



July 30, 2024

DeMariah Koger
Pesticide Reevaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Submitted to Docket: EPA-HQ-OPP-2015-0433

RE: Request for Comment: Thiram Registration Review Amended Proposed Interim Decision

Dear Ms. Koger:

CropLife America (CLA)¹ and the American Seed Trade Association (ASTA)² appreciate the opportunity to provide these comments to the United States Environmental Protection Agency (EPA or the Agency) on EPA's April 30, 2024 amended Proposed Interim Decision (PID) for thiram. The amended PID for thiram proposes to cancel all commercial seed treatment uses except for on-farm seed treatment for liquid formulations based primarily on occupational handler risks of concern identified in EPA's assessment. However, EPA's operator exposure modeling is fundamentally flawed and based on erroneous assumptions and essentially arbitrary inputs. EPA's proposed cancellation of commercial seed treatment uses for thiram would be extremely problematic for our stakeholders, 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.

Given the critical importance of thiram as a seed treatment tool in the vegetable and specialty crop industry, and the likely consequences of a cancellation, CLA and ASTA ask that EPA consider information submitted by our member companies and other stakeholders to more accurately portray worker exposure during commercial seed treatment applications based on realistic operational conditions. CLA and ASTA also ask that EPA collaborate with stakeholders, including CLA and ASTA's members, to consider other mitigative measures short of a drastic and overbroad cancellation. Indeed, considering less drastic measures is necessary to fulfill EPA's statutory mandate to factor the considerable benefits of thiram 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).

CLA and ASTA members, and other stakeholders, have taken, and continue to take, affirmative measures to minimize potential human health and environmental risks from seed treatment. CLA, ASTA, and their member companies are committed to coordinating with the Agency on developing an improved operator exposure model and identifying mitigative measures that will protect workers and help ensure thiram

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.


continues to meet the FIFRA standard to prevent “unreasonable risk to man or the environment,” without the significant disruption that complete cancellation of commercial seed treatment uses would cause. 7 U.S.C. § 136(bb).

In that spirit, we have offered the enclosed comments and information and encourage the Agency to consider our stakeholder input on the proposed ban for thiram use in commercial seed treatments. CLA and ASTA fully support the comments submitted by our member companies. Should you have any questions or comments, please feel free to contact us at mbasu@croplifeamerica.org and pmiller@betterseed.org.

Sincerely,



Manojit Basu, Ph.D.
Vice President, Science Policy
CropLife America



Pat Miller
American Seed Trade Association

CC: Anne Overstreet, PRD
Ed Messina Director, OPP
Kimberly Nesci, Director, USDA OPMP

Summary of Proposed Action

On April 30, 2024, EPA published an amended PID for thiram which proposes to cancel all commercial seed treatment uses except for on-farm seed treatment for liquid formulations based at least in part on occupational handler risks of concern identified in their assessment. The amended PID states that EPA “proposes to cancel commercial seed treatment uses due to occupational handler risks of concern.” PID at 45. This proposal, which differs from EPA’s original 2021 PID, arises from the updated seed treatment policies incorporated into the 2023 Human Health Draft Risk Assessment (HHdra). *Id.* EPA updated the occupational exposure assessment for registered seed treatment uses reflecting the recent updates to Standard Operating Procedures (SOPs) and seed treatment scenarios (Policies 14.1 and 15.2).^{3,4} *Id.* In 2022, EPA updated the Seed Treatment Policy 14 with the goal of incorporating more contemporary and reliable data than those used in previous seed treatment worker exposure assessments. *Id.* The update resulted in higher worker exposure estimates for some occupational scenarios than in previous risk assessments. *Id.* When all else was equal from the previous assessments (e.g., toxicity reference values are the same), EPA concluded that there was a significant increase in the estimated dermal and/or inhalation risks of concern for workers conducting certain seed treatment activities for thiram.

Thiram’s Importance As a Seed Treatment

Thiram has been used as a seed treatment since it was first registered in 1948 and has a long history of safe use. EPA concluded in a 2020 analysis that use of thiram did not pose a concern based on continued low frequency and severity of thiram incidents reported both in EPA’s Incident Data System (IDS) and SENSOR-Pesticides.⁵ Additionally, thiram is the preferred choice as a seed treatment for vegetable seed exporters because of its broad functionality and low cost, and the extensive list of countries where it is registered.

Thiram is a common seed treatment for field seed crops such as rice, grasses grown for seed, and cotton, and is also widely used as a seed treatment on horticultural seed, such as marigold and ornamental sunflowers; and vegetable seed, such as cucumbers, tomatoes, carrots, onions, peppers and spinach. Vegetable seed production requires dry, full-year growing conditions, which are unavailable in many other countries. Specialty crops, such as flower seed, may be disproportionately negatively affected by the cancellation of commercial seed treatment uses for thiram. Due to the relatively small size of the specialty crop seed industry, there are few registered seed treatment product options. For example, if seed treatment uses for thiram are cancelled, it will cause a profound impact on the ability of US-based companies to export flower seed to international markets. It is likely this flower seed export and re-export business will be lost to competitors in Asia and Latin America, where seed treatment products are more readily available for use on specialty crops such as flower seeds. US exports of ornamental flower and vegetable seeds to those countries use thiram, which is essential in protecting those seeds in shipment by addressing phytosanitary concerns related to imported seed. The US is a participant in the International Plant Protection Convention (IPPC), a multilateral convention on plant protection under the authority of the Food and Agriculture Organization of the United Nations (FAO). APHIS has jurisdiction over the US’s implementation of its obligations under the IPPC, including by addressing phytosanitary concerns of its export partners. *See* 7 C.F.R. § 371.3(b)(vi); 7 C.F.R. § 353.2 (“After assessing the phytosanitary condition

³ ExpoSAC, HED, OPP. January 2022. Standard Operating Procedures (SOPs) for Seed Treatment. Policy 14.1.

⁴ ExpoSAC, HED, OPP. January 2022. Standard Values for Amount of Seed Treated and/or Planted Per Day. Policy 15.2.

⁵ EPA Memorandum. Thiram: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment. April 2020. EPA-HQ-OPP-2015-0433-0616_content

of the plants or plant products intended for export, relative to the receiving country's regulations, an inspector issues an internationally recognized phytosanitary certificate, a phytosanitary certificate for reexport, or an export certificate for processed plant products if warranted.”). Several countries, such as Mexico, Ecuador, Kenya, Saudi Arabia, and the Philippines, require certain seeds to be treated with pesticide(s) to address phytosanitary concerns and thiram is a widely-used option for this purpose. Therefore, movement of treated seeds internationally is also a significant concern should thiram seed treatment registrations in the US be cancelled.

Thiram has a different mode of action (Fungicide Resistance Action Committee Code M3) from other widely used chemistries, such as Captan, making it an integral part of the recommended fungicide rotation regimen necessary to prevent resistance development in devastating plant pathogens. EPA should consider that eliminating multi-site protectant options from the seed treatment toolbox would likely drive unintended consequences on usage of other fungicide active ingredients. For example, treaters and growers may be forced to resort to using higher rates, higher application frequencies, and larger numbers and combinations of single-site fungicides in seed treatments and in tank mixes, thus potentially escalating fungicide resistance to newer chemistries. The United States Department of Agriculture (USDA)⁶ believes that maintaining the sporadic use of older, reliable tools is warranted when it helps to preserve the safe use and efficacy of newer, but also resistance-prone, chemistries.

Cancellation of commercial seed treatment uses for thiram could reduce the amount and choice of treated seed on the market, which would in turn reduce the availability of this important precision agricultural technology. Reduced availability of treated seed or treated seed options could increase over-the-top pesticide applications, thus potentially increasing farmworker and environmental exposures to off-target pesticide movement. Also important to consider is the potential for increasing emissions from sprayers that may traverse fields with multiple passes to plant and spray, where they could have avoided some of those passes by planting treated seed. Fewer treated seed options also present a significant limiting factor in Integrated Pest Management (IPM) programs. Thus, EPA's proposal to cancel commercial seed treatment uses ultimately may result in *fewer* environmentally protective treatment options. EPA's proposal to cancel commercial seed treatment uses based on an overly conservative model and in lieu of other potentially less severe mitigation options fails to fulfill EPA's statutory mandate to carefully consider both the risks *and benefits* of the pesticide. *See, e.g., Papas v. Upjohn Co.*, 926 F.2d 1019, 1022 (11th Cir. 1991) (pesticides “have important environmental effects” and their use is “based on a careful balancing of benefit versus risk”).

To avoid this result, 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. We request the Agency to continue to have dialogue with CLA, ASTA and other stakeholders to improve the risk assessment by incorporating real-world data, explore reasonable mitigations to reduce exposure, and maintain the use of thiram and other chemistries for commercial seed treatment.

Occupational Exposure for Seed Treaters

CLA, ASTA, and our member companies 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.

⁶Comment submitted by USDA. Posted May 20, 2022. <https://www.regulations.gov/comment/EPA-HQ-OPP-2015-0433-0577>.

Beginning on page 45 of the amended PID, EPA developed several lists of questions for registrants and stakeholders, divided by seed treatment risk scenarios, including cleaning, treating, loading/planting, and packaging in both commercial seed treatment facilities and on-farm treating/planting scenarios. CLA and ASTA understand and appreciate that EPA is interested in gaining better insights on worker exposure scenarios related to seed treatment. To help facilitate this understanding, registrants and other key stakeholders are conducting outreach to gather information regarding industry policies and seed treatment technology improvements in response to some of EPA's questions in the thiram PID. This information will be submitted to the Agency during this comment period and for upcoming regulatory decision comment periods for other active ingredients with seed treatment uses. It is imperative that the Agency continue to consider this real-world data and incorporate refinements into the worker exposure assessments.

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. The seed-treatment industry has changed greatly in its cleaning processes and technology since the original studies that the model is based on were conducted. Seed treatment businesses commonly do not clean out their equipment at midday, but rather between seed lots where the seed treatment and/or seed type would change. Keeping seed lots free of other types of seed is important, which in some cases is the main reason for the cleaning, especially for high-value vegetable seeds. Therefore, cleanout frequency would not necessarily be directly related to pounds of seed treated per 8-hour shift. 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, such as for some small-seeded vegetables, a cleanout scenario is non-existent due to the self-cleaning, enclosed nature of the treating equipment or the fact that cleaning consists only of a quick spray and wipe between treatments. The exposure studies represented in EPA's model were for large-scale equipment where workers had potential contact with residues, which is not an appropriate comparator for many seed treatments. In fact, even large continuous-flow drum treaters are now sometimes cleaned by different methods than having a worker access the drum. 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 externalities.

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 facilities have Industrial Hygiene (IH) SOPs in place as required by the Occupational Safety and Health Administration (OSHA).⁷

⁷ Indeed, OSHA, pursuant to its authority under the Occupational Safety and Health Act (OSH Act), imposes a general standard on air contaminants that requires employers to limit employee exposure of some substances to certain specified levels, either through engineering controls, personal protective equipment, or other mechanisms.

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.

Real-world scenarios illustrate the flaws in EPA's modeling, which cannot be used as a basis for cancelling nearly all seed treatment uses for a critically important active ingredient. EPA's current default daily throughput value for commercial treating of most large-seeded vegetables is 339,500 pounds of seed per day and was based on survey values for field corn⁸. The calculations in Table 1 illustrate that applying the corn value to all large-seeded vegetables is inappropriate and fails to account for differences in planted acres across crops:

Table 1. Comparison of commercial seed treating throughput values using actual planted acres.

Crop	2024 Planted acres ⁹	Seeding Rate (lb/A) ¹⁰	Lb of seed needed ¹¹ (planted acres x seeding rate)	Time to treat lb of seed needed based on planted acres
Corn	91,475,000	30	2,744,250,000	8,083 days
Pumpkin	69,100	5	345,500	1 day

Table 1 compares the treating days for field corn and pumpkin, one a field crop and one a large-seeded vegetable, using the survey throughput value for field corn that EPA applies to large-seeded vegetables. Using EPA's assumptions, it would only take one day to treat all the pumpkin seed needed to plant the entire U.S; however, it would take 8,083 days to treat all the corn seed needed to plant the entire US. Clearly, using a single default value for these two very different crops is problematic. We encourage the Agency to reassess this scenario and use a more realistic pounds of seed treated per day value based on real-world available data.

Concluding Remarks

Thiram is an important component of sound resistance management and IPM programs. Seed treatments are a mandatory component of many importing countries' phytosanitary regulations, and banning thiram use would block access by US growers to important export markets. Pesticides, including seed treatments, are rigorously and routinely tested and proven to be safe and effective tools contributing to the 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 thiram and other chemistries as

See 29 C.F.R. § 1910.1000. Even if this limit applies to treatment of an EPA-approved pesticide, the stringent PPE and other worker protection requirements already in place through the EPA-approved label are more than sufficient, and ASTA's and CLA's members' operational practices in compliance with those label restrictions operate well within OSHA's limits.

⁸ EPA's Policy 15.2, *Standard Values for Amount of Seed Treated and/or Planted per Day*, January 2022.

⁹ USDA National Agricultural Statistics Service: nass.usda.gov/Statistics_by_Subject

¹⁰ EPA Standard Operating Procedure (SOP) Policy 15.2, *Standard Values for Amount of Seed Treated and/or Planted Per Day*, January 2022.

¹¹ BEAD's values for maximum seeding rates for corn, squash, and watermelon (30, 6, 9 lb/A respectively).

seed treatments. CLA and ASTA strongly support a robust commitment to agricultural innovation by the US government so that US 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 horticulture. CLA and ASTA 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 thiram under FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5). CLA, ASTA, and their 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.