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Environmental Protection Agency
1200 Pennsylvania Ave, NW
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Submitted to Dockets: EPA–HQ–OPP–2011-0865; EPA-HQ-OPP-2008-0844; EPA-HQ-OPP-2011-0581

Re: Request for Comment on Clothianidin's, Imidacloprid's, and Thiamethoxam's Updated Occupational Exposure Assessments for Seed Treatment Uses in Support of Registration Review

Dear Mr. Khan:

On July 26, 2024, the Environmental Protection Agency (EPA or the Agency) published in the Federal Register a Notice of the Agency's draft human health and/or ecological risk assessments for the registration review of several neonicotinoid pesticides. At the same time, EPA published an Updated Occupational Exposure Assessment for Seed Treatment Uses in Support of Registration Review for those products ("neonicotinoid OEAs"). With this notice, the Agency opened the public comment period. CropLife America (CLA)[1], American Seed Trade Association (ASTA)[2], and the Growing Matters Coalition[3] appreciate the opportunity to provide these comments to EPA on the neonicotinoid OEAs. We also appreciate the Agency's extension of the public comment period to allow stakeholders to submit substantive, technical comments.

Interests of CLA, ASTA, and Growing Matters in the Neonicotinoid OEAs

CLA, ASTA, and Growing Matters offer a valuable and unique perspective to the Agency as it continues its Registration Review of clothianidin, thiamethoxam, and imidacloprid. CLA's members, which include members of Growing Matters, own EPA registrations for scores of seed treatment products. ASTA's members are also key participants in the seed treatment value chain. ASTA's members constitute over 95% of the active seed companies in the United States. Of the $16–17 billion in annual seed sales by

[1] Established in 1933, CropLife America represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

[2] Founded in 1883, ASTA is a voluntary, not-for-profit trade association representing approximately 740 companies that develop, produce, and distribute seeds for use in agriculture in the United States and abroad.

[3] Growing Matters Coalition (www.growingmatters.org), established in 2013, is a cross-registrant stewardship coalition committed to scientific discourse on the stewardship and benefits of neonicotinoid insecticides in North America. Registrant membership is comprised of BASF, Bayer, Mitsui Chemicals Agro., Syngenta and Valent U.S.A. The membership is represented by cross-functional participants from communications, government affairs (Federal and state), industry relations, regulatory, science, and stewardship.

ASTA's members, more than 75% cover seeds that are treated with pesticides. These seed treatments are often applied to seeds by ASTA's members, in accordance with the seed treatments' FIFRA labels. Moreover, CLA, Growing Matters, and ASTA members have developed stewardship programs to help educate farmers and pesticide applicators on the correct handling and management of seed treatment products and treated seed.

CLA's and ASTA's members, and U.S. agriculture, would be impacted directly and significantly by overly conservative restrictions on neonicotinoid seed treatment uses as a result of the neonicotinoid OEAs. CLA's members have invested substantial resources to obtain and maintain the registrations, sale, and use of seed treatment pesticides, and rely on revenue from the sale and distribution of these products. CLA's members also participate extensively in EPA's regulatory process for pesticide registrations in bringing new seed treatment pesticides to market. CLA's members have submitted voluminous scientific data, comments, and analyses, and have spent countless hours meeting with EPA and, for some products, scientific advisory panels ("SAPs"), to support EPA's finding that these pesticides and their specific uses as seed treatments meet the legal safety criteria required for pesticide registration under FIFRA.

ASTA's members similarly invest substantial funds in research, development, and production of new seed varieties/cultivars and seed-treatment products. Relying on the seed treatment registrations issued by EPA and the continued marketability of their treated seed, ASTA's members have also invested millions of dollars in research and development of seed treatment equipment and improvements to the seed treatment application process and made additional capital investments in employee and customer training, marketing materials, and packaging. Each of these organizations has a substantial interest in the issues raised in the neonicotinoid OEAs.

Importance of Neonicotinoid Seed Treatments to U.S. Agriculture

Seed treatments and treated seed offer many important benefits to U.S. agriculture. Seed treatments provide a precise mode of applying pesticides, protecting the seed during its most vulnerable developmental stages and before emergence from the soil. This method of protection helps to suppress and control pathogens, insects, or other pests that threaten seed viability and health from the time the seed enters the soil through its development. Indeed, the pests these pesticides are designed to mitigate can damage both seed and developing seedling at or below the soil surface, and treated seeds are often the only tool that growers have to protect this vulnerable stage of plant growth. Seed treatments help safeguard expensive, high-value, high-quality seed and, thus, growers' seed investments.

Since their introduction decades ago, seed treatments have been rapidly adopted by growers for numerous reasons. In addition to their effectiveness, seed treatments are easy for growers to handle and use, permit earlier and faster planting, allow for precise and low dose applications of pesticides, and provide an economical alternative to traditional soil or broadcast applications. Seed treatments ultimately reduce the overall amount of pesticides used when compared to other application techniques, and because of their targeted application, also minimize off-target exposure. Seed treatments are also crucial components in modern integrated pest management (IPM), enabling growers to control some of their most challenging pests and reduce the likelihood of resistance.

Clothianidin, thiamethoxam, and imidacloprid, in particular, are critically important neonicotinoid insecticides that help control a wide range of harmful insect pests. These pesticides are used as seed treatments on numerous types of crop seeds planted in the United States, including soybeans, grain, cotton, corn, beets, peanuts, onions, leafy vegetables, rice, and more. Millions of acres of crops treated with these pesticides are planted every year. Seed treatments have proven remarkably successful in

controlling pests and improving plant populations and crop yields. Seed treatments permit more seeds to reach crop maturity, and produce healthier, more abundant crops on the same acreage than those same seeds would without treatment. For example, an analysis of 1,550 field studies conducted over twenty years shows that neonicotinoid seed treatments provide average yield increases between 3.6 and 71.3 percent in eight major North American crops.[4]

In sum, the rise in use of seed treatment products is a reflection of the efficacy and quality of these products, their importance to the agricultural economy, and their value in meeting growers' needs to better protect their investment.

Occupational Exposure for Seed Treaters

In February 2020, the Agency released the initial proposed interim decisions (PIDs) for the registration review of several neonicotinoids based on existing data and models, as well as the draft human health risk assessment that included an occupational and residential exposure assessment of all uses of the neonicotinoids (i.e., foliar, in furrow, seed treatments, and commercial and residential non-crop uses); however, the model used in that assessment did not have exposure scenarios specific for seed treatment applications. At that time, the Agency was relying on individual seed treatment exposure data and previous risk assessments, instead of using a standardized approach. In early 2022, the Agency developed a specific seed treatment occupational exposure model and policies for seed treatment scenarios (ExpoSAC Policies 14.1 and 15.2)[5],[6] that only analyzed seed treatment scenarios using exposure data it had received years before.

The 2024 neonicotinoid OAEs comprehensively update EPA's prior analyses of dermal and inhalation exposure and risk estimates for seed treatment uses using this new and updated exposure data and policies. When all else is equivalent to previous assessments (e.g., toxicity reference values are the same), these revisions resulted in higher worker exposure and risk estimates than previously estimated. As part of this assessment, the Agency has also solicited information from stakeholders on extensive sets of questions regarding cleaning, treating, loading/planting, and packaging scenarios for both commercial and on-farm treating/planting for dozens of crops treated with thiamethoxam, to determine if chemical-specific use information aligns with the data and assumptions supporting the updates to policies 14 and 15.

The neonicotinoid OEAs identified risks of concern for several crops across both on-farm and commercial seed treatment based on the new model. However, EPA's operator exposure modeling is overly conservative, arising from use of erroneous assumptions and essentially arbitrary inputs, as laid out more fully below. We are very concerned that certain values used in the worker exposure assessments do not differentiate among different types of seeds and do not incorporate new technologies and regulations and/or internal company policies focused on reducing worker exposure.

Several factors used in the model compound the conservatism of the model, which is based on already unnecessarily conservative assumptions and fails to account for the inherent variability across different types of seeds and equipment used for treating. For instance, the default cleanout time used in the model, 2.5 hours, is not realistic for all scenarios. *See* Policy 14 at 10. The seed-treatment industry has updated its cleaning processes, procedures and technology since the conduct of the original studies on which the

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[4] *See* AgInfomatics, LLC, *The Value of Neonicotinoids in North American Agriculture*, Executive Summary, at vi (2015), https://aginfomatics.com/uploads/3/4/2/2/34223974/executive_summary_neonicotinoids.pdf.

[5] https://www.epa.gov/system/files/documents/2022-01/exposac-policy-14_seed-treatment-exposure-data.pdf ("Policy 14")

[6] https://www.epa.gov/system/files/documents/2022-01/exposac-policy-15_amount-seed-treated-planted.pdf

model is based. For example, seed treatment businesses commonly clean out their equipment between seed lots and/or seed type, rather than at midday. Keeping seed lots free of other types of seed drives cleaning frequency, especially for high-value vegetable seeds. Therefore, cleanout frequency is not necessarily related to pounds of seed treated per 8-hour shift as EPA's model assumes. Cleanout timing is also dependent on the type of seed being treated, as that can dictate the type of equipment which could be used.

Apart from the variation in the frequency of cleanouts, the nature and extent of the cleanout for each piece of the equipment (e.g., rotary bowl, pump, mix tank, lines and drying components) can also differ. In some instances, this process can take no longer than 15-30 minutes. In other cases, like for small-seeded vegetables, the self-cleaning and enclosed features of the treating equipment render cleanout unnecessary or minimized, requiring only a quick spray and wipe between treatments. The exposure studies represented in EPA's model assumed use of large-scale equipment where workers had potential contact with residues through worker access to the drum. This is an inappropriate comparison for many seed treatments. Moreover, even large continuous-flow drum treaters forming the basis for EPA's assumptions are now sometimes cleaned using alternative methods. Some treaters, for example, will run old seed and a little water through the drum, with the seed, rather than a person, scrubbing the inside of the drum. In all cleanout scenarios, workers carefully follow the label instructions for the use of gloves, coveralls and safety glasses during the treatment process and cleanout. EPA's arbitrary one-size-fits-all approach does not adequately consider these variables.

Further, modern commercial seed treatment facilities have many engineering controls, such as direct injection, and local exhaust ventilation, that reduce worker exposure. Virtually all commercial seed treatment systems are now closed, and some systems feature a closed cleanout process. Additionally, all commercial seed-treatment facilities have Industrial Hygiene (IH) SOPs in place as required by the Occupational Safety and Health Administration (OSHA), *see* 29 U.S.C. § 654(a)(1).

EPA's operator exposure model wholly fails to account for this extensive variation in equipment and cleanout practices. It is imperative that the Agency continue to update the occupational exposure and risk estimates to show the impacts of additional PPE (beyond what is listed on current labels as prescribed by internal IH SOPs) for certain steps, including cleanout. Certain scenarios may no longer present risks of concern when using the highest levels of PPE (i.e., engineering controls plus gloves and PF10 respirators). Based on the potential risks identified in an individual chemistry's assessment, reasonable label mitigations should be considered before cancelling commercial seed treatment uses.

We are concerned that EPA will respond to these new assessments with unnecessary and overly conservative measures that are not reflective of actual risks of exposure. Such a response would be extremely problematic for our members, set a negative precedent for how other seed treatments are evaluated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC § 136 *et seq*, and likely would not ultimately benefit human health or environmental safety. Our members, and other stakeholders, have taken, and continue to take, affirmative measures to minimize potential human health and environmental risks from seed treatment. CLA, Growing Matters, ASTA, and our member companies are committed to coordinating with the Agency on developing an improved operator exposure model and identifying mitigation measures that will protect workers and help ensure neonicotinoids continue to meet the FIFRA standard to prevent "unreasonable risk to man or the environment," without significant disruption to these seed treatment uses that are critical to agriculture. 7 U.S.C. § 136(bb).

We are committed to continuing to work with stakeholders to better understand the aspects of seed treatment where refinements to the occupational exposure models could be achieved based on real-world scientific data. Given the critical importance of neonicotinoids as a seed treatment tool in U.S. agriculture,

we ask that EPA consider information submitted by our member companies and other stakeholders to more accurately assess worker exposure during seed treatment applications based on realistic operational conditions. We encourage the Agency to continue to have dialogue with CLA, Growing Matters, ASTA and other stakeholders to improve the risk assessment by incorporating real-world data, processes, and procedures. We also ask that EPA collaborate with stakeholders, including CLA, Growing Matters, and ASTA's members, before considering any further restrictions, as is necessary to fulfill EPA's statutory mandate to factor the considerable benefits of neonicotinoids as a seed treatment in its decision making. *See* 7 U.S.C. § 136(bb) (whether pesticide poses "unreasonable risk to man or the environment" includes "taking into account the economic, social, and environmental costs and benefits" of the product).

Concluding Remarks

Neonicotinoids are a crucial component of resistance management and IPM programs. Pesticides, including seed treatments, are rigorously and routinely tested and proven to be safe and effective tools contributing to more efficient production of food, fiber, and fuel. Our collective member companies remain committed to product safety and stewardship efforts that support the proper use of neonicotinoids and other chemistries as seed treatments. We strongly support a robust commitment to agricultural innovation by the U.S. government so that U.S. agriculture has access to the best tools for driving innovation and job growth, and consumers continue to have access to a wide variety of safe and affordable food and fiber. We request that EPA carefully consider information submitted by industry stakeholders to develop a holistic and comprehensive risk/benefit assessment of the ongoing health and safety of neonicotinoids under FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5). CLA, Growing Matters, ASTA, and our member companies look forward to collaborating with EPA on more realistic exposure models and mitigation measures to preserve the viability of this important precision agricultural technology.

CLA, Growing Matters, and ASTA fully support the comments submitted by our member companies in this regard. Should you have any questions or comments, please feel free to contact us at mbasu@croplifeamerica.org and pmiller@betterseed.org.

Sincerely,

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CropLife America

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The Growing Matters Coalition

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