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Via Email and U.S. Certified Mail

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NOTICE OF INTENT TO SUE UNDER SECTION 11 OF THE ENDANGERED SPECIES ACT FOR VIOLATIONS RELATING TO EPA'S REGISTRATIONS OF ENLIST ONE & ENLIST DUO

On behalf of the organizations listed below, the Center for Food Safety hereby provides formal notice of their intent to sue the U.S. Environmental Protection Agency (EPA) for violations of the Endangered Species Act (ESA), 16 U.S.C. §§ 1531–44, relating to its decision to approve the registrations of Enlist One and Enlist Duo on January 12, 2022, and its subsequent decision to amend the registrations for both herbicides on March 24, 2022. This letter provides formal notice pursuant to section 11 of the ESA, 16 U.S.C. § 1540(g).

EPA violated the ESA by failing to consult with the expert wildlife agency, U.S. Fish & Wildlife Service (FWS), before approving and amending the registrations of Enlist One and Enlist Duo. In addition to EPA's ongoing violations of the ESA's consultation requirements, EPA has failed to insure, through consultation with the expert wildlife agencies, against jeopardy to threatened and endangered species and adverse modification of designated critical habitats. Moreover, EPA has, and continues to violate, its duty to prevent irreversible commitments of resources during formal consultation, foreclosing the implementation of reasonable alternatives for current and future growing seasons.¹

¹ For a summary of the violations discussed in this notice letter, see the Conclusion.

I. LIST OF THE ORGANIZATIONS GIVING NOTICE

The following organizations intend to sue EPA for violating the ESA.

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II. ENDANGERED SPECIES ACT

The ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”² As recognized by the U.S. Supreme Court, the ESA “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”³ Simply put, “[t]he plain intent of Congress in enacting this statute was to halt and reverse the trend toward species extinction, *whatever the cost*.”⁴ In all ESA analyses and decisions, agencies must “give the benefit of the doubt to the species,”⁵ and use the best scientific and commercial data available.⁶

Section 7 of the ESA imposes substantive and procedural requirements on action agencies like EPA.⁷ These requirements apply to *all* actions involving discretionary federal involvement or control, including any discretionary actions “authorized, funded, or carried out” by EPA under the Federal Insecticide Fungicide Regulation Act (FIFRA).⁸ This includes EPA’s decision to renew or amend the registration of a currently approved pesticide product.

A. Section 7(a)

Section 7(a)(2) requires EPA, “in consultation with and with the assistance of the [expert wildlife agencies], to insure that any [authorized] action . . . 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”⁹ In fulfilling the requirements of section 7(a)(2), EPA must use the best scientific and commercial data available.¹⁰

Section 7(a)(4) further requires EPA to “confer with the [expert wildlife agencies] on any agency action [that] is likely to jeopardize the continued existence of any [proposed listed species] . . . or result in the destruction or adverse modification of [any proposed] critical habitat.”¹¹

² *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180, 185 (1978).

³ *Id.* at 174–75.

⁴ *Id.* at 184 (emphasis added).

⁵ *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

⁶ 16 U.S.C. § 1536(a)(2).

⁷ *Id.* §§ 1536(a)–(d); *see also* 50 C.F.R. § 402.01(a) (“This part interprets and implements sections 7(a)–(d) [of the ESA].”).

⁸ 50 C.F.R. §§ 402.03; § 402.02 (“action”); § 402.42(a) (“EPA retains discretion to initiate early, informal, or formal consultation as described in §§ 402.11, 402.13, and 402.14 for any FIFRA action.”).

⁹ 16 U.S.C. § 1536(a)(2).

¹⁰ *Id.*

¹¹ *Id.* § 1536(a)(4).

1. “May Affect” Determination

Section 7(a)(2) requires EPA to consult with the expert wildlife agencies to “insure” that its pesticide registration actions will not “jeopardize” any “listed species,”¹² or “adversely modify” any “critical habitats.”¹³ EPA must “review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat.”¹⁴ “If such a determination is made, formal consultation [with the expert wildlife agency] is required.”¹⁵

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.”¹⁶ The effects of an action “may occur later in time and may include consequences occurring outside the immediate area involved in the action.”¹⁷

The “may affect” threshold is extremely low. 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.”¹⁸ “*Any possible* effect, whether beneficial, benign, adverse or of an undetermined character,” triggers the consultation requirement.¹⁹

2. Formal Consultation

If EPA determines that a proposed action “may affect” any listed species or critical habitat, EPA must continue with formal consultation.²⁰ 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,” and (3) the expert wildlife agency concurs in writing.²¹

a. Initiating Formal Consultation

EPA must submit a written request to initiate formal consultation with an expert wildlife agency.²² This request must include specific information regarding the proposed action, including a description of “the effects of the action and an analysis of any cumulative effects.”²³ EPA must also describe “all areas to be affected directly or indirectly by the [proposed] action, and not merely the

¹² *Id.* § 1536(a)(2). An action “jeopardize[s] the continued existence” of a species if it is reasonably “expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.” 50 C.F.R. § 402.02.

¹³ *Id.* (“critical habitats” are “areas designated as [such] in 50 C.F.R. Part 17 or 226”); (“adverse modification” is “a direct or indirect alteration that appreciably diminishes the value of critical habitat . . . for the conservation of a listed species”); (“listed species” are “any threatened or endangered species . . . in 50 C.F.R. §§ 17.11–17.12”)

¹⁴ *Id.* § 402.14(a).

¹⁵ *Id.*

¹⁶ *Id.* § 402.02 (“effects of the action”).

¹⁷ *Id.*; *see also id.* § 402.17.

¹⁸ *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc); *see also W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011).

¹⁹ *Cal. ex rel. Lockyer v. USDA*, 575 F.3d 999, 1018–19 (9th Cir. 2009) (internal quotations omitted).

²⁰ 50 C.F.R. § 402.14(a).

²¹ *Id.* § 402.13(b); *see also id.* § 402.14(a), (b).

²² *See id.* § 402.14(c).

²³ *Id.*

immediate area involved in the action (i.e., the action area as defined at § 402.02).²⁴ EPA must provide the expert wildlife agency “with the best scientific and commercial data available.”²⁵

b. Biological Opinions

During formal consultation, the expert wildlife agency formulates an 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.”²⁶ In reaching an opinion, the expert wildlife agency evaluates the effects of the action and cumulative effects on the listed species or critical habitat, and then adds these effects to the environmental baseline to determine whether jeopardy is likely. If the expert wildlife agency determines jeopardy is likely, the agency will work with EPA and applicants to identify reasonable and prudent alternatives to avoid violation of section 7(a)(2).²⁷

c. Following Formal Consultation

Formal consultation concludes when the expert wildlife agency issues the biological opinion.²⁸ Following the issuance of a biological opinion, EPA must use the expert opinion to “determine whether and in what manner to proceed with the action in light of its section 7 obligations.”²⁹

B. Section 7(d)

Section 7(d) prohibits EPA from making any irreversible or irretrievable commitments during consultation. After initiating formal consultation, EPA and the 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 alternatives which would avoid violating section 7(a)(2).”³⁰ “This prohibition is in force during the consultation process and continues until the requirements of section 7(a)(2) are satisfied.”³¹

C. Citizen Suit Provision

Under ESA’s citizen suit provision, “any person may commence a civil suit on [their] own behalf” “to enjoin any . . . agency . . . who is alleged to be in violation of any provision of this chapter or regulation issued under the authority thereof.”³² “The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce any such provision or regulation.”³³ This letter provides written notice of EPA’s alleged violations.³⁴

²⁴ *Id.*

²⁵ *Id.* § 402.14(d).

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.* § 402.14(m)(1).

²⁹ *Id.* § 402.15(a); *see also id.* § 402.42(a)(8) (“EPA must comply with § 402.15 for all FIFRA actions.”).

³⁰ *Id.* § 402.09.

³¹ *Id.*

³² 16 U.S.C. § 1540(g)(1)(A).

³³ *Id.* § 1540(g)(1).

³⁴ *See id.* § 1540(g)(2)(A).

III. RELEVANT ACTIONS

A. Registration Decisions

On January 11, 2022, EPA renewed the registrations of Enlist One and Enlist Duo for an additional seven-year period, until January 2029.³⁵ These registrations authorize the continued use of Enlist One and Enlist Duo on soybean, cotton, and corn crops in 34 states. On March 24, 2022, EPA amended the registrations of Enlist One and Enlist Duo.³⁶ These amendments remove county-level restrictions and other label requirements.

B. Effects Determinations

1. Initial Effects Determination (May 2021)³⁷

Based on EPA's evaluation of the draft labels submitted by the applicant on May 14, 2021, EPA concluded that use of Enlist products "may affect" numerous listed species and habitats.³⁸ In addition, EPA concluded Enlist products are likely to adversely affect multiple listed species and designated critical habitats.³⁹ EPA further determined that use of Enlist products would jeopardize the continued existence of 88 listed species, and adversely modify 34 designated critical habitats.⁴⁰

2. Revised Effects Determination (January 2022)⁴¹

In January 2022, EPA re-evaluated the potential effects based on the revised labels submitted by the applicant on January 10, 2022. Based on the revised labels, which included reliance on county-level prohibitions as mitigation, EPA determined that use of Enlist products would continue to adversely affect 110 listed species and 38 critical habitats.⁴² However, EPA "determined that use of the Enlist products is not likely to jeopardize listed species or adversely modify designated critical habitats" due to the added labeling language.⁴³ EPA also determined that the "added mitigation measures will minimize the potential for take."⁴⁴

³⁵ Memo Supporting Decision to Extend Registrations for Enlist One & Enlist Duo (Jan. 11, 2022) ("Decision Memo").

³⁶ Addendum to EPA's January 2022 Decision Memo, Expanding Use to Additional Counties (Mar. 29, 2022) ("Amended Decision Memo").

³⁷ 2022 ECOLOGICAL RISK & ENDANGERED SPECIES ASSESSMENT FOR USE ON GENETICALLY MODIFIED HERBICIDE-TOLERANT CORN, SOYBEAN, & COTTON IN SUPPORT OF REGISTRATION RENEWAL DECISION FOR ENLIST ONE & ENLIST DUO PRODUCT (JAN. 10, 2022) ("Initial Effects Determination").

³⁸ *Id.* at 159, 190.

³⁹ *Id.* at 195–99.

⁴⁰ *Id.* at 200–05.

⁴¹ EVALUATION OF MITIGATIONS ON ENLIST ONE & ENLIST DUO LABELS TO ADDRESS LISTED SPECIES RISKS IDENTIFIED IN THE 2022 ECOLOGICAL RISK & ENDANGERED SPECIES ASSESSMENT FOR USE ON GENETICALLY MODIFIED HERBICIDE-TOLERANT CORN, SOYBEAN, & COTTON IN SUPPORT OF REGISTRATION RENEWAL DECISION FOR ENLIST ONE & ENLIST DUO PRODUCTS (JAN. 10, 2022) ("Revised Effects Determination").

⁴² *Id.* at 37 tbl.11 (summarizing revised effect determinations based on product labels submitted January 2022). "The effects determinations summarized in Table 11 supersede the determinations in the previous assessment." *Id.*

⁴³ *Id.* at 37.

⁴⁴ *Id.*

3. Amended Effects Determination (March 2022)⁴⁵

In March 2022, EPA re-evaluated the potential effects based on the proposed amended labels submitted by the applicant on February 23, 2022 (Enlist One) and March 15, 2022 (Enlist Duo). EPA evaluated the potential effects to listed species and designated critical habitat in 128 counties previously not requested by the product registrant for initial consideration. EPA found “there may be effects to 15 listed species and 3 designated critical habitats [off-]field in these 128 counties.” In addition, EPA found that use of Enlist of Enlist products is likely to adversely affect 6 listed species and 1 designated critical habitat in these 128 counties, bringing the total number of likely adverse effect determinations to 116 listed species and 39 designated critical habitats.⁴⁶ However, EPA ultimately “continue[d] to predict a not likely [jeopardy] determination for the use of Enlist One and Enlist Duo in this action.”⁴⁷

4. Re-evaluated Effects Determination (Currently Approved Labels)⁴⁸

Most recently, in June 2022, EPA re-evaluated the potential effects based on the currently approved labels, submitted by the applicant on March 29, 2022, using an updated method of analyzing overlap between listed species and the action area (i.e., “overlap analysis”).⁴⁹ EPA evaluated the potential effects to 93 listed species and 60 designated critical habitats for which EPA had previously made a “no effect” determination.⁵⁰ From this analysis, EPA found that use of Enlist products is likely to adversely affect an additional 46 listed species and 60 designated critical habitats,⁵¹ bringing the total number of likely adverse effect determinations to 142 listed species and 97 designated critical habitats.

In sum, EPA first determined that the registrations may affect hundreds of listed species and their habitats when it initially reviewed the proposed labels. In every subsequent assessment, EPA has found that the registrations will adversely affect numerous listed species and critical habitats.

C. Formal Consultation

1. Request to Initiate Consultation

Despite concluding that the proposed labels may affect—and potentially jeopardize—numerous listed species and designated critical habitats in its initial effects determination, EPA did

⁴⁵ ECOLOGICAL RISK & ENDANGERED SPECIES EFFECTS DETERMINATION FOR THE EXPANSION OF ENLIST ONE & ENLIST DUO PRODUCT USE ON GENETICALLY MODIFIED HERBICIDE-TOLERANT CORN, SOYBEAN, & COTTON IN 128 COUNTIES & REMOVAL OF ENLIST DUO COUNTY PROHIBITIONS IN MINNESOTA (MAR. 24, 2022) (“Amended Effects Determination”).

⁴⁶ *Id.* at 3–4, 4 tbl.1 (Summary of Effects Determinations for the Use of Enlist One and Enlist Duo in the Proposed 128 Counties Based on Labels Dated Feb. 23, 2022 & Mar. 15, 2022).

⁴⁷ *Id.* at 3–4.

⁴⁸ RE-EVALUATED EFFECTS DETERMINATIONS FOR 93 LISTED SPECIES & 60 DESIGNATED CRITICAL HABITATS FOR ENLIST ONE & ENLIST DUO PRODUCT USE ON GENETICALLY MODIFIED HERBICIDE-TOLERANT CORN, SOYBEAN, & COTTON (JUN. 16, 2022) (“Re-evaluated Effects Determination”).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

not submit a written request to initiate formal consultation with the FWS until January 10, 2022.⁵² On the next day, EPA announced that its decision to renew the registrations of Enlist One and Enlist Duo for an additional seven-year period.⁵³ Rather than initiate formal consultation as soon as it determined that its decision may affect listed species and critical habitats, EPA delayed consultation until the last possible day. It also failed to wait until that consultation was completed before issuing its registration action.

EPA initiated formal consultation with the FWS because EPA’s “effects determination for the proposed labels concluded that the action is likely to adversely affect one or more individuals of a number of listed species and their designated critical habitats.”⁵⁴ EPA also requested that FWS provide written concurrence on EPA’s “not likely to adversely affect” determinations.⁵⁵ This consultation is ongoing.

2. Consultation Update (Amended Labels)

On March 28, 2022, EPA notified FWS that it had completed an effects determination based on the proposed amendments to remove county-level prohibitions in the labels approved on January 11, 2022.⁵⁶ On the next day, EPA announced its decision to expand use of Enlist One and Enlist Duo to 128 additional counties.⁵⁷ Rather than notify FWS as soon as it received the applicant’s proposed amendments, EPA waited until the last possible day to inform the expert wildlife agency.

3. Consultation Update (Overlap Update)

Following discussions with FWS staff during the consultation process, EPA “reconsidered its earlier overlap approach for [its previous registration decisions].”⁵⁸ If EPA had initiated consultation after determining that the proposed labels “may affect” listed species, as required under the ESA, FWS would have been able to provide input on EPA’s overlap analysis *before* EPA made a final decision.

In line with EPA’s updated overlap approach, EPA “reassessed the determinations for any on-field species where the overlap of that species’ entire range with the *entire action area* was [greater than] 1%.”⁵⁹ EPA identified 93 additional species with overlap in the action area that had been excluded from its January and March assessments. From these additional species, EPA determined that its action is “likely to adversely affect” 46 additional listed species and 60 additional designated critical habitats.⁶⁰ Although the updated approach increased the number of “may affect” and “likely

⁵² See Letter from Jan Matuszko, EPA, to Gary Frazer, Assistant Director for Endangered Species, FWS (Jan. 10, 2022) (“Consultation Initiation Letter”).

⁵³ See Decision Memo, *supra* note 35.

⁵⁴ Consultation Initiation Letter, *supra* note 52.

⁵⁵ *Id.*

⁵⁶ Letter from Jan Matuszko to Gary Frazer (Mar. 28, 2022) (“Consultation Update Letter re: Amendments”).

⁵⁷ Amended Decision Memo, *supra* note 36.

⁵⁸ Letter from Jan Matuszko to Gary Frazer (Jun. 27, 2022) (“Consultation Update Letter re: Re-evaluated Effects Determination”).

⁵⁹ RE-EVALUATED EFFECTS DETERMINATION, *supra* note 48.

⁶⁰ *Id.* EPA’s updated approach “identified 60 additional designated critical habitats that could be within the action area that were [no effect] in the January or March assessments,” all of which are “likely to adversely affect” listed species.

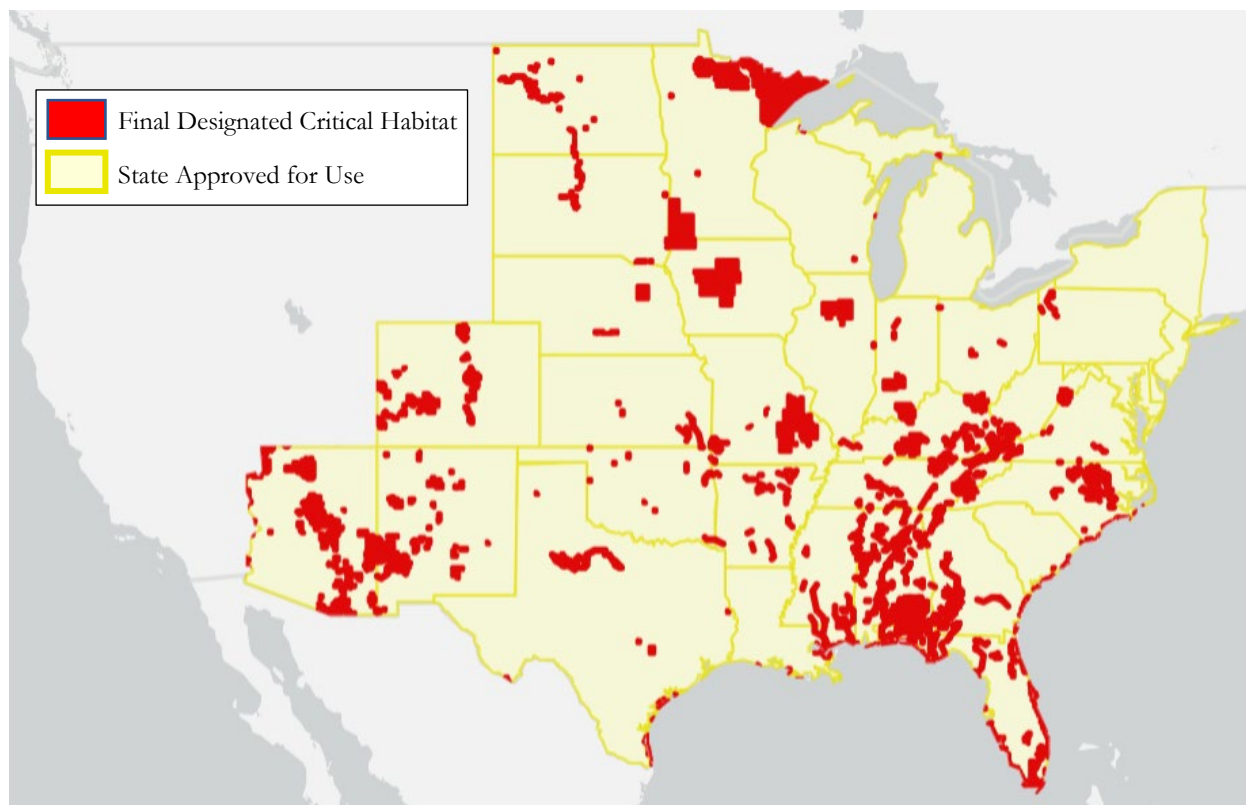
to adversely affect” determinations, “EPA predicts none of the additional species or critical habitats would likely rise to the level of jeopardy or adversely modification.”⁶¹

IV. POTENTIAL EFFECTS ON LISTED SPECIES & HABITATS

Enlist One and Enlist Duo are highly toxic herbicides containing the active ingredient 2,4-D choline salt. Both herbicides are approved for use on genetically engineered corn, cotton, and soybean crops with resistance to 2,4-D, glyphosate, and glufosinate (i.e., Enlist-resistant crops) throughout the growing season. As a result, these herbicides threaten crops in neighboring fields, as well as plant and animal species in surrounding areas.

EPA’s decision to approve the registrations of Enlist One and Enlist Duo has several adverse effects on species in the action area, including numerous listed species and designated critical habitats. Enlist products directly affect species through direct application, spray drift, runoff, erosion, rainfall, and other routes of exposure. These products also indirectly affect species through habitat loss, decreased food sources, pollination, and other impacts. For a list of listed species with current range in the states approved for use of Enlist One and Enlist Duo, please see **Appendix A**.

Map of Designated Critical Habitat in States Approved for Use of Enlist One & Enlist Duo



⁶¹ *Id.*

EPA has already acknowledged that Enlist products are toxic to numerous plant and animal species, including federally protected threatened and endangered species and designated critical 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.⁶² Enlist products are also toxic to many animals that play an important role in local food webs and ecosystems, including fish, invertebrates, mammals, pollinators, and birds.⁶³

EPA has also acknowledged that use of Enlist products will likely adversely affect numerous listed species and their habitats. EPA's registrations may directly affect plants and animals found on treated fields and surrounding areas. For example, spray drift and runoff from Enlist applications threaten flowering plants that provide nectar for pollinators and habitat for other animal species. The use of Enlist products may also affect listed species, such as endangered whooping cranes, which rely on treated fields for food and shelter during migration. 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.

1. 2,4-D Effects

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."⁶⁴ Even with mitigation measures in place, EPA found "there are still potential runoff risks for terrestrial and wetland plants."⁶⁵

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."⁶⁶ 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."⁶⁷ 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."⁶⁸ EPA also found adverse direct risks to on-field monarch butterflies, and potential indirect adverse effects to on-field and off-field milkweeds.⁶⁹

⁶² 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")

⁶³ *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.")

⁶⁴ *Id.* at 8.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

2. Glyphosate Effects

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."⁷⁰ Even with spray drift reduction measures, EPA confirmed "there is still potential risk to terrestrial and wetland plants from runoff." *Id.*

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."⁷¹ 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."⁷²

V. ESA VIOLATIONS

A. EPA has violated its duties under section 7 of the ESA.

EPA's registration decisions regarding Enlist One and Enlist Duo triggered EPA's duty to comply with section 7 of the ESA and its implementing regulations. EPA is tasked with registering these herbicide products under FIFRA, and EPA retains discretionary authority and control over these registrations.⁷³ EPA has failed to comply with the substantive and procedural requirements of section 7 of the ESA.

EPA has violated its duties under section 7(a)(2) by failing to initiate and complete formal consultation *before* taking final agency action. Despite concluding that the proposed registrations "may affect" hundreds of species and habitats, EPA did not request formal consultation until the day before approving the registrations for an additional seven-year term. EPA did the same when it decided to remove hundreds of county-level restrictions from product labels. In addition to violating its mandatory duty to consult with the expert wildlife agency, EPA has also violated its duty to prevent jeopardy to listed species and adverse modification of critical habitats. In addition, EPA violated its duty to maintain the status quo during consultation under section 7(d).

B. Duty to Consult

1. EPA has a mandatory duty to consult with the expert wildlife agency.

Section 7(a)(2) requires EPA to consult with the expert wildlife agencies whenever a proposed registration action "may affect" listed species or designated critical habitats.⁷⁴ The purpose of consultation is to obtain the expert opinion of wildlife agencies to determine whether the action is

⁷⁰ *Id.* at 14.

⁷¹ *Id.*

⁷² *Id.*

⁷³ See *supra* note 8.

⁷⁴ See 50 C.F.R. § 402.14(a).

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.”⁷⁵

As discussed above, EPA knew that use of Enlist products “may affect” hundreds of listed species and habitats months before it made the final registration decisions at issue. 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. In its initial effects determination based on the proposed labels submitted in May 2021, EPA again confirmed that use of Enlist products “may affect” numerous listed species and habitats.⁷⁶ Under ESA’s consultation requirements, EPA was required to initiate formal consultation as soon it determined the proposed registration “may affect” listed species.⁷⁷

2. EPA violated its duties by delaying formal consultation.

Although the registrations clearly surpassed the low “may affect” threshold for formal consultation,⁷⁸ EPA unlawfully delayed consultation in a bold attempt to escape its duties under the ESA. Rather than initiate formal consultation at the earliest stage possible, as required under ESA’s implementing regulations, EPA did not initiate formal consultation until the day before authorizing the registrations.⁷⁹ Therefore, because EPA failed to initiate consultation as soon as EPA determined that the proposed registrations “may affect” hundreds of listed species and critical habitats, EPA violated the formal consultation procedures and its duties under the ESA. EPA also continues to violate its consultation duties because formal consultation is ongoing.

The ESA requires formal consultation with the expert wildlife agency at the earliest opportunity to ensure EPA, as the action agency, does not take any action that will jeopardize listed species or critical habitats.⁸⁰ By strategically delaying formal consultation until EPA has already authorized the registrations, EPA has shut out the expert wildlife agency from the decision-making process, making it impossible for EPA to fully evaluate potential jeopardy to endangered and threatened species and their habitats before taking final action. Therefore, EPA’s delay in initiating consultation violated the purpose of consultation and the formal consultation procedures outlined in ESA’s implementing regulations.

The undersigned parties intend to seek declaratory and injunctive relief to ensure EPA does not continue to evade duties under the ESA in this action—or any future pesticide registration actions—by delaying formal consultation.

3. EPA violated its duties by failing to complete consultation.

EPA violated its substantive duty to avoid jeopardy and adverse modification to listed species and their habitats under section 7(a)(2) by failing to consult with FWS before approving the registrations.⁸¹ EPA cannot abrogate its separate, substantive duty to “insure” that its registration

⁷⁵ *Id.*

⁷⁶ See INITIAL EFFECTS DETERMINATION, *supra* note 37.

⁷⁷ See 50 C.F.R. § 402.14(a).

⁷⁸ See *supra* notes 17-19.

⁷⁹ See *supra* notes 52-53.

⁸⁰ See 16 U.S.C. § 1536(a)(2).

⁸¹ *Id.*

actions are not likely to jeopardize the existence of listed species or adversely modify their critical habitat.⁸² For the same reasons that EPA unlawfully failed to satisfy its procedural duty to initiate consultation, EPA has also violated its substantive duty to insure against jeopardy of protected species or adverse modification of designated critical habitat.

C. Duty to Prevent Jeopardy

EPA has a duty to ensure that its actions comply with the ESA. EPA cannot meet its obligations by refusing to initiate formal consultation and relying on its own, legally flawed jeopardy determination in place of the expert opinion.

1. EPA improperly relied on informal meetings to prevent jeopardy.

EPA did not fulfill its consultation duties simply by meeting with FWS during the decision-making process on various pesticide issues.⁸³ The ESA and its implementing regulations provide specific procedures for initiating and terminating formal consultation,⁸⁴ and EPA has violated these procedures by delaying consultation until the day before announcing its final decision. Although ESA's regulations provide several opportunities for EPA to consult with FWS *before* initiating formal consultation, these informal consultations are entirely optional, and they are *not* intended to replace or delay formal consultation. Moreover, EPA's informal meetings with FWS do not constitute "early consultation" or "informal consultation" under the procedures outlined in the regulations.⁸⁵ Thus, EPA's blatant disregard for the ESA's formal consultation requirements is improper.

In addition to violating the procedures outlined in the regulations, EPA failed to ensure the registration decisions would not jeopardize listed species or adversely modify their habitats through consultation. The consultation requirement is meant to ensure that EPA does not take actions "likely to jeopardize the continued existence" of endangered species or "result in the destruction or adverse modification" of their critical habitat.⁸⁶ Because EPA decided to register Enlist products before giving FWS an opportunity to review the proposed registrations and formulate an expert opinion on the likelihood of jeopardy, EPA's registrations threaten to jeopardize listed species and adversely modify designated critical habitats. The undersigned parties intend to seek declaratory and injunctive relief to ensure EPA does not continue to rely on informal meetings to skirt its formal consultation duties in this action—or any future pesticide registration actions.

⁸² See, e.g., *Pyramid Lake Paiute Tribe of Indians v. U.S. Dept. of Navy*, 898 F.2d 1410, 1415 (9th Cir. 1990) ("federal agency cannot abrogate its responsibility to ensure that its actions will not jeopardize a listed species"); *Stop H-3 Ass'n v. Dole*, 740 F.2d 1442, 1460 (9th Cir. 1984); see also *Nat'l Wildlife Fed. v. Coleman*, 529 F.2d 359, 369 (5th Cir. 1976) ("federal agency . . . must determine whether it has taken all necessary action to insure that its actions will not jeopardize the continued existence of" a listed species or critical habitat).

⁸³ EPA falsely asserts that it complied with the ESA because it "began informal consultation with the FWS on October 13, 2021." ESA Section 7(d) Consistency Determination re: GF-3335 (Enlist One) Registration (Jan. 10, 2022), ESA Section 7(d) Consistency Determination re: Enlist Duo Registration (Jan. 10, 2022).

⁸⁴ See *supra* note 21.

⁸⁵ See 50 C.F.R. §§ 402.13 (informal consultation), § 402.11 (early consultation).

⁸⁶ 16 U.S.C. § 1536(a)(2); see also *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1127 (9th Cir. 2012) ("[a]rbitrarily and capriciously relying on a faulty [BiOp] violates this duty."); *id.* at 1127–28 ("agency cannot meet its section 7 obligations by relying on a [BiOp] that is legally flawed or by failing to discuss information that would undercut the opinion's conclusions."); see also *Colo. Emntl. Coal. v. Off. of Legacy Mgmt.*, 302 F. Supp. 3d 1251, 1272 (D. Colo. 2018) ("agency behaves arbitrary and capriciously when it relies on a BiOp resulting from a materially defective consultation").

2. EPA improperly relied on its own determinations to prevent jeopardy.

EPA did not fulfill its duties simply by preparing an effects determination and reaching its own opinions on the likelihood of jeopardy. EPA's effects determination is merely the first step of the formal consultation process. It is not meant to replace the expert wildlife agency's biological opinion. In fact, the regulations specifically contemplate coordination with the expert wildlife agencies during the preparation of EPA's effects determination. For example, the expert wildlife agency must "[p]rovide relevant species information" and "guidance to assist [EPA] in completing its effects analysis in the initiation package" upon request.⁸⁷ Moreover, the regulations encourage EPA to coordinate with the expert wildlife agency during the preparation of its initiation package "[t]o maximize efficiency and ensure that it develops the appropriate level of information."⁸⁸

Although EPA's effects determination *can* include its "conclusion whether or not the FIFRA action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and a description of any reasonable and prudent alternatives that may be available,"⁸⁹ this conclusion is not intended to replace the biological opinion of the expert wildlife agency. The ESA expressly tasks the expert wildlife agency, not EPA, with formulating an opinion on whether a proposed action is likely to jeopardize listed species.⁹⁰ If FWS wanted to adopt any part of EPA's effects determination in its final expert opinion, it can do so.⁹¹ However, FWS has not yet issued a final biological opinion. Thus, EPA cannot rely on its own effects determinations to comply with the ESA.

EPA violated its duties under the ESA by relying on its own determinations, prepared by its own staff, without any coordination or consultation with the expert wildlife agency. Although EPA could have requested information and assistance from FWS during the preparation of its effects determination to facilitate the formal consultation process and improve its effects determinations, EPA failed to do so. For example, EPA failed to request a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area.⁹² Instead, EPA chose to rely on an outdated list from a previous consultation on an entirely different pesticide registration. EPA also failed to request FWS to provide available information (or references thereto) describing the applicable environmental baseline for each species or habitat that EPA determined may be affected by the registration actions.⁹³ In addition, EPA failed to request FWS to designate a Service Representative to work with EPA in the development of the effects determination.⁹⁴ EPA's refusal to consult with the expert wildlife agency during the decision-making process violates its duty to prevent jeopardy through consultation under section 7(a)(2).

⁸⁷ 50 C.F.R. § 402.14(l)(3)(i).

⁸⁸ *Id.* § 402.14(l)(2).

⁸⁹ *Id.* § 402.40(b)(1).

⁹⁰ *Id.* § 402.14(g)(4);

⁹¹ *Id.* §§ 402.14(h)(3)(i); § 402.46(c)(1)(i).

⁹² *Id.* §§ 402.12(c)(1); § 402.43.

⁹³ *Id.* § 402.43.

⁹⁴ *Id.* § 402.44(a).

Accordingly, EPA violated its duty to consult and avoid jeopardy under section 7(a)(2) by re-interpreting the express terms and purpose of the ESA. The undersigned parties will seek declaratory and injunctive relief to ensure EPA does not continue to violate the ESA in this action—or any future pesticide registration actions.

In sum, EPA’s actions contradict the procedures provided in ESA’s implementing regulations, as well as the purpose of formal consultation. Because EPA decided to register Enlist products before initiating formal consultation with the expert wildlife agency, EPA’s registration actions threaten to jeopardize listed species and adversely modify critical habitats, in violation of section 7(a)(2) of the ESA.

3. EPA unlawfully restricted each step of its effects determinations.

At each step of EPA’s effects determinations and mitigation evaluations, EPA unlawfully constricted the scope of its analysis. Consequently, EPA’s assessments do not accurately reflect the potential risks to listed species and critical habitats, in violation of EPA’s duty to avoid jeopardy and use the best available science and methods.

a. Action Area

EPA approved the use of Enlist products on millions of acres of corn, cotton, and soybean fields in 34 states. The action area includes hundreds of threatened and endangered species and designated critical habitats.⁹⁵ In its effects determinations, EPA identified numerous listed species and designated critical habitats within 1,500 meters of corn, cotton, and soybean fields in the 34 states approved for use.⁹⁶ If EPA had evaluated the listed species and habitats in *all* areas directly or indirectly affected by the action, “and not merely the immediate area involved in the action,” as required under the ESA,⁹⁷ EPA would have identified several additional listed species and habitats in the action area.

EPA also unlawfully narrowed its analysis of listed species located within the action area (i.e., “overlap analysis”). In June 2022, nearly six months after authorizing the continued use of Enlist One and Enlist Duo and four months after removing hundreds of county-level prohibitions, EPA determined that it had improperly excluded numerous listed species and critical habitats from its previous effects determinations because its overlap analysis was overly restrictive.⁹⁸ EPA only reconsidered its overlap approach due to its formal consultation with FWS,⁹⁹ demonstrating that EPA’s effects determinations excluded several listed species and their habitats. EPA could have identified these issues before taking final action if it had initiated formal consultation at the earliest possible time, as required.

⁹⁵ See Appendix A (Listed Species With Current Range in States Approved for Use of Enlist One & Enlist Duo).

⁹⁶ See INITIAL EFFECTS DETERMINATION, *supra* note 37, at Table 4-3 (List of Listed Species of Concern) and Table 4-4: (List of Listed Species Designated Critical Habitats of Concern).

⁹⁷ 50 C.F.R. § 402.02 (“action area”).

⁹⁸ See RE-EVALUATED EFFECTS DETERMINATION, *supra* note 48.

⁹⁹ See Consultation Update Letter re: Re-evaluated Effects Determination, *supra* note 52.

b. *“May Affect” Determination*

In addition to restricting the number of listed species and habitats in the affected area, EPA further constricted its analysis based on unlawful conditions and hurdles, such as FWS’s life history and habitat descriptions. FWS does not provide descriptions for many species under its jurisdiction.¹⁰⁰ From other documents and summaries on FWS’s website, many of these species are potentially affected by EPA’s registrations. Thus, EPA unlawfully excluded species based on life history descriptions.

EPA also improperly constricted its analysis based on the environment of the species, habitats, and exposure (i.e., on-field, within 30 meters of the field (terrestrial), within 1,500 meters of the field (wetland or aquatic non-wetland)) and type of effect (direct or indirect). EPA does not have the expertise or resources to properly review the life history and habitat information for listed species. Thus, EPA unlawfully constricted its analysis based on habitat and life history factors.

Based on EPA’s unlawful species-specific and habitat-specific refinements, EPA determined that the registrations “may affect” 20 listed animals on-field, 49 listed plants, 5 listed species with an obligate relationship with terrestrial plants, and 155 generalist species. EPA also made “may affect” determinations for 2 on-field animal designated critical habitats, 3 plant designated critical habitats, and 62 generalist designated critical habitats. This analysis likely underestimates the total number of listed species and critical habitats that may be affected by EPA’s registrations because EPA unlawfully constricted its analysis.

c. *“Likely to Adversely Affect” Determinations*

EPA further restricted its analysis of potentially affected species to determine the “likely adversely affected” species. EPA’s effects determinations were based on several factors outside its expertise and authority, such the “effects to other resources that the listed species rely upon (i.e., for prey, pollination, habitat and/or dispersal). For example, for terrestrial environments (within 30 meters of the field), EPA summarily concluded that non-plant dependent species were not likely adversely affected because the “effects on plants were not reasonably expected to translate through the ecosystem to impact non-plant dependent taxa.”¹⁰¹ Even though these “species require other species to complete their life cycle,” and their prey may depend on plants, EPA did not consider the indirect effects from loss of food sources and habitat.¹⁰² EPA improperly relied on the same assumptions in its subsequent effects determinations of off-field listed species.

EPA determined the registrations were not likely adversely affect any designated critical habitats that did not include principal constituent element (PCEs) descriptions about the “integral plant portions of the habitat,” potentially numerous adversely affected habitats.¹⁰³ EPA also excluded designated critical habitat “if the PCEs did not describe the habitats of larval (glochidia) hosts.”¹⁰⁴ For those PCEs “identified as agricultural fields,” EPA made a NLAA determination for the designated critical habitat because “these are maintained by the agricultural practice and likely

¹⁰⁰ FWS’s Data Explorer includes 10,317 distinct species. However, FWS only provides habitat, food, movement, and/or species descriptions for 1,731 distinct species. FWS does not provide such information for 9,331 distinct species.

¹⁰¹ INITIAL EFFECTS DETERMINATION, *supra* note 37, at 156–57.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

include the use of pesticides.”¹⁰⁵ EPA failed to consider whether its decisions would increase use of Enlist products or any other pesticides on these fields. Thus, EPA’s approach to evaluating the likelihood of adverse effects for designated critical habitats is improper because EPA relied on unlawful assumptions outside its expertise.

d. Jeopardy Determination

Based on EPA’s unlawfully restricted effects determination, EPA evaluated whether its actions were likely to jeopardize the continued existence of a species. For the listed species and designated critical with LAA determinations, EPA evaluated whether the effects are likely to lead to jeopardy or adverse modification based on information in FWS’s Draft Biological Opinion for Malathion (2021). Specifically, EPA relied on the overall vulnerability of the listed species and other risk modifiers outlined in the FWS Draft Malathion BiOp. Rather than consult with expert wildlife agency directly, EPA attempted to bypass the consultation process by relying on outdated information from FWS’s previous biological opinions on a different pesticide product. EPA also relied on FWS’s draft BiOp in its subsequent jeopardy determinations.¹⁰⁶ Thus, EPA improperly relied on this biological opinion to meet its ESA obligations.

EPA also evaluated factors outside its expertise to reach a “no jeopardy” determination. For example, if a listed animal species “utilizes multiple terrestrial and wetland habitat types or does not depend on plants for the primary diet, EPA determined it would not likely lead to jeopardy.”¹⁰⁷ EPA failed to consider the indirect effects to the species, such as loss of food sources and feeding habitat during an important stage of its lifecycle. Therefore, EPA’s jeopardy determinations fail to “insure” against jeopardy and adverse modification to listed species and critical habitats.

4. EPA improperly relied on labeling requirements to prevent jeopardy.

Based on EPA’s unlawfully restricted effects determination, EPA concluded that mitigation measures to avoid and minimize effects to listed species were necessary to prevent adverse effects to listed species and critical habitats. Instead of consulting with FWS, as required under the ESA, EPA only coordinated with Corteva (the applicant and manufacturer of Enlist products), deliberately excluding the expert wildlife agency from the decision-making process. Based on EPA’s flawed evaluation of its own mitigation measures, EPA unilaterally determined that the county-level prohibitions and runoff measures included in the final approved labels avoid exposures to listed species that use corn, cotton, or soybean fields and minimize off-site transport via runoff and spray drift. Because EPA subsequently removed the vast majority of county-level prohibitions in the final labels,¹⁰⁸ 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

¹⁰⁵ *Id.*

¹⁰⁶ *See, e.g.*, AMENDED EFFECTS DETERMINATION, *supra* note 45, at 9 (“For the species that overlap with the current action, EPA then followed the methodology outlined in [INITIAL EFFECTS DETERMINATION] and made effects determinations and the likelihood of jeopardy or adverse modification.”); RE-EVALUATED EFFECTS DETERMINATION, *supra* note 48, at 4 (“For the eight additional [on-field] species with LAA determinations, EPA also looked at the potential for jeopardy/adverse modification using the process from the Enlist assessment.” (citing section 4 of the INITIAL EFFECTS DETERMINATION)).

¹⁰⁷ INITIAL EFFECTS DETERMINATION, *supra* note 37, at 158.

¹⁰⁸ *See* Amended Decision Memo, *supra* note 36.

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 relied on runoff measures to mitigate jeopardy to numerous listed species.

EPA cannot rely on mitigation measures to obtain a “no effect” determination under the ESA unless the measures sufficiently protect wildlife and habitats.¹⁰⁹ Based on evidence in the record demonstrating noncompliance with previous labels and other user data, the measures in the revised labels are not likely to change when or how users apply Enlist products or reduce exposure to Enlist products. Moreover, the measures threaten to *increase* potential risks because they are not specific or binding. Thus, EPA improperly relies on measures in the final approved labels to conclude that the registrations and amendments would not result in jeopardy or adverse modification.¹¹⁰ EPA thus violated the ESA by failing to implement “reasonable and prudent measures” to prevent jeopardy.¹¹¹

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.¹¹² 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.”¹¹³ 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. 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.”¹¹⁴ 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.

5. EPA improperly relied on initial effects determination.

Although EPA has acknowledged some of the flaws with its initial effects determination, EPA continues to rely on this determination and the approach outlined therein for all subsequent effects determinations. In doing so, EPA improperly restricts its analysis to a subset of the species and habitats considered in its initial effect determination. EPA’s piecemeal approach is unlawful because it fails to capture the individual and cumulative impacts of its registration decisions on listed

¹⁰⁹ See *Nat’l Family Farm Coalition v. EPA*, 966 F.3d 893, 901, 927 (9th Cir. 2020) (*Enlist II*) (“[M]itigation measures that merely ‘reduce,’ but cannot scientifically ‘eliminate’ an ‘effect’ probably compel a ‘may affect’ finding.” (citing *Karuk Tribe*, 681 F.3d at 1028)).

¹¹⁰ See, e.g., *Pollinator Stewardship v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (vacating EPA’s unconditional registration of sulfoxaflor because EPA failed to provide evidence to support its decision that a lower application rate and other mitigation measures would protect bees).

¹¹¹ “Reasonable and prudent measures” are “actions the [expert wildlife agency] believes necessary or appropriate to minimize the impacts, i.e., amount or extent, of incidental take.” 50 C.F.R. § 402.02.

¹¹² The ESA defines “conservation” as “the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided [under the ESA] are no longer necessary.” 16 U.S.C. § 1532. “Conservation recommendations” are “suggestions of the [expert wildlife agency] regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.” 50 C.F.R. § 402.02.

¹¹³ *Id.* (emphasis added).

¹¹⁴ BALANCING WILDLIFE PROTECTION & RESPONSIBLE PESTICIDE USE: HOW EPA’S PESTICIDE PROGRAM WILL MEET ITS ESA OBLIGATIONS 27 (APR. 2022) (“ESA Workplan”) (emphasis added).

species and their critical habitats. Therefore, EPA’s “no jeopardy” determinations regarding the revised labels and amended labels are arbitrary, capricious, and in violation of the ESA.

For example, in its effects determination on the proposed amendments to remove 128 county-level prohibitions, EPA only conducted new analyses for the “newly identified species that overlap with the current action and for which EPA did not conduct ESA analyses in [the initial effects determination] (five species and one critical).”¹¹⁵ As a result of EPA’s restricted analysis, “EPA did not identify any species or [critical habitats] that was not included in the [initial] effects determination that would potentially result in a determination of likely jeopardy or likely adverse modification”¹¹⁶ EPA also concluded that the nationwide mitigation measures in the existing labels would sufficiently mitigate any potential effects. Thus, for the reasons stated above, EPA’s registrations fail to meet the ESA’s protective standards because EPA improperly relied on its flawed effects analysis and mitigation evaluation.

In sum, EPA violated its duty under section 7(a)(2) to “insure” against jeopardy to listed species and adverse modification of their habitats by failing to consult with the expert wildlife agency and improperly restricting its effects analysis and mitigation evaluations.

D. Duty to Use Best Available Science

The ESA requires EPA to use the best scientific and commercial data available to complete its effect determinations. EPA must not “disregard available scientific evidence that is in some way better than the evidence it relies on.”¹¹⁷ EPA violated its duties under the ESA by ignoring available data and continuing to rely on outdated methods outside its expertise.

1. EPA failed to use best available data to make effects determination.

EPA violated the ESA by renewing the registrations of Enlist One and Enlist Duo using the risk quotient/level of concern approach in its effects determination. There is better data available, and the expert wildlife agencies would have relied on this data if EPA had properly consulted with these agencies before authorizing the registrations.

In 2013, the National Academy of Sciences (NAS) issued a final report with recommendations regarding the best available scientific approaches and data for ESA consultations on pesticide uses.¹¹⁸ In this report, the NAS 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 2017.¹¹⁹ 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 to

¹¹⁵ See, e.g., AMENDED EFFECTS DETERMINATION (March 2022), *supra* note 45, at 9 (“The methods used for this evaluation followed those described in Section 4 of [the INITIAL EFFECTS DETERMINATION].”).

¹¹⁶ *Id.* at 13.

¹¹⁷ *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014).

¹¹⁸ NAT’L RESEARCH COUNCIL, ASSESSING RISKS TO ENDANGERED & THREATENED SPECIES FROM PESTICIDES (2013).

¹¹⁹ See *Enlist II*, *supra* note 109, 966 F.3d at 926–27.

Congress EPA and the consultation agencies sent to Congress in November 2014.”¹²⁰ The EPA and the expert wildlife agencies did not, however, specifically agree that EPA could use the risk quotient/levels of concern approach for the registrations of Enlist One or Enlist Duo in 2022, nearly a decade later.¹²¹

Moreover, there is evidence that EPA’s risk quotient/level of concern approach is neither “highly conservative” or “protective of non-target species, including endangered species.”¹²² In addition, EPA has significantly delayed implementation of NAS’s proposed approach. Although the Ninth Circuit upheld EPA’s reliance on the flawed risk quotient approach in registering Enlist Duo 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.”¹²³ However, EPA continues to rely on the flawed risk quotient approach, rather than adopt the recommended probabilistic approach. Therefore, EPA has violated the ESA by refusing to use the best available science in its effects determinations.

2. EPA ignored recently added threatened or endangered species.

EPA did not use the best available information regarding listed species or habitats. According to EPA, the agency used listed species and designated critical habitat locations provided by the expert wildlife agencies in November 2020. EPA knew this information was outdated at the time of its analysis.¹²⁴ Although EPA did not consider “[s]pecies and designated [critical habitats] that have been added to the list since November 2020” in its initial effects determination, EPA did delete any species and designated critical habitats “that were removed from the list (*i.e.*, delisted due to recovery or extinction) since November 2020.”¹²⁵ EPA acknowledged that “several new species were added since November 2020; however, because spatial files for these species are not available for this assessment.”¹²⁶ Even though spatial files were not available in a specific format (*i.e.*, shapefiles), data regarding the species range *was* readily available in multiple forms, and EPA could have easily analyzed this data and added it to its overlap map.

EPA has yet to consider these species in any of its subsequent determinations. Since November 1, 2020, FWS has added at least 15 listed threatened or endangered species in states approved for use of Enlist One or Enlist Duo.¹²⁷ Thus, EPA unlawfully ignored recently added species and habitat information in its effects determinations.

¹²⁰ *Id.* at 926 (citing U.S. EPA ET AL., INTERIM REPORT TO CONGRESS ON ESA IMPLEMENTATION IN PESTICIDE EVALUATION PROGRAM (2014)).

¹²¹ In 2014, EPA and the consultation agencies . . . specifically agreed that the risk quotient/levels of concern approach could be used for the registration process for Enlist Duo while EPA began implementing NAS’s new approach.” *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ INITIAL EFFECTS DETERMINATION, *supra* note 37, at 150.

¹²⁵ *Id.*

¹²⁶ *Id.* (“Since EPA downloaded the list of federally threatened and endangered species in November 2020, several updates to the list have been made.”).

¹²⁷ See FWS Data Explorer, Listed Species With Listing Date On or After 11/1/2020.

3. EPA ignored actual use data and future trends.

EPA also violated its duty to use the best available science for failing to consider recent use data in its effects determinations and mitigation evaluations, even though this information was available to EPA at the time of its assessments. In addition, EPA ignored historical data and future trends in its effects analysis and mitigation evaluations.

E. Duty to Maintain Status Quo under Section 7(d)

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.¹²⁸ “This prohibition . . . continues until the requirements of section 7(a)(2) are satisfied,”¹²⁹ meaning that EPA cannot make irreversible commitments until FWS has issued an opinion, and EPA has determined that the action can proceed without jeopardizing listed species or adversely modifying critical habitats. Section 7(d) was enacted “to ensure that the status quo would be maintained during the consultation process, to prevent agencies from sinking resources into a project in order to ensure its completion regardless of its impacts on endangered species.”¹³⁰

1. EPA unlawfully foreclosed implementation of alternatives.

EPA’s registration decisions “foreclos[e] the formulation or implementation of any reasonable and prudent alternative measures” during the consultation period.¹³¹ By authorizing the continued use of Enlist One and Enlist Duo—and expanding its uses to hundreds of additional counties, EPA’s registration decisions facilitate the rapid expansion of the Enlist weed control system. As a result, operators who invest in the Enlist weed control system will not be able to adopt certain alternative weed control options or best management practices in current or future growing seasons. Thus, EPA’s decision not only forecloses the implementation of alternative measures *during* the consultation period, but also subsequent growing years as well. Accordingly, EPA’s decision directly violates its duties under section 7(d), in addition to the intent behind this requirement.

CONCLUSION

EPA has violated, and continues to violate, section 7 of the ESA and its implementing regulations in at least the following ways:

- **Duty to Consult (Section 7(a))**
 - **Effects Determination**
 - EPA has failed to provide FWS with an effects determination “based on the best scientific and commercial data available.”¹³² EPA’s violation is ongoing because FWS has not issued a biological opinion yet.

¹²⁸ 16 U.S.C. § 1536(d); 50 C.F.R. § 402.09.

¹²⁹ 50 C.F.R. § 402.09.

¹³⁰ *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1034–35 (9th Cir. 2005).

¹³¹ 16 U.S.C. § 1536(d); 50 C.F.R. § 402.09.

¹³² 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.40(b)(3).

- EPA has 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].”¹³³ EPA’s violation is ongoing because FWS has not issued a biological opinion yet.
 - EPA has failed to provide FWS with an effects determination containing an accurate “description of the effects of the action.”¹³⁴ EPA’s violation is ongoing because FWS has not issued a biological opinion yet.
 - EPA has failed to provide FWS with an effects determination containing an accurate “analysis of any cumulative effects.”¹³⁵ EPA’s violation is ongoing because FWS has not issued a biological opinion yet.
 - EPA has failed to provide FWS “with the best scientific and commercial data available . . . during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat.”¹³⁶ EPA’s violation is ongoing because FWS has not issued a biological opinion yet.
 - **Formal Consultation on Listed Species & Critical Habitat (Section 7(a)(2))**
 - EPA failed to initiate formal consultation with FWS after determining that the registrations may affect listed species or critical habitat.¹³⁷
 - EPA has failed to “determine whether and in what manner to proceed with the action in light of its section 7 obligations and the [FWS’s] biological opinion.”¹³⁸ EPA’s violation is ongoing because FWS has not issued a biological opinion yet.
 - **Conference on Proposed Species & Critical Habitats (Section 7(a)(4))**
 - EPA has failed to confer with FWS on actions likely to jeopardize the continued existence of proposed species.¹³⁹ EPA’s violation is ongoing because EPA has not conferred with FWS yet.
 - EPA has failed to confer with FWS on actions likely to result in the destruction or adverse modification of proposed critical habitat.¹⁴⁰ EPA’s violation is ongoing because EPA has not conferred with FWS yet.
- **Duty to Prevent Jeopardy & Adverse Modification (Section 7(a)(2))**
 - EPA has failed to insure, through consultation with the expert wildlife agencies, that the registration actions are not “likely to jeopardize the continued existence” of any threatened or endangered species.¹⁴¹ EPA’s violation is ongoing.
 - EPA has failed to insure, through consultation with the expert wildlife agencies, that the registration actions are not likely to “result in the destruction or adverse modification” of any critical habitats.¹⁴² EPA’s violation is ongoing.

¹³³ 50 C.F.R. § 402.14(c)(1)(ii).

¹³⁴ *Id.* § 402.14(c)(1)(iv).

¹³⁵ *Id.*

¹³⁶ *Id.* § 402.14(d).

¹³⁷ *Id.* § 402.14(a); *see also id.* § 402.42(a)(5).

¹³⁸ *Id.* § 402.15(a); *see also id.* § 402.42(a)(8).

¹³⁹ 16 U.S.C. § 1536(a)(4); *see also* 50 C.F.R. §§ 402.10(a); § 402.10(b); § 402.48.

¹⁴⁰ *See supra* note 139.

¹⁴¹ 16 U.S.C. § 1536(a)(2).

¹⁴² *Id.*

- **Duty to Prevent Irreversible Commitments (Section 7(d))**

- 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.”¹⁴³ EPA’s violation is ongoing.

For the reasons stated above, the listed organizations intend to sue EPA for declaratory and injunctive relief, and any other relief deemed necessary, as well as fees and costs.¹⁴⁴ This letter was prepared based on good faith information and belief after diligent investigation.

Sincerely,

/s/Kristina Sinclair

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¹⁴³ 16 U.S.C. § 1536(d).

¹⁴⁴ *See id.* § 1540(g)(4).