October 20, 2016

Office of Pesticide Programs Docket
Environmental Protection Agency (EPA/DC)
Mail Code 28221T
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Submitted via Regulations.gov (Docket ID No.: EPA-HQ-OPP-2009-0317)


Dear Sirs:

CropLife America (CLA) appreciates the opportunity to provide comment on the Environmental Protection Agency’s (EPA or the Agency) recent request for comments on the Registration Review: Draft Malathion Human Health Risk Assessment [(Fed. Reg. Notice: 2016-22881; September 22 2016); Docket ID No.: EPA-HQ-OPP-2009-0317]. 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 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.

The Registration Review: Draft Malathion Human Health Risk Assessment was posted on the EPA docket (EPA-HQ-OPP-2009-0317) on September 22, 2016, with comments due no later than November 21, 2016- a 60-day comment period. The 258-page draft human health risk assessment document includes a number of sections and reviews common to organophosphate assessments, including specific modeling data for drinking water assessment, and use of epidemiologic studies to support the Food Quality Protection Act (FQPA) safety factor. The issues raised in the Draft Assessment are of critical importance to CLA members’ registrations and registration reviews, and require significant time to review and verify, particularly in the view of the important role they play in EPA’s assessments of human health impacts.

CLA requests that the timeframe for review and comment be extended an additional 60 days, to be submitted to the Docket no later than January 21, 2017. Several of the documents necessary for the in-depth review and verification are not yet posted on Regulations.gov; many of the models and assumptions used for the analyses must be tested. Further, the sheer length and
depth of information included requires careful review, which cannot be adequately accomplished in the 60 days currently allocated.

Thank you for your timely consideration of this request. Questions or concerns may be directed to me via email (jcollins@croplifeamerica.org) or telephone (202-833-4474).

Sincerely,

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

Cc: Mr. Richard Dumas, Pesticide Re-Evaluation Division
Mr. Steven Snyderman, Chemical Review Manager, RMIB III, EPA-PRD