complete Endangered Species Act (ESA) assessment is not included. Such preliminary screening is a component of a Tier One (unrefined) ecological risk assessment.

In some instances where Tier One assessments are reported, exposure refinements must be considered to represent environmentally relevant exposures. For example, in such a refined assessment, residues of glyphosate and its salts resulting from 'predicted' spray drift would be further studied and likely would result in more ecologically relevant and reduced levels.

When ecological risk assessments are based on assumptions that do not reflect ecological and environmental conditions relevant to the application or potential exposure of glyphosate, residues are concluded to be higher than levels found when registrant data are used quantitatively. The preliminary nature of the Tier One assessments result in exaggerated exposure levels not supported by the weight of the scientific evidence or relevant environmental observations.

## **The Toxicology Database for Glyphosate Adequately Represents Data to Characterize Toxicity and Quantify Risk with Food and Non-Food Exposures**

Glyphosate is characterized as having low acute toxicity for oral, dermal and inhalation routes, and exhibits low toxicity across species, durations, life stages, and routes of exposure.

EPA's re-evaluation of the potential human carcinogenic potential of glyphosate included a weight of evidence evaluation. Data evaluated included animal toxicity, genotoxicity and extensive review of epidemiological studies reported in the literature. EPA conclusions regarding any risks to human health are consistent with EPA's most recent human health risk assessment.<sup>1</sup> In its review of epidemiological studies reported in the literature, EPA noted that while it identified several dozen glyphosate environmental epidemiological studies, few were reported to be relevant because, "few of these studies reflected an *a priori* research interest in the potential role of glyphosate and chronic disease outcomes, and most studies were hypothesis-generating in nature." While EPA notes its review of epidemiologic study literature, the studies were largely discounted because the design of those studies did not permit any conclusion that was hypothesis-based.

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<sup>1</sup> U.S. EPA Office of Pesticide Programs. 2017. "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential." See T. Bloem *et al.*, EPA File #D398547 (November 14, 2012).

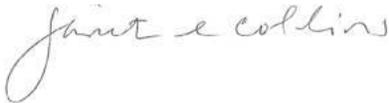
In sum, the toxicological database used by EPA provides a strong scientific basis for its risk/safety determination; CLA is supportive of EPA's use of the toxicological database for its human health risk assessment in its conclusions regarding the human health risk of exposure to glyphosate and its salts.

## **Conclusions**

CLA continues to support EPA's risk-based approach to regulatory decision making, and its use of the weight of scientific evidence in drawing its conclusions. We look forward to the opportunity to review and comment on EPA's refined ecological risk assessment.

Should you have any questions or wish to discuss any of these issues further, please contact me directly at [jcollins@croplifeamerica.org](mailto:jcollins@croplifeamerica.org) or 202.833.4474. Thank you for your consideration of these comments as well as those referenced from CLA member companies, the Joint Glyphosate Task Force, and RISE.

Respectfully,

A handwritten signature in cursive script that reads "Janet E. Collins".

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