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To whom it may concern:

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 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.

On January 7, 2016, the United States Environmental Protection Agency (“EPA” or “the Agency”) announced the availability of and opened a 45 day public comment period on its draft guidelines for human health exposure assessment. Following requests for additional time for review and comment filed by CLA and others, EPA extended the comment period through March 22 2016.

CLA appreciates the opportunity to provide comments on guidance for human health exposure assessment referenced in Notice of Availability of Draft Guidelines for Human Exposure Assessment, EPA-HQ-ORD-2015-0684. These draft guidelines are intended for public review to be followed by external peer review conducted under contract with an independent contractor. Public review of this draft guidance document is particularly important as it represents the first update of EPA guidance for human health exposure since 1992 (EPA/600/Z-92/001). As stated in the Notice of Availability, the field of exposure science has undergone significant transformation in methods and approaches since the 1992 guidance. It is the EPA intent to update the guidelines to reflect updated methods and approaches. Specifically, the update focuses on human exposure to chemical agents (stressors) and presents general principles of exposure science (including assessment and monitoring); and is intended to focus on exposure assessment as currently practiced by programs at EPA. Further, the guideline provides links to
exposure assessment tools and technical documents that address particular exposure assessment needs.

CLA members believe that the new material included on planning and conducting observational human exposure measurement studies, as well as consideration of life stages and sensitive populations in exposure assessments, is particularly relevant and important given the use of such study outcomes in current risk analysis for pesticides and pesticide active ingredients. It is, however, somewhat concerning that EPA acknowledges information provided in this draft document is the most current science used in EPA exposure assessments, and that it incorporates information about EPA current policies. If the document is a draft of information intended for external and independent peer review, how is it that this draft approach is part of the EPA exposure assessments and policies currently used in risk assessment by the Agency?

CLA has some very specific comments (Appendix document) regarding elements of the guidelines that are incomplete, lack detail or context, or are not readily understood. Links to documents, provided in the draft do not always function- we have highlighted that in some cases. We recognize the task before us, of reviewing and updating guidance that is over 20 years old—particularly given the changes in the scientific foundations as well as the tools used in the conduct of a risk assessment. For that reason, CLA will continue to review this draft and collect comments and concerns, and when the Peer Review Panel report is released for public comment, will plan to comment generally and specifically on that draft.

We appreciate the opportunity to provide brief comments now, and also the opportunity to assess differences in this new guidance as compared with that of the historic documents used for human health exposure. Should you have any questions regarding this set of comments and questions, please feel free to contact me directly. We look forward to working with EPA as these guidelines are fully developed and tested for relevance and validity in assessing human exposure.

Respectfully

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