



December 21, 2016

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

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

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

Re: Registration Review: Draft Malathion Human Health Risk Assessment; Notice of Availability
(Docket ID No.: EPA-HQ-OPP-2009-0317; FR Doc. 2016-22881, September 22, 2016)

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, FR Doc. 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 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 258-page Malathion Human Health Risk Assessment document (EPA-HQ-OPP-2009-0317-0080) (Risk Assessment) includes several sections and reviews common to all organophosphate (OP) assessments, including the use of epidemiological studies to support retention of the Food Quality Protection Act (FQPA) 10X Safety Factor (the FQPA Safety Factor) and specific modeling data for drinking water assessment. The issues raised in the Risk Assessment are of critical importance to CLA members' registrations and registration reviews. CLA will focus its comments on the Risk Assessment's use of epidemiological data and the Agency's approach to drinking water assessments (Drinking Water Assessment for Registration Review of Malathion; EPA-HQ-OPP-2009-0317-0076).

Use of Epidemiological Data

A key concern of CLA members is EPA's repeated approach to the use of certain epidemiological studies in the regulation of OPs, including malathion. Specifically, we are concerned with EPA's reliance on the Mother's and Newborn Study of North Manhattan and South Bronx, conducted by Columbia University (Columbia Study); Mount Sinai Inner-City Toxicants, Child Growth and Development Study (Mount Sinai Study); and the Center for Health Assessment of Mothers and Children in Salinas Valley (CHAMACO Study) (collectively the Studies). EPA's flawed reliance on these Studies, which are of questionable relevance, has resulted in EPA broadly and erroneously concluding that, "there is sufficient uncertainty (from studying chlorpyrifos) in the human dose response relationship for neurodevelopmental

effects which prevents the agency from reducing or removing the statutory 10X FQPA Safety Factor. For preliminary human health risk assessments for the OPs, a value of 10X will be applied.”¹ This same Literature Review also is part of the supporting documentation in the malathion docket. The potential impact of this approach to EPA’s risk assessment process and regulation of pesticides generally is profound. It is of critical importance to all stakeholders that EPA’s risk assessment process be based on well-understood, and broadly accepted scientific concepts of risk assessment. EPA’s reliance on epidemiological studies of questionable validity and relevance, while minimizing and/or excluding a vast body of toxicological and other valid and relevant data, seems to signal a departure from the scientific concepts of risk assessment on which EPA has relied, and must rely, for its regulatory determinations, and a movement toward an unnecessarily more precautionary approach.

The Agency has stated that it will retain the FQPA Safety Factor for malathion. As part of its analysis, EPA claims to have identified “uncertainty” regarding its risk assessment approach based on the Studies.² CLA understands that the underlying data for these Studies have never been disclosed to the Agency, and, thus, EPA has never had the opportunity to review and scrutinize the data to assure data quality. To generalize the application of the FQPA Safety Factor to all OPs is, therefore, scientifically questionable. EPA’s approach to these Studies is particularly troubling, given that EPA itself has acknowledged the risks and limitations in relying on epidemiological studies for regulatory decision-making. Indeed, the Agency has created a Draft Framework to guide its use of epidemiological data in assessing risk, in which EPA states that such data must be used in “the most ... transparent way.”³

In relying on the Studies, the Agency has departed from its historical weight of evidence approach to human health risk assessment and elevated the importance of epidemiology, despite all its acknowledged limitations, above the extensive, robust toxicological database for malathion. The weight given by EPA to the Studies is inconsistent with the Agency’s statutory mandate to assess risks and make regulatory decisions based on valid, complete, and reliable scientific data. EPA’s weighting of the Studies is also inconsistent with the Agency’s own Draft Framework. CLA has taken note of the 2002 publication by the Columbia University researchers wherein exposure to pesticides within the cohort included organophosphates, carbamates, pyrethroids and fungicides.⁴ Of considerable interest is that malathion was not detected in any of the samples collected.⁵ The researchers stated that the Columbia Study illustrates the challenge in conducting epidemiological studies of residential pesticide use. CLA encourages the Agency to carefully consider its approach to epidemiological studies, with respect to malathion specifically, and the potential impact on its regulatory process for malathion, organophosphates, and pesticides in general.

Our members also take issue with the Agency’s characterization of its approach to the use of epidemiological data as “stepwise, objective and transparent,”⁶ as EPA appears to have ignored the standards it imposes on registrants by accepting and relying on the Studies. CLA’s pesticide registrant members routinely provide extensive scientific data to the Agency in support of registration submissions.

¹ U.S. Environmental Protection Agency, *Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides*, Sept. 15, 2015, EPA-HQ-OPP-2010-0119-0023 (the Literature Review).

² U.S. Environmental Protection Agency. 2016. Malathion; Human Health Draft Risk Assessment for Registration Review. EPA-HQ-OPP-2009-0317.

³ U.S. Environmental Protection Agency, *Draft Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment*, January 10, 2007 (Draft Framework).

⁴ Whyatt RM, et al., *Residential Pesticide Use During Pregnancy Among A Cohort Of Urban Minority Women*, *Envir. Health Persp.* 110: 5, 2002.

⁵ *Id.*

⁶ *Ibid. Literature Review (2015).*

These submissions must meet rigorous standards relating to study conduct and data evaluation.⁷ Of particular relevance, EPA’s pesticide regulations require that “[r]ecords containing research relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, all underlying raw data, and interpretations and evaluations thereof ... be retained as long as the registration is valid and the producer is in business.”⁸ EPA’s regulations also describe detailed laboratory practices “intended to assure the quality and integrity of data submitted” pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act, including a requirement that “raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained.”⁹ Pesticide applicants must adhere to these standards when conducting studies for registration purposes.¹⁰

These regulations and standards underscore the value of studies whose underlying raw data is available to the Agency for review. EPA’s reliance on unverifiable epidemiological study outcomes, and studies that cannot be replicated, is inconsistent with EPA requirements that CLA’s members must follow, and with the Agency’s own guidance on epidemiological data (requiring that it be used in “the most ... transparent way”).¹¹ Further, EPA proposes to rely on the Studies to the exclusion of the extensive body of contrary evidence in the literature and in the body of data provided for each registration undergoing registration review.

EPA’s failure to obtain and review the raw data upon which the Studies are based is arbitrary and suggests a lack of commitment to the robust, science-based regulatory process that Congress has established for regulating pesticides. It also calls into question the credibility of EPA’s decision-making process and whether its decisions are supported by substantial evidence on the record. Practically, the absence of raw data prevents EPA and its stakeholders, including registrants, from testing the Studies’ results or cross-checking any of the factors EPA itself identified as key to evaluation of epidemiological data, i.e., the reliability and validity of exposure estimates, appropriate consideration of confounding factors, verification of the study’s statistical analysis, evaluation of potential bias in observational research, and external validity and generalizability, among others.

Drinking Water Modeling Assessment

CLA is concerned about EPA’s continued use of highly conservative models to estimate potential pesticide exposure via drinking water.¹² Along with these models, EPA selects conservative environmental fate data points as inputs. For example, among the six scenarios in the EPA assessment to support the malathion draft risk assessment is the Washington State application scenario (the ‘maximum aerial scenario’). In this scenario, the food only component represents 24% of the steady state population adjusted dose (ssPAD). Combined with drinking water, this calculation represents 240% of the acute population adjusted dose (aPAD) for the US population. While the scenarios are modeled to be highly conservative, multiple layers of conservatism result in estimates of pesticide levels in drinking water that are often many orders of magnitude above the highest observed monitoring results. The drinking

⁷ See, generally, 40 C.F.R. § 158.

⁸ 40 C.F.R. § 169.2(k).

⁹ 40 C.F.R. § 160.190; see also 40 C.F.R. §§ 160.33(f) (requiring that raw data be archived), 160.51 (requiring facilities for the storage of raw data), 160.130(e) (requiring that study data be recorded during conduct of the study), 160.195(b) (establishing retention periods for raw data).

¹⁰ 40 C.F.R. § 158.70(b).

¹¹ *Ibid.* Draft Framework (2007).

¹² See CLA Comments on Pesticide Registration Review: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides, December 24, 2015, EPA-HQ-OPP-2015-0386-0007, attached hereto.

water alone, in this scenario, would represent over 200% of the aPAD. This is not a realistic estimate, particularly given the low level of exposure calculated from the dietary assessment.

As evidenced above, EPA's approach to determination of the drinking water exposure is flawed and places unrealistic assumptions on the drinking water model(s) input(s). CLA members and others in the agricultural community have repeatedly requested that EPA identify more relevant approaches to estimating pesticide concentrations in drinking water. It is important to acknowledge that the estimated levels of pesticides in drinking water should be directly associated with the input parameters including application rates, timing of application, number of applications, and other factors. Direct measurement of those parameters in real time can provide the documentation needed to support changes in Agency assumptions regarding exposure to pesticides from drinking water.

We recommend that EPA consider assessment of the outcomes from drinking water exposure models as compared with results from water monitoring studies to rationalize the models to reflect more realistic outcomes. Consideration of the assumptions in the drinking water models also could improve the outcomes to more effectively mirror data derived from direct sampling and monitoring.

In conclusion, CLA disagrees with the outcomes of EPA's Health Effects Division's draft Human Health Risk Assessment and the Environmental Fate and Effects Division's draft Drinking Water Assessment. Our stated concerns have been communicated previously with respect to the drinking water models, use of epidemiological study outcomes in regulatory risk assessment and retention of the FQPA Safety Factor as outlined in the EPA Literature Review.¹³ Before EPA considers regulatory decision making based on its assessments in this docket, it should consider and respond to previously reported FIFRA Scientific Advisory Panel recommendations about the use of epidemiological studies and retention of the FQPA Safety Factor,¹⁴ and consider stakeholder input on both the use of epidemiological studies and drinking water modeling¹⁵.

Thank you for your consideration of these comments. Should you have any questions, please contact me by email or telephone.

Respectfully submitted,



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¹³ CLA Comments on Chlorpyrifos and Literature Review, EPA-HQ-OPP-2010-0119-0039 (February 22, 2016).

¹⁴ See SAP 2008-04 Minutes, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos, EPA-HQ-OPP-2008-0274-0064 (December 17, 2008); FIFRA SAP, February 2-4, 2010, Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment, EPA-HQ-OPP-2009-0851; FIFRA SAP, April 10-13, 2012 US Environmental Protection Agency FIFRA SAP Meeting on Chlorpyrifos Health Effects, EPA-HQ-OPP-2012-0040; FIFRA SAP, June 12-14, 2012, Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine, EPA-HQ-OPP-2012-0230; Transmittal of Meeting Minutes of the April 19-21, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with "Chlorpyrifos: Analysis of Biomonitoring Data," EPA-HQ-OPP-2016-0062-0140 (July 25, 2016).

¹⁵ CLA Comments on drinking water in the assessments of sulfonylureas. 2015. EPA-HQ-OPP-2015-0386; Pesticide Registration Review: Draft Human Health and Ecological Risk Assessments for Sulfonylureas and Certain Other Pesticides.