

Mr. Richard Keigwin  
Director  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW  
Washington, DC 20460

Via Regulations.gov

**Re: CropLife America, American Seed Trade Association, and Biological Products Industry Alliance Comments to the U.S. Environmental Protection Agency on the Treated Seed Petition, Docket ID No. EPA-HQ-OPP-2018-0805, 83 Fed. Reg. 66260 (Dec. 26, 2018)**

Dear Mr. Keigwin:

CropLife America (“CLA”), the American Seed Trade Association (“ASTA”), and the Biological Products Industry Alliance (“BPIA”) appreciate the opportunity to provide these comments to the U.S. Environmental Protection Agency (“EPA” or the “Agency”) on the petition submitted to EPA on April 26, 2017 by various groups challenging EPA’s application of the provisions of 40 C.F.R. § 152.25(a), the Treated Article Exemption, to pesticide-treated seed (the “Petition”). Established in 1933, CLA is a national, private, not-for-profit trade association representing companies that develop and sell crop protection products for agriculture and pest management in the United States. Founded in 1883, ASTA is a voluntary, not-for-profit trade association representing approximately 740 companies that develop, produce, and distribute seeds for use in agriculture in the United States and abroad. BPIA is the leading organization dedicated to fostering the use of biological technology, including biopesticides and biostimulants, and represents over 130 member companies around the world ranging from small, innovative sole proprietors to large, international corporations.

As explained herein, the Petition seeks to impose a regulatory process on agriculture that would entirely duplicate EPA’s existing exercise of its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.*, while having no impact on human health or environmental safety. All pesticides approved for use as seed treatments in the United States are subject to rigorous, scientifically robust review under FIFRA and FFDCA. Moreover, EPA, in partnership with CLA, ASTA, BPIA, their members, and other stakeholders, has taken and continues to take affirmative measures to address pollinator health and other environmental impacts alleged in the Petition. CLA, ASTA, and BPIA respectfully request that EPA deny the Petition.

Following the Introduction (Section I), Section II of these comments provides a general overview of the regulatory framework governing seed treatment pesticides and treated seed. Section III reviews EPA’s comprehensive regulation of seed treatment pesticides under FIFRA, and EPA’s proper exercise of its authority under FIFRA to extend the Treated Article Exemption to treated seed, allowing for efficient, effective regulation of pesticides used to treat seed. As demonstrated below, EPA can and should deny the Petition without reaching the substantive

issues asserted by Petitioners, as those issues are squarely addressed in the context of EPA’s registration determinations and ongoing review of seed treatment pesticide product registrations, and without altering its application of the Treated Article Exemption to treated seed. Nonetheless, for a complete record, Section IV provides a response to each of the substantive claims asserted in the Petition for the record, demonstrating that none find support in the scientific evidence.

## **I. Introduction**

### **A. The Petition**

On April 26, 2017, a group of beekeepers, farmers, and non-governmental organizations (“Petitioners”) submitted the Petition to EPA. The Petition requests that EPA amend or formally re-interpret the Treated Article Exemption, set forth in 40 C.F.R. § 152.25(a), to communicate to regulated entities that the Treated Article Exemption does not apply to seeds that are treated with a pesticide prior to planting. Petitioners thus ask EPA to declare that pesticide-treated *seed* is subject to regulation under FIFRA as a *pesticide*—apart from and in addition to EPA’s existing regulation of the pesticide products applied to treated seed. Petitioners also request that EPA “aggressively” enforce FIFRA’s labeling and other requirements as to treated seed. On December 26, 2018, EPA published a notice seeking public comment on the Petition.

### **B. The Importance of Seed Treatments and Treated Seed to U.S. Agriculture**

Seed treatments and treated seed offer many important benefits to U.S. agriculture. Seed treatments provide a precise mode of applying pesticides, protecting the seed during its most vulnerable developmental stages and before emergence from the soil. This method of protection helps to suppress pathogens, insects, or other pests that threaten seed viability and health from the time the seed enters the soil through its development. Seed treatments help safeguard expensive, high-value, high-quality seed and thus, growers’ seed investments.

Since their introduction decades ago, seed treatments have been rapidly adopted by growers for numerous reasons. In addition to their effectiveness, seed treatments are easy for growers to handle and use, permit earlier and faster planting, allow for precise and low dose applications of pesticides, and provide an economical alternative to traditional soil or broadcast applications. Contrary to Petitioners’ claims that “aggressive marketing” of seed treatment products has resulted in increased insecticide use, Petition at 12, seed treatments *reduce* the overall amount of pesticides used when compared to traditional broadcast sprays. Because of their targeted application, seed treatments also minimize off-target exposure. Seed treatments are also critical components in modern integrated pest management (IPM), enabling growers to control some of their most challenging pests and reduce the likelihood of resistance.

Because seed treatments help control a wide variety of harmful insects, pests, and diseases, they are applied to numerous types of crop seeds planted in the United States, including soybeans, grain, cotton, corn, beets, peanuts, onions, leafy vegetables, rice, and more. Seed treatments have proven remarkably successful in controlling pests and improving plant populations and crop yields. Seed treatments permit more seeds to reach crop maturity, and produce healthier, more abundant crops on the same acreage than those same seeds would

without treatment. For example, an analysis of 1,550 field studies conducted over twenty years shows that neonicotinoid seed treatments provide average yield increases between 3.6 and 71.3 percent in eight major North American crops.<sup>1</sup>

In sum, the rise in use of seed treatment products is a reflection of the efficacy and quality of these products, their importance to the agricultural economy, and their value in meeting growers' needs to better protect their investment.

### **C. CLA, ASTA, and BPIA's Interest in the Petition**

CLA, ASTA, and BPIA have valuable and unique perspectives to offer the Agency as it considers the Petition. CLA's member companies produce, sell, and distribute virtually all of the critical crop protection products and other pesticides registered by EPA under FIFRA. CLA's members own EPA registrations for all of the seed treatment products identified in the Petition, as well as scores of other seed treatment products.

ASTA's members are also key participants in the seed treatment value chain. ASTA's members constitute over 95% of the active seed companies in the United States. Of the \$16–17 billion in annual seed sales by ASTA's members, more than 75% cover seeds that are treated with pesticides. These seed treatments are often applied to seeds by ASTA's members, in accordance with the seed treatments' FIFRA labels. Moreover, ASTA has developed stewardship programs to educate on the correct application methods for seed treatment products.

BPIA is dedicated to fostering the use of biological technology, including biological products used as components of seed treatment programs in agriculture. BPIA's members include companies that develop and sell seed treatment technologies.

CLA, ASTA, and BPIA's members would be impacted directly and significantly by the relief sought in the Petition. CLA's members have invested significant resources to obtain and maintain the registrations, sale, and use of seed treatment pesticides, and rely on revenue from the sale and distribution of these products. CLA's members also participate extensively in EPA's regulatory process for pesticide registrations in bringing new seed treatment pesticides to market. CLA's members have submitted voluminous scientific data, comments, and analysis, and have spent countless hours meeting with EPA and, for some products, scientific advisory panels ("SAPs"), to support EPA's finding that these pesticides and their specific uses as seed treatments meet the legal safety criteria required for pesticide registration. *See infra* Section III. If the treated seed were itself required to be registered as a pesticide, all of these efforts would be needlessly duplicated, at enormous expense to CLA and its members. *See* Order Granting Mot. to Intervene at 7, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. May 13, 2016), ECF No. 62.

ASTA's members similarly invest substantial funds in research, development, and production of new seed products. Relying on the seed treatment registrations issued by EPA and

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<sup>1</sup> *See* AgInfomatics, LLC, *The Value of Neonicotinoids in North American Agriculture*, Executive Summary, at vi (2015), [https://aginformatics.com/uploads/3/4/2/2/34223974/executive\\_summary\\_neonicotinoids.pdf](https://aginformatics.com/uploads/3/4/2/2/34223974/executive_summary_neonicotinoids.pdf).

the continued marketability of their treated seed products, ASTA's members have also invested millions of dollars in research and development of seed treatment equipment and improvements to the seed treatment application process and made additional capital investments in employee and customer training, marketing materials, and packaging. Thus, any action affecting the status of seed treatment registrations, or the availability of treated seed, would significantly and adversely impact ASTA's members, including eliminating jobs. *Id.* at 8. BPIA's members, who are focused on development of products based on naturally derived chemistry and many of whom are also members of CLA and ASTA, would be impacted by the relief sought in the Petition for reasons outlined above.

## **II. Regulatory Framework**

### **A. EPA's Regulation of Pesticides Under FIFRA**

Under FIFRA, EPA conducts effective, rigorous evaluations of every pesticide product marketed, sold, or distributed in the United States, including products used to treat seeds. *See* 7 U.S.C. §§ 136a(c)(5), 136j(a)(1). A FIFRA registration operates as a product-specific license that confers upon the registrant certain legally protectable rights. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) (“A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute.”). To obtain a pesticide registration, an applicant must submit extensive scientific data to EPA to demonstrate that use of the product in accordance with its label will not pose “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits” of the product.<sup>2</sup> 7 U.S.C. § 136(bb). The product label establishes the scope of the registration, and is submitted to and approved by EPA as a core element of every registration. *See, e.g., id.* § 136a(c)(1)(C). Every registered product is required to display an EPA-approved label that enumerates approved uses, applications, and directions for use. Use of a pesticide in a manner inconsistent with that label is unlawful. *Id.* § 136j(a)(2)(G).

In conducting its risk-based determination of whether registration of a pesticide product meets the FIFRA standard, EPA reviews extensive data pertaining to the pesticide's active ingredient as well as formulations and particular uses of the pesticide, including use as a seed treatment. 7 U.S.C. § 136a; 40 C.F.R. §§ 152.100–152.119. EPA's expert scientists also conduct sophisticated risk assessments that identify and analyze potential risks that could be associated with various uses, including risks to beneficial or “non-target” organisms, such as

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<sup>2</sup> FIFRA's implementing regulations describe the types of data and information EPA generally requires to support registration. *See* 40 C.F.R. § 158.1(a). The data requirements for registration “are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.” 40 C.F.R. § 158.130(a). These include specific requirements for data regarding product chemistry, product performance, and the toxicological and ecological effects of the pesticide products. *See* Subpart A, 40 C.F.R. Part 158. The regulations also confer upon EPA significant discretion and flexibility to request additional data, beyond that specifically described in the regulations, as needed to appropriately evaluate a pesticide product's potential to cause “unreasonable adverse effects to man or the environment.” *See, e.g.,* 40 C.F.R. § 158.30(b).

honey bees.<sup>3</sup> Only upon determining that a pesticide use will not have an unreasonable adverse effect on the environment will EPA allow the use. 7 U.S.C. § 136a(c)(5)(C), (D); *see also id.* § 136(bb) (defining “unreasonable adverse effects”). In addition, FIFRA authorizes EPA to conditionally register a pesticide under certain circumstances, such as where certain required data are not yet available. But as with all pesticides, “conditionally” registered products must satisfy FIFRA’s rigorous “no unreasonable adverse effects” standard for registration. *Id.* § 136a(c)(7)(B), (C).

Once a pesticide is registered by EPA, FIFRA requires that EPA conduct reassessments of the data required to support a pesticide registration every fifteen years, known as Registration Review. *Id.* § 136a(g). This periodic review is required to ensure that, as scientific capabilities for assessing risk develop and as policies and pesticide use practices change over time, all registered products continue to meet the statutory standard of “no unreasonable adverse effects.” *Id.* § 136(bb). Pesticide registrants also have an affirmative obligation to report to EPA on an ongoing basis information regarding unreasonable adverse effects of a registered pesticide product. *Id.* § 136d(a)(2). FIFRA additionally provides EPA with ongoing enforcement authority over pesticide registrations and authorizes EPA to issue stop sale, use, or removal orders and to impose civil and criminal penalties for violating FIFRA’s requirements. *See, e.g., id.* §§ 136k, 136l.

Implementing the FIFRA regulatory requirements and registration standard requires EPA to conduct hundreds of complex scientific and regulatory assessments and determinations every year. Over the four-year period from FY 2014 to 2017, EPA issued registration decisions for 105 new conventional pesticide active ingredients and 836 new uses for existing conventional pesticides, while opening 271 registration review dockets and issuing 288 registration review final work plans and 152 registration review decisions.<sup>4</sup> This ongoing volume of assessments shows the Agency’s extensive regulatory and technical expertise and engagement and requires efficient and effective regulatory approaches.

All of the neonicotinoid pesticide products and their individual uses as seed treatments at issue in the Petition have cleared EPA’s robust, science-based registration process under FIFRA and have been found to “perform [their] intended function without unreasonable adverse effects on the environment,” including pollinators. 7 U.S.C. § 136a(c)(5)(C). In addition, EPA regulations generally require that any pesticide product intended for use in treating seeds contain an EPA-approved dye. *See* 40 C.F.R. 153.155(a). The purpose of the dye is to impart an unnatural color to signal to users that the seed has been treated with a pesticide.

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<sup>3</sup> *See* EPA, Overview of Risk Assessment in the Pesticide Program, <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program> (last updated Aug. 31, 2017).

<sup>4</sup> EPA, *Implementing the Pesticide Registration Improvement Act – Fiscal Year 2017* at Appendix A, Table 3, Number of PRIA Actions Completed (March 1, 2018), <https://www.epa.gov/sites/production/files/2018-02/documents/fy17-pria-annualrpt-table3.opp.pdf>; *id.* at Pesticide Reevaluation Programs, [https://www.epa.gov/sites/production/files/2018-03/documents/mf-accomp-reevaluation-fy17-final\\_1.pdf](https://www.epa.gov/sites/production/files/2018-03/documents/mf-accomp-reevaluation-fy17-final_1.pdf).

## **B. Exemption from FIFRA Regulation for “Treated Articles”**

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

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

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

*Id.* Thus, an article will be deemed exempt from regulation under FIFRA as a treated article if the following three conditions are satisfied: (i) the article contains or is treated with a pesticide; (ii) the pesticide is intended to protect the article itself; and (iii) the pesticide is registered for this use. In the examples provided in the regulation, depending on the claims made regarding the sale of the treated paint or the treated wood, EPA would generally consider neither the paint nor the wood a pesticide.

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

## **C. Regulation of Treated Seed Under the Federal Seed Act**

In addition to EPA’s regulation of the pesticides used to treat seeds, treated seed is separately regulated by the United States Department of Agriculture (“USDA”) under the Federal Seed Act (“FSA”), 7 U.S.C. §§ 1551–1611, which regulates the interstate shipment of agricultural and vegetable seeds. Administered by USDA’s Agricultural Marketing Service, the FSA’s implementing regulations set forth labeling and other requirements for treated seed aimed at facilitating uniformity, transparency, and fair competition within the seed trade. *See* 7 C.F.R. Part 201.<sup>5</sup> For example, Section 201.31a(a) of the FSA regulations requires that all treated seed be labeled with the name of the seed treatment product (*e.g.*, “Treated with [pesticide name]”). Section 201.31a(d) requires that labels on seed treated with certain classes of substances bear

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<sup>5</sup> *See also* USDA, *Labeling Requirements for Chemically Treated Seed* (Sept. 2017), <https://www.ams.usda.gov/sites/default/files/media/LabelingRequirementsforChemicallyTreatedSeed.pdf>.

restrictions for use (e.g., “Do not use for food, feed, or oil purposes.”). EPA recommends that these labeling requirements for treated seed be included on the labels for pesticide products approved for use as seed treatments.<sup>6</sup>

### **III. Petitioners’ Request for Relief is Without Legal Basis**

#### **A. Seed Treatment Pesticides Are Subject to Rigorous EPA Regulation**

Petitioners claim that systemic pesticides applied as seed treatments “are not regulated by EPA under FIFRA,” and that the Agency must close “an existing regulatory loophole for seeds coated with systemic pesticides.” Petition at i. These claims are incorrect.

All pesticides used for seed treatments are subject to FIFRA’s registration requirements; in issuing and reviewing registrations for such uses, EPA has subjected the products, their specific uses, and their potential human health and environmental impacts to rigorous, scientifically robust review as required by FIFRA. There is no basis for Petitioners’ assertions that seed treatment pesticides present unforeseen or enhanced risks, Petition at 12, as the risks of these products and their specific uses as seed treatments were carefully weighed through EPA’s regulatory processes under FIFRA. By approving all of the seed treatment pesticide products, EPA made an express determination that their use to treat seed, and the sale and use of such treated seed, would not cause “unreasonable adverse effects.” 7 U.S.C. § 136a(c)(5)(C), (D).

The Treated Article Exemption is not a loophole to circumvent the FIFRA registration standard. EPA’s application of the Treated Article 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. Petition at 4, 9, 12 n.27, & Table 1. Indeed, throughout the Petition, 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. Petition at 13–14, 30–32.

Petitioners’ selective citation of certain EPA, U.S. Fish and Wildlife Service (“FWS”), USDA, and SAP record materials to support their claims, *see, e.g.*, Petition at 30–32, grossly understates the rigor of EPA’s reviews and ignores EPA’s efforts to address all of the alleged substantive shortcomings raised in the Petition. For example, Petitioners cherry-pick quotes from the transcript of a 2012 meeting of EPA’s SAP, convened to evaluate EPA’s proposed scientific framework for assessing potential pesticide risks to pollinators. But the SAP made no scientific findings regarding whether pesticides cause harm to pollinators, and indeed expressly recognized in its written report that “[a] number of factors/agents have been hypothesized as

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<sup>6</sup> See EPA, Label Review Manual, ch. 18, at 18-9, [https://www.epa.gov/sites/production/files/2014-06/documents/chap-18\\_0.pdf](https://www.epa.gov/sites/production/files/2014-06/documents/chap-18_0.pdf).

potential contributors to recent declines in honey bee health in general,” and “[c]urrently, *no factor has been identified as the single cause.*”<sup>7</sup>

Petitioners’ reliance on the FWS’s decision to phase out the use of neonicotinoid pesticides in agricultural practices on National Wildlife Refuge lands is similarly misplaced. On August 2, 2018, the FWS withdrew this decision, observing that use of neonicotinoid pesticides on refuge lands should be considered on a case-by-case basis.<sup>8</sup> In any case, FWS’s prior decision in furtherance of its own program objectives expressed no scientific judgment as to effects of neonicotinoid pesticide products on pollinators and other wildlife and has no bearing on EPA’s expert scientific determination that these products meet FIFRA’s registration standard and are safe for general agricultural use, including as seed treatments, by growers across the country.

Petitioners contend that EPA’s application of the Treated Article Exemption to treated seed is arbitrary and capricious, claiming it is “counter to the available evidence” regarding alleged effects, citing *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983). Petition at 37. Petitioners’ reliance on *Motor Vehicles* is misplaced. Contrary to Petitioners’ claim, EPA’s actions do not run “counter to the available evidence.” 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. EPA’s determination is scientifically sound and consistent with the Agency’s regulatory authority and discretion.

Finally, Petitioners state that EPA’s regulatory approach to treated seed is improper as contrary to decisions by European regulatory authorities. Petition at 14–15. But Petitioners’ references to the European Union’s (“EU’s”) regulation of treated seed are wholly inapposite here. EU decisions related to the regulation of pesticides under entirely different statutory authority and standards<sup>9</sup> have no bearing on EPA’s exercise of its authority under FIFRA. All seed treatment pesticide products, including the neonicotinoid products identified in the Petition, have cleared EPA’s rigorous, science-based review under FIFRA and have been found—based on extensive scientific data—to “perform [their] intended function without unreasonable adverse effects on the environment,” including pollinators. 7 U.S.C. § 136a(c)(5)(C).

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<sup>7</sup> See Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held September 11–14, 2012 on “Pollinator Risk Assessment Framework,” SAP Minutes No. 2012-06, at 9, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0047> (emphasis added).

<sup>8</sup> Memorandum from Gregory J. Sheehan, Principal Deputy Director, Withdrawal of the Memorandum Titled, “Use of Agricultural Practices in Wildlife Management in the National Wildlife Refuge System” (July 17, 2014), U.S. Fish and Wildlife Service (Aug. 2, 2018).

<sup>9</sup> See, e.g., European Commission Regulation 1107/2009; <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107> (EU regulation concerning the placing of plant protection products in the market).

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

EPA’s application of the Treated Article Exemption to treated seed falls squarely within the Agency’s regulatory authority and discretion. Petitioners attempt to read qualifications or limitations into the Treated Article Exemption that are neither supported nor required by the statute, the regulations, or sound administrative practice. The Petition provides no basis for the relief Petitioners seek.

**1. EPA Appropriately Determined that Seed Treatment Pesticides Are Intended to Protect the Plant Organism at All Stages of Development**

Petitioners assert that the Treated Article Exemption cannot apply to treated seed because “the coated crop seeds are not treated primarily to protect the seed itself, but rather to protect the growing plant.” Petition at ii; *see also id.* at 34. But FIFRA authorizes EPA to exercise its regulatory authority and discretion in determining that, for purposes of the Treated Article Exemption, the “article itself” that is treated and protected is the plant organism in its various stages from seed to seedling to growing plant. Petitioners have identified 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” through its various growth stages.

Indeed, EPA’s interpretation of and application of the Treated Article Exemption to treated seed is consistent with other federal laws and regulations construing seeds as part of the plant organism as a whole. EPA’s own regulations define “living plant” to include “seed.” *See* 40 C.F.R. § 174.3 (“*Living plant* means a plant, plant organ, or *plant part* that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, *seeds*, fruits, leaves, roots, stems, flowers, and pollen.” (emphasis added)). The Plant Protection Act similarly defines “plant” as including “a seed.” 7 U.S.C. § 7702(13). The Federal Seed Act defines “treated” in the context of treated seed as “given an application of a substance or subjected to a process designed to reduce, control, or repel disease organisms, insects or other pests which attack *seeds or seedlings growing therefrom.*” 7 U.S.C. § 1561 (emphasis added).

Even if a seed treatment product’s “predominant” purpose were “to protect the growing plant from pests that prey on living plant tissues,” this would not preclude application of the exemption. The Treated Article Exemption properly applies to treated seed because EPA can carry out the “purposes of FIFRA” through registration of the seed treatment pesticide products.<sup>10</sup> EPA’s review of seed treatment pesticide products under FIFRA includes

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<sup>10</sup> *See* Pest Management Regulatory Agency, Health Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States 2* (2003), [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt\\_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2003-02-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2003-02-eng.pdf) (“2003 Harmonization Guidance”) (explaining that “[i]n issuing this regulation, the EPA reasoned that the risks of treated seeds . . . could adequately be regulated by means of the registration of the treating pesticide”).

consideration of the risks, benefits, and potential impacts of each use through the full life stage of the plant, including the potential for residues in the grown plant or harvested crop.<sup>11</sup>

EPA's reference, in deliberative, non-binding guidance, to protection of "the seed itself" is not dispositive or limiting. *See, e.g.*, 2003 Harmonization Guidance at 2. EPA has never suggested, as Petitioners contend, that such language means that EPA must somehow draw a line between the "seed" and "the growing plant," or that pesticide product applied to the seed to protect all stages of the growing plant would bar application of the exemption, particularly when doing so would be inconsistent with its own regulations. Moreover, EPA's longstanding application of the Treated Article Exemption to treated seed undermines Petitioners' interpretation.

Petitioners assert that the Treated Article Exemption cannot apply to treated seed because all of the pesticide product used for treatment "does not remain in or on the 'treated article.'" Petition at 34. But as the U.S. District Court for the Northern District of California court ruled in *Anderson v. McCarthy*, a recent lawsuit challenging EPA's application of the Treated Article Exemption to treated seed, the reference in the regulation and 2003 Harmonization Guidance to treatment "for the protection of the article itself" means that the treatment must be "intended for" the article itself. No. C 16-00068 WHA, 2016 WL 6834215, at \*5 (N.D. Cal. Nov. 21, 2016). In determining whether the Treated Article Exemption should apply, the focus is "on the pesticidal treatment's intended purpose rather than its potential effects." *Id.* As discussed above, the potential effects of the pesticidal treatment are considered and regulated by EPA in connection with the registration of the pesticide product.

## **2. EPA Addresses "Dust-Off" Within Its Existing Regulatory Framework**

Contrary to Petitioners' claim, application of the Treated Article Exemption to treated seed in no way prevents or limits EPA from addressing concerns about dust-off from treated seed. *See, e.g.*, Petition 13–14 (contending that EPA's risk assessments "ignore numerous risks of planting the resulting seeds, such as the toxic abraded dust-off, due to EPA's inclusion of the coated seeds themselves under the Treated Article Exemption"). EPA adequately addresses dust-off within the context of individual registration decision-making, as part of its ongoing risk assessment work for neonicotinoid Registration Review processes, and through its work with agricultural stakeholders on new and innovative technologies.

In June 2014, President Obama issued a memorandum establishing an interagency Pollinator Health Task Force, co-chaired by USDA and EPA, to develop a National Pollinator Health Strategy aimed at promoting the health of honey bees and other pollinators. In support of this Strategy, EPA accelerated Registration Review and initiated ecological risk assessments for all neonicotinoid pesticides—including the products identified in the Petition—specifically focused on potential risks to pollinators.<sup>12</sup>

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<sup>11</sup> 40 C.F.R. Part 158.

<sup>12</sup> *See* EPA, Schedule for Review of Neonicotinoid Pesticides, <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides> (detailing schedule for review of

In January 2016, EPA completed and released for public comment the first of these pollinator assessments, *Preliminary Pollinator Assessment to Support the Registration Review for Imidacloprid*, based on seventy-five open-literature studies as well as extensive data submitted by registrants.<sup>13</sup> As just one example of how EPA considers dust-off in the context of its reviews of individual pesticides, EPA’s assessment for imidacloprid considered that honey bees may be exposed to pesticides through “drift of abraded seed coat dust.”<sup>14</sup> EPA concluded that “obtaining quantitative estimates of this route of exposure is also considered highly uncertain,” and determined that the Agency will “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 modification, etc.).”<sup>15</sup> EPA received 1,534 comments on its preliminary pollinator risk assessment for imidacloprid, including comments from ASTA, CLA, and several of the Petitioners.<sup>16</sup> EPA has conducted assessments for other neonicotinoids and expects to complete its Registration Review of these pesticides this year.<sup>17</sup> Petitioners have failed to establish how EPA’s existing reviews of pesticides approved for use as seed treatments are insufficient to address the dust-off concerns asserted in the Petition.

In addition to its scientific review of potential risks to pollinators through the registration and Registration Review processes, FIFRA authorizes EPA to seek additional information from the applicant or registrant on potential dust-off risks at any time. Indeed, FIFRA’s regulations caution registration applicants that “EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.” 40 C.F.R. § 158.30(b); *see also* 40 C.F.R. § 158.75 (FIFRA authorizes EPA to impose additional data requirements on registrants if data routinely required are insufficient to evaluate the pesticide’s satisfaction of FIFRA’s registration standard).

In concert with EPA’s regulatory focus on pollinator issues, EPA and participants in the agricultural value chain, including CLA, ASTA, BPIA, and their members, have worked to develop strategies for managing pesticide risks to pollinators, including through research, new technologies, best practices, and other stewardship activities. In March 2013, EPA convened a Pollinator Summit, a public meeting with industry, growers, beekeepers, and other stakeholders, to discuss these issues. ASTA and CLA collaborated to develop a comprehensive seed treatment stewardship guide, based on research and safety information from a variety of industry sources,

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Imidacloprid, Clothianidin, Thiamethoxam, Dinotefuran, and Acetamiprid).

<sup>13</sup> *See, e.g.*, Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid, EPA-HQ-OPP-2008-0844-0140 (Jan. 4, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0140>.

<sup>14</sup> *Id.* at 37.

<sup>15</sup> *Id.*

<sup>16</sup> *See, e.g.*, Imidacloprid Registration Review, <http://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=EPA-HQ-OPP-2008-0844> (listing comments submitted by Petitioner Bret Adee, Petitioner American Bird Conservancy, Petitioner Center for Food Safety, ASTA, and CLA, among others).

<sup>17</sup> EPA, Schedule for Review of Neonicotinoid Pesticides, <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides>.

that includes best practices for seed treatment use aimed at reducing risks to non-target organisms, including pollinators;<sup>18</sup> ASTA and CLA presented the stewardship guide during the 2013 Pollinator Summit,<sup>19</sup> and the guide and other extensive stewardship materials are made available and updated online.<sup>20</sup>

CLA's, ASTA's, and BPIA's members have also worked to promote the development of new seed-planting technologies aimed at reducing pollinators' exposure to dust from treated seed. For example, Bayer CropScience has developed seed lubricant technology shown to reduce dust released by treated seed by 60–90% compared to other products, reducing potential risks to pollinators.<sup>21</sup> Stakeholders also have focused on developing technologies for cleaning and de-dusting treated seed and enhancements in polymer coatings, all aimed at minimizing dust-off.<sup>22</sup>

As the efforts detailed above demonstrate, Petitioners' request that EPA regulate treated seed under FIFRA in order to address dust-off and other alleged environmental impacts is a "solution" in search of a problem. EPA already addresses dust-off through its exercise of its regulatory authority under FIFRA to review pesticides used as seed treatments on a registration-by-registration basis. Petitioners have simply provided no basis for their request that EPA upend its regulatory approach as to an entire class of treated seed products.

### **3. EPA's Application of the Treated Article Exemption Does Not Limit its Enforcement Authority as to Treated Seed**

Petitioners wrongly assert 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. *See* Petition at 29. Petitioners concede that "EPA requires labels to be placed onto the bags or containers, or onto the affixed tags, of the unregistered pesticidal seeds," but contend that these "sparse warnings" are insufficient and that the "label language itself is unenforceable." *Id.* Petitioners ignore that the seed bag or tag label language is imposed by EPA on a product-by-

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<sup>18</sup> *The Guide to Seed Treatment Stewardship*, <http://www.seed-treatment-guide.com/wp-content/uploads/2013/03/Guide-to-Seed-Treatment-Stewardship.pdf>; *see also* Insect Pollinators and Pesticide Product Stewardship, [https://growingmattersorg.files.wordpress.com/2019/02/syng\\_4098\\_2\\_1\\_insect\\_pollinator\\_brochure\\_updates\\_mech2\\_hrcrops.pdf](https://growingmattersorg.files.wordpress.com/2019/02/syng_4098_2_1_insect_pollinator_brochure_updates_mech2_hrcrops.pdf) (pollinator stewardship brochure developed by Bayer, Syngenta, and Valent).

<sup>19</sup> <https://www.epa.gov/sites/production/files/2013-11/documents/lisa-nichols-seed-treatment-guide.pdf>.

<sup>20</sup> <https://seed-treatment-guide.com/>.

<sup>21</sup> *See Bayer CropScience Announces Commercial Availability of its New Seed Lubricant, Fluency Agent* (Feb. 25, 2014), <https://www.cropscience.bayer.us/news/press-releases/2014/02252014-0037-bcs-announces-commercial-availability-of-fluency-agent>.

<sup>22</sup> *See, e.g.,* Palle Pedersen, *Formulation Technology Innovation and Improvements*, <https://www.epa.gov/sites/production/files/2013-11/documents/palle-pederson-formulation-technology.pdf> (Syngenta presentation); Mike FcFatrigh, *Activity and Advances in Seed Coating Technology* (Mar. 5, 2013), <https://www.epa.gov/sites/production/files/2013-11/documents/mike-mcfatrigh-seed-applied-additives.pdf> (BASF presentation).

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. Petitioners also ignore that registrants have an affirmative obligation under FIFRA to report to EPA incidents involving harm or potential harm to pollinators, *see* 7 U.S.C § 136d(a)(2), and EPA has imposed an accelerated ten-day requirement for submitting such reports.<sup>23</sup> Concerns regarding label language 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.

Nothing about the application of the Treated Article Exemption precludes EPA from imposing label language on a product-by-product basis to address dust-off concerns.

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

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

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

Abrogating the Treated Article Exemption for treated seed and requiring individual 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. For example, each and every seed treatment pesticide and seed combination—of which there are hundreds, if not thousands—would need to be registered individually. *See, e.g.*, Decl. of Rachel Lattimore in Supp. of Mot. to Intervene ¶ 10, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. Mar. 16, 2016), ECF No. 26-1. In addition, 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. *See, e.g.*, Decl. of Andrew LaVigne ¶ 7, Decl. of Richard Wilkins ¶ 8, Decl. of Gary Adams ¶ 9, Decl. of Gary Stoner ¶ 7, and Decl. of Chris Novak ¶ 6, *Anderson v. McCarthy*, No. C 16-00068 WHA (N.D. Cal. Mar. 16, 2016), ECF Nos. 26-2–26-6. Farmers would also be subjected to onerous reporting and recordkeeping requirements that

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<sup>23</sup> *See* Letter from Steven Bradbury, EPA Office of Pesticide Programs to Registrants of Nitroguanidine Neonicotinoid Products (July 22, 2013), <https://www.epa.gov/sites/production/files/2013-11/documents/bee-july2013-letter.pdf>.

would draw time and resources away from farming operations that are currently operating on slim or negative margins. *See id.* All of these burdens would be imposed without any substantive benefits to health or safety, which are already comprehensively addressed through EPA’s review of the seed treatment pesticide products. The duplicative regulation Petitioners seek would run counter to the government’s commitment to streamline regulatory requirements, promote regulatory efficiency, and reject constrictive regulations that do not serve statutory purposes. *See, e.g.*, Executive Order (EO) 13771, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9,339 (Jan. 30, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02451.pdf>.

#### **IV. Petitioners’ Request for Relief Has No Substantive Support.**

Notably, the Petition does not ask EPA to amend or cancel any registration for any seed treatment pesticide product, does not identify any EPA registration decisions on pesticide seed treatment products that fail to meet the “no unreasonable adverse effects” risk/benefit standard under FIFRA, and does not identify any way in which EPA’s application of the Treated Article Exemption limits the Agency’s ability to review the data on risks and benefits and make appropriate substantive registration decisions regarding the use of pesticide products on treated seed.

For the reasons noted above, EPA may and should deny the Petition without reaching the substantive issues asserted by Petitioners. EPA has addressed and can continue to address each of the issues Petitioners have raised within the context of its registration determinations and ongoing review of seed treatment pesticide product registrations and without altering its application of the Treated Article Exemption to treated seed. Nonetheless, the following comments are provided for the record in response to Petitioners’ inaccurate and unsupported assertions.

##### **A. The Scientific Literature Cited in the Petition Does Not Support the Petitioners’ Claims or Provide a Basis for Relief.**

Petitioners allege that “major reviews and studies” reveal harms associated with treated seed. None of the cited publications support the Petitioners’ claims.

For example, Petitioners claim that a major review by Petitioner American Bird Conservancy found that “a *single* corn kernel treated with any of the common neonicotinoids could kill a songbird and just one-tenth of a treated corn kernel is enough to adversely affect a songbird’s reproduction.” Petition at 16. But most songbirds are unable to consume corn kernels, due to gape limitation and/or inability to digest.<sup>24</sup> Indeed, EPA has recently indicated that corn kernels do not present a risk to small and medium passerines due to their inability to consume that size seed.<sup>25</sup> And Petitioners’ propounded statement fails to provide appropriate

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<sup>24</sup> Craig W. Benkman & H. Ronald Pulliam, *Comparative Feeding Ecology of North American Sparrows and Finches*, 69 *Ecology* 1195 (1988); Mary F. Willson & Janet C. Harmeson, *Seed preferences and digestive efficiency of cardinals and song sparrows*, 75 *Condor* 225 (1973).

<sup>25</sup> *See* Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review, EPA-HQ-OPP-2008-0844-1256, at 6 (Nov. 28, 2017),

context by omitting the amount of active ingredient that would need to be present on the kernel to give rise to the alleged risks.

Petitioners also contend that “more than eighty to ninety percent” or “up to ninety percent” of the insecticide applied to treated seed is “abraded off the seed as dust” or “sloughed off the seed into the surrounding soil.” Petition at 2, 10, 34. In support of these figures, Petitioners cite only Goulson (2014), a short note claiming that a single neonicotinoid, imidacloprid, is linked to bird declines.<sup>26</sup> Goulson (2014) cites Sur (2003), a technical study to determine the nature of imidacloprid residue in different crops from seed treatment or soil applications.<sup>27</sup> That study found “uptake” rates of 1.6% to 20% in the plant samples. Sur (2003)

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<https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1256> (“[S]eeds of corn . . . are considered too large for consumption by small and medium size passerine birds, which make up the majority of avian species in the United States.”); *see also* Memorandum from Donald Brady, EPA, Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance (Mar. 31, 2016), <https://www.epa.gov/sites/production/files/2016-04/documents/interimseedtreatmentguidance2016.pdf>.

<sup>26</sup> Goulson (2014) relies on Hallman (2014), which claimed to find a correlation between population trajectories of breeding birds and concentrations of imidacloprid in surface waters in an agricultural region in the Netherlands. *See* Dave Goulson, *Pesticides linked to bird declines*, 511 *Nature* 295 (2014), <https://www.nature.com/articles/nature13642.pdf>; Caspar A. Hallmann et al., *Declines in insectivorous birds are associated with high neonicotinoid concentrations*, 511 *Nature* 341 (2014). The claimed correlation is not proof of cause and effect. In fact, Figure 6 of Hallman (2014) shows that species found near surface waters with the highest concentration of imidacloprid actually *increased* after imidacloprid use began. Moreover, the mechanism described for impacts to avian populations in Hallman (2014) and Goulson (2014) is a reduction in the insect resource base. But there is very little empirical evidence to show that avian populations respond to a reduced food supply in agricultural and grassland habitats. In fact, a number of studies have concluded that food abundance is not linked to population trends or reproductive success in passerines in agricultural or grassland habitats. *See, e.g.*, Pierre Mineau & Cynthia Palmer, American Bird Conservancy, *Impact of the nation’s most widely used insecticides on birds* (2013), at 39, [http://abcbirds.org/wp-content/uploads/2015/05/Neonic\\_FINAL.pdf](http://abcbirds.org/wp-content/uploads/2015/05/Neonic_FINAL.pdf) (citing studies and concluding that “the link between impacts on the insect food of birds and population declines of farmland bird species is difficult to establish unequivocally”). Contrary to Petitioners’ claims, more recent research examining avian population trends on a finer spatial scale (and particularly corn and soybean cropping intensity adjacent to census routes) does not support widespread and across-species declines in avian populations in crop-intensive areas. *See* Jason B. Belden et al., *Relative abundance trends of bird populations in high intensity croplands in the central United States*, 14 *Integrated Env’tl. Assessment & Mgmt.* 692 (2018). In addition, Hill et al. (2014) found that habitat availability is a more plausible explanation for declines in U.S. grassland bird species than insecticide use. Jason M. Hill et al., *Habitat availability is a more plausible explanation than insecticide acute toxicity for U.S. grassland bird species declines*, 9 *PLoS One*, at e98064 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4028314/pdf/pone.0098064.pdf>.

<sup>27</sup> Goulson (2014) at 296 & n.4; Robin Sur & Andreas Stork, *Uptake, translocation and metabolism of imidacloprid in plants*, 56 *Bulletin of Insectology* 35 (2003),

at 35–36 & Table 1. Goulson wrongly assumes that the remaining “bulk of the active ingredients . . . enter the soil and soil water.” Goulson (2014) at 295 & Figure 1. This ignores the metabolism and degradation of the active ingredient inside and outside the plant. In fact, Sur et al. (2003) identified “[t]hree principal metabolic pathways of imidacloprid in plants . . . showing a quick degradation of the [active substance], especially after seed or soil application.” *Id.* at 39. Goulson’s claim that all of the pesticide not captured in the uptake analysis moved to and remains in soil and soil water is theoretically wrong and experimentally disproven.<sup>28</sup>

Other studies cited by Petitioners are similarly unreliable. Petitioners cite Alburaki et al. (2015), which claimed that neonicotinoid exposures increase pathogen risks and weaken honeybee colonies. Petition at 16–17; Mohamed Alburaki et al., *Neonicotinoid-coated Zea mays seeds indirectly affect honeybee performance and pathogen susceptibility in field trials*, 10 PLoS One, at e0125790 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4436261/>. No pesticides were detected in bees or samples taken from the studied hive. Only clothianidin was detected at low levels in direct corn pollen samples, and foraging on corn pollen was extremely low (1%). The virus levels detected were more likely attributed to infestations of the Varroa mite, a known vector of the Black Queen cell virus and other pathogens. In addition, Petitioners do not mention studies that exposed bees to the bee pathogen *Nosema ceranae* (a microsporidian fungus) and found that infection rates were not increased, but significantly lowered if the bees were simultaneously exposed to a neonicotinoid.<sup>29</sup>

Petitioners also cite Botias et al. (2016), which claimed that neonicotinoid canola seed treatments in the UK caused “frequently high-level contamination of marginal vegetation.” Cristina Botias et al., *Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects*, 566 Sci. Total Env’t 269 (2016). The authors focus on a small number of inexplicably high residue detections of the neonicotinoid thiamethoxam in field margin foliage when, in fact, the median residues of thiamethoxam fell below the limit of detection, thus contradicting the authors’ claim of widespread contamination. The high residues reported are also of questionable validity given the unlikely parent-to-metabolite ratio (*i.e.* high reported field margin plant foliage residues associated with metabolite residues that were below

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<https://pdfs.semanticscholar.org/ccce/69d4dd40fe771946f72b0d4d2d44b83cb177.pdf>.

<sup>28</sup> Other research demonstrates that Goulson’s broad claims regarding dust-off are also inconsistent with the fate of thiamethoxam in the environment. For example, one study found that, in addition to plant uptake, degradation, sequestration, and transportation processes cause thiamethoxam concentrations to markedly decrease in soil and soil pore water, making it unlikely that 80–90% of thiamethoxam’s chemical coating moves off the seed to surrounding air, soil, marginal vegetation and water. Martin J. Hilton, Tim D. Jarvis, and Dean C. Ricketts, *The degradation rate of thiamethoxam in European field studies*, 72 Pest Mgmt. Sci. 388 (2016), <https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.4024>.

<sup>29</sup> Cedric Alaux et al., *Interactions between Nosema microspores and a neonicotinoid weaken honeybees (Apis mellifera)*, 12 *Envtl. Microbiology* 774, 776, Fig. 2 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2847190/pdf/emi0012-0774.pdf>; Jeffery S. Pettis et al., *Crop pollination exposes honey bees to pesticides which alters their susceptibility to the gut pathogen Nosema ceranae*, 8 PLoS ONE, at e70182 (2013), <https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0070182&type=printable>.

the limit of detection). In addition, the authors' Hazard Quotient approach, used to suggest a risk to non-target organisms, was invalid, and the authors acknowledge that concentrations were typically below lethal concentrations of these pesticides.

David et al. (2016) similarly does not support Petitioners' claims. Petition at 18; Arthur David et al., *Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops*, 88 *Env't Int'l* 169 (2016). That study claimed widespread contamination of marginal vegetation near treated-seed canola fields with neonicotinoids and other chemicals. *Id.* It also reported inexplicably high thiamethoxam residues that cannot be rationally explained and that are inconsistent with reported residues of the metabolite clothianidin. In addition, the authors' suggestion of potential synergisms between neonicotinoids and DMI fungicides is contrary to previous published data.

Petitioners also point to Mogren and Lundgren (2016), which claimed that "set-aside vegetation strips did not protect bees from nutritional harms caused by adjacent corn fields planted with clothianidin-coated seeds." Petition at 19–20; Christina L. Mogren & Jonathan G. Lundgren, *Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status*, 6 *Sci. Reps.* 29608 (2016). This study used an invalid analytical method (ELISA) to characterize residues in leaf tissue and honey, undermining the credibility of its findings. The study reported similar concentrations of neonicotinoids in samples collected at both organic farms (where no neonicotinoids were applied) and conventional farms, which is highly unlikely.

Petitioners also cite Rundlöf, et al. (2015), which claimed that a seed treatment containing the neonicotinoid clothianidin applied to spring oilseed rape seeds in Sweden caused adverse effects on wild bumblebees and other wild bees.<sup>30</sup> Petition at 20; Maj Rundlöf et al., *Seed coating with a neonicotinoid insecticide negatively affects wild bees*, 521 *Nature* 77 (2015). Importantly, the seed treatment rate applied in the Rundlöf study was 2.5 times greater than the maximum rate permitted under the clothianidin label approved by EPA under FIFRA. This study is thus of limited relevance to clothianidin's use as a seed treatment for canola in the

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<sup>30</sup> Consistent with other studies, the Rundlöf study reported no significant effects on honeybees. Some other studies include: Daniel Rolke et al., *Large-scale monitoring of effects of clothianidin-dressed oilseed rape seeds on pollinating insects in Northern Germany: effects on honey bees (*Apis mellifera*)*, 25 *Ecotoxicology* 1648 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5093180/> (no effects on honey bees at oil-seed rape grown from clothianidin-treated seeds); Guido Sterk et al., *Large-scale monitoring of effects of clothianidin-dressed OSR seeds on pollinating insects in Northern Germany: effects on large earth bumble bees (*Bombus terrestris*)*, 25 *Ecotoxicology* 1666 (2016), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5093213/pdf/10646\\_2016\\_Article\\_1730.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5093213/pdf/10646_2016_Article_1730.pdf) (no effects on bumble bees at oil-seed rape grown from clothianidin-treated seeds); Britta Peters, Zhenglei Gao, & Ulrich Zumkier, *Large-scale monitoring of effects of clothianidin-dressed oilseed rape seeds on pollinating insects in Northern Germany: effects on red mason bees (*Osmia bicornis*)*, 25 *Ecotoxicology* 1679 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5093198/> (no effects on red mason bees at oil-seed rape grown from clothianidin-treated seeds).

United States. Moreover, the study's limited sample size and omission of key information, including information about species distribution through the individual plots, precludes a robust conclusion about potential effects associated with clothianidin use. The study also failed to account for patchiness effects and other relevant factors (*e.g.*, flower density, landscape structure) that could impact the study's findings with respect to solitary bee nesting.

The Petitioners also cite Woodcock et al. (2016), which claimed that the use of neonicotinoid-treated canola seed contributed to the extinction of wild bee species in the United Kingdom. Petition at 20; Ben A. Woodcock et al., *Impacts of neonicotinoid use on long-term population changes in wild bees in England*, 7 *Nature Comms.* 12459 (2016). The authors of this study confuse correlation with causation; the suggestion of a causal link between neonicotinoid seed treatment use and changes in wild bee populations is based on highly speculative assumptions. For example, the authors define "exposure to neonicotinoids" only according to the presence and proportion of neonicotinoid-treated oilseed rape in a 25 km square area (an area seven times the size of Central Park); but the presence of a certain quantity of a treated crop in such a large area alone does not necessarily indicate exposure. The authors also fail to appropriately account for other relevant factors known to impact the development of wild bee populations, such as climate patterns and agricultural practices. The data presented in this study simply do not substantiate the study's claims.

Finally, the Petitioners cite Petitioner Center for Food Safety's ("CFS") own report on alleged aquatic contamination by neonicotinoids, which they claim describes neonicotinoid levels in ground and surface waters exceeding safe levels, including many EPA benchmarks. Petition at 27–28. This report is rife with issues, most notably its misrepresentation of thiamethoxam levels in surface waters. In addition, the report's use of imidacloprid-based toxicity endpoints as a universal toxicity threshold for all neonicotinoids does not account for variances in toxicity among neonicotinoids. The report also uses overly conservative chronic and acute ecological reference values. Finally, the report's suggestion of synergism among neonicotinoids in mixture has no basis, and indicates a neonicotinoid exposure scenario that is not supported by monitoring data.

## **B. EPA Has Taken Affirmative Measures to Address Pollinator Safety**

The Petition makes a number of claims about alleged risks to pollinators and other costs associated with treated seed. In addition to being unfounded and unsupported by the scientific evidence, as outlined above, the Petition ignores the substantial resources the Agency has devoted to addressing risks to pollinators, including honey bees, both as part of the regulatory review of specific pesticide products and more broadly as part of the Agency's mandate to protect environmental health.

In April 2011, EPA's Pesticide Program Dialogue Committee ("PPDC") formed a Pollinator Protection workgroup. This workgroup, comprised of a broad array of stakeholders from academia, agriculture, government, various NGOs, and industry, including representatives from CLA and ASTA and several of their members, provided information to EPA on complex pollinator protection issues, including: (1) science-based risk management approaches, including appropriate labeling restrictions and training, (2) state approaches to and authority for addressing pollinator protection issues, (3) stakeholder experience in improving management practices, and

(4) international communication, among others. The PPDC more recently formed a Pollinator Protection Plan Metrics workgroup, also comprised of key agricultural stakeholders across industry, academia, government, and the non-profit sector, to make recommendations to EPA regarding metrics to be used to measure the effectiveness of state and tribal plans.<sup>31</sup>

In September 2012, EPA convened a public meeting of its FIFRA Scientific Advisory Panel (“SAP”) to evaluate a proposed tiered framework for quantitatively assessing potential risk to pollinators associated with agricultural pesticide use.<sup>32</sup> The Panel, comprised of scientists with expertise in toxicology, chemistry, and entomology, among other disciplines, provided guidance and recommendations to EPA on data needs and methods for quantifying exposures and effects and characterizing potential risks to pollinators. Commenters and their members submitted comments to the SAP and participated in the SAP meeting.<sup>33</sup>

As an outgrowth of the SAP meeting, EPA has devoted significant resources to developing protocols and methods and to identifying data needs for assessing potential pesticide risks to pollinators. In 2014, in partnership with Health Canada Pest Management Regulatory Agency and California Department of Pesticide Regulation (“DPR”), EPA developed guidance for risk assessors to use in characterizing pesticide risks to bees, which specifically outlined a risk assessment process for evaluating pesticide seed treatments.<sup>34</sup> The 2014 Guidance for Assessing Pesticide Risks to Bees describes a tiered process for analyzing exposure risks to individual bees and bee colonies. In 2016, EPA supplemented the 2014 guidance with guidance specifically targeted at risk assessors in EPA’s Office of Pesticide Programs (“OPP”), the branch of EPA responsible for regulating pesticide use.<sup>35</sup> This supplement provides guidance on the exposure and effects (toxicity) studies that OPP staff should consider when evaluating a pesticide’s potential risks to bees. In 2016, EPA issued an additional guidance document, which provides interim guidance to both the public and OPP staff for determining when the toxicity data described in the earlier guidance are required.<sup>36</sup>

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<sup>31</sup> EPA, Pesticide Program Dialogue Committee: Pollinator Protection Plan Metrics Workgroup, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-0>. The workgroup’s recommendations to the Agency are available here: <https://www.epa.gov/sites/production/files/2017-11/documents/session-2-mp3-metrics-workgroup.pdf>.

<sup>32</sup> See EPA, *White Paper in Support of the Proposed Risk Assessment Process for Bees* (Sept. 11, 2012), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0004>.

<sup>33</sup> See EPA, Transmittal of the Meeting Minutes of FIFRA Scientific Advisory Panel Meeting held September 11–14, 2012 on “Pollinator Risk Assessment Framework,” SAP Minutes No. 2012-06, at 10, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0047>.

<sup>34</sup> See EPA, Pollinator Risk Assessment Guidance, <https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance> (last updated Aug. 20, 2018).

<sup>35</sup> EPA, *Guidance on Exposure and Effects Testing for Assessing Risks to Bees* (July 2016), <https://www.epa.gov/sites/production/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf>.

<sup>36</sup> EPA, *Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees during Registration and Registration Review* (Aug. 2016), [https://www.epa.gov/sites/production/files/2016-08/documents/bee\\_guidance.pdf](https://www.epa.gov/sites/production/files/2016-08/documents/bee_guidance.pdf).

To complement its existing pollinator risk assessment guidance, EPA just recently issued a “frequently asked questions” (FAQ) document for registrants and contract laboratories conducting honeybee toxicity testing.<sup>37</sup> The FAQ is intended to increase the transparency and clarity of the risk assessment process, and provides answers to general study questions and guidance on EPA’s requirements with respect to specific types of toxicity testing.<sup>38</sup>

In addition to the above efforts, in 2013, EPA instituted new labeling requirements for registrants of neonicotinoid pesticides in order to strengthen protections for pollinators.<sup>39</sup> EPA has also reiterated registrants’ affirmative obligation under FIFRA to report to EPA any pesticide incidents involving harm or potential harm to pollinators and imposed an accelerated ten-day timeframe for submitting such reports.<sup>40</sup> *See* 7 U.S.C. § 136d(a)(2) (mandating that pesticide registrants report on an ongoing basis “factual information regarding unreasonable adverse effects on the environment of [a] pesticide”).

Finally, as noted above, in support of the interagency Pollinator Health Task Force’s National Pollinator Health Strategy, EPA accelerated Registration Review for all neonicotinoid pesticides. EPA completed and released for public comment its first pollinator assessment for imidacloprid in 2016, and its assessments for other neonicotinoids are underway and expected to conclude in 2019.<sup>41</sup> EPA’s commitment to pollinator safety is well-established, comprehensive, and effective at addressing Petitioners’ concerns.

### **C. The Petition’s Claims Regarding Threatened and Endangered Species Are Unfounded**

The Petition claims that treated seed “may affect broad groups of non-target animals,” including “many threatened and endangered species protected under the [Endangered Species Act (“ESA”)].” Petition at 23–26. As an initial matter, EPA need not address these claims to resolve the Petition. The Petition does not attribute any of the purported deficiencies in EPA’s processes with respect to threatened and endangered species to EPA’s application of the Treated Article Exemption. Petitioners have not requested that EPA complete consultation under the ESA on any pesticide product or change its determinations on the potential impacts of the use of pesticides to treat seeds on listed species, and the Petition does not ask EPA to change its position on any substantive ESA issue. Moreover, EPA’s consultation obligations with respect to pesticide product approvals, including numerous seed treatment products, are being addressed in ongoing court cases, including *Ellis, et al. v. Keigwin, et al*, Case No. 3:13-cv-01266-MMC (N.D. Cal. Mar. 21, 2013), brought by Petitioner CFS.

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<sup>37</sup> EPA, Honeybee Toxicity Testing Frequently Asked Questions (Aug. 16, 2018), <https://www.epa.gov/sites/production/files/2018-08/documents/pollinator-faq.pdf>.

<sup>38</sup> *Id.*

<sup>39</sup> *See* EPA, New Labeling for Neonicotinoid Pesticides, <https://www.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides>.

<sup>40</sup> *See* Letter from Steven Bradbury, EPA Office of Pesticide Programs to Registrants of Nitroguanidine Neonicotinoid Products (July 22, 2013), <https://www.epa.gov/sites/production/files/2013-11/documents/bee-july2013-letter.pdf>.

<sup>41</sup> EPA, Schedule for Review of Neonicotinoid Pesticides, <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides> (last updated Aug. 15, 2018).

Even if these issues were properly addressed through the petition process, the Petitioners have failed to identify compelling support for their superficial assertions of purported harm to certain threatened and endangered species from treated seed. Petition at 23–24. Petitioners rely largely on expert declarations by Drs. John Stark, John Losey, and Pierre Mineau, submitted in the *Ellis* litigation. *Id.* These declarations, and subsequent efforts by the same individuals, were repeatedly and definitively refuted by the declarations of Drs. Dwayne Moore and Anne Fairbrother submitted in the *Ellis* litigation, and the opinions they contain did not hold up on deposition.<sup>42</sup> For example, the Petition claims that Drs. Stark, Losey, and Mineau identified certain listed species as “potentially affected by coated seed use.” Petition at 23–24. Even if this unsupported proposition were the case, it would not establish any actual harm to any species, or that the registered uses posed “unreasonable adverse risks” that would preclude registration under the FIFRA standard. *See* 7 U.S.C. § 136a(c)(5)(C).

Moreover, Drs. Mineau, Losey, and Stark have not made a scientifically defensible case that seed treatment products registered by EPA or the resulting treated seeds will “harm” or have any “potential effects” on any listed species. For the most part they rely on simplistic assertions that “clothianidin and thiamethoxam, or in some instances neonicotinoids or pesticides in general, are ‘toxic’ to organisms, and because there is some overlap where neonicotinoids may be used with occurrences of listed species, then the ‘risk of harm is therefore high.’”<sup>43</sup> They “ignore or fail to account for key factors that dramatically reduce or eliminate exposure of listed species to these chemicals, and therefore risk,” and rely on “scientifically unsubstantiated assumptions, and on many occasions pure speculation.”<sup>44</sup> Indeed, the species identified do not have any meaningful exposure to agriculture, or the major threats to the species are from other sources, such as habitat loss, alteration, and fragmentation.<sup>45</sup> The opinions of these individuals simply do not provide a scientific basis for the alleged harms to threatened and endangered species asserted in the Petition.<sup>46</sup>

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<sup>42</sup> *See* Decls. of Dwayne R.J. Moore, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. Sept. 30, 2015 & Jan. 5, 2018), ECF Nos. 237-19, 299; Rebuttal Decl. of Dwayne R.J. Moore, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. May 18, 2018), ECF No. 349; Decl. of Ann Fairbrother, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. Sept. 30, 2015), ECF No. 237-18.

<sup>43</sup> Moore Decl. (Sept. 30, 2015), ¶ 18.

<sup>44</sup> *Id.* ¶¶ 19–20; *see also id.* Fairbrother Decl. (Sept. 30, 2015), ¶¶ 13–21 (identifying critical flaws in the declarations of Drs. Losey, Stark, and Mineau, including that they “ignore or fail to adequately quantify key factors that are required to meaningfully assess potential risks to listed species from the use of particular pesticides, including, for example, the probability that the species will actually eat a treated plant,” assume all neonicotinoids “act essentially identically in the environment and on species of interest,” and “speculate that concentrations of clothianidin and thiamethoxam . . . ‘may’ or ‘could’ be at levels sufficiently high as to cause a risk of toxicity to aquatic invertebrates,” even though “the best available sampling data contradict their claims”).

<sup>45</sup> *See* Moore Decl. (Sept. 30, 2015), ¶¶ 22–108; Moore Decl. (Jan. 5, 2018), ¶¶ 52–62; Moore Rebuttal Decl. (May 18, 2018), ¶¶ 11–16; Fairbrother Decl. (Sept. 30, 2015), ¶¶ 22–80.

<sup>46</sup> *See* Moore Decl. (Sept. 30, 2015), ¶¶ 19–21, 109; Moore Decl. (Jan. 5, 2018), ¶ 63; Moore Rebuttal Decl. (May 18, 2018), ¶ 17; Fairbrother Decl. (Sept. 30, 2015), ¶ 21.

The Petition provides no support whatsoever for the “non-exhaustive” list of additional “threatened and endangered terrestrial insects that EPA should consider as an additional starting point.” Petition at 24. Even a quick review of the information on these species shows that they face no threats from treated seeds. Most (eight out of eleven)<sup>47</sup> have very restricted ranges and extremely limited, if any, exposure to agriculture.<sup>48</sup> Three of the additional species listed by Petitioners have a broader distribution across several states, but their life history and feeding ecology preclude their exposure to treated seed and the resulting plants.<sup>49</sup>

Finally, the Petition selectively quotes language from FWS’s Rusty Patched Bumble Bee (“RPBB”) listing decision stating that neonicotinoid seed treatments “have been strongly implicated as the cause of the decline of . . . rusty patched bumble bees, due to the contemporaneous introduction of neonicotinoid use and the precipitous decline of the specie.” Petition at 16. The listing decision does not rely on the best available data and contains multiple factual and scientific inaccuracies. FWS relies on the misapplication of a dataset the authors concede is highly flawed, unsystematic, and of questionable reliability. And as Dr. Moore has explained, the decline in RPBB occurrence began well before there was any significant neonicotinoid seed treatment use, and “many of the counties from which the RPBB has disappeared in the last 20 years have little corn and soybean production,” while “RPBB has continued to persist in counties with intensive corn and soybean production where neonicotinoid use is highest.”<sup>50</sup> The FWS listing document identified numerous other potential causes for the collapse, including spillover of the microsporidium *Nosema bombi* that afflicted commercial bee colonies at the time, or other pathogens.<sup>51</sup>

#### **D. Treated Seed Does Not Negatively Impact Crop Yields**

Petitioners’ contention that the use of treated seed does not improve crop yields is unavailing. Petition at 26–27. Petitioners contend that a 2015 analysis by EPA’s Biological and Economic Analysis Division (BEAD) is the most “detailed” report on the efficacy of seed treatments for soybeans and showed a lack of benefits in most cases. *Id.* However, the Petition

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<sup>47</sup> Petitioners’ list contains eleven species, only ten of which are numbered. Petition at 24.

<sup>48</sup> Eight of the species are found only in specific counties in a single state (California, Oregon, or Florida), with habitats that preclude any significant exposure to agriculture even within those ranges. *See* NatureServe, NatureServe Explorer: An online encyclopedia of life [web application], <http://explorer.natureserve.org>. For example, the San Bruno Elfin, a butterfly species, is found only in three counties surrounding San Francisco, with a habitat consisting of “Bare rock/talus/scree, Cliff, Shrubland/chaparral,” and thus would face no exposure from pesticides used on treated corn, soybeans, or other crop seeds. *See* NatureServe Explorer Report on *Callophrys mossii bayensis* (San Bruno Elfin) (accessed Mar. 25, 2019).

<sup>49</sup> For example, the American Burying Beetle, present in limited populations across nine states, is a carrion feeder in both the adult and larvae stages and thus does not feed on and would not be exposed to treated seed or plants. *See* NatureServe Explorer Report on *Nicrophorus Americanus* (American Burying Beetle) (accessed Mar. 25, 2019).

<sup>50</sup> Moore Rebuttal Decl. (May 18, 2018), ¶ 16.

<sup>51</sup> *Id.*

ignores the more recent BEAD analysis,<sup>52</sup> in which BEAD “upwardly revised their estimated net return for use of thiamethoxam or clothianidin treatments on soybean seeds to \$23/acre for mid-southern states and \$17/acre for Midwestern states.”<sup>53</sup> “On a national basis, these figures translate into \$215 million dollars per year in net returns to U.S. soybean farmers.”<sup>54</sup>

Numerous studies, reports, and expert declarations refute the Petition’s assertions that neonicotinoid seed treatments are “overused” and that the data do not show yield benefits from neonicotinoids. For example, Stewart, et al. (2014)<sup>55</sup> reported that the use of neonicotinoid treated seed for early planted soybean resulted in increased yields ranging from one to three bushels per acre. Another analysis by Gaspar et al. (2014)<sup>56</sup> found that use of neonicotinoid treated soybean seed led to improved economic returns and reduced the economically optimum seeding rate, in part because of improved yields. The Petition’s claims that treated seed results in yield reductions is also not borne out by the scientific evidence. *See, e.g.*, McCornack and Ragsdale (2006),<sup>57</sup> Magalhaes, et al. (2009),<sup>58</sup> Johnson et al. (2009),<sup>59</sup> Ohnesorg et al. (2009),<sup>60</sup> and Whitworth et al. (2005)<sup>61</sup> (showing no statistical difference in yields between plots planted with treated seed those that received only sprayed insecticides).

The Petition cites Petitioner CFS’s own report to claim that there is a “broad lack of independent data showing economic justification for [neonicotinoids] use on seeds.” Petition at

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<sup>52</sup> EPA, Biological and Economic Analysis Division (BEAD) response to public comments submitted in response to BEAD’s assessment entitled “Benefits of Neonicotinoid Seed Treatments to Soybean Production,” Dec. 5, 2017, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0737-0948>.

<sup>53</sup> Moore Decl. (Jan. 5, 2018), ¶ 16 (citing BEAD response to public comments submitted in response to BEAD’s assessment entitled “Benefits of Neonicotinoid Seed Treatments to Soybean Production” (2017)).

<sup>54</sup> *Id.*

<sup>55</sup> Scott Stewart & Angela McClure, *2014 Insect Control Recommendations for Field Crops*, University of Tennessee Extension 19, <https://extension.tennessee.edu/eastern/Documents/Grain%20Conference%202014/Insect%20Control%20recommendations%20for%20field%20crops%202014.pdf>.

<sup>56</sup> Adam P. Gaspar, Paul D. Mitchell, and Shawn P. Conley, *Economic Risk and Profitability of Soybean Fungicide/Insecticide Seed Treatments at Reduced Seeding Rates*, 55 *Crop Sci.* 924 (2015).

<sup>57</sup> Brian P. McCornack & David W. Ragsdale, *Efficacy of Thiamethoxam to Suppress Soybean Aphid Populations in Minnesota Soybean*, 5 *Crop Mgmt.*, doi:10.1094/CM-2006-0915-01-RS.

<sup>58</sup> Leonardo C. Magalhaes, Thomas E. Hunt, and Blair D. Siegfried, *Efficacy of Neonicotinoid Seed Treatments to Reduce Soybean Aphid Populations Under Field and Controlled Conditions in Nebraska*, 102 *J. Econ. Entomology* 187 (2009).

<sup>59</sup> Kevin D. Johnson et al., *Probability of Cost-effective Management of Soybean Aphid (Hemiptera: Aphididae) in North America* 102 *J. Econ. Entomology* 2101 (2009).

<sup>60</sup> Wayne J. Ohnesorg, Kevin D. Johnson, and Matthew E. O’Neal, *Impact of Reduced-risk Insecticides on Soybean Aphid and Associated Natural Enemies*, 102 *J. Econ. Entomology* 1816 (2009).

<sup>61</sup> Whitworth, R.J., *Information for 2005 Soybean Seed Treatment Trial - Scandia, KS*. Kansas State University Research and Extension (2005).

26. But a large volume of academic data, practical field trials, and articles published in peer-reviewed journals by agronomic experts shows otherwise. These were presented in the expert declarations submitted by Defendant-Intervenors in the *Ellis* litigation:

- “Neonicotinoid seed treatments have been widely adopted because of their efficacy, ease of use, and reduced risks for pesticide handlers. Seed treatments also have many economic benefits, particularly in the southern U.S. Corn farmers experience net returns of \$23/acre when using a neonicotinoid seed treatment compared to corn without an insecticide seed treatment.” Moore Decl. (Jan. 5, 2018), ¶ 16.
- “[T]reatment of cotton seeds with thiamethoxam or clothianidin has provided an increase in farmers’ net returns of \$57/acre in Arkansas, Louisiana, Mississippi, and Tennessee, whereas treatment of soybean seeds equates to an increase in net returns of \$12.50/acre in the mid-southern states.” *Id.* (footnotes omitted).
- “[D]ata from hundreds of field studies found yield gains [from neonicotinoid seed treatments] ranging from 15% to 20% for corn, sorghum, wheat and cotton to 3.6% for soybean” compared to not using any pest control treatment,” and “smaller, but still substantial” yield gains compared to use of alternative treatments “ranging from 5.9% for sorghum, 4.0% for corn, and 2.3% for wheat to 0.7% for cotton and 0.2% for soybean” compared to use of alternative pesticide treatments. Decl. of Paul Mitchell ¶ 59, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. Jan. 5, 2018), ECF No. 301.
- “A variety of field research has found similar yield responses and positive returns on investment for neonicotinoid products in multiple crops in several states.” *Id.* ¶ 60.
- Based on “[e]conomic analysis of farmer survey data,” “the average value of neonicotinoid seed treatments in 2015 for farmers using them was \$16.76 per acre for corn, \$13.28 per acre for soybean and \$17.35 per acre for cotton, net of the seed treatment cost (Hurley and Mitchell 2017).” *Id.* ¶ 62. This equates to total value to farmers from using neonicotinoid seed treatments in these three crops, compared to the next best alternatives, of \$1.5 billion. *Id.* ¶ 63.
- Neonicotinoid seed treatments are critical for providing control of potentially devastating pests such as wireworm, white grub, and corn billbug that are specific to the southeastern U.S. Decl. of Dominic Reisig ¶¶ 8–32, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. Jan. 5, 2018), ECF No. 300.
- Research shows significant reduction in crop damage and substantial yield benefits from use of neonicotinoid seed treatments in the southeastern U.S. *Id.* ¶¶ 14–15, 27–31.
- Research confirms that neonicotinoids are superior to any other class of pesticides at controlling the corn billbug, which has a long history of devastating southeastern corn crops. *Id.* ¶¶ 16–25.
- Neonicotinoid seed treatments also have a more favorable profile with respect to potential

human health and ecological risks than available alternatives. *Id.* ¶¶ 7, 13, 24.

- In the past, corn growers faced “significant threats and suffered substantial crop losses due to seed corn maggot and chinch bugs,” but “[s]erious infestations” of these pests are no longer observed due to the “excellent control” provided by neonicotinoid seed treatments. Decl. of Scott Stewart ¶¶ 22–23, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. Jan. 5, 2018), ECF No. 304.
- In the south, neonicotinoid provides significant yield benefits by controlling the southern corn rootworm. *Id.* ¶¶ 24–25.
- Field trial studies from southern and mid-southern states show clear yield benefits to farmers from use of neonicotinoids on cotton, grain sorghum, and wheat. *Id.* ¶¶ 27–32.

Finally, Petitioners, citing their own “report,” contend that the purported lack of impacts of the recent prohibition of most neonicotinoid seed treatment uses in Europe shows that the products do not provide significant economic benefits. Petition at 26. Setting aside “the very different geographies, conditions, crops and agricultural practice” between Europe and the United States,” a “recent report reviewing 13 studies on the impacts of the neonicotinoid ban on rapeseed (canola) in Europe shows the profound negative impacts of the ban, including yield losses from 1 to 22%, economic losses of over 500 million EUR annually, shifts of acreage to other crops (or countries) and increased use of foliar pyrethroid applications.” Decl. of Scott Stewart ¶¶ 77–78, *Ellis v. Keigwin*, No. 3:13-cv-01266-MMC (N.D. Cal. May 18, 2018), ECF No. 352 (citing HFFA Research, Banning neonicotinoids in the European Union (2017), [https://www.ecpa.eu/sites/default/files/documents/HFFA\\_Research\\_Paper\\_neonics\\_internet\\_protection.pdf](https://www.ecpa.eu/sites/default/files/documents/HFFA_Research_Paper_neonics_internet_protection.pdf)).

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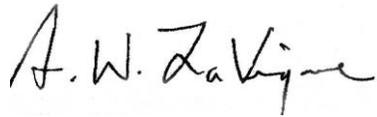
CLA, ASTA, and BPIA appreciate the opportunity to provide these comments in support of EPA’s current interpretation of the Treated Article Exemption with respect to pesticide-treated seed. Should EPA have any questions or wish to discuss these issues further, please do not hesitate to contact us.

Thank you for your consideration of these comments.

Sincerely,



Chris Novak  
CropLife America



Andrew W. LaVigne  
President/CEO  
American Seed Trade Association



Keith J. Jones  
Executive Director  
Biological Products Industry Alliance