



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 28, 2023

Dear AAPCO and SFIREG Colleagues:

Gary Bahr (SFIREG Chair, WA Dept of Ag)  
Liza Fleeson Trossbach (AAPCO President)  
Amy Brown (SFIREG POM Working Committee Chair)  
Hotze Wijnga (SFIREG EQI Working Committee Chair)  
Amy Sullivan (AAPCO Executive Secretary)

RE: EPA Response to 08/31/2022 – State FIFRA Issues Research and Evaluation Group (SFIREG) Treated Seed Issue Paper

Thank you for the submission of the SFIREG “Treated Seed Issue Paper.” The Agency appreciates SFIREG’s discussion on this topic and its willingness to share insights from State Lead Agencies (SLAs) and the Joint Working Committees (JWC) of SFIREG. The issue paper identified a number of questions and concerns relating to treated seeds and requests that EPA:

- 1) More comprehensively regulate treated seeds;
- 2) Explain how treated seeds are included in risk assessments;
- 3) Evaluate the wide-scale impact to pollinators;
- 4) Evaluate seed treatment residues in crop production locations and soil;
- 5) Evaluate the impact to non-target organisms and aquatic systems from use of treated seeds;
- 6) Identify mechanisms to obtain better information on use of treated seeds;
- 7) Evaluate the impact of the use of treated seeds on the other types of applications such as soil or foliar applications (i.e. replacement and reduction in use of other types of applications);
- 8) Evaluate the availability of data systems to track active ingredients used to treat seeds;
- 9) Provide stronger oversight of seed treatment applicators as a way to address other issues with treated seeds;
- 10) Determine if states can use label information transferred onto the seed bag tags to enforce under existing authorities and if having the EPA registration number on seed bag tags would enhance that authority.

Since the issuance of this treated seed issue paper from SFIREG on August 31, 2022, EPA released a response to a petition on treated seeds (hereafter known as petition response) submitted by the Center for Food Safety (CFS) with and on behalf of other stakeholders on September 28, 2022. The petition and EPA’s response to it can be found in the docket EPA-HQ-OPP-2018-0805 at [www.regulations.gov](http://www.regulations.gov).<sup>1</sup> In the petition response, EPA noted that "On August

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<sup>1</sup> Since the issuance of the response to the petition, EPA announced an ESA Workplan Update in November 2022. The Agency presented the current mitigation language for labels and bag tags of products registered for seed

31, 2022, EPA received a letter from State FIFRA Issues Research and Evaluation Group (SFIREG) identifying a number of issues and questions relating to assessment of pesticides used to treat seed and use of treated seed. These issues or questions are addressed in this response and/or may be further addressed in the anticipated ANPRM [Advanced Notice of Proposed Rulemaking].” This document summarizes EPA’s responses (as outlined in the petition response) to some of the SFIREG issues and identifies those issues that may be addressed in the ANPRM. EPA intends to release the ANPRM in September 2023.

### **SFIREG Issue Paper Issues Addressed in the Petition Response (Issues 1-5)**

In the treated seed petition response, EPA addressed similar issues to those identified by SFIREG in their issue paper such as regulation of treated seeds, risk assessments for treated seeds, impacts to pollinators, seed treatment residues, and impact to non-target organisms. EPA has included a summary of responses to these points below and further information on these topics can be found in the petition response.

#### *1. Regulation of treated seeds*

In sections IV.C.1 to IV.C.3 of the petition response, EPA explained how the Agency handles treated seeds under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and how the treated article exemption applies to treated seeds. In summary, to grant a pesticide registration, FIFRA requires EPA to consider whether the pesticide has “unreasonable adverse effects” to human health and the environment.<sup>2</sup> FIFRA section 2(bb) defines “unreasonable adverse effects on the environment” to mean, among other things, “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”<sup>3</sup> EPA is required to review each pesticide registration every 15 years to determine whether the pesticide continues to satisfy the FIFRA standard for registration.<sup>4</sup> Section 25(b)(2) of FIFRA provides that the Administrator may, by regulation, exempt from the requirements of FIFRA, including the registration requirements, any pesticide which the Administrator determines to be of “a character which is unnecessary” to be subject to FIFRA “in order to carry out the purposes” of FIFRA.<sup>5</sup> Several exemptions under FIFRA section 25(b)(2) were adopted in 1988 and included a “treated articles and substances” exemption which includes conditions that must be met for a treated article to be exempt from FIFRA registration

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treatment and requested comments on questions relating to refining additional language. For more information on the ESA Workplan Update see <https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species>.

<sup>2</sup> 7 U.S.C. § 136a(c)(5).

<sup>3</sup> 7 U.S.C. § 136(bb).

<sup>4</sup> 7 U.S.C. § 136a(g) and 40 C.F.R. part 155, subpart C. “Registration review” is the term used for this process.

<sup>5</sup> 7 U.S.C. § 136w(b)(2).

requirements.<sup>6</sup> As EPA explained in its response to the treated seed petition, treated seeds satisfying those conditions for the exemption are exempted from FIFRA registration requirements.

EPA discussed in section IV.D of the petition response the impacts of creating a registration program for each pesticide-treated seed crop, which could include increased cost and complexity to stakeholders. EPA also discussed the measures it has taken and is taking to make sure that labeling instructions are reaching the user of the treated seed. EPA is also currently working on an ANPRM to seek additional information on the use of treated seeds and to explore the possibility of developing and issuing a potential rule pursuant to section FIFRA 3(a)<sup>7</sup> (referred to as a FIFRA 3(a) rule in this document). The potential FIFRA 3(a) rule can provide EPA with greater oversight regarding the use of treated seeds and address the enforcement issues brought up by stakeholders, but, as discussed in the petition response, without the cost of requiring registration of each pesticide-treated seed crop.

### *2. Risk assessments for treated seeds*

In the petition response, EPA detailed how treated seeds are included as part of the required review for a registered pesticide (when initially registered and in registration review). EPA conducts thorough assessments of the use of the registered pesticide to treat seed and use of the treated seed, including assessing risks to human health and multiple taxa (*e.g.*, aquatic organisms, birds, bees, and other pollinators). This assessment includes consideration of the exposures and impacts from use of the treated seed. Potential risks based on available data for seed treatment uses are summarized in registration and registration review documents. For additional information, see section IV.A. of the petition response.

### *3. Impact to pollinators*

In the petition response, EPA also detailed its assessment of impacts to pollinators during the course of registration and registration review. During the course of these assessments, impacts to bees and other pollinators are assessed and have been documented in individual risk assessment documents for each active ingredient. For more information, see section IV.A. of the petition response.

### *4. Seed treatment residues in crop production locations and soil*

In the petition response, EPA described the assessments that are conducted for each individual active ingredient (when initially registered and in registration review). These assessments include human and ecological exposures and risks from use of pesticides with systemic properties. Thus,

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<sup>6</sup> Pesticide Registration Procedures; Pesticide Data Requirements, Final Rule, 53 Fed. Reg. 15952 (May 4,1988).

<sup>7</sup> FIFRA section 3(a) authorizes EPA to issue a regulation to “limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18” “[t]o the extent necessary to prevent unreasonable adverse effects on the environment.”

residues of an applied pesticide that that might be in the seed, seedlings, and plants are considered in EPA's assessments. For more information, see section IV.C.3. of the petition response.

5. *Evaluate the impact to non-target organisms and aquatic systems from use of treated seeds*

In the ecological risk assessments, EPA conducts thorough reviews of multiple taxa, including aquatic organisms. Additionally, EPA quantitatively and qualitatively characterizes the possible transport routes and exposures of non-target organisms (e.g., through consumption of treated seeds, runoff from fields where seeds are planted, consumption of plant matrices grown from treated seeds). For more information, see section IV.A of the petition response.

**SFIREG Issue Paper Issues that Will be Raised in the ANPRM (Issues 6-10)**

Some of the issues that were raised in the SFIREG issue paper either were not included or not completely covered in the petition response such as better information on use of treated seed, impacts of the use of treated seeds on the other types of applications (such as soil or foliar applications), data systems to track treated seed use, stronger oversight on applicators, and enforcement authority of treated seeds. EPA is planning to include these issues in the upcoming ANPRM. In this ANPRM, EPA will request comments on a variety of topics to increase knowledge of treated seeds and other articles and inform a potential FIFRA 3(a) rule. FIFRA section 3(a) authorizes EPA to issue a regulation to “limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18” “[t]o the extent necessary to prevent unreasonable adverse effects on the environment.” Any rule finalized under section 3(a) of FIFRA would be enforceable under FIFRA section 12(a)(2)(S). The ANPRM is intended to explore whether and to what extent a FIFRA section 3(a) rule should be considered to allow enforcement relating to use of the treated seed that is not consistent with certain instructions on the treating pesticide label and as reflected on the seed bag tag.

6. *Identify mechanisms to obtain better information on use of treated seeds*

In the petition response, EPA discussed the availability of data systems that have been used to track treated seeds. One of these systems was Kynetec USA, Inc. Kynetec USA, Inc. was the primary source of agricultural usage data for seed treatment in the years 2005-2014. Kynetec USA, Inc. ceased supporting the use of their historical seed treatment data due to reliability concerns and has not provided more current seed treatment usage data since 2015. However, EPA estimates of usage for seed treatments in risk assessments in recent years has been based on conservative assumptions or surrogate information to account for the lack of quantitative information. EPA intends to work with federal and state agencies and issue an ANPRM to seek more information on usage of treated seed. Since the discontinuation of the Kynetec USA, Inc. seed treatment data, OPP continues to seek to identify, evaluate, and procure additional sources of usage data for seed treatments. For more information, see section IV.A. of the petition response.

More recently, data from two sources, Ben Kirk and Kline and Company, were identified, procured, and determined to meet EPA data quality standards. EPA will consider these sources for gathering information on treated seed use and will include questions regarding additional mechanisms to obtain better data on use of treated seeds in the upcoming ANPRM.

7. *Evaluate the impact of the use of treated seeds on the other types of applications such as soil or foliar applications (i.e. replacement and reduction in use of other types of applications)*

EPA is also considering requesting comments on replacement and use reduction of other pesticides applications from use of treated seeds in the upcoming ANPRM. EPA interprets replacement and use reduction to mean any reduction in amount of an active ingredient used in application types, such as foliar and soil applications, due to use of treated seeds. Despite not being addressed in the petition response replacement and use reduction of some active ingredients due to the use of treated seeds is looked at on a case-by-case basis during the process of registration and registration review for an active ingredient. Any change in use patterns is part of EPA's review of an active ingredient during registration review. EPA will include questions on the reduction of other application types such as soil or foliar application due to the use of seed treatments in the ANPRM.

8. *Evaluate the availability of data systems to track active ingredients used to treat seeds*
9. *Provide stronger oversight of seed treatment applicators as a way to address other issues with treated seeds*
10. *Determine if states can use label information transferred onto the seed bag tags to enforce under existing authorities and if having the EPA registration number on seed bag tags would enhance that authority*

Issues 8 through 10 that were raised in the SFIREG issue paper were not addressed in the petition response and EPA will seek comments on these issues in the upcoming ANPRM.

EPA again thanks SFIREG for bringing these issues to our attention. We look forward to continuing our work with SFIREG, AAPCO, state, and EPA Regional partners on these and other important pesticide issues. Please reach out to Quinn Gavin ([gavin.quinn@epa.gov](mailto:gavin.quinn@epa.gov)) with any questions regarding this response or to continue discussion on collaborative outreach opportunities.

Sincerely,

Ed Messina, Esq.  
Director, Office of Pesticide Program  
Office of Chemical Safety and Pollution Prevention