November 2, 2017

OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

Submitted via Regulations.gov Docket ID No. EPA-HQ-OPP-2010-0230-0033

Re: Registration Review; Draft Human Health and/or Ecological Risk Assessments for Benfluralin, Bromuconazole, Carbaryl, Clodinafop-propargyl, Deltamethrin, Diflufenzopyr, Esfenvalerate, Lufenuron, and Mepiquat Chloride/Mepiquat Pentaborate; Notice of Availability. Docket ID No. EPA-HQ-OPP-2010-0230-0033; 82 FR 36135 (August 3, 2017).

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA or Agency) Registration Review; Draft Human Health and/or Ecological Risk Assessments for Benfluralin, Bromuconazole, Carbaryl, Clodinafop-propargyl, Deltamethrin, Diflufenzopyr, Esfenvalerate, Lufenuron, and Mepiquat Chloride/Mepiquat Pentaborate; Notice of Availability. Docket ID No. EPA-HQ-OPP-2010-0230-0033; 82 FR 36135). CLA's comments specifically address the documents "Carbaryl Drinking Water Assessment for Registration Review" (Docket ID No. EPA-HQ-OPP-2010-0230-0037) and "Carbaryl: Draft Human Health Risk Assessment in Support of Registration Review" (Docket ID No. EPA-HQ-OPP-2010-0230-0034).

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, the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

Carbaryl is an effective, broad-spectrum insecticide that plays a critical role in resistance management for many agricultural commodities including fruits, nuts, vegetables, and grain crops. Carbaryl is also used as a rotation insecticide (e.g., with pyrethroids) for controlling or delaying development of resistance in target pest populations, affecting crops such as citrus, pecans and cherries. In addition to its insecticidal properties, carbaryl is used extensively in apple orchards as a thinning agent to optimize fruit size and quality. Without carbaryl, growers would likely rely on alternative, less reliable, thinning agents or on manual farm labor with limited or unpredictable availability.

The following comments address CLA's concerns with EPA's draft carbaryl drinking water risk assessment. CLA also advocates for greater transparency in the Agency's draft carbaryl dietary risk assessment and the use of physiologically-based pharmacokinetic (PBPK-PD) modeling.

I. The carbaryl drinking water assessment for registration review does not go beyond a screening-level assessment.

EPA's screening-level assessment is based on conservative assumptions that overestimate carbaryl concentrations in drinking water. CLA believes that EPA's assessment can be improved by incorporating refinements to produce more realistic exposure assessments. Notably, the assessment should be refined by incorporating percent crop area (PCA) and percent crop treated (PCT) adjustment factors (the assessment assumes 100% crop area treated). The specific carbaryl uses indicated on the label allow for an assessment of crop co-occurrence in the landscape, assignment of scenarios by regions, and use of regional PCA factors. As such, this information would provide the basis for customized carbaryl use patterns that can be used to refine exposure estimates. By assuming 100% PCA, and not considering regional scenario differences, crop distributions, or variability in predicted concentrations, the assessment fails to incorporate available information that would otherwise provide a more accurate and realistic representation of exposure.

EPA has referenced several studies on monitoring drinking water concentrations. However, it does not appear to have included monitoring data in the assessment in a meaningful way. The studies and data presented in the assessment highlight the extreme over-estimates of modeled concentrations compared to observed results. Also, EPA has referenced outdated monitoring data, collected prior to 2004, that are not reflective of current use practices or use intensities for carbaryl. In most cases, the upper percentile concentrations reported in the monitoring studies are orders of magnitude lower than the modeling results, indicating a need for refinement to the modeling-based drinking water assessment.

EPA should incorporate additional refinements to improve estimated drinking water concentrations in flooded crops such as rice and cranberries. These refinements would include better assessments of receiving water bodies, and more complete scenario inputs such as environmental fate, application timing and rate, cropping parameters, and timing of flooding events. EPA also should include assessment estimates of foliar and soil degradation, not simulated by EPA's Pesticide in Flooded Application Model to estimate carbaryl concentrations in released flood waters. CLA asks that EPA refine its assessment to include all relevant crop data and application scenarios to generate a more realistic estimate of drinking water concentrations.

II. The uncertainties section of the draft drinking water risk assessment does not adequately capture key factors or the impact on the conservatism of the assessment.

EPA did not adequately capture all sources of uncertainty that led to exposure overestimates in its draft drinking water assessment. For example, the predicted carbaryl concentrations in surface water represent a highly vulnerable watershed assumed to have 100% crop area coverage, 100% treated with carbaryl, and all applications occurring on the same day.

As the extensive summary of monitoring data demonstrates, these assumptions significantly overstate observed concentrations of carbaryl and, as such, are major sources of unsupported conservatism and uncertainty.

EPA acknowledges uncertainties resulting from the fact that it modeled its application timing assumptions on limited information on target pests and actual timing, and that this information gap led to the conservative assumption that initial applications take place during relatively wet periods (the rainiest part of the year) on average. CLA believes that application timing should be updated to reflect label information that provides detailed target pest lists for each crop for which carbaryl is approved, as well as available information on timing of insect pressure during the season. This would lead to more predictive exposure modeling.

III. The use of Data-Derived Extrapolation Factors (DDEF) developed through use of PBPK-PD Modeling provides more accurate risk values establishing human toxicity when compared to default values and highly conservative uncertainty factors.

CLA supports comments submitted by NovaSource/Tessenderlo Kerley, Inc., (TKI) discussing the assessment of risk values derived from carbaryl-specific PBPK-PD models. The use of such models to ascertain exposure scenarios more specifically derives refined points of departure for the acute dietary risk assessment, and gravitates away from broad-use, undefined uncertainty factors. A PBPK-PD model can provide a more accurate, science-based picture of the dose at the affected tissue, with less uncertainty, than can be obtained from data based on observations of animal responses. Risk assessors can work with the biologically effective dose, also called the internal dose metric, rather than the administered dose, to derive a dose-response relationship. The use of DDEF to demonstrate the extent to which rodent studies provide human-relevant data is a significant improvement for pesticide compound reviews since the Agency is precluded from conducting human trials. We encourage the Agency to continue to incorporate PBPK-PD modeling in this and future assessments.

IV. EPA process lacked transparency when it failed to release the detailed draft carbaryl dietary risk assessment.

CLA requests that the full dietary risk assessment be released. Consequently, the calculation and percentile derivation of 99.9% appear unsupported without further existing data.

In summary, EPA must refine its drinking water and human health and drinking water risk assessments to reflect the available higher-tier data and information on carbaryl use patterns and target pests.

CLA understands the Agency has analytic values, and identifies use of the already reviewed PBPK-PD model for carbaryl. EPA[1] has reviewed a PBPK-pharmacodynamic (PD) model of carbaryl developed for humans. Further, it is possible to use this human PBPK-PD model to derive points of departure (PODs) for carbaryl based on 10% RBC AChE inhibition for various exposure scenarios (e.g., dietary food exposure, drinking water exposure, occupational exposure and residential exposure). The model, when used in calculating risk factors, significantly lowers risk values for a dietary and a drinking water assessment.

CLA requests the Agency highlight the preliminary and highly conservative nature of these assessments, and clarify for stakeholders that screening-level assessments are conservative assessments intended only to provide estimates of potential risk rather than actual risk.

Should you have any questions or wish to discuss this matter further, please contact us directly by email or telephone listed below.

Thank you for your consideration of these comments.

Respectfully,

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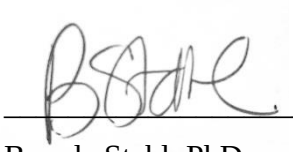

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[1] EPA (2016). https://www.epa.gov/sites/production/files/201701/documents/ache_white_paper_for_hsrb_122016.pdf