



February 9, 2024

Susan Bartow
Chemical Review Manager, Pesticide Reevaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Submitted to Docket: EPA-HQ-OPP-2023-0420-0001

RE: Pesticides; Review of Requirements Applicable to Treated Seed and Treated Plant Products;
Request for Information and Comments. 88FR 70625. October 12, 2023

Dear Ms. Bartow:

CropLife America (CLA),¹ the Agricultural Retailers Association (ARA),² and the American Seed Trade Association (ASTA)³ appreciate the opportunity to provide these comments to the United States Environmental Protection Agency (EPA or the Agency) on EPA's October 12, 2023 Advanced Notice of Proposed Rulemaking (ANPR) concerning the Agency's approach to regulation of seeds treated with a pesticide registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC § 136 *et seq.* We also appreciate the Agency's comment deadline extension, as there are concurrent open dockets on which our members are developing substantive technical comments.

All pesticides approved for use as seed treatments in the United States (US) are subject to rigorous, scientifically robust review under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA has long considered seeds treated with pesticides, being articles treated with pesticides to protect the seeds themselves, to be "of a character which is unnecessary" to be subject to FIFRA, and thus exempt from registration under FIFRA's Treated Article Exemption. A departure from EPA's current interpretation would impose a new regulatory process on agriculture that duplicates EPA's existing exercise of its authority under FIFRA, with no countervailing impact on human health or environmental safety. CLA,

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 ARA is a 501(c)(6) non-profit trade association that represents the interests of agricultural retailers and distributors across the United States on legislative and regulatory issues. As the political voice for agricultural retailers and distributors, ARA advocates on critical issues, educates legislators and collaborates with regulatory officials on important issues affecting the industry.

³ 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.

ASTA, and ARA respectfully request that EPA reinforce its interpretation of the Treated Article Exemption to exempt treated seeds from redundant registration under FIFRA.

Unnecessary changes to EPA's long-standing interpretation of the Treated Article Exemption with respect to treated seed 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 potentially increase over-the-top pesticide applications, which may potentially increase farmworker and environmental exposure to off-target pesticide movement. Also, it is important to consider the potential for increasing emissions from sprayers that may traverse fields with multiple passes to plant and spray, where they could have combined some of those passes by planting treated seed. Fewer treated seed options could also limit Integrated Pest Management (IPM) programs significantly.

Moreover, EPA, in partnership with CLA, ASTA, ARA, their members, and other stakeholders, have taken and continues to take affirmative measures to minimize human health and environmental risks attributable to seed treatment pesticides. Our comments are divided below into the following sections: Introduction and summary of the ANPR; Comments on specific issues, as listed in the ANPR, related to treated seed; Benefits of treated seed; Comments on our collective interests in the ANPR; The existing regulatory framework; and Concluding remarks summarizing why no additional rulemaking is necessary to ensure adequate labeling and use of treated seeds.

We 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, pmiller@betterseed.org, or richard@aradc.org.

Sincerely,



Manojit Basu, Ph.D.

Vice President, Science Policy,
CropLife America



Richard Gupton, IOM, JD

Senior Vice President of Public
Policy & Counsel, Agricultural
Retailers Association



Pat Miller

Director State Affairs, American
Seed Trade Association

CC: Ed Messina Director, OPP
Kimberly Nesci, Director, USDA OPMP

I.	Introduction and Summary	4
II.	Interests of CLA, ASTA and ARA in the ANPR.....	6
III.	Comments on the specific issues, as requested in the ANPR, related to treated seed.....	7
1.	EPA is requesting comment on use and usage of treated seed products including storage, planting, and disposal of treated seed	7
a.	Storage and Disposal	7
b.	Planting and additional handling instructions.....	9
c.	Use and Usage	10
2.	EPA is requesting comment on the effectiveness of instructions on treated seed labeling to mitigate potential risks; recommendations or alternative instructions to increase the clarity of instructions on treated seed product (i.e., seed tag labeling) for the end user.....	10
IV.	Benefits of Seed Treatment Pesticides to US Agriculture.....	15
1.	Environmental Health and Safety Improvements	17
2.	Stewardship Efforts.....	18
V.	Regulatory Framework.....	19
1.	EPA’s Regulation of Pesticides Under FIFRA.....	19
2.	Exemption from FIFRA Regulation for “Treated Articles”	21
3.	Regulation of Treated Seed Under the Federal Seed Act	22
VI.	No Additional Rulemaking is Necessary to Ensure Adequate Labeling and Use of Treated Seeds. 23	
1.	The Treated Article Exemption is Narrowly Tailored to Treated Seeds that are Used in Accordance with the Pesticide Product Label.	23
2.	The Existing Regulatory Framework for Treated Seeds Adequately Accomplishes EPA’s Labeling Goals	24
VII.	Conclusion.....	25

I. Introduction and Summary

In April 2017 the Center for Food Safety (CFS) *et al.* filed a petition seeking amendment to, or a formal re-interpretation of, the Treated Article Exemption (the Petition).⁴ In summary, the Petition requested that EPA “clearly communicate to the regulated community that systemic pesticidal seeds intended to kill insect pests of the plants [grown from those seeds] are not included under the Treated Article Exemption and are therefore subject to FIFRA’s requirements for registration and labeling.” The Petition also requested that EPA aggressively enforce FIFRA’s registration and include labeling requirements for each separate seed product coated with a systemic insecticide.

EPA did not agree with the Petition claims and thus did not grant the Petition requests to either interpret or amend 40 CFR § 152.25(a) to categorically exclude seed treated with systemic pesticides from exemption under that provision.⁵ EPA stated in its response denying the Petition that “seeds” (or any other particular article) need not be expressly included in the regulation for the exemption to apply. Any “article” or “substance,” including seed, may be exempt from FIFRA requirements if it meets the conditions for the exemption:

- the article contains or is treated with a pesticide; and
- the pesticide is intended to protect the article itself; and
- the pesticide itself is registered for this use by EPA.

In addition, EPA confirmed that the treated article exemption regulatory text appropriately covers any seed treated with such a registered pesticide if the use of the pesticide and the treated seed is consistent with all use directions, advisory statements and exclusions on the label for the registered pesticide and accompanying seed tag, and claims made for the seed treatment are limited to seed and what the seed becomes.

However, EPA acknowledged the importance of complete and clear instructions on the use of the pesticide to treat seed and for the distribution, sale, and use of seed treatment pesticides. As a result, while the Agency did not grant the Petition’s requests, it noted that it intended to issue an ANPR.

On October 12, 2023, EPA issued an ANPR soliciting “comments and information to determine whether to amend its approach for allowing treated seed and treated paint products to be wholly exempt from FIFRA requirements (e.g., through issuance of a rule pursuant to FIFRA section 3(a) to regulate distribution, sale, and use of treated seed product and/or other administrative action).”⁶ EPA’s “longstanding position” has been that the Treated Article Exemption, FIFRA section 25(b)(2)—which permits EPA to exempt from FIFRA any pesticide that EPA determines to be “of a character which is unnecessary” to be subject to FIFRA “in order to carry out the purposes” of FIFRA—authorized exempting treated seeds qualifying for the exemption because “EPA’s assessment of the treating

⁴ See 40 C.F.R. §152.25

⁵ <https://www.regulations.gov/document/EPA-HQ-OPP-2018-0805-0104>

⁶ *Pesticides; Review of Requirements Applicable to Treated Seed and Treated Paint Products; Request for Information and Comments*, 88 Fed. Reg. 70,625 (Oct. 12, 2023)

pesticide comprehensively addresses the use of and exposure to the treating pesticide and to the article or substance that is permissibly treated and distributed, sold, and used consistent with labeling instructions.”⁷ Nevertheless, the Agency requested comment on whether “a FIFRA section 3(a) rule and/or other administrative action [was] necessary or appropriate to prevent unreasonable adverse effects on human health and the environment,” including “to allow for enforcement of certain use instructions on labeling of treated seed and treated paint as an alternative to registration of such products.”⁸

Specifically, the ANPR stated that “EPA intends to ensure that treating pesticide labeling instructions include: (1) the requirement that seed bag tag labeling accompany the treated seed when distributed and sold; (2) that such labeling include specified clear and effective instructions on use of the treated seed, including the name of the active ingredient and pesticide product used (including the EPA product registration number), and instructions on the storage, planting, and/or management of spilled or excess treated seed, as appropriate; and (3) that the distribution or sale of the treated seed products without such labeling is the distribution or sale of an unregistered pesticide.” *Id.* at 70,629. The ANPR uses the term “treating pesticide” or “treating pesticide product” when referring to the pesticide used to treat the subject article, whether seed, paint, or other item. The agriculture industry refers to pesticides used to treat seed as “seed treatment pesticides” and we use this term throughout our comments.

EPA also posited that “[o]ther regulatory approaches could include limiting the scope of the exemption so that some FIFRA requirements would still apply (e.g., requiring seed treatment facilities to identify as establishments)” or “addressing specific use concerns through further action during registration review for specific active ingredients (e.g., clarifying labeling instructions, further reducing or eliminating use of the treating pesticide for some seed or paint treatments, or including further terms and conditions on the registration for expiration of the use or imposition or use restrictions should contrary to labeling instructions be reported).” *Id.* at 70,632.

Noting that “states and other stakeholders have raised questions about the clarity and enforceability of instructions specifically relating to the use of treated seed products (i.e., instructions relating to the storage, planting, and management of the treated seed),” the ANPR asks for comments on how the Agency can “improve labeling on both treating pesticide labeling and labeling on treated seed products (e.g., seed bag tags) during registration and registration review processes,” as well as the “use and usage of treated seed products, including storage, planting, and disposal of treated seed, and on whether or to what extent treated seed products are being distributed, sold, and/or used contrary to treating pesticide labeling instructions for each separate crop seed product.” *Id.* at 70,626. “[T]he Agency is seeking any specific information from all stakeholders to further inform . . . whether there are specific cases of use contrary to label instructions.” *Id.*

⁷ *Id.* 88 Fed. Reg. at 70,627

⁸ *Id.* at 70,627

As set forth more fully below, CLA, ASTA, ARA, and our members fully support EPA's reasoning in denying the Petition. Moreover, industry has been actively engaged in seed-treatment stewardship for over ten years, to help ensure that those applying seed treatment pesticides to agricultural seeds (hereafter "seed treaters") and those planting treated seed are doing so responsibly, and that they are supported with technology and instructions for use to minimize off-site movement, environmental impact, and worker exposure to the treating pesticides. In light of the comprehensive existing regulatory framework over treated seeds and complementary stewardship from industry, there is no need for additional regulation of treated seed as outlined in the ANPR.

II. Interests of CLA, ASTA and ARA in the ANPR

CLA has a valuable and unique perspective to offer the Agency as it considers any further rulemaking. CLA's member companies produce, sell, and distribute virtually all the critical pesticide products registered by EPA under FIFRA. CLA's members own EPA registrations for scores of seed treatment pesticides.

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 ASTA's members, more than 75% include seeds that are treated with pesticides. These seed treatment pesticides are often applied to seeds by ASTA and ARA's members, in accordance with the EPA-approved labels. Moreover, ASTA has developed stewardship programs to educate farmers and pesticide applicators on the correct handling and management of seed treatment pesticides and treated seed.

CLA, ARA, and ASTA members would be impacted directly and significantly by any rule that imposes any additional or duplicative regulatory requirements for treated seeds. CLA members have invested significant 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 members also participate extensively in EPA's regulatory process for pesticide registrations in bringing new seed treatment pesticides to market. CLA 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.

ASTA members similarly invest substantial funds in research, development, and production of new seed treatment products. Relying on the seed treatment registrations issued by EPA and the continued marketability of their treated seed products, ASTA members have also invested millions of dollars in research and development of seed treatment equipment and improvements to the seed treatment application process and have 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 ANPR.

III. Comments on the specific issues, as requested in the ANPR, related to treated seed**1. EPA is requesting comment on use and usage of treated seed products including storage, planting, and disposal of treated seed****a. Storage and Disposal**

FIFRA registered seed treatment pesticides require a minimum of EPA-defined use, storage, and disposal instructions on the pesticide label and on the treated seed tag. Treated seed may be available to end users in bulk seed boxes, bags, or envelopes, but in our comments, we will refer to the treated seed product label as a seed tag. CLA, ARA, and ASTA member companies abide by these requirements by including on seed tags relevant EPA required storage and disposal statements as well as the advisory statements and limitations under the Directions for Use found on the seed treatment pesticide labels. Examples of this language are provided below:

- Store treated seed away from food, feed, and feedstuffs.
- DO NOT allow children, pets, or livestock to have access to treated seed.
- When opening this bag or handling (e.g. loading, pouring) treated seed or seed pieces wear:
 - Long pants and long-sleeved shirt
 - Shoes and socks
 - Chemical-resistant gloves
- Excess treated seed may be used for ethanol production only if:
 - By-products are not used for livestock feed,
 - No measurable residues of pesticides remain in ethanol by-products that are used for agronomic practice, and
 - Consistent with local regulations
- Dispose of seed packaging or containers in accordance with local requirements. Do not use empty seed bags for any other purpose.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting, in particular at row ends and field corners.
- Dispose of all excess treated seed. Leftover treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements.
- DO NOT contaminate water bodies when disposing of planting equipment washwater or rinsate.
- Dispose of seed packaging in accordance with local requirements.

These statements represent clear and consistent permitted and prohibited practices and guidance to growers, facilities, and seed treaters that may vary in presentation, such as wording and significance of restrictions, among seed treatment pesticide labels and seed tags. Some additional label language may include safety and health recommendations, plant back intervals, restricted entry interval, environmental hazards, groundwater advisory, or other restrictions. We are in favor of creating a discussion panel, with EPA and other interested stakeholders, to develop more standardized seed tag language that will reduce complexity and ease implementation for registrants and users.

Storing treated seed is done according to the seed treatment pesticide label(s) and treated seed tag instructions, in secure containers where conditions maintain their quality. Proper storage is critical to ensure healthy seeds that germinate and perform as expected, and current label instructions on the treating pesticide and treated seed product are clear and adequate regarding storage requirements.

Aspects of seed production, such as when and where seed is produced in order to meet demands for an upcoming season in the US, what is required for processing and preparing the seed for planting (e.g., delinting seed), volume demands of a seed type, and how long a seed type retains acceptable germination and vigor, influence how far in advance of planting the seed is treated. For some crops that do not face consistent pest pressure and require minimal processing in preparation for cultivation, it is common to apply desired treating pesticides “just in time”, i.e., within a few days of transporting to the grower customer. In this case, seed is only treated by order of a customer, minimizing the need for warehouse storage, and reducing the potential for unsold treated seed. This approach is not applicable for all crops, such as corn, where customer treatment demands, and projected cultivation volumes require seed treatment in advance of customer order and based on demand projections. This requires storage of treated seed, which is easily achieved in a manner compliant with the clear label requirements and may result in treated seed that is not sold at the end of the planting season. Treated seed unsold after the planting season, or returned to the dealer by the grower, is disposed of in accordance with federal and local requirements or, often, returned to the supplier who will store applicable seed types in cold storage for use the following season, if germination and the treatment remain compliant with standards and regulations.

Another change to highlight in the treated seed industry is the use of seed boxes, for certain crops and volumes, which has positively affected both environmental and worker exposure aspects of treated seed usage. The language, described above, is affixed to the seed box, commonly in booklet form provided by the seed treatment pesticide registrant. There are approximately 2 million seed boxes in use today, almost exclusively for corn and soybeans. Each box will hold 50 units of seed, or 2,500 pounds. A single box costs \$600, usually paid by the seed supplier/dealer, which creates incentive for users to return the seed box to the vendor. After planting, private companies clean the boxes for re-use, with collection of all residues managed according to regulations. The boxes are easier and safer to handle and store. As an example, full seed boxes can be stored stably four-high, and empty boxes can be stacked six-high. Direct worker contact with the treated seed is potentially reduced when seed boxes are utilized because the seed is transferred to seed tenders/planters without human touch as there is no bag to tear open and pour. There is less waste with seed boxes when compared to seed bags because each bag must be disposed of after use in accordance with regulations (for treated seed). However, it is important to note that seed boxes have not and will not completely replace seed bags or envelopes.

Our collective members have worked with The Pesticide Stewardship Alliance (TPSA), to develop and maintain an interactive Treated Seed Life-Cycle Management Guidance Map.⁹ TPSA is an organization of federal, state and local governmental agencies; educational and research institutions; public organizations; private corporations; and individuals that are actively involved in different aspects of

⁹ Treated Seed Life-Cycle Management Guidance Map – TPSA (tpsalliance.org)

pesticide stewardship, including disposal of unwanted or unusable products and the management of emptied containers. The Treated Seed Life-Cycle Management Guidance Map was developed to aggregate reliable information about regulations and disposal options pertaining to pesticide treated seeds, including individual state contacts. The TPSA Treated Seed Life-Cycle Management Guidance Map and ASTA Treated Seed Stewardship Guide¹⁰ provide users of seed treatment pesticides or treated seed with additional guidance on disposal that is compliant with federal and local regulations. We welcome discussion with EPA on how to support further dissemination of these resources to users.

b. Planting and additional handling instructions

Planting instructions also appear on seed treatment pesticide labels and direct the seed treater to include this or a similar statement on the seed tag: “Treated seed must be incorporated into the soil at the recommended depth. Ensure that all planted seeds are thoroughly incorporated by the planter during planting. Additional incorporation may be required to thoroughly cover exposed seeds.”

Furthermore, depending on the physicochemical and toxicological properties of the active ingredient (ai) or ai(s), additional language may be required on the seed treatment pesticide label in the Use Restrictions section. This language could include a minimum planting depth, maximum pounds (lbs) of ai per acre (A) per year, and the maximum number of times treated seed can be planted on the same acres per year. Based on the ai, additional restrictions on lb ai/A/year may also be required for combinations of seed treatment and foliar pesticide applications. Other statements, such as groundwater advisories, grazing restrictions, plant-back restrictions, dust-off reduction, or pollinator protection measures, may also be required. Some examples include:

- To reduce seed dust which can drift onto blooming crops or weeds, ensure that planting equipment is functioning properly in accordance with manufacturer’s recommendations.
- This compound may be highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust, which can drift to blooming crops or weeds.
- ACTIVE INGREDIENT is highly toxic to bees exposed to direct treatment, and effects are possible as a result of exposure to translocated residues in blooming crops.
- Regardless of application method, do not apply more XX lb ai /A/year.
- Surface Water Advisory: This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features including ponds, streams, and springs will reduce the potential loading of ACTIVE INGREDIENT from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or

¹⁰ The Guide to Seed Treatment Stewardship | ASTA & CropLife America (seed-treatment-guide.com)

irrigation is expected to occur within 48 hours. Sound erosion control practices will reduce this product's contribution to surface water contamination.

- Groundwater Advisory: ACTIVE INGREDIENT is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.
- DO NOT plant crops within x days after planting SEED TREATMENT PRODUCT-treated seed.
- In the event of crop failure or harvest of a crop grown from this seed, the field may be replanted immediately with *list of crops with tolerances established for the active ingredient*. For all other crops, the minimum plant back interval is 12 months from the date this seed was planted.
- A cover crop without a tolerance for ACTIVE INGREDIENT may be planted for purposes of erosion control or soil improvement; however, the crop must not be grazed or harvested for food or feed.

c. Use and Usage

EPA rigorously assesses both the use of the seed treatment pesticide on a crop seed and use of the treated seed, comprehensively addressing the use of and exposure to the seed treatment pesticide and to the treated crop seed that is permissibly treated and distributed, sold, and used consistent with labeling instructions. Consistent with EPA's approach for foliar and soil pesticide use, these assessments rely on conservative assumptions which include basing an assessment on worst-case, highest vulnerability conditions and assuming all cropped area in an assessment scenario is sown with treated seed. By granting a pesticide registration for seed treatment use, EPA confirms, under these worst-case use and usage assessment assumptions, that use of the seed treatment pesticide and treated seed meets defined regulatory safety standards. Refinement of worst-case use and usage assumptions considered by EPA in these assessments with actual use and usage data would not identify new or elevated risk but would only reduce risk estimates or predicted environmental impacts. Therefore, submission of use and usage information, not required by existing regulation, should remain voluntary to refine assessment when needed. This ensures consistency with the evaluation approach for seed treatment and foliar or soil pesticide uses and avoids the unnecessary resource expense of obtaining, processing, and storing unnecessary use and usage data.

2. EPA is requesting comment on the effectiveness of instructions on treated seed labeling to mitigate potential risks; recommendations or alternative instructions to increase the clarity of instructions on treated seed product (i.e., seed tag labeling) for the end user.

The seed tag is the primary means by which instructions are communicated to downstream distributors, sellers, and users, typically the farmers, of such treated seed to enable responsible use and minimize risks to human health and the environment. Input from ARA members, who treat seed, indicated that the information on the seed tag was "very clear."

It is common for seed treatment pesticides to contain multiple ais and/or seed to be treated with more than one pesticide. Therefore, it is sometimes difficult to reconcile the required statements from multiple seed-treatment pesticides onto seed tags, which can lead to multiple statements with the same intent and which can add length and complexity to the seed tag. As a service to seed companies and seed treaters, many of our collective members have developed seed tags in booklet form, in addition to more traditional seed tags, which are then provided, along with the treating pesticide(s), to the seed treater. Input from ARA members, who treat seed, confirmed that the process is well-understood and that they apply a tag to the treated seed container, whether bag or, more commonly, seed box, that is supplied by the seed treatment pesticide registrant. As described above, seed boxes are increasingly common for certain crops and seed volumes.

CLA, ASTA, and ARA have requested that EPA work with registrants to harmonize this seed tag language. In March 2017, we jointly provided EPA a summary of seed tag language with recommendations to increase clarity of instructions on treated seed for the end user. Ultimately, these recommendations were never finalized or accepted by EPA; however, this ANPR has provided us with an opportunity to revisit these discussions. We are interested in continuing dialogue with EPA and interested stakeholders on alternative options to reduce the amount of text on seed tags. These options may be inclusion of only extremely critical restrictions on the seed tag itself, with other restrictions provided via a QR code, or equivalent digital option. CLA, ASTA, and ARA propose forming a coalition with EPA to harmonize required language for labels of seed treatment pesticides and treated seed tags that should minimize confusion of the end user and create consistency.

In advance of the future proposed dialogue with the Agency, here we provide specific feedback on language proposed by EPA in reference 5 to the ANPR.¹¹

EPA Proposal	Comment
“Use of On-Farm Treated Seed (when treated seeds are not for sale or distribution) Treated seed sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12.”	EPA’s characterization of the requirement for on-farm treated seed could be clarified in accordance with the following revised language: Seed treated in a manner not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore subject to enforcement pursuant to FIFRA section 12.
“Treated seeds are for planting purposes only. Do not use for food, feed, or oil purposes.”	The first statement is not necessary as it is already understood by the end user. Because the second statement is required on treated seed tag labeling by section 201.31a(d) of the Federal Seed Act (FSA), a requirement for this statement by EPA would create duplicative regulation and accountability with no added benefit to the user or human and environmental health. EPA could simply add a clarification: “This statement is required by the Federal Seed Act Regulations [7 CFR § 201].
“Do not use treated seeds for fuel or ethanol production purposes.”	Risk associated with use of treated seed for ethanol or fuel production can be mitigated with proper label requirements approved by EPA. EPA is committed to risk-based regulation and as such should support this potential use of sustainable disposal options with appropriate requirements such as: “Excess treated seed may be used for ethanol production only if (1) by-the by-products of ethanol production are not used for livestock feed, and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.”
“Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting. Additional incorporation may	We recommend the statement be revised to: “Properly calibrate/adjust planting equipment prior to use in order to achieve optimal planting efficiency. Additional incorporation may be required to thoroughly cover exposed seeds.”

¹¹ USEPA. 2023. Labeling Instructions for Pesticide-Treated Seed and Pesticide-Treated Paint Products. www.regulations.gov/document/EPA-HQ-OPP-2023-0420-0002

EPA Proposal	Comment
be required to thoroughly cover exposed seeds.”	The requirement for “all planted seeds” to be thoroughly incorporated is unattainable and inconsistent with EPA’s assumptions in evaluation of the safety, and registrability, of the use and usage of treated seed. Features of the landscape being planted, including presence of rocks and uneven surfaces, will prevent 100% incorporation of sown seeds even with precision planting equipment. Attempts to cover all unincorporated seed by walking fields after sowing are unlikely to be 100% effective and are unnecessary as the few treated seeds that may remain on the soil surface are a <i>de minimis</i> risk to human health and the environment. EPA’s risk assessments currently consider: (1) a percentage of the sown seeds remain unincorporated based on the planting equipment used, (2) the attractiveness of individual seed types as a food item by wildlife (e.g., soybean seed impedes birds digestion and gossypol is toxic to birds and all non-ruminating mammals and thus avoided), and (3) literature that concludes it is not an effective foraging strategy for wildlife to roam recently planted fields for unincorporated treated seed.^{12, 13, 14, 15, 16} Risk management needs for use and usage should continue to be defined by robust risk assessments and no blanket requirements/restrictions, such as no broadcasting or 100% incorporation, should be accepted.
“If seed spilled during loading or planting exceeds 1 pound, dispose of seeds in accordance with disposal language below.”	The basis for establishing different disposal requirements for excess of 1 lb of seed is unclear.
“ADVISORY DUST-REDUCING TECHNIQUE	Many seed types and seed treatment protocols yield treated seed product with low dust-off potential. In addition, seed flow lubricants are not compatible with all seed types or planting equipment,

¹² Gadelha, I.C.N., N.B.S. Fonseca, S.C.S. Oloris, M.M. Melo and B. Soto-Blanco. 2014. Gossypol toxicity from cottonseed products. The Scientific World Journal, vol. 2014, Article ID 231635, 11 pp. <http://dx.doi.org/10.1155/2014/231635>.

¹³ Martin, A.C., H.S. Zim and A.L. Nelson. 1951. American Wildlife and Plants: A Guide to Wildlife Food Habits. Dover Publications, New York, NY. Dabbert, C.B. and T.E. Martin. 1994. Effects of diet composition and temperature on food choice of captive mallards. Southwestern Naturalist 39:143-147.

¹⁴ Diaz, M. 1990. Interspecific pattern of seed selection among granivorous passerines: Effects of seed size, seed nutritive value and bird morphology. Ibis 32:467-476.

¹⁵ Galle, A.M., G.M. Linz, H.J. Homan and W.J. Bleier. 2009. Avian use of harvested crop fields in North Dakota during spring migration. Western North American Naturalist 69:491-500.

¹⁶ <https://www.epa.gov/sites/default/files/2016-04/documents/interimseedtreatmentguidance2016.pdf>

EPA Proposal	Comment
Fluency agents are recommended to be applied to treated seed prior to the planting.”	potentially impacting singulation at planting. The following is a recommended revision: “ADVISORY DUST-REDUCING TECHNIQUE Application of seed flow lubricants (or planting lubricants) to treated seed prior to planting may reduce seed coat abrasion dust.” Confirm compatibility of planting lubricants with seed type and planting equipment prior to use.” Alternatively, EPA could add a preceding phrase to provide clarity to its draft language, as follows: “Where compatible and appropriate, seed flow lubricants are recommended to be applied to treated seed prior to the planting.”
“The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements: • This seed has been treated with (insert name of active ingredient of pesticide). • Do not use for food, feed, or oil purposes.”	These statements are required on treated seed labels by the FSA. A requirement for this statement by EPA would create duplicative regulation and accountability with no added benefit to the user or human and environmental health.
“This seed has been treated with [INSERT PRODUCT NAME(s) (EPA REG. NO(s))] containing [INSERT NAME(S) OF ACTIVE INGREDIENT(S)]. Any seed treated with [PRODUCT NAME] that is sold or distributed for a use not permitted by the following labeling does not...”	EPA should remove the product (brand) name and EPA Registration Number from the requirements for the following reasons: • A single EPA registration number may be associated with multiple product (brand) names and lead to confusion if both are required. • EPA registration number is not necessary or appropriate for the seed bag tag because the specific first aid, application rate and other compliance information on the formulated product label is the obligation of the seed treatment applicator, not the end user of the treated seed product. • The FSA requires treated seed tags to list the active ingredients of seed treatment pesticides. • Inclusion of seed treatment pesticide name and EPA registration number will add considerable length and complexity to the treated seed tag labeling.

IV. Benefits of Seed Treatment Pesticides to US Agriculture

Seed treatments are the precise applications of biological organisms, products, and/or chemical ingredients to suppress, control, or repel plant pathogens, insects, or other pests, protecting the seed during its most vulnerable developmental stages and before emergence from the soil. Commonly used seed treatments for control of plant pests and pathogens are insecticides, fungicides, and nematicides. Seed treatments are applied to numerous types of crop seeds planted in the United States, including soybeans, grain, cotton, corn, beets, peanuts, onions, leafy vegetables, and rice. Seed treatment increases the value of the harvested crop through improved yield and significantly higher commodity prices since 2005.¹⁷

As evidenced by its rapid adoption in the US, seed treatment offers considerable benefits for growers and allows them to produce high-quality crops. Seed treatments are easy for growers to handle and use, contribute to earlier and faster planting, improved seedling emergence and health, especially in no-till or conservation tillage systems, higher plant populations, and higher crop yields. Faster planting is important as it can often mean that pre-planting fumigant and spraying in furrow are not required. Following planting, seed treatments offer effective control against early season, below-ground and above-ground pests and diseases and reduce the need for additional rescue treatments or replanting. Seed treatments ultimately reduce the overall amount of pesticides used when compared to traditional broadcast sprays, and because of their targeted application, also minimize off-target exposure. Seed treatments are critical components in modern integrated pest management (IPM), enabling growers to control some of their most challenging pests and reduce the likelihood of development pest resistance to pesticides.

An evaluation of 550 studies including peer-reviewed and extension service publications that reported performance of neonicotinoid-based treatments allowed for 5,271 pairwise comparisons that concluded, compared to no-insecticide controls, neonicotinoid-based seed-treatment pesticides consistently produced better results as it relates to yield, crop damage, or pest control and lead to better net income and percent of income/hectare (ha) for the grower.¹⁸

Yield data meta-analysis can provide a broad view of the impact of seed treatments on yield across varied conditions. Three meta-analyses compared yields of neonicotinoid-treated corn, cotton, and soybean seed to fungicide-only treated seed in trials across the Mid-South (Arkansas, Louisiana, Mississippi, and Tennessee). All three analyses showed that the use of neonicotinoid seed treatments, in some areas and some years, can provide significant economic benefits to growers. Ninety-one corn trial yields were compared on a state-by-state basis and yields from trials with neonicotinoid-treated seed were significantly higher than from fungicide-only.¹⁹ A similar analysis of 100 cotton trials, showed

¹⁷ The Role of Seed Treatment in Modern US Crop Production. A Review of Benefits. 2013. Report produced by CropLife Foundation. <https://www.betterseed.org/wp-content/uploads/TheRoleofSeedTreatmentinModernUSCropProduction.pdf>

¹⁸ Grout, Koenig, Kapuvair, McArt. 2020. Neonicotinoid Insecticides in New York State: economic benefits and risk to pollinators. Cornell University.

¹⁹ North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, B.R. Leonard, and D.M. Dodds. 2018. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Corn (*Zea mays*) Production Systems. *Journal of Economic Entomology* 111(1): 187-192.

significantly greater yields for the neonicotinoid-treated seed trials compared to fungicide-only treated seed trials on a state-by-state basis.²⁰ Finally, an analysis of 170 soybean trials, demonstrated the impact that neonicotinoid seed treatments had on yield by controlling a commonly occurring complex of multiple pests. State-by-state analysis showed significantly greater yields from use of neonicotinoid-treated seed compared to fungicide-only treated seed.²¹

A study examining the effect of insecticide seed treatments on controlling curly top in sugar beet by controlling the beet leafhopper that vectors the disease-causing virus suggested neonicotinoid seed treatments could be used to extend curly top control in sugar beet with resistance.²² The researchers further demonstrated that sugar beet production in areas with curly top would likely suffer considerably without the neonicotinoid seed treatments.^{23,24}

Other researchers have demonstrated the importance of fungicide and insecticide seed treatments for controlling many economically important pests and diseases, such as the Old World bollworm and *Phytophthora* root and stem rot, in a variety of climates and crops.^{25, 26, 27, 28, 29, 30} Seed treatments have proven remarkably successful in controlling pests and improving plant populations and crop yields, as noted above in the cited peer-reviewed studies. 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

²⁰ North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, and D.M. Dodds. 2018. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Cotton (*Gossypium hirsutum* [Malvales: Malvaceae]) Production Systems. *Journal of Economic Entomology* 111(1): 10-15.

²¹ North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, and D.M. Dodds. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Soybean (*Glycine max*) Production Systems. *Journal of Economic Entomology* 109(3): 1156-1160. 2016.

²² Strausbaugh, C.A., E.J. Wenninger, and I.A. Eujayl. Control of Curly Top in Sugar Beet with Seed and Foliar Insecticides. *Plant Disease* 98(8): 1075-1080. 2014.

²³ Strausbaugh, C.A., and E.J. Wenninger. Foliar Insecticides for the Control of Curly Top in Idaho Sugar Beet, 2018. *Plant Disease Management Reports* 1: 13. 2019.

²⁴ Strausbaugh, C.A., and E.J. Wenninger. Foliar Insecticides for the Control of Curly Top in Idaho Sugar Beet, 2019. *Plant Disease Management Reports* 9:14. 2020.

²⁵ Humann, R.M., K.D. Johnson, M.J. Wunsch, S.M. Meyer, J.G. Jordahl, E.C. Bauske, J.M. Halvorson, A.J. Friskop, K.A. O'Bryan, T.J. Gulya, and S.G. Evaluation of Oxathiapiprolin for the Management of Sunflower Downy Mildew. *Plant Disease* 103(10): 2498-2504. 2019.

²⁶ Hummel, N.A., A. Meszaros, D.R. Ring, J.M. Beuzelin, and M.J. Stout. Evaluation of Seed Treatment Insecticides for Management of the Rice Water Weevil, *Lissorhoptrus oryzophilus* Kuschel (Coleoptera: Curculionidae), in Commercial Rice Fields in Louisiana. *Crop Protection* 65: 37-42. 2014.

²⁷ Plummer, W.A., G.M. Lorenz, N.M. Taillon, N.R. Bateman, B.C. Thrash, S.G. Felts, J.P. Schafer, T.B. Newkirk, C.A. Floyes, C. Rice, T. Harris, Z. Murray, and A. Whitfield. Evaluation of Insecticide Seed Treatment Combinations for Control of Rice Water Weevil, *Lissorhoptrus oryzophilus*, in Arkansas. *B.R. Wells Rice Research Studies Arkansas Agricultural Experiment Station, University of Arkansas System* 676: 120-124. 2021.

²⁸ Paez Jerez, P.G., A.C.L. Alves, J.E. Quinteros Cortes, L.M. Ribeiro, J.G. Hill, M. T. Vera, M.P. Gonzatto, R.M. Pitta, and E.J.G. Pereira. Diamide Seed Treatment May Protect Early Soybean Growth Stages Against *Helicoverpa armigera*. *Crop Protection* 168. 2023. (<https://doi.org/10.1016/j.cropro.2023.106214>)

²⁹ Hegstad, J.M., A.P. Gaspar, L. Feng, K. Lackermann, A. Hudson, and M. Howieson. Agronomic and Efficacy Evaluations of Oxathiapiprolin as a Soybean Seed Treatment. *Agronomy Journal* 113(6): 4850-4864. 2021.

³⁰ Kandel, Y.R., C.A. Bradley, M.I. Chilvers, F.M. Mathew, A.U. Tenuta, D.L. Smith, K.A. Wise, and D.S. Mueller. Effect of Seed Treatment and Foliar Crop Protection Products on Sudden Death Syndrome and Yield of Soybean. *Plant Disease* 103(7): 1712-1720. 2019.

percent in eight major North American crops.³¹ Seed treatment pesticides also play a key role in resistance management or foliar applied chemistry and insect traits.³²

Because of seed treatment's targeted accuracy, they selectively control pests (including nematodes), while ensuring beneficial insects remain available to keep other potential insect pests in check. Their targeted use provides an efficient use of pesticides and reduces the amount of chemicals used on large areas of farmland (Figure 1). Because they are below the soil surface, treated seeds help minimize the exposure of pesticides to off-target plants and animals. The precise application of a pesticide via seed treatment reduces soil surface exposure by up to 90 percent compared to in-furrow applications and up to 99 percent compared to a surface foliar application.³³

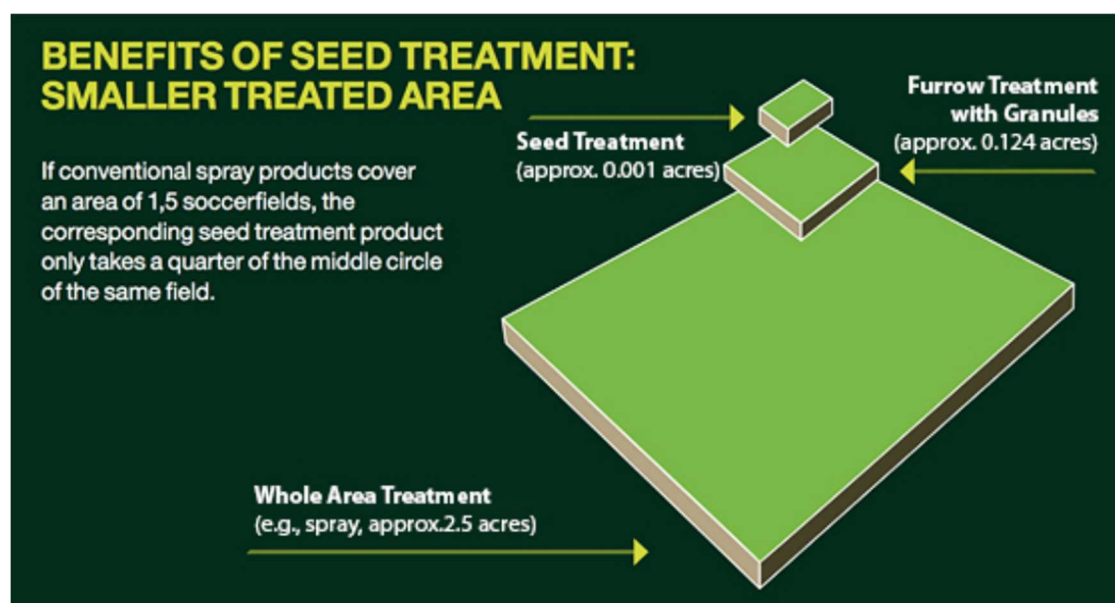


Figure 1. The benefits of treated seed as demonstrated by a smaller treated area for seed treatment relative to in-furrow or a conventional spray application treatment area.³⁴ (source: Bayer)

1. Environmental Health and Safety Improvements

Seed treatment application equipment technology has improved from a gross application of fluid ounces 100 pounds of seed to a precise application of micrograms of ai per individual seed. Computerized treating systems calculate the total seed treatment product application rate for each lot of seed, adjust the seed and product flow, and make corrections as necessary for each new lot of seed.

³¹ See AgInformatics, LLC, *The Value of Neonicotinoids in North American Agriculture*, Executive Summary. 2015. https://aginformatix.com/uploads/3/4/2/2/34223974/executive_summary_neonicotinoids.pdf.

³² Reisig, D. Insect Management in ThryvOn Cotton. North Carolina State University Extension Publication. 2023. go.ncsu.edu/readext?915674.

³³ The role of seed treatment in modern us crop production. 2013. A report from CropLife Foundation. <https://www.betterseed.org/wp-content/uploads/TheRoleofSeedTreatmentinModernUSCropProduction.pdf>

³⁴ ASTA & CLA Seed Treatment Guide. The Guide to Seed Treatment Stewardship. <https://seed-treatment-guide.com/>

The integration of innovative materials such as polymers and seed flow lubricants has improved traditional seed treatment processes, reducing dust-off and abrasion that can be created during transportation and planting, as well as increasing flowability with reduced build-up of additives during seed-treating. These innovations have transformed seed handling, performance, and safety, further reducing the risk to the environment and human health.

To mitigate against unintentional release of the active ingredient into the environment during production, movement, storage and use of treated seed, seed dealers and growers are encouraged by industry to adhere to seed treatment quality control and stewardship guidelines and to follow best seed planting practices.³⁵ Growers are also recommended to monitor weather conditions during planting and use planting equipment that has been designed with dust reducing technology or modified with dust deflectors installed aftermarket to deflect air flow downward to reduce release of seed dust into the air.³⁶

2. Stewardship Efforts

All seed treatment pesticides, including those with neonicotinoid pesticides, undergo rigorous testing and EPA review prior to their registration for commercial use. The EPA carefully considers effects on many non-pest organisms, including honey bees, when they approve new seed treatment pesticide uses. In fact, EPA data has shown low risk to pollinators from treated seed in recent assessments.

As an example, hundreds of independent studies on neonicotinoids and bees indicate that, when used according to label instructions, seed treatments are not harmful to bee colonies. At normal field doses, the potential exposure to bees is far below levels that would cause concern. Most experts agree that many factors such as parasites, diseases, inadequate nutrition, lack of available forage, adverse weather, other pesticides, and hive management practices play a role in hive health and honey bee populations. The Varroa mite is the “single most detrimental pest of honey bees,” according to the US Department of Agriculture (USDA).³⁷

To minimize environmental exposures via drift of treated seed dust, seed treatment pesticides include instructions requiring the use of dust-reducing techniques and ways of measuring the efficacy of those techniques. As described and cited above, there is a concerted effort across the agricultural industry to reduce the potential dust-off exposure and the abrasion of treated seed during planting. Mitigation of dust-off has resulted from modifications of planting equipment, increased use of dust-reducing lubricants in planters at planting time, improvements of seed coating technologies, protocols utilizing polymers and seed coatings, and improved communication between beekeepers and farmers prior to and during planting time.

³⁵ ASTA_SeedGuide_Applicators_Update2021.pdf (seed-treatment-guide.com)

³⁶ ISO 17962:2015: Agricultural Machinery - Equipment for Sowing - Minimization of the Environmental Effects of Fan Exhaust from Pneumatic Systems.

³⁷ USDA Agricultural Research Service. Varroa Overview. <https://www.ars.usda.gov/pacific-west-area/tucson-az/carl-hayden-bee-research-center/research/varroa/varroa-overview/>

The agricultural industry communicates the stewardship of treated seed at planting time on an annual basis. As an example, below is a summary of several recommendations for mitigating dust-off proposed by the Growing Matters Coalition.³⁸

- Application of seed coating during seed treatment. For certain seed types such as corn, a polymer coating improves the adhesion of the treatment coating to the seed and reduces dust-off and abrasion potential.
- Development of a threshold to measure efficacy of seed coating and means to measure the efficacy of the seed coating (i.e., Heubach testing, which is the industry standard for testing the retention of the applied seed treatment).
- Use of seed flow lubricants at planting time. This is a best management practice option for a grower at planting time for certain row crops such as corn and soybeans.

The seed treatment industry is dedicated to stewardship throughout the lifecycle of treated seed, from initial application on the seed, to planting, to disposal of excess treated seed. Advancements in formulation of treating products, including seed treatment pesticides, are improving the retention of the treatment on the seed, and improving flowability of the treated seed through the planting equipment, thereby reducing exposure from abrasion and dust-off.

V. Regulatory Framework

1. EPA's Regulation of Pesticides Under FIFRA

Under FIFRA, EPA conducts effective, rigorous evaluations of every pesticide product marketed, sold, or distributed in the US, including products used to treat seeds. *See* 7 USC §§ 136a(c)(5), 136j(a)(1). An EPA registration operates as a product-specific license that confers upon the registrant certain legally protected rights. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) (“A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute”). 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.³⁹ 7 USC § 136(bb). The product label establishes the scope of the registration and is submitted to and approved by EPA as a core element of every registration. *See, e.g., id.* § 136a(c)(1)(C). As part of that review, EPA ensures that the treating pesticide

³⁸ Growing Matters. BeSure! About Stewardship: Adopt best-management practices while planting <https://growingmatters.org/besure>.

³⁹ FIFRA's implementing regulations describe the types of data and information EPA generally requires to support registration. *See* 40 C.F.R. § 158.1(a). The data requirements for registration “are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.” 40 C.F.R. § 158.130(a). These include specific requirements for data regarding product chemistry, product performance, and the toxicological and ecological effects of the pesticide products. *See* Subpart A, 40 C.F.R. Part 158. The regulations also confer upon EPA significant discretion and flexibility to request additional data, beyond that specifically described in the regulations, as needed to appropriately evaluate a pesticide product's potential to cause “unreasonable adverse effects to man or the environment.” *See, e.g.,* 40 C.F.R. § 158.30(b).

label includes instructions for the user of the treating pesticide that (1) the seed tag must accompany the treated seed when distributed and sold; and (2) the seed tag must include adequate instructions concerning the use, storage, and disposal of the treated seed, and that failure to do so in accordance with the label constitutes distribution or sale of an unregistered pesticide.⁴⁰ Every registered product is required to display an EPA-approved label that enumerates approved uses, applications, and directions for use, and the label must “accompany[] the pesticide . . . at any time.” *Id.* § 136(p)(2). Use of a pesticide in a manner inconsistent with its 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 and formulations and the particular uses of the pesticide, including use as a seed treatment. 7 USC § 136a; 40 CFR §§ 152.100–152.119. EPA’s expert scientists also conduct sophisticated risk assessments that identify and analyze the potential risks that could be associated with the various uses, including risks to beneficial or non-target organisms, such as honey bees.⁴¹ Only upon determining that a pesticide use will not have an unreasonable adverse effect on human health or the environment will EPA allow the use. 7 USC § 136a(c)(5)(C), (D); *see also id.* § 136(bb) (defining “unreasonable adverse effects”). In addition, FIFRA authorizes EPA to conditionally register a pesticide under certain circumstances, such as where certain required data are not yet available. But as with all pesticides, “conditionally” registered products must satisfy FIFRA’s rigorous “no unreasonable adverse effects” standard for registration. *Id.* § 136a(c)(7)(B), (C).

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 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.

Implementing the FIFRA regulatory requirements and registration standard requires EPA to conduct hundreds of complex scientific and regulatory assessments and determinations every year. From fiscal year (FY) 2015 through FY2018, EPA issued registration decisions for 98 new conventional pesticide active ingredients; approved more than 1,700 new uses for existing conventional pesticides; and

⁴⁰ See EPA Sept. 27, 2022 Response to Center for Food Safety Citizen Petition, at 39-40, <https://downloads.regulations.gov/EPA-HQ-OPP-2018-0805-0104/content.pdf>.

⁴¹ See EPA, Overview of Risk Assessment in the Pesticide Program, <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program> (last updated Aug. 31, 2017).

completed review of nearly 300 labels in FY2018 alone.⁴² Additionally, over the period from FY2020 to 2022, EPA completed 212 risk assessments for pesticide registration decisions for new active ingredients; in FY2022, the Agency opened 35 registration review dockets, and completed 25 draft risk assessments and 16 registration review cases.⁴³ This ongoing volume of assessments shows the Agency's extensive regulatory and technical expertise and engagement and requires efficient and effective regulatory approaches.

Registered neonicotinoid pesticides that have been 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 USC § 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. *See* 40 CFR 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.

2. 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, relevant here, (2) of a character not requiring FIFRA regulation in order to carry out the purposes of the Act. 7 USC § 136w(b).

Using that authority, EPA issued regulations implementing the Treated Article Exemption. 40 CFR § 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; (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 USC § 136w(b). The Treated Article

⁴² EPA, *Implementing the Pesticide Registration Improvement Act – Fiscal Year 2018* at Appendix A, Table 3, Number of PRIA Actions Completed (Feb. 13, 2020), <https://www.epa.gov/sites/default/files/2020-01/documents/fy18-pria-annualrpt-table3.pdf>; *id.* at Pesticide Reevaluation Programs, <https://www.epa.gov/sites/default/files/2020-01/documents/improve-reevaluation-fy18.pdf>.

⁴³ EPA, *Justification of Appropriation Estimates for the Committee on Appropriations for FY2024*, at 81, <https://www.epa.gov/system/files/documents/2023-04/fy24-cj-15-program-performance.pdf>.

Exemption eliminates duplicative regulation and promotes comprehensive consideration of a pesticide product's overall potential risks, impacts, and benefits. The Exemption, particularly when evaluated alongside the complementary jurisdiction of USDA over seed, adequately addresses EPA's mandate under FIFRA without need for further rulemaking.

3. Regulation of Treated Seed Under the Federal Seed Act

All seed, including treated seed, is regulated by USDA under the FSA, 7 USC §§ 1551–1611, which regulates the interstate shipment of agricultural and vegetable seeds. It is unlawful “to transport or deliver for transportation in interstate commerce,” or to import into the United States, treated seeds unless the container bears a label (i) stating that the seeds have been treated; (ii) identifying the commonly accepted name of the chemical substance used to treat the seed, (iii) including any appropriate cautionary statements concerning its use, and (iv) describing any process used in such treatment. *See* 7 USC §§ 1571, 1581. 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 CFR Part 201.⁴⁴ For example, Section 201.31a(a) of the FSA regulations requires that all treated seed be labeled with the name of the substance or active ingredient used to treat the seed (*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.”). Further, “[t]he complete record for any lot consisting of or containing treated seed shall include records necessary to disclose the name of any substance or substances used in the treatment of such seed, including a label or invoice or other document received from any person establishing the name of any substance or substances used in the treatment to be as stated, and a representative sample of the treated seed.” 7 CFR § 201.7a. EPA recommends that these USDA-administered and enforced labeling requirements for treated seed also be included on the EPA labels for pesticide products approved for use as seed treatments.⁴⁵ This ensures that both seed treaters and growers who plant seed have access to sufficient information regarding how to treat seed in the manner approved by EPA under FIFRA and handle and manage seed once treated.

Section II of this comment letter details the steps our collective members have taken to not only meet these regulatory requirements but also additional stewardship efforts for seed treaters and growers.

⁴⁴ *See also* USDA, Labeling Requirements for Chemically Treated Seed (Sept. 2017),

<https://www.ams.usda.gov/sites/default/files/media/LabelingRequirementsforChemicallyTreatedSeed.pdf>.

⁴⁵ *See* EPA, Label Review Manual, Ch. 18, at 18-9, https://www.epa.gov/sites/production/files/2014-06/documents/chap-18_0.pdf.

VI. No Additional Rulemaking is Necessary to Ensure Adequate Labeling and Use of Treated Seeds.

1. The Treated Article Exemption is Narrowly Tailored to Treated Seeds that are Used in Accordance with the Pesticide Product Label.

All pesticides used for 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. By approving all the seed treatment pesticide products, EPA made an express determination that their use to treat seed, and the sale and use of such treated seed, would not cause "unreasonable adverse effects." 7 USC § 136a(c)(5)(C), (D).

The Treated Article Exemption in no way circumvents the FIFRA registration standard. Rather, EPA's application of the Treated Article Exemption to treated seed reflects a determination that EPA has already assessed the potential human health and environmental impacts of the treating pesticide and determined that this particular use is safe when used in accordance with the EPA-approved label.

Moreover, as EPA recognized in the ANPR, treated seed products are already subject to stringent regulatory requirements within EPA's purview to qualify for the Treated Article Exemption in the first instance; failure to adhere to any one of these requirements would cause the treated seed product to fall outside of the Treated Article Exemption and require registration under FIFRA. Critically, a treated article is exempt from the requirements of FIFRA only if, among other conditions, the pesticide product used to treat the article is "registered for such use" under FIFRA section 3. EPA has interpreted this requirement to require that (1) the treating pesticide be registered for seed treatment on the specific seed crop at issue, (2) the use of the registered treating pesticide product, and the distribution and sale of the treated seed, is consistent with the registered pesticide's product label, and (3) that the use of the treated seed is consistent with the instructions on the registered pesticide label, as communicated on the seed tag.⁴⁶ Thus, "if the treating pesticide requires that the treated seed bag tag include specific labeling information and instructions, but such bag tag does not include the required labeling or instructions, the 'registered for such use' condition is not met" and the Treated Article Exemption does not apply.⁴⁷ The Treated Article Exemption similarly would not apply "if the treated seed product is not used consistent with the instructions on treating pesticide labeling as communicated on the seed bag tag."⁴⁸ The narrow criteria of the Treated Article Exemption, which already limits its application to treated seeds used in accordance with the registered pesticide product label, makes any further

⁴⁶ See 88 Fed. Reg. at 70,628 (noting that conditions for application of Treated Article Exemption "include that a pesticide 'registered for such use' is used, which EPA has interpreted to require compliance with labeling instructions relating to distribution, sale, and use of the pesticide registered under FIFRA to treat seed and the distribution, sale, and use of the treated seed itself."); Sept. 27, 2022 Response to Citizen Petition at 40.

⁴⁷ 88 Fed. Reg. at 70,628.

⁴⁸ *Id.*; accord Sept. 27, 2022 Response to Citizen Petition at 40 ("The distribution or sale of a treated article or substance in a manner inconsistent with instructions on the registered treating pesticide labeling means that the treated article or substance does not meet the 'registered for such use' criterion and the exemption does not apply to the treated article or substance.").

rulemaking unnecessary to prevent “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits” of the product. 7 USC § 136(bb).

2. The Existing Regulatory Framework for Treated Seeds Adequately Accomplishes EPA’s Labeling Goals

As set forth above, the existing regulatory framework among the respective federal agencies — EPA and USDA — comprehensively requires that treated seeds be labeled appropriately and used in accordance with their label. Any rulemaking under FIFRA section 3(a) to further regulate the distribution, sale, and use of treated seed is not necessary to accomplish the objectives identified in the ANPR and would unnecessarily duplicate prevailing EPA and USDA requirements, with no additional benefit to humans or the environment.

First, EPA stated that it sought through the ANPR to ensure that the seed tag accompany the treated seed when distributed and sold.⁴⁹ A FIFRA section 3(a) rule is not necessary to accomplish this goal because the Agency already requires pesticide registrants, as a condition of registration, to include the EPA-approved label language that must be placed onto the bags, containers, or affixed tags of treated seeds, thereby directing seed treaters to label resulting treated seed with information regarding handling and management of treated seed. Registrants are, and necessarily must be, complying with this requirement in order to maintain their pesticide registrations.⁵⁰

Second, EPA stated in the ANPR that it sought to ensure that such labeling accompanying the treated seed “include specified clear and effective instructions on use of the treated seed, including the name of the active ingredient and pesticide product used (including the EPA product registration number), and instructions on the storage, planting, and/or management of spilled or excess treated seed, as appropriate.”⁵¹ Similarly here, registrants of pesticides approved for use on seeds are already required to (i) label the treating pesticide product with directions for use and the name of the active ingredient, and (ii) direct that the seed tag also contain information regarding directions for use and the name of the active ingredient. The Federal Seed Act provides a third layer of regulation regarding directions for use and name of the active ingredient. *See* 7 USC § 1571; 7 CFR § 201.31a(a). Publicly available seed treatment pesticide labels make clear that registrants are readily complying with EPA’s requirements to include on the pesticide label information that is specific to seed treatment use and seed bag label requirements.⁵²

Third, EPA proposed issuing a rule pursuant to FIFRA section 3(a) providing that the distribution or sale of the treated seed products without clear and effective labeling is the distribution or sale of an unregistered pesticide. As described in Section III.A., *supra*, however, EPA has already interpreted the

⁴⁹ 88 Fed. Reg. at 70,629.

⁵⁰ *See* EPA, Label Review Manual, Ch. 18, at 18-9, https://www.epa.gov/sites/production/files/2014-06/documents/chap-18_0.pdf.

⁵¹ 88 Fed. Reg. at 70,629.

⁵² *See, e.g.*, Syngenta Cruiser 5FS® Product Label at 7-8, https://www.syngenta-us.com/current-label/cruiser_5fs; BASF Poncho® Product Label at 12-14, <https://www.cdms.net/ldat/ldGUU006.pdf>; Bayer Goucho 600® Product Label at 2, https://assets.greenbook.net/23-53-06-21-11-2022-Gaoucho_600_-_label.pdf.

Treated Article Exemption to apply only to treated seeds that are “registered for such use,” meaning that (i) their seed bag tag contains the instructions required by the EPA-approved pesticide label and (ii) the seeds are used in accordance with that label. Accordingly, because the existing regulatory framework administered together by EPA and USDA already requires that registrants include appropriate information and instructions on the seed tag, there is no need for a new FIFRA section 3(a) rule. Maintaining the existing regulatory framework preserves the jurisdiction of the respective regulatory agencies and avoids redundant registration that would undo the regulatory efficiencies the Treated Article Exemption sought to effectuate.

VII. Conclusion

Seed treatment pesticides have been rigorously tested and proven to be safe and effective tools contributing to the more efficient and sustainable production of food, fiber, and fuel while playing a key role in farmers’ IPM programs. Our collective member companies remain committed to stewardship efforts that support the proper use, storage, and disposal of treated seed, and the safe handling of the treating pesticide. In that spirit, we have offered the enclosed comments and information and encourage the Agency to consider our stakeholder input on any potential changes to the Treated Article Exemption.