UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 27, 2022

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Center for Food Safety
2009 NE Alberta Street, Suite 207
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SUBJECT: Center for Food Safety (CFS) *et al*. Citizen Petition to the U.S. Environmental Protection Agency Seeking Rulemaking or a Formal Agency Interpretation for Plant Seeds Coated with Systemic Insecticides (April 26, 2017)

Dear Mr. Kimbrell:

Thank you for engaging with us on this important topic. The U.S. Environmental Protection Agency's (EPA or the Agency) recognizes the need to provide clear information about seeds that are treated with pesticides (*i.e.,* treated seeds). As such, the Agency has considered your request and concerns, and in response, EPA notes that it has been reviewing and will continue to review labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review to verify the completeness of these instructions for both use of the treating pesticide and the distribution, sale, and use of the treated seed. EPA also intends to work with the States and other federal agencies and to issue an advanced notice of proposed rulemaking (ANPRM) to seek additional information on pesticide seed treatment and to explore the option of issuing a rule pursuant to FIFRA section 3(a) to regulate the use of pesticide-treated seed, which may prove to be a more efficient and less resource intensive solution to some of the concerns raised in the petition.

This letter constitutes the Agency's response to the petition filed on April 26, 2017, by CFS on behalf of itself and 10 others seeking "amendment to, or a formal re-interpretation of, [the Treated Article Exemption], 40 C.F.R. §152.25(a)" (the Petition). In summary, the Petition requests 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." Petition at 38. The Petition also requests "that EPA aggressively enforce FIFRA's registration and include labeling requirements for each separate seed product coated with a systemic insecticide." *Id*. Specifically, the Petition asks EPA to:

(1) "Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself [].
(2) *Alternatively*, publish a final, formal, Agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds

for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.

(3) Aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical."

Petition at 3 - 4.

The Petition claims that the above requests are justified because, among other things, EPA fails to adequately assess the risks from use of seed treatment pesticides that have systemic properties and use of the seed treated by such pesticides, and the treated article exemption may not cover seed treated without an adequate assessment of the risks.

As discussed in more detail in the response below, EPA does not agree with the Petition claims relating to EPA assessments. EPA, in fact, fully assesses both the use of the treating pesticide[1] on a seed crop and use of the treated seed. Such assessments take into account the fate of the pesticide when used to treat seed, including any potential uptake and distribution into the developing seedling and plant, and the risks from those exposures. For example, EPA's assessments fully consider the impact of the availability of the pesticide on the treated seed to all taxa, using various tools and modeling allowing EPA to estimate consumption by birds and mammals of pesticide-treated seed. In addition, the treated article exemption regulatory text appropriately covers any seed treated with such a registered pesticide product if use of the pesticide and the treated seed is consistent with all instructions on the registered pesticide product and seed bag tag labeling and claims made for the seed treatment are limited to seed and what the seed becomes. As a result, and as explained further below, EPA does not agree with the Petition claims and thus does not grant the Petition requests to either interpret or amend 40 C.F.R. § 152.25(a) to categorically exclude seed treated with systemic pesticides from exemption under that provision.

However, EPA acknowledges the importance of complete and clear instructions on the use of the pesticide product to treat seed and the distribution, sale and use of each separate treated crop seed product. As the Petition and comments reflect, the seed bag tag labeling is the primary means by which instructions are communicated to downstream distributors, sellers, and users, typically the farmers, of such treated seed. Given the importance of the labeling instructions on FIFRA section 3 pesticide products and seed bag tags, EPA has been reviewing and will continue to review labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review. EPA intends to verify the completeness and clarity of these instructions for both use of the treating pesticide and the distribution, sale, and use of the treated seed that is

[1] The Petition frequently refers to pesticides used to treat seeds as a "coating," "coating products" or "coating chemicals." However, because that term may suggest that the petition is addressing use of materials or approaches that are not pesticides to coat the seed, EPA is using the term "treating pesticide" throughout this response. Under the Federal Seed Act (FSA), a "coated seed" is any seed that has been "covered with a coating material." 7 C.F.R. § 201.3(q). Coating material includes "any substance that changes the size, shape, or weight, of the original seed," but does not include "rhizobia, dyes, polymers, biologicals, or pesticides." 7 C.F.R. § 201.3(nn). In contrast, if a seed has been "treated," then the seed has been "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." 7 U.S.C. § 1561(23).

intended to be covered by the treated article exemption. For example, EPA intends to ensure that treating pesticide labeling instructions to the user of the treating pesticide include (1) the requirement that seed bag tag labeling accompany the treated seed when distributed and sold; and (2) that such labeling include adequate use, storage, and disposal instructions of the treated seed and that the distribution or sale of the treated seed in a manner inconsistent with those instructions is the distribution or sale of an unregistered pesticide. EPA also intends to work with the States and other federal agencies and to issue an ANPRM to seek additional information on whether or to what extent pesticide-treated seed is being distributed, sold, or used in a manner inconsistent with treating pesticide labeling instructions for each separate crop seed product and will consider actions appropriate to the circumstances, which might include enforcement where there is a FIFRA violation or administrative action on the treating pesticide registration, *e.g.,* to clarify labeling or reduce use of the treating pesticide. The ANPRM will also explore the option of issuing a rule pursuant to FIFRA section 3(a) to regulate pesticide-treated seed to ensure distribution, sale, and use of the treated seed is consistent with treating pesticide and treated seed labeling instructions. EPA believes that such a rule could be a more efficient and less resource intensive means to address some of the concerns raised in the petition than the solutions requested by the Petition. However, EPA does not, at this time, agree with the Petition that there is a violation necessitating aggressive enforcement.

If you have any questions regarding this letter, please feel free to contact Linda Arrington of my staff at (202) 566-2279 or via e-mail at arrington.linda@epa.gov.

Sincerely,

Ed Messina Digitally signed by EDWARD MESSINA
Date: 2022.09.27 15:46:37 -04'00'

Edward Messina, Esq., Director
Office of Pesticide Programs

## EPA Response to the April 2017 Petition from Center for Food Safety and Others Relating to EPA Regulation of Pesticide-Treated Seed

# I. Legal Framework

## A. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Treated Article Exemption

With some limited exceptions, FIFRA precludes the distribution and sale of any pesticide that is not registered under FIFRA.[2] Applications for registration of a pesticide may be submitted to EPA but must meet the requirements in FIFRA sections 3(c) and 33.[3] Those requirements include, among other things, submission of complete labeling of the pesticide, including claims made for the pesticide and instructions on use; complete data in support of that registration request; and requisite fees in support of that application.[4] FIFRA section 3(c)(4) requires EPA to issue a Federal Register notice in relation to "each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern."[5]

To grant a pesticide registration, FIFRA requires EPA to consider whether the pesticide has "unreasonable adverse effects" to human health and the environment.[6] 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."[7] EPA is required to review each pesticide registration every 15 years to determine whether the pesticide continues to satisfy the FIFRA standard for registration.[8]

To make a determination as to whether a pesticide meets the FIFRA standard, EPA first typically looks to determine whether a particular use of a pesticide poses a meaningful risk (often referred to as a "risk of concern"). If a use does not pose a risk of concern, EPA generally finds the use to meet the standard for registration. If the use does pose a risk of concern, EPA takes steps to determine whether that risk may be mitigated, for example, through changes to use instructions to limit application of the pesticide to a lower concentration, duration, or frequency, taking into

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[2] 7 U.S.C. § 136a(a).

[3] 7 U.S.C. §§ 136a and 136w-8.

[4] 7 U.S.C. § 136a(c); 7 U.S.C. § 136a(b); and 7 U.S.C. § 136w-8. *See also* 40 C.F.R. part 152 for application procedures and part 158 for data requirements.

[5] 7 U.S.C. § 136a(c)(4). *See also* 40 C.F.R. § 152.105 (implementing FIFRA section 3(c)(4), requiring a notice of receipt "for application for registration of a product that contains a new active ingredient or that proposes a new use").

[6] 7 U.S.C. § 136a(c)(5).

[7] 7 U.S.C. § 136(bb).

[8] 7 U.S.C. § 136a(g) and 40 C.F.R. part 155, subpart C. "Registration review" is the term used for this process.

consideration the benefits of the use of the pesticide and the impacts of potential mitigation on the user. If the Agency determines that changes to the registration are necessary, or if the risks associated with the use are not justified by the benefits associated with that use, the Agency will initiate appropriate administrative action under FIFRA section 6 unless necessary changes (if any are possible) are made by the registrant.[9] If, on the other hand, the Agency determines that the risks associated with a use are justified by the benefits, taking into consideration any mitigation measures incorporated into the labeling and terms of registration, the use would be found to meet the FIFRA standard for registration.

It is a violation under FIFRA to sell or distribute an unregistered pesticide or to use a registered pesticide in a manner inconsistent with its labeling.[10] FIFRA section 12 does not make it a violation to use an unregistered pesticide. However, EPA may, by regulation, impose limits on the distribution, sale, and use of any pesticide that is not registered "to the extent necessary to prevent unreasonable adverse effects on the environment," and compliance with such regulation is enforceable under FIFRA section 12(a)(2)(S).[11]

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.[12] Several exemptions under FIFRA section 25(b)(2) were adopted in 1988 and included a "treated articles and substances" exemption.[13] Since 1988, EPA has issued other exemptions under the authority of FIFRA section 25(b)(2).[14]

The text of the exemption for "treated articles and substances" provides the following:

> The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA and are

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[9] 7 U.S.C. § 136d.

[10] 7 U.S.C. §§ 136j(a)(1)(A) and 136j(a)(2)(G). Use of a pesticide in a manner inconsistent with its labeling means to "use any registered pesticide in a manner not permitted by the labeling," with several exceptions. Those exceptions include, for example, "applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation …," and "employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling." 7 U.S.C. § 136(2)(ee)(1) and (3).

[11] 7 U.S.C. §§ 136a(a) and 136j(a)(2)(S).

[12] 7 U.S.C. § 136w(b)(2).

[13] Pesticide Registration Procedures; Pesticide Data Requirements, Final Rule, 53 Fed. Reg. 15952 (May 4,1988).

[14] *See* 59 Fed. Reg. 2751 (Jan. 19, 1994) (amending 40 C.F.R. § 152.25 to add an exemption for natural cedar pesticides and meeting specific conditions); 61 Fed. Reg. 8878 (Mar. 6, 1996) (amending 40 C.F.R. § 152.25 to add an exemption for certain pesticides characterized as minimum risk and meeting specified conditions); and 66 Fed. Reg. 37772 (July 19, 2001) (creating a new subpart 174, which included an exemption of unique pesticides meeting specified conditions).

therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

> (a) ***Treated articles or substances.*** 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.[15]

## B. Endangered Species Act (ESA)

Congress enacted the ESA in 1973 to, among other things, conserve species deemed to be endangered or threatened.[16] The ESA requires a list of all endangered or threatened species to be maintained.[17] The ESA imposes certain legal requirements protecting "listed species," including that federal agencies "ensure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat.[18]

Section 7(a)(2) and its implementing regulations delineate a process for determining the biological impacts of a proposed action known as section 7 consultation.[19] Through this process, the agency proposing the relevant action (referred to as the action agency) must determine whether its action "may affect" a listed species or its designated critical habitat.[20] If the action agency determines that the action will have "no effect" on listed species or their designated critical habitat, it need not "consult" under section 7.[21] If, however, the action agency determines that the action "may affect" listed species or their designated critical habitat, the action agency must pursue either informal or formal consultation with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (collectively, the Services).[22]

EPA's process for making effects determinations involves the preparation and issuance of Biological Evaluations (BEs), which contain EPA's analyses of the effects of a pesticide on listed species and their designated critical habitat. It also includes any conclusions that the

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[15] 40 C.F.R. § 152.25.

[16] *See* 16 U.S.C. §§ 1531(b), 1532(6), 1532(20), 1533.

[17] *Id.* at § 1533(c).

[18] *Id.* at § 1536(a)(2).

[19] 16 U.S.C. § 1536(a)(2); 50 C.F.R. part 402.

[20] 50 C.F.R. § 402.14.

[21] *See* 50 C.F.R. § 402.12.

[22] *See* 50 C.F.R. §§ 402.13-402.14; and 50 C.F.R. part 402, subpart D (includes optional procedures for consultation on FIFRA actions).

pesticide "may affect" and is "likely to adversely affect" any of these listed species or their designated critical habitats. The BE is used to initiate consultation with the Services, if needed. This evaluation encompasses all registered uses and approved product labels for pesticide products containing these chemicals.[23]

Formal consultation is required unless the action agency determines, with the Services' written concurrence, that the proposed action is "not likely to adversely affect" a listed species or modify its designated critical habitat.[24] The Services review the information provided in the BE, consider it in light of the status and needs of the particular species and habitat potentially affected, and provide EPA with a Biological Opinion (BiOp). In their BiOp, the Services document their determination of whether a pesticide is likely to jeopardize the continued existence of the species and whether there will be adverse modification to designated critical habitat.[25] If jeopardy or adverse modification is determined, the Services, with input from EPA, will work with the registrants of pesticide products containing the active ingredient at issue in the BiOp to address any necessary additional protections for listed species.[26]

## II. Petition Background

On April 25, 2017, EPA received a petition filed by the Center for Food Safety (CFS) on behalf of beekeeper, farmer, and public interest groups. The Agency published a notice in the Federal Register,[27] announcing the availability of the petition for a 60-day public comment period and posted the petition in the public docket. The comment period was extended for an additional 30 days and closed on March 26, 2019. In response to the request for comment, EPA received 16,343 comments, of which 100 were substantive comments (see Appendix A), including comments from the Petitioner with nearly 100 articles or study references (see Appendix B). The rest of these comments were signatures provided in a spreadsheet as part of a mass comment campaign in support of the Petition from CFS, *et. al*. The comments in their entirety can be found in docket EPA-HQ-OPP-2018-0805. The Agency has considered all comments in developing this response.

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[23] *See* 50 C.F.R. §§ 402.14; 402.46; and 402.40.

[24] 50 C.F.R. § 402.13(a).

[25] "The Services [may] also authorize any "take" (unintended injury or killing of individual listed species) that would otherwise be prohibited, as long as measures to minimize take are implemented." *See* Assessing Pesticides under the Endangered Species Act found at https://www.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act.

[26] EPA Releases Draft Biological Evaluations of Three Neonicotinoids for Public Comment (August 26, 2021) found at https://www.epa.gov/pesticides/epa-releases-draft-biological-evaluations-three-neonicotinoids-public-comment#:~:text=For%20Release%3A%20August%2026%2C%202021,for%20public%20review%20and%20comment.

[27] Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated With Systemic Insecticides, 83 Fed. Reg. 66,260 (December 26, 2018).

## III. Pesticides Referenced in the Petition

The Petition highlights 3 neonicotinoid pesticides that are registered for use in treating seeds: clothianidin, imidacloprid, and thiamethoxam[28] and references 15 seed treatment products containing those pesticides.[29] Below is a general description of the 3 neonicotinoids highlighted in the Petition and a description of their use patterns:[30]

### *Clothianidin and Thiamethoxam*

- *General Description*: Clothianidin and thiamethoxam are systemic, neonicotinoid insecticides with unique spectrums of activity that act on the nicotinic acetylcholine receptors (nAChRs) of the central nervous system of insects. They are in the N-nitroguanidine group of neonicotinoids, in subclass 4A of the Insecticide Resistance Action Committee (IRAC) mode of action classification scheme. Clothianidin is also a major metabolite of thiamethoxam. At the time this response was developed, there were 45 active end-use products registered under Section 3 of FIFRA (commonly referred to as a Section 3 registration) containing clothianidin and 77 containing thiamethoxam.

- *Use Pattern*: The target pests for clothianidin and thiamethoxam products include a diverse set of foliar- and soil-dwelling insect pests, such as aphids, whiteflies, thrips, caterpillars, beetles, flies, stinkbugs, and others. Clothianidin and thiamethoxam products are registered for use on a wide variety of crops (*e.g.,* corn, cotton, soybeans, root and tuber vegetables, pome fruit, stone fruit, berries, tree nuts, legumes, cereal grains, oilseed crops, and herbs). They are also registered on non-agricultural use sites such as turf, poultry houses, and ornamental plants. Products containing clothianidin and

[28] Although acetamiprid is noted on page 1 of the Petition as a neonicotinoid, the Petition does not otherwise address this pesticide. It is not listed at Table 1 of the Petition and its products are not identified in note 17 of the Petition. Acetamiprid is a cyano-substituted neonicotinoid (as opposed to the nitroguanidine-substituted neonicotinoids, mentioned in Table 1 of the Petition), and its target pests include primarily piercing sucking pests, but also select lepidopteran and coleopteran species. Of note, while acetamiprid is registered for use patterns similar to the other neonicotinoids listed in Table 1 of the Petition, less acetamiprid is typically applied nationally in a given year (*i.e.,* fewer pounds applied and fewer acres treated). Also, the ecological risk assessment for acetamiprid did not identify colony-level risks to honeybees; thus, the additional bee risk assessment conducted for the other neonicotinoids addressed in this response was not conducted for acetamiprid. *See* Acetamiprid Proposed Interim Registration Review Decision (PID) (January 22, 2020) found in docket EPA-HQ-OPP-2012-0329-0064 at https://www.regulations.gov/document/EPA-HQ-OPP-2012-0329-0064. The draft BE for acetamiprid is planned for early 2023 with a final BE following in early 2024. Additionally, a revised PID for acetamiprid will be released in early 2023.

[29] This Petition states that it addresses all pesticides intended for seed treatment, including both those listed in Table 1 and other older or newer pesticidal seed products not listed in Table 1. Petition at 13. The issues raised in this Petition are addressed in registration and registration review for any active ingredient used to treat seed, and the responses to the issues raised in this Petition generally apply to other pesticides used to treat seed.

[30] *See* Clothianidin and Thiamethoxam: Proposed Interim Registration Review Decision at 17-18 (January 22, 2020). This document can be found in docket EPA-HQ-OPP-2011-0865-1190 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-1190. *See* Imidacloprid: Proposed Interim Registration Review Decision at 14-15 (January 22, 2020). This document can be found in docket EPA-HQ-OPP-2008-0844-1619 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1619.

thiamethoxam can be applied via methods such as aerial, ground foliar sprays, soil treatments, chemigation, and as a seed treatment. The largest agricultural use for clothianidin and thiamethoxam products, in terms of total pounds of active ingredient (lbs a.i.) applied, has been in the form of seed treatments, although foliar and soil use constitute a greater amount used per acre.[31]

***Imidacloprid***

- *General Description*: Imidacloprid is an N-nitroguanidine neonicotinoid insecticide, which causes irreversible blockage of the postsynaptic nicotinic acetylcholine receptors. It is a subclass 4A of the Insecticide Resistance Action Committee (IRAC) mode of action classification scheme. It is a xylem- and phloem-mobile systemic compound that is readily taken up by the roots and leaves of the plants and translocated through the plant via transpiration. There are more than 500 FIFRA Section 3 and Section 24(c) (Special Local Needs) products containing imidacloprid registered in the United States.

- *Use Pattern*: The target pests for imidacloprid products include a diverse set of foliar- and soil-dwelling thrips, aphids, whiteflies, beetles, grubs, and wireworms. Imidacloprid products can be applied to a variety of agricultural crops, including but not limited to, root and tuber vegetables, fruiting vegetables, oilseed crops, citrus fruit, leafy green vegetables, cucurbit vegetables, and tropical and subtropical fruits. Imidacloprid products are also registered on non-agricultural use sites including, but not limited to, turf and ornamentals, forestry, Christmas tree plantations, pet spot-on and collar products, baits and pellets, and in farm/residential/commercial areas. Products can be applied via liquid spray, broadcast granules, baits, and as a seed treatment. The largest agricultural use for imidacloprid, in terms of total pounds of active ingredient (lbs a.i.) applied, has been in the form of seed treatments, although foliar and soil use constitute a greater amount used per acre.[32]

The Agency initiated the registration review of imidacloprid in 2008 and clothianidin and thiamethoxam in December 2011 with the publication of the Preliminary Work Plans (PWPs). The PWPs outlined how EPA planned to conduct the registration review of these chemicals, including what data were needed for the updated risk assessments and the timeline for those data submissions along with the steps and schedule for release of decision documents. EPA released the Proposed Interim Decisions (PIDs) for these chemicals on January 22, 2020, and the draft BEs on August 26, 2021. After taking public comments on the draft BEs, on June 16, 2022, EPA submitted final BEs to the Services, and initiated formal consultation for imidacloprid,

[31] *See* Clothianidin and Thiamethoxam: Proposed Interim Registration Review Decision at 17-18 (January 22, 2020). This document can be found in docket EPA-HQ-OPP-2011-0865-1190 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-1190.

[32] *See* Imidacloprid: Proposed Interim Registration Review Decision at 14 (January 22, 2020). This document can be found in docket EPA-HQ-OPP-2008-0844-1619 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1619.

clothianidin, and thiamethoxam.[33] EPA intends to issue revised PIDs for each of the three neonicotinoids (anticipated in early 2023) and open a 60-day public comment period.

## IV. Petition Response

The Petition raises a number of concerns relating to EPA registration of pesticides for use in treating seeds, arguing that seeds treated with systemic pesticides, particularly those listed in Table 1 of the Petition, should not be covered by the treated article exemption because FIFRA section 25(b)(2), the authority for such exemption, is limited. Section IV.A summarizes and responds to those claims and comments that are specific to EPA assessments of systemic pesticides used to treat seed and points to the decision documents, assessments, and BEs for further information. Section IV.B summarizes and responds to other claims including questions relating to the benefits of the pesticides listed in Table 1 of the Petition for use in treating seeds. Section IV.C summarizes and responds to the specific requests relating to interpretation or amendment of the treated article exemption at 40 C.F.R. § 152.25(a) so that such treated seeds would no longer be exempt from registration under FIFRA. Section IV.D, addresses the Petition claims and comments specific to registration of treated seed and enforcement.

Each section of this response starts with a summary of the claims raised in the Petition, followed by comment summaries, and ending with EPA's response to the Petition claims and related comments. In the sections below summarizing public comments, the relevant comments to each claim are cited by the last four digits of their associated docket number in public docket EPA-HQ-OPP-2018-0805 at www.regulations.gov.

### A. Petition Claims Relating to Sufficiency of EPA Review of Pesticides Intended to Treat Seeds

Summary of Petition: The Petitioner claims that EPA has failed to fully assess the adverse effects of certain pesticides on treated seeds following seed treatment, stating that the exemption allows chemicals intended for seed treatment to avoid a comprehensive determination of whether the seeds and associated dust off, soil, and water contamination constitute an unreasonable and adverse effect on the environment. The Petitioner refers to Table 1 of the Petition for "coating products" that EPA has approved since January 1, 2010, noting that the "the large majority of the coating products listed in Table 1 were 'conditionally registered' under FIFRA, indicating that key information needed for their full risk evaluation was not produced by the registrants to allow an unconditional registration." Petition at 13-14.

The Petition specifically highlights risks to bees and other pollinators, aquatic species, birds, and endangered species. The Petitioner claims that the assessments for treated seeds are ignoring numerous risks with planting of treated seed, such as toxic abraded dust-off, which are affecting bees and other pollinators. *Id.* The Petition specially refers to the EPA's 2016 *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* stating that the "[m]itigation of risks from abraded seed coating are addressed *outside* of this process" and that

[33] EPA Releases Final Biological Evaluations of Three Neonicotinoids (June 16, 2022) found at https://www.epa.gov/pesticides/epa-finalizes-biological-evaluations-assessing-potential-effects-three-neonicotinoid.

similar claims are made in "Preliminary RAs for both thiamethoxam and clothianidin," but without any evidence to support how those risks are addressed. *Id.* The Petitioner also expresses a concern that these risks are a consequence of the "gross overuse of this systemic class of insecticides" and treated seeds, "imposing a potentially catastrophic hazard to aquatic systems around the nation." Petition at 8-11. The Petition notes that "[r]esearchers across the United States are finding high levels [of these chemicals], exceeding vital standards set by experts to protect aquatic life." Petition at 27. The Petition refers to "contamination caused by coated seeds in a wide variety of rural habitats nationwide, typically via pathways that EPA failed to consider adequately when it approved the coating products." Petition at 28. The Petition alleges that neonicotinoid treated seeds "may affect broad groups of non-target animals" including "threatened and endangered species protected under the ESA" and that EPA has failed to comply with ESA requirements. Petition at 23 - 26.

Summary of Comments: Many comments in support of the Petition broadly support the claim that EPA's assessments do not adequately assess impacts and are generally insufficient to allow for the continued use of the treated seeds (0003, 0009, 0013, 0018, 0021, 0023, 0024, 0027, 0040, 0069, 0077, 0083, 0094, 0097, 0103). Additionally, comments in support of the Petition requests generally agree that there has been an increase in use of neonicotinoids (0013, 0027, 0069, 0077, 0083, 0094).

Many comments opposing the Petition requests state that EPA already registers the seed treatment products and during the course of the registration decision, EPA fully evaluates use of the pesticide to treat seed and the use of that treated seed, so separate registration of treated seeds would be unnecessary, redundant, and costly, while providing no benefits to public health or the environment (0025, 0030, 0031, 0032, 0035, 0036, 0037, 0041, 0045, 0046, 0047, 0049, 0050, 0051, 0053, 0055, 0057, 0058, 0060, 0062, 0066, 0068, 0072, 0073, 0078, 0079, 0081, 0085 , 0086, 0087, 0088, 0089, 0091, 0092).

EPA Response: As part of its review of the registered pesticide (when initially registered and in registration review), EPA conducts thorough assessments of the seed treatment uses, including assessing risks to human health and multiple taxa (*e.g.,* aquatic organisms, birds, and 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 the pesticides specified in Table 1 of the Petition, this includes PIDs, multiple human health and ecological assessments, and Final BEs that were previously the subject of public comment. Many of these documents have been open for public comment since the Petition was filed, and the issues raised by the Petition on EPA's assessments for seed treatment use of the pesticides in Table 1 of the Petition are addressed in those documents and not repeated here (Appendix C).

However, in summary, EPA disagrees with the Petition claims relating to the adequacy of EPA assessments. EPA's assessment of data submitted with an application allow it to determine whether the intended use of the pesticide, including as part of a treated article, meets the FIFRA standard for registration under FIFRA section 3(c)(5) or FIFRA section 3(c)(7), whichever is

applicable. For pesticide products intended for seed treatment, the data required are consistent with the data generally required for registration of pesticides intended for foliar treatment.[34] EPA's exposure estimates are based on use and usage information[35] that takes into account the maximum application rates.[36] This assessment considers the fate of the pesticide used to treat the seed and its uptake and distribution into the developing seedling and plant.[37] In the ecological risk assessments, 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). The risk assessments also acknowledge that the extent of dust generated from abrasion of treated seed during planting depends on multiple factors (*e.g.,* the seed, sticking agents, seeding equipment, weather) that limit the extent to which this potential route of exposure can be quantified.[38] Notably, exposure to aquatic organisms is generally expected to be much lower from seed treatment compared to foliar and soil applications based on the estimated environmental concentrations.[39] The recently released final BEs for each of the neonicotinoids took this

[34] Additional data are not currently required to support treatment on seed for the treated seed to be exempt under the treated article exemption but EPA intends to issue an ANPRM to get public comments on these issues.

[35] For a discussion on usage information, *see, e.g.,* Response to Public Comments Received on Draft Biological Evaluations for Imidacloprid, Thiamethoxam, and Clothianidin at 16-17 (June 2022), found at https://www3.epa.gov/pesticides/nas/final/cloth-imi-thixam-rtc.docx. As explained in that document, Kynetec USA, Inc., the primary source of agricultural usage data for seed treatment in the years 2005-2014, no longer supports the use of their historical data due to reliability concerns, nor provides more current seed treatment usage data. However, EPA estimates usage for seed treatment using 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 use of treated seed. In addition, OPP continues to work to identify, investigate, and procure additional sources of usage data for seed treatments. As suitable data are procured and determined to meet EPA data quality standards, they will be integrated into usage analyses to help inform risk assessments.

[36] Maximum Seed Application Rate (mg a.i./kg seed) = (Application rate x 2.2 x 106) / (100 x 2.2) = (Application rate x 10,000). Application Rate (lbs a.i./cwt) = (Application rate (fl oz/cwt) x decimal % of a.i. in formulation) / (128 fl oz/gallon) x density of product (lbs/gallon). Maximum Application Rate (lbs a.i./A) = (Maximum seeding rate x application rate (lbs a.i./cwt)) / 100 lbs/cwt. Found at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-rex-version-15-users-guide-calculating-pesticide#Section2_1.

[37] Uptake of the pesticide in the seedling/plant is often described using terms like "systemic" or "systemicity."

[38] *See* Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review at 95 and 99-101 (November 27, 2017) found in docket EPA-HQ-OPP-2011-0865-0242 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-0242; Final Bee Risk Assessment to Support the Registration Review of Imidacloprid at 26-27 (January 14, 2020) (Final Bee Assessment – Imidacloprid) found in docket EPA-HQ-OPP-2008-0844-1611 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1611; and Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid at 107 (December 22, 2016) found in docket EPA-HQ-OPP-2008-0844-1086 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1086.

[39] *See, e.g.,* Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid at 92-93 (December 22, 2016). This document can be found in docket EPA-HQ-OPP-2008-0844-1086 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1086.

information into account.[40] For discussion on these and other issues raised by the Petition and comments, see the relevant documents in the dockets for each pesticide.[41]

The Petition identifies concerns about reports of "uncontained dust" or "toxic dust clouds," broad contamination beyond treated fields, and concerns regarding mitigation of "risks from abrased seed coatings." As explained in EPA's assessments, EPA fully assesses risks to non-target organisms and has qualitatively characterized concerns with dust-off. As a result, although EPA qualitatively addresses these exposures in its assessments, EPA announced that it would focus "its resources on mitigating risks from this exposure pathway through best management practices and working with the regulated community in the development of alternative technologies to reduce dust-off during planting (*e.g.,* alternative fluency agents, equipment modifications, etc.)."[42]

As also further discussed in EPA's assessments, EPA considers all exposure pathways when assessing risks to aquatic taxa. To assess the exposure to the aquatic environment specifically, EPA models, using the Pesticide Water Calculator (PWC), the potential contribution to surface water and groundwater due to runoff and leaching of pesticides associated with treated seed uses, using assumptions that are the same as those for foliar/soil uses and application rates equal to the amount of product in seeds applied per acre.[43] In addition, and notably, EPA's modeling indicates that runoff of neonicotinoids from seed treatment use is substantially less than that which is predicted to runoff from soil and foliar spray applications. This is likely because the overall mass of active neonicotinoid active ingredients applied to the field from seed treatments is generally less than that from foliar spray/soil applications and because seeds are planted below the soil surface.[44] In addition to this modeling, EPA evaluates all available monitoring data from

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[40] *See, e.g.,* Final National Level Listed Species Biological Evaluation for Clothianidin at 3-14 and Appendix 4-5 at 2-3 (June 16, 2022) ("For those species where a LAA determination was made based on the quantitative analysis using the MAGtool and spray uses, potential exposure to treated seeds would serve as an additional line of evidence supporting that LAA determination."). This document can be found at https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-clothianidin.

[41] *See* the following dockets: Imidacloprid Registration Review in docket EPA-HQ-OPP-2008-0844 at https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0844. Thiamethoxam Registration Review in docket EPA-HQ-OPP-2011-0581 at https://www.regulations.gov/docket/EPA-HQ-OPP-2011-0581. Clothianidin Registration Review in docket EPA-HQ-OPP-2011-0865 at https://www.regulations.gov/docket/EPA-HQ-OPP-2011-0865.

[42] Final Bee Assessment - Imidacloprid at 44 (January 14, 2020).

[43] The PWC "simulates pesticide applications to land surfaces and pesticide's subsequent transport to and fate in water bodies, including surface water bodies as well as simple ground water aquifers." *See* https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.

[44] Generally, applications to soil (including seed treatments) are assumed to place most of the pesticide mass below the 2-cm runoff extraction zone of the model resulting in reduced mass of the pesticide carried by runoff. For ease of comparison, Table 4 of the imidacloprid drinking water assessment summarizes application rates for seed, soil and foliar treatments. Given the multiple foliar applications versus the single seed treatment, generally, the application rates (and hence environmental loading) for seed treatments are lower than for the other routes of applications. Drinking Water Exposure Assessment in Support of the Preliminary Risk Assessment for the Registration Review of Imidacloprid at 13 (December 22, 2016). This document can be found in docket EPA-HQ-OPP-2008-0844-1854 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1854.

multiple sources on the occurrence and magnitude of pesticides in aquatic ecosystems including streams, lakes, estuaries, rivers, and agricultural drainage areas/ditches to help inform aquatic exposure assessments.[45]

EPA's assessments also consider the impact of the availability of the pesticide on the treated seed to bees, birds, aquatic species, and mammals and evaluates the risks related to that exposure. For example, EPA estimates consumption by birds and mammals of pesticide-treated seed. Both acute and chronic risks to these taxa are assessed using the Terrestrial Residue Exposure model (T-REX) (v. 1.5.2).[46] This model relies on estimates of the amount of pesticide on the treated seed based on maximum application rates, and the consumption rates of seeds for various sizes of birds and mammals based on their weight and compares that exposure estimate to the corresponding acute and chronic toxicity data.

EPA notes that the FIFRA risk assessments for the neonicotinoids addressed in the petition published between 2017 and 2020 thoroughly considered the ecological impacts from use of treated seed.[47] In addition, in June 2022, EPA published its Final BEs and initiated formal consultation with the Services for each of the active ingredients in Table 1 of the Petition. Those Final BEs took into account the findings in the ecological assessments, including, for example, that exposures of aquatic organisms is much lower from seed treatment compared to foliar and soil applications based on the estimated environmental concentrations. Similar to the FIFRA risk assessments, the BEs also considered the potential for the direct consumption of treated seeds by birds and mammals and impacts to bees. Those Final BEs state that "[f]or those species where a LAA determination was made based on the quantitative analysis using the MAGtool and spray

[45] For example, "[s]urface water monitoring data with imidacloprid were available from over 7,000 samples spanning approximately 15 years." Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid at 9 (December 22, 2016). This document can be found in docket EPA-HQ-OPP-2008-0844-1086 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1086.

[46] For more information on this model, please refer to https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-rex-version-15-users-guide-calculating-pesticide.

[47] As reflected in the *Final Bee Assessment* documents, residues in crops grown from treated seed were generally not expected to cause colony-level risks and were orders of magnitude below those associated with foliar or soil applications and below risk thresholds identified for bees. Final Bee Assessment - Imidacloprid (January 14, 2020) ("For registered seed treatment uses of imidacloprid on honey bee-attractive crops which are not harvested prior to bloom, results from this assessment indicate there is a low potential for risk from oral exposures to imidacloprid," "residues for all but two uses are below the honey bee colony-level endpoints, indicating a low potential for colony-level risk," and the "two uses for which a colony-level risk is indicated are bean and peanut" but the "strength of evidence supporting with this risk finding is considered 'weakest.'") at 17 and 227 – 229; and Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam (Final Bee Assessment - Clothianidin and Thiamethoxam) at 16-17 ("a low risk conclusion is made for on field exposures associated with all clothianidin and thiamethoxam seed treatment uses, except clothianidin applications to turmeric seed pieces" where risk cannot be precluded due to uncertainties such as the timing of cultivation relative to bloom periods,). The Final Bee Assessment - Clothianidin and Thiamethoxam can be found in docket EPA-HQ-OPP-2011-0865 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-1164.

uses, potential exposure to treated seeds would serve as an additional line of evidence supporting that LAA determination."[48]

Claims relating to the risks specific to a pesticide used to treat any article or substance are concerns that may be raised in the context of registration and registration review activities, but such concerns are not relevant to whether the treated article exemption applies. EPA's general framework for assessing risks of pesticides is through its registration actions, *e.g.,* in registration review during which EPA would review all registered uses and their potential for unreasonable adverse effects on the environment (including pesticides used to treat seeds and the impacts of those uses). Whether EPA has failed to assess any particular use appropriately or whether there are unreasonable adverse effects from any particular use is a fact-specific inquiry conducted during each registration action and any specific concerns about how EPA has assessed a particular pesticide use should be raised in the context of that registration action. That fact specific inquiry can include and has included consideration of the types of issues raised as part of this Petition. Moreover, as discussed further below, EPA is reviewing and will continue to review labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review to verify the completeness of these instructions for both use of the treating pesticide and the distribution, sale, and use of the treated seed. EPA will also be working with State and other federal agencies and seeking additional information on seed treatment issues including whether or to what extent there is any new information indicating that use of the treated seed is generally shown to be inconsistent with those instructions. Any new information will be taken into account in new registration actions. However, as discussed further below in section IV.C, these types of claims do not impact whether the treated article exemption applies. The exemption applies if the criteria for the exemption are met and that is a fact-specific inquiry unrelated to the assessment of the pesticide use in question.

### B. Other Petition Claims Relating to Use of Treated Seed

Summary of Petition: The Petitioner broadly asserts that exempting treated seed from FIFRA requirements "has allowed these unregistered, unlabeled insecticides to outcompete and displace other *FIFRA-registered* insecticides and other less risky crop protection methods in U.S. agricultural markets." Petition at 12. Furthermore, the Petition claims that many of these treated seed uses are prophylactic and that prophylactic use is "incompatible with the principles of Integrated Pest Management." Petition at 12. Finally, the Petition asserts that "use of neonicotinoid coated seeds actually provides no net yield benefit to farmers across the majority of crop planting contexts" and can actually decrease the yield. Petition at 26-27.

In addition, the Petition claims that as a result of the claimed impacts to bees, "for Beekeeper Petitioners Anderson, Adee, and Hackenberg and other beekeepers represented by Petitioners American Beekeeping Federation, American Honey Producers Association and Pollinator

[48] *See, e.g.,* Final National Level Listed Species Biological Evaluation for Clothianidin at Appendix 4-5 at 3 (June 16, 2022) ("For those species where a LAA determination was made based on the quantitative analysis using the MAGtool and spray uses, potential exposure to treated seeds would serve as an additional line of evidence supporting that LAA determination."). This document can be found at https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-clothianidin.

Stewardship Council, their honey production and the overall profitability of their business have drastically declined, while their workloads and personal stress have multiplied." Petition at 21.

Summary of Comments: The comments in favor of the Petition generally agree with the Petition on the lack of benefits and costs of seed treatment (0009, 0024, 0094). Multiple comments point to the prophylactic use of pesticides with little evidence of an increase in productivity (0009, 0024, 0094) with one comment pointing to alternatives that are available to reduce this prophylactic and unnecessary use (0094). One comment agrees with the Petition that the pesticide labels contain language that the "seed coating may actually harm the seed by reducing germination or seedling vigor" (0069).

Comments opposing the Petition requests generally focus on the utility of treated seed, including as an alternative to foliar and soil treatments (0008, 0011, 0017, 0025, 0030, 0031, 0032, 0034, 0036, 0037, 0039, 0041, 0042, 0043, 0044, 0045, 0046, 0047, 0049, 0050, 0051, 0054, 0056, 0057, 0058, 0059, 0060, 0064, 0066, 0067, 0068, 0071, 0073, 0075, 0078, 0079, 0081, 0088, 0089, 0091, 0092, 0093). Other comments opposing the petition requests point to the benefits that treated seeds bring to U.S. agriculture and how they are essential for crop yields (0011, 0025, 0031, 0032, 0036, 0042 0044, 0049, 0054, 0059, 0067, 0073, 0080).

EPA Response: As an initial matter, the Petitioners fail to demonstrate how any of these claims are relevant to their request for EPA to exclude treated seeds from the treated article exemption. Whether treated seeds have had wide acceptance in the marketplace or whether they had an impact on the beekeeping business is immaterial to whether treated seeds meet the conditions in the treated article exemption. In addition, as noted above, the registration review documents referenced in Appendix C include assessments of the impacts and benefits with use of the pesticides identified in Table 1 of the Petition.

EPA disagrees with the Petition claim that exemption of neonicotinoid-treated seed allows such treated seed use to outcompete other applications of safer pesticides and there is nothing in the Petition or comments to support this stated claim. The extent to which any pesticide is chosen is typically based on a number of factors, including efficacy and the number of applications needed to obtain that efficacy, the need to address multiple pests for the same crop, and cost of the chosen pesticide as compared to alternatives, including alternatives that may be compatible with IPM and biological control measures. In addition, in this particular case, many of the primary alternatives for use of the neonicotinoids are organophosphate and pyrethroid insecticides (either as seed treatments, foliar, soil, or all application methods), which have their own concerns with human health and environmental risks including disruption of IPM programs.[49] Finally, while EPA agrees with the Petition and comments that seed treatments can be prophylactic, the same can be said of soil-applied treatments with many other insecticides. In either case, it is often impossible to reliably scout for below-ground crop pests that can cause major damage to crops at their most vulnerable life stages.

[49] *See* Biological and Economic Analysis Division's (BEAD) Response to Comments on the Preliminary Risk Assessments and Benefit Assessments for Citrus, Cotton, Soybean Seed Treatment, and Other Crops Not Assessed for Neonicotinoid Insecticides at 3 (December 23, 2019). This document can be found in docket EPA-HQ-OPP-2011-0581-0382 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0581-0382.

EPA also disagrees with the Petition and comments claiming that neonicotinoids decrease crop yields. For example, on the issue of crop yield, while a 2014 EPA assessment of the benefits of neonicotinoid seed treatments in soybean found no yield increase in soybean at the national level, the assessment found a 0-1.7% operating revenue benefit nationally from lower pesticide costs and a higher yield in the southern United States.[50] Moreover, any comparison to studies attempting to broadly claim decreased yield as a result of a pesticide treatment would need to consider comparable environmental conditions or other factors impacting yield (*e.g.,* Varroa mite infestations) which the Petition did not do. As to the Petition claim that these pesticides, when used as a seed treatment, are phytotoxic and thus support decreased yield claims, that claim appears to be based on the cautionary statements from products such as the "Prosper Evergol" product. However, yield reductions described in those statements apply only to low quality or damaged seeds that are treated and the potential impact from mechanical seeding, and not to healthy seeds.

EPA understands the concerns raised on behalf of beekeepers that "honey production and the overall profitability of their business have drastically declined, while their workloads and personal stress have multiplied." Data from USDA National Agricultural Statistics Service (see table below) show a dramatic decline in U.S. honey production over the past two decades. At the same time, the number of honey-producing colonies has risen slightly and the value of honey production per colony has increased substantially. Although there has been a decrease in honey yield per colony, there has also been a shift in emphasis from honey production to the provision of pollination services. According to USDA/ERS,[51] pollination services accounted for 11% of beekeeper revenues compared to 53% from honey sales in 1988. By 2016, revenues from each accounted for about 41% of total beekeeper revenues. Notably, real beekeeper revenue per colony more than doubled between 1988 and 2016.

**United States Honey Production, 1998-2000 and 2018-2020.**

| | 1998-2000 average | 2018-2020 average | Percent Change |
|---|---|---|---|
| Number of Colonies | 2,637,000 | 2,782,000 | 5 |
| Yield Per Colony (lb honey) | 81.4 | 54.9 | -32 |
| Production (lb honey) | 214,627,000 | 152,841,000 | -29 |
| Value of Production ($) | $135,112,000 | $320,860,000 | 137 |
| Average Value per Colony ($) | $51 | $115 | 125 |
| Source: USDA NASS Quick Stats (https://quickstats.nass.usda.gov/). Value per colony calculated by EPA as average value of production divided by average number of colonies. | | | |

[50] Benefits of Neonicotinoid Seed Treatments to Soybean Production at 2 (October 15, 2014). This document can be found in docket EPA-HQ-OPP-2014-0737-0002 at https://www.regulations.gov/document/EPA-HQ-OPP-2014-0737-0002.

[51] Ferrier *et al*. 2018; https://www.ers.usda.gov/webdocs/publications/88117/err-246.pdf?v=4610.7. Notably, the Petition claim that workloads or personal stress have multiplied for beekeepers specifically as a result of use of neonicotinoid-treated seed is not supported by the Petition. In fact, the claim that seed treatment alone is the cause of any claimed bee impacts is not supported by the bee assessments for these pesticides. *See* Final Bee Assessment - Clothianidin and Thiamethoxam at 16-17 (January 14, 2020).

USDA ERS have also described the relatively recent origin of a number of biotic stressors.[52] These include Varroa mites, which were first detected in the U.S. in the late 1980s; deformed wing virus, which also appeared in the 1980s; and *Nosema ceranae*, a fungal pathogen first detected in the mid-2000s. Thus, the data available do not support a linkage between the use of treated seed and a drastic reduction in honey production nor the overall profitability of the beekeeper business, as claimed by the Petition.

## C. Petition Claims Relating to the Treated Article Exemption

The Petition raises a number of broad claims relating to EPA registration of pesticides for use in treating seeds, arguing that seeds treated with systemic pesticides, particularly those listed in Table 1 of the Petition, should not and cannot be covered by the treated article exemption. The Petition primarily focuses on one element of the exemption, arguing that seed treated with systemic pesticides, particular those listed in Table 1 of the Petition, are not treated for the protection of the seed itself and therefore such treated seeds do not meet that particular element of the treated article exemption. However, the Petition also raises other more general claims relating to application of the treated article exemption to treated seed. EPA's response to each of these claims and related comments are addressed below.

### (1) General Claims

Summary of Petition: The Petition broadly states that the treated article exemption should not and does not cover seed treated with systemic pesticides, specifically those listed in Table 1 of the Petition, because the FIFRA section 25(b)(2) finding that such pesticides are "of a character which is unnecessary to be subject to" FIFRA that is necessary for establishment of the exemption cannot be made for such pesticide-treated seed.

The Petition notes that the regulatory treated article exemption was "first promulgated in 1988" and that "[p]esticide-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption." Petition at 10. The Petition also states that EPA "publicly stated a view on the Treated Article Exemption and pesticide-coated seeds in a paper issued jointly by EPA and the Pest Management Regulatory Agency of Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States"* but that it "provides no coverage or analysis of systemic insecticide or neonicotinoid-coated seeds." *Id.*

In addition, according to the Petition, treated seeds cannot qualify for the treated article exemption because "EPA is not allowed to *register* a pesticide which will cause unreasonable adverse effects on the environment" and thus "EPA may not *exempt* pesticides that would cause unreasonable adverse effects on the environment." As a result, the Petition states that EPA cannot make the necessary FIFRA section 25(b) finding. Petition at 33. The Petition asserts that extending the treated article exemption to treated seeds "violates the basic FIFRA safety standard" and "its plain language" because EPA cannot make the finding that such seeds "will not cause unreasonable adverse effects to the environment" given "these seeds *do* cause

[52] *Id.* at 23-24.

unreasonable adverse effects to the environment, including to the pollinators that support U.S. agriculture and make up the livelihoods of the Beekeeper Petitioners." Petition at 34-35 (emphasis provided).

The Petition further states that "EPA's exemption allows manufacturers of the various pesticidal seeds to evade the two classes of EPA notices that must go in the Federal Register under FIFRA and EPA's regulations." Petition at 36, citing 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102. The Petition asserts that this failure "denies Petitioners and the public essential notice by which they could be allowed to comment to EPA on proposed registrations" and "denies Petitioner beekeepers the information needed to protect their bees from fields planted with the numerous exempted crop seeds." *Id*.

The Petition further asserts that "EPA's exemption of these coated seeds violates its duty under ESA to ensure that its actions do not jeopardize the continued existence of any protected species." *Id.* The Petition states that "the pesticidal seeds unregulated by EPA 'may affect' many protected species either directly or indirectly" and that EPA has never consulted with the expert Services to determine whether its exemption of coated seeds is likely to jeopardize these species." *Id.* The Petition notes that "this assessment is missing from EPA's registration of the liquid coating products and active ingredients" and "even if EPA were to consult under the ESA on these products, to date the agency has ignored the full effects of the use of the coated seeds in the field due to its exemption." *Id*.

The Petition states that "EPA's current interpretation of the Treated Article Exemption and practice of exempting coated seeds from registration and labeling is *ultra vires*," and that "EPA's exemption of coated seeds is also arbitrary and capricious under the APA." Petition at 36 – 37 (emphasis provided) (citing 5 U.S.C. §§ 706(2)(A) and (C)). The Petition explains that "EPA's actions are arbitrary and capricious because they are counter to the available evidence that coated seeds cause significant adverse effects on the environment." Petition at 37. In addition, the Petition claims that "EPA's interpretation of the Treated Article Exemption as to coated seeds is inconsistent with its other interpretations in comparable situations where the Agency found a treated article not to be exempted due to adverse pesticidal effects beyond the article itself, including its non-exemption of anti-fouling boat paint and other articles." Petition at 37 and n. 81.

For these and other reasons summarized in sections IV.C.1-4, the Petition asks that EPA either interpret the exemption not to apply to pesticide-treated seed or to amend the regulation to exclude application of the treated article exemption to pesticide-treated seed. These requests are generally limited to pesticides with systemic properties, particularly those in Table 1 of the Petition.

Summary of Comments: There are numerous comments supporting the claims made in the Petition (0003, 0012, 0013, 0020, 0021, 0022, 0023, 0024, 0027, 0038, 0040, 0052, 0069, 0077, 0083, 0084, 0094, 0097, 0103). One comment collected signatures from people in favor of the Petition (0102). Some comments (0024, 0083) take the position that treated seed is different from other treated articles. One comment (0024), for example, distinguishes fungicides mixed into paint from treated seed because, the comment claims, such fungicides "mixed into paint do not

wash off the paint translocating to non-painted areas." In contrast, the comment notes that research shows that neonicotinoids on treated seeds do not stay on the seed but move into the surrounding soil and water and pose hazards to non-target organisms during the growing season and into the next season.

Another comment (0083) supporting the Petition acknowledges that EPA takes the position that treated seed may be exempt under the treated article exemption because EPA has adequately assessed the risks in the registration process for the treating pesticide. The comment specifically cites to a document jointly issued in 2003 by EPA and Canada's Pest Management Regulatory Agency, titled *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* ("*Harmonization*"). The comment quotes language from the *Harmonization* document acknowledging that "pesticide-treated seeds are considered to be pesticides themselves because they are a mixture of substances that are intended to prevent, destroy, repel or mitigate a pest" and that "EPA reasoned that the risks of treated seeds that meet the above criteria could adequately be regulated by means of registration of the treating pesticide" because when "evaluating the risks of the seed treatment, the EPA could also evaluate the risks from exposure to the seed treated according to the label instructions and forgo the need for a separate evaluation and registration of the treated seed." However, referring to the conditional registration of clothianidin and thiamethoxam, this comment states that EPA did not adequately assess the environmental risks to bee and "non-bee pollinators including hover flies and bee flies," thus the comment argues that "EPA cannot apply the treated article exemption to seeds treated with these pesticides, or any other pesticide whose risks have not been fully assessed."

One comment (0060) opposing the Petition generally takes the position that the treated article exemption "is not a loophole to circumvent the FIFRA registration standard" and that application of the exemption to treated seed "does not mean that the seed treatment products are not regulated under FIFRA, a fact Petitioners recognize and concede by identifying fifteen such products that EPA has registered since 2010." That comment further notes that the Petition "grossly understates the rigor of EPA's reviews" and "Petitioners repeatedly cite record materials reflecting EPA's rigorous reviews of these seed treatments (where they believe such materials support their position), including the comprehensive risk assessments issued for imidacloprid, clothianidin, and thiamethoxam, each of which Petitioners name in their Petition, as well as reports from the 2012 National Stakeholders Conference on Honeybee Health and the 2012 Scientific Advisory Panel on Pollinator Risk Assessment." The comment explains that the Petition "cherry-pick quotes" and "ignores EPA's efforts to address all of the alleged substantive shortcomings raised in the Petition."

Other similar comments state that because of EPA's review of the treating pesticides, the treated article exemption helps to avoid duplicative regulations where treated seed meets the requirements for the exemption (0008, 0029, 0036, 0043, 0056, 0057, 0058,0059, 0060, 0061, 0062, 0068, 0072, 0079). Many of these comments (0044, 0061, 0074, 0085, 0089, 0091) state that the treated article exemption does not constitute an abdication of the EPA's responsibilities under FIFRA, that EPA has the authority to determine what is exempt from FIFRA, and that treated seeds fall into that category. One comment notes that although PR Notice 2000-1 and 40 C.F.R. § 174.3 do not specifically reference treated seeds, those references support concluding

that the exemption covers treated seed (0074). One comment states that the Petition makes reference to the policy of other countries relating to treated seeds but that the policies of other countries are entirely different and have no bearing on the United States system (0060).

As to whether EPA's action is *ultra vires* or arbitrary and capricious, one comment (0060) states that EPA's actions do not run "counter to the available evidence." Rather, the comment reiterates that "EPA has made a determination based on a thorough, careful regulatory process that includes review of data and information that the seed treatment pesticide products identified in the Petition pose no unreasonable risk to the environment." As a result, the comment states that "EPA's determination is scientifically sound and consistent with the Agency's regulatory authority and discretion."

EPA Response: EPA agrees with the Petition that EPA first adopted the treated article exemption in 1988 and that the codified regulatory text and the proposed and final rule preambles do not discuss whether the exemption applies to pesticide-treated seed. However, as discussed further below, the regulatory text does not require explicit identification of an article in the regulatory text for the exemption to apply. Nor does the regulatory text require additional FIFRA unreasonable adverse effect findings or FIFRA section 25(b) findings for the exemption to apply. Rather, the regulatory text identifies specific conditions for the application of the exemption and only those conditions are relevant to a determination by any person choosing to use, sell, or distribute the article.

The regulation, adopted in 1988, provides that "pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified."[53] Listed in that regulation in paragraph (a) is the following:

> "*Treated articles or substances.* 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."[54]

A review of regulatory actions prior to adoption of the 1988 rule reveals that certain types of pesticide-treated articles were, by regulation, expressly deemed outside the jurisdictional scope of the statutory authority for regulating pesticides. For example, EPA's 1975 regulations identified specific types of pesticide-treated products that would not be considered "pesticides" and therefore would not be subject to regulation under FIFRA. These products included paints and paint coatings, building materials, and fabrics treated to protect the paint and paint coating,

[53] 40 C.F.R. § 152.25; Pesticide Registration Procedures; Pesticide Data Requirements, Final Rule, 53 Fed. Reg. 15952, 15977 (May 4, 1988) (1988 Final Rule).

[54] 40 C.F.R. § 152.25(a).

material, or fabric itself.[55] EPA explained in that rulemaking that before registering "a fungicide for use as an additive in paints or other formulated coatings, [EPA] must make the determination that the pesticide's composition is such as to warrant the claims made, it will be used without causing unreasonable adverse effects on man or the environment, and it otherwise complies with the requirements of the Act."[56] As a result, EPA was "satisfied that a thorough review of the fungicide, with a view toward its end use, will protect man and the environment from unreasonable adverse effects."[57] Though not explicitly stated, that rationale similarly applied to other types of treated articles, *i.e.,* building materials and fabrics, that were already excluded from statutory reach. The thorough review of the treating pesticide under the statutory standard was offered as justification for the decision to exclude specific pesticide-treated articles and substances from FIFRA authority.

In 1984, EPA proposed to amend its 1975 regulations to exempt certain types of pesticides from FIFRA requirements under the authority of FIFRA section 25(b)(2). That proposal did not include an exemption for treated articles or substances. Instead, EPA proposed to expand the

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[55] Registration, Reregistration, and Classification Procedures, Final Rule, 40 Fed. Reg. 28242, 28272 (July 3, 1975) (EPA 1975 Final Rule). Prior to issuance of the 1970 Reorganization Plan #3, 35 Fed. Reg. 15623, the United States Department of Agriculture (USDA) regulated pesticides as "economic poisons." Early USDA regulations excluded from the definition of "economic poison" a number of products that EPA later deemed pesticides or that were pesticides but exempted from regulation under the later adopted FIFRA section 25(b)(2). 24 Fed. Reg. 10842 (1959) (excluding from the definition of "economic poison" products "intended to kill or repel moles, wolves, birds, or dogs," building materials "treated with insect repellant materials to prevent their being attacked by insects," "preparations intended to prevent fouling of ships' bottoms by barnacles or other marine animals," and "woolens which have been treated with mothproofing materials to prevent their destruction by cloths moths"). In 1971, EPA issued regulations under its new authority adopting many of the USDA regulations on jurisdictional matters relating to certain types of treated articles such as building materials, paints, and fabrics. Reorganization and Republication, 36 Fed. Reg. 22369 (Nov. 25, 1971) (moving EPA regulations issued in response to the 1970 Reorganization Act at 7 C.F.R. Part 2762 to 40 C.F.R. Part 162); EPA 1971 Final Rule, 36 Fed. Reg. 22496, 22504-22505 (Nov. 25, 1971) (excluding from the definition of "fungicide," "[p]aints which are treated to protect the paint itself and bear no claims for protecting painted surfaces or other objects by preventing or destroying fungi," and excluding from the definition of "economic poisons" "[b]uilding materials, such as lumber, fiber boards, wallpaper paste, and paints, which have been treated to protect the material itself against any pest and which bear no claims for protection of other surfaces or objects" and "[f]abrics which have been treated to protect the fabric itself from insects, fungi, or any other pest, and which bear no claims for protection of other surfaces or objects"); and *see* EPA 1975 Final Rule, 40 Fed. Reg. at 28245 and 28272. FIFRA was amended in 1972 by the Federal Environmental Pesticide Control Act (FEPCA), Pub. L. 92-516, 86 Stat. 973, and EPA's 1975 and 1988 rulemakings were in large part to implement those amendments. The FEPCA included the authority for exemptions under FIFRA section 25(b)(2) and increased authority over pesticides generally. The FEPCA can be found at https://www.govinfo.gov/content/pkg/STATUTE-86/pdf/STATUTE-86-Pg973.pdf#page=1.

[56] 1975 Final Rule, 40 Fed. Reg at 28245-28246.

[57] *Id.* In contrast, EPA determined that "paint products intended to be applied to a surface to kill mildew organisms and paint products formulated to kill or prevent the growth of mold in food processing plants, dairies and breweries are considered to be pesticides and will require registration in accordance with FIFRA, as amended." 1975 Final Rule, 40 Fed. Reg at 28245-46. Thus, EPA required registration of pesticides that were used to treat paint products for the purpose of addressing pests to surfaces, while, based on its review of the pesticide excluding from statutory jurisdiction the paints that were treated for the protection of the paint or paint coating itself. *Id.* at 28245 and 28286 ("paint products intended to be applied to a surface to kill mildew organisms and paint products formulated to kill or prevent the growth of mold in food processing plants, dairies and breweries are considered to be pesticides and will require registration in accordance with FIFRA").

existing jurisdictional exclusion to all products classified as "treated articles or substances."[58] EPA proposed determining that "[a]rticles or substances treated with pesticides to protect the articles or substances themselves, 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" do not have a pesticidal effect and are therefore not pesticides subject to FIFRA regulation "[u]nless a pesticidal claim is made."[59] Thus, similar to the existing regulatory exclusion for paints, building materials, and fabrics, the newly proposed jurisdictional exclusion for treated articles and substances would not apply to the article or substance unless the intended protection was only for the "articles or substances themselves." Instead of finalizing this jurisdictional approach for "treated articles or substances," EPA's 1988 final rule codified, with some amendments to the 1984 proposed text, an exemption under the authority of FIFRA section 25(b)(2) for any "treated article or substance" that is a pesticide and that meets the two conditions for the exemption identified in the regulatory text.[60]

The two conditions for the exemption are generally consistent with the regulatory background on EPA's historical jurisdictional approach for paints, building materials, and fabrics.[61] The first condition is that the pesticide used to treat the article or substance be used "to protect the article or substance itself." This condition embodied the previous jurisdictional condition that the treatment of the paint, building material or fabric be "to protect the material itself." However, in contrast to the proposed rule the regulatory text for the final rule does not preclude a pesticidal claim in relation to that protection.[62] The second condition is that the treating pesticide be "registered for such use." This codified the necessary predicate addressed in the 1975 rulemaking for the jurisdictional determination, *i.e.,* that EPA's thorough assessment of the treating pesticide product, including any exposure and risk to human and ecological health from use of the treating pesticide and use of the treated article, would protect "man and the environment from unreasonable adverse effects."[63]

EPA agrees with those comments that conclude that the treated article exemption applies to any "article" or "substance" that is a pesticide and that meets the regulatory conditions for the exemption. Similar to the pre-1988 jurisdictional regulatory provisions, the regulatory text for the treated article exemption requires no agency action applying the exemption to a particular

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[58] Pesticide Registration and Classification Procedures, Proposed Rule 49 Fed. Reg. 37916, 37937 (September 26, 1984) (1984 Proposed Rule).

[59] EPA's 1984 Proposed Rule, 49 Fed. Reg. at 37937.

[60] 1988 Final Rule, 53 Fed. Reg. at 15977. Whether pesticide-treated seed is a 'pesticide' is addressed in section IV.C.2 of this response.

[61] Similarly, EPA's 1971 regulation provided that embalming fluids were not subject to FIFRA authority, while EPA's 1984 proposed rule identified embalming fluids as pesticides but exempted under FIFRA section 25(b)(2). EPA 1971 Final Rule, 36 Fed. Reg. at 22504-22505 (November 25, 1971); and EPA's 1984 Proposed Rule, at 37938. That exemption was made final in the 1988 final rule. 1988 Final Rule, 53 Fed. Reg. at 15977.

[62] EPA 1971 Final Rule, 36 Fed. Reg. at 22505; and 1975 Final Rule, 40 Fed. Reg. at 28245 and 28272.

[63] 1975 Final Rule, 40 Fed. Reg. at 28245-28246.

treated article.[64] Rather, the exemption regulation is drafted to allow decisions about whether the conditions for the exemption apply to a specific treated article to be made by those persons using a registered pesticide product to treat an article and by those persons distributing, selling, or using the treated article.[65] No additional FIFRA findings are required as part of this decision. However, EPA may at any time investigate the use of a pesticide product to treat an article and the distribution, sale, and use of such pesticide-treated article, and may conclude based on that investigation that a condition for the exemption does not apply. If the exemption does not apply, the distribution or sale of the treated article is the distribution or sale of an unregistered pesticide and subject to enforcement under FIFRA section 12(a)(1)(A).

EPA also agrees with those comments that "seeds" (or any other particular article) need not be expressly included in the regulation for the exemption to apply. The regulatory text identifies, in parentheticals, types of treatments of articles or substances that might be covered by the phrase "for the protection of the article or substance itself," *i.e.,* "(*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) …"[66] (emphasis added). The use of "for example" in the parenthetical makes clear that there was no intent for the exemption to be limited to treated paints or wood, and thus the regulation need not expressly reference treated seed as an article. Any "article" or "substance," including seed, may be exempt from FIFRA requirements if it meets the conditions for the exemption.

EPA has issued statements over the years to elucidate on the conditions for application of the exemption. Those statements provide some context for interpreting the two conditions applicable for the exemption to apply. Pesticide Registration Notice (PRN) 2000-1 provides guidance addressing the applicability of the exemption to antimicrobial pesticides. In that document, EPA explains that the regulatory condition "to protect the article or substance itself" excludes pesticide-treated articles and substances with public health claims and provides acceptable wording to avoid such claims. That PRN also explains that the regulatory condition "registered for such use" requires that the presence of the pesticide in the article or substance be the result of treatment using a pesticide registered for the use and requiring that the registered pesticide be

[64] To the extent that the Petition suggests, through reference to "EPA exempts or EPA's "practice of exempting," or any similar phrasing, that EPA grants individual exemptions, that is not the case. *See*, *e.g.,* Petition at i, and 35-37.

[65] EPA often receives requests for an opinion on whether a product might be a treated article exempted under 40 C.F.R. § 152.25. FIFRA section 33(b)(3), Table 18 of FIFRA, identifies a variety of submissions to EPA which require an EPA response within a specified period of time, assuming the submission is submitted consistent with FIFRA and EPA regulations, including the submission of fees specifically required by that section. One type of submission, M-0009 in Table 18, allows a person to inquire whether a particular product is a pesticide or a pesticide device. This is a voluntary submission, and an EPA response would merely communicate how the exemption may or may not apply to a pesticide product under the facts presented and based on the text of the regulation; it does not "grant" the exemption.

[66] 40 C.F.R. § 152.25(a) (emphasis added).

expressly labeled for the precise use in question; broad general use patterns are not permitted.[67] Similarly, in EPA's Response to a Petition from the International Center for Technology Assessment (ICTA Response) EPA explains that the regulatory reference to treatment of the "article … itself" does not include articles with express claims of protection against pests such as bacteria and viruses and stating that "registered for such use" includes any pesticide registered for the precise use in question.[68] Finally, in August 2000, EPA announced in the Federal Register the availability for comment of a draft statement by both the United States and Canada with "information on how seed treatment products are currently regulated."[69] In that document, EPA states:

> In issuing this regulation, the EPA reasoned that the risks of treated seeds that meet the above criteria could adequately be regulated by means of registration of the treating pesticide. In evaluating the risks of the seed treatment, the EPA could also evaluate the risks from exposure to the seed treated according to the label instructions and forgo the need for a separate evaluation and registration of the treated seed.

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[67] Pesticide Registration Notice 2000-1 (PRN 2000-1). For example, EPA explained that it "has interpreted 40 C.F.R. § 152.25(a) to mean that the registration and the labeling of the antimicrobial pesticide intended for incorporation into the treated article or substance needs to include specific listings of the articles or substances that may be treated. Accordingly, in registration actions over the past several years, EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives, or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 C.F.R. § 152.25(a)." EPA sought public comment on a draft version of that statement. 63 Fed. Reg. 19256 (April 17, 1998). *See also*, https://www.epa.gov/safepestcontrol/consumer-products-treated-pesticides; and https://www.epa.gov/coronavirus/there-anything-i-can-do-make-surfaces-resistant-sars-cov-2-covid-19.

[68] ICTA Petition Response at 7-9. For example, on the issue of bacterial and viral claims, EPA agreed with the position in the ICTA Petition that "articles that are pesticides with express claims of protection against pests such as bacteria and viruses may not qualify for the treated article exemption" and that a number of products listed in an Appendix to the ICTA Petition "appear to include antimicrobial claims to protect more than the article itself, claims which are otherwise impermissible under the treated article exemption." *Id.* EPA advised that "[t]o the extent that any unregistered pesticide articles are being sold or distributed in the United States, EPA will address them, as appropriate, through its general FIFRA enforcement program." *Id.* at 8*; and see id.* at 14 (the "appropriateness of any enforcement strategy is subject to many factors, and the Agency needs to maintain the ability to adapt its enforcement strategies as appropriate."). However, in response to the concern that registered pesticides include an active ingredient containing nanosilver, an ingredient being reviewed as a new active ingredient, EPA explained that "application of the treated article exemption is available if a registered pesticide is used, consistent with any terms and conditions for use of the registered pesticide. Thus, pesticide products registered as containing silver but later found to contain nanosilver are nonetheless registered and as long as a registered silver product is used to treat an article consistent with the terms and conditions on such use, the treated article exemption may apply." *Id.* at 8. A copy of this response can be found in the docket EPA-HQ-OPP-2008-0650 at https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0650.

[69] Pesticides; Harmonization of Treated Seed Policies and Requirements in Canada and the United States; Notice of Availability, Notice, 65 Fed. Reg. 52752 (August 30, 2000). *See also*, https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2003/harmonization-regulation-pesticide-seed-treatment-canada-united-states-dir2003-02.html.

Thus, EPA explains that, because its assessment of the treating pesticide addresses the risks from exposure to the treated seed, registration of the treated seed would be unnecessary. This explanation for the FIFRA section 25(b)(2) exemption of a treated article, here the treated seed, is similar to that provided in its 1975 Final Rule for its jurisdictional determinations, *i.e.,* that "thorough review of the [treating pesticide], with a view toward its end use, will protect man and the environment from unreasonable adverse effects."[70] This document is EPA's first explicit statement that pesticide-treated seed may be exempt from FIFRA requirements under 40 C.F.R. § 152.25(a).

These statements are further discussed in the sections below responding to the Petition claims and comments relevant to each condition for application of the exemption to pesticide-treated seed. However, it is notable that in the years that EPA has been the federal authority for regulating pesticides, EPA has no record of registering or, until this petition, being asked to register seed treated with a pesticide registered for that use under FIFRA section 3.

Taking the above history and statements into account, EPA agrees with those comments noting that it has been EPA's longstanding position that FIFRA section 25(b)(2) authorized EPA to adopt the 1988 final rule exempting pesticide-treated products because EPA's assessment of the treating pesticide comprehensively addresses the use of and exposure to the treating pesticide and to the authorized article or substance treated. EPA disagrees with the Petition claim that allowing exemption of treated seeds is "arbitrary and capricious under the APA" or *ultra vires* where risk concerns are claimed with use of the treating pesticide or use of the treated seed. As already explained in section IV.A and B, whether use of a pesticide to treat an article and use of that pesticide-treated article may cause unreasonable adverse effects is a determination made by EPA during the registration and registration review processes. During these processes, EPA conducts a thorough assessment of the pesticides used to treat seeds and use of the seeds that are treated, including the possible transport routes and exposures of non-target organisms. No new assessment or risk finding is necessary for the exemption to apply. Likewise no new FIFRA section 25(b)(2) finding specific to each and every article or substance treated is required. Rather, the only conditions applicable to a determination as to whether the treated article exemption applies are those stated in the regulatory text. Any concern that EPA's review is inadequate for any reason is not one of those conditions but may be raised during the registration or registration review processes. In sum, any risk or other concern with a pesticide-treated article is a concern that may be raised in registration and registration review processes, but whether the treated article exemption applies to a pesticide-treated article is addressed by consideration of the conditions in the regulatory text. Thus, it is not arbitrary or capricious or *ultra vires* to acknowledge that the regulatory exemption applies if the conditions expressly stated in the regulation are satisfied.

The Petition cites to a label for boat bottom paint for the broad claim that EPA's interpretation of the exemption of treated seed is "inconsistent with its other interpretations in comparable situations where the agency found a treated article not to be exempted due to adverse pesticidal effects beyond the article itself, including its non-exemption of anti-fouling boat paint and other articles." It is unclear what the Petition citation is intended to demonstrate. However, EPA agrees that anti-fouling boat paint products are pesticides under FIFRA and may be subject to FIFRA

[70] 1975 Final Rule, 40 Fed. Reg at 28245-28246.

registration requirements if the preservative treated paint product is labeled for the protection of the boat. In such case, the paint would not meet the exemption condition that the treatment be to "protect the article or substance itself," *i.e.,* the paint or paint coating.[71] That condition and the issues raised specific to that condition are more fully discussed later in this response.

EPA disagrees with the Petition claims that "EPA's exemption allows manufacturers of the various pesticidal seeds to evade the two classes of EPA notices that must go in the Federal Register under FIFRA and EPA's regulations." The requirements of FIFRA section 3(c)(4) and the requirements of 40 C.F.R. § 152.102, the statutory and regulatory provisions cited by the Petition, are met when EPA receives any application for use of a pesticide to treat seed. FIFRA section 3(c)(4) requires EPA to issue a Federal Register notice in relation to "each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern."[72] EPA's regulation at 40 C.F.R. § 152.102 interprets "changed use pattern" as used in FIFRA section 3(c)(4) to apply to applications for a "new use," and EPA issues the requisite Federal Register notices when it receives applications for new seed treatment uses.[73]

Finally, EPA disagrees with any suggestion that EPA's current processes are lacking in transparency or in an opportunity for comment in relation to the use of pesticides to treat seeds. Whether as a part of registration or registration review, EPA's assessment of pesticides intended to treat seed is transparent and, in many if not most cases, includes the opportunity for public comment on the proposed decisions during which the concerns raised in the Petition can be raised. For example, as noted above, concerns relating to whether the pesticide on the treated seed causes unreasonable adverse effects are concerns that can be raised during the registration approval process, beginning with EPA's FIFRA section 3(c)(4) notice of the submission of an application for a new active ingredient or an application for new use of the pesticide product to treat seed. That notice is published in the Federal Register, and while that notice does not announce an EPA proposed decision on the matter, it does generally identify the intended seed use of the pesticide registration requested. In addition, some proposed decisions on applications for registration are the subject of notice and an opportunity for public comment.[74] Finally, the

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[71] For example, one such pesticide product includes claims that it is "an advanced antifouling paint containing cuprous oxide for the prevention of barnacles, algae, coral, and other sessile marine fouling organisms" and "[r]ecommended for the underwater surfaces of steel vessels operated in all coastal and oceanic waters." *See* label with Registration #10250-54 at https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:9800357154239::NO::P8_PUID,P8_RINUM:35740,10250-54.

[72] 7 U.S.C. § 136a(c)(4).

[73] 40 C.F.R. § 152.102 requires a "notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a notice of issuance." In addition, the regulation requires the "notice of issuance" to "describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application." *Id.* In compliance with this obligation to issue a notice of issuance of the registration for new active ingredients and new uses, EPA issues the relevant notice in the Federal Register with the relevant information.

[74] *See* https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions. In addition, seed treatment uses and proposed tolerance actions may also be the subject of notice and comment if the seed treatment use results in residues in food or feed. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 408(d).

pesticide products specifically addressed in the Petition at Table 1 involve three pesticide active ingredients and each of those active ingredients is currently in registration review. EPA has issued for public comment proposed interim decisions (PIDs) for each of those active ingredients and each of those PIDs assess the exposure and risks specific to use of the pesticide products to treat seed and use of the treated seed. The public comment periods for that effort have closed, but a new opportunity for comment is planned in response to revised PIDs for each of the three neonicotinoids (anticipated in early 2023). Thus, petitioners and commenters have had and will again have the opportunity to provide comments similar to those raised in the Petition in the registration and registration review processes.[75]

Other related claims and comments are further discussed below, including those specific to each of the conditions in 40 C.F.R. § 152.25 and EPA's interpretation of those conditions as applied to treated seed. However, EPA disagrees with the specific request to interpret or amend the regulation to preclude exemption of seed treated where concerns are raised that such seed presents an unreasonable adverse effect on the environment or otherwise does not meet FIFRA or other requirements. Those issues are appropriately raised in the context of the registration and registration review processes for each individual pesticide; reinterpretation of the treated article exemption or amendment to the exemption is not necessary to address those concerns. Moreover, as explained in section IV.A, EPA's assessments are comprehensive and include exposures and risks specific to use of the treated article, and thus no new or additional assessment would be conducted simply if pesticide-treated seed were required to be registered under FIFRA. As discussed in section IV.D, EPA does not believe amending the regulatory text to require registration of treated seed is the better solution to address the enforcement concerns raised by the Petition.

**(2) Are Pesticide-Treated Seeds "Pesticides"?**

Summary of Petition: The Petition states that pesticide-treated "seeds fit the definition of 'pesticide' and that they have devastating impacts to the environment and Petitioners' interests …" Petition at i. It further explains that "[s]ystemic neonicotinoid-coated seeds clearly fit within FIFRA's definition of 'pesticide' because they are a 'mixture of substances that are intended to prevent, destroy, repel or mitigate a pest,' and would otherwise require registration prior to sale. 7 U.S.C. § 136(u)(1)." Petition at 31. The Petition also asserts, "[s]eeds coated with liquid formulations of [neonicotinoids] are pesticide delivery devices" and the "purpose of this technology is to carry the active ingredient via the growing plants' circulatory systems into the

[75] *See, e.g.*, Clothianidin: Comment submitted by Larissa Walker, Pollinator Program Director Center for Food Safety (CFS) (August 24, 2017) found in docket EPA-HQ-OPP-2011-0865 at https://www.regulations.gov/comment/EPA-HQ-OPP-2011-0865-0207; Thiamethoxam: Comment submitted by Center for Food Safety (CFS) (August 24, 2017) found in docket EPA-HQ-OPP-0581-0044 at https://www.regulations.gov/comment/EPA-HQ-OPP-2011-0581-0079; Imidacloprid: Comment submitted by Larissa Walker, Pollinator Program Director, Policy Analyst, Center for Food Safety (CFS) (April 26, 2016) found in docket EPA-HQ-OPP-2008-0844 at https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0844-0883, and Comment submitted by Larissa Walker, Pollinator Program Director, Policy Analyst, Center for Food Safety (CFS) (August 18, 2017) found in docket EPA-HQ-OPP-2008-0844 at https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0844-1209; and Comment submitted by Peter T. Jenkins, Of Counsel, Center for Food Safety (CFS) (November 30, 2017) found in docket EPA-HQ-OPP-2008-0844 at https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0844-1254.

tissues of the plants, which ultimately are typically hundreds or even thousands of times larger in dimension and mass than the seed itself. Petition at 7.

Summary of Comments: A comment (0027) supporting the Petition generally refers to the treated seed as pesticides because, for example, treated seeds contain active ingredients used for pesticidal purposes, advertisements for the treating pesticides include claims of "seed-applied insecticides," and the seeds are "distributed and sold by companies that acknowledge and claim that the seeds will be used for pesticidal purpose." One comment (0024) elaborates on that statement saying that a Corn Dust Consortium Report found that "neonicotinoid seed treatments are used on a wide range of crop plants, including soybean, cotton, canola, wheat, sunflower, potato, and many vegetables" and that the Report makes "clear pesticide coated seeds are a pesticide application."

Other similar comments refer to pesticide-treated seed as "[s]eed-delivery of pesticides" (0027) or as "simply a pesticide delivery vehicle, more akin to the solid matrix that forms the substrate for pesticide granules than treated wood or paint. Therefore, the seed, in this case, is more accurately categorized as an 'inert' ingredient in a pesticide formulation than a treated article" (0069).

EPA Response: EPA agrees with the Petition and comments that pesticide-treated seed products are generally going to be classified as "pesticides" as that term is defined in FIFRA and EPA regulations. If such treated seed were not pesticides, such seed would not be subject to registration requirements under FIFRA or to the treated article exemption.

FIFRA defines a pesticide, in relevant part, as "any substance or mixture…intended for preventing, destroying, repelling, or mitigating any pest."[76] EPA regulations interpreting that statutory definition similarly provide that a "pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, *i.e.,* use for the purpose of preventing, destroying, repelling, or mitigating any pest …" and identify three criteria for determining whether a product is intended for a pesticidal purpose.[77] Those include whether:

- The distributer or seller "claims, states, or implies (by labeling or otherwise)" that the substance (1) "can or should be used as a pesticide," or (2) "consists of or contains an active ingredient and … can be used to manufacture a pesticide";[78]
- The seller or distributer "has actual or constructive knowledge that the substance will be used, or is intended to be used, for pesticidal purpose";[79] and

[76] FIFRA § 2(u), 7 U.S.C. § 136(u); *see also* 40 C.F.R. § 152.3.

[77] 40 C.F.R. § 152.15.

[78] 40 C.F.R. § 152.15(a). "Active ingredient" is defined as a substance that "will prevent, destroy, repel, or mitigate any pest." 7 U.S.C. § 136(a)(1); 40 C.F.R. § 152.3.

[79] 40 C.F.R. § 152.15(c).

- The substance "consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose …, [or] (2) use for manufacture of a pesticide."[80]

EPA agrees with the Petition and comments that the type of treated seed discussed in the Petition will generally be found to meet these conditions. It has been EPA's longstanding position that "pesticide-treated seeds are considered to be pesticides themselves because they are a mixture of substances that are intended to prevent, destroy, repel or mitigate a pest."[81]

First, the pesticides listed in Table 1 of the Petition that are used to treat seed include labeling identifying the pesticidal purpose for the treated seed. For example, "Sepresto 75 WS applied at 6.7 – 13.3 g per 100 kg seed (0.11 oz to 0.21 oz/100 lb of seed) offers suppression of wireworm activity on seed and young seedlings." In addition, the seed treated with those pesticides must include labeling, called seed bag tags, identifying the seed as pesticide-treated and with instructions on the permissible use of the pesticide-treated seed.[82]

Second, the seed treated with the pesticides addressed in Table 1 of the Petition "consists of or contains one or more active ingredients" and the active ingredients in or on the seed have no "significant commercial valuable use" other than for a clear "pesticidal purpose." Thus, even absent labeling or marketing communicating the pesticidal purpose for the treated seed, pesticide-treated seed would generally meet the last criterion and thus would be classified as a pesticide.

Given the above, EPA generally agrees with the Petition that seed treated with a pesticide is a pesticide subject to the requirements of FIFRA, unless otherwise exempt from FIFRA requirements. However, whether pesticide-treated seed can also be argued to operate as an application of the treating pesticide has not been previously considered.[83]

**(3) Is the Seed Treated with a Pesticide to Protect the Seed Itself?**

Summary of Petition: The Petition generally takes the position that the plain language of the treated article exemption does not include "systemic insecticide-coated seeds" because the pesticide used to treat the seed is not intended "to protect the article or substance itself" as the regulation requires. Petition at 34.

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[80] 40 C.F.R. § 152.15(b).

[81] *Harmonization*, at 2.1.

[82] *See, e.g.,* Difenoconazole Interim Registration Review Decision at 26-28 (identifying treating pesticide label instructions requiring particular language on seed bag tags) (March 31, 2022). This document can be found in docket EPA-HQ-OPP-2015-0401-0065 at https://www.regulations.gov/document/EPA-HQ-OPP-2015-0401-0065.

[83] EPA has not interpreted the regulatory term "article" in 40 C.F.R. § 152.25(a), as suggested by the comment (0069), to exclude a solid material containing an active ingredient, and does not see a basis to distinguish something the comment refers to as a "solid matrix that forms the substrate for pesticide granules" from wood or paint coatings.

Specifically, the Petition alleges that a predominant number of the labels for seed treatment pesticides identified in the Petition state that the treatment is to "protect the growing plant," distinguishing the plant from the seed. Petition at ii; *see also* Petition at 34-35. The Petition asserts that "the vast majority of cases, the coatings are not intended to protect the seed itself from any disease, pest, or predator" of the seed, but, instead, the "coating chemicals are *systemic*, meaning they are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant." Petition at 2 (emphasis provided).

To support the position that the registered pesticides are not intended to protect the seed, the Petition identifies in a footnote "fifteen new coating product registrations and their label language" that EPA has approved since January 1, 2010 and notes that "[a]ll but two of those products (*i.e.,* thirteen out of fifteen) lack a clear label claim that the neonicotinoid ingredient protects the planted seed itself; the labels generally state that the neonicotinoids are to kill "chewing and sucking insect pests" of the growing *plants*, not of the seeds." Petition at 9-10, and 34 n. 17 (emphasis provided). As a result, the Petition concludes that the "neonicotinoid ingredients are predominately aimed at protecting the growing crop plants, later in time, as demonstrated by the EPA-approved labels placed on the bottles/containers of the liquid coating products." Petition at 9.

The Petition states that because the pesticide must be "for the protection of the article … itself" it "should be a necessary condition that the treatment largely remain *on the treated article.*" Petition at 34 (emphasis provided). Specifically, the Petition states that "[c]lear and convincing evidence shows that the pesticidal "protective" effect of the scraped, blown, and sloughed-off neonicotinoid coatings "extends beyond the seed itself," and extends far beyond the full-grown plants." *Id.* The Petition asserts that "up to ninety percent of the insecticide is either scraped off the seeds and blown away as dust during machine planting or sloughed off into the surrounding soil and groundwater." Petition at 10. The Petition states that the bulk of the "coating chemicals move off the seed and plant into the surrounding air, soil, marginal vegetation and waters," illustrating "that the bulk of the treatment does not remain in or on [the seed]" for the benefit of the seed article. Petition at 34.

The Petition also refers for support to the 2003 *Harmonization* document issued by EPA and the Pest Management Regulatory Agency of Canada. Petition at 10. That document, according to the Petition, "mentions pesticide-coated seeds, but it provides no coverage or analysis of systemic insecticide or neonicotinoid-coated seeds" and concludes that pesticidal protection may not extend "beyond the seed itself." Petition at 10-11. Thus, the Petition asserts that systemic, neonicotinoid-coated seeds do not qualify for the exemption. *Id.*

Finally, the Petition asserts because seed treatment is actually not protective of the seed, but harms the seed in many instances, the seed treatment is not for the protection of the seed. For this proposition, the Petition refers to "label warnings [that] frequently indicate that the neonicotinoids actually may *harm* the seeds and result in reduced germination and/or reduction of seed and seedling vigor." Petition at 10 (emphasis provided).

Summary of Comments: Some comments supporting the Petition (0027, 0069) generally take the position that seed treated with systemic pesticides are meant to protect the developing plant and that such treatment is not to protect the article, the seed, itself. These comments note that some pesticide products routinely advertise that the treatments are intended to destroy pests of the growing and fully developed plant, with little mention of seeds. One comment (0027) points to an example of a DuPont advertisement relating to the product Lumisena™ for control of "Phytophthora in soybeans and downy mildew in sunflower crops" and that a DuPont fact sheet for Lumisena™ states that the "Phytophthora fungus can kill plants at all stages of growth." Referring also to the active ingredient in Lumisena™, the comment points to the technical product release which states that "[r]esearch studies show that oxathiapiprolin provides outstanding protection for soybean seeds and young plants against Phytophthora…," and that the seed treatment's "[s]ystemic control improves root and plant health." From this and other similar language, the comment concludes that the corn seed treatment is advertised as an "insecticide that is applied by way of the seed in order to protect corn." Another comment references both the intended benefit to the plant from use of a systemic pesticide on the seed and the plant claims present on the treating pesticide label (0097). This comment states that label claims regarding plants should not be removed to "remain outside FIFRA jurisdiction under the Treated Article Exemption."

Other comments opposing the Petition assert that a typical seed includes all parts of the seed, including an embryo, a supply of nutrients for the embryo, and a seed coat, and that the seedling that emerges from the planting of the seed is part of the seed (0028, 0035, 0044, 0045, 0046, 0060, 0066, 0075, 0080, 0087). Therefore, these comments state that treatment of that seed satisfies this criterion of the treated article exemption, even if the treatment also benefits the seedling. Some comments note that the Petition identifies no authority requiring EPA to draw a distinction between the plant organism as seed, seedling, or growing plant, or to exclude from the exemption seed treatments that are intended to protect "the plant itself" and point to EPA regulations at 40 C.F.R. § 174.3 and the Plant Protection Act for support in concluding that the plant includes the seed (0060, 0088). Those comments also find support in the commonality between the text of the treated article exemption and the definition of "treated" in Federal Seed Act 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." One comment (0088) notes that this commonality "recognizes the basic scientific understanding of a seed as a biological organism of form" and that a "viable seed is a form of a seedling (embryo) in nature's protective packaging (seed coat) with stored nutrients (cotyledon) until environmental conditions are suitable for release (germination) from the protective seed coat." A similar comment (0089) states that the main benefit derived from the use of insecticides is to protect the cotyledon which is technically part of the seed. Other comments (0036, 0074) point out that the Petition did not identify why EPA would need to distinguish between seeds and seedlings in the treated article exemption. Multiple comments claim that EPA should refrain from actions that result in creating conflicting definitions among federal agencies and distinguishing between seed and plant in this context would do that (0016, 0033, 0045, 0075, 0088).

One comment (0060) notes that the Petition's reference to the *Harmonization* document does not support the claim that the pesticide protection can only be focused on the seed in its original state

for the exemption to apply. Rather, the comment stresses that EPA has never interpreted the exemption or this discussion in the *Harmonization* document to be so limiting, that such a position would be inconsistent with EPA's regulations and its historic registration of seed treatments and the application of the exemption to the treated seed.

EPA Response: A treated article is only exempt from the requirements of FIFRA if it meets the conditions for the exemption, including that the pesticide treatment is "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)." EPA does not agree with the Petition or comments taking the position that this criterion allows claims only for protection of the seed in its original form. As noted above in section IV.A and B, EPA fully assesses the exposure and risks with use of a treating pesticide and the use of the treated article or substance, during its consideration of an application for registration of the pesticide for that use and during registration review. This assessment includes human and ecological exposures and risks with use of pesticides with systemic properties. Thus, residues of the pesticide that might be in the seed, seedling, or plant are considered in EPA's assessment. In addition, the plain language of the regulatory text, specifically the parenthetical text, supports that the exemption allows protection that extends to other forms of the treated article or substance after the specified article or substance is treated and used. The parenthetical example includes as potentially exempted both the paint that is treated and the treated paint after it is used and becomes a different form of the original treated product, *i.e.,* the "paint coating." Thus, EPA reads this regulatory text to similarly apply to the article treated, *i.e.,* the seed, and the treated article in use and what the article becomes, *i.e.,* the seed after it is planted.

Analogous examples outside of the treated seed context include antimicrobial treatments of plastic products, where, for example, the plastic is used to create spun fibers or threads which are then used to produce fabric and textile products. In each of these cases, while the protection may benefit the original form of the treated article, the protection can extend beyond the article in its original form to the article as it is used. That is particularly the case for plastics, where a benefit is intended for the finished textile product while in use. In that case, and consistent with the guidance in PRN 2000-1, if the treated plastic and any downstream form of the original treated plastic product do not claim protection other than for the plastic or downstream product itself, EPA has read this condition for the exemption to apply.[84]

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[84] For example, the end products for the active ingredient at issue in *NRDC v. EPA*, 735 F.3d 873 (9th Cir. 2013), included a treatment product for direct application as a surface coating to already created textiles and a treatment product incorporated into fibers that were then used to create the textiles. Similarly, the end product in *NRDC v. EPA,* 857 F.3d 1030 (9th Cir. 2017) involved incorporation of the active ingredient into non-food-contact plastics, including plastics that can be woven into textiles. In contrast, and similar to certain paint products intended for protection of the boat, EPA does register textile products that are intended for the protection of the person wearing or using the product. For example, permethrin is registered for "the treatment of clothing and footwear to deter ticks and other blood-feeding arthropods, such as chiggers." *See* Permethrin: Proposed Interim Registration Review Decision at 23 (March 26, 2020). This document can be found in docket EPA-HQ-OPP-2011-0039-0129 at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0039-0129. The treated clothing in that case must be registered. *See* NO FLY ZONE (EPA Registration No. 83588-1) ("The fabric in this [garment/gear] has been treated with the active ingredient Permethrin.") at https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:15946711492108::NO::P8_PUID,P8_RINUM:482454,83588-1.

Consistent with that guidance, the labeling referenced by the Petition relating to protection of the seed and seedling does not invalidate application of the exemption, even if the pesticide acts systemically.[85] Importantly and contrary to Petition claims, EPA is not aware of any inappropriate labeling claims for the pesticides listed in Table 1 of the Petition or for the 15 products specified in note 17 of the Petition. The labeling claims for each of the products listed by the Petition permissibly refer to the seed and the growing seedling. For example, the INOVATE Seed Protectant product label (EPA Registration No. 59639-176) states that "A fungicide and insecticide seed treatment product providing systemic seed and seedling protection against listed early season seedling diseases and insects of soybeans."[86] EPA further disagrees with the Petition conclusion that claims relating to "chewing and sucking insect pests" are only pests of the growing plant. For example, southern corn rootworm, fire ants, and wireworms are chewing and sucking pests and will all attack seeds, and these are some of the target pests for the pesticides listed in Table 1 of the Petition.[87]

EPA also disagrees with the position in the Petition and comments that if a portion of the treating pesticide can be "scraped, blown, and sloughed-off" from the seed, that the pesticide is not intended to "protect the article itself." The regulatory text simply does not include the requirement that the pesticide used to treat the article or substance generally be contained by the article or substance in use. The question raised by the condition is what the intent of the pesticide treatment is, not whether the pesticide never leaves the article. Notably, the examples provided in the regulatory text, *i.e.,* treated paint and wood, can be the types of pesticide treatments that leach or volatilize some amount of the pesticide used to treat the article or substance, and those are issues assessed as part of EPA's review of the treating pesticide and the treated article.[88] In

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[85] EPA need not conclude, as comments suggest, that the seed, seedling, and plant are the same article based on regulations at 40 C.F.R. Part 174. As explained in this response, the plain language of the treated article exemption supports application of the exemption to the seed article that is treated, even if there are additional claims relating to seedlings. Notably, the unique pesticides addressed by Part 174, *i.e.,* plant-incorporated protectants (PIPs), are not subject to the treated article exemption for reasons articulated in 40 C.F.R. 174.1 (because the characteristics of PIPs "distinguish them from traditional chemical pesticides," PIPs are subject to "different regulatory requirements, criteria, and procedures than traditional chemical pesticides"). Rather, PIPs must be registered under FIFRA if not exempt under 40 C.F.R. Part 174, and living plants containing the PIP may be exempt from FIFRA requirements pursuant to 40 C.F.R. 152.20(a).

[86] INOVATE Seed Protectant (EPA Registration No. 59639-176). This document can be found at https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:1867965938416::NO::P8_PUID,P8_RINUM:503372,59639-176.

[87] However, even assuming there are products with inappropriate claims, that is an issue specific to those products. The failure of an article to meet the conditions for the exemption means that article is unregistered and subject to enforcement. It does not mean EPA should revise its approach for an entire set of treated articles. *See* ICTA Response at 8 (referring to Appendix A products that may not meet the conditions for the exemption to apply and EPA's acknowledgment that addressing those issues was a matter for the general FIFRA enforcement program).

[88] *See, e.g.*, Registration Review Draft Risk Assessment for Copper-8-quinolinolate (Bis(8-quinolinolato)copper(II)) at 28 (June 3, 2021). ("The leaching of wood preservative into the soil and subsequent exposure is much less (>10x) than that attributed to direct contact with the treated wood itself. Therefore, the exposure from soil is expected to be a minimal additional contribution compared to the exposure from contact with the treated wood, and only contact to treated wood is quantified in this assessment."). This document can be found

fact, EPA's assessments for the pesticides listed in Table 1 of the Petition generally consider whether and how the registered pesticide may spread to the environment with use of the treating pesticide and use of treated seed, including "scraped, blown, and sloughed-off neonicotinoid coatings."[89] Similarly, in the case of treated textiles, "down-the-drain" scenarios have been used to determine whether a textile use results in pesticide release of water of concern.[90]

Finally, EPA does not agree with the Petition claim that seed treatment pesticides specified in Table 1 of the Petition may actually harm the seed and thus that the treatment is not intended for the protection of the seed. There is nothing to support this claim. The required non-target phytotoxicity data (i.e., vegetative vigor and seedling emergence)[91] evaluated in the neonicotinoid ecological risk assessments did not suggest phytotoxicity concerns for treated seeds.[92] In terms of labeling claims, the only reference to harm to the seed on the labels cited by the Petition is reference to the mechanical harm to the seed or harm to seed of poor vigor or quality, not to harm solely from the pesticide treatment of the seed.[93] To be clear, EPA does not read "to protect the article or substance itself" to require perfect protection of the treated article or substance or to require EPA to verify that the treatment will provide the protection claimed. Rather, as explained in EPA guidance issued in PRN 2000-1, pesticide preservatives are known to provide protection to paint from "deterioration of the paint film or coating," to wood "from fungus or insect infestations which may originate on the surface of the wood," or to textiles to "inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew." The PRN distinguishes this kind of claimed protection from pesticides with claims and uses "suggesting health or other benefits beyond mere preservation of the treated article

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in docket EPA-HQ-OPP-2010-0454-0012 at https://www.regulations.gov/document/EPA-HQ-OPP-2010-0454-0012.

[89] *See* Appendix C for assessments and other documents addressing issues of this kind in the context of EPA review of pesticides listed in Table 1 of the Petition.

[90] *See* Decision Document: Conditional Registration of HeiQ AGS-20 as Materials Preservative in Textiles at 37 (December 1, 2011). This document can be found in docket EPA-HQ-OPP-2009-1012-0064 at https://www.regulations.gov/document/EPA-HQ-OPP-2009-1012-0064.

[91] *See* 40 C.F.R. Part 158, Subparts G.

[92] *See, e.g.,* Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review at 34-35 (November 28, 2017) ("Two studies were submitted on the toxicity of imidacloprid TEP to terrestrial plants (Table 4-4). In both studies (seedling emergence and vegetative vigor), no significant adverse effects were observed at the maximum single application rate registered for imidacloprid (0.5 lb a.i./A)."). This document can be found in docket EPA-HQ-OPP-2008-0844-1256 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1256.

[93] For example, the referenced label for Sepresto 75 WS reads "Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed." Moreover, the types of cautionary statements such as those cited by the Petition are common among all treating pesticides and would not typically be used to determine that the intent of the pesticide is to harm the treated crop or commodity.

itself." As noted above, seed treatments are similar to paint and textile preservatives as they are generally known for protection of the seed in its original form and what the seed becomes.

The Petition points to nothing in the *Harmonization* document or other guidance that conflicts with this reading of the regulatory text. The *Harmonization* text referenced by the Petition provides the following:

> The term "for the protection of the [seed] itself" means that the pesticidal protection imparted to the treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed. Unless claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed are made in conjunction with the distribution or sale of the treated seed within the U.S., the EPA will presume that the seed will have been treated "for the protection of the seed itself."

This statement merely restates the portion of the criteria relating to protection of the article itself, substituting reference to the word "article" that receives the pesticide treatment with reference to the seed receiving the treatment. It similarly repeats a phrase used in PRN 2000-1 relating to public health claims that are not appropriate for exempted treated articles because such claims "imply or express protection that extends beyond the treated article or substance itself," again substituting the word "seed" for the reference to an article. Nothing in this guidance statement suggests an interpretation of the treated article exemption that would preclude the treating pesticide from providing protection, for example, to the seed *and* seedlings. That is because such an interpretation would be inconsistent with the plain language of the exemption that permits the exemption to apply to the treated article and what the treated article may become when in use. Likewise, nothing in this guidance statement suggests that the possibility of dust-off makes the exemption inapplicable. Instead, this guidance statement merely ensures that seed treatments may not be used for purposes beyond the seed as treated and in use and makes clear that unless there are claims of that kind, EPA generally presumes the seed is treated for protection of the seed itself. [94] For example, the exemption and this guidance statement would not permit a seed treatment for a purpose that is not intended to address a pest of a seed and the growing seedling,

[94] However, EPA regulations make clear that "each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices" and that the "Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration." 40 C.F.R. Part 158.400(e)(1). Registrants must be able to support the performance of the pesticide for its intended purpose should EPA request such data at any time, though EPA does not generally require submission of data to support the performance of an agricultural pesticide product. *See* 40 C.F.R. Part 158, Subparts E (for product performance); and 7 U.S.C.A. 136a(c)(5) (EPA "may waive data requirements pertaining to efficacy, in which case [EPA] may register the pesticide without determining that the pesticide's composition is such as to warrant the proposed claims of efficacy"). Instead, EPA generally assumes an agricultural pesticide works as it is intended and that assumption is similarly made for pesticides used to treat seeds. *Harmonization* at 2. However, EPA emphasizes that while it does not generally require product performance data to support any agricultural protection claim, including a seedling claim and its relationship to the treated article exemption, data to support such claim must always be available upon request and may be requested by EPA at any time; this reading of the exemption does not permit a claim that cannot be supported by product performance data.

*e.g.,* use of treated seed as a bait, or for an insecticidal purpose wholly unrelated to an agricultural pest, *e.g.,* for use to address mosquitos to protect public health.[95]

**(4) Is the Seed Treated with a Pesticide that is "Registered for Such Use"?**

Summary of Petition: As noted in part (1) of this section, the Petition makes a variety of different claims suggesting additional conditions for the exemption apply or suggesting an interpretation of existing conditions to preclude certain types of seed treatment where the Petition believes risk concerns exist. While the Petition does not explicitly address this criterion that the pesticide used be "registered for such use," it does assert that "EPA is not allowed to *register* a pesticide which will cause unreasonable adverse effects on the environment" and thus "EPA may not *exempt* pesticides that would cause unreasonable adverse effects on the environment" because EPA could not make the FIFRA section 25(b) finding that such pesticides are "of a character which is unnecessary to be subject to FIFRA." Petition at 33 (emphasis provided). In addition, while the Petition claims and specific requests are generally targeting the neonicotinoid pesticides, some claims also focus generally on pesticides with systemic properties and which may not yet be registered for use on seed. For example, the Petition states that the claimed risk concerns "apply to other non-neonicotinoid, systemic seed coating products that EPA has already approved or has indicated its intent to approve, including, but not limited to, Fipronil, Sulfoxaflor, Cyantraniloprole and Flupyradifurone." Petition at 32. The Petition notes that "[s]ome of these may not yet be registered for seed coating use; however, based on EPA's practices with the neonicotinoids, it is foreseeable EPA will approve them for that use" and that "[i]f so approved they are likely to present the same class of harms to Petitioners as do neonicotinoid-coated seeds." *Id.*

The Petition also states that "EPA misuses its labeling authority and arbitrarily assumes that the seed coating companies—applying the liquid coatings mostly in industrial buildings—can be given warnings and use directions adequate to ensure that FIFRA's safety standards will be met during the actual use of the pesticidal seeds in the environment." Petition at 30. As a consequence the Petition notes that exempted treated seed does not include enforceable FIFRA labeling. Petition at 34.

Summary of Comments: One comment (0083) that supports the Petition claims that because EPA granted conditional registrations, "the environmental risks posed by seeds treated with clothianidin and thiamethoxam have not been adequately assessed in the registration for these pesticides". The comment states that using its own standard, "EPA cannot apply the treated article exemption to seeds treated with [clothianidin or thiamethoxam], or any other pesticides whose risks have not been adequately assessed." Relating to the labeling issue raised by the Petition, one comment (0097) agrees with the Petition stating that "[r]equiring registration and labeling of seeds treated with pesticides pursuant to FIFRA would allow for oversight as a

[95] While EPA generally agrees with the comment that removal of an impermissible claim does not guarantee that the treated article exemption applies, EPA notes that removal of a claim can impact whether this criterion is met. See PRN 2000-1 (The article may not be distributed or sold unless either the article is registered under FIFRA or the public health claim for the unregistered article is "removed and the article otherwise qualifies for the exemption"). Claims made in the labeling of treating pesticide products and the articles or substances are the primary means of determining the intent with use of the treating pesticide and the treated product.

regulated pesticide. Pesticide-treated seed labels include cautions and directions on the bag of seed as mandated by the label of the FIFRA-registered pesticide used to treat the seeds however, the resulting seed product label is unenforceable under FIFRA and State pesticide laws."

Comments (*e.g.,* 0088, 0044) supporting application of the treated article exemption to pesticide-treated seed note that the exemption does not allow the pesticide to avoid the FIFRA registration/registration review process for its intended use, but clearly states there is an exemption for the article treated if the treatment product is registered for such use. These comments generally take the position that the pesticide product is subjected to EPA's rigorous risk assessments, including Human Health Risk Assessments, Ecological Risk Assessments, Bee Risk Assessments, Aggregate Risk Assessments, Cumulative Risk Assessments, Occupational Risk Assessments, and the multitude of models and intermediate data requirements to accomplish these risk assessments.

EPA Response: A treated article is only exempt from the requirements of FIFRA if it meets the conditions for the exemption, including that the pesticide product used to treat the article is "registered for such use" under FIFRA section 3. The first issue to address in determining whether the "registered for such use" criterion is satisfied is whether *any* registered pesticide product is used to treat the article. If not, this criterion is not satisfied, and the exemption does not apply.

The plain language of the regulation is focused on whether the treating pesticide product used is in fact "registered" under FIFRA for the use in question, not whether the treating pesticide *should* have been registered for that use. Thus, concerns raised by the Petition and comments about the risk with use of a treated article or concerns about data requirements identified on a FIFRA section 3(c)(7) conditional registration are not relevant considerations in determining whether a pesticide product is "registered." A registered pesticide is a pesticide product that has been granted a registration status under FIFRA section 3.

A risk-related issue similar to the one raised by the Petition was addressed in 2015 in response to a different petition. In that case, the petition was concerned with residues of nanosilver in treated articles stemming from use of a registered pesticide.[96] There, the petition raised risk concerns with the presence of nanosilver active ingredients in treated articles and additionally claimed that the exemption should not apply because, though the nanosilver ingredient was present in a registered pesticide product, the labeling did not identify the silver present in the product as nanosilver. In response, EPA explained that "pesticide products registered as containing silver but later found to contain nanosilver are nonetheless registered and as long as a registered silver product is used to treat an article consistent with the terms and conditions on such use, the treated article exemption may apply."[97]

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[96] Citizen Petition for Rulemaking to the United States Environmental Protection Agency, ICTA (submitted May 1, 2008). This document can be found in docket EPA-HQ-OPP-2008-0650-0002 at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0650-0002.

[97] ICTA Petition Response at 8. *See also, In the Matter of Behnke Lubricants, Inc., Docket No. FIFRA-05-2007-0025* (Jan. 5, 2009) (lubricant product with antimicrobial claims was an unregistered pesticide and the burden of proving the exemption applies, *i.e.,* that a registered pesticide was used to treat the lubricant, is a defense to the Complaint and must be demonstrated by the Respondent).

Similarly, and as noted in part (1) of this section, raising risk concerns as to a pesticide product ingredient does not alone invalidate the registration of the product used to treat seeds. For purposes of determining whether the treated article exemption applies, the question is whether the pesticide is in fact "registered" under FIFRA section 3 at the time it is used for the use in question, not whether it should have been registered. In addition, even though a pesticide registered under FIFRA section 3(c)(7) may have outstanding data requirements, if the treating pesticide product remains registered under FIFRA section 3 for the specific seed treatment use in question, it is considered a "registered" pesticide product for purposes of the treated article exemption. Notably, as summarized in section IV.A, EPA thoroughly assesses whether a pesticide poses unreasonable human health or ecological risks, and therefore it is inaccurate to suggest that the regulatory exemption exempts from FIFRA requirements a pesticide product that in fact poses unreasonable risk concerns. In any case, those issues are addressed in the context of the registration or registration review decisions, and not as a challenge to the application of the regulatory criteria to exemption of a treated article.

The second issue to address in determining whether the "registered *for such use*" criterion is met is whether the particular use is registered, and this requires more than a superficial examination of whether the treating pesticide product is registered under FIFRA for some uses. In the context of seed treatment and seed use, this is a three-part question: (1) is the treating pesticide product registered under FIFRA section 3 for use on the specific seed crop in question; (2) is the use of the registered treating pesticide product and the distribution and sale of the treated seed consistent with any instructions on the registered pesticide product labeling; and (3) is the use of the treated seed consistent with any instructions on the registered pesticide product labeling, as communicated on the seed bag tag labeling. If the answer to any of those questions is no, the treated seed is not an exempted treated article.[98]

As to the first part of this question, if the specific seed crop is not identified as a permissible seed treatment use on the FIFRA section 3 pesticide product labeling, the treatment of that seed crop is not "registered for such use." In such case, any such seed treated with that pesticide is not covered by the exemption and distribution, sale, or use of such seed is the distribution, sale, or use of an unregistered and unexempted pesticide. That is the case even if the treating pesticide product is generally registered for an agricultural purpose. This is consistent with guidance issued in PRN 2000-1, providing that "[b]ecause of the wide range of exposure scenarios associated with the use of treated articles …, the Agency has interpreted 40 C.F.R. § 152.25(a) to mean that the registration and the labeling of the [treating pesticide product] needs to include specific listings of the articles or substances that may be treated." As cautioned in PRN 2000-1, "it is not sufficient that the … pesticidal substance in the treated article merely resemble or have activity like a registered pesticide." Rather, the pesticide product used must actually be registered under FIFRA section 3 and for the seed crop in question.

[98] Similarly, "intended for use or used in the manner specified" as used in the introduction to 40 C.F.R. § 152.25 and as applied to treated articles or substances pursuant to subsection (a) also requires that the intended use and the actual use of the pesticide-treated article or substance be in a manner consistent with any specifications on the registered treating pesticide product or article labeling.

In this regard, the Petition refers to the possibility of other currently registered pesticide products that might be approved in the future for use on seed. However, until those pesticides are registered under FIFRA section 3 for use on the specific seed crop in question, use to treat the specific seed crop would be the use of an unregistered pesticide and thus not "registered for such use" under the treated article exemption.[99] As a result, any seed treated with such a pesticide product is unexempted, unregistered treated seed, and the distribution or sale of such seed is a violation under FIFRA section 12(a)(1)(A).[100] Although not relevant to the issue of whether the treated article exemption applies, as noted in part (1), the risks concerns raised by the Petition in relation to these other currently registered pesticides may be raised in response to any application for the seed treatment use, as noticed in the Federal Register pursuant to FIFRA section 3(c)(4).

As to the second part of this question, instructions on the treating pesticide and treated seed bag tag labeling, not just identification of the specific seed crop, are relevant to whether the treating pesticide product used was registered for "such use" under FIFRA. Relevant labeling instructions might include, for example: (1) instructions on the particular application method or quantity limitations when treating the seed; or (2) instructions relating to labeling of the treated seed prior to its distribution or sale, *e.g.,* printing a seed bag tag with particular instructions on the use of the treated seed and ensuring that the seed bag tag accompanies the treated seed when distributed.[101] 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.[102] In such case, the distribution and sale of the treated seed

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[99] 7 U.S.C. § 136j(a)(1)(A). This use would also be the use of a registered pesticide in a manner inconsistent with its labeling and a violation under FIFRA section 12(a)(2)(G).

[100] For example, use of a pesticide product to treat an article pursuant to a FIFRA section 5 experimental use permit is a permissible but limited use authorization, but it is not a FIFRA section 3 registration and thus seed treated pursuant to an EUP is not exempted from FIFRA requirements under the treated article exemption. Similarly, use of a pesticide product outside of the United States to treat an article intended for import into the United States is use of a pesticide "registered for such use" only if the pesticide product used is one that is registered for the seed treatment use under FIFRA section 3. This is the case even if the pesticide product used includes an ingredient that is registered under FIFRA section 3 for the use in question. Distribution and sale of an article treated with pesticide products not deemed "registered for such use" is the distribution and sale of an unregistered pesticide and a violation under FIFRA section 12(a)(1)(A).

[101] *See*, *e.g.*, Captan Proposed Interim Registration Review Decision, Case Number 0120 (March 2022) found in docket EPA-HQ-OPP-2013-0296 at https://www.regulations.gov/docket/EPA-HQ-OPP-2013-0296.

[102] For example, EPA has required instructions specific to the type of article and use of the article. *See, e.g., In the Matter of Robbins Association/Irrigation-Mart, Inc.*, Docket No. FIFRA-04-2010-3007(b) (Jan. 26, 2010) (CCA-treated tomato stakes were pesticides, not exempted treated articles, because the use of CCA on tomato stakes was not authorized by the pesticide product label); *In the Matter of Free State Lumber Company, Inc.*, Docket No. FIFRA-04-2009-3039(b) (July 9, 2009) (treated wood was not an exempted treated article because the preservative used was not registered for use on dimensional wood to be used on farms); *In the Matter of BMT Commodity Corp.*, Docket No. FIFRA-05-2008-0017 (June 5, 2008) (unregistered use of copper sulfate as the active ingredient for incorporation into burlap, jute or Hessian cloth made any such treated material an unexempted pesticide requiring registration); *In the Matter of Freeman & Patrick Wood Products, L.L.C.*, Docket No. FIFRA-04-2006-3016(b) (June 7, 2006) (CCA treated wood did not qualify as an exempted treated article because the preservative was not

would be distribution and sale of an unregistered pesticide product, enforceable under FIFRA section 12(a)(1)(A). Similarly, instructions on the treating pesticide and treated seed bag tag labeling are also relevant to the third part of this question. Relevant labeling instructions in this regard might include, for example, instructions on the permissible use, including method of disposal, of the treated seed and seed bag. The use of the treated seed in a manner inconsistent with instructions on the registered treating pesticide labeling as communicated on the seed bag tag means that the treated article*, i.e.,* the treated seed, does not meet the "registered for such use" criterion and the exemption does not apply to the treated seed. However, EPA agrees with the Petition that it is this misuse of an unregistered pesticide that is not currently enforceable under FIFRA section 12.

FIFRA section 2(ee)(1) provides some further guidance on this issue. It is a violation of FIFRA section 12(a)(2)(G) to use a registered pesticide "in a manner inconsistent with its labeling" and FIFRA section 2(ee) defines this phrase to mean the "use of a pesticide in a manner not permitted by the labeling." While this definition further identifies some exceptions to this general rule, none allow use of a registered pesticide to treat a seed crop unless the pesticide is actually registered for that seed crop use. Thus, as previously noted, unless the seed crop is specifically listed as a registered use of the pesticide, use of the registered pesticide on the seed crop is a violation of FIFRA section 12(a)(2)(G). The exception at FIFRA section 2(ee)(1), however, clarifies that use of a registered pesticide product in a lesser dose, concentration, or frequency is generally deemed consistent with the labeling instructions on the treating pesticide, unless there is some contrary instruction on the labeling. The same would hold true with use of the treated seed, *i.e.,* that planting the treated seed in a lesser dose, concentration, or frequency is generally deemed consistent with the labeling instructions unless there is some contrary instruction on the labeling. In contrast, use of the treating pesticide product or use of the treated seed in greater dose, concentration, or frequency than provided on the treating pesticide or seed bag tag labeling would not be consistent with the instructions in the labeling for that use. Thus, for example, if the treating pesticide and thus the seed bag tag labeling include instructions on the interval for planting of a treated seed, *e.g.,* to reduce the potential for injury to bees, then any planting outside that interval that would lead to a greater dose, concentration or frequency, would be inconsistent with the instructions on the registered pesticide and seed bag tag labeling and thus not "registered for such use" under the treated article exemption.

In sum and as discussed further in the next section of this response, EPA agrees with the Petition that clear and complete labeling on the treating pesticide and seed bag tags is critical so that farmers are aware of the appropriate use of the treated seed, but disagrees with the Petition claims that no labeling in relation to pesticide-treated seed is required or enforceable simply because the regulatory text of the treated article exemption might be read to cover pesticide-treated seed product. Thus, EPA also disagrees with the Petition claim that this interpretation of the treated article exemption "misuses its labeling authority." Finally, EPA also disagrees with the Petition conclusion that any issues or concerns with labeling of a particular product or type of

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registered for use on dimensional wood to be used as skirt boards); and *In the Matter of Cook County Wood Preserving, Inc.*, Docket No. FIFRA-04-2006-3033(B) (Sept. 20, 2006) (treated wood was not an exempted treated article because preservative was not registered for use on dimensional wood to construct poultry houses and trailers that would haul animals).

product alone merits an interpretation or amendment to the treated article exemption to broadly preclude covering pesticide-treated seed. As noted in part (1) of this section, whether a condition applies is a product specific inquiry; the outcome of such a product specific inquiry does not provide a basis for a wholesale change in the interpretation of the exemption or an amendment to the exemption. Issues specific to the request for registration of treated seed and enforcement of treating pesticide and seed bag tag labeling relating to the use of the treated seed are addressed in the next section below.

## D. Registration of Treated Seed and Enforcement Claims

Summary of Petition: As noted above, the Petition states that it is the farmers who need and desire "clear label warnings and strong directions in order to protect their own surrounding environment" and that EPA's current labeling framework for treated seeds is inadequate to provide this information to farmers sufficient "to ensure that FIFRA's safety standards will be met during the actual use of the pesticidal seeds in the environment." Petition at 29-30.

Furthermore, the Petition takes the position that EPA's assessment of the labeling of seed is inadequate and unenforceable. Specifically, the Petition states that "EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values." However, "[w]hile these amount to admissions of the seeds' pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions." Petition at 29 citing as an example, EPA, Sulfoxaflor—Final Cancellation Order, dated Nov. 12, 2015, p.2, at https://www.epa.gov/sites/production/files/2015-11/documents/final_cancellation_order-sulfoxaflor.pdf.

Even if enforceable, the Petition states that "the seed bag or tag language is utterly inadequate to reduce or mitigate the harm caused by contaminated neonicotinoid dust and talc, or the grown plants themselves, to honeybees—including those owned by the Beekeeper Petitioners. Further, the bag labels are inadequate to protect against the vast spectrum of other environmental and economic impacts, including, but not limited to, damage to soil health, harm to ESA-protected species and the extensive water contamination described above." Petition at 29.

For support, the Petition refers to beekeeper statements that

> "the exemption of toxic dust coming off of the neonicotinoid-coated corn seeds means there are no legal consequences for the seed coaters or pesticide manufacturers whose chemicals killed our bees. Neither the state enforcement agents nor EPA's enforcement agents will take any action to stop or mitigate the harms. There are no enforceable labels on the seed bags that the farmer must follow to not cause dust-off that will kill honeybees. My direct experience is that whatever language EPA asks to be put on those seed bags is inadequate to protect bees. From my perspective, my right as a beekeeper to obtain pesticide law enforcement for such dust-off kills has become non-existent. That reduces not only my ability to protect my valuable livestock, but also my ability to make any civil or other claim that I might seek to bring

against those in the chain of production and use of these pesticides." Petition at 29-30.

It is for these and other reasons that the Petition requests EPA either to interpret the treated article exemption not to apply to seed treated with systemic pesticides or to amend the exemption to exclude seed treated with systemic pesticides, and in either case to require registration of such treated seed under FIFRA and to aggressively enforce FIFRA's registration and labeling requirements for each separate seed product treated with systemic pesticides.

Summary of Comments: Comments supporting the Petition generally agree that treated seeds should be registered along with the seed treatment products (0021, 0024, 0027, 0040, 0052, 0069, 0077, 0097). These claims are concerned that seeds treated with pesticides are currently unregulated and that more information is needed to fully understand the effects they have on the environment (0024, 0027, 0040, 0069, 0077, 0097). Some comments agree with the Petitioner that registering treated seeds would allow for oversight as a regulated pesticide. One comment (0097) specifically notes that requiring "registration and labeling of seeds treated with pesticides pursuant to FIFRA would allow for oversight as a regulated pesticide." The comment notes that "treated seed labels include cautions and directions on the bag of seed as mandated by the label of the FIFRA-registered pesticide used to treat the seeds" but that "the resulting seed product label is unenforceable under FIFRA and State pesticide laws" and raised concerns that "when seeds are not handled and used in accordance with the label directions there is a greater likelihood of harm to the surrounding environment or wildlife. Where treated wood, paints, or plastics have specific structural or domestic uses, a treated seed intended for planting, when left exposed or otherwise misused, is readily accessed and ingested by wildlife as food. [The New Jersey Department of Environmental Protection] experienced a case of substantiated harm to wildlife when pesticide-treated seeds, not entirely incorporated into the soil as directed on the label, were eaten and resulted in the death of over 100 red-wing blackbirds. The exemption for treated seeds precluded [The New Jersey Department of Environmental Protection] from citing or enforcing for misuse or environmental harm/damages" (0097).

Comments opposing the Petition claim that bags of treated seeds are already tagged with treatment information and associated restrictions (0014, 0047, 0051, 0068, 0071, 0081, 0086). One comment (0060) notes that the Petition wrongly asserts that the treated article exemption "limits EPA's enforcement capabilities, including with respect to the enforceability of label language on seed tags or seed bags." That comment notes that the Petition concedes that "EPA requires labels to be placed onto the bags or containers, or onto the affixed tags, of the unregistered pesticidal seeds." The comment states that Petitioners ignore that the seed bag or tag label language is imposed by EPA on a product-by-product basis as part of the registration of the seed treatment pesticide products under FIFRA and required as a condition of registration—including for the fifteen products specifically identified in the Petition" and that "registrants have an affirmative obligation under FIFRA to report to EPA incidents involving harm or potential harm to pollinators," including a requirement for an "accelerated ten-day requirement for submitting such reports." Finally, the comment notes that labeling issues "are more effectively addressed within the context of a particular registration decision and the scientific review and assessment conducted by EPA's expert scientists in connection with that decision," including with respect to addressing dust-off concerns.

According to numerous comments, registration of treated seed would lead to increased use of foliar applications and thus increased use of the pesticides (0032, 0034, 0035, 0037, 0041, 0045, 0062, 0064, 0073, 0088). With this switch to increase foliar application can be a switch to more harmful alternatives including restricted use pesticides (RUPs) (0049). Similar other comments claim that the exemption is necessary for tailoring seed treatments to local needs which is important to take advantage of the regional benefits provided by seed treatment (0011, 0031, 0043, 0047, 0064, 0068, 0071, 0085, 0086). These comments generally take the position that as a result of the above benefits, seed treatment is essential, but that, because EPA's assessment on the treating pesticide comprehensively assesses the human health and environmental consequences with use of treated seed, there is little benefit and great cost with requiring the registration of treated seed. Specifically, comments state that removing the opportunity for treated seed to be exempt under the treated article exemption and thus requiring registration for "each and every treated seed product would create enormous new burdens on the Agency, state regulatory bodies, farmers, and the regulated pesticide industry" (0011, 0026, 0028, 0031, 0034, 0043, 0045, 0047, 0049, 0050, 0051,0053, 0054, 0055, 0059, 0060, 0061, 0062, 0064, 0068, 0071, 0072, 0073, 0075, 0079, 0081, 0085, 0086, 0087, 0088, 0091, 0092, 0093). One comment (0060) notes that "each and every seed treatment pesticide and seed combination—of which there are hundreds, if not thousands—would need to be registered individually" which raises the question of whether "agricultural retailers, seed processing facilities, and some farms that apply seed treatments might be required to register with EPA as pesticide manufacturing facilities under FIFRA." That comment also points out that reporting and recordkeeping requirements applicable to FIFRA registered pesticides "would draw time and resources away from farming operations that are currently operating on slim or negative margins." For example, other comments point out that processing costs would increase (0049), existing stock could be stopped from being sold and leave a segment of time when treated seeds are wholly unavailable (0051, 0071), and registration would trigger separate state regulatory requirements (0068, 0071, 0085, 0086) all of which would increase costs for growers. These comments generally note that this would be done without any substantive benefits to health or safety, which are already comprehensively addressed through EPA's review of the seed treatment pesticide products and that registration of the treated seed would be duplicative of that effort.

EPA Response: EPA agrees with the Petition and comments that where the treating pesticide labeling includes instructions about how the treated seed may or may not be distributed, sold, or used, persons intending to distribute, sell, or use the treated seed need to know what those instructions are and need to communicate those instructions to any other downstream distributors, sellers, or users of the treated seed. EPA also agrees that farmers are often the "users" who need and desire clear labeling instructions for each separate crop seed product that are consistent with the instructions in treating pesticide labeling. As the Petition and comments reflect, the seed bag tag labeling is the primary means by which instructions are communicated to downstream distributors, sellers, and users of the treated seed.[103] In this regard, EPA is

[103] While some recent state actions regulating neonicotinoid pesticides and neonicotinoid treated seed are examples of state concerns with adequacy of seed bag tag labeling and use of seed treated with systemic pesticides, EPA does not have information indicating that farmers are misusing treated seed. *See* N.J. STAT. ANN. § 13:1F-4.3 (classifying neonicotinoid pesticides as restricted use); MD CODE ANN., AGRIC. § 5-2A-02 (restricting sales and use of neonicotinoid pesticide); VT STAT. ANN. tit. 6 § 1105a (requiring adoption by rule of best management practices for the use of neonicotinoid treated article seeds); WASH. REV. CODE ANN. § 17.21.445 (requiring state department of

reviewing and will continue to review labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review to verify the clarity and completeness of these instructions for both use of the treating pesticide and the distribution, sale, and use of the treated seed. EPA intends to ensure that treating pesticide labeling instructions to the user of the treating pesticide include, for example, (1) the requirement that seed bag tag labeling accompany the treated seed when distributed and sold; and (2) that such labeling include adequate use, storage, and disposal instructions and that the distribution or sale of the treated seed in a manner inconsistent with those instructions is the distribution or sale of an unregistered pesticide. As noted in the previous section, seed that is not labeled or that is improperly labeled pursuant to the instructions on the treating pesticide labeling is not an exempted treated article because the seed is not labeled consistent with the treating pesticide labeling instructions and thus the seed is not treated with a pesticide "registered for such use." In such case, because the unlabeled or improperly labeled pesticide-treated seed is not exempt from FIFRA requirements, any distribution or sale of such unregistered and unexempted treated seed would constitute an enforceable violation under FIFRA section 12(a)(1)(A). Thus, EPA does not agree with the Petition that these labeling instructions are "sparse warnings superficially aimed at protecting pollinators and other environmental values."

EPA disagrees with the Petition claim that instructions on the treating pesticide labeling, which are based on EPA's assessment of exposures and risks and relating to permissible distribution, sale, and use of the pesticide-treated seed, are inherently inadequate to ensure proper use of the treated seed. EPA has no evidence to suggest that labeling instructions on the treating pesticide labels or seed bag tags are generally being ignored by the user of the treating pesticide or the treated seed. However, EPA intends to work with states and other federal agencies to seek additional information on whether or to what extent pesticide-treated seed is being distributed, sold, or used in a manner inconsistent with treating pesticide labeling instructions for each separate crop seed product and will consider actions appropriate to the circumstances, which might include enforcement where there is a FIFRA violation or administrative action on the treating pesticide, *e.g.,* to clarify labeling or reduce use of the treating pesticide. Further, because EPA acknowledges that FIFRA section 12 does not make it a violation to use an unregistered pesticide, EPA also intends to issue an ANPRM to seek, for example, additional information on use of treated seed and to explore the possibility of a FIFRA section 3(a) rule to regulate treated seeds and allow clear enforcement of any misuse of such treated seed. 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

agriculture to develop recommendations and measures to mitigate risks of harm to bees from use of neonicotinoid pesticides and treated seed). Other states directly regulate the use and disposal of treated seed. *See* NEB. REV. STAT. ANN. § 66-1351 (generally prohibiting the use of treated seeds in ethanol production); WIS. ADMIN. CODE ATCP § 29.57 (regulating planting, prohibiting certain uses, and regulating disposal of treated seed); WYO. CODE R. 010.0005.28 § 12 (regulating use of treated seed in minor crop production). While EPA will be reviewing these labeling issues in the course of registration and registration review of the treating pesticides, EPA will coordinate further with USDA and states on this matter.

to prevent unreasonable adverse effects on the environment."[104] Any rule finalized under section 3(a) of FIFRA would be enforceable under FIFRA section 12(a)(2)(S). While EPA acknowledges that it could readily enforce the misuse of pesticide-treated seed if the seed were already required to be registered as a pesticide under FIFRA, a FIFRA section 3(a) rule may address the concerns raised by the Petition relating to enforcement, without the potential for the significant costs summarized below to the seed treatment industry, farmers, and EPA with registration of treated seed.

EPA agrees with certain comments that the impact with creating a registration program for each pesticide-treated seed crop would likely result in increased cost and complexity to stakeholders. For example, EPA is concerned that granting the Petition request to register all seed treated with systemic pesticide would require:

- Registration of all seed treated with systemic pesticides, including every treatment combination and possibly even seed varietals. For example, any change to the active ingredients or even proportion of active ingredients in a product would need a new registration for commercial seed treatment facilities.
- Registration of agricultural retailers, seed processing facilities, and some farms that apply seed treatments as registered establishments. For example, because agricultural retailers, seed processing facilities, and on farm treatment would be producing pesticides, *i.e.,* the treated seed, and those pesticides are intended for sale or distribution, those entities would be subject to requirements for establishments, *e.g.,* requiring an establishment number and submission of production reports to the EPA annually.
- Amending existing registrations of treating pesticides to preclude use of the registered pesticide unless the resulting treated seed is covered by a FIFRA section 3 registration.

The likely result would be: (1) a significant transition cost to farmers, during which availability of treated seed will be limited; (2) reduced flexibility to farmers to treat seed on the farm to tailor treatments to specific needs; (3) termination of tank mixing at commercial seed treatment facilities, which would eliminate the flexibility of tank mixing according to farmers' requests; and (4) increased costs to seed producers. However, this increased cost and complexity would not change how EPA assesses the risks or determines appropriate mitigation for pesticides used to treat seeds or use of the treated seed.

Finally, granting the Petition request to compel registration of pesticide-treated seed where the conditions for the exemption are met would require amending the treated article exemption regulatory text, as requested by the Petition, to exclude all or some pesticide-treated seed from the scope of the exemption. Such rulemaking, and the process of creating a registration program for pesticide-treated seed, would be time consuming and with little benefit given EPA assessments fully address exposures and risks from use of treating pesticides and the pesticide-treated seed. EPA does not, as a result, believe such an effort is more beneficial or more efficient than an ANPRM to seek the needed information to determine whether or to what extent

[104] On August 31, 2022, EPA received a letter from the 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.

pesticide-treated seed is being distributed, sold, or used in a manner inconsistent with instructions for each separate seed crop and to explore the option of a FIFRA section 3(a) rule to address any enforcement concerns raised.

## V. Conclusion

The Petition claims that EPA fails to fully assess the adverse effects of seed treatment pesticides generally and in particular those that have systemic properties, specifically those listed in Table 1 of the Petition. However, EPA explains in the above responses why its assessment of these pesticides is thorough and that such concerns can and are being addressed in the context of registration and registration review actions. Specifically, the human health and ecological risk assessments for each pesticide identified in the Petition consider all exposure scenarios and make appropriate estimates of exposures, and therefore fully assess human health and ecological risks. These assessments have been announced for public comment, including more recent public comment opportunities in the registration review process. Moreover, EPA has recently issued BEs and initiated formal consultation for these pesticides, to comply with ESA requirements, and has sought additional public comments on those assessments. Finally, EPA is planning to work with the registrants to identify appropriate mitigation to avoid adverse effects estimated by the BE. In addition to the thorough assessment, the Agency believes that the seed treatments provide benefits including reducing the use of other pesticides that may have more harmful effects, preserving crop quality, and preventing pest damage.

The Petition claims that EPA incorrectly exempts treated seeds under the treated article exemption. As explained above, an "article" or "substance" that is a pesticide is exempt under 40 C.F.R. § 152.25(a) if the two conditions for the exemption are met. Those conditions are (1) that the pesticide used to treat the article or substance is used to protect the article or substance itself and (2) that the treating pesticide is registered for such use. EPA reads the first criterion to be met if pesticide-treated seed is treated to protect the seed and what the seed becomes. The pesticides identified by the Petition all have claims for protection of the seed in addition to the seedling, and none include claims unrelated to protection of the seed or what the seed becomes. While EPA does not typically require verification of protection claims, EPA may require submission of data to support claims such as those related to seed treatment. EPA reads the second criterion to be met if the pesticide-treated seed is treated with a pesticide that is registered under FIFRA section 3 for use on the particular seed crop, if that pesticide is used consistent with labeling instructions for use on seed, and if the pesticide-treated seed is distributed, sold, and used consistent with the treating pesticide labeling instructions. Thus, EPA disagrees with the Petition claims that pesticide-treated seed does not qualify for the exemption if treated with a systemic pesticide, a pesticide for which risk concerns have been raised, or a pesticide that is conditionally registered, if the conditions for the exemption are met. As a result, EPA denies the Petition request to either interpret or amend 40 C.F.R. § 152.25(a) to categorically exclude seed treated with systemic pesticides from exemption under that provision. However, as to the Petition request relating to enforcement matters, EPA intends to work with the States and other federal agencies to determine whether or to what extent pesticide-treated seed is being distributed, sold, or used in a manner inconsistent with treating pesticide labeling and will pursue enforcement as appropriate. In addition, EPA intends to issue an ANPRM seeking comment on issues raised in this response such as labeling claims and use and usage data for treated seeds.

The ANPRM will also explore the option of issuing a FIFRA section 3(a) rule to regulate pesticide-treated seed under FIFRA section 3(a) to ensure distribution, sale, and use of the treated seed is consistent with treating pesticide and treated seed labeling. EPA believes that such a rule could be a more efficient and less resource intensive means to address some of the concerns raised in the petition than the solutions requested by the Petition.

## Appendix A: Comments and Commenters

| Comment Number | Commenter |
|---|---|
| 0003 | Anonymous |
| 0004 | Anonymous |
| 0005 | Tyler Hydrick |
| 0006 | Anonymous |
| 0007 | Germains Seed Technology |
| 0008 | Florida Fruit and Vegetable Association (FFVA) |
| 0009 | Anonymous |
| 0010 | Anonymous |
| 0011 | Gerard Denny |
| 0012 | Anonymous |
| 0013 | Anonymous |
| 0014 | Anonymous |
| 0015 | Anonymous |
| 0016 | Don Parker |
| 0017 | Anonymous |
| 0018 | Anonymous |
| 0019 | Anonymous |
| 0020 | Anonymous |
| 0021 | Anonymous |
| 0022 | Anonymous |
| 0023 | Heartland Beekeeping Partnership |
| 0024 | Pollinator Stewardship Council |
| 0025 | Beet Sugar Development Foundation |
| 0026 | Oklahoma Cotton Council |
| 0027 | Beyond Pesticides |
| 0028 | Alabama Cotton Commission |
| 0029 | Florida Fertilizer & Agrichemical Association |
| 0030 | American Sugarbeet Growers Association |
| 0031 | National Barley Growers Association |
| 0032 | U.S. Canola Association |
| 0033 | South Texas Cotton & Grain Association |
| 0034 | Plains Cotton Growers |
| 0035 | Agricultural Council of Arkansas |
| 0036 | DuPont Crop Protection |
| 0037 | General Manager of Grimmway Farms |
| 0038 | Anonymous |
| 0039 | Virginia Agribusiness Council |
| 0040 | Anonymous |
| 0041 | National Sorghum Producers |
| 0042 | American Farm Bureau Federation |
| 0043 | National Council of Farmer Cooperatives (NCFC) |
| 0044 | Texas Farm Bureau |
| 0045 | National Cotton Council of America |
| 0046 | California Cotton Ginners and Growers Association |
| 0047 | Amalgamated Sugar |
| 0049 | American Crystal Sugar Company |
| 0050 | North Carolina Agribusiness Council |
| 0051 | Agricultural Retailers Association (ARA) |
| 0052 | Anonymous |
| 0053 | New York Farm Bureau |
| 0054 | Delta Council |

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| 0055 | Mississippi Farm Bureau Federation |
| 0056 | National Sunflower Association |
| 0057 | AgriGrowth |
| 0058 | American Soybean Association (ASA) |
| 0059 | National Corn Growers Association |
| 0060 | Crop Life America, American Seed Trade Association, Biological Products Industry Alliance |
| 0061 | Alabama Farmers Federation |
| 0062 | North Carolina Farm Bureau Federation |
| 0064 | Helena Agri-Enterprises, LLC |
| 0066 | Arkansas Farm Bureau Federation |
| 0067 | Pennsylvania Farm Bureau |
| 0068 | Pesticide Policy Coalition |
| 0069 | Center for Biological Diversity |
| 0070 | National Cotton Ginners Association |
| 0071 | National Association of Wheat Growers (NAWG) |
| 0072 | Nutrien |
| 0073 | Oklahoma Farm Bureau |
| 0074 | USDA |
| 0075 | Louisiana Farm Bureau |
| 0076 | Arizona Farm Bureau Federation |
| 0077 | Christopher Lish |
| 0078 | Betaseed Incorporated |
| 0079 | Syngenta |
| 0080 | National Onion Association |
| 0081 | USA Rice |
| 0083 | NY Attorney General |
| 0084 | Anonymous |
| 0085 | Georgia Fruit and Vegetable Growers Association |
| 0086 | Oregonians for Food and Shelter, Oregon Farm Bureau, Oregon Wheat, Oregon Seed Council |
| 0087 | Rolling Plains Cotton Growers (RPCG) |
| 0088 | The National Cotton Council |
| 0089 | Mid -South Entomologist Working Group |
| 0091 | National Potato Council |
| 0092 | Minor Crop Farmer Alliance |
| 0093 | Southern Cotton Growers, Inc. |
| 0094 | CFS |
| 0095 | CFS |
| 0097 | New Jersey Department of Environmental Protection |
| 0098 | CFS |
| 0099 | CFS |
| 0100 | CFS |
| 0101 | CFS |
| 0103 | CFS |
| 0048 | Amalgamated Sugar (Repeat) |
| 0063 | Agricultural Retailers Association (ARA) (Repeated) |
| 0065 | National Cotton Council of America (Repeated) |
| 0082 | Agricultural Retailers Association (ARA) (Repeated) |
| 0090 | National Onion Association (Repeated) |
| 0096 | Minor Crop Farmer Alliance (Repeated) |
| 0102 | List of Petition signatures |

## Appendix B: CFS Comment Attachments

| Comment Number | Title | Publication Year |
|---|---|---|
| 0095 | Assessment of acute sublethal effects of clothianidin on motor function of honeybee workers using video-tracking analysis | 2018 |
| | A systemic problem with pesticides | 2018 |
| | Effects of a pyrethroid and two neonicotinoid insecticides on population dynamics of key pests of soybean and abundance of their natural enemies | 2017 |
| | Neonicotinoid insecticides negatively affect performance measures of non-target terrestrial arthropods: a meta-analysis | N/A |
| | Application of the combination index (CI)-isobologram equation to research the toxicological interactions of clothianidin, thiamethoxam, and dinotefuran in honeybee, Apis mellifera | 2017 |
| | Seed-dressing systemic insecticides and honeybees | N/A |
| | Widespread use and frequent detection of neonicotinoid insecticides in wetlands of Canada's prairie pothole region | 2014 |
| | Field evidence of bird poisonings by imidacloprid-treated seeds: a review of incidents reported by the French SAGIR network from 1995 to 2014 | 2016 |
| | High pesticide risk to honey bees despite low focal crop pollen collection during pollination of a mass blooming crop | 2017 |
| | Effects of clothianidin on aquatic communities: Evaluating the impacts of lethal and sublethal exposure to neonicotinoids | 2017 |
| | The impact of the nation's most widely used insecticides on birds | 2013 |
| | Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review | 2014 |
| | Occurrence of neonicotinoids in guttation liquid of maize – soil mobility and cross-contamination | 2017 |
| | A worldwide survey of neonicotinoids in honey | 2017 |
| | Pesticide-laden dust emission and drift from treated seeds during seed drilling: a review | 2013 |
| | Complex mixtures of dissolved pesticides show potential aquatic toxicity in a synoptic study of Midwestern U.S. streams | 2017 |
| | Crop pollination exposes honey bees to pesticides which alters their susceptibility to the gut pathogen Nosema ceranae | 2013 |
| | An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 2: impacts on organisms and ecosystems | 2017 |
| | Transport of a neonicotinoid pesticide, thiamethoxam, from artificial seed coatings | 2017 |
| | Supplementary materials for "A worldwide survey of neonicotinoids in honey" (EPA-HQ-OPP-2018-0805-0095_Attachment13 above) | 2017 |
| 0098 | Human exposure to neonicotinoid insecticides and the evaluation of their potential toxicity: An overview | 2017 |
| | Sublethal effects of the neonicotinoid insecticide thiamethoxam on the transcriptome of the honey bees (Hymenoptera: Apidae) | 2017 |
| | Worldwide decline of the entomofauna: A review of its drivers | 2019 |
| | Systemic insecticides (neonicotinoids and fipronil): trends, uses, mode of action and metabolites | 2014 |
| | Current pesticide risk assessment protocols do not adequately address differences between honey bees (Apis mellifera) and bumble bees (Bombus spp.) | 2016 |
| | Assessment of the environmental exposure of honeybees to particulate matter containing neonicotinoid insecticides coming from corn coated seeds | 2012 |
| | Sulfoxaflor exposure reduces bumblebee reproductive success | 2018 |
| | Neonicotinoid seed treatments: limitations and compatibility with integrated pest management | 2017 |
| | Call to restrict neonicotinoids | 2018 |
| | Declines in insectivorous birds are associated with high neonicotinoid concentrations | 2014 |
| | First evidence found of popular farm pesticides in drinking water | N/A |

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|---|---|---|
| | PowerPoint slides summarizing the findings of various studies | N/A |
| | Synergistic effects of pathogen and pesticide exposure on honey bee (Apis mellifera) survival and immunity | N/A |
| | Beyond the Birds and the Bees: Effects of neonicotinoid insecticides on agriculturally important beneficial invertebrates | 2013 |
| | Long-term yield trends of insect-pollinated crops vary regionally and are linked to neonicotinoid use, landscape complexity, and availability of pollinators | 2017 |
| | Part-per-trillion LC-MS/MS determination of neonicotinoids in small volumes of songbird plasma | 2018 |
| | How neonicotinoids can kill bees: the science behind the role these insecticides play in harming bees | 2016 |
| | Exposure of native bees foraging in an agricultural landscape to current-use pesticides | 2015 |
| | Widespread occurrence of neonicotinoid insecticides in streams in a high corn and soybean producing region, USA | 2014 |
| | Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA | 2018 |
| 0099 | Quantification of imidacloprid uptake in maize crops | 2005 |
| | Widespread detections of neonicotinoid contaminants in central Wisconsin groundwater | 2018 |
| | Effects of neonicotinoid insecticides on physiology and reproductive characteristics of captive female and fawn whitetailed deer | 2019 |
| | Bees May Be Getting Addicted to the Pesticides Many Blame for Their Decline | 2018 |
| | Environmental fate of soil applied neonicotinoid insecticides in an irrigated potato agroecosystem | 2014 |
| | Occurrence of neonicotinoid insecticides in finished drinking water and fate during drinking water treatment | 2017 |
| | Bee friendly' pesticide cuts colonies by half, study finds | N/A |
| | Intersections between neonicotinoid seed treatments and honey bees | 2015 |
| | Multiple routes of pesticide exposure for honey bees living near agricultural fields | 2012 |
| | Overview of the status and global strategy for neonicotinoids | 2010 |
| | Planting of neonicotinoid-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit | 2017 |
| | General and species-specific impacts of a neonicotinoid insecticide on the ovary development and feeding of wild bumblebee queens | 2017 |
| | Insecticide resistance signals negative consequences of widespread neonicotinoid use on multiple field crops in the U.S. cotton belt | 2018 |
| | Neonicotinoids and water: Nature drowned in pesticides | N/A |
| | Neonicotinoids thiamethoxam and clothianidin adversely affect the colonisation of invertebrate populations in aquatic microcosms | 2018 |
| | Neonicotinoids in bees: a review on concentrations, side-effects and risk assessment | 2012 |
| | Nanostructural and mechanical property changes to spider silk as a consequence of insecticide exposure | 2017 |
| | Hummingbirds and bumble bees exposed to neonicotinoid and organophosphate insecticides in the Fraser Valley, British Columbia, Canada | 2018 |
| | Chronic sublethal stress causes bee colony failure | 2013 |
| | Immunosuppression in honeybee queens by the neonicotinoids thiacloprid and clothianidin | 2017 |
| 0100 | The neonicotinoid insecticide thiacloprid impacts upon bumblebee colony development under field conditions | 2017 |
| | Peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules | 2018 |
| | First evidence of neonicotinoid residues in a long-distance migratory raptor, the European honey buzzard (Pernis apivorus) | 2018 |
| | Effects of neonicotinoid pesticides on promoter-specific aromatase (CYP19) expression in Hs578t breast cancer cells and the role of the VEGF pathway | 2018 |
| | Scientists find widely used pesticides in Ontario wild turkeys | 2018 |

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| | Caste- and pesticide-specific effects of neonicotinoid pesticide exposure on gene expression in bumblebees | 2019 |
| | Imidacloprid and chlorpyrifos insecticides impair migratory ability in a seed-eating songbird | 2017 |
| | The combined effects of a monotonous diet and exposure to thiamethoxam on the performance of bumblebee micro-colonies | 2017 |
| | A case for comprehensive analyses demonstrated by evaluating the yield benefits of neonicotinoid seed treatment in maize (Zea mays L.) | 2017 |
| | Large-scale deployment of seed treatments has driven rapid increase in use of neonicotinoid insecticides and preemptive pest management in U.S. field crops | 2015 |
| | Neonicotinoid insecticide travels through a soil food chain, disrupting biological control of non-target pests and decreasing soya bean yield | 2014 |
| | Peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules | 2018 |
| | Pesticides found to affect bees' genes | 2019 |
| | Common pesticide can make migrating birds lose their way, research shows | 2017 |
| | A review of the direct and indirect effects of neonicotinoids and fipronil on vertebrate wildlife | 2014 |
| | An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 1: new molecules, metabolism, fate, and transport | 2017 |
| | Pesticides, including neonicotinoids, in drained wetlands of Iowa's prairie pothole region | 2016 |
| | An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 3: alternatives to systemic insecticides | 2018 |
| | Peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering the uses as seed treatments and granules | 2018 |
| | Can the exposure of Apis mellifera (Hymenoptera, Apiadae) larvae to a field concentration of thiamethoxam affect newly emerged bees? | 2017 |
| 0101 | Larval exposure to the neonicotinoid imidacloprid impacts adult size in the farmland butterfly Pieris brassicae | 2018 |
| | Gene expression changes in honey bees induced by sublethal imidacloprid exposure during the larval stage (and supplementary data) | 2017 |
| | Impaired associative learning after chronic exposure to pesticides in young adult honey bees | 2018 |
| | An overview of the environmental risks posed by neonicotinoid insecticides | 2013 |
| | Assessment of acute sublethal effects of clothianidin on motor function of honeybee workers using video-tracking analysis | 2018 |
| | Chronic contact with realistic soil concentrations of imidacloprid affects the mass, immature development speed, and adult longevity of solitary bees | 2019 |
| | Study disputes popular pesticides' effectiveness | 2018 |
| | Effects of neonicotinoids on bees: an invalid experiment | 2017 |
| | Neonicotinoids act like endocrine disrupting chemicals in newly emerged bees and winter bees | 2017 |
| | Neonicotinoid pesticides and nutritional stress synergistically reduce survival in honey bees | 2017 |
| | A common neonicotinoid pesticide, thiamethoxam, alters honey bee activity, motor functions, and movement to light | 2017 |
| | Chronic exposure to neonicotinoids reduces honey bee health near corn crops | 2017 |
| | Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning | 2014 |
| | Neonicotinoid pesticide limits improvement in buzz pollination by bumblebees | 2017 |
| | Potential human exposures to neonicotinoid insecticides: A review | 2018 |
| 0103 | A neonicotinoid insecticide reduces fueling and delays migration in songbirds | 2019 |

## Appendix C: List of Documents Supporting the Neonicotinoid Registration Review

### Human Health Risk Assessments

- Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment. October 30, 2019.
- Imidacloprid. Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments. February 11, 2019.
- Thiamethoxam. Response to Comments on the Thiamethoxam Draft Risk Assessments for Registration Review. November 12, 2019.

### Ecological Risk Assessments

- Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. January 14, 2020.
- Final Bee Risk Assessment to Support the Registration Review of Imidacloprid. January 14, 2020.
- Attachment 1. Tier II Method for Assessing Combined Nectar and Pollen Exposure to Honey Bee Colonies. January 14, 2020.
- Attachment 2. Residue Bridging Analysis for Foliar and Soil Agricultural Uses of Neonicotinoids. January 14, 2020.
- Attachment 3. Residue Bridging Analysis for Foliar and Soil Non-Agricultural Uses of Neonicotinoids. January 14, 2020.
- Attachment 4. Residue Bridging Analysis for Seed Treatment Uses of Neonicotinoids. January 14, 2020.
- EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran). January 6, 2020.
- Clothianidin Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments. January 8, 2020.
- Imidacloprid: Response to Public Comments Related to the Preliminary Risk Assessments and Addendum to the Non-Pollinator Risk Assessments in Support of Registration Review (Docket No. EPA-HQ-OPP-2008-0844). January 8, 2020.
- Thiamethoxam: Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments. January 6, 2020.
- Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoid using Raby et. al. (2018) toxicity data. January 7, 2020.
- Response from the Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments and Benefits Assessments Supporting the Registration Review of the Nitroguanidine-substituted Neonicotinoid Insecticides. January 16, 2020.
- Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid. December 22, 2016.

- Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review. November 27, 2017.
- Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review. November 29, 2017

**Proposed Interim Decisions**

- Clothianidin and Thiamethoxam Proposed Interim Registration Review Decision, Case Numbers 7620 and 7614 (Docket No. EPA-HQ-OPP-2011-0865-1190). January 22, 2020.
- Imidacloprid Proposed Interim Registration Review Decision, Case Number 7605 (Docket No. EPA-HQ-OPP-2008-0844-1619). January 22, 2020.

**Final Biological Evaluations**

- Final National Level Listed Species Biological Evaluation for Clothianidin. June 16, 2022.
- Final National Level Listed Species Biological Evaluation for Imidacloprid. June 16, 2022.
- Final National Level Listed Species Biological Evaluation for Thiamethoxam. June 16, 2022.
- Response to Public Comments Received on Draft Biological Evaluations for Imidacloprid, Thiamethoxam, and Clothianidin. June 2022.

**Benefits Assessments**

- Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam). December 6, 2019.
- BEAD Response to Comments on Risk Assessments & 2017 Benefit Assessments.
- Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops. August 30, 2018.
- Benefits of Neonicotinoid Insecticide Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit.
- Benefits of Neonicotinoid Insecticide Use in Berries (Strawberry, Caneberry, Cranberry, and Blueberry) and Impacts of Potential Mitigation. December 6, 2019.
- Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation. December 11, 2019.
- Benefits of Neonicotinoid Insecticides Usage in Grapes and Impacts of Potential Mitigation. October 23, 2019.
- Estimate of Area Treated per Day for Insecticides in Poultry Houses and Amount of Clothianidin Handled per Day When Using a Mechanically Pressurized Handgun. July 9, 2019.
- Review of "The Value of Neonicotinoids in North American Agriculture" prepared by AgInfomatics, LLC, for Bayer CropScience L.P., Mitsui Chemicals Agro, Inc., Syngenta Crop Protection, LLC, and Valent U.S.A. LLC. November 4, 2019.

- Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent. December 11, 2019.
- Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments. April 22, 2019.
- Biological and Economic Analysis Division's (BEAD) Response to Comments on the Preliminary Risk Assessments and Benefit Assessments for Citrus, Cotton, Soybean Seed Treatment, and Other Crops Not Assessed for Neonicotinoid Insecticides. December 23, 2019.
- Benefits of Neonicotinoid Seed Treatments to Soybean Production. October 15, 2014.