April 21, 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-2017-0011**

Re: Registration Review; Neonicotinoid Risk Assessments, Work Plans, and Updated Schedules; Notice of Availability; Docket ID No. EPA-HQ-OPP-2017-0011; 82 FR 60599; Dec 21, 2017.

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 December 21, 2017, EPA made available, for a 60-day public comment period, four separate dockets under its "Registration Review; Neonicotinoid Risk Assessments, Work Plans, and Updated Schedules;" [EPA-HQ-OPP-2017-0011]. Within separate dockets were neonicotinoid risk assessments, neonicotinoid benefits assessments, and draft human health and/or ecological risk assessments for four pesticides. Included in Docket ID EPA-HQ-OPP-2017-0011 were the draft ecological non-pollinator risk assessment (assessing risks to birds, mammals, non-target insects, and plants) for the registration review of imidacloprid (EPA-HQ-OPP-2008-0844), and draft human health and non-pollinator ecological risk assessments for the registration review of clothianidin, thiamethoxam, and dinotefuran (EPA-HQ-OPP-2011-0865; EPA-HQ-OPP-2011-0920; EPA-HQ-OPP-2011-0581, respectively**)**.

At the request of stakeholders, including CLA, on February 15, 2018, EPA extended the public comment period for "Registration Review; Neonicotinoid Risk Assessments, Work Plans, and Updated Schedules: [EPA-HQ-OPP-2011-0011] an additional sixty (60) days, from February 20, 2018, to April 21, 2018. CLA appreciates the opportunity to comment on these issues.

Our colleagues at the Responsible Industry for a Sound Environment (RISE) have provided broad comments on the many benefits of neonicotinoids that control insects in agricultural production as well as in non-agricultural settings. Those benefits, also summarized in the dockets, include neonicotinoids' remarkable selectivity in function, which results in lower use

rates to provide sufficient pest control while minimizing environmental and human exposures. Risk assessments conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are driven by risk-based scientific evidence, and include the appropriate benefit assessment which results in a realistic determination of the value of pesticides in agricultural and residential pest control. We strongly support the common sense, risk benefit statements made in RISE's comments submitted to the docket.

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 each of the above-named pesticides. For pesticide-specific technical details of the ecological and human health risk assessments, CLA supports its member companies' comments [Bayer US and Valent USA, LLC (clothianidin and imidacloprid), Landis International, Inc. (imidacloprid and dinotefuran), and Syngenta (thiamethoxam)].

1. Screening-level Assessments That Do Not Account for Relevant Environmental or Animal Behavior Factors

EPA's assessments are based on unrealistic assumptions and unreliable data that result in highly exaggerated exposure/hazard/risk predictions which are not supported by the weight of the scientific evidence or relevant environmental observations.

EPA has conducted screening-level assessments that rely on baseline assumptions which do not adequately consider environmental, agronomic, or animal behavior factors. Reliance on such baseline assumptions results in highly exaggerated risk conclusions not representative of real-world risks. In order that informed risk management decisions can be made, further consideration of data reliability, baseline assumption refinements, and additional lines of evidence (e.g., lack of real-world negative impacts on birds and mammals over the many years of extensive neonicotinoid use) is essential.

2. Unrealistic Consumption Data for Birds and Mammals in its Risk Assessments

EPA's human health risk assessments make unrealistic assumptions about dietary exposure of birds and mammals to neonicotinoids. For example, the assumption that 100% of a diet comes from a single feed source and contains the highest neonicotinoid residues, does not reflect real world exposure and food consumption.

The assumption that a bird or mammal eats treated seed with maximum neonicotinoid loading, every day, for a chronic exposure duration (or eating treated forage/food in a field with soil or foliar treatments) in no way reflects relevant pesticide exposure for such animals or birds. Further not considered are realistic agricultural issues, such as all treated seeds are not wildlife feed sources (e.g. soybean, potato, canola, sugarbeet, cotton), and that modern planting equipment minimizes the quantity of treated seeds remaining above ground, reducing accessibility as food. Additionally, pelleting, palatability, and color of seeds generally act as deterrents for consumption of treated seeds.

These overly conservative exposure scenarios result in unrealistic risk estimates that are not reflected in real-world impacts on birds and mammals. Further, these exposure scenarios are not supported by many years of widescale use and the scientific studies supporting their use.

3. **Assumptions and Conclusions About the Impact of Water Sources on Exposure are not Realistic**

EPA applies conservative levels of regulation to all aquatic systems, regardless of their purpose or ecological relevance. For example, agricultural drainage canals and ditches are not designed to provide habitat for aquatic organisms and often do not support colonization by aquatic invertebrates. Natural habitats and agricultural structures deserve a level of protection from potential risk that should be established during problem formulation. The Agency includes monitoring data from agricultural structures, not generally the habitat of aquatic organisms, as evidence that acute and chronic toxicity endpoints are exceeded.

CLA believes that EPA should consider the water system's function and attributes when setting appropriate protection goals; non-relevant monitoring data should not be included in assessments. Further, it is unclear why the Agency would also include monitoring data from Ontario, Saskatchewan and Quebec, Canada; Sidney Australia; and Osaka Japan in its environmental reviews. Given the vast unique agricultural landscape in the United States, none of those geographies are comparable.

4. **Reliance on Overly Conservative, Theoretical Modeling for Prediction of Water Concentrations Significantly Overstates Potential Exposure**

EPA's aquatic assessment is highly conservative in its reliance on theoretical water modeling concentrations that do not account for all current label restrictions. Further, the assessments are based on highly conservative assumptions of maximum rates, maximum number of applications, direct proximity to water bodies, and conservative environmental fate inputs.

These theoretical exposures are not supported by monitoring data provided in EPA's own assessments in the dockets. As stated earlier, use of higher-tiered data, such as monitoring data, should be from areas that represent registered pesticide uses rather than use of monitoring data from geographies such as Australia or Japan to evaluate uses in North America, as reported in the dockets.

5. **Application of the Most Conservative Endpoint to Represent the Entire Aquatic Invertebrate Community Overestimates Exposure**

EPA applies the lowest available aquatic invertebrate toxicity value to assess potential risk to all aquatic invertebrates. This practice does not account for lower toxicity seen in other species that represent the diversity of real-world aquatic invertebrate communities.

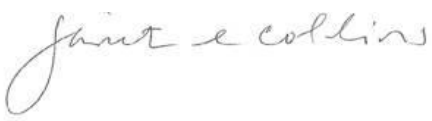
Reliance on the single lowest endpoint for risk evaluations does not reflect a weight-of-the-evidence approach that would consider the consistency of the response across studies and compounds in the same class to ensure that conclusions based on the data are sufficiently robust to make informed risk management decisions.

Conclusions and Request

CLA and its members are concerned about the generally conservative assumptions made in the neonicotinoid risk assessments and the failure to move to refined assessment tools to establish relevant risk management outcomes for the neonicotinoids. Given the benefits of neonicotinoids to agriculture, their low mammalian toxicity, their role in resistance management, and the effective control of numerous classes of pests, we strongly encourage EPA to move to greater reliance on refined assessment tools that better reflect environmental and human exposure to this class of chemistry.

Should you have any questions or wish to discuss any of these issues further, please contact me directly at jcollins@croplifeamerica.org or 202.833.4474. Thank you for your consideration of these comments as well as those referenced from CLA member companies and RISE.

Respectfully,



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