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12 **UNITED STATES DISTRICT COURT**
13 **NORTHERN DISTRICT OF CALIFORNIA**
14 **SAN FRANCISCO DIVISION**

15 JEFF ANDERSON, *et al.*,

16 Plaintiffs,

17 v.

18 GINA MCCARTHY, *et al.*,

19 Defendants,

20 and

21 CROPLIFE AMERICA, *et al.*,

22 Defendant-Intervenors.

Case No. 3:16-cv-00068-WHA

**DEFENDANT-INTERVENORS' NOTICE
OF MOTION AND MOTION FOR
SUMMARY JUDGMENT**

(The Honorable William H. Alsup)

Date: October 27, 2016

Time: 8:00 a.m.

Courtroom: 8, 19th Floor

NOTICE OF MOTION

1
2 Notice is hereby given that Defendant-Intervenors CropLife America (“CropLife”),
3 American Seed Trade Association (“ASTA”), Agricultural Retailers Association, American
4 Soybean Association, National Cotton Council of America, National Association of Wheat
5 Growers, and National Corn Growers Association (collectively “Intervenors”) hereby move this
6 Court for summary judgment in favor of Intervenors and Defendants United States Environmental
7 Protection Agency and Administrator McCarthy (hereinafter jointly referred to as “EPA”)
8 (together with Intervenors, “Defendants”) on all claims. Intervenors’ Motion shall come on for a
9 hearing before the Honorable William H. Alsup, United States District Judge, on October 27,
10 2016, at 8:00 a.m., or as soon as this matter may be heard, in Courtroom 8 on the 19th Floor of
11 the Philip E. Burton Courthouse and Federal Building, 450 Golden Gate Avenue, San Francisco,
12 California.
13
14

RELIEF REQUESTED

15
16 Pursuant to Civil Rule L.R. 7-2, Intervenors respectfully move for summary judgment for
17 Defendants on all claims. In support of the Motion, Intervenors rely on the accompanying
18 Memorandum of Points and Authorities and join in the motion for summary judgment filed by
19 EPA.
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Cases

Alabama-Coushatta Tribe v. United States,
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Almond Hill Sch. v. U.S. Dep’t of Agric.,
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American Farm Bureau v. EPA,
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Cal. Native Plant Soc’y v. Norton,
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Conservation Cong. v. Finely,
2012 WL 2989133 (N.D. Cal. June 28, 2012), *aff’d*, 774 F.3d 611 (9th Cir.
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Ctr. For Biological Diversity v. U.S. Dep’t of Hous. & Urban Dev.,
241 F.R.D. 495 (D. Ariz. 2006) 14

Donelson v. United States,
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Fiedler v. Clark,
714 F.2d 77 (9th Cir. 1983) 15

Friends of Endangered Species, Inc. v. Jantzen,
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Mut. Pharm. Co. v. Ivax Pharms., Inc.,
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Nat’l Wildlife Fed’n v. Caldera,
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 4 762 F. Supp. 2d 34 (D.D.C. 2011)..... 2

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INTRODUCTION

1
2 Plaintiffs' complaint alleges that EPA has wrongly applied the "treated article" exemption
3 under FIFRA's implementing regulations, 40 C.F.R. § 152.25 (1989), to seed treated with
4 pesticides. It is Plaintiffs' contention that pesticide-treated seed should, itself, be subject to
5 duplicative and unnecessary review and registration as a pesticide under the Federal Insecticide,
6 Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136, *et seq.* Each of Plaintiffs' claims
7 constitutes an impermissible programmatic attack on EPA's existing pesticide regulatory
8 program—specifically, the interplay between EPA's regulation of pesticides registered to be
9 applied as seed treatments and what Plaintiffs characterize as its categorical application of the
10 treated article exemption to the treated seed. As a result, each of these claims is non-justiciable as
11 a matter of law, entitling Defendants to summary judgment in their favor.

12 In bringing these improper programmatic claims, Plaintiffs seek to make an end-run
13 around Congress's express determination not to include a private right of action under FIFRA.
14 Plaintiffs further seek to impose a regulatory process on agriculture that would be entirely
15 duplicative of EPA's existing exercise of its authority under FIFRA, while having no impact on
16 human health or environmental safety. The pesticides used for seed treatments are themselves
17 subject to rigorous, scientifically robust review and approval under FIFRA. Pursuant to, and also
18 independent of, that review and approval, EPA, in partnership with Intervenors, Intervenors'
19 members, and other stakeholders, has taken and continues to take affirmative measures to address
20 pollinator safety, the concern cited in the complaint. For all of these reasons, and for reasons
21 stated in EPA's motion,¹ Intervenors respectfully request that the Court grant summary judgment
22 for Defendants as to all claims.

STATEMENT OF THE CASE

A. Background on EPA's Regulation of Pesticides

24 Pesticides are among the most heavily regulated substances in the United States. EPA
25 regulates pesticides under a comprehensive, science-based regime pursuant to its authority under
26 FIFRA.
27

28 ¹ Intervenors join fully EPA's motion for summary judgment.

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

15 In conducting its risk-based determination of whether registration of a pesticide product
16 meets the FIFRA standard, EPA reviews extensive data pertaining to the pesticide’s active
17 ingredient as well as formulations and particular uses of the pesticide, including use as a seed
18 treatment. 7 U.S.C. § 136a; 40 C.F.R. §§ 152.100–152.119. EPA’s expert scientists also conduct
19 a variety of risk assessments that identify and analyze potential risks that could be associated with
20 various uses, including risks to beneficial or “non-target” organisms, such as honey bees.³ Only
21

22 ² FIFRA’s implementing regulations describe the types of data and information EPA generally
23 requires to support registration. *See* 40 C.F.R. § 158.1(a). The data requirements for registration
24 “are intended to generate data and information necessary to address concerns pertaining to the
25 identity, composition, potential adverse effects and environmental fate of each pesticide.” 40
26 C.F.R. § 158.130(a). These include specific requirements for data regarding product chemistry,
27 product performance, and the toxicological and ecological effects of the pesticide products. *See*
28 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).

³ *See* <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

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

7 Once a pesticide is registered by EPA, FIFRA requires that EPA conduct periodic
8 reassessments of the data required to support a pesticide registration every fifteen years, known as
9 Registration Review. *Id.* § 136a(g). This periodic review is required to ensure that, as scientific
10 capabilities for assessing risk develop and as policies and pesticide use practices change over
11 time, all registered products continue to meet the statutory standard of “no unreasonable adverse
12 effects.” *Id.* § 136(bb). FIFRA additionally provides EPA with ongoing enforcement authority
13 over pesticide registrations and authorizes EPA to issue stop sale, use, or removal orders or to
14 impose civil and criminal penalties for violating FIFRA’s requirements. *See, e.g., id.* §§ 136k,
15 136l.

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

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

24 FIFRA provides that the Administrator is authorized to exempt certain pesticide products
25 from regulation under FIFRA, including those that are determined to be: (1) adequately regulated
26 by another federal agency; or, relevant here, (2) of a character not requiring FIFRA regulation in
27 order to carry out the purposes of the Act. *Id.* §136w(b).

28 Under regulations implementing this provision, EPA has determined that “treated articles”

1 are “exempt from all provisions of FIFRA.” 40 C.F.R. § 152.25(a). Treated articles or
2 substances are defined as:

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

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

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

14 In addition to EPA’s regulation of the pesticides used to treat seeds, treated seed is
15 separately regulated by the United States Department of Agriculture (“USDA”) under the
16 Federal Seed Act (“FSA”), 7 U.S.C. §§ 1551–1611, which regulates the interstate
17 shipment of agricultural and vegetable seeds. Administered by the USDA’s Agricultural
18 Marketing Service, the FSA’s implementing regulations set forth labeling and other
19 requirements for treated seed aimed at facilitating uniformity, transparency, and fair
20 competition within the seed trade. *See* 7 C.F.R. Part 201.⁴ For example, Section
21 201.31a(a) of the FSA regulations requires that all treated seed be labeled with the name
22 of the seed treatment product (*e.g.*, “Treated with [pesticide name]”). Section 201.31a(d)
23 requires that seed treated with certain classes of substances contain restrictions for use on
24 the label (*e.g.*, “Do not use for food, feed, or oil purposes.”). EPA recommends that these
25 labeling requirements for treated seed be included on the labels for pesticide products
26

27
28 ⁴ *See also* <https://www.ams.usda.gov/sites/default/files/media/ChemTreatedLabel%5B1%5D.pdf>.

1 approved for use as seed treatments.⁵

2 **D. EPA Action to Address Pollinator Safety**

3 In addition to its regulation of the specific seed treatments at issue in this litigation, EPA
4 and other stakeholders, including Intervenors and their members, beekeepers, growers, and
5 environmental activist organizations, have taken affirmative steps to more broadly evaluate and
6 address potential risks that crop protection products, including the seed treatment products at
7 issue here, may pose to pollinators, including honey bees. In April 2011, EPA's Pesticide
8 Program Dialogue Committee ("PPDC"), a diverse group of EPA stakeholders established to
9 provide feedback to EPA on pesticide regulatory, policy, and program implementation issues,⁶
10 formed a Pollinator Protection workgroup. *See* Administrative Record ("AR") 00153-57. This
11 group, comprised of a broad array of stakeholders from industry, academia, agriculture,
12 government, and various environmental activist organizations, including representatives from
13 Intervenor CropLife and several of its members, provides information on an ongoing basis to
14 EPA on complex pollinator protection issues including: (1) science-based risk management
15 approaches, including appropriate labeling restrictions and training, (2) state approaches to and
16 authority for addressing pollinator protection issues, (3) stakeholder experience in improving
17 management practices, and (4) international communication, among others. *Id.* at 154.

18 In September 2012, EPA convened a public meeting of its FIFRA Scientific Advisory
19 Panel ("SAP") to evaluate a proposed tiered framework for quantitatively assessing potential risk
20 to pollinators associated with agricultural pesticide use.⁷ The Panel, comprised of scientists with
21 expertise in toxicology, chemistry, and entomology, among other disciplines, provided guidance
22 and recommendations to EPA on data needs and methods for quantifying exposures and effects
23 and characterizing potential risks to pollinators. Plaintiffs and Intervenors and their members
24

25 ⁵ *See* EPA's Label Review Manual, ch. 18, https://www.epa.gov/sites/production/files/2014-06/documents/chap-18_0.pdf, at 18-9.

26 ⁶ *See* <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about>.

27 ⁷ The SAP is a Federal advisory committee established under FIFRA to provide expert scientific
28 advice and recommendations to the Agency. 7 U.S.C. § 136w(d)(1).

1 submitted comments to the SAP and participated in the SAP meeting.⁸

2 As an outgrowth of the SAP meeting, EPA has devoted substantial resources to
3 developing protocols and methods and identifying data needs for assessing potential pesticide
4 risks to pollinators. EPA, in partnership with Health Canada Pest Management Regulatory and
5 California Department of Pesticide Regulation (“DPR”), developed guidance for risk assessors to
6 use in characterizing pesticide risks to bees, which specifically outlined a risk assessment process
7 for evaluating pesticide seed treatments.⁹ The guidance describes a tiered process for analyzing
8 exposure risks to individual bees and bee colonies. EPA recently supplemented this 2014
9 guidance with guidance specifically targeted at risk assessors in EPA’s Office of Pesticide
10 Programs (“OPP”), the branch of EPA responsible for regulating pesticide use. This supplement
11 provides guidance on the exposure and effects (toxicity) studies that OPP staff should consider
12 when evaluating a pesticide’s potential risks to bees.¹⁰ Just in the past several weeks, EPA issued
13 an additional guidance document, which provides interim guidance to both the public and OPP
14 staff for determining when the toxicity data described in the earlier guidance are required.¹¹

15 In addition to the above, in 2013, EPA instituted new labeling requirements for registrants
16 of neonicotinoid pesticides in order to strengthen protections for pollinators.¹² EPA has also
17 reiterated registrants’ affirmative obligation under FIFRA to report to EPA any pesticide
18 incidents involving harm or potential harm to pollinators and imposed an accelerated ten-day
19 timeframe for submitting such reports.¹³ *See* 7 U.S.C. § 136d(a)(2) (mandating that pesticide
20 registrants report on an ongoing basis “factual information regarding unreasonable adverse effects
21 on the environment of [a] pesticide.”).

22 In concert with EPA’s regulatory focus on pollinator issues, EPA, Intervenor, and other

23 _____
24 ⁸ *See* Final FIFRA SAP Pollinator Meeting Report, EPA-HQ-OPP-2012-0543, available at
<https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0047>.

25 ⁹ *See* <https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance>.

26 ¹⁰ <https://www.epa.gov/sites/production/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf>.

27 ¹¹ https://www.epa.gov/sites/production/files/2016-08/documents/bee_guidance.pdf.

28 ¹² *See* <https://www.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides>.

¹³ *See id.*

1 participants in the agricultural value chain have worked to promote the development of new seed-
2 planting technologies aimed at reducing pollinators' exposure to dust from treated seed.¹⁴ In
3 March 2013, EPA convened a Pollinator Summit, a public meeting with industry, growers,
4 beekeepers, and other stakeholders to discuss strategies for managing pesticide risks to honeybees
5 and other pollinators, including through research, new technologies, best practices, and other
6 stewardship activities.¹⁵ Advancements in seed treatment technologies discussed during the
7 Pollinator Summit include technologies for cleaning and de-dusting treated seed and
8 enhancements in polymer coatings, both aimed at minimizing dust-off.¹⁶

9 In June 2014, President Obama issued a memorandum establishing an interagency
10 Pollinator Health Task Force, co-chaired by USDA and EPA, to develop a National Pollinator
11 Health Strategy aimed at promoting the health of honey bees and other pollinators. In support of
12 this Strategy, EPA accelerated Registration Review and initiated ecological risk assessments for
13 all neonicotinoid pesticides—including the products identified in Plaintiffs' complaint—
14 specifically focused on potential risks to pollinators.¹⁷ In January 2016, in collaboration with the

15
16 ¹⁴ For example, Intervenor CropLife's member Bayer CropScience has developed seed lubricant
17 technology shown to reduce dust released by treated seed by 60–90% compared to other products,
18 reducing potential risks to pollinators. See [https://www.cropscience.bayer.us/news/press-
19 releases/2014/02252014-0037-bcs-announces-commerical-availability-of-fluency-agent](https://www.cropscience.bayer.us/news/press-releases/2014/02252014-0037-bcs-announces-commerical-availability-of-fluency-agent); see also
20 Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid, EPA-HQ-
21 OPP-2008-0844-0140 at 255–56 (describing improvements in technology aimed at reducing
22 potential pollinator exposure from seed treatment applications, including new seed lubricants
23 used during planting operations and new design standards for pneumatic planting equipment).

24 ¹⁵ For example, Intervenors ASTA and CropLife have collaborated to develop a comprehensive
25 seed treatment stewardship guide, based on research and safety information from a variety of
26 industry sources, that includes best practices for seed treatment use aimed at reducing risks to
27 non-target organisms, including pollinators. See [http://www.seed-treatment-guide.com/wp-
28 content/uploads/2013/03/Guide-to-Seed-Treatment-Stewardship.pdf](http://www.seed-treatment-guide.com/wp-content/uploads/2013/03/Guide-to-Seed-Treatment-Stewardship.pdf). ASTA presented the
29 stewardship guide during the 2013 Pollinator Summit. See
30 [https://www.epa.gov/sites/production/files/2013-11/documents/lisa-nichols-seed-treatment-
31 guide.pdf](https://www.epa.gov/sites/production/files/2013-11/documents/lisa-nichols-seed-treatment-guide.pdf).

32 ¹⁶ See, e.g., [https://www.epa.gov/sites/production/files/2013-11/documents/palle-pederson-
33 formulation-technology.pdf](https://www.epa.gov/sites/production/files/2013-11/documents/palle-pederson-formulation-technology.pdf) (Syngenta presentation);
34 [https://www.epa.gov/sites/production/files/2013-11/documents/mike-mcfatrigh-seed-applied-
35 additives.pdf](https://www.epa.gov/sites/production/files/2013-11/documents/mike-mcfatrigh-seed-applied-additives.pdf) (Bayer presentation).

36 ¹⁷ See <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides>
37 (detailing schedule for review of Imidacloprid, Clothianidin, and Thiamethoxam).

1 California Department of Pesticide Regulation, EPA completed and released for public comment
 2 the first of these pollinator assessments, *Preliminary Pollinator Assessment to Support the*
 3 *Registration Review for Imidacloprid*,¹⁸ based on seventy-five open-literature studies as well as
 4 extensive data. The Assessment noted that, “[w]ith respect to potential exposure via drift of
 5 abraded seed coat dust, the Agency is working with different stakeholders to identify best
 6 management practices and to promote technology-based solutions that reduce this potential route
 7 of exposure.”¹⁹ EPA received 1,025 comments on its preliminary pollinator risk assessment for
 8 imidacloprid, including comments from a number of parties to this lawsuit,²⁰ including Plaintiffs.
 9 EPA’s preliminary assessments for three other neonicotinoids (clothianidin, thiamethoxam, and
 10 dinotefuran) are expected later this year, with a fourth (acetamiprid) to follow in 2018.²¹

11 As shown above, EPA, working with other stakeholders like USDA and Intervenors and
 12 their members, and pursuant to its pesticide regulatory authority under FIFRA, has undertaken
 13 extensive efforts to protect pollinators from pesticides, only some of which are described here.
 14 Plaintiffs seek to compel duplication of these efforts by mandating the regulation of the treated
 15 seed itself, notwithstanding EPA’s rigorous and comprehensive regulation of pesticide seed
 16 treatments. In any case, as set forth below, Plaintiffs seek an overhaul of EPA’s existing program
 17 for regulating pesticides used as seed treatments, including the longstanding application of the
 18 treated article exemption to seed that meet the exemption’s criteria, thereby avoiding the
 19 duplicate effort of regulating the seed itself as a pesticide after treatment. This type of broad
 20 attack on EPA’s regulatory authority renders each of their claims non-justiciable.

23 ¹⁸ See, e.g., Preliminary Pollinator Assessment to Support the Registration Review of
 24 Imidacloprid, EPA-HQ-OPP-2008-0844-0140.

25 ¹⁹ *Id.* at 14.

26 ²⁰ See, e.g.,

27 <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 Plaintiff American Bird
 28 Conservancy, Plaintiff Bret Adey, Plaintiff Center for Food Safety, Intervenor ASTA, Intervenor
 the American Soybean Association, Intervenor CropLife, and Intervenor National Cotton Council
 of America, among others).

²¹ <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides>.

1 **E. Procedural History**

2 Plaintiffs, comprised of beekeepers, growers, and public interest organizations, filed suit
3 on January 6, 2016, alleging that EPA should regulate treated seed, in addition to pesticides used
4 as seed treatments, and that its failure to do so violates FIFRA and the APA. Specifically,
5 Plaintiffs allege that EPA's purportedly categorical application of the treated article exemption to
6 treated seed is beyond EPA's authority (Count I), invalid for failure to comply with the APA
7 rulemaking procedures (Count III), and arbitrary and capricious and contrary to FIFRA and APA
8 (Count IV). They further allege that EPA has failed to regulate and enforce FIFRA with respect
9 to treated seed (Count II). Plaintiffs claim EPA's failure to regulate treated seed has caused
10 environmental and economic harm, including harm to honey bees. As set forth below, Plaintiffs
11 have failed to establish that their claims are justiciable, entitling Defendants to summary
12 judgment in their favor.

13 **STANDARD OF REVIEW**

14 Summary judgment must be granted if "there is no genuine dispute as to any material fact
15 and the movant is entitled to judgment as a matter of law." *Save Strawberry Canyon v. U.S.*
16 *Dep't of Energy*, 830 F. Supp. 2d 737, 745 (N.D. Cal. 2011) (quoting Fed .R. Civ. P. 56(a)). The
17 APA provides for judicial review of agency actions causing legal wrongs or adversely affecting a
18 person within the meaning of a relevant federal statute. 5 U.S.C § 702. "The APA modifies the
19 usual summary judgment standard." *Cal. Native Plant Soc'y v. Norton*, No. 01CV1742 DMS
20 (JMA), 2004 WL 1118537, at *4 (S.D. Cal. Feb. 10, 2004). Under the APA, a court may
21 overturn an agency action only where such action is found to be "arbitrary, capricious, an abuse
22 of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Conservation*
23 *Cong. v. Finely*, 2012 WL 2989133, at *5 (N.D. Cal. June 28, 2012) ("When the court reviews a
24 government agency's final action, the Rule 56 standard for summary judgment is amplified by 5
25 U.S.C. § 706(2) of the [APA]."), *aff'd*, 774 F.3d 611 (9th Cir. 2014). Under this arbitrary and
26 capricious standard, "administrative action is upheld if the agency has 'considered the relevant
27 factors and articulated a rational connection between the facts found and the choice made.'"

1 *Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976, 982 (9th Cir. 1985) (quoting *Balt.*
2 *Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 105 (1983)).

3 Summary judgment serves as an appropriate mechanism for deciding whether the
4 administrative record supports the agency’s decision and whether the agency complied with the
5 APA. *Occidental Eng’g Co. v. INS*, 753 F.2d 766, 769–70 (9th Cir. 1985). In reviewing a
6 motion for summary judgment in an administrative action, “there are no disputed facts that the
7 district court must resolve.” *Id.* at 769. Rather, “the function of the district court is to determine
8 whether or not as a matter of law the evidence in the administrative record permitted the agency
9 to make the decision it did.” *Id.*

10 ARGUMENT

11 Each of Plaintiffs’ claims asserts a broad, wholesale challenge to what Plaintiffs
12 characterize as EPA’s regulatory “policy” with respect to of a broad category of treated seed.
13 Because these claims target EPA’s implementation of FIFRA as a whole, rather than a discrete
14 and final agency action or a non-delegable duty EPA has allegedly failed to perform, they are
15 non-justiciable programmatic claims, and must be dismissed. Plaintiffs’ claims are not made
16 justiciable by contending that an EPA bee inspection guidance document is “final agency action,”
17 an argument without any factual or legal basis, or by simply making reference to specific
18 products used for seed treatment. Identifying examples of claimed flaws in an entire program is
19 not sufficient to overcome the Supreme Court’s clear prohibition on programmatic challenges. In
20 bringing these improper programmatic claims, Plaintiffs impermissibly seek to derive a private
21 right of action under FIFRA where one does not exist. It is appropriate for the Court to finally
22 resolve these threshold jurisdictional issues before reaching the merits of Plaintiffs’ claims. *See*
23 *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 93–94 (1998) (court must confirm its own
24 jurisdiction before reaching the merits of any dispute).

25 **A. Plaintiffs’ Suit Constitutes an Improper Programmatic Challenge to EPA’s** 26 **Regulation of Pesticides, Which Includes EPA’s Approach to the “Treated Article”** 27 **Exemption.**

28 Plaintiffs broadly challenge EPA’s approach to the “treated article” exemption, and,

1 correspondingly, the Agency’s framework for regulating pesticide products used as seed
 2 treatments, under the APA and FIFRA. Because FIFRA does not authorize a general private right
 3 of action, Plaintiffs’ claims purport to arise under the provisions of the APA permitting suits
 4 challenging final agency action. 5 U.S.C. § 704. For a claim to be justiciable under the APA,
 5 Plaintiffs must identify and challenge an “agency action” that is both discrete and final. *Norton v.*
 6 *S. Utah Wilderness Alliance*, 542 U.S. 55, 62–63 (2004) (“SUWA”). “Agency action” is defined
 7 to include “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent
 8 or denial thereof, or failure to act.”²² 5 U.S.C. § 551(13).

9 The Supreme Court has clarified that courts may not exercise jurisdiction over broad,
 10 programmatic challenges that are not directed to a specific, final agency action with an immediate
 11 or threatened effect on the plaintiffs. In *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 890–91
 12 (1990), plaintiffs challenged the Bureau of Land Management’s (“BLM”) “land withdrawal
 13 review program,” *i.e.*, BLM’s ongoing process of reviewing land withdrawal applications,
 14 developing of land use plans, and classifying public lands for certain uses. *Id.* at 890. The Court
 15 determined that Plaintiffs’ claims, which alleged defects in the land withdrawal review program
 16 as a whole, constituted an improper programmatic challenge. “[F]laws in the entire ‘program’ . . .
 17 cannot be laid before the courts for wholesale correction under the APA” but rather must be
 18 corrected by BLM or Congress. *Id.* at 893. Instead, a plaintiff must “direct its attack against
 19 some particular ‘agency action’ that causes it harm.” *Id.* at 891. The Court explained that:

20 Except where Congress explicitly provides for our correction of the administrative
 21 process at a higher level of generality, we intervene in the administration of the laws
 22 only when, and to the extent that, a specific “final agency action” has an actual or
 23 immediately threatened effect. . . . Until confided to us . . . more sweeping actions
 24 are for the other branches.

25 *Id.* at 894; *see also Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 726, 734–35 (1998) (plaintiff
 26 environmental groups’ claims challenging Forest Service’s land resource management plan were
 27 not justiciable because they failed to identify a “concrete” and “site-specific” logging decision

28 ²² Claims challenging an agency’s failure to act arise under § 706(1) of the APA.

1 reviewable under the APA) (citing *Lujan*, 497 U.S. at 894).

2 In *SUWA*, the Supreme Court clarified that *Lujan*'s prohibition on programmatic
3 challenges applies equally to an agency's alleged "failure to act." 542 U.S. at 63. (2004).
4 There, plaintiffs brought suit against the BLM broadly challenging its "failure to act to
5 protect public lands in Utah from damage caused by [off-road vehicle] use." 542 U.S. at
6 60. The Court observed that "[an alleged] 'failure to act' is properly understood to be
7 limited," as with other agency actions, "to a *discrete* action." *Id.* at 63. This "limitation to
8 discrete agency action precludes the kind of broad programmatic attack [the Court]
9 rejected in [*Lujan*]." *Id.* at 64. The wholesale relief plaintiffs were seeking would
10 inappropriately "inject[] the judge into day-to-day agency management." *Id.* at 67. The
11 APA did not contemplate this type of "pervasive oversight by federal courts over the
12 manner and pace of agency compliance with . . . congressional directives . . ." *Id.*

13 Similarly to *Lujan* and *SUWA*, Plaintiffs broadly attack an agency's, here EPA's,
14 regulatory program, not any specific agency action. Plaintiffs have alleged that EPA has
15 categorically applied the treated article exemption to treated seed and that its application is
16 beyond the Agency's authority (Count I) and contrary to FIFRA and the APA (Counts III
17 and IV). Plaintiffs have failed to identify a "discrete" and "circumscribed" agency action
18 on which these claims are premised, *SUWA*, 542 U.S. at 62, but instead challenge EPA's
19 decision-making with respect to an entire class of products.²³ This is precisely the type of
20 impermissible programmatic challenge the Supreme Court struck down in *Lujan*.

21 Plaintiffs' failure to act claim (Count II) fares no better. Plaintiffs complain that
22 EPA's failure to regulate seeds treated with neonicotinoid pesticides as pesticides
23 themselves is unlawful under FIFRA (Count II). By Plaintiffs' own admission, Plaintiffs'
24 failure to act claim is not tied to a specific, discrete agency action but rather to EPA's
25 interpretation of the treated article exemption with respect to treated seed as a whole:
26 "EPA's policy choice to not regulate this entire class of conduct (the sale, labeling, and
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28 ²³ Tellingly, Plaintiffs' complaint misleadingly refers to EPA's exemption of "a whole class of pesticides," rather than seeds. Compl. ¶¶ 75–76.

1 planting of neonicotinoid-coated seeds) has nothing to do with individual non-
2 enforcement decisions. Instead, EPA has a broad policy of exemption of these products
3 from FIFRA” Compl. ¶ 83. But in order to maintain a justiciable claim, Plaintiffs
4 must identify and challenge those “individual non-enforcement decisions,” instead of
5 EPA’s general regulatory practice with respect to treated seed and seed treatments. *See*
6 *Lujan*, 497 U.S. 893–94. Plaintiffs’ omnibus approach is fatal to its claim as a matter of
7 law.

8 Plaintiffs’ claims here are similar to the improper programmatic claims struck down in
9 *American Farm Bureau v. EPA*, 121 F. Supp. 2d 84 (D.D.C. 2000). There, plaintiffs broadly
10 challenged EPA’s implementation of the Food Quality Protection Act (“FQPA”), alleging that
11 EPA did not take actions required by the FQPA relating to evaluation of new pesticide uses and
12 reevaluation of the safety of authorized pesticides. In dismissing four claims brought under the
13 APA, the court reasoned that plaintiffs sought a wholesale review of EPA’s approach to
14 establishing and continuing pesticide registrations and food safety tolerances for these pesticides.
15 *Id.* at 101. The plaintiffs did not challenge a single, *specific* EPA decision to deny or cancel a
16 tolerance or registration, but rather pointed to cancellation agreements for certain pesticides as
17 examples of EPA’s noncompliance with FFDCA and FIFRA. *Id.* at 103. Very similarly,
18 Plaintiffs in this case seek wholesale review of EPA’s compliance with FIFRA in its treatment of
19 broad categories of treated seed, rather than any specific, individual action. *See also, e.g.,*
20 *Alabama-Coushatta Tribe v. United States*, 757 F.3d 484, 490–91 (5th Cir. 2014) (upholding
21 dismissal of complaint structured “as a blanket challenge to all of the government’s actions with
22 respect to all permits and leases granted for natural resource extraction” as an impermissible
23 programmatic challenge). Plaintiffs’ programmatic approach here fails as non-justiciable.

24 **B. Plaintiffs’ Programmatic Claims Are Not Made Justiciable By their Reliance on**
25 **EPA’s Bee Inspection Guidance and Specific Treated Seed Products.**

26 Plaintiffs’ programmatic challenge is not made justiciable by their identification of EPA’s
27 2013 *Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents* (the “Inspection
28 Guidance”) as an alleged “final agency action.” As EPA has argued, the Inspection Guidance is

1 an informal guidance document developed for use by enforcement personnel, rather than the
2 general public, and is not an “agency action” as that term is understood under the APA. EPA
3 Mem. in Supp. of Mot. to Dismiss, at 7–8 ECF No. 21. Even if it constituted an “agency action,”
4 it is not “final” because it is not the consummation of a relevant agency decision-making process
5 and has no legal effect. *Id.* at 8–12.

6 Even if this Court were to find that the Agency’s Inspection Guidance constituted a “final
7 agency action,” which it does not, that would not be enough to cloak the underlying
8 impermissible programmatic challenge. The Supreme Court has made clear that simply pointing
9 to examples of flaws in an entire program does not permit a party to lay the entire program before
10 the courts “for wholesale correction under the APA.” *Lujan*, 497 U.S. at 893–94; *see also Sierra*
11 *Club v. Peterson*, 228 F.3d 559, 567 (5th Cir. 2000) (environmental groups may not “challenge an
12 entire program by simply identifying specific allegedly-improper final agency actions within that
13 program”); *Ctr. For Biological Diversity v. U.S. Dep’t of Hous. & Urban Dev.*, 241 F.R.D. 495,
14 500 (D. Ariz. 2006) (granting summary judgment on programmatic claims, observing that any
15 specific, final agency actions identified were mere examples of the alleged overall, ongoing
16 violations of NEPA). Regardless of how the Inspection Guidance is characterized, it is EPA’s
17 implementation of FIFRA and resulting “policy” with respect to treated seed in general that is the
18 subject of Plaintiffs’ claims. Claims seeking this type of judicial oversight over EPA’s
19 compliance with its statutory directives are not permitted. *SUWA*, 542 U.S. at 64.

20 Nor are Plaintiffs’ claims saved by their identification of specific treated seed and seed
21 treatment products. *See Compl.* ¶¶ 39, 53–54 (listing examples of “unregistered pesticidal crop
22 seeds” and their corresponding seed treatments). Merely identifying specific products as
23 examples of unlawfulness in an entire program is not sufficient to make a programmatic claim
24 justiciable. *See Nat’l Wildlife Fed’n v. Caldera*, No. CIV.A. 00-1031(JR), 2002 WL 628649 at
25 *3–4 (D.D.C. Mar. 26, 2002) (dismissing programmatic claims, reasoning that twenty-three
26 specifically challenged permits were mere examples of what plaintiffs alleged to be rampant
27 unlawfulness in overall program); *Donelson v. United States*, No. 14-CV-316-JHP-FHM, 2016
28 WL 1301169, at *4 (N.D. Okla. Mar. 31, 2016) (dismissing programmatic claim for lack of

1 subject matter jurisdiction and reasoning that plaintiffs could not identify specific leases as
2 examples of allegedly improper final agency actions to support a sweeping argument that the
3 BIA's entire leasing program violated NEPA). Plaintiffs' complaint seeks review of EPA's
4 overall approach to regulating an entire class of products—an improper programmatic challenge
5 on which Defendants are entitled to judgment as a matter of law. *See Lujan*, 497 U.S. at 892–93.

6 **C. Plaintiffs Seek to Derive a Private Right of Action under FIFRA Where It Does Not**
7 **Exist.**

8 In bringing their claims as a wholesale challenge to EPA's regulation of pesticides used as
9 seed treatments and implementation of the treated article exemption, Plaintiffs have highlighted
10 the fact that there is no general private right of action for non-registrants to enforce FIFRA. *See,*
11 *e.g., Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 941 (C.D. Cal. 2006) (“[T]here
12 is no private right of action to enforce FIFRA and its implementing regulations.”); *Fiedler v.*
13 *Clark*, 714 F.2d 77, 79 (9th Cir. 1983) (holding there to be no private right of action under
14 FIFRA); *see also Turner v. EPA*, 848 F. Supp. 711, 716 (S.D. Miss. 1994) (dismissing
15 distributor's suit under FIFRA alleging product was not subject to regulation under FIFRA
16 “[b]ecause there is no private right of action for nonregistrants under FIFRA”). Congress, in
17 debating FIFRA's enforcement scheme, specifically considered and decided *not* to include a
18 private right of action. *See Almond Hill Sch. v. U.S. Dep't of Agric.*, 768 F.2d 1030, 1038 (9th
19 Cir. 1985) (“Indeed, the House-Senate Conference Committee explicitly rejected the use of
20 private suits to enforce [FIFRA]. This explicit rejection of a proposed amendment to authorize
21 private suits is a strong indication that Congress was opposed to private actions to enforce the
22 provisions of FIFRA.”) (citing Conf. Rep. No. 92–1540, *reprinted in* 1972 U.S.C.C.A.N. 4130,
23 4134); *see also Rodriguez v. Am. Cyanamid Co.*, 858 F. Supp. 127, 131 (D. Ariz. 1994)
24 (“Congress specifically considered and rejected amendments to FIFRA that would have provided
25 for citizen suits.”). In bringing suit to challenge a purported program under FIFRA, Plaintiffs
26 impermissibly seek to inject a private right of action into FIFRA where one does not exist, further
27 supporting that their claims are non-justiciable.

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CONCLUSION

Plaintiffs seek to challenge EPA’s “policy” with respect to broad categories of treated seed. *See, e.g.*, Compl., ¶ 84 (“EPA’s . . . policy of non-enforcement”) ¶ 89 (EPA’s “practice” of “not regulat[ing] coated seed products”); ¶ 98 (EPA’s “misapplication of the ‘treated article’ exemption”). Courts have consistently refused to entertain programmatic attacks, like this one, on the general day-to-day operations of federal agencies and in lieu of challenges to specific, individual actions, as required under the APA. Each of Plaintiffs’ Counts I through IV constitutes a non-justiciable programmatic challenge, entitling Defendants to judgment as a matter of law. For these reasons and for reasons stated in EPA’s motion for summary judgment, Intervenor respectfully request that the Court enter summary judgment for Defendants as to all claims.

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