UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY
518 C Street NE, Suite 200
Washington, DC 20002

PESTICIDE ACTION NETWORK
NORTH AMERICA
2029 University Avenue, Suite 200
Berkeley, CA 94704

ALIANZA NACIONAL DE CAMPESINAS
P.O. Box 20033
Oxnard, CA 93034

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue NW
Washington, DC 20460

MICHAEL S. REGAN
in his official capacity as Administrator,
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Defendants.

Civil Action No. 23-1633

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

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LIST OF EXHIBITS

LIST OF ABBREVIATIONS AND ACRONYMS

APA	Administrative Procedure Act
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
GE	Genetically Engineered

INTRODUCTION

1. Plaintiffs Center for Food Safety, Pesticide Action Network North America, and Alianza Nacional de Campesinas challenge Defendant Environmental Protection Agency's (EPA) January 11, 2022 decision to renew the registrations for the herbicides Enlist One and Enlist Duo, *see* Ex. A,[1] and March 28, 2022 decision to remove hundreds of county-level application restrictions from product labels, *see* Ex. B.[2] EPA's initial registrations and subsequent amendments (collectively, "registration decisions") violate both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y, and the Endangered Species Act (ESA), 16 U.S.C. §§ 1531–44.

2. This is an administrative law case for declaratory and equitable relief challenging EPA's failure to properly evaluate the risks of two harmful herbicides–Enlist One and Enlist Duo (which includes glyphosate)–as required under FIFRA and the ESA. Shortly before EPA decided to extend the registrations for these herbicides for an additional seven years, until 2027, the Ninth Circuit held that EPA's previous registrations for these herbicides were unlawful. In its rush to renew the registrations for Enlist One and Enlist Duo, EPA again failed to comply with its statutory duties. EPA also ignored new evidence confirming that both herbicides have harmful effects on the environment and local communities, including the health of those exposed to the herbicides through work on nearby farms.

3. Enlist One and Enlist Duo are herbicides containing a highly toxic and harmful active ingredient known as 2,4-D. Enlist Duo also contains the active ingredient glyphosate. These herbicides are sold across the country for over-the-top use on corn,

[1] EPA, *Memorandum Supporting Decision to Extend Registrations for Enlist One & Enlist Duo* (Jan. 11, 2022) (attached as Exhibit A) [hereinafter Decision Memo].
[2] EPA, *Addendum to Memorandum Supporting Decision to Extend Registrations for GF-3335 (Enlist One) & Enlist Duo, Expanding Use to Additional Counties* (Mar. 29, 2022) (attached as Exhibit B) [hereinafter Amended Decision Memo].

soybean, and cotton crops that have been genetically engineered to be resistant to 2,4-D, glyphosate, and glufosinate.

4. Although these herbicides are marketed as a "solution" to glyphosate-resistant weeds in corn, soybean, and cotton production, they threaten to increase the spread of new herbicide-resistant weeds because EPA failed to properly mitigate risks, making it harder for farmers to manage troublesome weeds. Moreover, these herbicides threaten to damage crops, native plants, and wildlife habitats in surrounding areas.

5. Glyphosate is the second active ingredient in Enlist Duo. Mounting evidence shows that it has the potential to cause serious health problems, including non-Hodgkin's lymphoma. EPA's approval of Enlist Duo fails to grapple with the real-world and laboratory evidence of the carcinogenic potential of glyphosate, despite the conclusions of scientists and researchers inside and outside EPA.

6. This is the latest in a series of lawsuits regarding EPA's authorization of Enlist products. In 2020, the Ninth Circuit held that EPA's previous registrations violated FIFRA by substantially underestimating risks to milkweed plants and monarch butterflies.

7. The Ninth Circuit also vacated EPA's human health risk assessment for glyphosate in 2022, based on EPA's lack of substantial evidence for its conclusion that glyphosate poses no health risks and specifically that it is not likely to cause cancer. *Nat. Res. Def. Council v. EPA*, 38 F.4th 34 (9th Cir. 2022) (*Glyphosate*).

8. The challenged registration decisions represent EPA's continued pattern of ignoring its duties under FIFRA and the ESA in the pesticide review process.

FIFRA

9. EPA's decisions to extend and amend the registrations of Enlist One and Enlist Duo violates FIFRA.

10. First, EPA's decisions were not supported by substantial evidence because EPA understated the risks associated with increased use of Enlist products, including increased damage to nearby crops, increased harm to wildlife and the environment,

including threatened and endangered species and their habitats, and increased spread of herbicide resistance.

11. Second, EPA's decisions were not supported by substantial evidence because EPA overstated the effectiveness of Enlist products against problematic multiple-herbicide-resistant weeds and failed to fully consider how Enlist products increase the spread of herbicide resistance.

12. Third, EPA's decision to register Enlist Duo is not supported by substantial evidence because EPA discounted or ignored the human health risks from the pesticide, including the active ingredient glyphosate and its connection to non-Hodgkins lymphoma and other health harms.

ESA

13. EPA's decisions to extend and amend the registrations of Enlist One and Enlist Duo also violate the ESA. On October 11, 2022, Plaintiffs provided a notice of intent to sue to EPA. *See* Ex. C.

14. First, EPA violated its duty to consult with the expert wildlife agency by failing to consult with U.S Fish and Wildlife Service (FWS) before renewing the registrations and amendments at issue here.

15. Second, EPA violated its duty to prevent jeopardy to threatened and endangered species and their habitats by renewing the registrations and amendments at issue here.

16. Third, EPA violated its duty to prevent irreversible commitments of resources during formal consultation, effectively foreclosing the adoption of alternatives in the future, by renewing the registrations and amendments at issue here.

Requested Relief

17. Plaintiffs ask this Court to declare that (1) EPA violated FIFRA by renewing and amending the registrations for Enlist One and Enlist Duo without substantial

evidence, and (2) EPA violated the ESA by failing to complete formal consultation before making its decision.

18. Plaintiffs ask that the Court vacate these registrations and grant relief as necessary to halt the use and sale of Enlist One and Enlist Duo until EPA complies with its duties under FIFRA and the ESA. Plaintiffs also ask this Court to grant relief as necessary to redress any harm to wildlife and the environment caused by EPA's registration decisions.

JURISDICTION & VENUE

19. This Court has jurisdiction under section 16(a) of FIFRA, 7 U.S.C. § 136n(a), because EPA issued the Registration Decisions without a public hearing. The Court has jurisdiction under the ESA's citizen suit provision, 16 U.S.C. § 1540(g)(1), because Plaintiffs provided notice of intent to sue on October 11, 2022. *See* Ex. C. The Court also has jurisdiction under 28 U.S.C. §§ 1331 (federal question), § 2201 (declaratory relief), and § 2202 (additional relief).

20. This Court is the proper venue for this action under 28 U.S.C. § 1391(e) because Defendant EPA is an agency of the United States, and Defendant Michael Reagan is an officer acting in his capacity who resides in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district. Venue is also proper under 16 U.S.C. § 1540(g)(3)(a) because EPA's violations occur in this district.

21. This case challenges EPA's decision to authorize producers to spray Enlist One and Enlist Duo on corn, cotton, and soybean crops in 34 states. Plaintiffs represent thousands of farmers, farmworkers, residents, gardeners, outdoor enthusiasts, and wildlife advocates in the states approved for use of Enlist, including hundreds of members who are adversely affected by the use of Enlist near their homes, farms, gardens, work, and recreational sites. EPA's decision also adversely affects Plaintiffs by harming the personal and professional interests of conservationists.

PARTIES

I. Plaintiffs

22. Plaintiffs are nonprofit organizations dedicated to protecting the environment and public health, including workers, from the adverse effects of industrial agriculture, including the herbicides approved for use in the challenged decisions.

23. Plaintiff **Pesticide Action Network North America** (PANNA) is a California-based, nonprofit corporation founded in 1982 to combat the proliferation of pesticide-intensive, monocrop agriculture. PANNA's mission is to advance a vision of agriculture that replaces the use of hazardous pesticides with healthier, ecologically-sound pest management. In addition to having thousands of members who are conservationists, many of PANNA's members are also farmers, who live, farm, and recreate in many locations where the approved dicamba use has been sprayed or will be sprayed. Since the outset of the dicamba controversy, PANNA has worked to reduce the negative health and livelihood impacts of pesticide drift in the states where over-the-top dicamba has been approved for use. PANNA and its members are and will continue to be adversely affected by EPA's Registration Decisions. *See infra* ¶¶ 273–89.

24. Plaintiff **Alianza Nacional de Campesinas** (Alianza) is a nonprofit organization of farmworker women, comprised of 12 member organizations based across 20 states and Washington D.C. Alianza addresses a wide range of topics affecting farmworker women (campesinas), including the effects of pesticide exposure on farmworker women and their families. Alianza maintains a campaign, the Satchel (Moralitos), dedicated to creating public awareness about the health risks posed by pesticide exposure to farmworker women and their families. Alianza members hold community events where they teach women how to protect themselves from pesticide exposure, what to do in the event of an exposure, and what the current EPA policies are on legal pesticide use. Alianza is actively working to strengthen pesticide protections for farmworkers, by pushing for more protective legislation, and as here, engaging in public

interest litigation to protect the interests of farmworker women, their families, and their communities. Alianza and its members are and will continue to be adversely affected by EPA's Registration Decisions. *See infra* ¶¶ 273–89.

25. Plaintiff **Center for Food Safety** (CFS) is a nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; Hawaii; and Washington, D.C. Since its inception in 1997, CFS's mission has been to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. This mission includes a flagship CFS program on the adverse environmental and socioeconomic impacts of pesticides. CFS has specifically worked on the dicamba controversy since its inception. CFS represents more than a million farmer and consumer members, in every state throughout the country, including thousands of members in the 34 states approved for use of Enlist One and Enlist Duo in the challenged registration decisions. CFS and its members are and will continue to be adversely affected by EPA's Registration Decisions. *See infra* ¶¶ 273–89.

II. Defendants

26. Defendant U.S. EPA is the federal agency tasked with administering the FIFRA. EPA is responsible for registering all pesticides used in the United States and ensuring compliance with all applicable laws and regulations under FIFRA. As the action agency, EPA must also comply with the ESA's substantive and procedural requirements.

27. Defendant Michael S. Regan is the Administrator of the EPA. He is responsible for ensuring compliance with all applicable laws and regulations, including FIFRA and ESA. Plaintiffs are suing Defendant Regan in his official capacity.

STATUTORY BACKGROUND

I. FIFRA

28. EPA regulates the use, sales, and labeling of pesticides (including herbicides such as Enlist One and Enlist Duo) under FIFRA. 7 U.S.C. §§ 136–136y. The main mechanism for regulating pesticides is the pesticide registration process. *See Id.* §

136a(a). Before any pesticide can be used in the United States, EPA must first register the pesticide by issuing a license that provides all the terms and conditions for the lawful sale, distribution, and use of the pesticide. *Id.* § 136a(c). The terms and conditions specify the exact product, as well as its approved uses (e.g., where it can be used, how it can be applied, what crops it can be sprayed on). *See* 40 C.F.R. §§ 152.115, § 156.10.

A. Unreasonable Adverse Effects on the Environment

29. Before registering or re-registering a pesticide, EPA must determine that the pesticide "will not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice." 7 U.S.C. § 136a(c)(5)(D). An "unreasonable adverse effect on the environment" includes "any unreasonable risk to [people] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).

30. FIFRA applies a cost-benefit analysis "to ensure that there is no unreasonable risk created for people or the environment from a pesticide." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 522–23 (9th Cir. 2015). EPA may deny an application for registration when "necessary to prevent unreasonable adverse effects on the environment." *Id.*; 7 U.S.C. § 136a(a).

31. In reviewing an application for registration, EPA must apply the "unreasonable adverse effects" standard. *Id.* This standard requires EPA to analyze not just the pesticide's benefits, but also its environmental, economic, and social costs. *Id.* EPA must also sufficiently explain how the purported benefits outweigh those costs. *Id.*

32. In applying this standard, EPA must carefully consider "every relevant factor that the [agency] can conceive into account," including aesthetic values, wildlife hazards, and pesticide drift. S. Rep. No. 838, 92d Cong. 2d Sess., reprinted in 1972 U.S.C.C.A.N. 3993, 4032–33 (emphasis added). As explained in the legislative history, "[i]f a pesticide is such that when used in accordance with its label or common practice it is injurious to

man, other vertebrates, or useful plants, it cannot be registered under the Act and cannot be sold or distributed in interstate commerce." *Id.* at 3996.

B. Unconditional Registrations

33. To register or re-register a pesticide, the manufacturer must submit an application describing how the pesticide will be used, its claimed benefits, the ingredients, and the results of any studies concerning the product's health, safety, and environmental effects. 7 U.S.C. § 136a(c).

34. To ensure that EPA can properly weigh the costs and benefits of a pesticide, the applicant must submit sufficient data concerning the pesticide's health, safety, and environmental effects. *See Pollinator Stewardship*, 806 F.3d at 523; 7 U.S.C § 136a(c)(5).

35. The registration decisions at issue here are unconditional registrations. In comparison to conditional registrations, unconditional registrations impose a higher standard on the data required, as well as a different standard for reviewing risk.

36. Before EPA can issue an unconditional registration, EPA must first determine that "no additional data are necessary." 40 C.F.R. § 152.112(c).

37. EPA must then find that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C.§ 136a(c)(5)(C). EPA must also find that "when used in accordance with widespread and commonly recognized practice," the pesticide "will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D). EPA can only issue an unconditional registration if it determines that the pesticide will "not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice." 40 C.F.R. § 152.112(e).

38. Thus, an unconditional registration requires two prerequisite findings. First, EPA must find that the pesticide performs its intended function. 7 U.S.C. § 136a(c)(5)(C). Second, EPA must find that the pesticide "will not generally cause unreasonable adverse

effects on the environment" when used according to common and widespread practice. *Id*. § 136a(c)(5)(D).

C. Judicial Review

39. Under FIFRA, any final agency action "not following a hearing," such as the registrations at issue here, are "judicially reviewable by the district courts of the United States." 7 U.S.C. § 136n(a).

D. Standard of Review

39. EPA's registrations can only be upheld if they are "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b); *Nat. Res. Def. Council v. EPA*, 857 F.3d 1030, 1035 (9th Cir. 2017) (*Nanosilver II*). To meet the "substantial evidence" standard, the administrative record must show "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence." *Nanosilver II*, 857 F.3d at 1036 (internal quotation marks omitted).

40. EPA's registrations may only be upheld "on the basis articulated by the agency itself." *Nat'l Family Farm Coalition v. EPA*, 960 F.3d 1120, 1133 (2020) (*Dicamba*) (citing *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (*Nanosilver I*) (internal quotation marks omitted). This standard "affords an agency less deference than the arbitrary and capricious standard." *Pollinator Stewardship*, 806 F.3d at 533.

41. EPA's "reasoning must also be coherent and internally consistent." *Glyphosate*, 38 F.4th at 44. If EPA's registrations are inconsistent with its own analyses and guidelines, EPA's registrations are not supported by substantial evidence. *Id.*; *see also Nat. Res. Def. Council v. EPA*, 31 F.4th 1203, 1210 (9th Cir. 2022).

42. Because EPA violated FIFRA, this Court should "set aside," or vacate, EPA's Registration Decisions. *See, e.g., Glyphosate*, 38 F.4th at 52; *Pollinator Stewardship*, 806 F.3d at 532–33.

II. Endangered Species Act

43. The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978). The ESA's statutory scheme "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185.

44. The ESA requires EPA to "insure" that registration decisions are "not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat." 16 U.S.C. § 1536(a)(2). The ESA imposes a variety of procedural and substantive requirements to ensure that agencies do not harm species listed under the ESA (listed species) or critical habitats. *Nat'l Ass'n of Home Builders v. Defenders of Wildlife,* 551 U.S. 644, 652 (2007).

A. Duty to Consult Under Section 7(a)(2)

45. The centerpiece of the ESA is Section 7(a)(2), which provides that each federal agency "shall, in consultation with and with the assistance of the [Services], insure that any action authorized . . . by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species . . . ." 16 U.S.C. § 1536(a)(2); *see also* 50 CFR § 402.02 ("action" includes "the granting of licenses" and "actions directly or indirectly causing modifications to the land, water, or air"). In fulfilling this requirement, agencies "shall use the best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

46. To achieve this substantive requirement, ESA's implementing regulations impose specific procedural duties on federal agencies. EPA "shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat." 50 CFR § 402.14(a) (emphasis added). "If such a determination is made, formal consultation is required." *Id.*

47. "Section 7 imposes on all agencies a duty to consult with either the [FWS] or the NOAA Fisheries Service before engaging in any discretionary action that may affect a listed species or critical habitat." *Karuk Tribe of California v. U.S. Forest Serv*. 681 F.3d 1006, 1020 (9th Cir. 2012) (emphasis added); *see also Ctr. for Biological Diversity v. EPA*, 56 F.4th 55, 62 (D.C. Cir. 2022). "If an agency determines that an action 'may affect' critical species or habitats, formal consultation is mandated." *Karuk Tribe*, 681 F.3d at 1126. "The purpose of consultation is to obtain the expert opinion of wildlife agencies to determine whether the action is likely to jeopardize a listed species or adversely modify its critical habitat and, if so, to identify reasonable and prudent alternatives that will avoid the action's unfavorable impacts." *Id*. at 1020.

1. Triggering Formal Consultation

48. EPA must "review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat." 50 C.F.R. § 402.14(a). "If such a determination is made, formal consultation is required . . . ." *Id*.

49. To determine whether a proposed action "may affect" any listed species or critical habitat, EPA must evaluate "all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action." 50 C.F.R. § 402.02. The effects of an action "may occur later in time and may include consequences occurring outside the immediate area involved in the action." *Id*.

50. The "may affect" standard is extremely low. *See Growth Energy v. EPA*, 5 F.4th 1, 30 (D.C. Cir. 2021). If a proposed action has "any chance of affecting listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Id*. (citing *Karuk Tribe*, 681 F.3d at 1027).

51. If EPA determines that a proposed action "may affect" any listed species or critical habitat, EPA must continue with formal consultation. EPA may only terminate the

consultation process before initiating formal consultation if (1) EPA determines that a proposed action is "not likely to adversely affect" any listed species or critical habitat, (2) EPA reached this determination "as a result of informal consultation with the [expert wildlife agency] under § 402.13§ 402.13," and (3) the expert wildlife agency concurs in writing. *Id*. 402.13(b). 40 C.F.R. § 402.14(a)-(b).

52. EPA may consult with the expert wildlife agencies to determine whether formal consultation or a conference is required. 50 C.F.R. § 402.13(a). During informal consultation, the expert wildlife agency may suggest modifications to the action to avoid the likelihood of adverse effects to listed species or critical habitat. *Id*. § 402.13(b). If EPA determines that the action is not likely to adversely affect listed species or critical habitat, and the expert wildlife agency concurs in writing, "the consultation process is terminated, and no further action is necessary." *Id*. § 402.13(b).

53. Unlike optional consultation procedures, EPA must confer with the expert wildlife agencies "on any action which is likely to jeopardize the continued existence of any proposed species or result in the destruction or adverse modification of proposed critical habitat." 50 C.F.R. § 402.10.

2. Initiating Formal Consultation

54. For FIFRA actions, EPA may initiate consultation by delivering a written request for consultation to the expert wildlife agency, along with "an effects determination." *Id*. § 402.40(b)§ 402.40(b). EPA's effects determination must contain a summary of the information on which the determination is based, detailing how the FIFRA action affects the listed species or critical habitat. *Id*. § 402.46. In preparing the effects determination, EPA must use the best available science. *Id*.

3. During Formal Consultation

55. After initiating consultation, the "agency and . . . applicant shall not make any irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any

reasonable and prudent alternative measures which would not violate subsection (a)(2) of this section." 16 U.S.C. § 1536(d). "This prohibition is in force during the consultation process and continues until the requirements of section 7(a)(2) are satisfied." 50 CFR § 402.09. *See supra*.

4. Following Formal Consultation

56. "Formal consultation is terminated with the issuance of the biological opinion." 50 CFR § 402.14(m)(1). At the end of the formal consultation process, the FWS must provide an official "biological opinion" on "whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat." *Id*. § 402.14(g)(4); 16 U.S.C. § 1536(b)(3)(A). If FWS concludes that the proposed action is likely to jeopardize a listed species, the opinion must provide "reasonable and prudent alternatives" to the proposed action. 16 U.S.C. § 1536(b)(3)(A); 50 CFR § 402.14(h)(2). And if a "jeopardy" biological opinion is issued, the agency must either implement the reasonable and prudent alternatives or terminate the action altogether. 16 U.S.C. §§ 1536(b)(4), (g); § 1538(a).

57. EPA has additional responsibilities following the issuance of a biological opinion. *See* 50 C.F.R. § 402.42(a)(8) ("EPA must comply with § 402.15 for all FIFRA actions."). After the expert wildlife agency issues a biological opinion, EPA must use the opinion to "determine whether and in what manner to proceed with the action in light of its section 7 obligations." *Id*. § 402.15(a).

B. Duty to Maintain Status Quo Under Section 7(d)

58. Section 7(d) prohibits EPA from making any irretrievable and irreversible commitments of resources "which [have] the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures" deemed necessary to avoid jeopardy or adverse modification. 16 U.S.C. § 1536(d). "This prohibition . . . continues until the requirements of section 7(a)(2) are satisfied," 50 C.F.R. § 402.09.

59. The purpose of this prohibition is "to ensure that the status quo is maintained during consultation, so as to avoid a circumstance in which a large-scale commitment of resources is made during the consultation process, which resources cannot be diverted or redirected to other productive uses if the outcome of consultation is that the project would violate the 'no jeopardy' requirement of § 7(a)." *Oceana v. Bureau of Ocean Energy Mgmt.*, 37 F. Supp. 3d 147, 176 (D.D.C. 2014) (internal quotations omitted); see also *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1034–35 (9th Cir. 2005).

C. Judicial Review

60. The ESA's citizen suit provision authorizes any person to "commence a civil suit . . . to enjoin any . . . agency . . . who is alleged to be in violation of any provision of [the ESA] or [implementing] regulations . . . ." 16 U.S.C. § 1540(g)(1)(A). This provision also provides that "district courts shall have jurisdiction . . . to enforce any such provision or regulation." *Id.* § 1540(g).

D. Standard of Review

61. The Administrative Procedure Act (APA) governs judicial review of EPA's registrations in district court. *See, e.g.*, *Glyphosate*, 38 F.4th at 44–45; *Karuk Tribe of Cal.*, 681 F.3d at 1017. Under the APA, this Court must "hold unlawful and set aside" any actions, findings, or conclusions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To meet this standard, EPA "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (internal quotations omitted).

62. EPA's registration decisions are arbitrary and capricious if EPA "relied on factors Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation that runs counter to the evidence before

the agency." *Id.* EPA's registrations are also arbitrary and capricious if they are "internally inconsistent." *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1145 (9th Cir. 2015).

STATEMENT OF FACTS

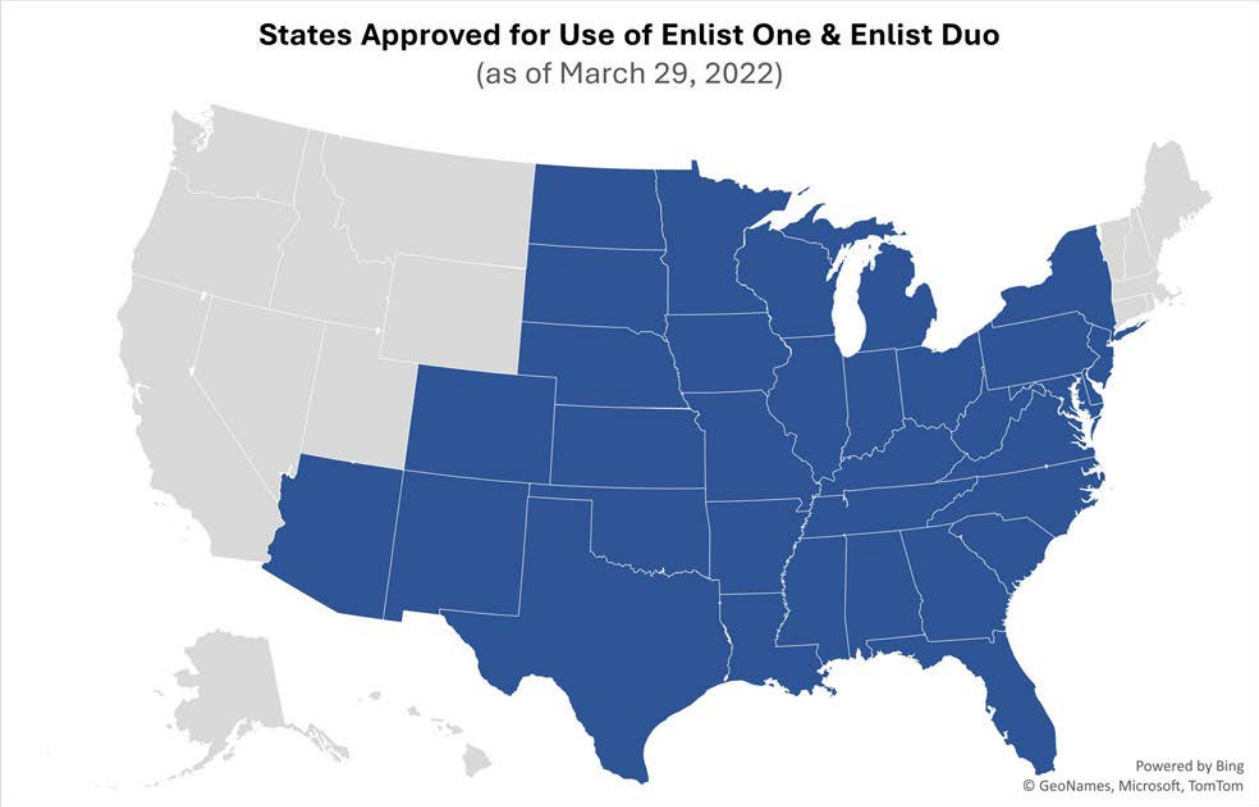
I. Enlist One & Enlist Duo

63. Enlist One and Enlist Duo (Enlist products) are both herbicides containing the choline salt of 2,4-dichlorophenoxyacetic acid choline salt ("2,4-D"), an active ingredient with highly toxic effects on crops, plants, pollinators, and other species. Enlist Duo contains two active ingredients–2,4-D and glyphosate dimethylammonium salt ("glyphosate"),[3] whereas Enlist One only contains 2,4-D.[4]

A. Approved Uses

64. Both Enlist products are approved for controlling weeds in corn, soybean, and cotton operations in 34 states. Enlist products can be sprayed on corn, soybean, and cotton crops that have been genetically engineered to be resistant to 2,4-D (i.e., Enlist-resistant crops) throughout the growing season. Specifically, both Enlist products can be applied "any time before or after planting, but before [crops] emerge[]" (preplant through preemergence), as well as after Enlist-resistant crops have emerged from the soil (postemergence).

[3] Enlist Duo contains 24.4% 2,4-D choline salt, and 22.1% glyphosate dimethylammonium salt.
[4] Enlist One contains 55.7% 2,4-D choline salt.



65. Corteva Agriscience LLC sells both Enlist One and Enlist Duo, as well as the genetically engineered corn, cotton, and soybean seeds with resistance to Enlist products (i.e., the Enlist weed control system). Because Enlist-resistant crops are designed to survive application of 2,4-D (and glyphosate for Enlist Duo), Enlist One and Enlist Duo can be sprayed on these crops after they have emerged from the soil without the risk of injury.

66. Enlist products are approved for preplant use on conventional soybean crops, as well as preplant, preemergence, and postharvest use on conventional corn crops, even though these crops are not resistant to Enlist. In addition, Enlist can be sprayed on uncultivated (or fallow) fields before planting any corn, soybean, or cotton crops, up until emergence.

67. In the challenged registration decision, EPA approved preplant, preemergence, and postemergence (over-the-top) uses of Enlist One and Enlist Duo on three Enlist-resistant crops: Enlist corn (DAS-40278-9), Enlist cotton (DAS-81910-7), and

Enlist soybean (DAS-68416-4). In addition, EPA approved both Enlist products for (1) preplant, preemergence, and postharvest uses on conventional corn; (2) preplant use on conventional soybean; and (3) preplant uses and preemergence uses in fallow systems with Enlist-resistant or conventional corn, cotton, or soybean. EPA may expand the approved uses of Enlist products in the future, as it has done so repeatedly since registering Enlist Duo in 2014. *See supra*.

B. Environmental Effects

68. Enlist One and Enlist Duo have numerous adverse effects on the environment. Both Enlist products contaminate the environment directly and indirectly through direct application, spray drift, vapor drift, runoff, rainfall, erosion, and other routes of exposure. 2,4-D pollution has increased dramatically since the commercialization of Enlist-resistant crops, and it will continue to increase as more farmers and pesticide applicators adopt the Enlist weed control system and increase use of Enlist products to compensate for increased weed resistance.

69. Enlist products kill plants on sprayed fields through direct application. Enlist also harms plants in nearby areas through spray drift or runoff. For example, perennial milkweed is a plant found in agricultural areas where Enlist products are sprayed, including sprayed fields and nearby areas.

70. Enlist products harm vegetables, fruits, grapes, beans, potatoes, cotton, flowers, ornamental plants, and other crops growing on neighboring properties. Small amounts of Enlist can have devastating effects on certain crops and plants. Enlist products typically harm crops on neighboring farms through spray drift, which occurs when droplets enter the air and travel to nearby areas through wind. The risk of spray drift depends on wind speed, weather, application rate, and other factors. Spray drift from Enlist applications can cause significant damage to highly sensitive crops, such as cotton that is not genetically engineered with resistance to Enlist products. Enlist products can also cause secondary off-target movement through vapor drift, which occurs when

chemicals volatize into the atmosphere. The risk of volatilization depends on temperature, wind speed, addition of glyphosate, and other factors. Other potential routes of exposure are runoff and direct application.

71. Enlist products contaminate groundwater and drinking water sources. Enlist products also contaminate surface waters, such as streams, rivers, and lakes. Once it enters a waterbody, it can take years for it to breakdown. Enlist products typically enters nearby waterbodies through surface runoff, which occurs when Enlist products flow off the surface of sprayed fields to nearby areas through rainwater, stormwater, irrigation, and other sources. Enlist products can also leach into the soil and enter groundwater sources through runoff. Other potential routes of exposure are drift and erosion.

2. Wildlife

72. EPA's decision to approve the registrations of Enlist One and Enlist Duo has several adverse effects on plants and animals, including numerous listed species and designated critical habitats in the action area. Enlist products directly affect these species through direct application, spray drift, runoff, erosion, rainfall, and other routes of exposure. Enlist products indirectly affect species through habitat loss, decreased food sources, and other impacts.

73. Enlist products directly affect the survival, growth, or reproduction of individual plants and animals. Both 2,4-D and glyphosate are toxic to several species found on target fields and nearby areas, such as mammals, birds, bats, fish, amphibians, insects, and pollinators.

74. Enlist products also indirectly affect species by decreasing food sources and destroying feeding, breeding, and spawning habitats. Both 2,4-D and glyphosate are toxic to numerous plants, including crops on nearby fields and plants that provide

important feeding and breeding habitats for other species.[5] Enlist products are also toxic to many animals that play an important role in local food webs and ecosystems, including fish, mammals, pollinators, and birds.[6]

75. Many species, including threatened and endangered species, can be exposed to Enlist products through a variety of routes, including spray drift, soil contamination, and surface runoff from sprayed fields. Many species are exposed to Enlist through direct application on sprayed fields or contact with residues on sprayed fields and crops. In addition, several species are exposed to residues through their consumption of prey, such as insects that had been on sprayed fields during an application. Many species are also exposed to Enlist products in the environment due to runoff or spray drift.

76. Spray drift can kill or damage plants growing in natural areas and habitats near sprayed fields, destroying important feeding, breeding, and spawning habitats for several species, and depleting food sources for animals that consume those plants. For example, bees and other pollinators are directly exposed to Enlist when they feed on crops and plants sprayed with Enlist, or any plants in the nearby area exposed to Enlist runoff or spray drift. Importantly, spray and vapor drift from Enlist applications can also indirectly affect pollinators, such as monarch butterflies, by destroying important breeding and spawning habitats and depleting food sources. For example, spray drift and runoff from Enlist applications threaten flowering plants that provide nectar for adult monarch butterflies and food for monarch larvae.

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[5] *See, e.g.*, INITIAL EFFECTS DETERMINATION, *supra* note 37, at 153 ("toxicity data for 2,4-D and glyphosate show that both monocots and dicots are sensitive to these active ingredients").

[6] *Id*. at 43 ("In general, 2,4-D choline salt is slightly toxic to fish and invertebrates . . . "); 45 ("In general, on an acute exposure basis, 2,4-D is . . . slightly toxic to mammals, and moderately toxic to birds . . . ."); 46 ("Based on the LD50, 2,4-D choline salt is moderately toxic to mammals on an acute basis."); 68 ("EPA concluded that 2,4-D poses a risk to larval terrestrial invertebrates located on Enlist corn, cotton and soybean fields. The results of this analysis suggest that there may be exceedance of the adult chronic endpoint.").

3. 2,4-D Effects

77. In EPA's 2,4-D ecological assessment for non-listed taxa, EPA found "potential on-field (on the site of application) risks to terrestrial vertebrates (mammals, birds, amphibians, and reptiles), terrestrial invertebrates (including bees and monarch butterflies), and terrestrial plants." Even with mitigation measures in place, EPA found "there are still potential runoff risks for terrestrial and wetland plants."

78. With respect to listed species, EPA found "potential on-field risks for terrestrial animals that utilize corn, soybean and/or cotton fields, as well as several listed plant species that are considered on the field." EPA also found "potential risks to terrestrial, wetland and aquatic plants that are exposed to runoff and listed animal species that depend upon plants in areas receiving runoff." In addition, EPA acknowledged the 2,4-D component of Enlist products has "potential indirect effects to animals, primarily from the runoff exposure to plants," "because plants play an important role in terms of shelter, food, and habitat for animals." EPA found direct effects to on-field monarch butterflies and indirect effects to on-field and off-field milkweeds.

4. Glyphosate Effects

79. Similarly, in EPA's glyphosate ecological assessment for non-listed taxa, EPA found "potential on-field (on the site of application) risks to birds, reptiles, and terrestrial phase amphibians, and terrestrial plants." Even with spray drift reduction measures, EPA confirmed "there is still potential risk to terrestrial and wetland plants from runoff." *Id.*

80. With respect to listed species, EPA found "potential on-field effects to terrestrial animals that utilize corn, soybean and/or cotton fields," as well as "several listed plant species that are assumed to be on these types of fields based on FWS documentation of the species habitat or distribution." EPA also found "potential effects to terrestrial and wetland plants that are exposed to runoff and listed animal species that depend upon plants in terrestrial and wetland areas receiving runoff from Enlist treated

corn, cotton or soybean fields." EPA found "potential indirect effects to animals, primarily from the runoff exposure to plants," "because plants play an important role in terms of shelter, food, and habitat for animals." For monarch butterflies, EPA concluded "there are potential indirect adverse effects from glyphosate effects to on-field and off-field milkweed."

5. Listed Species & Habitats

81. As noted above, Enlist products have adverse effects on numerous listed species and their habitats. EPA's registrations may directly affect plants and animals found on treated fields and surrounding areas. Enlist products may also affect listed species, such as endangered whooping cranes, which rely on treated fields for food and shelter during migration.

82. Even with mitigation measures in place to reduce spray drift and runoff, EPA found that use of Enlist products will likely adversely affect listed species and critical habitats.

83. Despite this, EPA failed to engage and complete consultation with FWS.

C. Agronomic Effects

84. Spray drift from Enlist applications threaten crops in neighboring fields. Multiple studies show that 2,4-D spray drift can severely injure crops, and the risk of injury increases with increased exposure. Some crops, such as broccoli and bell peppers, are sensitive to very low doses of 2,4-D, potentially delaying maturity, reducing total crop yield, and increasing production costs.[7]

85. The combination of 2,4-D and glyphosate can also have increased impacts than either active ingredient alone. According to one study, "[t]he combination of 2,4-D

[7] M. Mohseni-Moghadam et al., *Response of Bell Pepper and Broccoli to Simulated Drift Rates of 2,4-D and Dicamba*, 29 WEED TECH. 226 (2015); *see also* B. Dintelmann et al., *Investigations of the Sensitivity of Ornamental, Fruit, & Nut Plant Species to Driftable Rates of 2,4-D & Dicamba*, 34 WEED TECH. 331 (2020).

plus glyphosate caused greater injury and shoot length reduction in grapes than glyphosate applied alone."[8]

86. Spray drift can adversely affect nearby farms by damaging crops, reducing yields, and increasing production costs. U.S. organic and other non-GE farmers must invest in various avoidance practices to minimize accidental crop mixing, such as buffer strips or delayed crop planting.[9] However, with the widespread adoption of the Enlist weed control system, which allows users to spray Enlist products on Enlist-resistant crops after emergence, avoidance practices are becoming less effective and more costly.

87. In addition, spray drift can increase the spread of herbicide-resistant weeds, making it more difficult for farmers to manage weeds on their fields. Due to reliance on Enlist products alone as the sole method of controlling weeds, the increased use of the Enlist weed control system will increase the number of herbicide-resistant weeds that survive after each application, which can then propagate and spread to neighboring farms, impacting farmers who played no role in their development. These multiple-herbicide-resistant weeds impose substantial costs on farmers, including forcing farmers who elect to use chemical methods to spray increasingly toxic herbicides, imposing huge costs on farmers and the environment.

II. EPA's History of Regulating Herbicides & Genetically Engineered Crops

88. For decades, EPA has been improperly authorizing harmful herbicides, many containing the same active ingredients as Enlist One and Enlist Duo, as "safer" alternatives to existing chemical options. As history repeatedly shows, EPA's failure to properly regulate these herbicides has devastating impacts on the environment and

[8] M. Mohseni-Moghadam et al., *Response of Wine Grape Cultivars to Simulated Drift Rates of 2,4-D, Dicamba, Glyphosate, & 2,4-D or Dicamba Plus Glyphosate*, 30 WEED TECH. 807 (2016).

[9] C. GREENE ET AL., ECON. RESEARCH SERV., ECONOMIC ISSUES IN THE COEXISTENCE OF ORGANIC, GE, & NON-GE CROPS (2016), https://www.ers.usda.gov/publications/pub-details/?pubid=44044.

accelerated the spread of problematic weeds with resistance to multiple herbicides (*i.e.*, the very weeds that they are supposed to kill).

89. Both 2,4-D and glyphosate have been sold in other forms for decades. The specific form of 2,4-D found in Enlist (2,4-D choline salt) has been registered since 2011,[10] but 2,4-D has been sold in other forms since the 1950s.[11] Glyphosate has been used on corn, soybeans, and cotton crops since the 1970s, and the specific form used in Enlist Duo has been registered since 2007.[12]

A. Glyphosate

90. Glyphosate is a broad-spectrum herbicide used to control broad-leaf weeds and grasses in intensive crop operations. Roundup is the most popular and heavily applied glyphosate-based herbicide, first produced by Monsanto Technology LLC in 1974. Roundup contains glyphosate [N-(phosphonomethyl) glycine], an active ingredient registered in 1971, with several harmful environmental and human health effects.

91. While glyphosate was initially reported to be less toxic and less persistent in the environment relative to the herbicides that it replaced, since then numerous studies

[10] *See* Details for Enlist One (EPA Reg. No. 62719-695), https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:::::P8_PUID,P8_RINUM:518209,62719-695; Chemical Details for 2,4-D Choline Salt (CAS No. 1048373-72-3), https://ordspub.epa.gov/ords/pesticides/f?p=CHEMICALSEARCH:3::::1,3,31,7,12,25:P3_XCHEMICAL_ID:2274.

[11] Chemical Details for 2,4-D (CAS No. 94-75-7), https://ordspub.epa.gov/ords/pesticides/f?p=CHEMICALSEARCH:3::::21,3,31,7,12,25:P3_XCHEMICAL_ID:512.

[12] *See* Details for Enlist Duo (EPA Reg. No. 62719-649), https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:::::P8_PUID,P8_RINUM:506988,62719-649; Chemical Details for Glyphosate Dimethylammonium Salt (Glyphosate) (CAS No. 34494-04-7), https://ordspub.epa.gov/ords/pesticides/f?p=CHEMICALSEARCH:3:::NO::P3_XCHEMICAL_ID:2470.

have confirmed that glyphosate is harmful to the environment, including to threatened and endangered species and their habitats.[13]

92. Serious human health concerns have also surfaced in the decades since EPA's last human health risk assessment for glyphosate. In the past, EPA itself has found glyphosate to be a liver and kidney toxin, as well as a possible carcinogen. The World Health Organization declared that glyphosate is "probably carcinogenic to humans" in 2015,[14] and EPA's own scientists "acknowledged that some epidemiological studies provide evidence of an exposure-response relationship between glyphosate and [non-Hodgkin lymphoma]." *Glyphosate*, 38 F.4th at 46. Although EPA concluded in its interim registration review decision that glyphosate is not likely to cause cancer, the Ninth Circuit held that "this conclusion [was] in tension with parts of [EPA's] own analysis and with the guidelines it purports to follow." *Id.*

93. Thousands of lawsuits have been filed against Bayer (which now owns Monsanto), by over 100,000 plaintiffs alleging their non-Hodgkin lymphoma (NHL) came from glyphosate exposure and that Monsanto failed to warn of this cancer risk.[15] Monsanto lost three of the initial trials and one appeal. *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Super. Ct. 2018); *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019); *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021). To settle the bulk of the remaining class action suits, Bayer has agreed to a massive $10 billion settlement, one of the largest in U.S. civil litigation.

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[13] *See, e.g.*, M. Hébert et al., *Widespread Agrochemicals Differentially Affect Zooplankton Biomass & Community Structure*, 31 ECOLOGICAL APPLICATIONS e02423 (2021),

[14] World Health Organization, *Evaluation of 5 Organophosphate Insecticides & Herbicides*, 112 IARC MONOGRAPHS (Mar. 2015).

[15] This group of plaintiffs does not, for the most part, include farmworkers. And in one case a farmworker who was formerly part of class action suit is suing Monsanto and her former attorneys for civil rights violations, alleging that Monsanto and her firm dropped her from the settlement after discovering her non-citizen status. *Elvira Reyes-Hernandez v. Monsanto et. al.,* No. 1:23CV1 (W.D. Va. 2023).

94. People who work around, handle, and apply pesticides like glyphosate have high rates of exposure to these pesticides and are therefore most likely to suffer adverse health effects. EPA has failed to undertake any quantitative exposure risk assessment to determine whether occupational exposure to glyphosate causes unreasonable adverse effects. This includes a failure to assess the skin absorption of glyphosate, one of the primary ways that farmworkers are exposed to glyphosate.

95. Despite NHL being the most well-known cancer risk from exposure to glyphosate based on real world cases, EPA's cancer conclusion in its latest (and now withdrawn) human health risk assessment excluded NHL. Although EPA admitted that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data," EPA nonetheless concluded that glyphosate is "not likely to cause cancer."[16]

96. In reaching this conclusion, EPA discounted dozens of epidemiological studies and meta-analyses that showed a statistically significant association between an increased risk for NHL for people who have ever been exposed to glyphosate. EPA's Scientific Advisory Panel, a congressionally created expert body, agreed that there was a link, as did EPA's own Office of Research and Development. The Ninth Circuit rejected this conclusion. *See supra*.

97. EPA also contradicted the advice of the Scientific Advisory Panel by discounting animal studies showing tumors from glyphosate exposure. In doing so, EPA applied overly stringent demands that exceeded its own Cancer Guidelines for the benefit of glyphosate.

98. In reviewing EPA's 2020 interim registration review decision, the Ninth Circuit concluded that EPA failed to support its health conclusion by substantial evidence. *Glyphosate*, 38 F.4th at 45–52. The court held that when evaluating pesticides under

[16] EPA, OFF. OF PESTICIDE PROGRAM, REVISED GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL 137, 143 (Dec. 12, 2017).

FIFRA, EPA's reasoning "must also be coherent and internally consistent," and EPA's selection of the "not likely to cause cancer" descriptor conflicted with its determination that it could not make a conclusion as to whether glyphosate causes NHL. *Id.* at 44–46.

99. The Ninth Circuit also found that EPA's failure to consider the tumors found in animal studies did not comport with EPA's own Cancer Guidelines, and therefore also could not support a "not likely to cause cancer" conclusion. *Id.* at 47–51. The court vacated the human health portion of EPA's 2020 glyphosate approval. *Id.* at 52. EPA subsequently withdrew the entire interim registration review decision.[17]

100. Recent studies demonstrate the harmful health effects associated with glyphosate. For example, scientists found "that glyphosate exposure may be positively associated with certain urinary biomarkers of oxidative stress," a key characteristic of carcinogens.[18] Another recent study "show[ed] for the first time that glyphosate infiltrates the brain" and "elevates [pro-inflammatory cytokines in blood plasma], suggesting that exposure to this herbicide may have detrimental outcomes regarding the health of the general population."[19] In addition, scientists found glyphosate "in 99% of pregnant women in [a] Midwestern cohort," and evidence that "[h]igher maternal [glyphosate] levels in the first trimester were associated with lower [gestation-adjusted birth weight percentile] and higher [neonatal intensive care unit] admission risk."[20]

101. In addition to health risks, there is also evidence that the accumulation of glyphosate in the environment causes adverse health effects. Moreover, glyphosate use has led to the selection of glyphosate-resistant weeds and microorganisms in the

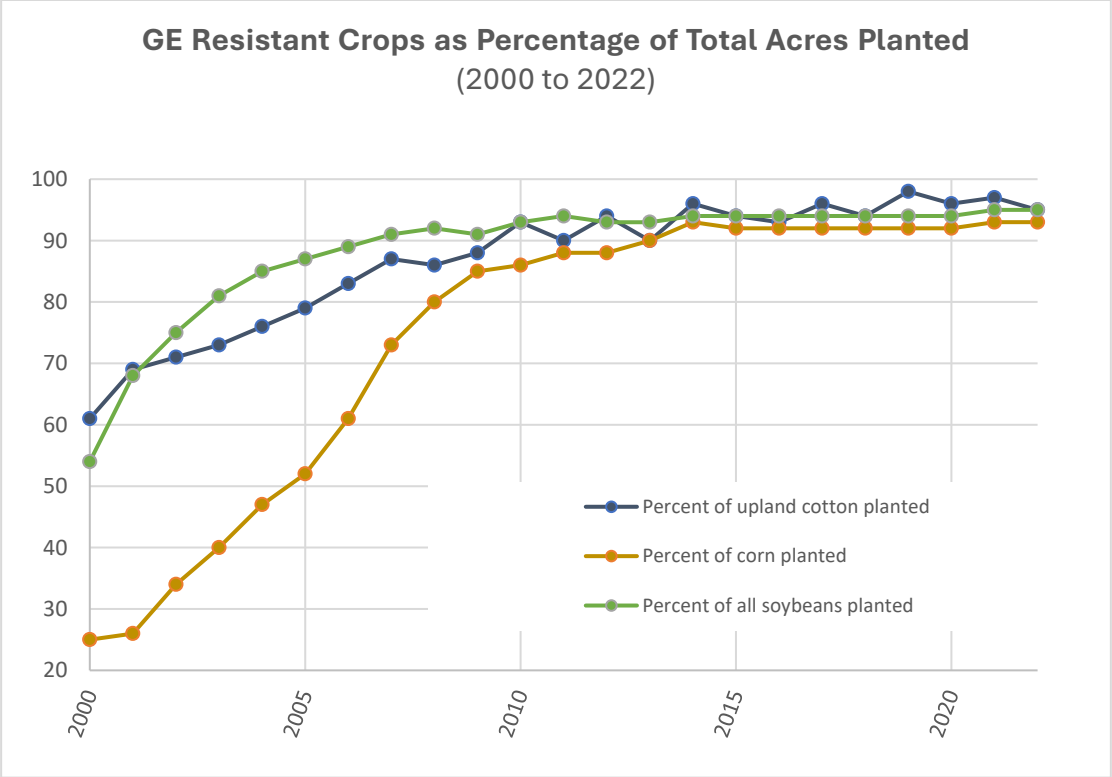
[17] EPA, Dkt. No. EPA-HQ-OPP-2009-0361, Withdrawal of the Glyphosate Interim Registration Review Decision (Sep. 21, 2022).
[18] V. Chang et al., *Glyphosate Exposure & Urinary Oxidative Stress Biomarkers in The Agricultural Health Study,* 115 J. NAT'L CANCER INSTITUTE 394 (2023).
[19] J. Winstone et al., *Glyphosate Infiltrates the Brain & Increases Pro-Inflammatory Cytokine TNFα: Implications for Neurodegenerative Disorders*, 19 J. NEUROINFLAMMATION 193 (2022).
[20] R. Gerona et al., *Glyphosate Exposure in Early Pregnancy & Reduced Fetal Growth: A Prospective Observational Study of High-Risk Pregnancies*, 21 ENVTL. HEALTH 95 (2022).

environment, which may contribute to the proliferation of plant and animal pathogens. Recent studies also confirm that repeated applications of glyphosate significantly reduce species richness and diversity on arable crop fields.[21]

102. Despite these significant environmental and health risks, glyphosate has been used on herbicide-resistant crops for almost three decades. In 1996, Monsanto introduced genetically engineered glyphosate-resistant soybeans, cotton, and corn for the first time, allowing farmers to spray glyphosate on weeds throughout the growing season without the risk of damaging crops after they emerged from the soil.

103. The introduction of glyphosate-tolerant crops led to a significant increase in the use of glyphosate-based herbicides and glyphosate-resistant crops. By 1998, more than 40% of soybean acres were planted with glyphosate-tolerant seeds.[22] By 2006, nearly 90% of acres were planted with glyphosate-tolerant soybeans. *Id.* Today, farmers use glyphosate-resistant seeds on approximately 90% of soybean acres and 92% of corn acres.[23] See table below.

[21] S. Andert et al., *Weed Response in Winter Wheat Fields on a Gradient of Glyphosate Use in the Recent Past*, 333 AGRICULTURE, ECOSYSTEMS & ENVIRONMENT 107977 (2022).
[22] S. Wechsler et al., *The Use of GE Dicamba-Tolerant Soybean Seeds Has Increased Quickly, Benefiting Adopters but Damaging Crops in Some Fields*, AMBER WAVES (Oct. 1, 2019), https://www.ers.usda.gov/amber-waves/2019/october/the-use-of-genetically-engineered-dicamba-tolerant-soybean-seeds-has-increased-quickly-benefiting-adopters-but-damaging-crops-in-some-fields.
[23] Nat'l Agric. Statistics Serv. (NASS), U.S. Dept. of Agric. (USDA), Adoption of GE Crops in the U.S. (last updated Sep. 14, 2022), https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.



104. Despite this exponential increase in glyphosate use, EPA last reviewed the impacts in 1993 (during reregistration) and has not completed its revised human health or ecological assessment as part of its registration review duties.[24]

105. Widespread and excessive use of glyphosate has accelerated the spread of glyphosate-resistant weeds.[25] Although Monsanto initially claimed that weed resistance to glyphosate was extremely unlikely, glyphosate-resistant weeds began to emerge in 2000, only four years after the commercialization of glyphosate-resistant crops. As glyphosate-

[24] EPA withdrew its "interim" registration review decision for glyphosate after the Ninth Circuit vacated the human health assessment and held EPA's failure to complete consultation was unlawful in June 2022. *See supra* note 17. EPA itself sought to redo its ecological assessment and cost-benefit analysis during the pendency of that litigation "in light of EPA's November 2020 draft biological evaluation for glyphosate and recent court decisions for other herbicides, among other reasons." *Id*.

[25] *See, e.g.*, D. HELLERSTEIN ET AL., USDA, ECON. INFORMATION BULLETIN NO. 208, AGRIC. RES. & ENVTL. INDICATORS 38 (2019) ("The heavy, and often exclusive, reliance on glyphosate in many areas led to the rapid emergence and spread of glyphosate-resistant weeds.").

tolerant crops rose in popularity, an increasing number of farmers started relying on glyphosate as their sole method of controlling weeds, rather than utilizing multiple different methods of weed management. As a result, some naturally resistant weeds survived (or "escaped") glyphosate applications.[26]

106. The number of glyphosate-resistant weeds has spread over time, reducing the effectiveness of glyphosate-based herbicides. Many farmers subsequently increased their glyphosate use to compensate for its declining effectiveness,[27] accelerating the spread of glyphosate resistance and overall amount of toxic chemicals applied to crops.[28] Some farmers sprayed glyphosate with other herbicides, increasing the overall amount of both glyphosate and other herbicides in the environment.[29] Today, there are nearly 200 glyphosate-resistant weeds in the United States.

107. The spread of glyphosate-resistant weeds has adverse effects on U.S. producers. Glyphosate-resistant weeds lower returns by decreasing yields and increasing costs for corn and soybean producers.[30] In addition, "corn and soybean producers who

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[26] *Id.* ("Heavy reliance on a single mode of weed control encourages the spread of weeds that are resistant to that mode, as resistant individual weeds survive and propagate.").
[27] *Id.* at 31 fig.2.7.1 (herbicide-resistant crops have increased glyphosate use from 1996 to 2017), 33 ("Though herbicide application rates initially declined following the commercialization of [herbicide-resistant] corn and cotton, these rates have increased over the course of the last decade, in part due to the development and spread of glyphosate-resistant weeds."), 38 ("Farmers responded to growing weed resistance by increasing their use of other old- and new-line herbicides, but also by increasing their application rates for glyphosate.").
[28] *Id.* at 38 ("Application rates (for all herbicides) increased by 20 percent from 1.67 pounds per acre in 2010 to 1.92 pounds in 2014, reflecting more intensive use.").
[29] M. LIVINGSTON ET AL., ECON. RES. SERV. (ERS), USDA, THE ECONOMICS OF GLYPHOSATE RESISTANCE MANAGEMENT IN CORN & SOYBEAN PRODUCTION (2015), https://www.ers.usda.gov/webdocs/publications/45354/52761_err184.pdf?v=209.9.
[30] J. Fernandez-Cornejo & C. Osteen, *Managing Glyphosate Resistance May Sustain Its Efficacy & Increase Long-Term Returns to Corn & Soybean Production*, AMBER WAVES (May 4, 2015), https://www.ers.usda.gov/amber-waves/2015/may/managing-glyphosate-resistance-may-sustain-its-efficacy-and-increase-long-term-returns-to-corn-and-soybean-production.

used glyphosate by itself received lower yields and returns than similar corn and soybean producers who used at least one other herbicide in combination with glyphosate."

108. EPA has long known that "overreliance on glyphosate and a reduction in the diversity of weed management practices have contributed to the evolution of glyphosate resistance in some weed species."[31] As biotech corporations, such as Corteva and Bayer, continue to push new GE Seed varieties and herbicide products, "U.S. farmers continue to adopt GE Seeds at a robust rate, and Seed varieties with multiple (stacked) traits have increased at a very rapid rate." Moreover, the development of other herbicide-resistant crops, such as dicamba and 2,4-D, "have enabled the substitution of glyphosate for more toxic and persistent herbicides." *Id*.

B. Dicamba

109. In response to the rapid spread of glyphosate resistance, manufacturers began developing genetically engineered crops with resistance to other herbicides, such as dicamba and 2,4-D. In 2016, Bayer Corp Science began selling GE dicamba-tolerant soybeans with resistance to both glyphosate and dicamba. By 2018, approximately 43% of U.S. soybean acres were planted with dicamba-tolerant seeds. The increase in dicamba-tolerant seed use from 2016 to 2018 was similar to the rate at which soybean farmers adopted glyphosate-tolerant soybeans from 1996 to 1998.[32]

110. State extension scientists warned EPA about the potential risks of approving new herbicide-resistant crops, noting that these new options would contribute to the spread of herbicide resistant weeds unless farmers used multiple different methods of weed control.[33] EPA ignored the warnings and approved dicamba for widespread use.

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[31] F. CORNEJO ET AL., ERS, USDA, REP. NO. 162, GE CROPS IN THE UNITED STATES 1, 24–25 (Feb. 1, 2014), http://dx.doi.org/10.2139/ssrn.2503388.

[32] S. Wechsler et al., *supra* note 22.

[33] *See, e.g.*, Bob Hartzler, *Mixed Message*, IOWA STATE EXTENSION (Apr. 5, 2016), https://crops.extension.iastate.edu/blog/bob-hartzler/mixed-message ("Introduction of new herbicide resistance traits . . . must be used in integrated programs to delay continued evolution of herbicide resistance.").

111. In 2020, the Ninth Circuit held that EPA improperly approved multiple dicamba-based herbicides for use on dicamba-resistant crops under FIFRA. *See Dicamba*, 960 F.3d at 1120. Specifically, the court held that EPA's registration decision was not supported by substantial evidence because EPA dramatically understated the risks associated with dicamba-based herbicides and entirely ignored the economic and social risks. *Id*. at 1137. EPA also failed to acknowledge the risk of an inability to comply with the complex label restrictions for the herbicides. *Id*. at 1139. Accordingly, the court held that the presumptive remedy of vacatur was appropriate. *Id*. at 1145.

112. As a result of EPA's failure to mitigate the risk of herbicide resistance, the rapid adoption and overuse of dicamba has led to the evolution of dicamba-resistant weeds. In 2019, only three years after introduction of dicamba-resistant crops, the effectiveness of dicamba began to wane in Tennessee, forcing farmers to significantly increase weed control costs.[34] Although farmers adopted dicamba-resistant crops at the same rate as glyphosate-resistant crops, weeds developed resistance to dicamba

[34] L. Steckel, *2019 Xtend Weed Management in Tennessee: We Have a Problem*, UNIV. OF TENN. EXTENSION (Jul. 29, 2019), https://news.utcrops.com/2019/07/2019-xtend-weed-management-in-tennessee-we-have-a-problem (noting that "weed control in the Xtend system was not near as good as the first few years this technology was used," and grass species were becoming increasingly "troublesome and expensive for growers to control").

significantly faster than they had in the past.[35] By 2022, dicamba-resistant weeds have been identified in several states, including Illinois, Tennessee, and Kansas.[36]

C. Enlist One & Enlist Duo

113. In response to growing glyphosate resistance, Corteva (formerly Dow AgroSciences LLC) invested heavily in another highly toxic chemical: 2,4-D. Corteva sought to expand its market share by developing crops with 2,4-D resistance for use with Enlist One or Enlist Duo.

114. Despite comments from experts, advocates, farmers, and the public raising concerns about the potential environmental risks of Enlist products, EPA registered Enlist Duo in 2014. Since then, EPA amended the registration for Enlist Duo in 2015, 2017, and 2022, dramatically expanding the approved uses–and adverse effects–of Enlist Duo.

115. In October 2014, EPA first registered Enlist Duo, which is a combination of 2,4-D choline salt and glyphosate, specifically for use on Enlist-resistant corn and

[35] *See, e.g.*, L. Steckel, *New Tactics Needed in Managing Weeds in Xtend Crops*, UNIV. OF TENN. (Jul. 8, 2019), https://news.utcrops.com/2019/07/new-tactics-needed-in-managing-weeds-in-xtend-crops ("It has become abundantly clear, in year three, that Engenia or XtendiMax mixed with glyphosate is not providing even close to the level of weed control that glyphosate alone did back in it[s] hay day."); L. Steckel, *Reports of Palmer Amaranth Escapes in Xtend Crops Continue to Mount*, UNIV. OF TENN. (Aug. 22, 2019), https://news.utcrops.com/2019/08/reports-of-palmer-amaranth-escapes-in-xtend-crops-continue-to-mount. Whereas glyphosate-resistant Palmer amaranth first emerged in Tennessee in 2006, ten years after adoption of glyphosate-resistant soybeans, dicamba-resistant Palmer amaranth emerged in 2019, only three years after adoption. *See* L. Steckel, *Dicamba-Resistant Palmer Amaranth in Tennessee: Stewardship Even More Important*, UNIV. OF TENN. (Jul. 27, 2020), https://news.utcrops.com/2020/07/dicamba-resistant-palmer-amaranth-in-tennessee-stewardship-even-more-important.

[36] D. Peterson et al., *Palmer Amaranth Resistance to 2,4-D & Dicamba Confirmed in Kansas*, KANSAS STATE AGRONOMY EUPDATE 734 (Mar. 1, 2019), https://webapp.agron.ksu.edu/agr_social/m_eu_article.throck?article_id=2110&eu_id=322 ("Recent research at K-State has confirmed the occurrence of dicamba and 2,4-D resistance in a Palmer amaranth population collected from . . . Riley County.").

soybean crops in six states.[37] In March 2015, EPA approved Enlist Duo for use on Enlist-resistant corn and soybean crops in nine additional states.[38]

116. In January 2017, EPA again authorized expanded use of Enlist Duo to 19 additional states, and approved use of Enlist Duo on Enlist-resistant cotton crops for the first time.[39] EPA issued a conditional registration for Enlist Duo on January 12, 2017, set to expire on January 12, 2022.[40] Later that month, EPA registered Enlist One, a standalone 2,4-D choline salt formulation, for the first time. EPA approved use of Enlist One on Enlist-resistant corn, soybean, and cotton crops in all 34 states approved for Enlist Duo.[41] EPA issued a conditional registration for Enlist One on January 31, 2017, set to expire on January 12, 2022.[42] In 2018, EPA again amended the label for Enlist One to reduce the minimum period of time between an application of Enlist herbicides and planting of soybean crops (i.e., plant back interval).[43]

117. Plaintiffs challenged EPA's previous registration decisions and amendments under the ESA and FIFRA. The Ninth Circuit agreed with Plaintiffs and held that EPA's previous registration decision violated FIFRA because EPA failed to properly evaluate the direct and indirect risks to milkweed and monarch butterflies. The court noted that other violations may arise in the future depending on available data.[44]

118. Since EPA's previous registration of Enlist One and Enlist Duo in 2017, EPA has received data from Corteva and state extension agencies that confirms farmers are

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[37] *See* Notice of Pesticide Registration for Enlist Duo (Oct. 15, 2014); Final Registration (Oct. 15, 2014); Response to Public Comments (Oct. 14, 2014); *see also* Enlist Duo Product Label (Oct. 15, 2014).
[38] *See* Label Amendment (Mar. 31, 2015); *see also* Enlist Duo Product Label (Mar. 31, 2015).
[39] *See* Final Registration Decision (Jan. 12, 2017); *see also* Enlist Duo Product Label (Jan. 12, 2017).
[40] Enlist Duo Product Label (Jan. 12, 2017).
[41] Enlist One Product Label (Jan. 31, 2017).
[42] Enlist Duo Product Label (Jan. 12, 2017).
[43] Enlist One Product Label (May 7, 2018).
[44] For further discussion of the procedural history, see Part IV.

not following product labels, use of Enlist products is increasing rapidly, and Enlist applications are causing serious damage to nearby crops and habitats. Despite growing evidence that Enlist is on track to become one of the most widely used and dangerous herbicides in U.S. soybean and cotton production, EPA refuses to learn from its past mistakes, choosing instead to ignore actual evidence of adverse effects and warning signs of future risk.

1. Increased Use of Enlist Products

a. Soybean

119. Enlist products were not commercially available to U.S. soybean producers until mid-2019, delaying the widespread adoption of Enlist products for nearly five years from the initial registration, until 2020.[45] *See* Memorandum on Use, Usage, and Current and Future Benefits of Enlist One and Enlist Duo Herbicides in Corn, Soybean, and Cotton from John Orlowski, Biological Analysis Branch, and Brad Kells, Economic Analysis Branch, EPA at 6 (Jan. 11, 2022) (Use Memo). Since the commercialization of Enlist-resistant soybeans, there has been a dramatic increase in the use of Enlist products in U.S. soybean production. *Id.* Although EPA acknowledged that use of Enlist products on soybean crops has increased in recent years, EPA does not provide any data from 2020 or 2021 in its benefits assessment. *Id.* EPA also acknowledged that use of Enlist products will continue to increase in the future but failed to estimate future usage or acreage based on available data or historical trends. *Id.*

[45] Press Release, Corteva Agriscience™ & MS Technologies™ Announce Launch of Enlist E3™ Soybeans for the U.S. in 2019 (Feb. 21, 2019) ("Enlist E3™ soybeans will be available in commercial quantities across all Corteva Agriscience™ brands in 2020 . . . ."), https://www.corteva.us/content/corteva/corporate/our-homepage/resources/media-center/corteva-and-ms-tech-announce-2019-us-enlist-e3-soybean-launch.html; Press Release, MS Technologies™ Announces Plans for Commercial Launch of Enlist E3™ Soybeans (Jan. 28, 2019) ("Growers can expect commercial sales of the soybeans to begin in 2019, with a much broader, full-scale launch in 2020."), http://www.mstechseed.com/news-room/release/ms-technologies-tm-announces-plans-for-commercial-launch-of-enlist-e3-tm-soybeans.

120. Market research confirms that the use of Enlist products has increased rapidly since 2019, when Corteva first released Enlist-resistant soybeans in the United States.[46] In early 2020, Corteva announced that it was "accelerating the ramp-up of Enlist E3™ soybeans . . . over the next five years."[47] As a result, "adoption of this technology has been rapid," and Corteva's market share has increased dramatically in recent years.[48] As of 2021, over one-third of soybean producers have already adopted the Enlist weed control system, and Corteva expects this number to increase in the future: "With an adoption rate on U.S. soybean acres of approximately 35% in 2021, the Enlist weed control system is the industry's fastest-growing soybean herbicide system, a trend [Corteva] expects to continue with the introduction of high-performing [Enlist-resistant] soybeans."[49] In 2022, Corteva "raised its . . . market penetration outlook to greater than

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[46] Press Release, Farmers Benefit From Wide Availability of Soybeans with Enlist E3™ Technology (Jul. 9, 2019), https://www.corteva.us/press-releases/farmers-benefit-from-wide-availability-of-soybeans-with-enlist-e3-technology.html ("Corteva projects that Enlist E3 soybeans will be planted on at least 10% of U.S. soybean acres in 2020."); Press Release, Corteva Agriscience™ and MS Technologies™ Announce Launch of Enlist E3™ Soybeans for the US in 2019 (Feb. 19, 2019), https://www.corteva.us/press-releases/corteva-and-ms-tech-announce-2019-us-enlist-e3-soybean-launch.html ("Robust ramp-up plans and extensive seed production will ensure that Enlist E3™ soybeans are broadly available to farmers in 2020.").

[47] Press Release, Corteva Agriscience to Accelerate Ramp Up of Enlist E3™ Soybeans to U.S. & Canadian Farmers for 2021 (Jan. 30, 2020), https://www.corteva.com/resources/media-center/corteva-agriscience-to-accelerate-ramp-up-of-enlist-e3-soybeans-to-us-and-canadian-farmers-for-2021.html ("During the five-year ramp-up period, Corteva is expected to significantly reduce the volume of products with [glyphosate resistance] beginning in 2021, with expected minimal use of the trait platform after the completion of the ramp-up of the Enlist weed control system.").

[48] Press Release, Acres of Enlist E3® Soybeans Rising – So Is Demand for Enlist™ Herbicides (Nov. 18, 2020), https://www.corteva.us/Resources/inputs-and-insights/Acres-of-Enlist-E3-Soybeans-Rising-So-is-Demand-for-Enlist-Herbicides.html.

[49] Press Release, Exclusive, New Pioneer® Brand A-Series Enlist E3® Soybeans Deliver the Total Performance Package (Mar. 9, 2022), https://www.corteva.us/content/corteva/corporate/our-homepage/resources/media-center/exclusive-new-pioneer-brand-a-series-enlist-e3-soybeans-deliver-the-total-performance-package.html; Press Release, New Class of Pioneer® Brand Seed Products

45% of U.S. soybean acres, up from greater than 40% expected previously."[50] As Corteva continues to roll out the Enlist weed control system, Corteva's market share will continue to rise exponentially. Despite Corteva's initial delay in releasing Enlist-resistant soybeans, the adoption rate of the Enlist weed control system has been similar to the rate at which farmers adopted dicamba-resistant and glyphosate-resistant soybeans.[51]

121. "Enlist Duo was most frequently applied without other herbicides." Use Memo at 6. Fifty-six percent of total soybean acres sprayed with Enlist Duo were sprayed with Enlist Duo alone. Enlist Duo is also mixed with other herbicides, including glufosinate, even though glufosinate is not an approved tank mix partner with Enlist Duo. *Id*. These results "indicate that users are confused by the different partners approved for the two Enlist products or are not checking or following the lists for approved tank mixes." *Id*.

122. According to market research, "Enlist One was frequently applied with glyphosate, but was also frequently applied alone." *Id*. "Enlist One was rarely applied with glufosinate." *Id*. EPA did not provide specific percentages.

b. Cotton

123. According to EPA, the use of 2,4-D on cotton acres has increased dramatically since EPA approved both Enlist One and Enlist Duo for use on cotton crops in

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Poised to Drive Farmer Success (Dec. 14, 2021), https://www.corteva.us/content/corteva/corporate/our-homepage/resources/media-center/new-class-of-pioneer-brand-seed-products-poised-to-drive-farmer-success.html.

[50] Corteva Reports Second Quarter and First Half 2022 Results (Aug. 4, 2022), https://www.corteva.us/content/dam/dpagco/corteva/global/corporate/files/press-releases/08.04.2022_2Q_2022_Earnings_Release_Graphic_Version_Final.pdf, Press Release, 2021 Fourth Quarter Earnings (Feb. 2, 2022), https://www.corteva.com/content/dam/dpagco/corteva/global/corporate/files/press-releases/02.02.2022_4Q_2021_Earnings_Release_Graphic_Version_Final.pdf.

[51] Between 2016 and 2018, the first two years of commercialization, roughly 40% of soybean acres were planted with dicamba-tolerant seeds. Likewise, between 1996 and 1998, the first two years of commercialization, roughly 40% of soybean acres were planted with glyphosate-resistant crops. *See* S. Wechsler et al., *supra* note 22.

2017. *See* Use Memo at 5.[52] However, EPA does not provide any specific data regarding the amount of Enlist products applied to cotton crops in its benefits assessment. *Id*.

124. Market data confirms that adoption of the Enlist weed control system in U.S. cotton production has increased rapidly. In 2018, U.S. cotton producers "sprayed enough Enlist herbicides to cover 1.5 million acres of [Enlist-resistant] cottonseed."[53] Corteva also reported that the total number of acres planted with Enlist-resistant cotton tripled in 2018."[54]

125. The number of Enlist-resistant cotton varieties on the market increased dramatically following commercialization.[55] In 2020, 75% of total upland cotton was planted with dicamba-resistant cotton, and 18% with Enlist-resistant cotton.[56] In 2017, only 3% of total upland cotton was planted with Enlist-resistant cotton.[57] For many of the approved states, the number of Enlist-resistant cotton planted exceeded the national average.

126. Actual use data confirms that most "Enlist products applied to cotton were applied after crop emergence." Use Memo at 5. About 90% of total cotton acres sprayed with either Enlist Duo or Enlist One were sprayed after crop emergence. *Id*.

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[52] Press Release, PhytoGen Releases Seven New Varieties With The Enlist® Cotton Trait For 2017 (Jan 5, 2017), https://phytogencottonseed.com/news/details/2017-new-varieties-enlist-trait; Press Release, Enlist® Weed Control System Expands With Addition of Enlist One™ Herbicide (Sep. 13, 2017), https://phytogencottonseed.com/news/details/enlist-weed-control-system-expands-with-addition.

[53] Shawna Hubbard, Corteva, Cotton Successes Offer Blueprint For Enlist E3™ Soybeans (2019), https://www.enlist.com/content/dam/hdas/enlist/pdfs/Cotton-Blueprint.pdf.

[54] *Id.*; Press Release, Tools, Collaboration Help Farmers Use Enlist™ Technology Successfully (Aug. 28, 2018), https://www.corteva.us/press-releases/tools--collaboration-help-farmers-use-enlist--technology-success.html.

[55] *See, e.g.*, Press Release, Enlist® Weed Control System Expands with Addition of Enlist One™ Herbicide (Sep. 2017), https://phytogencottonseed.com/news/details/enlist-weed-control-system-expands-with-addition.

[56] U.S. Cotton Varieties Planted: 2020 Crop (Oct. 2020).

[57] U.S. Cotton Varieties Planted: 2017 Crop (Sep. 2017).

127. According to user surveys, "it is common for cotton acres sprayed with Enlist products to be sprayed multiple times with Enlist products." Use Memo at 5. "About 35% of cotton acres sprayed with Enlist Duo were sprayed twice per year; the majority of these double applications were both made after crop emergence." *Id.* "About 75% of cotton acres sprayed with Enlist One were sprayed twice per year; the majority of these double applications were both made after crop emergence." *Id.*

128. Enlist Duo is also "frequently applied on its own." Use Memo at 6. "83% of total cotton acres treated with Enlist Duo were not mixed with other herbicide products." *Id.* "A tank mix of Enlist Duo and glufosinate was used on 7% of total cotton acres [sprayed with Enlist Duo]," even though "glufosinate is not an approved tank mix partner with Enlist Duo." *Id.* These results suggest that "users are confused by the different partners approved for the two Enlist products or are not checking or following the lists for approved tank mixes." *Id.*

129. "Enlist One is also applied on its own." *Id.* "10% of total cotton acres treated with Enlist One were treated with Enlist One alone." *Id.* In addition, "52% of total cotton acres treated with Enlist One [were] treated with a tank mix of Enlist One and glyphosate." *Id.* "However, less than 10% of total cotton acres treated with Enlist One were tank mixed with glufosinate." *Id.*

c. Corn

130. Corteva first launched Enlist-resistant corn in 2018.[58] Although EPA did not specify when Enlist was first used in U.S. corn production, Corteva reported that U.S. corn producers got their "first full commercial experience[] with Enlist corn" in 2018.[59] "In 2018

[58] Press Release, Dow Announces Launch of Enlist Corn in US and Canada (Jun. 14, 2017), https://corporate.dow.com/en-us/news/press-releases/dow-announces-launch-of-enlist-corn-in-us-and-canada.html ("Enlist corn will be widely available in the U.S. and Canada, and will be sold as both SmartStax® Enlist and PowerCore® Enlist hybrids.").
[59] Press Release, Tools, Collaboration Help Farmers Use Enlist™ Technology Successfully (Aug. 28, 2018), https://www.corteva.us/press-releases/tools--collaboration-help-farmers-use-enlist--technology-success.html.

and 2019, less than 15,000 total acres of corn were sprayed with either Enlist One or Enlist Duo." Use Memo at 5.

2. Increased Spread of 2,4-D Resistance

131. 2,4-D resistance emerged in the early 1990s, decades before Corteva developed the Enlist weed control system. By the time EPA registered Enlist Duo, 2,4-D-resistant weeds were confirmed in several states.[60] Since then, 2,4-D resistance has continued to spread in states approved for use of Enlist products, with new cases emerging in Kansas, Illinois, and Indiana.[61]

132. The spread of weeds with resistance to 2,4-D significantly reduces the utility of Enlist products. Before the commercialization of Enlist-resistant soybeans, experts warned about the dangers of Enlist products, noting that "the fact that there are already three *A. tuberculatus* populations with resistance to 2,4-D . . . should be emphasized to ensure that proper stewardship of these new technologies is followed."[62] However, EPA failed to consider resistance before approving Enlist One and Enlist Duo for use in 34 states in 2017. Consequently, the number of species with resistance to 2,4-D has increased dramatically since the commercialization of Enlist-resistant crops.

133. The increased use of Enlist One and Enlist Duo threatens to accelerate the spread of 2,4-D resistance by increasing use of 2,4-D on resistant weeds. In addition, increased use of Enlist products increases the spread of naturally resistant weeds because farmers typically rely on Enlist products as their only method of controlling weeds.

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[60] *See, e.g.*, M. Bernards et al., *A Waterhemp (Amaranthus Tuberculatus) Population Resistant to 2,4-D*, 60 WEED SCI. 379 (2012) (common waterhemp with resistance to 2,4-D in Nebraska).

[61] *See* Bob Hartzler, *Mixed Message*, *supra* note 33 ("The identification of 2,4-D resistant waterhemp in multiple states clearly shows that without wise use, the relief provided by these new tools will be short-lived.").

[62] L. Shergill et al., *Investigations of 2,4-D & Multiple Herbicide Resistance in a Missouri Waterhemp (Amaranthus tuberculatus) Population*, 66 WEED SCI. 386 (2018).

134. Actual use data demonstrates that Enlist products are rarely applied with other effective modes of action to control glyphosate-resistant weeds. *See, e.g.*, Use Memo at 13 ("[M]arket research data suggests that Enlist herbicides are frequently being applied alone or with only glyphosate, which is generally no longer an effective herbicide for control of Amaranthus species, including Palmer amaranth."). Although previous labels urged growers to use Enlist with other modes of action to reduce resistance, most applicators ignored the labels and used Enlist–and only Enlist–to control problematic herbicide-resistant weeds.

135. Widespread and exclusive reliance on Enlist products increases the spread of resistance by increasing the number of natural resistant weeds that escape each application. Although Enlist-resistant soybeans were not commercialized until 2019, state extension agencies have already received numerous reports of escapes following Enlist applications on soybean fields. *See supra*. In Tennessee, scientists have confirmed that neither 2,4-D or dicamba are effective against Palmer amaranth weeds, even in high amounts. *Id*.

136. State extension agencies have also confirmed that Enlist products are not effective against several problematic glyphosate-resistant weeds, including Palmer amaranth. *See supra*. Moreover, these reports demonstrate that repeated use of Enlist products on these weeds will increase the spread of resistance, decreasing the effectiveness of Enlist products and other herbicides. *Id*. Before extending the registrations of Enlist One and Enlist Duo for another seven years, EPA failed to add any mitigation measures to slow the spread of future resistance.

137. State extension scientists have repeatedly warned EPA about the risks of approving Enlist products without sufficient restrictions in place to prevent the spread of resistance. *See supra*. EPA is also aware of the costs and risks associated with increased resistance, such as the environmental impacts of increased use of 2,4-D and other herbicides to compensate for reduced effectiveness, and the economic costs associated

with increased 2,4-D spray drift and weed control costs. Although experts have explained that mitigating herbicide resistance "require[s] shifting from the current concept of basing weed management on single-year economic thresholds,"[63] EPA continues to ignore the long-term costs to the environment and farmers for the benefit of biotech companies that stand to profit from the spread of herbicide resistance and increased usage of their technologies.[64]

138. The evolution of weeds with resistance to 2,4-D and several other herbicides highlights the need for EPA to properly consider non-chemical and long-term weed management strategies in its cost-benefit analysis. In 2018, scientists confirmed an *A. tuberculatus* (waterhemp) population from Missouri with resistance to 2,4-D, atrazine, chlorimuron, fomesafen, glyphosate, and mesotrione, making it "the third 2,4-D–resistant population identified in the United States, and the first population resistant to six different herbicidal modes of action."[65] In 2019, scientists confirmed "the first global case of an *A. palmeri* population from Kansas with multiple resistance to 2,4-D, glyphosate, chlorsulfuron, atrazine and mesotrione, and reduced sensitivity to fomesafen."[66] They also found several effective chemical alternatives, including "glufosinate, paraquat, and saflufenacil alone or in tank-mixtures with [pre-emergence] herbicides," but the efficacy of these herbicides will also likely wane in the future. The spread of weeds with resistance to multiple herbicide classes, including 2,4-D, "underlines the need to use a diversified approach toward weed management that includes any of the appropriate cultural,

[63] J. Norsworthy et al., *Reducing the Risks of Herbicide Resistance: Best Management Practices & Recommendations*, 60 WEED SCI. 31, 31 (2012).
[64] *Id.* at 32 ("The long-term economic benefits of avoiding additional costs associated with managing [herbicide resistant] weeds are clear.").
[65] L. Shergill et al., *supra* note 62**Error! Bookmark not defined.**, at 386–94.
[66] V. Kumar et al., *Confirmation of 2, 4-D Resistance & Identification of Multiple Resistance in a Kansas Palmer Amaranth Population*, 75 PEST MGMT. SCI. 2925 (2019).

mechanical, and biological control tactics available in a given production system rather than relying on any one method alone."[67]

3. Increased Reports of 2,4-D Spray Drift

139. Experts have repeatedly warned EPA about the risks of spraying Enlist products near farms growing grapes, tomatoes cotton, and other crops with high sensitivity to 2,4-D. EPA was well-aware that approving 2,4-D for use in areas with highly sensitive crops would increase off-target injury and costs for farmers.[68]

140. Since authorizing the use of Enlist products on corn, cotton, and soybean crops in 34 states in 2017, EPA has received several reports of spray drift incidents involving 2,4-D. In 2018 and 2019 alone, EPA received multiple reports specifically involving damage to cotton fields from off-target movement of Enlist One or Enlist Duo. Memorandum on Incidents and Impacts of Potential Mitigation at 8 (Jan. 11, 2022) ("Impacts Memo"). These reports confirm that Enlist products have already damaged cotton crops on nearby farms. *Id.* at 8–9.

141. The number of spray drift incidents involving Enlist Duo has likely increased dramatically in recent years due to the commercialization of Enlist-resistant soybeans in early 2019. EPA also acknowledged that "the number of actual incidents associated with 2,4-D" is likely higher than what was reported to EPA. Ecological Risk Assessment at 91; *see also* Incidents Memo at 9 ("Additional incidents involving both 2,4-D and Enlist herbicides likely occurred during this time but were not reported to EPA.").

142. EPA's decision to renew the registrations for Enlist One and Enlist Duo threatens to increase the severity and frequency of 2,4-D spray drift damage to nearby

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[67] L. Shergill et al., *supra* note 62, at 386–94.

[68] *See, e.g.*, B. Hartzler & M. Owen, *Increased Dicamba Use Requires Enhanced Stewardship*, IOWA EXTENSION (Nov. 15, 2016), https://crops.extension.iastate.edu/cropnews/2016/11/increased-dicamba-use-requires-enhanced-stewardship ("Proper stewardship of [Enlist weed management systems] will be just as important as with the dicamba-based weed management system to prevent off-target injury.").

crops. Off-target movement of 2,4-D continues to pose a serious threat to neighboring farms, including damage to crops on nearby fields from off-target movement, as well as reduced yields, increased costs, and heightened tension between neighboring farmers. Widespread injury associated with off-target movement is likely to result in more resistance, reducing the effectiveness of alternative options and increasing overall weed control costs.

4. Increased Threat of 2,4-D Health Impacts

143. Recent studies have raised concerns regarding the carcinogenic effects of 2,4-D. For example, a 2020 longitudinal biomarker study linked 2,4-D exposure with increased systemic markers of oxidative stress.[69] Association between 2,4-D exposures and non-Hodgkin lymphoma (NHL) has also been reported, with a recent meta-analysis showing that highly exposed groups experience an elevated relative risk of NHL.[70] Further, the risk of pediatric leukemia increases in children residing near areas sprayed heavily with herbicides, including 2,4-D, raising concerns about the health impacts on children.[71] In addition, non-cancer outcomes such as birth defects and pediatric anatomical abnormalities have also been linked to 2,4-D.[72]

144. Before EPA first registered Enlist Duo in 2014, approximately one-third of America had detectable levels of 2,4-D in their urine.[73] Due to EPA's decision to expand

[69] C. Lerro et al., *2,4-D Exposure & Urinary Markers of Oxidative DNA Damage & Lipid Peroxidation: A Longitudinal Study*, 77 OCCUPATIONAL ENVTL. MED. 276 (2020).
[70] A. Smith et al., *2,4-D & Risk of Non-Hodgkin Lymphoma: A Meta-Analysis Accounting for Exposure Levels*, 27 ANN EPIDEMIOL. 281 (2017).
[71] C. Malagoli et al. *Passive Exposure to Agricultural Pesticides & Risk of Childhood Leukemia In An Italian Community*, 219 INT'L J. HYGIENE & ENVTL. HEALTH 742 (2016).
[72] K. Rappazzo et al., *Maternal Residential Exposure to Specific Agricultural Pesticide Active Ingredients & Birth Defects*, 111 BIRTH DEFECTS RES. 312 (2019); J. Hoppin et al., *Pesticides Are Associated with Allergic & Non-Allergic Wheeze Among Male Farmers*, 125 ENVTL. HEALTH PERSPECTIVES 535 (2017); S. Shrestha et al., *Pesticide Use & Incident Hypothyroidism in Pesticide Applicators in the Agricultural Health Study*, 126 ENVTL. HEALTH PERSPECTIVES 97008 (2018).
[73] M. Freisthler et al., *Association Between Increasing Agricultural Use of 2,4-D & Population Biomarkers of Exposure*, 21 ENVTL. HEALTH 23 (2022).

and extend the registrations of Enlist One and Enlist Duo, rates of exposure to 2,4-D products have likely increased dramatically in recent years, and these rates will continue to increase as a direct result of EPA's decision to extend the registrations of Enlist One and Enlist Duo for seven years. *Id*. "The expected trend of increased use of 2,4-D raises concerns about changes in population exposure, particularly for sensitive populations who may be more vulnerable to harmful effects of exposure." *Id*.

III. Previous Litigation

145. Plaintiffs sought review of both the initial registration of Enlist Duo in 2014, Pet. Review, *Nat. Res. Def. Council v. EPA* (*Enlist Duo I*), No. 14-73353 (9th Cir. Oct. 30, 2014), ECF No. 1-1, as well as the amendment in 2014, *CFS v. EPA*, No. 1571207 (9th Cir. Apr. 20, 2015), ECF No. 1-2; Pet. Review, *Nat. Res. Def. Council v. EPA*, No. 15-71213 (9th Cir. Apr. 20, 2015), ECF No. 1-2. The cases were consolidated. Order, *Enlist Duo I*, Jun. 2, 2015, ECF No. 66.s

146. While Plaintiffs' challenge was pending, EPA announced it had discovered Dow had filed a patent application with the U.S. Patent and Trademark Office claiming Enlist Duo's two active ingredients had synergistic effects—that the two ingredients combined were more potent than would be expected from their separate effects. In its submissions to EPA, however, Dow had not included the synergy data.

147. On November 24, 2015, EPA moved the Court to vacate the registration and remand it to EPA based on the synergy data, which EPA informed the Court could potentially affect EPA's assessment of the risks the pesticide poses to endangered plant and animal species. *See* Mot. Voluntary Vacatur & Remand, *Enlist Duo I*, ECF No. 121-1. On January 25, 2016, the Court granted the motion for remand but declined to vacate, so the registration remained in effect. Order, *Enlist Duo I*, ECF No.128.

148. On March 21, 2017, Center for Food Safety (CFS), National Family Farm Coalition (NFFC), Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, and Pesticide Action Network North America (Plaintiffs) petitioned the Ninth

Circuit to review and set aside EPA's final order granting EPA's January 12, 2017, conditional registration of Enlist Duo. Petitioners argued that EPA violated its duties under FIFRA by issuing the conditional registration without substantial evidence. Petitioners also argued that EPA violated its duties under the ESA by failing to "insure" that the registration would not jeopardize any listed species or their habitats.

149. On the same day, Natural Resource Defense Council (NRDC) also challenged EPA's 2017 actions. *See* Pet. Review, No. 17-70810 (9th Cir. Mar. 21, 2017), ECF No. 1-5. On May 3, 2017, the Court consolidated the Plaintiffs' Petition for Review with *NRDC v. Pruitt*, No. 17-70817 (9th Cir. Mar. 21, 2017). Order, ECF No. 14.

IV. Ninth Circuit Decision in *NFFC v. EPA*, 966 F.3d 893 (9th Cir. 2020) (*Enlist II*)

150. Plaintiffs challenged EPA's decisions to register Enlist Duo in 2014, 2015, and 2017. In 2020, the Ninth Circuit granted the petition in part, holding that EPA's decisions violated FIFRA and remanded to the agency. Specifically, the Ninth Circuit held that EPA's registration decision lacked substantial evidence because EPA failed to "consider[] how the destruction of milkweed on target fields would affect monarch butterflies." *Enlist II*, 966 F.3d at 930. The court "remand[ed] without vacatur so EPA can address the evidence that monarch butterflies may be harmed by the destruction of milkweed on target fields in determining whether the registration of Enlist Duo will lead to any 'unreasonable adverse effect' on the environment." *Id.*

A. Standing

151. The Ninth Circuit held that Petitioners had standing to assert that EPA's decisions lacked substantial evidence under FIFRA. Petitioners submitted declarations from members stating that "they enjoy watching the monarch butterfly migration where they live, that Enlist Duo is approved for use in their states, and that they are concerned they will no longer be able to enjoy observing monarch butterflies because of Enlist Duo's effects on milkweed." *Id.* at 909. Petitioners also submitted a member declaration stating that Enlist Duo is approved for use in his state, and "his crops are affected by the use of

the components of Enlist Duo on nearby fields," causing him to suffer "economic damage, including harm[] [to] his grapevines and . . . decrease [in] the amount of acreage he plants on." *Id.* at 910. Because these declarations established that Petitioners' members had standing, the court concluded that Petitioners had associational standing to bring FIFRA claims. *Id*. at 911.

152. The Ninth Circuit also held that Petitioners had standing to allege that EPA violated the ESA by failing to consult with the FWS before registering Enlist Duo. Petitioners submitted a declaration stating that a member "live[d] in a state where Enlist Duo is approved for use" and "enjoys observing endangered species where she lives, including the Indiana bat." *Id.* ("Because one of CFS's members has Article III standing, the organization also has associational standing to bring its ESA claims.").

B. FIFRA Violations

153. Petitioners argued that EPA lacked substantial evidence for its 2014, 2015, and 2017 registration decisions because EPA failed to: (1) properly assess harm to monarch butterflies from increased 2,4-D use on milkweed in target fields; (2) consider that Enlist Duo would increase the use of glyphosate over time; (3) correctly consider the volatility of Enlist Duo's 2,4-D component; and (4) consider the synergistic effects of mixing Enlist Duo with glufosinate.

1. Harm to Monarch Butterflies

154. Petitioners argued that "EPA failed to consider the harm of expanded 2,4-D use to certain monarch butterfly habitats." *Id.* at 916. The court noted that "EPA did assess some of these risks as part of its registration decisions." *Id*. For example, before approving the 2017 registration, "EPA performed a risk assessment that considered the 'toxic effects to non-target plants (a grouping that includes plants important to monarchs)'" and "found 'no concerns for terrestrial invertebrates (including monarchs)' because Enlist Duo would only affect [sprayed] fields—not non-target plants—as long as it was used under the [spray drift and runoff] 'conditions prescribed by the label.'" *Id.* at

916. Since then, new evidence regarding the risk of spray drift and runoff confirms that EPA did not properly assess the risks to nearby plants, animals, and pollinators.

155. Petitioners argued that "EPA should have considered how the destruction of milkweed on target fields would affect monarch butterflies." *Id.* at 917. Although "EPA acknowledged in its briefing that it did not assess those risks," the agency claimed that "it was not required to do so because 'farmers will control the same amount of milkweed on their crop fields through the use of herbicides or other means and at the same crop growth stages, with or without Enlist Duo.'" *Id.* The Ninth Circuit rejected EPA's explanation because "EPA did not assert this rationale as a reason for declining to assess the destruction of milkweed on target fields." *Id.* Further, even if EPA had properly asserted this rationale, "it would likely be premised on legal error" because "it says nothing about whether an effect would be 'adverse.'" *Id.* "Given the record evidence suggesting monarch butterflies may be adversely affected by 2,4-D on target fields, EPA was required, under FIFRA, to determine whether any effect was 'adverse' before determining whether any effect on the environment was, on the whole, 'unreasonable,'" and "EPA's failure to do so means that its decision was lacking in substantial evidence on this issue." *Id.*

2. Increase in Glyphosate Use

156. Petitioners argued that EPA improperly concluded that the registrations would have no unreasonable adverse effects because "glyphosate was already being used in the same locations and doses and on the same crops." *Id.* According to EPA, Enlist Duo's registration "would only impact which glyphosate product was used"—not how much glyphosate was used." *Id.* The court held that, "substantial evidence support[ed] EPA's conclusion that neither the initial 2014 registration of Enlist Duo—nor the subsequent approvals for new uses—will increase the overall use of glyphosate." *Id.* at 917. "[B]ecause corn, cotton, and soybean crops have long been genetically engineered to be glyphosate resistant, meaning that the use of glyphosate on these crops was nearly ubiquitous before Enlist Duo was registered in 2014." *Id.* at 917–18. "Even absent Enlist

Duo's registration, therefore, farmers would continue to use glyphosate on these same crops". *Id*. "Thus, there was no increased risk of unreasonable adverse effects caused by glyphosate in approving Enlist Duo." *Id*.

157. Since then, new evidence confirms that Enlist products increase the use of glyphosate and other harmful chemicals on crops currently sprayed with glyphosate-based products. *See id*. ("new data about glyphosate" will [not] go unconsidered").

3. 2,4-D Volatility

158. Petitioners argued that EPA "failed to properly consider 2,4-D's volatility—that is, its tendency to evaporate into a gas and drift to non-target plants." *Id*. Although "EPA's evaluation of 2,4-D volatility probably could have been better," the court held that substantial evidence supported EPA's conclusion because "there [was] no evidence in the record that its conclusion was wrong . . . in the five-plus years since Enlist Duo was originally approved." *Id*. at 920–21. Since then, new evidence regarding the risk of spray drift confirms that EPA's evaluation was improper.

4. Synergistic Effects

159. Petitioners argued that EPA failed to consider "the potential synergistic effect of mixing Enlist Duo with a different chemical called glufosinate." *Id*. The court rejected this argument because "[n]othing in the record suggests that such mixing has occurred in the five-plus years since Enlist Duo was first registered." *Id*. Because "EPA has stated that Enlist Duo cannot be tank-mixed with any product that has not been tested, approved, and listed on the website EnlistTankMix.com," "[a]nd no product containing glufosinate is listed on that website," "[i]t is therefore currently unlawful to mix Enlist Duo with glufosinate." *Id*. Although fears about mixing were speculative at the time, the court noted that "nothing prevents a Petitioner from approaching the EPA with concerns about synergy in the future." *Id*. Since then, Corteva has added multiple glufosinate products to the list of approved tank mixes for Enlist Duo (including Eraser and Lambda-Cy AG) and Enlist One (including Helena Glufosinate 280 SL).

C. ESA Violations

1. Mitigation Measures

160. The court held that EPA properly relied on "mitigation measures, including a 30-foot downwind buffer and certain label restrictions, to reach a 'no effect' finding as to plants and animals off the treated field." *Id.* at 924. As the court explained, unlike mitigation measures that "merely 'reduce'" an effect, "EPA was able to rule out any effect on plants and species off the sprayed field in partial reliance on mitigation measures." *Id.* at 925. The court also held EPA's label restrictions were "reasonable" mitigation measures under the ESA because they were "specific and binding plans." *Id.* Since then, new evidence reveals that EPA's mitigation measures do not protect listed species and habitats, and EPA's reliance on these measures is improper. *See supra*.

2. Use of Best Available Science

161. The court deferred to EPA's rationale for limiting the "action area" to the sprayed field, noting that "EPA had good—and science-based—reasons for limiting the action area to the treated field," and there was no "record evidence—such as data undermining EPA's scientific conclusion or showing that mitigation measures are not working—suggesting that the mitigation measures EPA selected are not 'specific and binding' and 'reasonably certain to occur.'" *Id.* at 928. Since then, new evidence reveals that EPA's mitigation measures do not protect listed species and habitats, and EPA's reliance on these measures is improper. *See supra*.

162. The court also deferred to EPA's rationale for using an outdated risk quotient/level of concern approach, noting that better data was not yet available. In 2013, the National Academy of Sciences recommended that EPA adopt a "probabilistic approach" to assessing risk to endangered species. However, this data was not available when EPA previously registered Enlist One and Enlist Duo in 2017. *See* Enlist II, 966 F.3d at 926–27. Thus, the Ninth Circuit held that EPA reasonably elected to "continue applying [its outdated risk quotient/level of concern] approach while it put a system in place to use

NAS's proposed approach, as set forth in the Interim Report . . . EPA and the consultation agencies sent to Congress in November 2014." *Id.* at 926.

163. Although the court upheld EPA's flawed risk quotient approach in 2014, the court noted that "we do not expect [this determination] to reoccur given EPA's commitment to gather the data necessary to implement NAS's new methodology going forward." *Id.* However, EPA continues to rely on the flawed risk quotient approach, rather than adopt the recommended probabilistic approach.

V. EPA's Registration Decisions

164. On April 5, 2021, roughly 8 months after the Ninth Circuit held that EPA's prior registrations were unlawful under FIFRA, Corteva submitted applications to extend the five-year registrations for an additional term, as both registrations were set to expire on January 12, 2022. Corteva did not request any uses beyond those already approved.

165. On the day before the prior registrations were set to expire, EPA extended the registrations for both Enlist Duo and Enlist One for an additional seven-year term, without any notice, public comment period, or consultation with the expert wildlife agencies.[74] These registrations are set to expire on January 11, 2029, securing Corteva's investment in these technologies and increasing their appeal to farmers.

166. As noted above, EPA previously issued conditional registrations, limited to five years. This time, EPA unconditionally registered Enlist One and Enlist Duo for seven years, until January 11, 2029. According to EPA, "[e]xtending the Enlist registrations for an additional seven years will enable corn, cotton, and soybean growers to have continued access for at least a limited time to a tool that is important to control glyphosate-resistant weeds, while simultaneously allowing EPA and states to monitor the impacts of the new mitigation measures and positioning the Agency to be responsive to any unexpected impacts." Decision Memo at 36. EPA further explained that the seven-year term "allows

[74] Enlist Duo Product Label (Jan. 11, 2022); Enlist One Product Label (Jan. 11, 2022).

EPA to monitor incidents of herbicide resistance." *Id.* at 37. However, as explained below, Enlist products are not an effective tool for controlling glyphosate-resistant weeds. In addition, EPA did not implement effective mitigation measures or monitoring methods.

167. On March 29, 2022, EPA amended the registrations for Enlist One and Enlist Duo to remove hundreds of county-level prohibitions without any prior notice, public comment, or consultation with the expert wildlife agencies.[75] In doing so, EPA again expanded Corteva's market share at the expense of the environment and wildlife.

168. EPA's registration decisions have numerous deficiencies, outlined below.

A. Current Use & Acreage

169. EPA acknowledges that the overall amount of 2,4-D applied has increased since Enlist products were approved, particularly for postemergence cotton and soybean crops. EPA also predicts that its registrations will increase the amount and number of acres applied with 2,4-D. However, EPA does not specify the amount of Enlist products applied to crops since its registration. Nor does EPA specify how much usage has increased since Enlist was approved.

1. Cotton

170. EPA underestimated Enlist usage and acreage in cotton production by failing to consider annual use data for Enlist One and Enlist Duo. In its benefits assessment, EPA acknowledged that use of all 2,4-D products on cotton crops increased dramatically between 2015 and 2019 but failed to specify how use of Enlist products increased since 2017, when EPA first registered Enlist products for use on cotton. *See* Use Memo at 5.[76] EPA also acknowledged that the average percent of all cotton acres sprayed with 2,4-D

[75] Enlist Duo Product Label (Mar. 29, 2022); Enlist One Product Label (Mar. 29, 2022).
[76] *See also* Use Memo at 5 ("From 2015–2019, an average of 2.8 million total acres of cotton were treated annually with 2,4-D products, including Enlist and non-Enlist products. However, usage of 2,4-D increased over this period, tripling in total cotton acres treated from 2015 to 2019 (Kynetec, 2020), therefore this average may not reflect current and future usage of all 2,4-D products in cotton.").

increased between 2015 and 2019 but failed to provide any data on the number of cotton acres sprayed with Enlist products since 2017. *Id.* EPA had access to this data during the registration process yet refused to use it.

171. EPA does not provide data on the number of cotton acres applied with Enlist products in 2020 or 2021. Instead, EPA relies on the annual average acres sprayed with 2,4-D (including Enlist products and non-Enlist products) from 2015 to 2019, even though Enlist Duo was not commercialized until 2017. Although EPA acknowledges that the number of cotton acres sprayed with 2,4-D tripled during this period, it does not specify how many acres were sprayed with Enlist products. By relying on 2,4-D use data from 2015 to 2019, EPA underestimated the amount of Enlist products applied to cotton crops.

172. EPA states that "on average[,] in 2018 and 2019, about 2% of national annual cotton acreage was treated annually with Enlist Duo," and "about 7% of annual cotton acres were treated with Enlist One." Use Memo at 5. However, "[t]he first usage of Enlist Duo in cotton was observed in 2017, and the first usage of Enlist One was observed in cotton in 2018." *Id.* Based on available data, Enlist products were sprayed on roughly 500,000 acres of cotton crops in 2017, and 1.5 million acres of cotton crops in 2018, which is approximately 4% of cotton acres planted in 2017, and 11% of cotton acres planted in 2018, respectively. The percent of acres sprayed with Enlist products has increased over time due to increased adoption. Accordingly, EPA's averages underestimate the increasing percent of cotton acres sprayed with Enlist products.

173. According to EPA, "available market research data from 2018 and 2019 is a reasonable estimate of the amount of Enlist products currently applied." *Id.* However, EPA failed to provide any use or acreage data from 2018 and 2019 in its assessment, making it impossible to estimate the amount of Enlist products applied.[77] EPA also failed to justify

[77] *See id.* ("On average in 2018 and 2019, about 2% of national annual cotton acreage was treated annually with Enlist Duo," and "about 7% of annual cotton acres were treated with Enlist One.") However, EPA does not provide data on the total number of cotton acres for each year, making it impossible to accurately evaluate this data.

relying on data from 2018 and 2019 as a proxy for current use when data for 2020 and 2021 was available. Thus, EPA's decision lacks substantial evidence.

2. Soybean

174. EPA underestimated the amount of Enlist products applied to soybeans. EPA does not provide any data on Enlist use on soybean acreage for 2020 or 2021. Instead, EPA relies on the annual average acres sprayed with 2,4-D (including Enlist products and non-Enlist products) from 2015 to 2019, even though "adoption of Enlist products began very late in this period," and the number of acres applied has increased substantially in recent years. Use Memo at 6. By relying on use data from 2018 and 2019, before widespread adoption of Enlist products for use on Enlist-resistant soybeans, EPA underestimated the amount of Enlist products applied to soybean crops.

175. EPA improperly relied on market research provided by Corteva from 2018 and 2019 to "estimate of the amount of Enlist products currently applied to soybean crops." Use Memo at 5. Although EPA acknowledged that rates have increased dramatically since 2019,[78] EPA did not consider the amount of Enlist applied to soybeans in 2020 and 2021, even though EPA had access to this data when it made its decisions in January and March 2022. Nor did EPA estimate the amount of Enlist that will be applied in 2022 based on the number of Enlist-resistant soybean seeds sold or planted in 2022.

B. Future Use & Acreage

176. Although EPA acknowledges that the amount of 2,4-D applied has increased in recent years–and will continue to increase because of the challenged decisions, EPA does not attempt to estimate the amount of Enlist products that will be applied in future

[78] *See* Use Memo at 7 ("BEAD expects that available market research data from 2018 and 2019 does not reflect the amount of Enlist products currently applied to soybean; further adoption of the technology may continue in the future. For information on trends of Enlist-tolerant soybean seed sales and sales of Enlist herbicide from 2019 to 2020, see the Confidential Appendix #2."); *see also id.* at 6 ("Future use of 2,4-D may be very different from past usage.").

seasons. At the time of its decision, EPA could have estimated future use based on the amount of Enlist applied in 2020 and 2021 or the amount of Enlist-resistant crops sold or planted in 2022. EPA's failure to estimate current or future use is concerning because increased use of Enlist threatens to increase the risks to the environment, including listed species and their habitats. By failing to estimate future increases in Enlist use, EPA underestimated the potential costs of its decisions.

C. Herbicide Resistance

177. EPA generally acknowledged that "use of Enlist herbicides contributes to the development of 2,4-D resistance by increasing the exposure of weeds to 2,4-D and increasing the chances of selecting for resistant biotypes within a weed population." Incidents Memo at 19. EPA also acknowledged that "use of Enlist herbicides can contribute to the development of weed resistance to other synthetic auxin type herbicides (WSSA Group 4) like dicamba, through cross-resistance." *Id.* However, EPA fails to fully consider how its decision will contribute to future 2,4-D resistance, cross-resistance, and the associated costs.

1. Future Resistance

178. EPA acknowledged that extending the registrations for Enlist One and Enlist Duo "would substantially increase the amount of 2,4-D applied and the number of acres sprayed with 2,4-D after crop emergence." Incidents Memo at 9. EPA further acknowledged that "[i]ncreased use of Enlist 2,4-D, especially after crop emergence, will increase selection pressure on 2,4-D and other synthetic auxin herbicides (WSSA Group 4)," *Id.* at 9, which would "promote resistance to 2,4-D, as well as cross resistance to dicamba and other synthetic auxin (WSSA Group 4) herbicides," such as dicamba and florpyrauxifen. *Id.* at 9. However, EPA does not quantify or consider how the increased use of Enlist will increase the spread of 2,4-D resistance. EPA's failure to estimate the risk of future resistance undermines its cost-benefit analysis because increased resistance threatens to increase weed control costs for farmers, 2,4-D spray drift damage, and other

risks. By failing to estimate future increases in 2,4-D resistance and cross-resistance, EPA underestimated the potential costs of its decision.

2. Current Resistance

179. EPA acknowledged that "any resistance to 2,4-D, whether associated with the Enlist herbicides or not, will potentially lower the benefits of the Enlist herbicides." Use Memo at 12. However, EPA failed to acknowledge any of the reports of 2,4-D resistance that have emerged after widespread use of Enlist herbicides, including reports linked to Enlist products.[79] By failing to fully consider confirmed cases of 2,4-D resistance, EPA underestimated the costs associated with increased resistance.

180. EPA makes no effort to determine whether Enlist One or Enlist Duo have been "specifically associated with reports of herbicide-resistant weeds" since the commercialization of Enlist-resistant crops in 2017 and 2019. Instead, EPA relies solely on the "annual reports from Corteva," which indicate Enlist has not been directly linked to reports of herbicide-resistant weeds. EPA entirely ignored reports from state extension scientists linking Enlist One to weed resistance in Tennessee as early as 2021.[80] Moreover, the actual number of escaped weeds is likely higher than reported because farmers are not likely to spot weeds unless they regularly walk their fields after applying Enlist One.[81] In addition, EPA ignored evidence that the standard rates (32 oz per acre) of Enlist One "provided no better Palmer control than the 0.5 lb rate of dicamba (40 to 50%)." *Id.* Moreover, like dicamba, Palmer amaranth escaped higher rates of Enlist One (128 ozs per

[79] Use Memo at 12 ("BEAD agrees that the instances of 2,4-D resistance currently confirmed in the U.S. are not associated with the Enlist system, as all confirmed reports of 2,4-D resistance occurred before widespread use of Enlist herbicides (Heap, 2021).").
[80] *See* L. Steckel & D. Foster, *Dicamba & 2,4-D: No longer "Palmer amaranth Herbicides" in Some Fields*, UNIV. OF TENN. EXTENSION (Jul. 7, 2021), https://news.utcrops.com/2021/07/dicamba-and-24-d-no-longer-palmer-amaranth-herbicides-in-some-fields ("We have gotten a couple reports on Palmer amaranth escaping Enlist One.").
[81] *Id.*

acre). *Id.* (concluding that "dicamba and Enlist One can no longer be thought of as 'Palmer amaranth herbicides'").

181. Despite new evidence demonstrating that use of Enlist products increase 2,4-D resistance, EPA continues to understate the risks associated with 2,4-D resistance. Although EPA acknowledges some instances of 2,4-D resistant weeds, EPA entirely ignores recent instances linked to use of Enlist products. As noted above, there are several confirmed cases of 2,4-D resistant weeds in areas approved for use of Enlist One and Enlist Duo, and state extension agencies have already received reports of weeds with resistance to Enlist products. The increased use of Enlist products on these weeds threatens to increase the spread of 2,4-D resistant weeds, reducing the effectiveness of these products, increasing costs for farmers, and increasing risks for nearby plants and animals. EPA also fails to fully consider how its decisions will increase 2,4-D resistance. Because most farmers rely solely on Enlist to control weeds, the increased use of Enlist products increases the spread of naturally resistant weeds, which increases the potential risks and costs.

182. EPA acknowledges that 2,4-D resistance harms "not only the user of Enlist 2,4-D, but also other users of synthetic auxin herbicides which are less effective due to resistance." Incidents Memo at 19. EPA also acknowledges that 2,4-D resistance can "reduce its efficacy for weed control in other crops as well." *Id.* However, EPA does not fully consider or evaluate the costs of increased resistance, such as increased weed control costs, increased amounts of 2,4-D applied to crops to compensate for decreased efficacy, increased environmental risks, and increased risks to listed species and their habitats. By failing to specify all the costs associated with increased resistance, EPA underestimated the potential costs of its decision.

3. Cross-Resistance

183. EPA acknowledged that the "[i]ncreased use of Enlist 2,4-D, especially after crop emergence," would "promote . . . cross resistance to dicamba and other synthetic

auxin (WSSA Group 4) herbicides." Incidents Memo at 9. However, EPA did not quantify or consider how the increased use of Enlist will increase cross-resistance to dicamba and other herbicides. By failing to consider how its decision increases resistance to dicamba and other herbicides, EPA failed to fully consider the potential costs and risks of its decision.

184. EPA acknowledged that decreased sensitivity to dicamba has contributed to 2,4-D resistance in two states: Tennessee, and Arkansas. *Id*. However, EPA understated the risk of future resistance by failing to investigate the link between 2,4-D resistance and dicamba resistance. EPA also understated the potential risks by failing to acknowledge several reported cases of dicamba resistance. Although there are multiple reported cases of dicamba resistance, EPA only acknowledged "decreased Palmer amaranth sensitivity to dicamba in at least five states." *Id*. EPA entirely ignored reports of dicamba resistance in several other states, including states approved for use of Enlist. *Id*. By failing to consider the risk of cross-resistance, EPA overestimated the effectiveness of Enlist products, and underestimated the costs associated with increased resistance.

185. EPA failed to consider how the use of Enlist Duo, which contains both 2,4-D and glyphosate, increases the spread of glyphosate resistance. EPA acknowledged that most soybean and cotton users rely exclusively on Enlist Duo to control glyphosate-resistant weeds, typically Amaranthus species. However, EPA did not assess how the exclusive and widespread use of Enlist Duo on weeds with resistance to glyphosate will increase the spread of resistance and decrease the effectiveness of 2,4-D and other modes of action. By failing to consider how its decision increases resistance to glyphosate, EPA failed to fully consider the potential costs and risks of its decision.

D. Benefits Assessment

186. In its previous benefits assessments, EPA found that Enlist Duo provides an additional mode of action to control broadleaf weeds during the growing season (after emergence), and an important tool for controlling broadleaf weeds resistant to commonly

used herbicides, particularly glyphosate.[82] Recent data confirms that EPA drastically exaggerated both benefits.

187. In the challenged registration decisions, EPA claimed that the "major benefits of the Enlist products remain largely similar to those identified in previous EPA assessments of Enlist." Decision Memo. Specifically, EPA noted that "the 2,4-D component of Enlist products is one of the extremely limited herbicide chemistries and herbicide modes-of-action available for postemergence control of problematic, multiple-herbicide-resistance broadleaf weeds in cotton and soybean." *Id*. There are several major issues with this conclusion.

1. Enlist products increase future resistance.

188. EPA dramatically overstates the effectiveness of Enlist products against multiple-herbicide-resistant weeds because EPA failed to fully consider how its decision accelerates 2,4-D resistance. *See supra*. Moreover, because EPA failed to mitigate the risk of future resistance in the revised labels, EPA's decision threatens to increase the spread of resistance, decreasing the effectiveness of 2,4-D, dicamba, and other herbicides against multiple-herbicide resistant weeds. In addition, EPA entirely failed to consider how the increased use of Enlist Duo, which contains 2,4-D and glyphosate, will increase glyphosate resistance. Thus, because EPA failed to properly consider the risks associated with resistance, EPA improperly determined that the benefits of Enlist products will increase "[a]s herbicide-resistance to herbicides such as glyphosate and glufosinate become a more common problem." Use Memo at 10.

2. Enlist products are ineffective against resistant weeds.

189. EPA overstates the benefits of Enlist products as an effective tool for postemergence control of problematic herbicide-resistant broadleaf weeds, like Palmer amaranth in soybean and cotton. In its decision, EPA claimed that use of the "Enlist weed

[82] *See* Phillips et al. (2014) (soybean and corn); Hawkins et al. (2016) (cotton).

control system, coupled with best management practices for herbicide resistance management can significantly help limit the further development of weed resistance." Decision Memo at 23–24. However, the record shows that farmers typically use the 2,4-D component of Enlist products as their only mode of action against glyphosate-resistant weeds, which increases the risk of escapes and accelerates the spread of 2,4-D resistance. Thus, EPA's benefits assessment contradicts evidence in the record showing that use of Enlist weeds will increase further development of weed resistance.

a. Users do not use Enlist products with glufosinate.

190. In its Decision Memo, EPA broadly concluded that "Enlist One (which only contains the 2,4-D choline salt) provides control of problematic multiple herbicide-resistant broadleaf weeds, and "also greater flexibility for users as it can be tank-mixed with other herbicides, especially glufosinate, which is not an approved tank mix partner for Enlist Duo." Decision Memo. However, EPA failed to weigh these benefits against new evidence showing that growers rarely apply Enlist One with other herbicides, potentially increasing the spread of herbicide-resistant weeds. Thus, EPA's benefits assessment contradicts evidence in the record showing that use of Enlist will increase spread of problematic multiple herbicide-resistant broadleaf weeds and make it more difficult for users to control these weeds.

191. In the benefit assessment, EPA cited reports from state extension agencies "suggest[ing] that the combination of Enlist One and glufosinate is the best option for control of multiple-herbicide resistant Palmer amaranth." Use Memo at 10. However, actual use data shows that Enlist One is rarely applied with glufosinate. *See Id.* at 10, 12. Although Enlist-resistant seeds are resistant to multiple modes of action, "growers are not actually applying herbicides containing those modes of action to their fields, as evidenced by the vast majority of growers in both soybean and cotton relying solely on 2,4-D for control of problematic Amaranthus species." *Id.* at 12. Thus, because actual use data

demonstrates that farmers do not use Enlist One will other effective modes of action to control glyphosate-resistant weeds, EPA's conclusion lacks substantial evidence.

192. Moreover, state extension agencies have reported that Enlist products are not effective against Palmer amaranth, and the repeated use of Enlist products threatens to accelerate the spread of resistant Palmer amaranth weeds. Despite citing other reports from these same agencies, EPA left conflicting reports out of its benefits assessment because they directly contradict EPA's main rationale for approving Enlist One and Enlist Duo. Thus, because EPA failed to consider recent user surveys and confirmed cases of weed resistance, EPA's conclusion lacks substantial evidence.

b. Users do not use Enlist products on non-glyphosate-resistant weeds.

193. EPA also claimed that Enlist Duo provides as an effective tool for postemergence control of problematic herbicide-resistant weeds because the "glyphosate component of Enlist Duo provides control of non-glyphosate resistant broadleaf and grass weeds." Use Memo at 10. As EPA explained in its decision memo, "[i]n cases where glyphosate-resistant weeds are not present, Enlist Duo will provide two effective modes of action for weed control as it contains 2,4-D choline salt and glyphosate." Decision Memo. However, actual use data demonstrates that most farmers used Enlist Duo on glyphosate-resistant weeds,[83] which means use of Enlist Duo threatens to accelerate the spread of glyphosate resistance. Actual use data also confirms that most farmers apply Enlist Duo alone, which means the increased use of Enlist Duo threatens to decrease the effectiveness of 2,4-D, dicamba, and other herbicides against glyphosate-resistant weeds. Thus, because EPA failed to consider actual use data in assessing the risks and benefits of Enlist Duo, EPA's conclusion lacks substantial evidence.

[83] In 2018 and 2019, most operators reported using Enlist products on soybeans and cotton to control glyphosate-resistant weeds, including 86% of sampled cotton growers who use Enlist Duo using it for glyphosate-resistance management. Use Memo (citing (Kynetec, 2020)).

194. EPA asserted that "Enlist One is also commonly tank mixed with glyphosate, allowing greater flexibility in glyphosate rates being applied as compared to Enlist Duo." However, EPA did not compare the amount of glyphosate used in Enlist One tank-mixes with the amount of glyphosate used in Enlist Duo applications. Thus, EPA's conclusion regarding the benefits of Enlist One lacks substantial evidence.

c. Users do not use Enlist products on glufosinate-resistant weeds.

195. EPA broadly claims that "in some cases," "use of 2,4-D choline salt . . . provides the only effective postemergence herbicide option to manage [problematic multiple-herbicide resistant weeds." Decision Memo. However, EPA does not attempt to specify or quantify the situations in which 2,4-D is the only effective option for postemergence control. Nor does EPA evaluate or quantify all the reported instances of 2,4-D resistance, i.e., the situations in which 2,4-D is not an effective option for postemergence control. Further, as discussed above, EPA does not fully consider how dicamba resistance confers resistance to 2,4-D. Recent evidence reveals that glufosinate-resistant weeds are less common than 2,4-D resistant weeds or glyphosate-resistant weeds,[84] meaning that EPA has overstated the benefits of Enlist products for use of glufosinate-resistant weeds. Without accurate data on current resistance to 2,4-D, dicamba, and glufosinate, EPA's conclusion lacks substantial evidence.

196. EPA cannot bootstrap Enlist products as a "benefit" by skewing the evidence to portray Enlist products as a lesser evil than dicamba when the adverse effects of dicamba are a direct consequence of EPA's own failure to regulate dicamba products. EPA itself is responsible for approving dicamba and ensuring that dicamba-based products do not cause unreasonable adverse risks to the environment. Thus, EPA cannot rely on dicamba to justify the registration of Enlist products, especially when the record

[84] According to the International Herbicide-Resistant Weed Database (last accessed on April 14, 2023), there are 5 species with resistance to glufosinate, 177 species with resistance to glyphosate, and 9 species with resistance to 2,4-D in the United States.

demonstrates that Enlist products pose the same—and in some cases, greater—risks than dicamba when controlling for delays in commercialization. Accordingly, EPA's conclusion lacks substantial evidence.

197. EPA overstates the benefits of Enlist products by ignoring other effective weed control options. According to EPA, "the 2,4-D component of Enlist products is one of only three effective non-glyphosate herbicides for postemergence control of problematic, multiple-herbicide-resistant broadleaf weeds in cotton and soybean." Use Memo at 10. However, EPA neglected to mention numerous other effective methods of controlling weeds in cotton and soybean.[85]

198. For corn crops, EPA expressly acknowledged that "the benefits of Enlist 2,4-D products are lower in field corn than in soybean and cotton" because there are numerous alternatives to Enlist products for postemergence control of weeds, including other 2,4-D products. Use Memo at 7. U.S. "[c]orn producers also have more herbicide options for control of problematic broadleaf weeds, including atrazine (WSSA Group 5) and HPPD inhibitor herbicides (WSSA Group 27)." *Id.* at 7–8. However, EPA failed to evaluate any of the other herbicides approved for postemergence control of weeds in corn, despite evidence that these products are more effective than 2,4-D for glyphosate-resistant weeds.[86] Without evaluating all available alternatives for pre- and post-

[85] *See, e.g.*, E. Barnes et al., *Control of Glyphosate-Resistant Common Ragweed (Ambrosia artemisiifolia L.) in Glufosinate-Resistant Soybean [Glycine max (L.) Merr]*, 8 FRONT. PLANT SCI. 1455 (2017) ("[A] number of herbicide options such as saflufenacil plus imazethapyr plus dimethenamid-P, suflentrazone plus cloransulam-methyl, paraquat, . . . and flumioxazin plus chlorimuron-ethyl are available for common ragweed control.").

[86] N. Soltani et al. *Glyphosate-Resistant Common Ragweed Control in Corn with Postemergence Herbicides*, 9 AGRIC. SCI. 670 (2018) ("dicamba, bromoxynil + atrazine, topramezone + atrazine and glufosinate applied [postemergence] are the most efficacious herbicides . . . for the control of [glyphosate resistant] common ragweed in [glyphosate resistant] corn"). Unlike bromoxynil + atrazine, dicamba, glufosinate and topramezone + atrazine, which reduced weed density by 97% to 87% when applied to post emergence to glyphosate-resistant corn, glyphosate and 2,4-D ester "applied [post emergence] did not cause any signification reduction in density of [glyphosate-resistant] common ragweed."

emergence control of glyphosate-resistant weeds, EPA cannot conclude Enlist products are more effective than alternatives. Thus, EPA's conclusion regarding the benefits of Enlist products in corn is not supported by substantial evidence.

199. In addition to ignoring effective alternatives for post-emergence control of glyphosate-resistant weeds, EPA improperly concluded that the benefits of Enlist products outweigh a subset of available alternatives—non-Enlist 2,4-D products—"in terms of increased crop safety and a longer postemergence application window." *Id*. According to EPA, one of the benefits of Enlist products is that it "can be applied to Enlist corn later in the growing season compared to non-Enlist 2,4-D products, which can allow postemergence control of later emerging weeds to deal with weed escapes." Use Memo at 7. However, Enlist products threaten to increase the risk to nearby crops with sensitivity to 2,4-D by increasing the number of postemergence applications. Despite this increased risk, EPA concludes that Enlist products are favorable to other 2,4-D products because "non-Enlist 2,4-D herbicides can, under certain conditions, injure non-2,4-D tolerant corn." *Id*. This rationale is flawed because the risk of spray drift damage to nearby crops also applies to Enlist products. Without comparing the risk of spray drift damage from Enlist applications and the alternatives, EPA cannot conclude Enlist products are less harmful to nearby crops. Thus, EPA's conclusion regarding the benefits of Enlist products in corn is not supported by substantial evidence.

200. EPA falsely asserts that Enlist has the potential to reduce the amount of "acres of soybean and cotton sprayed with over-the-top dicamba applications," and in turn, "off-target movement that have been associated with over-the-top dicamba uses in soybean and cotton." EPA's conclusion regarding dicamba is unsupported because EPA improperly assumes that growers who do not currently use dicamba will switch to dicamba if EPA does not approve Enlist.

201. The record fails to adequately show that dicamba and 2,4-D are the only two synthetic auxin herbicides for postemergence weed control in soybean and cotton. EPA

identified "far more herbicides that can control Palmer amaranth" in its 2018 dicamba benefits assessment.[87] EPA also assessed postemergence herbicide options in its 2020 benefits assessments of dicamba.[88] Thus, because growers can use pesticides other than dicamba to control postemergence weeds in soybean and cotton, EPA lacks support for its conclusion that growers will switch to dicamba in the absence of Enlist. *See Nanosilver II*, 857 F.3d at 1039 (finding that EPA improperly assumed that "current users of conventional-silver pesticides will replace those pesticides with [the approved chemical]").

202. The record also fails to show that farmers will only substitute Enlist products for existing dicamba weed control systems. If Enlist products replace systems with less off-target movement than 2,4-D or dicamba, EPA's decision would result in more overall drift and volatility risks. Because EPA entirely ignores the risk of Enlist products replacing weed control systems with *fewer* adverse effects than 2,4-D, EPA's decision lacks substantial evidence.

E. Ecological Risk Assessment

203. EPA confirmed that both 2,4-D and glyphosate have several ecological risks to plants and animals on sprayed fields, as well as nearby areas and waterbodies.

1. 2,4-D Ecological Risks

204. On-Field Direct Impacts: In its 2,4-D ecological assessment for non-listed species, EPA found "potential on-field (on the site of application) risks to terrestrial vertebrates (mammals, birds, amphibians, and reptiles), terrestrial invertebrates (including bees and monarch butterflies), and terrestrial plants." Ecological Risk at 8. EPA also identified "potential on-field effects to terrestrial animals that utilize corn, soybean[,]

[87] *See* 2018 Benefits Memo for Xtendimax (EPA-HQ-OPP-2016-0187-0966) at 14 (identifying 36 soybean herbicides, 14 of them post-emergence, and 30 cotton herbicides, 9 of them post-emergence).
[88] *See* EPA-HQ-OPP-2020-0492-0004 at 16-21 (soybeans); EPA-HQ-OPP-2020-0492-0005 at 14-19 (cotton).

and/or cotton fields as well as several listed plant species that are assumed to be on these types of fields." *Id.* at 9.

205. Off-Field Direct Impacts: For species in surrounding areas, EPA identified "potential effects to terrestrial and wetland plants that are exposed to runoff and listed animal species that depend upon plants in terrestrial and wetland areas receiving runoff from Enlist sprayed corn, cotton[,] or soybean fields." *Id.* In addition, EPA found "potential indirect effects to animals, primarily from the runoff exposure to plants," resulting from harm to plants that "play an important role in terms of shelter, food, and habitat for animals." *Id.*

206. Even with the 30-foot spray drift buffer intended to reduce off-field risk from spray drift (for non-target animals and plants), "there are still potential runoff risks for terrestrial and wetland plants." *Id.* "Monitoring data reinforce the risk conclusions for plants from runoff, as the data support this route of exposure for aquatic and emergent plants." *Id.*

207. EPA confirmed "there is a large amount of monitoring data available for 2,4-D with a high detection frequency (33%)," suggesting that "2,4-D is likely to runoff application sites and end up in a wide range of aquatic habitats." *Id.* at 39. This "data confirm[s] that concentrations of 2,4-D are expected to occur and exceed the wetland plant reference concentration frequently and across the landscape." *Id.*

208. EPA also determined that "2,4-D concentrations are likely to exceed the wetland plant reference concentration," which "occur in areas where Enlist products could be used (i.e., corn, soybean, and cotton growing regions)." *Id.*; *see also id.* at 76 (data "support the conclusions of risk to wetland species because they are detections downstream from wetland environments," and "confirm exposure and exceed the EECs that trigger wetland plant risk"). EPA's analysis revealed that "there is high confidence that 2,4-D concentrations are above the wetland reference concentration for a wide-range

aquatic system, and it is possible that these systems could be impacted by or could impact wetland areas." *Id*.

209. Indirect Impacts: "Furthermore, because plants play an important role in terms of shelter, food, and habitat for animals, there are potential indirect effects to animals, primarily from the runoff exposure to plants." *Id*. at 8. "For monarch butterflies, in addition to direct risks on-field, there are potential indirect adverse effects from 2,4-D effects to on-field and off-field milkweeds." *Id*. However, EPA does not specify or evaluate several other indirect effects relating to 2,4-D direct applications, spray drift, runoff, or any other potential routes of exposure.

2. Glyphosate Ecological Risks

210. On-Field Direct Impacts: In EPA's glyphosate ecological assessment for non-listed species, EPA also found "potential on-field (on the site of application) risks to birds, reptiles, and terrestrial phase amphibians, and terrestrial plants." *Id*. at 14.

211. Off-Field Direct Impacts: Even with the 30-foot spray drift buffer intended to reduce off-field risks for non-target animals, EPA determined that "there is still potential risk to terrestrial and wetland plants from runoff." *Id*. "Monitoring data reinforce the risk conclusions for plants from runoff, as the data support this route of exposure for aquatic and emergent plants." *Id*.

212. "[W]hen glyphosate containing products are applied, glyphosate often reaches aquatic systems," and "the detection frequency is slightly (9%) higher for years when Enlist Duo was registered." *Id*. at 105. This "suggest[s] that glyphosate is likely to occur in surface water, but concentrations are likely to be above the reference concentration for wetland plants." *Id*.

213. Indirect Impacts: "Furthermore, because plants play an important role in terms of shelter, food, and habitat for animals, there are potential indirect effects to animals, primarily from the runoff exposure to plants." *Id*. at 15. "For monarch butterflies, there are potential indirect adverse effects from glyphosate effects to on-field and off-field

milkweed." *Id*. However, EPA does not specify or evaluate several other indirect effects relating to direct applications, spray drift, runoff, or other routes of exposure.

3. EPA improperly excluded direct and indirect risks.

214. EPA's analysis of the adverse, ecological risks lacks substantial evidence because EPA failed to specify and evaluate several direct and indirect effects to plants and animals in the surrounding area. Many species rely on the areas affected by use of Enlist productions for habitat, shelter, prey, food sources, pollination. The species found in affected areas often play an important role in the food chain, meaning any adverse impacts to these species has rippling, widespread impacts to the entire ecosystem. Because EPA failed to fully consider these ecological impacts in its assessment, EPA's decision lacks substantial evidence.

215. For example, monarch butterflies and milkweed are likely exposed to Enlist products through spray drift and runoff. However, despite this significant adverse risk, EPA failed to evaluate the potential risks to monarch butterflies and milkweed in off-field areas with spray drift and runoff from Enlist applications. Thus, because EPA's decision is likely to significantly increase the amount of Enlist applications, as well as the risk of spray drift and runoff, EPA's decision will substantially increase adverse risks to milkweed plants and monarch butterflies found in surrounding areas. Because EPA failed to consider these risks, EPA's decision lacks substantial evidence.

4. EPA improperly concluded risks were reasonable.

216. Despite finding numerous adverse risks to plants and animals, EPA improperly concluded that these risks were reasonable because "[t]he spray drift reduction measures included on the May 2021 labels reduce spray drift to the point that off-field risks from spray drift for non-target plants and animals are not expected." Decision Memo at 25. However, the 2021 labels imposed the same 30-foot spray drift buffer as the 2017, 2015, and 2014 labels. Recent incident data confirms that these

buffers have not been effective against spray drift from Enlist applications. Thus, EPA's continued reliance on 30-foot spray drift buffers lacks substantial evidence.

217. Moreover, EPA acknowledged that "the May 2021 label did not have adequate measures to address the potential off-field risk to terrestrial and wetland plants from runoff." *Id*. "To address needed reductions in exposure, EPA and Corteva agreed upon a set of mitigations that are implemented on the Enlist product labels (January 2022)." Mitigation Evaluation at 15. "Some of these mitigations are required for all uses and others are available as a pick-list from which the applicator and land manager/grower could identify/choose mitigation measures appropriate for their fields." *Id.* EPA confirmed that the mitigations required for all uses did not sufficiently reduce the adverse environmental risks from runoff exposure. *Id.* (noting that "additional runoff concentration reduction is still needed; i.e., concentrations still need to be reduced by about a factor of 6x for scenarios with higher exposures"). However, EPA lacks evidence to support its conclusion that its proposed solution—a credit-based pick list—will achieve the amount of reductions needed to reduce unreasonable adverse risks to plants and animals in the surrounding area.

F. Labeling Restrictions & Failure to Mitigate Adverse Risks

218. Based on EPA's flawed evaluation of its own mitigation measures, EPA unilaterally–and unlawfully–determined that county-level prohibitions and runoff measures in the final labels sufficiently avoid harm to plant and animal species from direct exposure to Enlist products on target fields or off-site transport via runoff and spray drift. EPA improperly relied on these measures to mitigate the unreasonable adverse risks to plants and animals in nearby areas, in violation of FIFRA.

1. Noncompliance with Enlist One Labels

219. Although previous labels prohibited users from tank mixing Enlist One with glyphosate-based products, users reported using tank-mixes of Enlist and glyphosate, in violation of the label restrictions. *See, e.g.*, Decision Memo at 13 ("EPA is aware that Enlist

One may be tank mixed with other products that may include glyphosate."). Despite evidence of noncompliance, EPA "determined that restricting the use of Enlist One to prohibit mixing with glyphosate products is not necessary during the pendency of consultation" because the "label includes runoff mitigation that includes a prohibition of applications within 48 hours of when rainfall is predicted or irrigation occurs, and to saturated soils." *Id.* at 33. "When tank mixing, users must follow the most restrictive directions for use from any of the mixed products. Therefore, for tank mixes that include Enlist One, this mitigation would provide corresponding exposure reduction for all products included in the tank mix (e.g., including products containing glyphosate)." *Id.* However, EPA failed to evaluate how the added restrictions compare to the glyphosate restrictions. If they are less restrictive, the added restrictions are pointless. EPA also ignored whether users comply with glyphosate restrictions.

220. EPA further claims that the mitigation measures for runoff "will likely serve to reduce pesticide exposures in off-field terrestrial and wetland habitats, including Enlist One applications that involve tank mixing with glyphosate products. Therefore, these restrictions, in turn, would reduce the runoff exposures from glyphosate in contrast to exposure from glyphosate used separately were Enlist One not available." *Id.* EPA's reliance on runoff measures is unsupported by the available data. As noted above, the pick list credit system threatens to increase use of Enlist products, resulting in more runoff and other adverse effects in nearby habitats. EPA also entirely ignores the risk of noncompliance, despite acknowledging that users fail to comply with existing prohibitions on tank mixes.

221. "In the transition time between the extension of the Enlist One registration and the implementation of necessary mitigations on all glyphosate products resulting from consultation on the active ingredient glyphosate, runoff mitigations on Enlist One should provide some protection for listed species adjacent to fields where Enlist One is applied (because on-field and off-field mitigation practices serve to reduce runoff

concentrations of other pesticides applied to the same fields)." *Id.* at 33. However, EPA fails to fully quantify or evaluate these protections. Nor does EPA consider how its decision may affect future mitigation. Thus, EPA's decision to extend the registration of Enlist One for seven years, without sufficient mitigations in place to reduce runoff and compliance with existing label requirements, threatens to increase adverse risks.

222. EPA also refused to prohibit use of Enlist One in areas with species with sensitivity to glyphosate, despite evidence that users apply Enlist One with glyphosate-based products. "If EPA took a similar approach as it did for Enlist Duo to avoid exposure to on-field animals additionally exposed to glyphosate in tank mixes by off-labeling of specific counties that include the ranges of those animal species, it would prohibit tank mixes of Enlist One with glyphosate in the 39 counties. EPA has not done so because EPA expects that growers would forego the use of Enlist One and instead use glyphosate alone or with other companion herbicides for resistance management." *Id.* at 34. EPA's rationale contradicts the available data, which shows that users apply Enlist One with glyphosate-based products, not instead of these products.

223. "Since glyphosate labels do not currently include mitigations to avoid exposure to these listed animals nor do they contain mitigations to address potential run-off to the same extent, restricting the Enlist One product would potentially lead to increased likelihood of jeopardy and adverse modification where other glyphosate end use products are used in lieu of Enlist One." *Id.* However, EPA's rationale contradicts the available data, which shows that users apply Enlist One to control glyphosate-resistant weeds. Thus, EPA's concerns about users switching to glyphosate-based products to fight glyphosate-resistant weeds is unsupported by the evidence.

224. "EPA also acknowledges that through the consultation process, FWS could determine additional restrictions are necessary to further protect listed species and designated critical habitats." *Id.* However, EPA's decision forecloses the adoption of

future restrictions and alternative weed control methods because EPA refused to consult with FWS before issuing the registrations.

225. EPA also failed to consider mitigation to protect species survival and habitat recovery. This is because action agencies like EPA are not experts on the conservation of endangered species. Under ESA's implementing regulations, EPA's decision "jeopardizes" a species if it appreciably reduces "the likelihood of both the survival and recovery of a listed species . . . by reducing the reproduction, numbers, or distribution of that species." 50 C.F.R. § 402.02. As EPA acknowledged in its recent ESA Workplan for FIFRA actions, "EPA has historically focused on individual-level effects in determining whether a pesticide 'may affect' and is 'likely to adversely affect' individuals of a listed species or critical habitat." ESA-FIFRA Workplan (2022). "This determination, however, generally does not consider mitigation to protect survival and recovery for the entire species, which occurs only during formal consultation to evaluate jeopardy and adverse modification." *Id*. Thus, because EPA cannot properly evaluate whether its registration decisions will jeopardize a species without knowing the survival and recovery needs (i.e., "tipping points") of the species, EPA's registrations jeopardize listed species and habitats.

226. EPA also ignored evidence that noncompliance will increase due to contradictory language and additional restrictions in the final approved labels. EPA also ignored evidence that users failed to comply with the previous labels. EPA again relied on labeling requirements to reach its conclusion that the registrations will not cause adverse effects on the environment, despite evidence that users are not complying with restrictions in the previous labels.

227. Even assuming full compliance with the final approved labels, EPA's mitigation measures do not prevent jeopardy or adverse modification.

228. Thus, because the final labels fail to mitigate the adverse risks to the environment, EPA improperly relied on mitigation measures to meet FIFRA standards.

2. County-Level Prohibitions

229. EPA claimed to implement mitigations to "avoid exposure to on-field animals through off-labeling of specific counties for which listed species' ranges may be impacted." Decision Memo at 34. However, EPA did not restrict use in numerous counties where EPA identified potential effects to listed species and habitats. Moreover, EPA dramatically reduced the number of counties with prohibitions in the amendments issued on March 29, 2022. Consequently, EPA failed to prevent use of Enlist products in several areas where there are likely effects on listed species and habitats.

3. 30-foot Spray Drift Buffer

230. The amended labels require users to maintain a 30-foot in-field buffer in the direction the wind is blowing from any area except (1) planted agricultural fields (except those crops listed in the "Susceptible Plants" section), and (2) agricultural fields prepared for planting. There are also exceptions for roads and buildings.

231. According to EPA, the "proposed 30-foot spray drift setback from sensitive vegetation is sufficient to prevent exposures that would result in exceedances of the most sensitive terrestrial plant endpoints, therefore, potential risks from spray drift are considered to be low." Ecological Risk Assessment at 71. However, this is not a new measure. All previous labels for Enlist One and Enlist Duo also required a 30-foot spray drift buffer.

232. Recent data confirms that the spray drift buffer has not been effective, as spray drift incidents have increased since EPA first approved Enlist products. Enlist products have already caused spray drift damage to hundreds of acres of cotton crops. In 2018 and 2019, EPA received 16 reports of 2,4-D-related drift incidents involving Enlist One or Enlist Duo. Impacts Memo at 8. All these incidents involved significant damage to cotton fields in Texas, Oklahoma, or Mississippi. *Id.* The route of exposure was listed as drift from an adjacent Enlist field (10 incidents); wind-related or herbicide drift (4 incidents); and unknown (2 reports). *Id.* at 8–9. The reported damage to cotton crops was

significant, ranging from 13 to 800 acres. *Id.*; *see also* Ecological Risk Assessment at 71. According to EPA, this "suggest[s] that volatility-based exposure may have played a role." Ecological Risk Assessment at 71.

233. Moreover, damage relating to Enlist applications was significantly underreported in previous years because Corteva did not launch the Enlist weed control system for soybean crops until mid-2019. As EPA acknowledged, the use of Enlist products–and the risks to the environment–will likely increase in the future. Further, 2,4-D resistance has increased since EPA first approved Enlist products, despite language in previous labels about the potential risks and recommended practices for slowing the spread of future resistance.

234. Thus, available data from the first couple years of usage confirms that spray drift, runoff, resistance, and other adverse risks have increased since registration, and these risks have likely increased over time due to increased adoption and usage of the Enlist weed control system. Accordingly, mitigation measures in the previous labels failed to reduce or prevent adverse risks in the early years of adoption. Since then, adoption and usage of Enlist products have increased, along with the risk of herbicide resistance, environmental degradation, and other cumulative risks (e.g., climate change). EPA's continued reliance on these measures is unfounded.

235. Despite evidence that the spray drift buffer has failed to mitigate damage to nearby crops and plants, EPA continues to rely on this buffer to mitigate spray drift effects. *See* Ecological Risk Assessment at 71. Consequently, EPA's continued reliance on the 30-foot spray drift buffer is not supported by substantial evidence.

4. Runoff Measures

236. EPA concluded that "there are potential risks to non-listed and potential effects to listed terrestrial plants within 100 ft of [Enlist-resistant crops] as a result of surface runoff (i.e., sheet-flow)." Ecological Risk Assessment at 71. "Beyond this distance

from the edge of the field, the surface runoff is expected to transition into concentrated flow resulting in transport to wetland, riparian and aquatic habitats downgradient." *Id.*

237. According to EPA, the revised Enlist product labels "include several mitigations that are intended to reduce the volume of runoff and/or concentrations of pesticides in runoff." Mitigation Evaluation at 31. This includes a prohibition on Enlist applications within 48 hours of rain. However, the previous labels also included a 24-hour rainfast period to reduce mass runoff. Thus, EPA's continued reliance on this restriction is not supported by substantial evidence.

238. EPA identified specific measures that operators may implement to reduce runoff potential and off-field impacts, including residue and tillage management, cover crop and contour farming/strip cropping. Rather than require users adopt these measures, EPA allows users to select measures from a list of options (referred to as a "pick list") for "credits" based on "based on the relative reductions of the different practices." Mitigation Evaluation at 15. For sand or sandy loam soils, EPA determined that 4 credits are "needed to reduce the runoff concentrations such that jeopardy and adverse modification are not likely." *Id.* For loam or clay soils, EPA determined that 6 credits are needed. "In addition, these credits are needed to minimize take." *Id.*

239. Because EPA subsequently removed the vast majority of county-level prohibitions in the final labels, as discussed above, EPA's mitigation evaluation relies heavily on the added runoff requirements. However, EPA's evaluation of the runoff credit-system failed to consider actual use data, which reveals that most operators who use Enlist products do not have to make any changes to their applications to meet the required number of credits. Moreover, many users may be able to *increase* their applications and continue to meet the required number of credits under the current runoff credit system. Thus, EPA improperly relies on runoff measures to mitigate runoff.

240. EPA's mitigation measures are not likely to minimize 2,4-D and glyphosate concentrations in surface waters or nearby areas because most users already satisfy the

credit system, without making any changes to their operations. For example, the pick list gives users 4 credits for "no till, strip-till, ridge-till and mulch-till" management. However, 59% of corn acres, 55% of cotton acres, and 69% of soybean acres are currently planted as no-till or minimum tillage. Thus, most corn, cotton, and soybean producers can already receive at least 4 credits under EPA's pick list without reducing potential runoff or off-field impacts.

241. EPA's pick list also includes ineffective measures. In September 2021, EPA's EFED reviewed the available studies evaluating the effectiveness of vegetative buffers in reducing 2,4-D runoff exposure and found that "most studies indicate a less than 97% reduction in 2,4-D concentrations in runoff."[89] Since "mitigations resulting in 97% reduction in runoff would be needed to result in No Effect (NE) determinations for all listed species," EFED concluded that "a 5-m vegetative buffer is [not] sufficient (as the sole mitigation) to achieve No Effect determinations for all listed species." *Id*. Rather than require operators to implement a 5-meter vegetative buffer *in addition to* other effective mitigation measures, EPA authorized operators to use a 3-foot grassed vegetative barrier as their *only* runoff mitigation measure, in direct contradiction to EFED's conclusion. EPA did not provide any evidence to explain its dramatic change in position. Thus, EPA's mitigation measures do not prevent runoff because they allow operators to use ineffective barriers to meet their label requirements.

242. Despite finding that runoff from *all* Enlist applications pose a risk to non-listed and listed plants, EPA concluded that reducing the number of applications "can have substantial reductions in the exposure in both terrestrial and wetland environment." Mitigation Evaluation at 22. In reaching this conclusion, EPA only considered the differences between one, two, and three applications, without any discussion of the

[89] K, Garber et al., EPA, Response to White Papers Submitted to Corteva Relevant to Runoff Exposure & Risks of 2,4-D to Listed Species In Wetland & Terrestrial Habitats That Receive Runoff From [Enlist-Resistant Crops] 3 (Sep. 16, 2021)

potential risks. While the average amount of risk for a single application is lower than two or three applications, EPA's own calculations revealed that a *single* application still exceeds the EECs. Thus, EPA's evaluation is inconsistent with its own analyses and guidelines.

243. Nor do the labeling restrictions reduce the maximum number of applications allowed. EPA gives credits to growers with 1 or 2 applications per year, regardless of whether they actually reduced their total number of applications. Since most operators only spray Enlist products once or twice a year, they can receive this credit without making any reductions to their total number of applications. And for operators that only spray Enlist products once a year, they can *increase* applications to twice a year and still receive this credit. These results contradict EPA's reasoning.

244. The previous registration for Enlist products allowed for one preemergence application and two postemergence applications for a maximum possible total of three Enlist applications per season. For soybean, market research data from the first year of commercialization indicates that 80% of soybean acres sprayed with Enlist One or Enlist Duo were sprayed postemergence. Use Memo at 6. Moreover, 89% of acres were only sprayed once. *Id.* Because only 11% of soybean acres are sprayed twice with Enlist products, "most soybean growers would be eligible for points with this option." Incidents Memo at 16.

245. Similarly, most farmers spray Enlist products on cotton crops after they have emerged from the soil. Market research from the first two years of commercialization indicates that 90% of cotton acres sprayed with Enlist One or Enlist Duo were postemergence. Use Memo at 5. Moreover, 65% of acres sprayed with Enlist Duo were only sprayed once. *Id.* About 75% of cotton acres treated with Enlist One were sprayed twice per year (usually after crop emergence). *Id.* Thus, most cotton growers who spray Enlist Duo would be eligible for 4 points, and most cotton growers who spray Enlist One would be eligible for 2 points.

246. Moreover, even assuming some growers reduce the number of their applications, EPA fails to consider how its decisions will increase the total number of applications across all operations due to increased adoption and herbicide resistance. In addition, EPA has no basis for concluding this credit will sufficiently reduce exposure to runoff in terrestrial and wetland environments. "Based on the [risk quotients] calculated by [EPA] (which differ than those calculated by Corteva), mitigations resulting in 97% reduction in runoff would be needed to result in No Effect (NE) determinations for all listed species."[90] According to EPA's own analysis of terrestrial and wetland plant runoff exposure, "*all* [application and timing] scenarios result in exceedances of the vegetative vigor dicot non-listed and listed LOCs (RQ range 3.7-9.3 and 4.8-12.3, respectively)," including a single postemergence application.[91] This confirms that one application of Enlist products on Enlist-resistant crops is enough to harm plants in terrestrial and wetland environments.[92] EPA concluded that "2,4-D is likely to runoff application sites and end up in a wide range of aquatic habitats." Ecological Risk Assessment at 75. In addition, EPA found "risk to wetland species because the[re] are detections downstream from wetland environments,' which "confirm exposure and exceed the EECs that trigger wetland plant risk." *Id.* Because this credit only covers applications of 2,4-D, including Enlist products and non-Enlist products, it would not reduce the number of glyphosate applications among operators who use non-Enlist glyphosate products during the growing season.

247. In sum, EPA's credit system will result in more applications of harmful pesticides and other contradictory outcomes. This credit system will likely increase the overall number of applications and amount applied because growers can use Enlist with

[90] *Garber*, *supra* note 89, at 3.
[91] Table 2-27. Terrestrial Plant Exposure Zone: RQs for Most Sensitive Terrestrial Plant Taxa and Associated EeECs
[92] *Id.* at 75, 78 tbl. 2-28 (Wetland Plant Exposure Zone: Most Sensitive Terrestrial Wetland Plant Taxa and Associated EECs and RQs)

other pesticides. Even though an operator may end up applying more pesticides sequentially or tank mixed with Enlist, they can still get credits for applying Enlist once or twice.

248. Further, because EPA ignores application rate, there is no guarantee that a reduction in number of 2,4-D applications will result in a reduction in amount applied and runoff exposure. Instead of incentivizing growers to plan applications based on field conditions and other factors, EPA's measure encourages growers to increase the amount applied at one time to reduce the total number of applications.

249. Because EPA ignores the timing of applications and amount applied, the credit may increase the spread of resistance. EPA acknowledges elsewhere that increasing the amount of 2,4-D applied to post-emergence crops will increase selection pressure on 2,4-D and other synthetic alternatives such as dicamba.[97] However, EPA does not consider this risk when discussing measures for reducing pesticide loading. Moreover, EPA's mitigation measures may increase runoff and other adverse effects over the next seven years because EPA failed to consider evidence demonstrating that most users can *increase* the number of post-emergent Enlist applications and pounds of Enlist products applied and still satisfy the credit system.

5. Contradictory Labeling Language

250. The final approved labels include additional language without any substantive requirements. This language is entirely informational, but it may increase risks by introducing contradictory language and making labels more confusing and onerous on users.

251. For example, Corteva stresses the need for diversified management options in the final amended product labels.[93] The labels warn that "[w]here resistant biotypes exist, the repeated use of herbicides with the same modes of action can lead to the

[93] *See supra* notes 74 and 75.

selection for resistant weeds." *Id.* "Proactively implementing diversified weed control strategies to minimize selection for weed populations resistant to one or more herbicides is a best practice." *Id.* The labels also emphasize that the "continued availability of this product depends on the successful management of the weed resistance program." *Id.* Despite this language, however, the Enlist Duo label continues to encourage operators to forgo other herbicide control options in favor of Enlist products, contradicting all the language about how to slow the spread of resistance: "Hard to control weeds, such as Palmer amaranth, may require a total program approach including soil applied residual herbicide(s) followed by a single or sequential post herbicide application." *Id.* Although state extension scientists have raised concerns about the contradictory language in the product labels, EPA ignored the risks. As a result, this contradictory language threatens to accelerate the spread of resistance.

252. Additionally, EPA added revised environmental hazard language "to alert users of the products to the risks to pollinators and off-target plants due to runoff and to provide information on how to mitigate those risks." Decision Memo at 31. However, this language merely "inform[s] users of the potential hazards to the environment from use of the product and associated restrictions of use"; it does *not* actually impose any restrictions on the use of Enlist Duo or Enlist One. *Id.* Nor does EPA provide any explanation as to why the agency believes this added language will mitigate any potential effects of Enlist Duo or Enlist One.

253. Relatedly, some of the label requirements are contradictory or confusing, increasing the risk of noncompliance. For example, EPA's final labels contradict and undermine EPA's general efforts to improve compliance with the ESA in the pesticide registration program. As EPA explained, "EPA is not developing Endangered Species Protection Bulletins for the Enlist products because the county prohibitions are on the labels." *Id.* at 34. However, as EPA's subsequent amendments to the county-level prohibitions reveal, EPA may change the counties with use restrictions in the future, and

users need a consistent way to access the relevant information. EPA cannot rely on a database for some pesticides, but not Enlist products. As a result of EPA's inconsistent and confusing treatment for county-level prohibitions, users who properly check the Bulletin will falsely assume there are no county-level prohibitions for Enlist products, resulting in harm to listed species and critical habitats in the areas with use restrictions.

254. Moreover, this language will likely significantly delay implementation because it only requires users to obtain a Bulletin every 6 months, before the growing season has even started. In that time, EPA may have implemented necessary restrictions to prevent jeopardy and adverse modification. EPA's new and contradictory language thus gives users more leeway to ignore current label restrictions, increasing noncompliance and endangering plants and animals.

G. Duty to Consult

1. EPA improperly delayed formal consultation.

255. Section 7(a)(2) requires EPA to consult with the expert wildlife agencies whenever a proposed registration action "may affect" listed species or critical habitats. 16 U.S.C. § 1536(a)(2). EPA must "review its actions at the earliest possible time to determine whether [they] may affect listed species or critical habitat," and "[i]f such a determination is made, formal consultation is required." 50 C.F.R. § 402.14(a)

256. Based on EPA's previous registration decisions involving Enlist One and Enlist Duo, EPA should have known of the potential effects to listed species as soon as it received Corteva's application to extend its existing registrations back in April 2021.

257. In 2021, EPA reviewed the draft labels submitted by Corteva and again confirmed that the use of Enlist products "may affect" listed species and their designated critical habitats, triggering EPA's duty to consult with the expert wildlife agency, the U.S. Fish and Wildlife Service (FWS).

258. At each step of EPA's effects determination, EPA unlawfully constricted the scope of its analysis. EPA failed to properly evaluate the potential effects on listed species

and their habitats because EPA unlawfully constricted the scope of its analysis in each step of its effects determination, in violation of EPA's duty to use the best available science when reviewing the potential effects of its decision on listed species. *See* 40 C.F.R. §§ 402.40(b), § 402.46.

259. Although the registrations clearly surpassed the low "may affect" threshold for formal consultation, EPA unlawfully delayed initiating formal consultation until January 10, 2022, the day before issuing the final approved registrations. Due to EPA's significant delay in initiating formal consultation, EPA's decisions threaten to jeopardize listed species and adversely modify their designated habitats, in violation of the ESA and its regulations.

260. Corteva submitted final revised labels for both Enlist One and Enlist Duo on January 10, 2022. *Id.* On the same day, EPA initiated formal consultation with FWS "because [EPA] made [likely to adversely affect] determinations for certain listed species and designated critical habitats." Consultation Letter (Jan. 10, 2022). The next day, on January 11, 2022, EPA issued final approved registrations for Enlist One and Enlist Duo. Because ESA regulations require EPA to evaluate FWS's final biological opinion before making a decision, 50 C.F.R. § 402.15(a), EPA violated the ESA by issuing the registrations before completing formal consultation with the FWS and failing to ensure against jeopardy to listed species and against adverse modification of designated critical habitats. EPA's violations are ongoing as of the date of this filing because FWS has yet to issue its opinion.

2. EPA improperly relied on informal meetings.

261. EPA claims that it "informally consulted with FWS to get feedback on the approach used to assess adverse effects to listed species," as well as the "approach for proactively mitigating adverse effects." ESA Section 7 Consistency Determination for Enlist One at 3 (Jan. 11, 2022) & Enlist Duo at 3 (same). Unlike formal consultation, informal consultation is "an optional process that includes all discussions,

correspondence, etc., between the Service and [EPA]," "designed to assist [EPA] *in determining whether formal consultation . . . is required*." 50 C.F.R. § 402.13(a) (emphasis added). EPA did not consult with FWS to "determin[e] whether formal consultation . . . [was] required" because EPA had already completed its effects determination and determined that the registrations "may affect" and are "likely to adversely affect" several listed species by the time EPA met with FWS for the first time in September 2021. Thus, EPA's meetings do not constitute "informal consultation" under the ESA under 50 C.F.R. § 402.13(a).

262. Because EPA failed to properly coordinate with FWS during the decision-making process, EPA is responsible for any inefficiency in the formal consultation process. EPA had several opportunities to coordinate with FWS during the preparation of the effects analysis and other assessments. However, EPA failed to do so. EPA points to a handful of meetings with FWS as evidence of its efforts to coordinate with the agency before issuing the registrations. However, most of these meetings had nothing to do with Enlist products. In addition, all of these meetings occurred *after* EPA had already made its determination, triggering the agency's duty to initiate and complete formal consultation.

263. None of EPA's purported reasons for delaying consultation justify EPA's egregious delay and failure to comply with ESA's clear consultation procedures. Moreover, because EPA failed to consult with the expert wildlife agency about its effects determination before reaching a final decision on the registrations and amendments, EPA's registrations understated the risks to listed species and habitats and overstated the effectiveness of the mitigation measures.

264. Even though EPA does not have the expertise or resources to properly evaluate the likelihood of jeopardy to listed species and of adverse modification of critical habitats, EPA made and improperly relied upon its own jeopardy determinations in approving the registration decisions without consulting with the expert wildlife agency, as required under the ESA. Despite unilaterally–and unlawfully–determining that Enlist

herbicides are likely to jeopardize or adversely modify 183 threatened and endangered species and designated critical habitats, a determination that Congress expressly tasked to the expert wildlife agencies, EPA approved the use of Enlist herbicides for another seven years before completing consultation with the FWS.

H. Duty to Prevent Irreversible Commitment of Resources

265. Section 7(d) of the ESA prevents EPA and Corteva from making "any irreversible or irretrievable commitments of resources with respect to [the registration decisions,] which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternative measures." 16 U.S.C. § 1536(d). "This prohibition . . . continues until the requirements of section 7(a)(2) are satisfied," 50 C.F.R. § 402.09, "to ensure that the status quo is maintained during consultation." *Oceana*, 37 F. Supp. 3d at 176.

1. EPA's hasty decision foreclosed adoption of alternatives.

266. EPA falsely asserts that its decisions are not "irreversible or irretrievable commitment of resources" because they do not foreclose the future formulation or implementation of reasonable and prudent alternatives (RPAs) during the consultation period. However, EPA's registration decision allows for the ongoing sale and use of Enlist products, which are "likely to adversely affect" threatened and endangered species and their critical habitats, and recent market data confirms that adoption of Enlist products has increased because of EPA's unlawful decision to approve the use of these harmful products before completing consultation with the expert wildlife agency.

267. As a result of EPA's unlawful and hasty decision to extend the registrations for another seven years, Corteva has been able to expand its market share among U.S. corn, soybean, and cotton operations, foreclosing many farmers from adopting effective weed control alternatives in future growing seasons. Since launching Enlist-resistant crops for corn, cotton, and soybean production, adoption of the Enlist weed control system has increased dramatically. Adoption will continue to increase as Corteva

continues to roll out these products to new and existing markets, and Corteva has already confirmed its plans to invest in these products in the future. In fact, Corteva expects adoption among U.S. soybean operations to reach 40% in 2022. EPA also admitted that the use and adoption of Enlist products will likely increase in the future as Corteva continues to roll out the Enlist weed control system. This means that more farmers will be buying, growing, and harvesting Enlist-resistant crops, rather than other types of GE and/or conventional crops.

268. According to Corteva, EPA's decision to renew the registrations of Enlist One and Enlist Duo for an additional seven-year term "give[s] farmers further confidence in the [Enlist] weed control system."[94] Corteva has also indicated that rapid adoption of Enlist "will continue" due to "the recent re-registration of Enlist herbicides."[95]

269. Because Corteva already confirmed that it will invest in Enlist products, in reliance on EPA's registration decisions, many growers have already adopted the Enlist weed control system for the current growing season. EPA's decision thus constitutes an irreversible or irretrievable commitment of resources, in violation of the ESA.

2. EPA improperly relied on later-amendment clause.

270. "To address the possibility that additional measures may be necessary," EPA added the following language to the registration decision letters:

> If, after formal consultation with FWS, additional modifications are identified in the Service's Biological Opinion, EPA will notify Corteva in writing within 45 calendar days of the issuance of the Biological Opinion of any necessary required changes. Within

[94] Press Release, 2021 Fourth Quarter Earnings (Feb. 2, 2022), https://www.corteva.com/content/dam/dpagco/corteva/global/corporate/files/press-releases/02.02.2022_4Q_2021_Earnings_Release_Graphic_Version_Final.pdf.
[95] Press Release, Rapid Adoption of Enlist E3® Soybeans Includes First-ever Varieties of Pioneer® Brand A-Series E3 Soybeans (Jul. 14, 2022) ("Earlier this year, the EPA granted amended registrations for Enlist One® and Enlist Duo® herbicides for seven years through Jan. 11, 2029, giving farmers certainty in system availability for the foreseeable future."), https://www.corteva.us/press-releases/rapid-adoption-of-enlist-e3-soybeans-includes-first-ever-varieties-of-exclusive-pioneer-brand-a-series-enlist-e3-soybeans.html.

> 30 calendar days of receiving EPA's notice, Corteva must submit an amendment application incorporating any required changes, including amended labels. Alternatively, Corteva may respond by submitting a request for voluntary cancellation of this product. If Corteva fails to comply with this term, Corteva has agreed in prior written acceptance of these terms that EPA may cancel the registration under an expedited process under FIFRA 6(e).

Decision Memo at 37.

271. EPA cannot rely on a catchall clause to "to skirt the procedural requirements of § 7(d)." *Nat. Res. Def. Council v. Houston*, 146 F.3d 1118, 1127 (9th Cir. 1998) (agency violated section 7(d) by executing contracts before "completing" formal consultation despite clause "condition[ing] the terms on the final outcome" and allowing the agency to make "minor modifications to the contracts in order to comply with federal law"); *see also Env't Def. Ctr. v. Bureau of Ocean Energy Mgmt.*, 2018 WL 5919096 (C.D. Cal. Nov. 9, 2018) ("[T]he ESA itself prohibit[s] [agencies] from approving . . . permits before consultation with FWS is complete because doing so would constitute an 'irreversible or irretrievable commitment of resources.'"). Thus, EPA's registration decisions violate section 7(d).

VI. Plaintiffs' Injuries

272. Plaintiffs and their members are, and will continue to be, adversely affected by EPA's approval of Enlist One and Enlist Duo in 34 states.

273. Plaintiffs and their members are concerned about the detrimental impacts of EPA's decisions on farmers, farmworkers, rural communities, public health, and the environment, including endangered and threatened species and their habitats.

274. Plaintiffs' members include farmers, farmworkers, gardeners, wildlife enthusiasts, rural residents, and conservationists. They live, work, and recreate in many areas where Enlist products have been sprayed in the past and where they will continue to

be sprayed in the future as a result of EPA's decision to extend the registrations for another seven years.

A. Farmworkers

275. Plaintiffs' members include farmworkers in numerous states where Enlist products are approved for use. They work in agricultural areas adjacent to corn, cotton, soybean fields where Enlist products have been sprayed and will continue to be sprayed as a result of EPA's decision. They also have a higher rate of exposure to Enlist products in the environment because they live and work in agricultural communities where Enlist products have been sprayed and will continue to be sprayed.

276. EPA's decision to extend the registrations of Enlist One and Enlist Duo adversely affects Plaintiffs' members by increasing their exposure to Enlist products and risk of adverse health effects from glyphosate and 2,4-D. EPA's decision also adversely affects their families by increasing potential health effects from exposure to glyphosate and 2,4-D. EPA's decision adversely affects their personal, economic, recreational, and property interests in protecting the affected area from spray drift incidents, runoff, habitat loss, water contamination, crop injury, and other adverse effects associated with the use of Enlist products on crops near their workplaces and residences.

B. Conservationists

277. Plaintiffs' members include conservationists with aesthetic, recreational, vocational, and personal interests in protecting the environment from the adverse impacts of Enlist One and Enlist Duo. These members are heavily involved with maintaining natural habitats and creating a healthy environment for many diverse plant and animal species, including mammals, birds, pollinators, flowers, and plants. These members enjoy observing threatened and endangered species in their natural habitats, and they frequently visit areas where threatened and endangered plants and animals are known to exist. The use of Enlist One and Enlist Duo in areas where threatened and endangered plants and animals are known to exist will substantially impair Plaintiffs' members' ability

to view, study, photograph, and enjoy these species in their natural habitats, injuring members' recreational, aesthetic, and personal interests in protecting wildlife and their habitats. Moreover, the intensive use of Enlist products on corn, cotton, and soybean crops will substantially impair Plaintiffs' members' ability to enjoy their homes, gardens, local environments, and recreational sites, injuring members' recreational and personal interests in protecting sensitive species and biodiversity.

278. As a result of EPA's Registration Decisions, the overall amount of Enlist One and Enlist Duo sprayed on cotton, soybean, and corn crops will continue to increase dramatically each year, resulting in millions of additional pounds of 2,4-D and glyphosate in the environment. Moreover, as explained above, EPA's Registration Decisions threaten to increase the spread of herbicide resistance, increasing the amount of Enlist and other herbicides needed to control herbicide-resistant weeds, resulting in millions of additional pounds of 2,4-D, glyphosate, and other harmful chemicals in the environment.

279. The increased use of Enlist One and Enlist Duo on fallow fields at the beginning of the growing season and post-emergent crops during the summer and early fall will increase the amount of 2,4-D and glyphosate that enters the air, soil, and water through spray drift and runoff, contributing to increased drinking water pollution, injuries to crops on neighboring farms, harm to plants and animals found in the area, destruction of local wildlife habitats, jeopardy to endangered species that depend on local habitats for survival and reproduction, and other adverse impacts.

280. Plaintiffs and their members are directly harmed by the adverse environmental and ecological effects of EPA's registration decisions, including the adverse effects of 2,4-D and glyphosate exposure on local flowers, plants, insects, pollinators, and other wildlife species and habitats. Plaintiffs' members are also directly harmed by the detrimental effects of EPA's Registration Decisions on herbicide resistance, local agricultural practices, rural economies, water quality, and human health (including farmworkers, rural residents, and consumers).

C. Farmers & Gardeners

281. In addition, many of Plaintiffs' members are farmers and gardeners that grow vegetables, fruits, herbs, and other crops at risk of spray drift damage from Enlist applications. These members are rural community members who enjoy pollinators, birds, and other wildlife that rely on vulnerable plants for food, nesting, or breeding. The increased use of Enlist products on nearby fields harms their crops, hedgerows, gardens, and surrounding ecologically important flora.

282. EPA's registration of Enlist has already caused significant damage to farmers and gardeners' interests by harming crops and plants across thousands of acres. Some of Plaintiffs' members include farmers and gardeners who live and grow crops that have already been damaged by drift under EPA's previous registration, and EPA's recent registration decisions will increase the risk of spray drift damage to neighboring farms and gardens. The new registration will lead to increased use and more frequent applications of Enlist products, as well as more applications on postemergence crops, making it more likely that the use of Enlist products will harm crops and plants grown by Plaintiffs' members in affected areas.

283. Many of Plaintiffs' members are committed to reducing the use of pesticides and preserving the use of non-patented seed crops. Because of the registrations, these members face a lose-lose choice of either risking drift damage or losing their right to farm and safely plant the crops of their choice. Thus, EPA's registration decisions have, and will continue to, injure Plaintiffs' members' interests and ability to obtain and plant non-herbicide-resistant seeds, diminishing their ability to grow crops of their choice, and costing additional time and money to locate such seeds.

284. Because of EPA's registration decisions, Plaintiffs' members may have to adjust their planting season and seed choices if they wish to grow fruits and vegetables near areas approved for use of Enlist products. Some members may incur significant costs to build a buffer zone, install fencing, or move their garden to avoid damage from

Enlist applications. They may also need to limit their gardening, landscaping, and recreational activities to avoid their own exposure to spray drift.

285. For example, CFS member, Eric Pool, the owner of Berryville Vineyards, is concerned about spray drift continuing to harm his vineyard because grapes are highly sensitive to 2,4-D. He currently farms about ten acres of wine grapes and berries in Berryville, Illinois, an area where farmers use Enlist products on Enlist-resistant crops, and where farmers will continue to use Enlist products as a result of EPA's decision. He has suffered economic and labor costs resulting from extensive damage to his vineyard, and he has filed several complaints with the Illinois State Department of Agriculture regarding the adverse effects of Enlist applications on nearby fields.

D. Organizational Injuries

286. In addition to injuring Plaintiffs' members, EPA's registration decisions adversely affect Plaintiffs' organizational interests. Plaintiffs are nonprofit organizations dedicated to protecting the environment from the adverse impacts of industrial agriculture, including the increased use of harmful herbicides and GE herbicide-resistant crops. As a result of EPA's registrations, Plaintiffs have had to divert resources from other program areas to address the harms and injuries caused by EPA's decision to improperly extend the registrations of Enlist products for another seven years.

287. In sum, EPA's decision to register Enlist One and Enlist Duo directly harms the aesthetic, recreational, economic, and personal interests of thousands of Plaintiffs' members, as well as Plaintiffs' organizational interests in protecting the environment from the adverse effects of pesticides and industrial agriculture.

288. This Court can redress the injuries to Plaintiffs and their members by (1) declaring that EPA's registration decisions were unlawful, (2) setting aside EPA's registration decisions, halting the use and sale of Enlist One and Enlist Duo until EPA properly weighs the costs under FIFRA and consults with FWS under the ESA, and (3) granting relief as necessary to redress and prevent harm to wildlife and their habitats.

FIRST CAUSE OF ACTION

EPA's Registration Decisions Are Not Supported By Substantial Evidence

VIOLATIONS OF FIFRA

289. Plaintiffs reallege and incorporate by reference ¶¶ 1–289.

290. To unconditionally register a pesticide, EPA must conclude that (1) the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and (2) "when used in accordance with widespread and commonly recognized practice[, the pesticide] will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(C)(5). To amend the registration of a currently registered pesticide, applicants must submit all the materials necessary for EPA to make this determination. *Id.*; 40 C.F.R. § 152.50(f)(1).

291. FIFRA defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

292. EPA's registration decisions are not supported by substantial evidence because EPA (1) understated the risks and costs to human health and the environment; (2) overstated the claimed benefits; and (3) improperly relied on ineffective mitigation.

EPA understated the risks and costs of its decision.

293. EPA dramatically understated the risks and costs of its decisions because (1) EPA failed to accurately assess some risks and costs, and (2) EPA entirely ignored some risks and costs factors, including but not limited to usage, herbicide resistance, spray drift, runoff, and non-listed species. EPA further has no substantial evidence for its conclusion that Enlist Duo meets the FIFRA safety standard for human health.

Usage

294. EPA failed to fully consider or quantify current use of Enlist products.

295. EPA failed to fully consider or quantify future use of Enlist products.

Herbicide Resistance

296. EPA failed to fully consider or quantify current resistance to Enlist products.

297. EPA failed to fully consider or quantify future resistance to Enlist products.

298. EPA failed to fully consider or quantify costs to farmers relating to 2,4-D resistance, including increased weed control costs.

299. EPA failed to fully consider or quantify environmental risks relating to 2,4-D resistance, including increased use of Enlist and other herbicides to compensate for reduced efficacy.

Runoff

300. EPA failed to fully consider or quantify current runoff damage relating to Enlist products.

301. EPA failed to fully consider or quantify future runoff damage relating to Enlist products.

302. EPA failed to fully consider or quantify costs to farmers relating to runoff from Enlist applications, including damage to sensitive crops.

303. EPA failed to fully consider or quantify environmental risks relating to runoff from Enlist applications, including damage to plants and destruction of habitats.

Spray Drift

304. EPA failed to fully consider or quantify current spray drift damage from Enlist products.

305. EPA failed to fully consider or quantify future spray drift damage from Enlist products.

306. EPA failed to fully consider or quantify costs to farmers relating to drift damage from Enlist applications, including damage to sensitive crops.

307. EPA failed to fully consider or quantify environmental risks relating to drift damage from Enlist applications, including damage to plants and destruction of habitats.

Plants & Animals

308. EPA failed to fully consider or assess the direct risks to animal and plant species from runoff, spray drift, and other routes of exposure.

309. EPA failed to fully consider or assess the indirect risks to animals and plant species from loss of habitat, shelter, prey, pollination, and other threats.

Human Health

310. EPA failed to consider or quantify health risks to agricultural communities, including nearby farmers and farmworkers, wildlife enthusiasts, and conservationists.

311. EPA failed to fully consider or quantify the human health risks associated with glyphosate and 2,4-D, including increased risk of non-Hodgkin lymphoma.

312. EPA improperly relied on a flawed human health risk assessment for glyphosate.

Other Risks & Costs

313. EPA failed to consider or quantify economic and social risks to agricultural communities, including nearby farms, gardens, homes, and conservation areas.

314. EPA failed to fully consider or assess efficacy of existing mitigation measures in previous labels.

315. EPA failed to fully consider or assess efficacy of added mitigation measures in revised labels.

EPA overstated the benefits of Enlist products.

316. EPA dramatically overstated the benefits of its registration decisions because EPA failed to accurately assess the effectiveness of Enlist products against target weeds and potential impacts of its decision, including but not limited to the increased use of Enlist products, increased noncompliance with labeling requirements, and increased spread of herbicide resistance.

317. EPA failed to fully consider or assess current or future use of Enlist products.

318. EPA failed to fully consider or assess current noncompliance with existing labeling restrictions and mitigation measures.

319. EPA failed to fully consider or assess future noncompliance with added labeling restrictions and mitigation measures.

320. EPA failed to fully consider or assess the current efficacy of Enlist products against herbicide-resistant weeds.

321. EPA failed to fully consider or assess future efficacy of Enlist products against herbicide-resistant weeds.

322. EPA failed to fully consider effective alternatives for weed control.

323. Therefore, because EPA failed to properly evaluate the potential risks and benefits, EPA improperly concluded that the benefits outweighed the costs.

324. EPA played up the purported benefits of Enlist products and failed to evaluate their true costs. EPA based its decisions on a flawed cost-benefit assessment that failed to "take[] into account the economic, social, and environmental costs" of Enlist products, in violation of FIFRA, 7 U.S.C. § 136(bb).

EPA failed to mitigate adverse environmental risks.

325. In addition, EPA improperly relied on inadequate mitigation measures in the form of labeling instructions to determine that its decisions would not result in unreasonable adverse effects.

326. EPA ignored evidence that similar language in previous labels failed to reduce spray drift, runoff, water pollution, and other adverse environmental impacts.

327. EPA ignored evidence that similar language in previous labels failed to slow the spread of herbicide resistance.

328. EPA ignored evidence that users failed to comply with previous labels.

329. EPA ignored evidence that noncompliance would increase because of changes to product labels, increased herbicide resistance, and other factors.

330. EPA ignored evidence that added mitigation measures in revised labels will increase runoff, spray drift, and other adverse effects on the environment.

331. EPA failed to provide evidence that existing mitigation measures are effective.

332. EPA failed to provide evidence that newly added mitigation measures will be effective.

333. EPA failed to provide any evidence that mitigation measures will continue to be effective over the next seven years, the life of the challenged registrations.

334. Therefore, EPA's labeling restrictions fail to mitigate Enlist One and Enlist Duo's adverse effects on the environment because EPA ignored evidence that farmers have not complied with previous restrictions, and EPA did not provide any new evidence to demonstrate that farmers will comply with new restrictions. EPA also ignored evidence that even with full compliance, the labeling restrictions threaten to increase adverse impacts, such as spray drift, runoff, water pollution, and herbicide resistance.

335. For these reasons, EPA's registration decisions are not supported by substantial evidence, in violation of FIFRA.

SECOND CAUSE OF ACTION

EPA's Registration Decisions Violate the ESA and Its Regulations

VIOLATIONS OF ESA

336. Plaintiffs reallege and incorporate by reference ¶¶ 1–289.

337. Section 7(a)(2) of the ESA requires EPA to "insure," through consultation with the expert wildlife agencies, that its pesticide registration actions will not (1) "jeopardize the continued existence of any endangered species or threatened species" or (2) adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2). To ensure EPA complies with this requirement, the ESA requires EPA to consult with the expert wildlife agency whenever a proposed action "may affect" listed species or critical habitats. *Id.*; 50 C.F.R. § 402.14(a).

EPA's registrations are "actions."

338. Section 7(a)(2) requires consultation for any "action" that "may affect" a listed species or critical habitat. 16 U.S.C. § 1536(a)(2). "Action" includes "all activities . . . authorized, funded, or carried out [by EPA]." 50 C.F.R. § 402.02.

339. EPA's decision to renew the registrations of Enlist One and Enlist Duo for an additional seven-year term, as well as EPA's subsequent decision to remove label restrictions in hundreds of counties, are "actions" under the ESA, triggering the consultation requirement. *See id.*

EPA's registrations "may affect" listed species and critical habitats.

340. Section 7(a)(2) requires EPA to obtain the expert opinion of a wildlife agency whenever an action "may affect" listed species or critical habitats. 16 U.S.C. § 1536(a)(2). EPA "shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat." 50 C.F.R. § 402.14(a) (emphasis added). "If such a determination is made, formal consultation is required . . . ." *Id.* In determining whether to consult, EPA must use "the best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

341. The "may affect" threshold is low. "Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement." *See* 51 Fed. Reg. 19,926, 19,949 (Jun. 3, 1986); 50 C.F.R. § 402.14(a).

342. EPA's registration decisions "may affect" listed species and critical habitats in areas affected directly and indirectly by the continued and increased use of Enlist One and Enlist Duo on corn, soybean, and cotton crops in 34 states. Many protected species rely on corn, cotton, and soybean fields for habitat during their lifecycles. For example, whooping cranes often rest and feed in sprayed fields during migration. Numerous protected plant and animal species are also found in the areas adjacent or downwind from sprayed fields. For example, pollinators rely on fragmented patches of flowering plants in agricultural areas for feeding and breeding habitat. EPA's decisions threaten

species and habitats in the affected areas, both directly through direct application, spray drift, erosion, and runoff, and indirectly through loss of habitat, food sources, and pollination.

343. EPA confirmed that Enlist One and Enlist Duo threaten several plant and animal species. The active ingredients in Enlist products are toxic to numerous plants, including threatened and endangered plant species and plants that provide important feeding and breeding habitats for listed species. Enlist products are also toxic to several animal species, including species that play an important role in local food webs and ecosystems and listed species.

344. EPA confirmed that Enlist products may affect numerous listed species and their critical habitats. *See, e.g.*, Decision Memo at 25, 44 ("EPA preliminarily concluded that the uses of the two Enlist herbicide products as described on the May 2021 labels may affect . . . multiple listed species and designated critical habitats.").

345. Even with the revised labels in place, EPA determined that Enlist products may affect listed species and critical habitats. In addition, before eliminating county-level prohibitions in 128 counties, EPA concluded that doing so would likely adversely affect listed species and their habitats.

346. EPA also confirmed that spray drift from Enlist One and Enlist Duo threatens plants and animals on nearby areas. In 2018 and 2019, EPA found that Enlist One was specifically linked to 16 reported incidents of spray drift involving damage to nearby crops. EPA also found 12 incidents of adverse effects to wildlife from exposure to Enlist Duo, all of which were affected via drift from cotton fields. All reported incidents linked to Enlist products took place in areas with threatened and endangered species.

347. These impacts exceed the threshold triggering EPA's duty to obtain the expert opinion of a wildlife agency and complete formal consultation.

Failure to Consult under Section 7(a)

Effects Determination

348. EPA failed to provide FWS with an effects determination "based on the best scientific and commercial data available." 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.40(b)(3). EPA's violation is ongoing because FWS has not yet issued a final biological opinion.

349. EPA failed to provide FWS with an effects determination containing a "description of all areas to be affected directly or indirectly by the [registration] action[s]." 50 C.F.R. § 402.14(c)(1)(ii). EPA's violation is ongoing because EPA has not submitted a corrected effects determination.

350. EPA failed to provide FWS with an effects determination containing an accurate "description of the effects of the action." *Id.* § 402.14(c)(1)(iv). EPA's violation is ongoing because EPA has not submitted a corrected effects determination.

351. EPA failed to provide FWS with an effects determination containing an accurate "analysis of any cumulative effects." *Id.* EPA's violation is ongoing because FWS has not yet issued a final biological opinion.

352. EPA failed to provide FWS "with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat." *Id.* § 402.14(d). EPA's violation is ongoing because FWS has not yet issued a final biological opinion.

Formal Consultation (Section 7(a)(2))

353. EPA failed to promptly initiate formal consultation with FWS after determining that the registration decisions may affect listed species or critical habitat. 50 C.F.R. §§ 402.14(a); § 402.42(a)(5).

354. In its initial effects determination, EPA determined that the proposed registrations may affect numerous listed species and critical habitats. Under ESA's implementing regulations, EPA should have initiated formal consultation as soon as it made this determination. Instead, EPA delayed formal consultation for months. EPA

waited to initiate formal consultation until the day before approving Enlist One and Enlist Duo. By the time FWS received EPA's request to initiate consultation, it was too late for the expert wildlife agency to provide input on the registrations or mitigation measures.

355. EPA also failed to consult with the expert wildlife agency regarding the registration amendments. Rather than notify the expert wildlife agency as soon as it received the proposed amendments, EPA again delayed notifying FWS for months. EPA did not notify FWS until the day before amending the registrations to remove hundreds of county-level prohibitions from the labels. By the time FWS received EPA's consultation update letter, it was too late for the expert wildlife agency to provide input.

356. Thus, because EPA decided to approve the registrations of Enlist One and Enlist Duo before completing formal consultation with the FWS, EPA violated its mandatory consultation duties under section 7(a)(2). *See* 16 U.S.C. § 1536(a), (d); *see also* 50 C.F.R. §§ 402.14, § 402.13.

357. Because EPA issued a final decision before reviewing FWS's biological opinion, EPA also violated its responsibilities under the ESA regulations, 50 C.F.R. § 402.15(a), which require EPA to "determine whether and in what manner to proceed with the action in light of its section 7 obligations and the Service's biological opinion."

358. EPA continues to violate the ESA and its implementing regulations because FWS has yet to issue a final biological opinion, and formal consultation is ongoing.

Failure to Prevent Jeopardy & Adverse Modification under Section 7(a)(2)

359. Because EPA failed to consult with FWS before extending the registrations for an additional seven-year term and removing hundreds of county-level prohibitions, EPA also violated ESA's substantive requirement to "insure" that its registration decisions will not jeopardize any threatened or endangered species or adversely modify critical habitat. *See* 16 U.S.C. § 1536(a)(2).

360. EPA improperly relied on its own jeopardy determinations to approve the registration decisions without consulting with FWS. EPA does not have the expertise or

resources to properly evaluate the likelihood of jeopardy to listed species and adverse modification of critical habitats. For this reason, the ESA expressly requires the expert wildlife agency to make jeopardy determinations.

361. EPA has failed to insure, through completed consultation with the expert wildlife agency, that its registration actions are not "likely to jeopardize the continued existence" of any threatened or endangered species. 16 U.S.C. § 1536(a)(2). EPA's violation is ongoing because EPA has already approved the use of Enlist One and Enlist Duo, and FWS has not issued a final biological opinion.

362. EPA has failed to insure, through completed consultation with the expert wildlife agency, that the registration actions are not likely to "result in the destruction or adverse modification" of any critical habitats. *Id.*

363. EPA's violation is ongoing because EPA has already approved the use of Enlist One and Enlist Duo, and FWS has not issued a final biological opinion.

Failure to Prevent Irreversible Commitments under Section 7(d)

364. EPA has failed to prevent itself and Corteva from making "any irreversible or irretrievable commitment of resources" with respect to the registration actions, effectively "foreclosing the formulation or implementation of any reasonable and prudent alternative measures." 16 U.S.C. § 1536(d).

365. EPA's violation is ongoing because EPA has already approved the use of Enlist One and Enlist Duo, and FWS has not issued a final biological opinion.

PRAYER FOR RELIEF

Plaintiffs respectfully request that this Court:

1. Declare that EPA's Registration Decisions for Enlist One and Enlist Duo violate FIFRA and its implementing regulations;

2. Declare that EPA's Registration Decisions for Enlist One and Enlist Duo violate the ESA and its implementing regulations;

3. Declare that EPA failed to support its Registration Decisions for Enlist One and Enlist Duo with substantial evidence;

4. Declare that EPA failed to prevent jeopardy to listed species and adverse modification to their critical habitats before issuing its Registration Decisions for Enlist One and Enlist Duo;

5. Set aside or vacate EPA's Registration Decisions for Enlist One and Enlist Duo, in whole or in part, as needed to stop their sale and use;

6. Prohibit the continued use of any products that have already been manufactured or purchased under the now-vacated registrations;

7. Grant any other relief as may be necessary and appropriate to stop the use and sale of any products authorized by EPA's Registration Decisions for Enlist One and Enlist Duo before and after vacatur;

8. Award Plaintiffs the costs of this litigation, including reasonable attorneys' fees and expert witness fees; and

9. Grant such other relief as the Court deems just and proper.

Respectfully submitted,

DATE: June 6, 2023

/s/ Amy van Saun

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