December 1, 2016

Environmental Protection Agency
Mailcode 28221 T
1200 Pennsylvania Ave, NW
Washington, DC 20460


Please accept the following comments on behalf of the Center for Biological Diversity (“Center”) in response to the Environmental Protection Agency’s (“EPA”) proposed registration decision of Enlist Duo Herbicide under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”).

The Center is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has 1.1 million members and online activists dedicated to the protection and restoration of endangered species and wild places. The Center has worked for many years to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center’s Pesticides Reduction Campaign aims to secure programmatic changes in the pesticide registration process and to stop toxic pesticides from contaminating fish and wildlife habitats. We appreciate the opportunity to provide comment.

On October 15, 2014 the EPA registered “Enlist Duo,” a new pesticide product containing two active ingredients – 2,4-dichlorophenoxyacetic acid choline salt ("2,4-D") and glyphosate dimethylammonium salt ("glyphosate") – and “other ingredients.” The EPA registered the Enlist Duo product under Registration Number 62719-649 for control of annual and perennial weeds and use on genetically engineered ("GE") “Enlist” corn and soybeans in six states.¹ On March 31, 2015, the EPA amended the Enlist Duo product label to allow the use of Enlist Duo in nine additional states (15 states total).

The Center and others petitioned for judicial review of both the EPA’s decision to initially register the pesticide product Enlist Duo and its decision to amend the label to expand the use of Enlist Duo

¹ Final Registration of Enlist Duo™ Herbicide, EPA Docket # EPA-HQ-OPP-2014-0195-2417; see also Notice of Pesticide Registration, EPA Docket # EPA-HQ-OPP-2014-0195-2416 (10/15/2014) (registering Enlist Duo).
to nine additional states. Before the Center’s claims could be heard by the court on the merits, the EPA discovered that the applicant, Dow AgroSciences (“Dow”), had failed to provide the EPA with information, studies or data that Dow used in a patent application to the U.S. Patent and Trademark Office (“USPTO”) that claimed synergism between 2,4-D and glyphosate, the two active ingredients in Enlist Duo. The EPA sought a voluntary remand from the court because it could no longer represent to the court that its decision to register Enlist Duo was correct under FIFRA or the Endangered Species Act (“ESA”).

Meanwhile, Dow asked the EPA to more than double the number of states in which Enlist Duo could be used on GE corn and soybeans (from 15 states to 34 states). In addition, Dow has asked the EPA to expand the crop uses to include GE cotton in these 34 states.

The EPA is now proposing a new registration decision for Enlist Duo that has three components:

- First, the EPA is proposing to maintain the original registration of Enlist Duo, as amended, for use on GE soybean and corn in 15 states.
- Second, the EPA is proposing to add 19 states in which Enlist Duo may be used on GE soybean and corn.
- Third, EPA is proposing to add a new use of Enlist Duo for GE cotton in all 34 states where the EPA is proposing to register Enlist Duo for use on GE soybean and corn, listed above.

In addition to the comments outlined below, we incorporate previous comments the Center made regarding Enlist Duo registration by reference.

**THE EPA APPLIES AN UNLAWFUL FRAMEWORK TO ASSESS THE EFFECTS OF THE REGISTRATION OF ENLIST DUO**

Pursuant to FIFRA, the EPA registers pesticide products, not active ingredients. Yet here, for the new product Enlist Duo, the EPA has only assessed the adverse effects of the active ingredient 2,4-D, ignoring the adverse effects of the product, including the other active ingredient, glyphosate, and any other ingredients contained in the product mixture. The EPA’s framework for its assessments, which does not assess the adverse effects of the product, renders any registration decision unlawful under FIFRA because it will not be supported by substantial evidence. Likewise, the EPA cannot satisfy its ESA duty to ensure against jeopardy because it has not assessed the action it is authorizing: registration of the pesticide product Enlist Duo.

FIFRA prohibits the distribution or sale of any pesticide, unless the EPA registers it under FIFRA. Congress defined a “pesticide” as “any substance or mixture of substances” intended to prevent, 

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2 NRDC v. EPA consolidated with Center for Food Safety v. EPA, Case Nos. 14-73353, 14-73359, 15-71207, 15-71213 (9th Cir.).


4 An exception seems to be the recent vegetative vigor studies for the purported purpose of assessing synergistic effects on plants. The inadequacy of these studies is discussed below.
destroy, repel or mitigate any pest. 7 U.S.C. § 136(u); see also 40 C.F.R. § 152.1 (scope of registration procedures concern “the registration of pesticide products under FIFRA section 3”); 40 C.F.R. § 152.3 (“pesticide product” means a pesticide in the particular form in which the pesticide is intended to be distributed or sold); compare 7 U.S.C. § 136(a) (“active ingredient” means “an ingredient” that will destroy any pest). As the original Notice of Pesticide Registration sets forth, the EPA registered “the above named pesticide,” Enlist Duo, under the unique registration number 62719-649. And, as the D.C. Circuit Court of Appeals has explained, “[a] FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used.” Reckitt Benckiser Inc. v. EPA, 613 F.3d 1131, 1133 (D.C. Cir. 2010) (citing 7 U.S.C. § 136a(a), (c)-(e)).

FIFRA requires the EPA to determine whether: 1) the composition of the pesticide warrants the proposed claims for it; 2) its labeling and other material comply with the requirements of FIFRA; 3) it will perform its intended function without unreasonable adverse effects on the environment; and 4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. The EPA cannot comply with the mandates of FIFRA without undertaking the legally required assessment for the entire product, Enlist Duo.

The ESA requires the EPA to consult, when necessary, to ensure any action it authorizes will not cause jeopardy of an endangered or threatened species or adversely modify its critical habitat. The EPA’s authorization is the registration of the pesticide product, Enlist Duo, which will allow the sale, distribution and use of Enlist Duo. Accordingly, the EPA must assess whether the product, Enlist Duo, may affect any species listed as protected under the ESA.

The EPA has circumvented its duties to evaluate Enlist Duo as a pesticide product. Instead, the EPA gives a cramped explanation that registration of Enlist Duo is a “new use” because Enlist Duo contains two or more active ingredients, and the use being requested for this new combination product is currently registered for one or more of the active ingredients (in other products). Therefore, the EPA concludes, it only assesses the risks of the active ingredient that does not currently have products registered for that use. In other words, because there are already other registered products that contain glyphosate that can be used on GE corn and soybeans, the EPA only assessed the risk associated with 2,4-D on these crops, ignoring the effects of glyphosate and the other ingredients in the product Enlist Duo. The EPA’s approach does not comply with the law.

FIFRA discusses “new use” only in the context of an “amendment adding a new use to an existing registration” or “adding any new use to the registration,” which is the registration of a particular

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5 Pesticide products are labeled, not active ingredients.
6 7 U.S.C. § 136a(c)(5).
8 Proposed Registration of Enlist Duo™ Herbicide at 2, EPA Docket # EPA-HQ-OPP-2016-0594-0015.
pesticide product.\(^9\) When the EPA receives applications to register new uses for currently registered pesticide products, it is required to provide public notice.\(^10\) For example, the EPA recently provided notice of applications to register new uses for currently registered pesticide products, specifying each product by EPA Registration Number and the proposed new uses for each product.\(^11\) Here, the EPA is proposing to register a new product altogether, not simply approve additional uses for a registered product. The EPA regulations define “new use” in the context of a product containing a particular active ingredient, if no product containing the active ingredient is currently registered for that use pattern.\(^12\) The regulation does not contemplate, nor could it, defining “new use” to include registration of a new product with multiple active ingredients and limiting the “new use” to one of the active ingredients, but not the other, or the substance mixture contained in the product itself. The EPA’s attempt to characterize the registration of Enlist Duo as a “new use” violates FIFRA.

Recognizing it has a problem for the other active ingredient glyphosate, the EPA treats Dow’s application to register Enlist Duo as if it were a “me too” pesticide product registration. This interpretation is equally unavailing. The EPA asserts that it has authority to issue conditional registrations for pesticide products that are identical or substantially similar in uses and formulations to previously approved products that are already registered.\(^13\) The authority the EPA appears to be referencing, 7 U.S.C. § 136a(c)(7), is inapplicable for at least two reasons. First, this provision only applies to conditional registrations.\(^14\) Second, Enlist Duo is not identical or substantially similar to any currently registered pesticide and use thereof.\(^15\) As the EPA’s regulations provide, to determine whether a product is “identical to or substantially similar” to another product, involves the comparison of “product composition.” No other pesticide product is composed of 2,4-D and glyphosate for use on GE corn and soybeans.\(^16\) In fact, the substance mixture in Enlist Duo is unique enough that Dow applied to patent it.\(^17\) The EPA cannot slice glyphosate out of Enlist Duo to avoid assessing the adverse effects of the product by claiming this is just a “me too” registration because the products are not substantially similar. Moreover, the use of this product significantly increases the risk of unreasonable adverse effects on the environment, as it

\(^10\) 7 U.S.C. § 136a(c)(4); see also 40 C.F.R. § 152.102 (EPA will issue notice in the Federal Register “receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use” (emphasis added)).
\(^12\) 40 C.F.R. § 152.3
\(^13\) Registration of Enlist Duo™ Herbicide at 2 n.2, EPA Docket # EPA-HQ-OPP-2016-0594-0015
\(^14\) The EPA initially registered Enlist Duo pursuant to FIFRA Section 3(c)(5), not 3(c)(7). See, e.g. Declaration of Earl G. Ingram, Jr. ¶ 5 filed on behalf of the EPA in Center for Biological Diversity v. U.S. EPA, Civ. No. 16-cv-00175 (BAH), Doc. 16-2 (D.C.D.C. Decl. filed Nov. 23, 2016).
\(^15\) Other portions of FIFRA also demonstrate that a “me too” registration is for products that are “substantially similar in composition and labeling to a currently-registered pesticide” product; not new products that contain a new combination of active ingredients for new uses on GE crops. See 7 U.S.C. § 136a(c)(3)(B).
\(^16\) 40 U.S.C. § 158.30(b) (one purpose of registration data concerning product composition is to determine whether a product is “identical to or substantially similar” to another product, a determination that involves the comparison of product composition.”
will allow the frequent application of two toxic herbicides simultaneously and over-the-top of the crops (later in the growing season).

The EPA cannot avoid the fact that it is registering a pesticide product that is a new pesticide substance mixture. It must assess the adverse effects of the entire product on humans, the environment and species protected under the ESA.

**THE EPA HAS NOT COMPLIED WITH ITS DUTIES UNDER THE ENDANGERED SPECIES ACT**

The EPA’s proposed registration of the Enlist Duo product does not comply with the mandates Congress established in Section 7 of the ESA, as interpreted by the expert wildlife agencies in the ESA regulations and handbook, the courts, and as recently set forth by the National Academies of Sciences (“NAS”). Instead, for assessments of new herbicide tolerant crop uses, such as the proposed use of Enlist Duo on herbicide resistant corn, cotton and soybean, the EPA applies its FIFRA risk assessment to unlawfully avoid ESA “may affect” determinations. These “may affect” determinations require informal consultation and written concurrence from the wildlife agencies or formal consultation and a biological opinion.

The new Interim Approaches for effects determination, based on the National Academies of Sciences report entitled “Assessing Risks to Endangered and Threatened Species from Pesticides,”¹¹⁸ (hereafter “NAS report”) lays out an approach that the EPA should use as a guide to begin to comply with its obligations under the ESA.

Following the publication of the NAS report in 2013, the agencies have developed two policy documents to guide consultations on pesticide review and approvals moving forward: (1) *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes,*¹⁹ and (2) *Interim Approaches for National-level Pesticide Endangered Species Act Assessments Based on Recommendations of the National Academy of Science April 2013* (Hereafter “Interim Approaches”).²⁰

As laid out in the NAS report and *Interim Approaches*, the risk assessment and consultation process should follow three steps.²¹ These steps generally follow the three inquiries of the ESA consultation process: (1) the “no effect”/ “may affect” determination (2) the “not likely to adversely...

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²¹ NAS REPORT at Figure 2-1.
affect”/ “likely to adversely affect” determination (3) the jeopardy/no jeopardy and adverse modification/no adverse modification of critical habitat determination.

The agencies made clear at a November 15, 2013 public meeting that it would apply the NAS recommendations and Interim Approaches “day forward” and in November of 2014 made the same statement in a report to Congress. However, the EPA arbitrarily decided that it will only apply the Interim Approaches in the context of registration review. For new herbicide tolerant crop uses, the EPA states it will do “Overview Document-compliant” endangered species assessments. The Overview Document, and the assessment conducted for this new use of 2,4-D and Enlist Duo, reverts to the same “Risk Quotient” and “Level of Concern” approach that the NAS found is not adequate to determine the effects on endangered and threatened species. While EPA may not be legally bound by the NAS recommendations or the Interim Approaches, EPA is not free to violate the ESA.

The effects determinations associated with over-the-top 2,4-D usage and proposed registration of Enlist Duo on soybean, corn and cotton do not fulfill EPA’s obligations under the ESA. Listed below are inadequacies that have been identified with the current approach for assessing risk to endangered species that is encompassed in the following documents (Hereafter “Current Approach”) as well as measures that could be taken by EPA to become compliant with the ESA moving forward.

EPA Makes Improper “No Effect” Determinations

As the U.S. Fish and Wildlife Service (“FWS”) and National Marine Fisheries Service (“NMFS”) (collectively the “Services”) joint consultation handbook explains, an action agency such as the EPA is permitted to make a “no effect” determination, and thus avoid undertaking informal or formal consultations, only when “the action agency determines its proposed action will not affect listed species or critical habitat.” To put this in context, the

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22 INTERAGENCY APPROACH FOR IMPLEMENTATION OF NATIONAL ACADEMY OF SCIENCES REPORT: ASSESSING RISKS TO ENDANGERED AND THREATENED SPECIES FROM PESTICIDES, Public Meeting Silver Spring NOAA Auditorium (Nov. 15, 2013).
24 Id. at 21-22.
Services define “may affect” as “the appropriate conclusion when a proposed action may pose any effects on listed species or designated critical habitat.” The phrase “may affect” has been interpreted broadly to mean that “any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement.”

For this initial stage of review, exposure to a pesticide does not require that effects reach a pre-set level of significance or intensity to trigger the need to consult (e.g., effects do not need to trigger population-level responses). Under the Services’ joint regulations implementing the ESA, if an effect on a listed species is predicted to occur or is documented, then the EPA must undergo consultations with the Services. The courts have made abundantly clear that the “may affect” threshold is very low. A “may affect” determination is required when any “possible effect, whether beneficial, benign, adverse, or of an undetermined character” occurs.

Therefore, the no effect/may affect threshold is a very low bar. In the Current Approach, EPA uses Risk Quotients (“RQ”) and Levels of Concern (“LOC”) to make “no effect” findings -- thereby ruling out impacts to all aquatic plants and animals and all invertebrates that don’t have associated indirect effects. The RQ/LOC approach, which conflates a FIFRA determination with an ESA determination, is much too high of a threshold for an ESA “no effect” determination. Therefore, EPA has made a policy judgment that some level of impact to these species represents an acceptable level of risk. This is not permitted under the ESA, which requires consultation with the expert wildlife agencies whenever there is “any possible effect,” either through informal consultation and a written concurrence or formal consultation and a biological opinion.

The NAS report made several significant conclusions about the current ecological risk assessment process and its use of RQs, including:

- The EPAs “concentration-ratio approach” for its ecological risk assessments “is ad hoc (although commonly used) and has unpredictable performance outcomes.”

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Species Act (hereafter CONSULTATION HANDBOOK) at 3-13.
28 *Id.* at xvi (emphasis in original).
29 *Western Watersheds Project v. Kraayenbrink,* 632 F.3d 472, 496 (9th Cir. 2011) (brackets omitted) (quoting 51 Fed. Reg. at 19,949). The threshold for triggering ESA consultation “is relatively low.” *Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009); *Karuk Trib of Cal. V. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (*en banc*) (“any possible effect” on species or their habitat is sufficient).
30 50 C.F.R. § 402.14(a); *Karuk Tribe,* 681 F.3d at 1027 (“[A]ctions that have 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”).
31 *Karuk Tribe,* 681 F.3d at 1027 (quoting Lockyer, 575 F.3d at 1018); *Colorado Envt’l Coalition v. Office of Legacy Management,* 819 F. Supp. 2d 1193, 1221-22 (D. Colo. 2011) (citing cases).
32 *Center for Biological Diversity v. BLM,* 698 F.3d 1101 (9th Cir. 2012) (emphasis added).
33 50 C.F.R. §§ 402.13, 402.14; *Washington Toxics Coalition v. FWS,* 457 F.Supp.2d. 1158, 1178 (W.D. Wash. 2006); see also *Defenders of Wildlife v. EPA,* 420 F.3d 946, 961 (9th Cir. 2005); *Thomas v. Peters* 753 F.2d 754, 763 (9th Cir. 1985).
34 NAS Report at 149.
• “RQs are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes.”

• “The RQ approach does not estimate risk… but rather relies on there being a large margin between a point estimate that is derived to maximize a pesticide’s environmental concentration and a point estimate that is derived to minimize the concentration at which a specified adverse effect is not expected.”

The Current Approach uses the RQ/LOC method to preclude taxa from undergoing co-occurrence analyses (provided there were no possible indirect effects) as well as to make “no effect” findings for species that may co-occur with pesticide use.

The use of RQs and LOCs cannot be reasonably anticipated to accurately reflect the no effect/may affect threshold and cannot be used to make effects determinations. At Step 1, the EPA must gather sufficient data to complete the following two related inquiries: (1) the EPA must determine whether pesticide use areas will overlap with areas where listed species are present, including whether a use area overlaps with any listed species’ critical habitat (2) the EPA must determine whether off-site transport of pesticides will overlap with locations where listed species are present and/or critical habitat is designated. Off-site transport must include considerations of downstream transport due to runoff as well as downwind transport due to spray drift and volatilization when the best available science indicates such transport is occurring.

In making endangered species assessments, EPA categorically and arbitrarily assumes zero off-site exposure of listed species to 2,4-D via spray drift and volatilization, and either assumes zero or inconsequential exposure of aquatic and terrestrial organisms via runoff, despite clear evidence that 2,4-D may move off-site including into aquatic areas, even with a unidirectional field buffer in place. The field buffer that the EPA is proposing for the Enlist Duo label is only 30 ft upwind. That means that 2,4-D and glyphosate can be applied one inch or one-tenth of an inch away from the field edge on 3 sides of the field. There is absolutely no way that these chemicals will remain confined to the field boundaries. In EPA’s previous Final Registration decision, it states, “For aquatic organisms, the consideration of both spray drift and runoff loadings to surface waters did not trigger

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35 Id. at 15.
36 Id. at 14.
37 The Center acknowledges that in many areas, atmospheric transport is difficult to model and assess. However, in some areas, the impacts of atmospheric transport of pesticides are well understood. A recent study found that a variety of pesticides are accumulating in the Pacific chorus frogs (Pseudacris regilla) through atmospheric deposition at remote, high-elevation locations in the Sierra Nevada mountains, including in Giant Sequoia National Monument, Lassen Volcanic National Park, and Yosemite National Park Smalling, K.L., et al. 2013. Accumulation of Pesticides in Pacific Chorus Frogs (Pseudacris regilla) from California’s Sierra Nevada Mountains, Environmental Toxicology and Chemistry, 32:2026–2034.
concerns.” EPA’s own decision on Enlist Duo states that runoff loadings will occur. Whether or not they trigger concerns for the EPA simply does not matter for the purposes of the Endangered Species Act. Aquatic organisms will be affected by Enlist Duo.

Furthermore, according to the U.S. Department of Agriculture, the approval of Enlist Duo for use with Enlist corn and soybeans will lead to a massive increase in use of 2,4-D from 25.6 million pounds per year currently to 77.8-176 million pounds per year by 2020. If EPA’s TerrPlant model is accurate—something that EPA routinely asserts—then between 2.25 to 8.8 million pounds of Enlist Duo will run off treated fields each year into aquatic areas. In addition, the new proposed registration on Enlist cotton is estimated to lead to an increase in 2,4-D use on cotton from 1.1 million pounds per year currently to 6.2-9.3 million pounds per year by 2020, further increasing total runoff and drift from Enlist Duo applications. With the uncertainty surrounding the off-site movement of 2,4-D, even with an upwind field buffer, it is simply indefensible to assume that zero off-site exposure will occur in the effects determinations.

What the EPA should do to meet the legal requirements of the ESA is use the best available spatial data regarding where cotton, corn and soybeans are grown and the distribution and range of listed species to determine whether a pesticide’s use overlaps with species, and then make a “may affect”/”no effect” determination. The FWS ECOS website provides GIS-based data layers for each listed species with designated critical habitat. These maps are scalable and can achieve the precision needed to make accurate effects determinations regarding whether a pesticide will have “no effect” or “may affect” a listed species and are accurate enough to make determinations as to whether the use of a pesticide represents adverse modification of critical habitat. For species without associated critical habitat, EPA should request the most refined range data from experts at the FWS and NMFS.

Fortunately, these data have already been compiled in draft form for the nationwide ESA consultation that was recently completed for chlorpyrifos. The GIS data have not been made available to the public, so we have not had a chance to scrutinize these data to make sure they truly reflect not only the species’ range, but also the habitat needed for recovery. But, nevertheless, this analysis has already been done and is available for the EPA to use right now.

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38 Final Registration of Enlist Duo™ Herbicide (Docket #:EPA-HQ-OPP-2014-0195-2417).
42 EPA. Biological Evaluation Chapters for Chlorpyrifos ESA Assessment. ATTACHMENT 1-6: Co-Occurrence Analysis. Species ranges were provided to EPA from FWS and NMFS in the form of GIS mapping data. Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
As far as the spatial data on crop use, these data have been compiled as well.\textsuperscript{43} Importantly, the data compiled for the nationwide ESA consultation for chlorpyrifos spatially represents potential agricultural use sites for each crop, including soybeans, corn and cotton. Furthermore, it aggregates the use data for the previous 5 years to account for crop rotations, which are common for these crops. Some refinement to these maps will be needed, as they were generated based on offsite travel of chlorpyrifos.

Therefore, the EPA already has mapping data on the range and habitat of every single listed species in the U.S. and mapping data on all cotton, corn and soybean field sites in the U.S. \textbf{In short, all of the information needed to run a proper Step 1 “no effects” determination has been compiled and is available for the EPA to use right now.} Many scientists at the EPA and other agencies put in a lot of work to generate these data in a good faith effort to ensure proper compliance with the ESA moving forward in pesticide registrations. To disregard these data would violate the ESA mandate that the action agency (EPA) use the best available science to conduct its effects determination.

\textbf{The Assumption That Enlist Duo Will Not Leave the Field Boundary is Arbitrary and Capricious}

It is unbelievable to us that an agency so familiar with the extensive mobility of pesticides has actually stated in a publically available document that it believes a 30 ft. buffer on one side of a field is sufficient to assure \textit{absolutely} no movement of a pesticide from the field of application. Keep in mind that Enlist Duo can be applied within a centimeter of the field boundary on three sides of the field and only needs a 30 ft. buffer upwind on the fourth side.

This assumption can be seen only as an attempt by EPA to skirt its mandatory duty to consult under the Endangered Species Act for actions that may affect listed species. Examples from the EPA’s own ecological risk assessment for Enlist Duo plainly indicate that off-site transport will occur:

\begin{itemize}
  \item “2,4-D is an anionic (X-COO- H+) acid under most environmental conditions; it is expected to be mobile to moderately mobile.”\textsuperscript{44}
  \item “[R]esults suggest that,…most of the aquatic exposure is driven by runoff.”\textsuperscript{45}
  \item “Aquatic ecosystems potentially at risk from a stressor include water bodies adjacent to or downstream from the treated field; impounded bodies such as ponds, lakes, and reservoirs; and flowing waterways such as streams or rivers…”\textsuperscript{46}
\end{itemize}

\textsuperscript{43} EPA. Biological Evaluation Chapters for Chlorpyrifos ESA Assessment. ATTACHMENT 1-2, 1-3, 1-6. Cropland data layer (CDL) and Census of Agriculture (CoA) provided by USDA. Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
\textsuperscript{44} EPA, 2013. EFED environmental risk assessment of proposed label for Enlist (2,4-D choline salt), new uses on soybean with DAS 68416-4 (2,4-D Tolerant) and Enlist (2,4-D + glyphosate tolerant)) corn and field corn. Pg 9.
\textsuperscript{45} \textit{Id.} at 34.
• “In exposure calculation for non-target plants, the major contributor is run-off from the application site.”\textsuperscript{47}

• “[T]errestrial ecosystems potentially at risk could include the treated field and areas immediately adjacent to the treated field that may receive drift or runoff. Areas adjacent to the treated field could include other cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats, and other uncultivated areas.”\textsuperscript{48}

• “2,4-D exposures to aquatic species may occur through spray drift, runoff, volatilization, wet/dry deposition, and leaching to groundwater. The seedling emergence and vegetative vigor of non-target terrestrial plants and growth and biomass accumulation of aquatic plants adjacent to the site of 2,4-D choline salt application could be affected by runoff, drift, and volatilization from treated fields.”\textsuperscript{49}

• “…it is not unexpected that even small amounts of spray drift or runoff could cause adverse effects in non-target species.”\textsuperscript{50}

In fact, EPA’s own models indicate that Enlist Duo will move offsite as depicted in Table One and in Figure Three on the following pages.
Table One. Range of Estimated Environmental Concentrations of 2,4-D and 2,4-DCP for Surface Water\textsuperscript{51}

<table>
<thead>
<tr>
<th>Drinking Water Source (model)</th>
<th>Use Scenario (modeled rate)</th>
<th>Peak EEC (μg ae/L)</th>
<th>21-Day EEC (μg ae/L)</th>
<th>60-Day EEC (μg ae/L)</th>
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<td>22.7-20.0</td>
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<td>20.9-18.9</td>
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<td>32.5-32.5</td>
<td>21.4-21.3</td>
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<tr>
<td>MS Corn STD\textsuperscript{1}</td>
<td>57.8</td>
<td>41.3</td>
<td>27.3</td>
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<tr>
<td>(2app. X 1.0 lbs a.e./acre)</td>
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<tr>
<td>MS Corn STD\textsuperscript{2}</td>
<td>56.5</td>
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<td>Aquatic Exposure for 2,4-DCP (Degradate)</td>
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<tr>
<td>MS Corn STD\textsuperscript{3}</td>
<td>4.66\textsuperscript{5}</td>
<td>3.84\textsuperscript{6}</td>
<td>3.62</td>
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<tr>
<td>(3app. x 0.026 lbs a.e./acre\textsuperscript{3}) and (3app. x 0.028 lbs a.e./acre\textsuperscript{3})</td>
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\textsuperscript{1} Post Emergence 2 applications at 0.50 lb a.e./A
\textsuperscript{2} PRZM/EXAMS simulated EECs without spray drift fraction to evaluate spray drift contribution
\textsuperscript{3} PRZM/EXAMS simulation was performed only for MS Corn based on highest EECs observed in 2,4-D exposure
\textsuperscript{4} = 2,4-D application rate (1.0 lb a.e./A) x ([0.035, the maximum conversion rate for the terrestrial degradation of 2,4-D in the terrestrial environment to 2,4-DCP in laboratory studies] x (0.74, the molecular weight ratio of 2,4-D to 2,4-DCP))
\textsuperscript{5} = Sum of 0.024 lb from runoff contribution and 0.004 lb from spray drift
\textsuperscript{6} = Reported values are based on combining exposures from terrestrial runoff/erosion and spray drift contribution using post processing

\textsuperscript{51} Id. at 34-35.
The ecological risk assessment makes clear that, in addition to runoff, spray drift and volatilization will also cause 2,4-D and Enlist Duo to leave the application site and be transported to offsite areas:

• “The ecosystems at risk from exposure to a stressor are often extensive in scope; it may not be possible to identify specific ecosystems at the screening level. In general terms, terrestrial ecosystems potentially at risk could include the treated field and areas immediately adjacent to the treated field that may receive drift or runoff. Areas adjacent to the treated field could include other cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats, and other uncultivated areas.”

• “Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff, spray drift, or volatilization.”

• The Agency estimated the volatility flux from a submitted field volatility study performed with 2,4-D choline as well as 2,4-D dimethylamine salt (DMA) and 2,4-Dethylhexyl ester (EHE) at four different sites (MRID 48862902). Atmospheric concentrations at the 90th percentile of 2,4-D for corn are depicted at various distances in Figure 3.

Figure 3. Estimated 90th Percentile of 2,4-D Volatilization in the Atmosphere

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52 Id. at 21.
53 Id. at 59.
54 Id. at 39.
55 Id. at 23.
The EPA Arbitrarily Excluded Terrestrial Invertebrates from Effects Determinations

In the Ecological risk assessment for 2,4-D use on cotton, the EPA identified a data gap for chronic risk to terrestrial invertebrates:

“The following groups may be at direct risk from the proposed uses of 2,4-D choline salt:

- Mammals (acute and chronic)
- Birds, reptiles, terrestrial-phase amphibians (acute)
- Terrestrial plants
- Terrestrial invertebrates (presumed risk because of data gaps)”

and

“For terrestrial invertebrates, no direct risk concerns were identified for acute exposures to adults; however, because of data gaps, chronic risk concerns for adults and acute/chronic risks for larvae could not be precluded.”

Yet, despite the EPA’s justified concern for terrestrial invertebrates in the ecological risk assessment, the agency went against its own better judgment and actually precluded terrestrial invertebrates from analysis in the listed species effects determinations. The EPA even moved terrestrial insects from the grouping of taxa that may be at direct risk from 2,4-D to the group that had no LOC exceedances.

Therefore, even in its deficient attempt at endangered species effect determinations, the EPA still made arbitrary “no effect” determinations for all terrestrial insects. An agency cannot come to a “no effect” determination when it does not even have sufficient data to assess risk. The EPA must make a “may affect” finding for any terrestrial invertebrate that co-occurs in any geographical area that may contain a corn, cotton or soybean field, as well as any region that may be affected by offsite movement of Enlist Duo.

Effects Thresholds Are Not Protective and “Best Available Science” Is Not Used

The use of surrogate animals is an essential part of the risk assessment process. When measuring risk to humans, the EPA will often apply uncertainty factors to offset the assumptions that mice or rats are appropriate surrogates for human toxicity. Since lab...

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57 Id. at 2.
58 Id. at 10.
60 Id. at 5.
animals are generally inbred strains with little genetic heterogeneity between individuals (unlike the human population), EPA will apply a 10x uncertainty factor to account for this. An extra 10x uncertainty factor will be applied to account for probable differences in sensitivities between the test species and humans. Another 10x uncertainty factor is occasionally applied to account for heightened toxicity of the developing fetus and young children.

Uncertainty factors are problematic because they are not science based, but at least they partially offset some of the many assumptions that are made during risk assessment. In the current ecological risk assessment approach that EPA uses, no uncertainty factors are used for anything. That means that the sensitivity of the surrogate animal is assumed to be identical to every species in its taxa (and occasionally other taxa as well). So a bobwhite quail is assumed to have the exact same sensitivity to a pesticide as a hummingbird, a lizard and a salamander. In reality, this extensive use of surrogates will overestimate toxicity to some species and drastically underestimate it for others.

The failure to account for and incorporate this uncertainty into the ecological risk assessment is putting many species at risk of harm. This is especially true when it comes to endangered or threatened species. Every listed species has a population that is in peril, making potential harm to individuals much more likely to lead to adverse effects on the species’ population. Therefore, appropriate protections need to be put in place during the effects determination process to account for this extensive use of surrogacy and other uncertainties inherent with using models and estimating exposure. Not doing so would be a direct acknowledgement that harm may occur to some listed species.

The NAS report lays out an approach of using best available science and protective toxicity thresholds. The EPA has clearly relied on registrant supplied guideline studies for most of the analysis, and it is unclear to what extent the primary and gray literature were searched for studies related to toxicity. However, considerable efforts need to be taken so that studies with the most appropriate surrogate data are used. Studies should be of high scientific rigor but not necessarily comply with Good Laboratory Practice (“GLP”) guidelines. GLP guidelines were designed to prevent fraud and do not necessarily indicate a study is of higher scientific quality.

Many times, studies with more appropriate surrogates will not be available. In the Current Approach, the LD$_{50}$ or “no observable adverse effect level” (“NOAEL”) of the most appropriate surrogate species are used to estimate toxicity to listed species. These toxicity thresholds are not protective, especially with the uncertainty associated with them. When EPA uses LD$_{50}$, the concentration required to kill 50% of a population, as a threshold for acute toxicity, the end result is not the prevention of species extinction, but the enabling of it. The Interim Approaches and the current draft effects determination for chlorpyrifos lay out effects thresholds that are appropriately protective of listed species during the effects
determination and consultation process.\textsuperscript{61} Importantly, the threshold for direct effects is the concentration that would result in a one in a million chance of causing mortality to an individual or the NOAEL, whichever is lower.

Using protective toxicity thresholds is the only way EPA can make effects determinations that comply with the mandates of the ESA. As noted above, the “may affect” threshold is very low, necessitating the use of these protective toxicity values. Furthermore, as described in the consultation handbook, the “Not Likely to Adversely Affect” (“NLAA”) threshold is also quite low. The Services define NLAA as “when effects on listed species are expected to be discountable, insignificant, or completely beneficial.” Discountable effects are those that are extremely unlikely to occur and that the Services would not be able to meaningfully measure, detect, or evaluate” because of their insignificance.\textsuperscript{62} In the context of pesticides, only if predicted negative effects are discountable or insignificant can the EPA avoid the need to enter formal consultations with the Services, although such a determination requires informal consultation and a written concurrence from the Services.

The one in a million threshold is widely accepted in environmental regulation and used by EPA (including the Office of Pesticides Program), Food and Drug Administration (“FDA”), European Food Safety Authority (“EFSA”) and Canada’s Pest Management Regulatory Agency (“PMRA”) as the standard for negligible risk. Though mainly used to assess the probability of developing cancer due to chemical exposure, this negligible risk standard was adopted to reflect a risk that was so small as to not cause concern from a regulatory or public health perspective. In other words, a risk that is discountable or insignificant. The one in a million mortality threshold for “may affect” and “likely to adversely affect” reflects the ESA’s and the Consultation Handbook’s requirements – requirements that need to be met when assessing harm to listed species.

We note that this will likely have two effects: one will be the expansion of the pesticide exposure area beyond what current EPA models show, and the other will be more “may affect” and “likely to adversely affect” findings, due to the lower threshold of toxicity.

**EPA Does Not Follow The Effects Determination Process Outlined In The ESA**

In the Current Approach, EPA comes to many “may affect” findings only to revert back to a “no effect” finding after further analysis. This is not an appropriate protocol to use to determine effects to listed species. For instance in the additional species effects determinations, the EPA makes “may affect” findings for 4 species based on habitat co-

\textsuperscript{61} EPA. Biological Evaluation Chapters for Chlorpyrifos ESA Assessment. ATTACHMENT 1-4; Process for Determining Effects Thresholds (DOCX). Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment

occurrence with 2,4-D use in soybean, corn and cotton fields. EPA subsequently does an additional analysis and determines that all should be given a “no effect” designation. Once a “may affect” finding is made, EPA cannot simply revert back to a “no effect” finding. If EPA believes that the initial “may affect” finding is discountable or insignificant, then it must make a NLAA finding. An NLAA finding requires written concurrence with the Services, an essential step in the ESA consultation process. The reality is that EPA does not know what impacts will occur to endangered species, and this is not surprising because EPA has no expertise on endangered species. The reason that Congress required all agencies of the federal government to consult with the U.S. Fish and Wildlife Service is because that agency has the necessary expertise on endangered species, to address situations like registration of Enlist Duo for use with genetically engineered resistant crops, where the action agency callously ignores the almost certain impacts to endangered species in the name of expediency.

In addition, by categorically excluding off-site transport and runoff, and by assuming that some negative impacts would not exceed levels of concern, the EPA merged the “no effect”/“may affect” inquiry with the “not likely to adversely affect”/“likely to adversely affect” inquiry of Step 2 that requires concurrence with FWS or NMFS. This is the one thing that the EPA may not do because it is not the expert agency on assessing risks to endangered species. As the federal courts have made clear, Section 7 of the ESA “requires that EPA, in contemplating even actions deemed NLAA, ‘consult’ with the Services to ensure that its action be not likely to jeopardize listed species.”

**EPA makes indefensible NLAA findings**

Once EPA determined that a handful of species may co-occur with soybean, cotton and corn fields (made “may affect” findings), it then turned to a qualitative analysis of USFWS recovery plan documents to try to tease out species’ habitats. To do this, it takes one to two sentence narratives from these documents to support their conclusions that most species’ habitat does not co-occur with soy, corn and cotton fields. This is completely inadequate. First of all, a species habitat encompasses a broad contiguous area. Just because a listed butterfly prefers open areas with wild lupines does not mean that it spends 100% of its time in those areas. Many species have to travel throughout a large area of habitat to seek food or nesting materials or a mate. Second, just because a species habitat is not directly affected does not mean indirect effects are not occurring. For example, a cave dwelling species may

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63 EPA. Memorandum. 2,4-D Choline Salt: Addendum to EFED Ecological Risk Assessment and Listed Species Effects Determinations for GF2726 formulation of 2,4-D choline on GE corn, GE cotton, and GE soybean in AL, AR, AZ, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NM, NY, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV (Additional Species Effects Determinations). Docket ID EPA-HQ-OPP-2016-0594-0014.

64 50 C.F.R. § 402.13(a).

65 Washington Toxics Coalition v. FWS, 457 F.Supp.2d. 1158, 1178 (W.D. Wash. 2006); see also Defenders of Wildlife v. EPA, 420 F.3d 946, 961 (9th Cir. 2005); Thomas v. Peters 753 F.2d 754, 763 (9th Cir. 1985).
never leave the cave that it lives in, but its primary food source may come from outside the
cave and potentially be harmed by the use of Enlist Duo.

The ESA requires that EPA use the best available science to analyze effects to listed species.
Descriptions of a species’ habitat in written documents are not the best science available and
this is not even a scientific approach. Rather, the EPA has cherry-picked a few sentences
from lengthy documents and then made a sweeping assumption about an extremely complex
issue. As mentioned above, maps of species ranges and habitats have been compiled along
with maps of soybean, corn and cotton fields. Once the maps of these fields are refined to
reflect true offsite migration of Enlist Duo, a simple overlay of these two maps is all that
needs to be done. The EPA is going out of its way to make this as convoluted and
unscientific as possible.

**EPA Does Not Properly Measure Indirect Effects Or Critical Habitat Modification**

In the Current Approach, EPA includes some species in the co-occurrence analysis based on
possible indirect effects, however, proceeds to make “no effect” determinations if the
species’ habitat does not overlap with soybean, corn or cotton fields. This conveys a
complete lack of understanding of how indirect effects work. The following is a figure from
the chlorpyrifos draft ESA assessment conducted by EPA.  

![Figure 1-6 in Chapter 1. Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment](https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment)

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66 EPA. Biological Evaluation Chapters for Chlorpyrifos ESA Assessment. Figure 1-6 in Chapter 1. Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
Note that Species 3 habitat does not overlap with the pesticide use site, yet it still gets a “may effect” determination because it is dependent on a species that does overlap with pesticide use. This analysis was done properly, with correct assumptions being made about how species interact with one another and how seemingly safe pesticide use could have major unintended consequences.

Therefore, the Current Approach EPA uses to analyze indirect effects to listed species falls short of what is mandated under the ESA and unjustly discounts those effects. The protocol outlined in the Interim Approaches should be used to measure indirect effects to listed species.

Section 7 of the ESA prohibits agency actions that would result in the “destruction or adverse modification of [critical] habitat.” This inquiry is separate and distinct from the question as to whether a pesticide approval will result in jeopardy to any listed species. A no jeopardy finding (or a NLAA finding in an informal consultation) is not equivalent to a finding that critical habitat will not be adversely modified. While there is much overlap between these two categories (for example, as in Tennessee Valley Authority v. Hill where the proposed agency action to build a dam would both destroy a species’ habitat and kill individual members of the species in the same time) many agency actions do result in adverse modification to critical habitat without causing direct harms to species that do rise to the level of jeopardy. Indeed, the ESA’s prohibition on “destruction or adverse modification” of critical habitat does not contain any qualifying language suggesting that a certain species-viability threshold must be reached prior to the habitat modification prohibition coming into force.

In the current approach, this is completely disregarded. For example, in the additional species effects determinations 10 out of 11 critical habitats were judged “no modification” based on the sole criterion that the species did not use cotton, corn or soybean fields. That is an incorrect way to come to a “no modification” determination and does not comply with the ESA.

As three federal circuit courts have made abundantly clear, avoiding a species’ immediate extinction is not the same as bringing about its recovery to the point where listing is no longer necessary to safeguard the species from ongoing and future threats. Therefore, Section 7 requires that critical habitat not be adversely modified in ways that would hamper

68 437 U.S. 153 (1978)
70 EPA. Memorandum. 2,4-D Choline Salt: Addendum to EFED Ecological Risk Assessment and Listed Species Effects Determinations for GF2726 formulation of 2,4-D choline on GE corn, GE cotton, and GE soybean in AL, AR, AZ, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NM, NY, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV (Additional Species Effects Determinations). Docket ID EPA-HQ-OPP-2016-0594-0014.
the recovery of listed species. These potent pesticides with known adverse ecological effects have the potential to adversely modify critical habitat by altering ecological community structures, impacting the prey base for listed species, and by other changes to the physical and biological features of critical habitat. Accordingly, the informal consultation must separately evaluate whether these pesticide products and formulations will adversely modify critical habitat regardless of whether these pesticide products jeopardize a particular listed species. For example, if plant communities alongside a water body that has been designated as critical habitat suffer increased mortality, and this then results in increased temperatures or increased sedimentation, then that would represent adverse modification of critical habitat. Likewise, if pesticides are toxic to species lower in the food chain, and a threatened or endangered species feeds on those affected prey species, this impact to the food web would represent a clear example of adverse modification to critical habitat.

EPA’s evaluation must address impacts to critical habitat even if the direct effects on listed species fall below the NLAA or jeopardy thresholds.

EPA Must Assess Product Mixtures

Just as the EPA must consult with the Services regarding the registration of an active pesticide ingredient, EPA must also consult with the Services regarding the registration or approval of end use and technical pesticide products. Such consultations must also occur at the earliest possible time to ensure that specific product formulations do not result in jeopardy for a listed species or adversely modify critical habitat.

In addition, because end use formulations may result in mixes of the active ingredient with “other ingredients” before application, the EPA must consider during the consultation process the effects of these “inert” or “other” ingredients together with the active ingredient on listed species and set appropriate conservation restrictions accordingly. As noted in Washington Toxics Coalition v. U.S. Dept. of Interior, “other ingredients” within a pesticide end product may cause negative impact to listed species even if they are less toxic than the active ingredient being reviewed. “Other ingredients,” such as emulsifiers, surfactants, anti-foaming ingredients, and fillers may harm listed species and adversely modify critical habitat. Many of the more than 4,000 potentially hazardous additives allowed for use as pesticide additives are environmental contaminants and toxins that are known neurotoxins and carcinogens. The EPA has routinely failed to consult with the Services on the registration of “other ingredients,” potentially compounding harms to listed species by

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71 See Gifford Pinchot Task Force v. FWS, 378 F.3d 1059, 1069-71 (9th Cir. 2004) (finding a FWS regulation conflating the requirements of survival and recovery to be unlawful); see also N.M. Cattle Growers Ass’n v. FWS, 248 F.3d 1277, 1283 n.2 (10th Cir. 2001); Sierra Club v. FWS, 245 F.3d 434, 441-42 (5th Cir. 2001)
72 457 F. Supp. 2d 1158 (W.D. Wash 2006).
allowing such ingredients to be introduced widely into the environment. EPA must, as part of the consultation process, consider the range of potential impacts by using different concentrations and different formulations of the active ingredient, as well as the potential negative impacts of “other ingredients” used in end use products.

The EPA and Services must consider the environmental baseline as well as all cumulative effects when determining if the approval pesticides, formulations, or uses will jeopardize any threatened or endangered species. The Services define environmental baseline as “the past and present impacts of all Federal, State, or private actions and other human activities in an action area, the anticipated impacts of all proposed Federal projects in an action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions that are contemporaneous with the consultation in process.” Cumulative effects are defined as “those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.” Pesticide consultations must consider the interactions between the active ingredient under review and other pollutants in the present in the environment.

The Food Quality Protection Act of 1996 (“FQPA”) requires EPA to measure risk of a pesticide based on “… available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity.” The EPA has interpreted this to mean that only pesticides with a common mechanism of action be assessed in a cumulative risk assessment. We strongly disagree with this interpretation. First, the term “other substances” can include chemicals other than pesticides and also stressors that are not chemicals, like radiation and climate change. The EPA itself defines cumulative risk as “the combined risks from aggregate exposures to multiple agents or stressors,” where agents or stressors can be chemicals or “may also be biological or physical agents or an activity that, directly or indirectly, alters or causes the loss of a necessity such as habitat.” Second, the term “common mechanism of toxicity” does not dictate that the EPA only consider agents or stressors with a common mechanism of action. The National Research Council has recommended that the EPA use the endpoint of common adverse outcome rather than common mechanism of action to group agents that could act cumulatively. EPAs European counterpart, EFSA, has announced that it intends to measure cumulative risk based on cumulative assessment groups. EFSA notes that this new methodology “….rests on the assumption that pesticides causing the same specific

\[\text{Id. at xiv.}\]

\[\text{Id. at xiii.}\]


phenomenological effects, well defined in terms of site and nature, can produce joint, cumulative toxicity – even if they do not have similar modes of action.”

As for how this relates to EPA’s duty under the ESA, cumulative risk in the ESA needs to be interpreted very broadly as this piece of legislation is a precautionary document meant to ensure that no harm comes to listed species. Although the EPA interprets the scope of cumulative risk assessments under FQPA to be limited to the common mechanism effect, there is absolutely no such written or intended limit in the ESA. The EPA needs to begin discussions on how it will test true cumulative risk, the way it is broadly defined in the ESA, because current metrics and protocols that measure cumulative risk under FQPA are inadequate for the EPA to meet its legal obligations under the ESA.

Pesticides and their residues and degradates do not occur in single exposure situations and many different mixtures of pesticides occur in water bodies at the same time. The mixtures of these chemicals can combine to have additive or synergistic effects that are substantially more dangerous and increase the toxicity to wildlife. Thus, to fully understand the ecological effects and adverse impacts, the EPA and the Services must consider the pesticide’s use in the context of current water quality conditions nationwide. In particular, the use of pesticides in watersheds that contain threatened or endangered species and where water quality is already impaired could be particularly problematic. Therefore, the agencies must use the best available data to fully inform its ecological risk assessment by considering water quality.

The EPA must also analyze the mixtures of 2,4-D and other active ingredients, such as glyphosate to be compliant with the ESA. More information on this is discussed below.

In conclusion, the EPA should obtain the needed spatial data from within its own agency to make an informed “no effect” or “may affect” finding for each listed species that will likely overlap with the use of these pesticides or come into contact with its environmental degradates. If there is overlap, EPA must at a minimum conclude that the use of these pesticides “may affect” listed species. Where this occurs, EPA has a choice—(1) the EPA can elect to complete an informal consultation through a biological assessment (also known as a biological evaluation), or (2) the EPA can undergo formal consultation with the Services. If EPA completes a biological assessment and implements geographically-tailored conservation measures through Bulletins Live! Two, it may be able to reach NLAA determinations via the informal consultation process and alleviate the need for formal consultations. In the alternative, the EPA can move directly to formal consultation after

making “may affect” determinations for species where the impacts of pesticides are more complex and will take additional expertise to develop sufficient conservation measures.

The NAS report recognized that without real-world considerations of where listed species are located, the relative conservation status of listed species, the environmental baseline, and the interaction of pesticides with other active ingredients, pesticide degradates, and other pollutants, the EPA risk assessment process will not be able to make meaningful predictions about which endangered species will be adversely affected. Until the EPA can conduct realistic assessments, it should take a precautionary approach and enter into formal consultations with the Services as outlined in the Interim Approaches document. Implementing the recommendations above will help ensure that the EPA meets its obligations under both FIFRA and the ESA.

**ESA Consultation on Glyphosate Use is Required Before Enlist Duo Can be Registered**

Despite being far and away the most commonly used pesticide in the United States (four fold higher than the second most commonly used pesticide, atrazine), the EPA has never completed, or even attempted, endangered species consultation for glyphosate. The EPA will be in direct violation of the ESA if it registers the Enlist Duo product, which contains glyphosate, without first undergoing ESA consultation for the use of glyphosate on cotton, corn and soybeans. The EPA is under a court-ordered deadline to complete a nationwide ESA biological evaluation on glyphosate by June of 2020, with FWS to complete their biological opinions by June of 2022. We would like to be clear that this is just a deadline and that there is nothing preventing the EPA or FWS from completing this task before those dates. Therefore, a nationwide consultation on glyphosate can proceed right now and a decision to register Enlist Duo must be delayed until this occurs.

**THE PROPOSED REGISTRATION OF ENLIST DUO AND THE NEW USE OF 2,4-D VIOLATES FIFRA**

**Increased 2,4-D Use**

The EPA’s risk assessment approach is not designed to analyze risk due to increased total usage of a pesticide compared to current levels. It is simply designed to estimate exposure to a single chemical based on labeled usage rates on specific crops. This exposes one of the great shortcomings in EPA’s risk assessment approach – it is very short sighted. It takes a narrow approach to assess risk without taking into account the bigger picture of total usage of a particular pesticide or combined usage of multiple pesticides. Therefore, risk is typically underestimated and potential increases in total pesticide usage are not accurately assessed for potential harms.

It is incredibly likely that this proposed new use for 2,4-D and Enlist Duo registration will result in increased usage of 2,4-D on cotton, corn and soybean. In a USDA analysis on possible future

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increase in use of 2,4-D for deregulation of genetically engineered ("GE") Enlist soybean and corn, it predicted that 2,4-D use on corn and soybean would rise from 25.6 million pounds per year currently to 77.8-176 million pounds per year by 2020. In addition, the new proposed registration on Enlist cotton is estimated to lead to an increase 2,4-D use on cotton from 1.1 million pounds per year currently to 6.2-9.3 million pounds per year by 2020. So the proposed registration decision of Enlist Duo will lead to 2,4-D usage jumping from around 26.7 million pounds per year to 84-185.3 million pounds per year in the next four years.

Although this is likely an underestimate, as current labels urge users to spray higher than typical rates to slow weed resistance, it is a starting point for the EPA to begin to analyze the effects of total pesticide load on human and environmental health. This increase in 2,4-D usage would not likely displace other herbicide use and glyphosate use would be expected to stay roughly the same. The EPA needs to view registration decisions as not only a way to analyze the effects of labeled pesticide usage, but also as a way to ensure that total pesticide use does not increase. The EPA could take this into account in the cost-benefit analysis by analyzing the associated costs of labeled pesticide use as well as the costs associated with total pesticide load in the environment.

The Synergy Analysis of Glyphosate and 2,4-D is Inadequate

In all of the documentation we have found, it appears that the EPA based its initial synergy findings off of one patent application submitted by Dow (US 2015/0173371 A1, application # 14567574) and its associated provisional patent application (application # 61919135). In this patent application, Dow studied the effect of 2,4-D and glyphosate alone or in conjunction to 19 different species of weeds. The evidence for synergy between these two ingredients was extensive, with 79 out of 79 experimental conditions demonstrating synergy between the two ingredients as measured by the Colby equation.

In addition to this one patent application that the EPA analyzed, Dow has an earlier patent application that is still pending that also demonstrates synergy between 2,4-D and glyphosate (US 2015/0173371 A1, application # 14567574) and its associated provisional patent application (application # 61919135). In this patent application, Dow studied the effect of 2,4-D and glyphosate alone or in conjunction to 19 different species of weeds. The evidence for synergy between these two ingredients was extensive, with 79 out of 79 experimental conditions demonstrating synergy between the two ingredients as measured by the Colby equation.

In addition to this one patent application that the EPA analyzed, Dow has an earlier patent application that is still pending that also demonstrates synergy between 2,4-D and glyphosate (US


2009/0005248 A1, application # 12147853, submitted to docket). This patent was not cited in any EPA documentation on any of the Enlist Duo dockets and indicates that the EPA was not informed of the existence of this patent application by Dow, despite engaging with them specifically on this issue. This is a completely separate patent application than the one that the EPA identified and has a completely new dataset to analyze. In this patent application, Dow studied the effect of 2,4-D and glyphosate alone or in conjunction to 9 different species of weeds and found that 20 out of 20 experimental conditions demonstrated synergy between the two ingredients as measured by the Colby equation.

Therefore, in both of Dow’s patent applications regarding 2,4-D and glyphosate, 99 out of 99 experimental conditions showed synergy between the two ingredients. 100 percent of experiments on more than 20 different plant species showed synergy. You do not get numbers like that unless the effect you are seeing is real. These synergy findings are not the result of this being a “limited” dataset, as Dow has stated in the media—there is nothing limited about 99 different experiments showing the same thing. It is unclear how a simple set of guideline experiments so easily contradicted such an extensive demonstration of synergy made to an agency of the United States government. The endpoints and some of the plant species were different between the different datasets but the disparity between similar experiments done by the same lab is striking. The EPA is being played and it’s an absolute embarrassment that a corporation can give the United States government two different datasets showing the exact opposite findings. This should be extremely troubling to the EPA and clearly indicates that a third party is better suited to conduct further experimentation on the synergy between 2,4-D and glyphosate or any pesticide combination for that matter. The scientists at Dow are clearly not capable of conducting a proper, reproducible science experiment.

We find it odd that the guideline experiments that Dow submitted were not designed to detect synergy whatsoever. It is unclear how the EPA came to the conclusion that further buffers were not needed based on the few tables of data provided to the public in a 4 page document. The proper experimental protocol would be to carry out the exact same experiments done with Enlist Duo in the guideline studies with 2,4-D and glyphosate alone. We feel that it is not appropriate to compare the results from Enlist Duo to earlier guideline experiments done with 2,4-D, as differences in the experiments could have affected the results. These experiments really need to be done side-by-side with one another to be able to properly make comparisons between the toxicity of 2,4-D, glyphosate and Enlist Duo.

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In the patent applications, the EPA has data indicating that the combination of 2,4-D and glyphosate results in synergistic toxicity to more than 20 species of plants.\(^{89}\) Yet, the guideline experiments only test the effect of GF-2726 (Enlist Duo) on one of those species for seedling emergence and three of those species for vegetative vigor.\(^{90}\) Despite having absolutely no data to indicate that the evidence of synergy on the remaining species of plants that were tested in the patent applications are discountable, the EPA has determined that the guideline experiments are sufficient to contradict all of the evidence contained in Dow’s two patent applications. This is completely insufficient and more experimentation should be done to be confident that this mixture does not result in enhanced toxicity to any species of plants, not just commonly used surrogate plants.

The two patent applications from Dow that contain experimental evidence of synergy use the endpoint of “visual observation of injury” to assess weed damage following treatment. This is a more qualitative assessment of plant injury than the EPA typically requires to be submitted by registrants. However, that does not make it any less relevant than seedling emergence or vegetative vigor (survival, shoot height and shoot biomass). Seedling emergence and vegetative vigor are just two of many ways plant life can be harmed by chemical stressors. To insinuate that a pesticide is completely safe if it does not impair seedling emergence or vegetative vigor is completely inadequate, especially when there is an abundance of data indicating that glyphosate and 2,4-D synergize to cause enough harm to the plant structure that it can be visually distinguished from a healthy plant. Analyzing experiments with different endpoints should not be sufficient to dismiss the abundance of patent data. We understand that the EPA has historically used this very narrow analysis of plant health to inform its regulatory decisions, but when experiments using different endpoints exist, then those data need to be taken into account.

In the handful of tables provided for the review of seedling emergence and vegetative vigor\(^{91}\) it appears that there were some outlying data points in the seedling emergence dataset and certain data points were thrown out before calculation of the EC\(_{05}\), EC\(_{25}\) and EC\(_{50}\). Without access to how these values were calculated, we are unable to comment on that process, unfortunately. But we find it troubling that EC\(_{05}\) for the onion and the cabbage changed dramatically after the EPA eliminated certain doses from analysis.\(^{92}\) If multiple doses appear to be outliers and are subsequently thrown out, then that is an incomplete dataset and the EPA should require those studies to be performed again. These experiments are relatively quick and easy and do not require the use of animals.

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\(^{91}\) Id.

\(^{92}\) Compare both endpoints for cabbage and both endpoints for onion in the table containing data from MRID 49903201.
The EPA also arbitrarily uses the EC\textsubscript{25} values in identifying the most sensitive species for vegetative vigor,\textsuperscript{93} and by doing so does not use the most sensitive No Observable Adverse Effect Concentration (“NOAEC”) for monocots or dicots. The most sensitive NOAEC endpoint for a dicot is 0.0027 lb 2,4-D Choline Salt/A (cabbage). It is current EPA protocol to use the most sensitive endpoints for threshold determination and the use of this lower NOAEC would more closely align with EPA guidelines.

**The EPA Must Mandate Tank Mix Restrictions for Enlist Duo**

The EPA had analyzed a patent application that demonstrated synergy between glyphosate and 2,4-D, which prompted the agency to request further experimentation on the possible interaction of these chemicals. However, in focusing on the interaction between glyphosate and 2,4-D, the agency has completely ignored other interactions that will be enabled by a possible registration of Enlist Duo. In fact, in the proposed label for Enlist Duo,\textsuperscript{94} there are no tank mix restrictions based on toxicity. The only tank mix restrictions are based on how other pesticides could affect the spray drift properties of Enlist Duo. The label directs the user to a website with a list of about 50 different products that are allowed to be tank mixed with Enlist Duo, a list that will grow as Dow identifies more pesticide products that do not affect the spray drift properties of Enlist Duo.

The Center for Biological Diversity recently released a report detailing patent claims of synergy for products that have been approved in the last 6 years.\textsuperscript{95} In this report, we identify many pesticides as having evidence of synergy with either 2,4-D or glyphosate. For instance, a patent application from Dow indicates that the combination of 2,4-D and aminopyralid causes synergistic toxicity to plants.\textsuperscript{96} Additionally, the combination of glyphosate and dicamba has been shown to produce synergistic toxicity to plants as well.\textsuperscript{97} Yet the Enlist Duo label does not currently prohibit the co-application of Enlist Duo with dicamba or aminopyralid.\textsuperscript{98} This should in no way be taken as a comprehensive list of ingredients that synergize with Enlist Duo, just as a couple of examples.

The EPA has started limiting tank mixtures for newly registered active ingredients (see registration decisions for halaxifen-methyl and sulfoxaflor). However, it appears that the agency has arbitrarily decided that these measures are not necessary when registering this new end-use product. Patent data are without a doubt sufficient to support the hypothesis of a synergistic interaction between

ingredients. When there is evidence to support heightened toxicity of a chemical mixture, the EPA needs to either demonstrate that the heightened toxicity does not pose an unreasonable adverse effect to the environment or prohibit those chemicals from being mixed.

The EPA has a duty under FIFRA to ensure that end-use products do not cause unreasonable adverse effects on the environment. Since end-use products often contain chemicals that are not considered active ingredients (commonly called “inert” ingredients), synergy between any ingredients in the product must be analyzed and considered in the context of a registration decision.

The Agency has stated in the past that it cannot be confident whether issuance of registration can meet the standard in FIFRA without prior analysis of all available data regarding synergy. The agency is currently ignoring a wealth of information regarding synergy in patent applications and without language on the label prohibiting co-application of Enlist Duo with synergists, the EPA will be in violation of FIFRA by allowing these mixtures to occur.

**The EPA Must Analyze Risk from Glyphosate Before Registering Enlist Duo**

In its proposed registration decision to register Enlist Duo, the EPA states: “…the EPA confirms that the existing assessments for glyphosate on these crops reliably reflect and will not underestimate the potential exposures from this product.”

The last time the EPA re-registered glyphosate and did a full ecological and human health risk assessment was in 1993. Despite it being 23 years since the EPA last analyzed risk from this active ingredient, the agency still claims that the existing assessments are sufficient to determine the safety of the Enlist Duo product. In 1993 there was about 10-15 million pounds of glyphosate used each year compared to the more than 300 million pounds used currently. Since then glyphosate has been designated a probable human carcinogen by the International Agency for Research on Cancer and been implicated as one factor in the widespread loss of habitat for the Monarch butterfly, leading to the plummeting of its population numbers. EPA’s current assessment of

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99 Reckitt Benckiser Inc. v. EPA, 613 F.3d 1131, 1133 (D.C. Cir. 2010) (citing 7 U.S.C. § 136a(a), (c)-(e) and 7 U.S.C. § 136a(c)(5)(C), (D)).
glyphosate is outdated and completely insufficient given the wealth of new data available. EPA is already 8 years late in reviewing the registration of glyphosate and must delay registering any new end-use products containing glyphosate until registration review is complete.

Herbicide Resistance Management

Due to the indiscriminate use of glyphosate over vast acreage of Roundup Ready® crop monocultures, glyphosate-resistant weeds have evolved and are now present on an estimated 100 million acres in 36 different states. So far, these herbicide resistant weeds have cost farmers more than $1 billion in damages and have increased costs to farmers by as much as 7-fold.

The proposed Herbicide Resistance Management (“HRM”) plan is insufficient to deal with the current and future problem of 2,4-D resistance in weed species. EPA acknowledges that weed resistance is a significant problem and certain populations of weeds have already developed resistance to 2,4-D. The HRM plan provides absolutely no resistance prevention strategies. Resistance prevention is really where the focus needs to be; after all, preventing weed resistance is much more efficient and beneficial than managing the resistant species that are certain to develop.

There are some weak label requirements designed to prevent weed resistance from spreading. These requirements are, of course, dependent on individual farmers’ vigilance. Some farmers are likely to be very vigilant in scouting for 2,4-D “lack of performance,” while others will be less so. This decentralization of oversight will likely hamper management efforts and regionalize the severity of resistance that develops.

Furthermore, Dow has been put in control of confirming and reporting any 2,4-D weed resistance to the EPA – and the proposed registration may terminate in 5 years if EPA determines that this a problematic issue. It will, therefore, be in Dow’s best financial interest if there are no weed resistance issues that are reported. This sets up an inherent conflict of interest that should preclude Dow from being involved in this important data-gathering step. Dow, of course, should foot the bill, but a third party needs to do this analysis so as to avoid the inherent conflict of interest this situation presents.

This data-gathering step on the spread of 2,4-D resistance in the HRM plan is a baby step in the right direction, but without any serious prevention strategies, we are unsure what it will accomplish

in the grand scheme of things. Having data to analyze doesn’t really provide much comfort when the problem has already spread and is too late to stop. In addition, all of the data collected will be reliant on individual reporting, a very unreliable source of information that will lead to significant underestimation of the true scope of the problem.

Sure, Dow will have to set up a website and a hotline, but other than that all of the responsibility for identifying and reporting weed resistance is placed squarely on the farmer or user. Farmers have enough to worry about during the growing season, including ensuring that they are in compliance with pesticide labels that can be 80 pages or longer and incredibly complex. So now not only will farmers be on the hook for label compliance, but also for preventing the spread of herbicide resistant weeds. This HRM plan continues the troubling trend of farmers and users bearing all of the responsibility for ensuring that pesticides are used in a lawful manner while the companies that are profiting off of the sale of these pesticides get to wash their hands of any meaningful responsibility once a pesticide is registered.

The HRM plan is reactionary as opposed to proactive. It needs better resistance prevention strategies, including a requirement that 2,4-D be used only as a last resort as part of an integrative pest management strategy. The prophylactic use of herbicides is a key driving factor in weed resistance and this problem cannot be tackled if current agricultural practices are allowed to continue.

Moreover, the EPA’s proposed registration is vague as to the expiration of the registration after 5 years. If the EPA decides to register the Enlist Duo product, which the Center opposes without lawful compliance with the ESA and supportable risk assessment, the EPA must clarify that the expiration at the end of 5 years is a term of registration and would occur without any additional process. If it does not, the EPA will be in the same situation it has experienced with its conditional registration of flubendiamide.\textsuperscript{110} In addition, the EPA must provide additional public participation if it intends to remove the 5 year expiration date as a term of the registration and set forth what criteria would warrant allowing an extension of the registration.

**Conclusions**

While the Center is very encouraged that the EPA has finally recognized that it must comply with the ESA when it registers new pesticide products and uses under FIFRA, the EPA’s determination that this new Enlist Duo product would not adversely affect any endangered species is not based on the plain language of the ESA, the best available science, is not supported by substantial evidence and is arbitrary and capricious. Registration of Enlist Duo will have impacts on listed species and triggers the may affect requirement for Section 7 consultations under the ESA. There are also serious issues regarding mixtures and methodologies that similarly need to be addressed in order for the EPA to be compliant with FIFRA.

\textsuperscript{110} Bayer CropScience LP et al., EPA Docket Number FIFRA-HQ-2016-0001.
Respectfully submitted,

Nathan Donley, Ph.D.
Senior Scientist
Environmental Health Program
Center for Biological Diversity

Stephanie M. Parent
Senior Attorney
Environmental Health Program
Center for Biological Diversity