



July 7, 2021

Charles Smith
Acting Director Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

[Via Regulations.gov](https://www.regulations.gov)

Re: CropLife America and American Seed Trade Association Comments to the U.S. Environmental Protection Agency on Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions under Federal Insecticide, Fungicide, and Rodenticide Act, Docket ID No. EPA-HQ-OPP-2020-0537-0001, 86 Fed. Reg. 18232 (Apr. 8, 2021)

Dear Mr. Smith:

CropLife America (CLA) and the American Seed Trade Association (ASTA) appreciate the opportunity to provide these comments to the U.S. Environmental Protection Agency (EPA or the Agency) in response to the Advanced Notice of Proposed Rulemaking (ANPRM) on Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*

Established in 1933, CLA is a national, private, not-for-profit trade association representing companies that develop and sell crop protection products for agriculture and pest management in the United States. Founded in 1883, ASTA is a voluntary, not-for-profit trade association representing more than 700 companies that develop, produce, and distribute seeds for use in agriculture in the United States and abroad. CLA's member companies produce most of the crop protection and pest management products regulated by EPA under FIFRA, including pesticide products approved for use as seed treatments, while ASTA's members produce much of the agricultural seed used in the United States. CLA and ASTA represent their members' interests by, among other things, monitoring federal agency actions and related litigation of concern to the crop protection, pest control, and seed industries, respectively, and participating in such actions as appropriate.

EPA issued the ANPRM to solicit information on the current pesticide exemption provision process under FIFRA, including the classes of exemptions found in 40 C.F.R. § 152.25. 86 Fed. Reg. 18232 (Apr. 8, 2021). These comments focus specifically on the exemption for treated articles or substances found in 40 C.F.R. § 152.25(a) (the Treated Article Exemption) as applied to pesticide-treated seed (treated seed).

CLA has extensive experience with the regulatory processes and requirements that apply to seed and to pesticide products approved for use under FIFRA as seed treatments and, together with ASTA, can offer a unique perspective on the value, utility, and implementation of the Treated Article Exemption as applied to treated seed. CLA's members own EPA registrations for nearly all the seed treatment products on the market today. CLA's members have invested

hundreds of millions of dollars to obtain and maintain registrations authorizing the distribution and sale of seed treatment pesticides and rely on revenues generated by sales of these important products, which serve to provide the high value seed produced by ASTA's members. CLA's members participate heavily in EPA's registration process in bringing new seed treatment pesticides to market. CLA's members submit voluminous scientific data, comments, and analyses, and regularly meet with EPA to support EPA's finding that these pesticides and their specific uses as seed treatments meet the legal safety criteria required for pesticide registration.

As outlined more fully below, CLA and ASTA strongly support EPA's extension of the Treated Article Exemption to treated seed, which is fully consistent with EPA's authority under FIFRA and thoroughly addresses human health and environmental risks while eliminating duplicative regulation. EPA is soliciting comments to consider whether regulatory and policy changes are necessary to improve the efficiency of the exemption provisions under FIFRA. 86 Fed. Reg. at 18,233. These comments aim to explain how EPA's current approach to treated articles already preserves and promotes regulatory efficiency, while protecting the environment and human health.

Section I of these comments summarizes the benefits of seed treatments and treated seed to U.S. agriculture. Section II reviews the regulatory framework governing pesticides and treated seed. Section III addresses EPA's comprehensive regulation of seed treatment pesticides under FIFRA, and EPA's proper exercise of its authority under FIFRA to apply the Treated Article Exemption to treated seed, allowing for efficient, effective regulation of pesticides used to treat seed.

I. Seed Treatments and Treated Seed and their Importance to U.S. Agriculture

Seed treatment refers to the direct application of a pesticide to the surface of a seed prior to planting. Seed treatments, including bactericides, fungicides, and insecticides, help protect expensive, high-quality seed and, thus, growers' seed investments. Seed treatment insecticides and fungicides were first introduced decades ago to address seed-borne pathogens (*i.e.*, harmful microorganisms like bacteria or fungi); soil-borne pathogens that survive in soil or crop residue; and insects and other pests that feed on seeds and seedlings.

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 before emergence from the soil. This method of protection helps to suppress pathogens, insects, or other pests that threaten seed viability and health from the time the seed is planted through its germination and development. Seed treatments safeguard expensive, high-value, high-quality seed against threats that cannot easily be predicted ahead of planting. They also ensure optimum crop stand development to take full advantage of other agronomic inputs and crop yield potential.

Since their introduction decades ago, seed treatments have been widely 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. Compared to traditional broadcast sprays, seed treatments reduce the overall amount of pesticides used and the energy and fuel required for their application, reducing greenhouse gas emissions and promoting climate stability, among other benefits. Because of their targeted application, seed treatments also minimize off-target exposure. Seed treatments are also critical

components in modern integrated pest management (IPM), enabling growers to control some of their most challenging pests and reduce the likelihood of resistance.

Because seed treatments help control a wide variety of harmful insects, pests, and diseases, they are applied to numerous types of crop seeds planted in the United States, including soybeans, wheat, cotton, corn, beets, peanuts, onions, leafy vegetables, rice, and more. 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.¹

In sum, the rise in use of seed treatment products reflects 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.

II. Regulatory Framework for Pesticides and Treated Articles

A. EPA's Regulation of Pesticides Under FIFRA

Under FIFRA, EPA conducts rigorous scientific evaluations of every pesticide product marketed, sold, and distributed in the U.S., including products used to treat seeds. See 7 U.S.C. §§ 136a(c)(5), 136j(a)(1). To obtain a pesticide registration, an applicant must submit extensive scientific data to EPA to demonstrate that use of the product in accordance with its label will not pose “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits” of the product. *Id.* § 136(bb). Each registered product is required to display an EPA-approved label that enumerates approved uses, applications, and directions for use. See, e.g., *id.* § 136a(c)(1)(C). Use of a pesticide in a manner inconsistent with that label is unlawful. *Id.* § 136j(a)(2)(G).

In conducting its risk-based determination of whether registration of a pesticide product meets the FIFRA standard, EPA reviews extensive data pertaining to the pesticide's active ingredient as well as formulations and particular uses of the pesticide, including use as a seed treatment. 7 U.S.C. § 136a; 40 C.F.R. §§ 152.100–152.119. EPA's expert scientists carefully review all data submissions and conduct sophisticated risk assessments that identify and analyze potential risks that could be associated with various uses, including risks to beneficial and “non-target” organisms. Only upon determining that a specific pesticide use will not have an unreasonable adverse effect on the environment will EPA allow the use. 7 U.S.C. § 136a(c)(5)(C), (D); see *also id.* § 136(bb) (defining “unreasonable adverse effects”).

Once a pesticide is registered by EPA, FIFRA requires that EPA conduct reassessments of the data required to support a pesticide registration every fifteen years, known as Registration Review. *Id.* § 136a(g). This periodic review is required to ensure that, as scientific capabilities for assessing risk develop and as policies and pesticide use practices change over time, all

¹ See AgInformatics, LLC, *The Value of Neonicotinoids in North American Agriculture*, Executive Summary, at vi (2015), https://aginformatics.com/uploads/3/4/2/2/34223974/executive_summary_neonicotinoids.pdf.

registered products continue to meet the statutory standard of “no unreasonable adverse effects.” *Id.* § 136(bb). Pesticide registrants also have an affirmative obligation to report to EPA on an ongoing basis information regarding unreasonable adverse effects of a registered pesticide product. *Id.* § 136d(a)(2). FIFRA additionally provides EPA with ongoing enforcement authority over pesticide registrations and authorizes EPA to issue stop sale, use, or removal orders and to impose civil and criminal penalties for violating FIFRA’s requirements. *See, e.g., id.* §§ 136k, 136l.

EPA conducts hundreds of complex scientific and regulatory assessments and determinations every year under FIFRA. Over the four-year period from FY 2014 to 2017, EPA issued registration decisions for 105 new conventional pesticide active ingredients and 836 new uses for existing conventional pesticides, while opening 271 registration review dockets and issuing 288 registration review final work plans and 152 registration review decisions.² This ongoing volume of assessments shows the Agency’s extensive regulatory and technical expertise and engagement and requires efficient and effective regulatory approaches.

All pesticide products approved for use as seed treatments have cleared EPA’s robust, science-based registration process under FIFRA and have been found to “perform [their] intended function without unreasonable adverse effects on the environment,” including pollinators. 7 U.S.C. § 136a(c)(5)(C). In addition, EPA regulations generally require that any pesticide product intended for use in treating seeds contain an EPA-approved dye or that such a dye be added during the seed treatment process. *See* 40 C.F.R. 153.155(a). The purpose of the dye is to impart an unnatural color to signal to users that the seed has been treated with a pesticide and should not be used for food or feed.

B. Exemption from FIFRA Regulation for “Treated Articles”

FIFRA authorizes the Administrator to exempt certain pesticide products from regulation under FIFRA, including those that are determined to be: (1) adequately regulated by another federal agency; or (2) of a character not requiring FIFRA regulation in order to carry out the purposes of the Act. 7 U.S.C. § 136w(b).

Using that authority, EPA issued regulations implementing the Treated Article Exemption. 40 C.F.R. § 152.25(a). Under that exemption, EPA has determined that “treated articles” are deemed “exempt from all provisions of FIFRA.” *Id.* Treated articles or substances are defined as:

An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

Id. Thus, an article will be deemed exempt from regulation under FIFRA as a treated article if the following three conditions are satisfied: (i) the article contains or is treated with a pesticide;

² EPA, *Implementing the Pesticide Registration Improvement Act – Fiscal Year 2017* at Appendix A, Table 3, Number of PRIA Actions Completed (March 1, 2018), https://www.epa.gov/sites/production/files/2018-02/documents/fy17-pria-annualrpt-table3.opp_.pdf; *id.* at Pesticide Reevaluation Programs, https://www.epa.gov/sites/production/files/2018-03/documents/mf-accomp-reevaluation-fy17-final_1.pdf.

(ii) the pesticide is intended to protect the article itself; and (iii) the pesticide is registered for this use. In the examples provided in the regulation, depending on the claims made regarding the sale of the treated paint or the treated wood, EPA would generally consider neither the paint nor the wood a pesticide.

FIFRA gives EPA discretion to determine which treated articles are exempt from regulation under FIFRA (*i.e.*, “of a character which is unnecessary to be subject” to regulation), while the pesticide product used on the article remains subject to EPA review and registration. 7 U.S.C. § 136w(b). The Treated Article Exemption eliminates duplicative regulation of both the pesticide and the article it is used to treat. It also promotes comprehensive consideration of a pesticide product’s overall potential risks, impacts, and benefits.

C. Regulation of Treated Seed Under the Federal Seed Act

In addition to EPA’s regulation of the pesticides used to treat seeds, treated seed is separately regulated by the United States Department of Agriculture (“USDA”) under the Federal Seed Act (“FSA”), 7 U.S.C. §§ 1551–1611, which regulates the interstate shipment of agricultural and vegetable seeds. Administered by USDA’s Agricultural Marketing Service, the FSA’s implementing regulations set forth labeling and other requirements for treated seed aimed at facilitating uniformity, transparency, and fair competition within the seed trade. See 7 C.F.R. Part 201.³ For example, Section 201.31a(a) of the FSA regulations requires that all treated seed be labeled with the name(s) of the seed treatment product(s) (*e.g.*, “Treated with [pesticide name]”). Section 201.31a(d) requires that labels on seed treated with certain classes of substances bear restrictions for use (*e.g.*, “Do not use for food, feed, or oil purposes.”). EPA recommends that these labeling requirements for treated seed be included on the labels for pesticide products approved for use as seed treatments.⁴

III. The Treated Article Exemption as Applied to Treated Seed is a Valuable Exemption that Adequately Addresses Human Health and Environmental Risks While Eliminating Duplicative Regulation

A. Seed Treatment Pesticides Are Subject to Rigorous EPA Regulation

All pesticides used as seed treatments are subject to FIFRA’s registration requirements; in issuing and reviewing registrations for such uses, EPA has subjected the products, their specific uses, and their potential human health and environmental impacts to rigorous, scientifically robust review as required by FIFRA. The risks of these products and their specific uses as seed treatments are carefully weighed through EPA’s regulatory processes under FIFRA. In approving seed treatment pesticide products, EPA makes an express determination that their use to treat seed, and the sale and use of such treated seed, will not cause “unreasonable adverse effects.” 7 U.S.C. § 136a(c)(5)(C), (D).

The seed-treatment uses of a pesticide active ingredient and the potential dietary and worker exposure that may result are compared with other registered uses of the same active ingredient

³ See also USDA, *Labeling Requirements for Chemically Treated Seed* (Sept. 2017), <https://www.ams.usda.gov/sites/default/files/media/LabelingRequirementsforChemicallyTreatedSeed.pdf>.

⁴ See EPA, Label Review Manual, ch. 18, at 18-9, https://www.epa.gov/sites/production/files/2014-06/documents/chap-18_0.pdf.

in a comprehensive risk assessment, that considers exposures from all sources. Any potential human or environmental exposure to the pesticide applied to a treated seed is by no means ignored, overlooked, or forgotten by EPA.

EPA's application of the Treated Article Exemption to treated seed does not in any way diminish the rigor of the review process to which seed treatment pesticides are subject. To the contrary, all seed treatment pesticide products approved for use in the U.S. have cleared EPA's robust, science-based review under FIFRA and have been found—based on extensive scientific data—to “perform [their] intended function without unreasonable adverse effects on the environment,” including non-target organisms. 7 U.S.C. § 136a(c)(5)(C).

B. EPA's Application of the Treated Article Exemption to Treated Seed Is Consistent with its Authority Under FIFRA

EPA's application of the Treated Article Exemption to treated seed falls squarely within the Agency's authority under FIFRA. FIFRA authorizes EPA to exercise its regulatory authority and discretion in determining that, for purposes of the Treated Article Exemption, the “article itself” that is treated and protected is the plant organism in its various stages, from seed to seedling to growing plant. See 7 U.S.C. § 136w(b); 40 C.F.R. 152.25(a).

EPA's interpretation of and application of the Treated Article Exemption to treated seed is consistent with other federal laws and regulations construing seeds as part of the plant organism as a whole. See 40 C.F.R. § 174.3 (EPA regulation defining “living plant” to include “seeds”); 7 U.S.C. § 7702(13) (definition of “plant” in the Plant Protection Act includes “a seed”); 7 U.S.C. § 1561 (Federal Seed Act defines “treated” in the context of treated seed as “given an application of a substance or subjected to a process designed to reduce, control, or repel disease organisms, insects or other pests which attack *seeds or seedlings growing therefrom*”) (emphasis added). EPA has thus appropriately determined that seed treatment pesticides are intended to protect the plant organism at all stages of development, such that the treated seed itself is exempt from regulation under FIFRA by the Treated Article Exemption. See *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 6834215, at *5 (N.D. Cal. Nov. 21, 2016) (in determining whether the Treated Article Exemption should apply, the focus is “on the pesticidal treatment's intended purpose”).

The Treated Article Exemption properly applies to treated seed because EPA can carry out FIFRA's purpose of preventing unreasonable adverse effects on humans or the environment through registration of the seed treatment pesticide products.⁵ EPA's review of seed treatment pesticide products under FIFRA includes consideration of the risks, benefits, and potential impacts of each use through the full life stage of the plant, including the potential for residues in the grown plant and harvested crop and for non-target effects. Indeed, as part of the registration and Registration Review processes for all pesticides, EPA undertakes comprehensive risk assessments, including assessments of potential risks to non-target organisms, which require the development of extensive scientific data.⁶ FIFRA also authorizes EPA to seek additional information from the applicant or registrant on potential health or environmental risks at any

⁵ See Pest Management Regulatory Agency, Health Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States 2* (2003), https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2003-02-eng.pdf (“2003 Harmonization Guidance”) (explaining that “[i]n issuing this regulation, the EPA reasoned that the risks of treated seeds . . . could adequately be regulated by means of the registration of the treating pesticide”).

⁶ See 40 C.F.R. pt. 158.

time.⁷ CLA, ASTA, and their members participate extensively in these processes and invest enormous resources in research and testing to support EPA's scientific assessments. CLA, ASTA, and their members also work in concert with the Agency to develop and promote new and improved technologies aimed at minimizing off-target effects.⁸

C. Applying the Treated Article Exemption to Treated Seed Allows for Efficient, Effective Regulation

Application of the Treated Article Exemption to treated seed allows EPA to effectively regulate every pesticide product applied as a seed treatment for a specific crop in a centralized, comprehensive fashion. It also streamlines the regulatory process and avoids the immense and unnecessary burden of registering each individual treated product.

Seed treatment pesticide products provide enormous benefits to agriculture, the food supply, and the overall economy. *See, e.g.*, Decl. of Richard Wilkins ¶¶ 4–5, Decl. of Gary Adams ¶¶ 3–5, Decl. of Gordon Stoner ¶ 4, and Decl. of Chris Novak ¶¶ 3–4, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. Mar. 16, 2016), ECF Nos. 26-3–26-6 (seed treatment pesticides are vital to farmers' well-being; protection conveyed by seed treatments results in healthier plants and increased crop yields, among other benefits, and reduces the need for higher volumes of other pesticides, additional trips across the field to apply pesticides, rescue treatments (post-emergent pesticide applications to address pest infestation), replanting of failed crops, and costly higher-density seeding). They also require and receive scrutiny through FIFRA's comprehensive and demanding regulatory scheme. *See supra* Section III.A.

Retaining the Treated Article Exemption and its applicability to treated seed will continue to promote efficient regulatory processes and avoid applying unnecessary regulatory burdens on the Agency, state regulatory bodies, farmers, and other members of the agricultural value chain. Regulation under FIFRA would continue to appropriately focus on the pesticide products and their specific uses as seed treatments, rather than requiring each combination of seed treatment pesticide and crop seed variety—of which there are hundreds, if not thousands—to be registered separately as a pesticide. *See, e.g.*, Decl. of Rachel Lattimore in Supp. of Mot. to Intervene ¶ 10, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. Mar. 16, 2016), ECF No. 26-1. This is an efficient, sensible approach that avoids imposing unnecessary regulatory burdens on agricultural retailers, and seed processing facilities that apply seed treatments; without the Treated Article Exemption applied to treated seed, these entities and individuals could be forced to register with EPA as pesticide producing establishments under FIFRA. *See, e.g.*, Decl. of Andrew LaVigne ¶ 7, Decl. of Richard Wilkins ¶ 8, Decl. of Gary Adams ¶ 9, Decl. of Gary Stoner ¶ 7, and Decl. of Chris Novak ¶ 6, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. Mar. 16, 2016), ECF Nos. 26-2–26-6. It also avoids subjecting farmers to onerous reporting and recordkeeping requirements that would draw time and resources away from farming operations already operating on slim or negative margins. *See id.* The Treated Article Exemption as applied to treated seed eliminates all of these burdens, in recognition of the fact

⁷ 40 C.F.R. § 158.30(b); *see also* 40 C.F.R. § 158.75 (FIFRA authorizes EPA to impose additional data requirements on registrants if data routinely required are insufficient to evaluate the pesticide's satisfaction of FIFRA's registration standard).

⁸ *See, e.g.*, Palle Pedersen, *Formulation Technology Innovation and Improvements*, <https://www.epa.gov/sites/production/files/2013-11/documents/palle-pederson-formulation-technology.pdf> (Syngenta presentation); Mike FcFatrach, *Activity and Advances in Seed Coating Technology* (Mar. 5, 2013), <https://www.epa.gov/sites/production/files/2013-11/documents/mike-mcfatrach-seed-applied-additives.pdf> (BASF presentation).

that health and safety are already comprehensively addressed through EPA's FIFRA review of the seed treatment pesticide products.

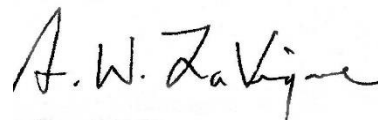
CLA and ASTA appreciate the opportunity to provide these comments in support of EPA's current regulatory approach to treated articles, including treated seed, under the Treated Article Exemption. Should EPA have any questions or wish to discuss these issues further, please do not hesitate to contact us.

Thank you for your consideration of these comments.

Sincerely,



Chris Novak
President and CEO
CropLife America



Andrew W. LaVigne
President/CEO
American Seed Trade Association