Case Nos. 17-70810, 17-70817

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
Petitioners,
v.
SCOTT PRUITT, et al.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

On Petition for Review from the
United States Environmental Protection Agency

PETITIONERS' OPENING BRIEF (REDACTED)

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CORPORATE DISCLOSURE STATEMENT
REQUIRED BY FED. R. APP. P. 26.1

National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, and Pesticide Action Network North America hereby certify that they have no parent corporations, and that no publicly held corporation owns more than 10% of any of the Petitioners' organizations.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

FEDERAL STATUTES

CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER

RULES

OTHER AUTHORITIES

JURISDICTIONAL STATEMENT

This Court has jurisdiction under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides for review in the courts of appeals of "any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). This Court has ruled that a public comment process constitutes a "public hearing" within the meaning of Section 16(b) of FIFRA. *United Farm Workers of Am. v. U.S. EPA*, 592 F.3d 1080, 1082-83 (9th Cir. 2010). EPA solicited and responded to public comments prior to approving Enlist Duo. *See* Excerpts of Record (ER) at ER50-92. Petitioners National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, and Pesticide Action Network North America (collectively, NFFC Petitioners) may bring this challenge because they were "a party" to the proceedings before Respondent U.S. Environmental Protection Agency (EPA), having submitted substantive written comments, and are "adversely affected" by EPA's orders registering Enlist Duo. 7 U.S.C. § 136n(b); ER116-28, 308-42, 414-56, 461-70, 483-501 (comments of NFFC Petitioners).

NFFC Petitioners have standing. An individual has Article III standing if he or she is under threat of suffering an injury-in-fact that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the respondent;

and it must be likely that a favorable judicial decision will prevent or redress the injury. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). A public interest organization like any of the NFFC Petitioners in turn has representational standing "when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). EPA's challenged actions threaten to directly injure NFFC Petitioners' members' environmental, recreational, aesthetic, and economic interests. *See* Crouch Decl. (A100-106)[1], ¶¶ 5-9 (attesting to effects of the action on her interests in whooping cranes); Buse Decl. (A93-99), ¶¶ 9-17; Limberg Decl. (A132-139), ¶¶ 6-21 (attesting to effects of the action on their interests in Indiana bats); Pool Decl. (A140-148) (attesting harm to his wine grape production), ¶¶ 8-16; Griffith Decl. (A113-118), ¶¶ 4-9; Ishii-Eiteman Decl. (A119-124), ¶¶ 6-11; Kimbrell Decl. (A125-131), ¶¶ 7-12; Suckling Decl. (A149-155), ¶¶ 4-14.[2]

[1] For the Court's convenience, copies of all concurrently-filed declarations are filed together herewith in the attached supporting Addendum of Declarations.

[2] Venue is proper because NFFC Petitioners include organizations that reside and/or have places of business within this Circuit. *See* Suckling Decl. (A149-155), ¶ 4; Ishii-Eiteman Decl. (A119-124), ¶ 2; Kimbrell Decl. (A125-131), ¶ 2.

Finally, NFFC Petitioners timely filed their petition for review within sixty days of entry of EPA's approval orders. *See* Pet. Review, No. 17-70810 (9th Cir. March 21, 2017).

ISSUES PRESENTED

1. Did EPA violate the ESA by:
   - improperly defining the "action area" for its Enlist Duo registration;
   - failing to use the best scientific and commercial data available;
   - failing to consult the expert wildlife agencies concerning Enlist Duo's potential effects on threatened and endangered species, despite ample record evidence that its registration of Enlist Duo "may affect" them; and
   - failing to consult the expert wildlife agencies concerning Enlist Duo's potential effects on designated critical habitat by relying on self-created, arbitrary rules for when EPA need not consult?
2. Did EPA violate FIFRA by approving Enlist Duo:
   - using the wrong legal standards;
   - based on inadequate data regarding 2,4-D's volatility risks; and

- for use in tank mixtures with other pesticides, including the pesticide glufosinate, without analyzing such mixtures' known synergistic effects?

STATEMENT OF THE CASE

This case challenges EPA's registration of Intervenor Dow AgroSciences' (Dow's) pesticide[3] product "Enlist Duo," containing the active ingredients 2,4-dichlorophenoxyacetic acid (2,4-D) choline salt and glyphosate dimethylammonium salt (glyphosate). ER1-36. This is the most recent of a series of EPA registrations and amended registrations of Enlist Duo. While these pesticides have been sold individually in other forms, this decision is a "new use" registration, because it approved a novel use of them: direct, "post-emergent" application to crops genetically engineered (GE) to survive being sprayed with both pesticides. ER28.

Enlist Duo and Genetically Engineered Crops

Dow's 2,4-D is a synthetic plant hormone, or auxin, that causes uncontrolled cell growth leading to plant death. *See* ER2013-14; ER2033. Glyphosate is a nonselective, systemic herbicide Monsanto developed and uses as the active

[3] Also referred to as an herbicide. "Pesticides" kill or control organisms considered to be pests, including insect and plant pests; "herbicides" are pesticides that kill plants. 7 U.S.C. § 136(u).

ingredient in its "Roundup" brand herbicides. *See* ER2141-43; ER1615; ER1620-23; ER160-63.

Because 2,4-D and glyphosate are severely toxic to natural plants, before genetic engineering, the pesticides could be used only before crops sprouted ("pre-emergent"),[4] to clear a field of early season weeds. *See, e.g.*, ER347. EPA's Enlist Duo registration entailed a "new use pattern" for 2,4-D: since 2,4-D kills natural cotton and soybean, and injures corn plants as they mature, Dow genetically engineered these crops with 2,4-D resistance to allow use of 2,4-D directly on soybean and cotton for the first time (*i.e,* "over the top"), and later in the season on growing corn plants. ER28. Dow combined its new 2,4-D resistance trait with glyphosate resistance so that all three genetically engineered Enlist crops can be sprayed with both pesticide active ingredients well into the growing season without harming them. ER2-4, 28. Consequently, the U.S. Department of Agriculture (USDA) conservatively estimates that regulatory approval of Enlist corn and soybean crops and Enlist Duo herbicide will result in a 200-600 percent increase in agricultural use of 2,4-D by 2020, ER353, and that the approval of Enlist cotton and the herbicide will result in a 5.7- to 8.6-fold increase in 2,4-D use in cotton

[4] This is true for glyphosate for all these crops. But for 2,4-D, corn has some natural resistance because it is in the grass family. Enlist corn can withstand higher doses of 2,4-D and later in the season.

production.[5] *See, e.g.,* ER4114; ER443 (projecting significant increases in 2,4-D use).

Dow markets and sells the patented GE Enlist Duo-resistant seeds (marketed as "Enlist" crops), along with its Enlist Duo pesticide, as a "weed control system."[6] Along with Monsanto's XtendiMax dicamba pesticide, Enlist Duo is the pesticide industry's quick fix "solution" to an agricultural epidemic it created with the prior generation of glyphosate-resistant GE crops: glyphosate-resistant "superweeds." ER1762-63, 68-69; ER347; ER2133. For the past twenty years, agrichemical companies have sold glyphosate-resistant GE crops, allowing growers to douse fields repeatedly with that chemical and kill weeds without killing the crop, and dramatically increasing overall pesticide output into the environment, making glyphosate the most used pesticide in history. These crops' widespread adoption also created a related problem: just as overuse of antibiotics breeds antibiotic-resistant bacteria, constant application of glyphosate to GE crop fields created an epidemic of glyphosate-resistant superweeds now infesting an estimated 100 million acres of U.S. farmland. ER448. Nor is the industry's doubling down on the

[5] USDA, *Dow AgroSciences Company Petition for Determination of Nonregulated Status of 2,4-D- and Glufosinate-Resistant DAS-81910-7 Cotton* 119 (Apr. 2015), https://www.aphis.usda.gov/brs/aphisdocs/13_26201p_fea.pdf.

[6] Dow Chem. Co., *Enlist Weed Control System*, http://www.enlist.com/en (last visited Apr. 10, 2018).

pesticide treadmill any panacea to the problems it has caused: experts predict its addition of 2,4-D resistance will massively increase 2,4-D agricultural use—without glyphosate reduction—and simply foster rapid evolution of still more intractable weeds, now resistant to both pesticides. ER416; ER448; ER455-56; *see* ER2.

Procedural History: *Enlist Duo I* and Significant Concerns Raised

This is the most recent in a series of EPA registrations and amended registrations of Enlist Duo. EPA first granted Dow's petition to register Enlist Duo on October 15, 2014. ER2. EPA's unconditional registration initially allowed its use in six states on new GE corn and soybean varieties bearing the trade name Enlist, which Dow genetically engineered specifically to be immune to 2,4-D and glyphosate. A coalition of many of the same petitioners in this case petitioned for review of that decision on October 30, 2014. Pet. Review, *Nat. Res. Def. Council v. U.S. EPA* (*Enlist Duo I*), No. 14-73353 (9th Cir. Oct. 30, 2014), ECF No. 1-1.[7]

On March 31, 2015, EPA amended its registration to allow Enlist Duo's use in nine additional states. ER2. Petitioners sought review of that decision. Pet. Review, *Ctr. for Food Safety v. U.S. EPA*, No. 15-71207 (9th Cir. Apr. 20, 2015),

[7] As in this case, NFFC Petitioners and Petitioner Natural Resources Defense Council (NRDC) separately challenged the registration. *See Ctr. for Food Safety. v. U.S. EPA*, No. 14-73359, ECF No. 1-2 (9th Cir. Oct. 30, 2014). And as here, the cases were consolidated. Order, *Enlist Duo I*, Dec. 11, 2014, ECF No. 11. All consolidated Petitioners are referred to collectively as "Petitioners."

ECF No. 1-2; Pet. Review, *Nat. Res. Def. Council v. U.S. EPA*, No. 15-71213 (9th Cir. Apr. 20, 2015), ECF No. 1-2. The cases were consolidated. Order, *Enlist Duo I*, June 2, 2015, ECF No. 66.

While Petitioners' challenge was pending, EPA announced it had discovered Dow had filed a patent application with the U.S. Patent and Trademark Office claiming Enlist Duo's two active ingredients had synergistic effects—that the two ingredients combined were more potent than would be expected from their separate effects. In its submissions to EPA, however, Dow had not included the synergy data. ER2-3.

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

On January 12, 2017, EPA:

1. reaffirmed its earlier decisions to register Enlist Duo on GE corn and GE soybean in 15 states;

2. approved Enlist Duo for use on GE corn and GE soybean in an additional 19 states, bringing to 34 the total number of states where Enlist Duo use is now authorized; and

3. approved a new use of Enlist Duo on GE cotton in all 34 states.

ER2. NFFC Petitioners filed the present Petition for Review challenging EPA's January 12, 2017 actions on March 21, 2017. Pet. Review, No. 17-70810 (9th Cir. Mar. 21, 2017), ECF No. 1-5. On May 3, 2017, the Court consolidated the present Petition for Review with *Natural Resources Defense Council v. Pruitt*, No. 17-70817 (9th Cir. Mar. 21, 2017). Order, ECF No. 14.

Enlist Duo and GE Crops

EPA acknowledged that the massive increase in 2,4-D use and extended window of its application could have significant impacts on public health, agriculture, and the environment. The approval covers 34 states with approximately 185 million acres of corn, soy, and cotton farmland.[8] The USDA conservatively estimated that the approval of Enlist crops and Enlist Duo herbicide will result in a *200-600 percent* increase in agricultural use of 2,4-D by 2020—and that was *before* EPA approved the pesticide for use on cotton. ER353. Application of 2,4-D to crops genetically engineered to withstand its application will likely accelerate weed resistance to the active ingredient, just as weed resistance to Enlist Duo's other active ingredient, glyphosate, prompted the purported need for this

[8] *See* Nat'l Agric. Statistics Serv., USDA, *Crop Acreage* (June 30, 2017), http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000.

registration. ER26-27 (admitting need to monitor weed resistance to 2,4-D). 2,4-D has also been associated with a wide range of human health impacts, ranging from neurological injuries to kidney, thyroid, and reproductive organ damage. ER1673-83; ER1737-39; ER2123-30. As discussed below, EPA's ecological risk assessments recognize 2,4-D is toxic to terrestrial and aquatic plants, birds, and mammals, and is known to injure such non-target organisms through volatilization of 2,4-D. ER2029-30; ER2021. EPA's own database for tracking pesticide-associated accidental kills recorded hundreds of such incidents. *See* ER2067.

Regarding glyphosate, EPA concluded that all proposed uses of Enlist Duo "on GE corn, soybeans, and cotton are already registered on other glyphosate products and are currently in use on these crops." ER3. Despite glyphosate never before having been mixed with 2,4-D for use on crops, EPA performed no new evaluation of glyphosate, which, since EPA last assessed it in 1993, has been determined to be a probable carcinogen.[9] Also since then, glyphosate has been recognized as a major cause of the precipitous, 90 percent decline of the monarch butterfly in less than twenty years, prompting the U.S. Fish and Wildlife Service

[9] *See* Press Release, Int'l Agency for Research on Cancer, World Health Org., IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides (Mar. 20, 2015), http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf.

(FWS) to determine that listing the butterfly as threatened or endangered under the Endangered Species Act (ESA) may be warranted.[10]

These harms were echoed in the public comments on the proposed registration. Commenters supplied EPA with studies, expert opinion, and practical first-hand evidence warning of devastating impacts from Enlist Duo's active ingredients. Specifically, the record contains copious evidence that Enlist Duo posed serious harm to neighboring crops and sensitive species due to 2,4-D's toxicity, its great volatility, as well as synergistic effects of using 2,4-D with pesticides.[11]

Unreasonable Adverse Effects of Enlist Duo

Despite overwhelming record evidence demonstrating harm to neighboring crops and U.S. agriculture from the use of Enlist Duo, EPA conditionally registered Enlist Duo's new uses on millions of acres across 34 states, without determining whether the massive increase and extended use of 2,4-D would "significantly increase the risk of unreasonable adverse effects" of the pesticide on the environment, the requisite finding for new use conditional registrations under

[10] 79 Fed. Reg. 78,775, 78,777 (Dec. 31, 2014).

[11] *See* ER 118-128; ER414-456; ER461-501; ER515-16; ER1356-70; ER2123-2130 (commenting on environmental and human health impacts of increased 2,4-D use); ER420-50; ER1198-1347 (harm to federally listed species); ER420-50; ER144-211 (harm from synergy with other chemicals); ER457-58; ER115-17; ER517-518; ER1195-97 (harms to agriculture and farmers).

FIFRA. *See* 7 U.S.C. § 136a(c)(7)(B). EPA instead concluded that the new uses of Enlist Duo would not have unreasonable adverse effects on the environment, and dismissed any harm from 2,4-D volatilization, even though EPA admitted it lacked sufficient data to assess such harms. EPA also authorized applications of Enlist Duo in mixtures with other pesticides, without requiring any testing of potential synergistic toxicity of such mixtures, even though synergistic effects had prompted EPA to vacate the registration previously, and in the face of identical evidence showing synergistic toxicity of 2,4-D mixtures with the pesticide glufosinate.

Endangered Species at Risk

Of the millions of acres across 34 states where Enlist Duo is used, EPA acknowledges some 531 species listed under the ESA as threatened or endangered, and 184 habitats designated as critical to their survival and recovery, are found near where EPA authorized spraying Enlist Duo. ER575. These include mammals, birds, plants, and insects, and include the whooping crane, Mexican wolf, California condor, and Indiana bat. EPA must comply with the ESA in addition to FIFRA's requirements for registering a pesticide. Section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), requires that, if the Enlist Duo registration may affect any of these many species or habitats, EPA must consult the federal agencies Congress designated as having wildlife expertise—the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS)—to "insure" EPA's action will not

likely jeopardize any of these species' continued existence nor adversely modify their habitats. *Id.*

EPA concluded that spraying a toxic weedkiller on millions of acres can have no effect on hundreds of endangered plants and animals on or near the spraying sites, *e.g.*, ER1457-67, and circumvented Congress's strict mandate that it consult the expert agencies.

EPA did this after admitting, following analysis, that registering Enlist Duo for use on millions of acres "may affect" most taxa of ESA-protected plants and animals, comprising hundreds of species. ER2030. Instead of complying with the ESA's mandate to consult the expert agencies, EPA effectively exempted itself from the law's procedural demands. EPA applied to the ESA context methods and standards EPA had developed to comply with FIFRA, a different statute with different standards, and reflecting policies different from the ESA's strict conservation mandate. EPA's "no effect" determinations therefore applied the wrong legal standards, used inappropriate data, made unsupported assumptions, and otherwise violated the ESA in the service of side-stepping EPA's obligation to obtain the expert agencies' input. As a consequence, EPA's registration threatens the continued existence of a vast array of imperiled species as well the habitats they need to survive and recover.

STANDARDS OF REVIEW

The Court may sustain EPA's Enlist Duo registration under FIFRA only if EPA's orders are "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). "The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement … that courts consider the whole record." *Universal Camera Corp. v. Nat'l Labor Relations Bd.,* 340 U.S. 474, 488 (1951). Judicial review must be "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Containerfrieght Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal citations and quotations omitted). Further, "the substantial evidence standard affords an agency less deference than the arbitrary and capricious standard." *Pollinator Stewardship Council v. U.S. EPA*, 806 F.3d 520, 533 (N.R. Smith, J., concurring) (citing *Universal Camera Corp.,* 340 U.S. at 477; *Union Oil Co. of Cal. v. Fed. Power Comm'n,* 542 F.2d 1036, 1040–41 (9th Cir. 1976)). Therefore, if EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence. To avoid being arbitrary and capricious, EPA "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations and quotations omitted). The Court's "review must not rubber-stamp ... administrative decisions that [the court deems]

inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1119 (9th Cir. 2004) (internal citations and quotations omitted). Any difference between these two standards of review is immaterial here, because EPA's decision to register Enlist Duo satisfies neither. If it finds EPA's actions violated FIFRA, this Court should set aside, or vacate, the registration. *Pollinator Stewardship,* 806 F.3d at 532-33.

EPA violated the E if its failure to consult the expert wildlife agencies in connection with its registrations of Enlist Duo was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *see Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). The ESA requires that federal agencies consult the expert wildlife agencies on any approval action that "may affect" any protected species or critical habitat. 50 C.F.R. § 402.14(a); *see* 16 U.S.C. § 1536(a)(2). This duty is triggered by "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (quoting *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018-19 (9th Cir. 2009) (quoting 51 Fed. Reg. 19,926, 19,949 (June 3, 1986)) (emphasis in *Lockyer*).

ARGUMENT

I. EPA VIOLATED THE ENDANGERED SPECIES ACT

EPA authorized spraying Enlist Duo on millions of acres across 34 states, home to hundreds of ESA-protected animal and plant species, and hundreds of their habitats that FWS specifically designated as "critical" to supporting their survival and eventual recovery. The ESA required EPA to comply with specific processes to prevent harm to these species and areas, including, most importantly, seeking guidance from the agencies with wildlife expertise before allowing the pesticide on the market. However, EPA doggedly avoided complying with the ESA's requirements, instead applying other standards that do not apply in the ESA context, or rules it invented that apply in no context at all. By doing so, EPA circumvented consulting the expert wildlife agencies Congress mandated it consult before repeatedly exposing hundreds of endangered species and habitats to a toxic weedkiller. EPA's systematic and unprecedented disregard of the ESA must be reversed.

A. The ESA's Consultation Process and Standards.

The ESA regulatory requirements with which EPA must comply when registering Enlist Duo are unambiguous. EPA has tried to circumvent them in the past and lost in the courts, but persists in essentially the same unlawful course of

conduct,[12] apparently believing it need not comply with a law Congress expressly provided applies to EPA no less than to every other federal agency.

1. Regulatory Background.

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). Congress spoke "in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution.'" *Id*. at 194. "[T]he plain language of the [ESA] … shows clearly that Congress viewed the value of endangered species as 'incalculable.'" *Id*. at 187.

Section 7 is the "heart" of the ESA, and one of the statute's most important protections. *Lockyer*, 575 F.3d at 1018. It mandates that "[e]ach federal agency" "insure" its action (here, registering Enlist Duo) is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C.

[12] EPA also used the same unlawful approach described in this brief in its registration of the pesticide XtendiMax, as discussed in the pending *National Family Farm Coalition, et al. v. United States Environmental Protection Agency*, No. 17-70196 (9th Cir. filed Jan. 20, 2017).

§ 1536(a)(2).[13] EPA's duty to insure against jeopardy and adverse modification is "rigorous." *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987).

2. Every Federal Agency Must Consult the Expert Wildlife Agencies Before Taking Any Action That Might Have Any Effect Whatsoever on Any ESA-Protected Species or Critical Habitat.

Of central importance to this case, Section 7(a)(2) and its regulations establish a process requiring EPA to evaluate its Enlist Duo registration's effects "in consultation with and with the assistance of" the agencies Congress designated as having special expertise in determining effects on endangered species: FWS (for terrestrial and freshwater species) and NMFS (for marine species).[14] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). In this context EPA is known as the "action agency," while FWS is the "expert agency." *See, e.g., Ctr. for Biological Diversity v. U.S. Forest Serv.*, 408 Fed. Appx. 64 (9th Cir. 2011). Consultation is required of "[e]ach federal agency," 16 U.S.C. § 1536(a)(2), and is "designed as an integral check on federal agency action, ensuring that such action

[13] "Jeopardize" means taking an action that "reasonably would be 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…." 50 C.F.R. § 402.02. Critical habitat means "the specific areas within the geographical area occupied by the species, at the time it is listed … on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

[14] For simplicity, we refer to FWS as the consulting expert agency.

does not go forward without full consideration of its effects on listed species." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 603 (1992) (Blackmun, J., dissenting). This consultation process to assess the registration's effects is integral to "insuring" EPA implements the ESA's substantive protections. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("[T]he strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with the substantive provisions.")

The first step in the Section 7(a)(2) process requires EPA to determine whether the registration "may affect" any listed species or designated critical habitat. If it *may*, EPA then *must* consult FWS. 50 C.F.R. § 402.14(a). Importantly, this "may affect" standard is extremely low:

> [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.

Karuk Tribe, 681 F.3d at 1027 (emphases added). Further:

> *Any possible effect*, whether beneficial, benign, adverse or of an undetermined character triggers the requirement.

Id. (quoting *Lockyer*, 575 F.3d at 1018-19) (quotation omitted) (emphasis in *Lockyer*). *See also W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011) (same).

If EPA's action meets this low "may affect" threshold, the law gives EPA only two options: it can consult FWS formally, or it can consult FWS informally. In formal consultation, FWS issues a Biological Opinion, containing FWS's expert opinion whether EPA's action is likely to jeopardize the continued existence of any species or adversely modify any critical habitat; if not, FWS may authorize any anticipated incidental harm, or "take." 50 C.F.R. § 402.14(h)(3), (i).

Informal consultation is the single exception to formal consultation where the "may affect" threshold has been reached. EPA may avoid formal consultation through informal consultation *only* if during informal consultation, FWS *concurs in writing* that while EPA's action "may affect" a species or habitat, the action is "not likely to adversely affect" it. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994) ("The consulting agency [FWS] must issue a written concurrence in the determination….").

In all of these analyses, EPA must "give the benefit of the doubt to the species." *Conner*, 848 F.2d at 1454 (citation omitted). It also must use the "best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

II. EPA VIOLATED THE ESA'S CONSULTATION MANDATES

A. EPA's Roles Under FIFRA and the ESA Are Very Different.

EPA concocted its own, third alternative to Section 7(a)(2)'s consultation requirement. EPA invented an approach that allows EPA to ignore the statute's and

regulations' standards and unilaterally make determinations the law allows only FWS to make. EPA applied methods developed for registering a pesticide under FIFRA, and appropriate only in relation to species not threatened with extinction. As a matter of law, FIFRA's approach does not fulfill EPA's duties under the ESA. *Wash. Toxics Coal. v. U.S. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005) (EPA must separately comply with the ESA in pesticide registrations). This is because FIFRA and the ESA reflect different policies, address different issues, apply different legal standards, and consequently assign EPA different duties. EPA's fundamental legal error was substituting FIFRA's less protective standards and processes for the ESA's, and refusing to consult the expert wildlife agencies.

First, unlike the ESA, FIFRA requires that EPA determine whether a pesticide has any "unreasonable adverse effects on the environment," and permits—indeed, requires—EPA to weigh the pesticide's costs and benefits when making this determination. *See* 7 U.S.C. § 136(bb) ("The term 'unreasonable adverse effects on the environment' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.").

But the ESA emphatically prohibits any such cost-benefit balancing: "The plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, *whatever the cost*." *Hill*, 437 U.S. at 184 (emphasis

added); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008) ("ESA's no-jeopardy mandate applies to every discretionary agency action—regardless of the expense or burden its application might impose.") (quotation omitted). Similarly, while pesticide regulation under FIFRA is among EPA's many missions, the ESA affords endangered species "the highest of priorities," *Hill,* 437 U.S. at 174, and "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185.

Second, while EPA, by side-stepping the consultation with FWS that Congress required of "[e]ach federal agency," demonstrates it believes it has special privileges when it comes to pesticides and their impacts, the ESA grants EPA no such special authority. EPA's mandate and pesticide expertise do not extend to endangered species' survival and recovery, nor to interpreting and applying the ESA's standards, which Congress assigned to FWS. *See* 16 U.S.C. § 1532(15). Congress did not exempt EPA from its explicit command that "[e]ach federal agency" seek FWS's expertise when dealing with ESA-protected species and habitats. 16 U.S.C. § 1536(a)(2). "'[This] interagency consultation process reflects Congress's awareness that expert agencies (such as [NMFS] and [FWS]) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species.'" *Nat. Res. Def. Council v. Zinke*,

Case No. 1:05–cv–01207 LJO–EPG, 2017 WL 3705108, at *5 (E.D. Cal. Aug. 28, 2017) (quoting *City of Tacoma, Wash. v. FERC*, 460 F.3d 53, 75 (D.C. Cir. 2006)).

Third, in the FIFRA context, EPA uses a risk assessment framework employing self-created "risk quotients" and "levels of concern" to determine "when a pesticide use as directed on the label has the potential to cause *adverse effects* on non-target organisms." ER2529 (emphasis added). EPA describes its scheme for assessing a pesticide registration's risks to all non-target species as follows:

> [T]he effects characterization is based on a deterministic approach using one point on a concentration-response curve (e.g., LC50). In this approach, [EPA's Office of Pesticide Programs] uses the risk quotient (RQ) method to compare exposure over toxicity. Estimated environmental concentrations (EECs) based on maximum application rates are divided by acute and chronic toxicity values….
>
> After risk quotients are calculated, they are compared to [EPA's levels of concern (LOCs)]. These [LOCs] are the Agency's *interpretative policy* and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide use as directed on the label has the *potential to cause adverse effects* on non-target organisms.

ER2529 (emphases added); *see* ER18-19 (EPA used this scheme in this case). EPA uses the identical approach to assess effects on endangered species; it merely changes the threshold to assume endangered species "may be potentially affected" when acute risk quotient >0.1, ER2529, and chronic risk quotient >1, ER2530.

These "risk quotients" and "levels of concern" are based on toxicity testing using EPA guidelines that were not designed to support compliance with the ESA, but rather contain "methodologies and protocols that are intended to provide data to inform regulatory decisions under [the Toxic Substances Control Act, Federal Insecticide, Fungicide and Rodenticide Act, and section 408 of the Federal Food, Drug and Cosmetic Act]."[15] *See, e.g.*, ER2031-32 (citing toxicity tests upon which EPA relies).

EPA uses the data it obtains from such sources and calculates "risk quotients" and "levels of concern" for various species, and as long as EPA's calculations yield a "risk quotient" below the value it unilaterally decides to use, EPA concludes its own "level of concern" has not been exceeded, declares there will be "no effect," and excludes FWS from the consultation process that the ESA mandates. ER2043-44; ER1045 ("EPA determines that there is 'no effect' on listed species if, at any step in the screening level assessment, no levels of concern are exceeded.").

B. EPA's Application of Its FIFRA-based Thresholds to Determine Whether to Consult Under ESA § 7(A)(2) Violates the ESA.

EPA's process for assessing whether registering Enlist Duo "may affect" any ESA-listed species or designated critical habitat, and therefore whether it must

[15] EPA, *OCSPP 850.2100: Avian Acute Oral Toxicity Test [EPA 712-C-025]*, at i (May 10, 2012), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0010.

consult FWS, uses calculations, models, jargon, and references to laboratory studies that give it a scientific patina. Whether EPA performed its calculations accurately is beside the point, as is whether FWS might have agreed with EPA's conclusions had EPA bothered to present them to FWS during consultation. EPA's analyses, by means of which EPA rationalized failing to consult FWS and obtain FWS's written concurrence, violates the ESA as a matter of law.

The ESA does not allow an agency to apply its own "interpretative policies" regarding risk, ER2529, such that EPA may use its own "risk quotients" and "levels of concern" while the Army Corps of Engineers may use different ones it prefers, and the Department of Transportation yet others. This would completely subvert the expert wildlife agencies' statutory role in the consultation process. Similarly, no agency may unilaterally determine its action has no "potential to cause *adverse* effects" on an ESA-protected species or habitat. *See* ER2529. As explained above, the ESA mandates consultation with FWS whenever any agency's action has "any chance" of having "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027. The ESA's regulations expressly provide that determining an action is not likely to cause *adverse* effects can only be made in consultation with FWS, with FWS's written concurrence, which EPA neither sought nor received in this

case for hundreds of species and habitats. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

EPA erroneously claimed the right to use these FIFRA concepts, thresholds, and "interpretive policies" to assess effects on ESA-protected species; instead of consulting FWS about harm risks, it simply consulted itself, using its own approach designed to administer a very different statute. The ESA denies EPA such authority. These policy determinations are due no deference, and are exactly what the ESA eliminated with its directive to consult and obtain FWS's sign-off when there is "any chance" of having "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027.

Moreover, EPA's use of the "risk quotients" it selects as the bright-line basis for a "no effect" determination is arbitrary. EPA has no expertise in endangered species conservation, but even where an agency has expertise, deference is not warranted unless the agency has "cogently explain[ed] why it has exercised its discretion in a given manner." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (quoting *Motor Vehicle Mfr's Ass'n*, 463 U.S. at 48).

The court in *Washington Toxics Coalition* resoundingly rejected an earlier EPA attempt—even with FWS's cooperation that time—to bypass the mandated consultation process in a manner similar to the self-consultation EPA attempts now. 457 F. Supp. 2d at 1179-80. The court explained the fundamental disconnect

between EPA's risk assessment process and the ESA's requirements, and why the former does not satisfy the latter:

> *The risk framework of FIFRA (no unreasonable adverse effects) does not equate to the survival and recovery framework of the ESA*. The risk framework is driven by laboratory tests, models of exposure and occasionally some monitoring information. The ESA framework is an integration of status of the species, environmental background condition, the extent of the action within the action area, as well as laboratory and field testing, modeling and field validation. All of this information feeds into an analysis to support the purpose of the ESA to conserve ecosystems upon which threatened and endangered species rely.

Id. at 1184 (quoting a NMFS scientist) (emphasis added); *see also id*. at 1185 ("EPA's risk assessment, designed to answer a question posed by FIFRA (*i.e.*, whether unreasonable adverse effects would result from use of the pesticide), was not designed to answer the question posed by the ESA (*i.e.*, whether an action may be considered 'not likely to jeopardize[.]'")).

EPA unlawfully circumvented the consultation process by raising the consultation bar high above the ESA's "may affect" standard as this Court and FWS interpret that term. In finding its Enlist Duo registration would have "no effect" on hundreds of listed species and critical habitats, EPA allowed itself to avoid consultation as long as the effect did not exceed EPA's own "level of concern," which measures the "potential to cause adverse effects," ER2529. This may be EPA's boundary of acceptability, but it is not the ESA's. EPA in its risk assessments admitted it employed this unlawful standard, declaring unilaterally

that its registration will "not … adversely affect" certain taxa of endangered species—a determination that can be made only after informal consultation with FWS, with FWS's written concurrence. *See, e.g.,* ER584 ("Proposed 2,4-D choline salt uses are *not expected to directly adversely affect* freshwater or estuarine/marine fish, aquatic phase amphibians, or freshwater or estuarine/marine invertebrates") (emphasis added); ER584 (same, for aquatic plants). This flatly violates the law. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

If EPA believed that whatever effect exposure to Enlist Duo might have on endangered species or their critical habitats was insignificant, the ESA mandates the process available: undergo informal consultation with FWS, and obtain FWS's written concurrence that EPA's action is "not likely to adversely affect" any listed species or critical habitat. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). Instead, EPA arrogated to itself FWS's prerogative, declaring that if the registration's effects on endangered species do not exceed its own "level of concern" and cause no "adverse effects," those effects equate to "no effect," obviating any need to consult, even informally. But those two standards differ significantly, and EPA lacks authority to impose its own interpretation of when consultation is triggered.

FWS's and NMFS's *Endangered Species Consultation Handbook*[16] underscores the distinction between "no effect" and the "not likely to adversely affect" standard EPA effectively applied here, while calling it "no effect":

> **Is not likely to adversely affect** - the appropriate conclusion when effects on listed species are expected to be *discountable, insignificant, or completely beneficial*.
>
> **Beneficial effects** are contemporaneous positive effects without any adverse effects to the species.
>
> **Insignificant effects** relate to the size of the impact and should never reach the scale where take occurs.
>
> **Discountable effects** are those extremely unlikely to occur. Based on best judgment, a person would not: (1) be able to meaningfully measure, detect, or evaluate insignificant effects; or (2) expect discountable effects to occur.
>
> ….
>
> **May affect** - the appropriate conclusion when a proposed action *may pose any effects* on listed species or designated critical habitat….

Consultation Handbook, *supra* n.16, at *xv-xvi* (emphasis and formatting added).

As a matter of law, therefore, an effect EPA deems "not adverse," insignificant, or even beneficial *cannot be classified as "no effect."* The ESA classifies such effects as "not likely to adversely affect" the species—but only if FWS concurs in writing after informal consultation. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). So regardless of the label EPA uses, the standard EPA actually

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[16] FWS & NMFS, *Endangered Species Consultation Handbook* (*Consultation Handbook*) (Mar. 1998), http://www.nmfs.noaa.gov/pr/pdfs/laws/esa_section7_handbook.pdf. This Court has relied on the *Consultation Handbook*. *See, e.g., Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1113 (9th Cir. 2012).

applied when determining risk to endangered species thus is fundamentally and inescapably at loggerheads with the ESA's mandate.

In *Karuk Tribe*, the plaintiff challenged the Forest Service's failure to consult before issuing notices of intent to conduct mining activities in ESA-protected salmon critical habitat. Mining interests argued the record contained "no evidence 'that even a single member of any listed species would be "taken" by reason' of the mining activities," and that the plaintiff had not identified "so much as a single endangered fish or fish egg ever injured by this [mining] activity." 681 F.3d at 1028 (citation omitted). This Court sitting *en banc* rejected industry's efforts to make the agency's procedural duty to consult the expert agencies dependent on evidence of actual harm, emphasizing that any risk triggers consultation. *Id.* The miners also argued that mitigation "assured" there would be "no impact whatsoever on listed species." *Id.* The Court observed that the argument "cuts against, rather than in favor of" the agency having no duty to consult, since the perceived need to reduce potential effects underscored that effects were possible, compelling consultation. *Id*.

By claiming an effect below its self-determined "level of concern," or lacking "adverse effects," has "no effect," and conflating the "no effect" and "not likely to adversely affect" standards, EPA unlawfully cut FWS out of the process

for determining the effect of EPA's Enlist Duo registration on endangered species and their critical habitats.

C. The Record Shows Enlist Duo "May Affect" Hundreds of Endangered Species, Requiring Consultation.

EPA admitted after initial risk assessments that the Enlist Duo registration "may effect" hundreds of ESA-protected species and their critical habitats. By manipulating the assessment process and utilizing the wrong standard, EPA erased all of these findings and converted them to "no effect" findings to avoid consultation.

Specifically, EPA repeatedly acknowledged that Enlist Duo, applied at the allowed rate, may affect many protected plant and animal species, even using its own "level of concern" standard. *See, e.g.*, ER2030 ("may … directly affect[]" most taxa of protected species); ER2074-75, 2079-81(EPA's "levels of concern" exceeded for many species); ER1773 (53 listed species in six states "potentially at risk," four of which remain at risk despite mitigation); ER1457 ("There are 168 species of potential concern in the 10 proposed 2,4-D choline corn and soy states …."); ER1062-63 (risks to numerous species); ER634-35 ("levels of concern" exceeded for mammals), ER642 ("Avian risk quotients exceeded the [level of concern] for acute effects on the treated field.").

Based on these admissions alone, and regardless of how EPA tries to couch its determinations, the Court must find that, as in *Karuk Tribe*, the "record in this

appeal includes ample evidence" that the action in question "may affect" endangered species. 681 F.3d at 1028. There, the Forest Service analogously admitted the mining activities "might cause" disturbance to protected salmon habitat, and the Court gave that phrase its "ordinary meaning," holding that a "may affect" conclusion had to follow "almost automatically," and ordering consultation. *Id.* at 1027 (holding that the "may affect" threshold could be resolved as a "textual matter."). The same is true of EPA's repeated admissions in this record.[17]

D. EPA Unlawfully Constricted the Registration's "Action Area."

EPA began the process of erasing these hundreds of "may affect" findings and converting them to "no effect" determinations by unlawfully redefining the registration's "action area." When evaluating whether its action "may affect" any listed species or critical habitat, EPA must examine all effects within the registration's "action area." 50 C.F.R. §§ 402.02, 402.12; *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 901 (9th Cir. 2002). EPA violated this by unlawfully constricting the registration's "action area" to just the sprayed crop fields themselves, excluding completely all surrounding areas beyond the fields' borders. However, "action area" is defined as "all areas to be affected *directly or*

[17] Similarly, as this Court held in *Kraayenbrink*, 632 F.3d at 496, the "sheer number of acres affected" by agency decisions of nationwide magnitude such as this one can "alone suggest" it "may affect" listed species. *Id.*

indirectly by the Federal Action and *not merely the immediate area involved in the action*." 50 C.F.R. § 402.02 (emphases added).

EPA initially admitted hundreds of listed species were within the registration's action area. *See, e.g.*, ER1772 ("53 species in the 6 states proposed for registration (Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin) were identified as *within the action area.*") (emphasis added); ER1456 ("168 species in the 10 [additional] states proposed for registration were identified as *within the action area.*") (emphasis added). This was appropriate, since EPA knows pesticides commonly drift well beyond sprayed fields, with harmful effects.

EPA also knew Enlist Duo specifically may travel beyond the borders of sprayed fields, ER2022 ("2,4-D is known to volatilize from the field and drift off site under certain environmental conditions."), and that it "can drift from the treated area and still be present at concentrations that exceed acute levels of concern for birds, mammals, and terrestrial plants," ER2077. In fact, the record reveals EPA was aware that by 2012, there had been thousands of reported incidents of terrestrial plants, aquatic plants, birds, fish, mammals, reptiles, and terrestrial insects having been killed by 2,4-D traveling off-site. ER2067.

EPA included label restrictions and directions for use, such as a very modest 30-foot buffer, ER20, and then concluded the registration would have "no effect" on any of the hundreds of species it had already identified as at-risk unless they

actually occupy the sprayed fields themselves. EPA therefore restricted the registration's "action area" to only the fields themselves, completely ignoring any risk to any species or habitat beyond their borders. *See* ER1457 ("157 of the 168 species originally identified as potentially at-risk can be given a 'no effect' determination based on the premise that they are not expected to occur on an action area encompassing the treated soybean and corn fields.").

This severe culling violated the ESA definition of "action area," as well as sound science, farming realities, and the record evidence. EPA knew Enlist Duo is toxic to birds, mammals, and of course (being an herbicide), plants. ER2063-64, 2067-68. EPA knew its label instructions might not eliminate all off-site drift, and therefore endangered species and their habitats might well be exposed to the toxic chemical, albeit at "reduced" levels that did not cause EPA "concern":

> While there are uncertainties in the risk conclusions for terrestrial invertebrates, it is *likely* that the spray drift mitigation measures on the Enlist Duo label will serve to *reduce* exposures to 2,4-D choline in areas off the treated site….

ER643; ER20 (buffer would "reduce" off-site exposure for birds); ER29 (measures "would *reduce the likelihood* of spray drift and volatilization" beyond fields) (emphasis added).

EPA thus could not—and did not—claim the buffers and other label restrictions would have "no effect" as the ESA and this Court define that term. To the contrary, EPA admitted its action may expose endangered plants and animals

and their critical habitats to a chemical toxic to them, and therefore there may well be effects—just not effects exceeding EPA's internal "level of concern," or that EPA considered "adverse." ER1043 ("The Agency makes no claim that drift and runoff do not occur," only that "exposures were only above levels of concern to organisms on treated fields."); ER585 (with mitigation, listed species exposure is "below levels triggering Agency risk concern"); ER29 ("these additional restrictions … limit *adverse* effects to within the treatment site itself….").

Thus, even assuming EPA's calculations were factually accurate, EPA's redefinition of the action area was erroneous as a matter of law, because it resulted in automatic "no effect" determinations for hundreds of endangered species and critical habitats exposed to a toxic chemical at "reduced levels" that EPA concluded are "unlikely" to cause "adverse" effects. An action area must include "all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the action." 50 C.F.R. § 402.02. It is not limited to areas where EPA's action causes "adverse effects" or "effects above EPA's level of concern," ER29, ER1043, but where the pesticide registration may cause "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027. This repeats the overarching theme of EPA's legal error: trying to jam a FIFRA square peg into an ESA round hole to avoid consultation.

Even if Enlist Duo were never to directly escape the crop fields' borders at all, the pesticide's application to the fields plainly has indirect effects on areas outside those borders. For example, ESA-protected species in surrounding areas consume prey—insects, rodents, reptiles—that may be in fields when they are sprayed, before moving out of the fields. Listed animals may drink water that flows out of sprayed fields, or eat seeds that blow out of them. EPA ignored these indirect risks, let alone declined to seek FWS's input in consultation, and this alone renders EPA's "action area" deficient. *See Wilderness Soc'y v. Wisely*, 524 F. Supp. 2d 1285, 1305 (D. Colo. 2007) (rejecting failure to consult regarding effects in broader action area); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 254 F. Supp. 2d 1196, 1212 (D. Or. 2003) (same).

In sum, EPA's action-area manipulations were wrong as a matter of law, leaving hundreds of species and habitats on millions of acres vulnerable to the weedkiller's effects. EPA had already admitted that, but for its drastic constriction of the action area, the Enlist Duo registration puts many of those species and habitats at risk, mandating consultation. *E.g.*, ER2030 (birds, mammals, terrestrial plants all "may be directly affected by the proposed uses of 2,4-D choline salt" on an acute or chronic basis, or both, and indirect effects on terrestrial invertebrates (such as honeybees) are possible). Since EPA's action area violates the ESA's

definition, EPA violated the ESA by failing to consult on any species or habitats outside the sprayed fields' borders.

E. EPA's Conclusion That Enlist Duo Will Have "No Effect" Even on Protected Species Within Sprayed Fields Also Was Unlawful.

EPA erred by excluding the hundreds of potentially-affected species and habitats surrounding Enlist Duo-sprayed crop fields. EPA again erred by then declaring the registration will have "no effect" even on the species it admitted are *in* those fields when they are sprayed, and consume food that has been sprayed with the toxic chemical.

EPA's initial risk assessment found the proposed Enlist Duo registration "may affect" virtually all of the 531 ESA-listed species that might come in contact with the pesticide. ER2030; ER649, ER621-28 (more extensive discussion of 2,4-D's toxicity). Having made these explicit "may affect" findings, ESA § 7(a)(2) required EPA to consult FWS at that point. 50 C.F.R. § 402.14(a). If EPA believed the registration was "not likely to adversely affect" any species or habitat, it had to obtain FWS's written concurrence. *Pac. Rivers Council*, 30 F.3d at 1054 n.8. It did not.

Instead, even after gerrymandering the registration's "action area" to include only the sprayed fields and thus exclude most species and habitats, EPA had to admit that no drift mitigation could prevent some of America's most iconic and critically endangered animals—such as the whooping crane, California condor,

jaguar, and gray wolf—from ingesting Enlist Duo, because they "would reasonably be expected to utilize corn, cotton, and soybean fields for resources important to the species." That is, they will be found within the shrunken action area as EPA unlawfully redefined it. ER653.

Again, once EPA realized it would be exposing endangered species to a toxic chemical, ESA § 7(a)(2) demanded it stop and consult FWS. Because the "may affect" threshold is so low, to NFFC Petitioners' knowledge no court has ever upheld an action agency's "no effect" determination where endangered species are found in the action area as EPA admits here. *See also* 50 C.F.R. §§ 402.13(a), 402.14(b)(1).

But EPA failed to do so. Instead, EPA unlawfully consulted no one but itself, and decided that whatever the risk of harm to these protected species might be, it was not severe enough to warrant seeking any input from FWS. EPA had no authority to exempt itself from the law.

1. EPA's Species-Specific Analyses Violated the ESA.

EPA's strategy to make "no effect" findings for the species found in the sprayed fields was to analyze its registration's impacts on those particular species, using more and more tenuous assumptions, until declaring the effects did not exceed EPA's "levels of concern." EPA then re-characterized these "may effect" circumstances as "no effect," sidestepping the required consultation altogether.

EPA did this with many species found in crop fields, ER653-78, but its analyses of the registration's effect on Indiana bats and whooping cranes exemplify its contortions.

a. Whooping Crane (*Grus Americana*)

The iconic whooping crane is among the world's most endangered animals. There were as few as twenty-one in 1954,[18] and conservation efforts have led to only a limited recovery; there are now a few hundred in the wild,[19] about 4 percent of its historic numbers. As FWS observed: "The whooping crane is a flagship species for the North American wildlife conservation movement, symbolizing the struggle for survival that characterizes endangered species worldwide."[20]

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[18] *See* FWS, *International Recovery Plan: Whooping Crane* (*Grus americana)* 1 (Mar. 2007), http://www.fws.gov/uploadedFiles/WHCR%20RP%20Final%207-21-2006.pdf.

[19] *Id*. at 1.

[20] *Id.*

EPA acknowledged "it is reasonable to conclude that the crane may be exposed to 2,4-D choline residues in prey on crop fields." ER667. But rather than make the required "may affect" finding and consult FWS, EPA estimated the crane's field metabolic rate, guessed the amount of prey it was likely to consume, and guessed the amount of Enlist Duo in hypothetical prey a hypothetical crane might consume. ER668.

EPA used this collection of guesses to calculate acute and chronic risk quotients, and compared these with EPA's internally-generated "levels of concern," or LOCs. *Id.* Because EPA's numbers fell below its LOC, EPA declared there would be "no effect." *Id.* But the risk quotients were not zero, *id*., and therefore required a "may effect" determination as a matter of law. *See supra* pp. 24-31. As explained above, if EPA believed the exposure was "not likely to adversely affect" the cranes, the ESA required EPA to engage in informal consultation and obtain FWS's written concurrence with this conclusion. 50 C.F.R. § 402.14(b); *Pac. Rivers Council*, 30 F.3d at 1054 n.8. EPA did not, violating Section 7(a)(2).

b. Indiana Bat (Myotis sodalis)

EPA went much further in its effort to evade consultation on the endangered Indiana bat, by cherry-picking data to help support an eventual "no effect" finding.

Indiana bats play a critical role in maintaining the balance of an ecosystem. A significant source of natural insect control, Indiana bats typically consume up to half of their body weight in insects each night. ER2238. Their population has continued to decline despite conservation and recovery efforts; less than half of those that existed when the species was listed as endangered remain. FWS's Indiana bat recovery team specifically identified pesticide contamination of the bats' food supply as a reason for their continued decline. ER2316-21.

After its screening assessment showed the Enlist Duo registration may affect the species along with other mammals, ER2079-80, EPA performed a species-specific assessment revealing the Indiana bat likely will suffer reproductive harm

by consuming 2,4-D-tainted prey, as a direct result of EPA's approval of Enlist Duo:

> A daily dose of 74 mg/kg-bw/day places the daily exposure of the bat is [sic] above the two-generation reproduction study (rat) [No Observable Effect Level] of 5 mg/kg-by/day used in the screening risk assessment, even when scaled. Consequently, *a "no effect" determination cannot be concluded for the Indiana bat* using just the lines of evidence found in the screening level risk assessment screening level risk methods.

ER1776 (emphasis added).

Again, this "may affect" determination required EPA to consult FWS. Yet, instead of either informally consulting FWS and seeking its concurrence that the registration is "not likely to adversely affect" this endangered species, *Pac. Rivers Council*, 30 F.3d at 1054 n.8, or entering formal consultation, EPA unlawfully assumed the prerogative to make all determinations itself.

EPA began the process of distancing itself from its prior analyses by declaring its underlying assumptions "conservative." ER1776. But this is exactly what the ESA requires: EPA *must* "give the benefit of the doubt to the species." *Conner*, 848 F.2d at 1454. Instead, EPA used this to justify "explor[ing] the roles of various assumptions of bat biology and habitat use to evaluate the likelihood of exceeding the toxic thresholds for growth and survival of offspring in laboratory reproduction testing." ER1776. In other words, it began trying to find a way to convert its "may affect" into "no effect."

Without expertise in bat biology, EPA guessed how often the bats were likely to visit sprayed fields, guessed how much of their diet would likely come from those fields, and guessed how much 2,4-D residue their prey likely would carry. EPA assumed no bat would obtain most of its diet from the fields, although the conservative assumption, based on the available data, would have been the opposite. ER1776-78. At no point did EPA test its assumptions with FWS.

EPA's modeling predicted the bats would be exposed to 2,4-D at levels laboratory tests showed "produced reduced pregnancies, and skeletal malformations as well as a reduction in the survival of pups." ER1780. EPA observed: "There is considerable uncertainty, in the absence of any further lines of evidence as to the toxicological significance of these short-term exposures predicted in the probabilistic model." *Id*. In the face of such "considerable uncertainty," instead of "giv[ing] the benefit of the doubt to the species," *Conner*, 848 F.2d at 1454, and consulting FWS to help resolve the "uncertainty," EPA continued its quest for a "no effect" finding.[21]

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[21] *See Wash. Toxics Coal*., 457 F. Supp. 2d at 1184-85 (quoting a NMFS scientist):

> To prevent [jeopardy to species], *the Services must treat evidence and uncertainty differently than most other agencies: to minimize risks to listed species*, we conduct our analyses and navigate our decision-making processes to avoid false conclusions at each step of a consultation ... (that is, the Services are biased to avoid the "false negative" conclusion or

EPA delved deeper into studies performed on rats (a taxonomic group only distantly related to bats) to try to determine the "toxicologically significant" dose of 2,4-D on the Indiana bat.[22] Critically, unable to avoid a "may affect" determination using the toxicity data in the rat studies on which EPA had relied for its screening risk assessment, EPA simply replaced it with a new assumption, that significantly higher doses of 2,4-D would not be toxic. EPA derived this assumption from a "hypothesis" for which EPA found support only in unpublished studies performed by the applicant, Intervenor Dow, that EPA "interpreted." ER1780. On the basis of this "hypothesis" and its "interpretations," EPA substituted a much higher toxicity threshold (55 mg/kg/day) for the significantly

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> minimize the risk of Type II error). Most other agencies, including EPA, conduct their assessments in ways that avoid concluding that agency actions had adverse effects when, in fact, such a conclusion is false (that is, they are biased to avoid the "false positive" conclusion or minimize the risk of Type I error).

Id. (emphases added.)

[22] There are a host of physiological and behavioral differences between rats and bats that make using rat toxicological data inappropriate for assessing risk to bats. Lab rats are much bigger (body mass) than Indiana bats and do not share the same physiology or locomotion. Unlike laboratory rats used in the various studies of 2,4-D toxicity, bats fly, navigate and eco-locate. If they are stressed due to chemical exposure their ability to fly and echolocate may be temporarily impaired.

lower levels EPA and other agencies had concluded would likely cause harm to small insect-eating mammals such as bats.[23] *Id.*

EPA then made more guesses of pesticide residues, the proportion of bat diet consisting of tainted insects, bat body weights, and amounts of pesticide likely to be applied, and ran more modeling runs, varying the assumptions. ER1781-83. Using habitat near agricultural fields as a surrogate for the proportion of the bats' diet originating from such fields—which obviously has a substantial impact on any calculation of pesticide load—EPA cherry-picked data to suit its purpose. The Indiana Bat Recovery Plan, ER224-2483—a standard source of "best available and current information" for species-specific assessments per EPA's policy, ER2550—reveals that from 55 to 67 percent of land near Indiana bat colonies is agricultural. ER2289. Instead of conservatively assuming bats obtain from 55 to 67 percent of their prey from agricultural land that will be sprayed with Enlist Duo, EPA

[23] *See* Forest Serv., USDA, *2,4-D Human Health and Ecological Risk Assessment Final Report*, at xxi, 3-15, 4-36 (Sept. 30, 2006) ("adverse effects could be expected" on small insect-eating mammals, such as the Indiana bat, from applications of 2,4-D at the rate EPA approved in this registration, 1 lb. a.e./acre) (emphasis added) (citing EPA's 2,4-D Reregistration Eligibility Decision (June 2005), *available at* http://www.fs.fed.us/foresthealth/pesticide/pdfs/093006_24d.pdf.)

assumed a smaller proportion. *Compare* ER1782 *with* ER1777.[24] Again, EPA left FWS out of the loop.

Applying these and other assumptions, EPA finally was able to get to the conclusion it sought: that Indiana bats would be unlikely to consume enough 2,4-D to "meet or exceed levels of toxicological concern for reproduction and development." ER1783.[25] EPA then took the toxicity threshold value of 55 mg/kg/day it derived through "hypothesis" and "interpretation" and plugged it into its risk assessments for every other endangered mammal that EPA concedes occupies and feeds in sprayed agricultural fields, and relying on that, concluded there would be "no effect" on any of them. *See, e.g.*, ER626; ER659-661 (using 55 mg/kg/day in risk assessments of endangered wolves); ER1458-61 (same for other mammals).

Importantly, EPA characterizes 55 mg/kg/day as the "NOAEL" for mammals—the level below which there is *No Observed Adverse Effect*.

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[24] *See also* ER1777 ("Old fields and agricultural areas seemed important in both studies, but bats likely were foraging most often along forest-field edges, rather than in the interior of fields, although errors inherent in determining the position of a rapidly moving animal through telemetry made it impossible to verify this."); ER1779 ("[T]he extent of foraging over agricultural land is expected to be less than the degree of foraging around the canopies of forested areas.").

[25] For its subsequent registration determination that Enlist Duo's use in additional states and on additional crops will have "no effect" on the endangered Indiana bat, EPA used the data and calculations from its previous assessment. *See* ER1459-60; ER656-57.

ER1458-61. And once again, "no adverse effect" is not the ESA standard for triggering consultation. EPA's fatal error throughout its assessments is that a "not likely to adversely affect" finding is not EPA's prerogative to make without FWS concurring in writing after consultation. 50 C.F.R. § 402.14(a), (b).

2. EPA Failed to Use the Best Scientific and Commercial Data Available.

a. EPA's Exposure Handbook Is an Inappropriate Source of Data for Assessing Risks to ESA-Protected Species.

The ESA imposes the additional, independent statutory mandate that EPA, like all federal agencies, use the "best scientific and commercial data available" when assessing its action's effects on ESA-listed species and habitats. 16 U.S.C. § 1536(a)(2). In addition to its other ESA violations, EPA violated this mandate in assessing impacts on whooping cranes, Indiana bats, and many other listed species.

For example, EPA relied on its 1993 Wildlife Exposure Factors Handbook (Exposure Handbook), produced at record identifier 6829 (ER2886-3147), for critical data. *See, e.g.,* ER656, 668 (citing USEPA 1993). The Exposure Handbook nowhere mentions whooping cranes or Indiana bats, nor any other endangered species, because EPA never intended that it be used for assessing effects on any endangered species, nor for any purpose after screening assessments show species may be affected.

On the contrary, the Exposure Handbook is designed for a different, narrow purpose: "to provide a convenient source of information and an analytic framework for *screening-level* risk assessments for *common* wildlife species." ER2592 (emphases added).

The Exposure Handbook emphasizes the need to obtain data for the particular species being assessed, ER2593 ("Exposure varies between different species and even between different populations of the same species…."), and contains no data about any type of crane or bat, let alone the endangered species for which EPA applied it.

As discussed, once the "may affect" threshold is reached, EPA must consult FWS, not perform more and more analyses until it imagines it can avoid consultation. But EPA persisted, filling data gaps with an Exposure Handbook that instructs EPA to obtain data about local populations—specifically, *by consulting FWS*. ER2595-96. Relying on this inappropriate source of critical data and its own FIFRA-based assessment standards, EPA concluded that because the total load of 2,4-D it guesstimated a whooping crane or Indiana bat would consume was less than its own "level of concern," spraying a toxic chemical on their food would have "no effect" on any of them. ER632-33. EPA's use of guesswork and data that expressly provides it is not appropriate for this purpose instead of even attempting to obtain the best available data by consulting FWS violated Section 7(a)(2).

F. EPA Also Violated the ESA by Failing to Consult the Expert Agencies About Designated Critical Habitat.

ESA § 7(a)(2) imposes an independent, additional duty on EPA to "insure" its Enlist Duo registration will not destroy or adversely modify any habitat that FWS, pursuant to ESA § 4(a)(3)(A), designated as "critical" to a listed species' survival and recovery. 16 U.S.C. § 1533(a)(3)(A). EPA's duty to consult FWS regarding potential effects on critical habitat is separate from its duty regarding effects on listed species themselves, but applies the same low bar: EPA *must* consult FWS if its registration "may affect" a listed species' designated critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b).

1. EPA Applied the Wrong Standard to Determine Whether Consulting on Critical Habitat is Necessary.

EPA perfunctorily dismissed its duty to consult FWS to ensure spraying millions of acres with a toxic weedkiller will not affect any critical habitat, falling far short of the ESA's requirements. First, EPA acknowledged FWS had designated 184 critical habitats for 531 species in and around fields in the 34 states where EPA authorized Enlist Duo spraying. ER679. EPA then invented rules from whole cloth about when its action will trigger consultation on critical habitat, and substituted them for the ESA's "may affect" standard, leading EPA to unlawfully circumvent consultation for *every single one* of 184 critical habitats. Here is the rule EPA created for itself:

> The Agency will conclude 'modification' of designated critical habitat if the range of designated critical habitat co-occurs with the states subject to the Federal action and one or more of the following conditions exist:
>
> 1. The available Services' information indicates that corn, cotton, or soybean fields are habitat for the species *and there is a "may affect" determination for the species* associated with 2,4-D choline salt, as labeled.
>
> 2. The available Services' information indicates that *the species uses corn, soybean, or cotton fields* and one or more effects on taxonomic groups predicted for 2,4-D choline salt on corn, cotton, and soybean fields *would modify one or more of the designated PCEs and PBFs*.
>
> If the above conditions are not met, EPA concludes "*no modification*."

ER679 (emphases added).

In other words, EPA decided that spraying Enlist Duo could not cause "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character" on critical habitat, triggering consultation, *Karuk Tribe*, 681 F.3d at 1027, unless EPA first found its action "may affect" *the listed species* for which part of its designated critical habitat is a sprayed field. Otherwise, the species must be shown to actually *use those fields*, *and* EPA must find that spraying Enlist Duo on the fields reduces their value as critical habitat. This made-up formula has nothing to do with what the ESA actually requires, and is riddled with legally erroneous assumptions.

Initially, overlap between protected species or critical habitat and the action area—which EPA admits exists here at least where sprayed fields are part of a

species' critical habitat—virtually mandates consultation because "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *id.*, is almost unavoidable under such circumstances.

Again, echoing the above myriad instances, EPA awarded itself authority it does not have—here, to decide whether critical habitat is "modified" by the Enlist Duo spraying EPA authorized. ESA § 7(a)(2) does not mandate consultation with FWS only where EPA's action "modifies" critical habitat, nor may EPA forego consultation if it finds "no modification." The law requires consultation for all "actions that have *any chance of affecting* … critical habitat." *Karuk Tribe,* 681 F.3d at 1027 (emphasis added). EPA again applied the wrong legal standard.

Second, EPA's assertion it will consult if "there is a 'may affect' determination for the species" for which critical habitat has been designated (if the species also uses agricultural fields) is a legal *non sequitur.* EPA conflates risks to species with risks to habitat, and attempts to restrict its habitat consultation duties to only situations where it also finds species risks, thus making assessment of effects on critical habitat superfluous. But the ESA imposes on EPA independent duties for each risk. 50 C.F.R. § 402.14(a) (consulting FWS "required" if "any action may affect listed species *or* critical habitat.") (emphasis added). Critical habitat may be affected regardless of whether an action may directly affect the

species itself. *See Greenpeace v. NMFS*, 55 F. Supp. 2d 1248, 1265 (W.D. Wash. 1999) (effects on species and habitat distinct and independent).

As discussed above, EPA erroneously failed to consult FWS regarding hundreds of listed species. By predicating its critical habitat "no effect" determinations on its earlier failures to make "may affect" findings regarding the ESA-protected species, EPA merely doubled down on its unlawful conduct. But even if EPA's "no effect" species' determinations had been correct, they would be irrelevant to its independent duty to consult on critical habitat.

2. EPA Unlawfully Excluded from Consideration All Critical Habitats Except Those Containing Sprayed Fields Occupied by Listed Species.

EPA's erroneous conclusion that consultation on critical habitat is not triggered unless a listed species "use[s] corn, cotton or soybean fields" caused it to categorically ignore almost all of the hundreds of designated critical habitats in the action area as EPA ultimately defined it—the sprayed fields. *See* ER679 ("One-hundred and seventy-six (176) species with critical habitat were judged to not use corn, cotton, or soybean fields and so the critical habitat determination for these was 'no modification.'"). This is not how critical habitat or the ESA works.

As a matter of law, whether members of an endangered species physically occupy some part of a designated critical habitat (here, corn, cotton and soybean fields) is completely irrelevant to whether spraying pesticide on those fields "may

affect" the habitat, triggering consultation. Critical habitat is designated to preserve specific habitat features, known as "primary constituent elements" (PCEs), which are the "physical or biological features" "essential to the conservation of the species" and "which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A)(i); 50 C.F.R § 424.12(b). According to FWS, an area may be designated because it provides any of a wide range of features:

> [A primary constituent element is a] physical or biological feature essential to the conservation of a species for which its designated or proposed critical habitat is based on, such as space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the species' historic geographic and ecological distribution.[26]

Any action impairing any PCE "may affect" the critical habitat, triggering consultation. *See Consultation Handbook*, *supra* n.16, at 4-24 (assessing effects of an action should consider "primary constituent elements of the critical habitat, including direct and indirect effects.").

Crucially, contrary to EPA's decision, a species' physical presence is unnecessary for designation as critical habitat. Critical habitat may include "specific areas *outside the geographical area occupied by the species* ... upon a

[26] FWS, *Endangered Species Glossary*, https://www.fws.gov/nc-es/fish/glossary.pdf (last visited Apr. 10, 2018).

determination by the Secretary that such areas are essential for the conservation of the species." 16 U.S.C § 1532(5)(A)(ii) (emphasis added); *see Consultation Handbook*, *supra* n.16, at xix ("Some designated, unoccupied habitat may never be occupied by the species, but was designated since it is essential for conserving the species because it maintains factors constituting the species' habitat.").

Consequently, EPA must assess *all potentially affected* critical habitat, whether sprayed fields or not, regardless of whether members of protected species may be present in them, because the habitat nonetheless may be important for the species' survival or recovery. *See Nat. Res. Def. Council v. Kempthorne*, 506 F. Supp. 2d 322, 381-82 (E.D. Cal. 2007) (biological opinion inadequate because it failed to assess impacts on all areas of critical habitat, whether or not occupied by endangered species); *see also Gifford Pinchot Task Force v. U.S. Fish and Wildlife Serv.*, 378 F.3d 1059, 1070 (9th Cir. 2004) ("[T]he purpose of establishing 'critical habitat' is for the government to carve out territory that is not only necessary for the species' survival but also essential for the species' recovery."). One obvious example: if agricultural fields within a species' critical habitat do not contain the listed species but do contain the species' prey, which may move out of the fields where the species may then consume it, then an action that reduces that prey "may affect" the habitat, triggering consultation.

Whether EPA's registration will *adversely affect* (or even "modify") any of the hundreds of critical habitats is not before this Court; a contrary determination requires FWS's written concurrence after informal consultation, in which EPA unlawfully refused to engage. 50 C.F.R. § 402.14(b)(1). EPA did not even meaningfully consider whether spraying the fields "may affect" these critical habitats, but instead violated the ESA as a matter of law by assuming effects on unoccupied critical habitat *cannot* trigger consultation.

3. EPA Failed to Properly Assess Effects on Critical Habitat Even Where Listed Species Occupy Sprayed Fields Within Critical Habitat.

For its assessment of the 4 percent of critical habitats where listed species do occupy agricultural fields, EPA relied on its previous listed species' effects determinations "to ascertain if any [species] were determined to be at risk for direct adverse effects." ER1080. Since EPA had already made erroneous "no effect" determinations for virtually all species as discussed above, this had a foregone conclusion. But EPA's assessment methodology violated the ESA as a matter of law, since as noted, an action "may affect" critical habitat regardless of whether it directly affects any members of the species.

EPA—finally—looked at the critical habitats' PCEs for those handful of species occupying the sprayed fields that are part of their critical habitats. *Id.* EPA's assessment was inadequate: it summarily dismissed any possibility that

spraying Enlist Duo on fields within critical habitat "may affect" them by declaring (with the single exception of the whooping crane,[27] which feeds in agricultural fields), "No PCE related to agriculture." *Id.* This is flatly contradicted by EPA's own description of the Virginia big-eared bat's PCEs, which include: "Foraging habitats include woodlands, old fields, and hay fields. Agricultural and man-made areas: corn, hay, and alfalfa fields." ER978-79. The whooping crane's critical habitat also has PCEs plainly relating to agricultural fields. *Id*. at 402. The record offers no explanation for these obvious inconsistencies. On this basis as well, EPA violated ESA § 7(a)(2).

III. EPA VIOLATED THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

In approving Enlist Duo, EPA ignored and violated numerous FIFRA mandates. First, EPA applied the wrong legal standard, and never made the statutorily-mandated findings, for a conditional approval of a pesticide new use. EPA approved Enlist Duo based on its conclusion that it generally would not cause unreasonable adverse effects on the environment, when it should have weighed simply whether the pesticide's new use would significantly increase the risk of such unreasonable adverse effects occurring. Regardless, EPA's approval is

[27] Since, as discussed *supra* pp. 39-41, EPA, ignoring the ESA's standards, had already determined that the effects eating grain sprayed with 2,4-D would not rise to "a level raising a concern," EPA concluded—again ignoring the standard applicable to critical habitat—that whooping crane critical habitat would not be "modified."

unlawful under either standard, because EPA lacked evidence to support its conclusion that 2,4-D volatilization would not injure non-target organisms off-field, and entirely failed to analyze the foreseeable harms of Enlist Duo's use in tank mixtures with the pesticide glufosinate. As a result, EPA cannot find that the widespread adoption of Enlist Duo's use in agriculture would not have unreasonable adverse effects on the environment, nor significantly increase the risks of such effects, in violation of FIFRA.

A. EPA Applied the Wrong Standard and Failed to Make Statutorily Required Findings.

EPA must approve, or "register," pesticides before they are used or sold. 7 U.S.C. § 136a(a). A registration can be unconditional, *id.* § 136a(c)(5), or conditional, *id.* § 136a(c)(7). *See Nat. Res. Def. Council v. U.S. EPA*, 857 F.3d 1030, 1036-37 (9th Cir. 2017). For unconditional registrations, EPA must conclude a pesticide will, *inter alia*, "not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D). For a conditional "new use" registration, however, which EPA approved here,[28] the standard is different. EPA must make two findings: "(i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed

[28] Enlist Duo is a "new use" of registered 2,4-D, defined as an "additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms." 40 C.F.R. § 152.3.

by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(B); *see also* 40 C.F.R. § 152.113(a)(1)-(2) (EPA can issue registration "only if" the agency has "all data," including "at a minimum, data needed to characterize any incremental risk that would result from the approval," and the approval "would not significantly increase the risk of any unreasonable adverse effect."). EPA unlawfully substituted the former standard for the latter.

The prior, 2014 registration at issue in *Enlist Duo I* was an unconditional registration. *See* ER1401. This time, EPA issued a conditional approval only. *See* ER4 (The "new use is being conditionally registered under FIFRA section 3(c)(7)(B) because of outstanding data that will be part of the registration review process."). Yet in the 2017 registration, EPA failed to find that either of the two conditional new use prerequisites were met.

First, as discussed below, EPA readily admits that, with regard to 2,4-D vapor drift and tank mixtures, the agency lacked sufficient data to assess harm from Enlist Duo's new uses. *See* 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(2).

Second, EPA applied the *unconditional* registration standard: that Enlist Duo will not "generally cause unreasonable adverse effects." ER30. EPA based its assessment, and decision, on the wrong legal standard, and never made the

required legal finding.[29] To have their registration upheld, EPA must support with substantial evidence not only that the Enlist Duo formulation will not affirmatively and generally cause unreasonable adverse effects, but that substantial evidence supports that the new, novel use of 2,4-D over-the-top of GE crops will not even *increase the risk* of such unreasonable adverse effects occurring, or that even the risk of such adverse effects coming to pass would be *minimal*.

Finally, EPA's decision was fatally flawed and not supported by substantial evidence under either standard: the record shows EPA's failure to analyze risks of using Enlist Duo will generally cause unreasonable adverse effects, and thus the approval significantly increased the risk of unreasonable adverse effects as well.

B. EPA Failed to Ascertain That Volatilization of 2,4-D From Enlist Duo Would Not Have Unreasonable Adverse Effect on the Environment.

Volatilization of 2,4-D damages neighboring crops and plants off-field. *See* ER2032 ("2,4-D is known to volatilize from the field and drift off site under certain environmental conditions."). Nonetheless, EPA concluded, based on deficient data, that 2,4-D volatilization from Enlist Duo would not unreasonably

[29] Notably in the original 2014 Enlist Duo Registration, EPA applied the correct legal standard for a *conditional* registration. *See* ER24-25 ("Based on these considerations, consistent with the requirements of FIFRA Sec. 3(c)(7)(B), EPA concludes that (i) the Agency has satisfactory data pertaining to the expanded uses of Enlist Duo on corn and soybeans; and (ii) approving this application as set forth below will not increase the risk of any unreasonable adverse effects on human health or the environment."). This underscores the agency's application of the wrong legal standard and failure to make the statutorily required findings this time.

affect the environment. *See* ER22. EPA's conclusion lacks support in substantial evidence, in violation of FIFRA. *See Pollinator Stewardship*, 806 F.3d at 531 ("[A]n agency cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support.") (citing *Tucson Herpetological Soc. v. Salazar*, 566 F.3d 870, 879 (9th Cir. 2009)).

EPA centered its entire assessment of 2,4-D volatilization on a laboratory study that EPA itself found deficient. ER2032, 2082 (describing deficient laboratory vapor-phase study); ER3190-94. The laboratory study provided visual observations of plant damage from 2,4-D vapor. ER2082. EPA used this single study to determine the acceptable threshold of harm—the highest air concentration of 2,4-D vapor that would not have unreasonable adverse effect on plants. ER2082-84. EPA then analyzed 2,4-D's volatilization risks by comparing the selected threshold against modeling projections of 2,4-D vapor concentrations. ER2082-84. The laboratory study thus supplied the guidepost for EPA's 2,4-D volatility assessment.

Yet, in its evaluation report of the study and its 2013 ecological risk assessment, EPA itself repeatedly emphasized that the submitted laboratory study was *deficient*. EPA described the study as "limited in scientific soundness," ER2020. EPA identified several critical deficiencies of the study: it was conducted without an untreated control group, nor adherence to either mandatory laboratory

practices or EPA's test guidelines. *See* 40 C.F.R. § 158.70(b) (requiring studies "adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160"); ER3191 (laboratory study was "[redacted]" and "[redacted]"). Significantly, EPA acknowledged visual observations of plant damage were meaningless for its risk assessment, which requires data measuring endpoints of effect on plant growth or weight. *See* ER2082 ("Plant damage endpoints are not normally quantitatively in risk assessments, and their sensitivity, compared with growth/weight endpoints, is unknown."); ER3192 (noting "[redacted]"). EPA therefore called for an *additional* study to supply the necessary data. ER2022 (recommending another "vapor-phase study with vegetative vigor endpoints" and that "[a]t a minimum, grape and cotton should be tested as these were the most sensitive species in the submitted vapor-phase study."); ER2032 (same).

However EPA *never received such a further study*. Rather, eager to push through Enlist Duo's registration, EPA claimed the laboratory data presented the "best information available" at the time,[30] and proceeded to set the harm threshold at a 2,4-D vapor concentration of 1.9 ug/m^3/hour, the level that caused 20 percent visual physical damage for grape, the most sensitive crop tested in the study.

[30] Despite numerous additional assessments of Enlist Duo since 2013, *see supra* pp. 7-9, EPA never updated its volatility assessment.

ER2082-84. EPA claimed in its January 2013 ecological risk assessment that 20 percent was a "conservative approach" for assessing harm from 2,4-D volatilization, but its detailed evaluation of the laboratory study, finalized just three weeks later, identified [redacted]. ER3192. EPA nonetheless used the 1.9 ug/m^3/hour threshold to conclude that 2,4-D volatilization is not a concern, because various modeling projections predicted concentrations of 2,4-D vapor below that level.

EPA's analysis lacks support in substantial evidence and must be rejected. In *Pollinator Stewardship*, this Circuit rejected EPA's conclusion that the pesticide sulfoxaflor would not have unreasonable adverse effect on honey bees, where EPA's conclusion was based on deficient studies, and where EPA itself had previously called for additional studies. *See* 860 F.3d at 530. The Circuit cited many of the same deficiencies found in the laboratory study here. *See id.* at 529 ("proper controls could have been used" and "the studies could have been replicated more times"). Just as in *Pollinator Stewardship*, here EPA could have, and should have, required Dow to submit a properly conducted study that supplied the data necessary for EPA's assessment of 2,4-D volatilization. EPA did not, and its conclusion that 2,4-D volatilization would not have unreasonable adverse effect on the environment was based entirely on an unreliable harm threshold. As this

Circuit previously explained, "[t]he limitations of the underlying data … mean that no such conclusion can be reached." *Id.* at 531.

C. EPA Failed to Consider Synergistic Effects of Mixing Enlist Duo With Glufosinate.

EPA was well aware combining different pesticides and chemicals can result in synergistic effects that render the combined pesticide formulations more toxic than the individual components. ER55 (recognizing that "combined [pesticide] mixtures" may "have enhanced activity or synergistic effects."); ER3 n.1. Indeed, EPA previously vacated its registration of Enlist Duo in order to assess "possible synergistic effects" between 2,4-D and glyphosate Dow claimed in a patent application. *See supra* pp. 7-9; ER2-3.

EPA was also aware of potential synergistic effects between 2,4-D and another pesticide active ingredient, glufosinate, but failed to assess such effects. Just like the 2,4-D and glyphosate patent application, Dow had also submitted a patent application[31] claiming "synergistic weed control" of pesticide combinations containing 2,4-D and glufosinate. *See* ER122; ER471-72 ("[T]he combination of

[31] While Dow subsequently withdrew the patent application claiming synergy between 2,4-D and glyphosate, the patent application asserting synergistic effects between 2,4-D and glufosinate is still active. *See* Mann, Richard K., *Synergistic Herbicidal Weed Control From Combinations of 2,4-D-Choline And Glufosinate*, http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220150157023%22.PGNR.&OS=DN/20150157023&RS=DN/20150157023 (last visited Apr. 10, 2018).

2,4-D choline and a salt of glufosinate exhibit synergism, i.e., the herbicidal active ingredients are more effective in combination than when applied individually."). Scientific studies before EPA also indicate such synergy. *See* ER129-143. Finally, EPA also knew that Enlist crops, which are genetically engineered to withstand applications of 2,4-D and glyphosate, are also engineered to withstand applications of glufosinate. *See* ER3202 ([redacted]); ER3188-89 ([redacted]).

Yet EPA allowed mixing Enlist Duo with other pesticides and chemicals—including glufosinate—without any assessment of the mixtures' potential synergistic effects. ER32-33. Instead, Enlist Duo can be "tank mixed" as long as the mixture has been tested for increased *spray drift*—but not for any synergistic effect that increases the mixture's toxicity. *See* ER32 (authorizing products for tank mixing with Enlist Duo that have been tested and found "not to adversely affect the spray drift properties of Enlist Duo").

EPA's failures to assess synergistic effects of glufosinate and Enlist Duo, or require any such testing before allowing their tank mixing, violate its statutory duty to ensure Enlist Duo's registration "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). The definition of "pesticide" plainly includes "*mixture of substances* intended for use as a plant regulator, defoliant, or desiccant." *Id.* § 136(u)(2) (emphasis added); 40

C.F.R. § 152.3 (same). EPA knew it had to assess synergistic effects when faced with *an identical claim* of "synergistic herbicidal weed control" between glyphosate and 2,4-D in a patent application. *See* ER1003-06 (requiring testing on seedling emergence and vegetative vigor to determine toxicity endpoints for the 2,4-D and glyphosate combination). In EPA's own words, without assessing such potential synergistic effects, EPA cannot "represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standards in FIFRA" or "support the finding that the registration will have no effect upon threated or endangered species." Mot. Voluntary Vacatur & Remand, *Enlist Duo I*, ECF No. 121-1. EPA violated FIFRA by failing to assess whether glufosinate and 2,4-D mixtures could have unreasonable adverse effects on the environment before authorizing them.

IV. THE COURT SHOULD VACATE THE REGISTRATION

The Court should set aside, or vacate, EPA's approval. Vacatur is the express statutory remedy provided by FIFRA. 7 U.S.C. § 136n(b). Indeed, remand without vacatur is permitted only in "limited circumstances," *Pollinator Stewardship,* 806 F.3d at 532; *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("rare circumstances"), and only when the agency can show that "equity demands" a departure from this presumptive remedy, *Pollinator*

Stewardship, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)).

This Court considers whether such "rare circumstances" for remand without vacatur are met by "weigh[ing] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *Id.* (internal quotation and citation omitted). As to the first factor, the FIFRA violations delineated above are serious legal errors. *See, e.g.*, *id.* at 532-33 (vacating pesticide registration); *Nat. Res. Def. Council*, 857 F.3d at 1042 (vacating the pesticide registration). Moreover, Congress has made clear ESA duties are even more important than EPA's FIFRA duties, weighing even more heavily in favor of vacatur. *See Karuk Tribe*, 681 F.3d at 1020 (the ESA's "consultation requirement reflects a 'conscious decision by Congress to give endangered species priority over the "primary missions" of federal agencies.'") (quoting *Hill*, 437 U.S. at 173).

In assessing disruptive consequences, this Court considers "whether vacating a faulty rule could result in possible environmental harm, and we have chosen to leave a rule in place when vacating would risk such harm." *Pollinator Stewardship*, 806 F.3d at 532; *see also Idaho Farm Bureau*, 58 F.3d at 1405-06. In *Pollinator Stewardship*, this Court held that "given the precariousness of bee populations, leaving EPA's registration of sulfoxaflor in place risks more potential

environmental harm than vacating it." 806 F.3d at 532. The exact same is true in this case for endangered species, as well as farmers and the environment more broadly.

CONCLUSION

In approving Enlist Duo for spraying on millions of acres across much of the United States, EPA violated both the ESA and FIFRA in ways that risk harm to human health, endangered species, and the environment. EPA persistently misapplied the legal standard that triggers its strict duty to consult the expert wildlife agencies to "insure" the registration does not jeopardize any listed species or harm critical habitat. Instead of consulting whenever it found the registration "may affect" a species or habitat as the ESA defines that term, EPA refused to consult unless its analyses demonstrated harm—and its analyses lacked the necessary expertise or data. With critical habitat impacts, EPA simply made up its own rules.

EPA also violated FIFRA. It applied the wrong legal standard for a conditional registration and failed to make the statutorily required findings. The agency based a critical finding that Enlist Duo's volatilization will not cause unreasonable harm by drifting on to neighboring fields on a study EPA itself acknowledged was deficient. And, despite the procedural history of this case, EPA allowed the pesticide to be tank mixed with other pesticides, such as glufosinate,

despite knowing the mixture may have synergistic effects, and therefore may cause unreasonable harm.

These ESA and FIFRA violations compel vacatur to protect health and the environment.

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STATEMENT OF RELATED CASES

There are no other related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points or more and contains 13,916 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: April 11, 2018.

/s/ Paul H. Achitoff
Paul H. Achitoff

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedLimitation Recognized by Krafsur v. Davenport, 6th Cir.(Tenn.), Dec. 04, 2013

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (3906)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 115-140.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136

§ 136. Definitions

Effective: August 3, 1996
Currentness

For purposes of this subchapter--

(a) Active ingredient

The term "active ingredient" means--

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term "adulterated" applies to any pesticide if--

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973.

(m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

(n) Ingredient statement

The term "ingredient statement" means a statement which contains--

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter--

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if--

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if--

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if--

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing--

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter--

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) Nematode

The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w) of Title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) of Title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of Title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term "registration" includes reregistration.

(aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term "weed" means any plant which grows where not wanted.

(dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data--

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term "nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include--

(1) dicyandiamide;

(2) ammonium thiosulfate; or

(3) any substance or mixture of substances. [1] --

(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization [2] urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj) [3] **Maintenance applicator**

The term "maintenance applicator" means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term "maintenance applicator" does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term "service technician" means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term "service technician" does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and--

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term "antimicrobial pesticide" means a pesticide that--

(A) is intended to--

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of Title 21 or a food additive regulation under section 348 of Title 21.

(2) Excluded products

The term "antimicrobial pesticide" does not include--

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

The term "antimicrobial pesticide" does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term "public health pesticide" means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term "vector" means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

CREDIT(S)

(June 25, 1947, c. 125, § 2, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 975; amended Pub.L. 93-205, § 13(f), Dec. 28, 1973, 87 Stat. 903; Pub.L. 94-140, § 9, Nov. 28, 1975, 89 Stat. 754; Pub.L. 95-396, § 1, Sept. 30, 1978, 92 Stat. 819; Pub.L. 100-532, Title I, § 101, Title VI, § 601(a), Title VIII, § 801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub.L. 102-237, Title X, § 1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub.L. 104-170, Title I, §§ 105(a), 120, Title II, §§ 210(a), 221, 230, Title III, § 304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

Notes of Decisions (9)

Footnotes

1 So in original. Probably should not have a period.

2 So in original. Probably should be followed by ", or".

3 So in original. No subsec. (ii) has been enacted.

7 U.S.C.A. § 136, 7 USCA § 136

Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

Currentness

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if--

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes--

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that--

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their

intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use

until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if--

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to--

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining--

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that--

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall--

(I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application--

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)--

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)--

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)--

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide

involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if--

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that--

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of--

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136*o*(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of--

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of--

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including--

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than--

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall--

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall--

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including--

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be--

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of Title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within--

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of--

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

CREDIT(S)

(June 25, 1947, c. 125, § 3, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 979; amended Pub.L. 94-140, § 12, Nov. 28, 1975, 89 Stat. 755; Pub.L. 95-396, §§ 2(a), 3-8, Sept. 30, 1978, 92 Stat. 820, 824-827; Pub.L. 100-532, Title I, §§ 102(b), 103, Title VI, § 601(b)(1), Title VIII, § 801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub.L. 101-624, Title XIV, § 1492, Nov. 28, 1990, 104 Stat. 3628; Pub.L. 102-237, Title X, § 1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894 to 1896; Pub.L. 104-170, Title I, §§ 105(b), 106(b), Title II, §§ 210(b), (c)(1), (d), (e), (f)(2), 222 to 224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494 to 1497, 1499, 1503, 1504, 1508, 1510; Pub.L. 108-199, Div. G, Title V, § 501(b), Jan. 23, 2004, 118 Stat. 419; Pub.L. 110-94, §§ 2, 3, Oct. 9, 2007, 121 Stat. 1000.)

Notes of Decisions (100)

7 U.S.C.A. § 136a, 7 USCA § 136a
Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136n

§ 136n. Administrative procedure; judicial review

Currentness

(a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of Title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

(d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

CREDIT(S)

(June 25, 1947, c. 125, § 16, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 994; amended Pub.L. 98-620, Title IV, § 402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub.L. 100-532, Title VIII, § 801(i), Oct. 25, 1988, 102 Stat. 2682; Pub.L. 102-237, Title X, § 1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Notes of Decisions (70)

7 U.S.C.A. § 136n, 7 USCA § 136n
Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 16. Conservation
Chapter 35. Endangered Species (Refs & Annos)

16 U.S.C.A. § 1532

§ 1532. Definitions

Currentness

For the purposes of this chapter--

(1) The term "alternative courses of action" means all alternatives and thus is not limited to original project objectives and agency jurisdiction.

(2) The term "commercial activity" means all activities of industry and trade, including, but not limited to, the buying or selling of commodities and activities conducted for the purpose of facilitating such buying and selling: *Provided, however*, That it does not include exhibition of commodities by museums or similar cultural or historical organizations.

(3) The terms "conserve", "conserving", and "conservation" mean to use and 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 pursuant to this chapter are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

(4) The term "Convention" means the Convention on International Trade in Endangered Species of Wild Fauna and Flora, signed on March 3, 1973, and the appendices thereto.

(5)(A) The term "critical habitat" for a threatened or endangered species means--

(i) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of section 1533 of this title, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and

(ii) specific areas outside the geographical area occupied by the species at the time it is listed in accordance with the provisions of section 1533 of this title, upon a determination by the Secretary that such areas are essential for the conservation of the species.

(B) Critical habitat may be established for those species now listed as threatened or endangered species for which no critical habitat has heretofore been established as set forth in subparagraph (A) of this paragraph.

(C) Except in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species.

(6) The term "endangered species" means any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary to constitute a pest whose protection under the provisions of this chapter would present an overwhelming and overriding risk to man.

(7) The term "Federal agency" means any department, agency, or instrumentality of the United States.

(8) The term "fish or wildlife" means any member of the animal kingdom, including without limitation any mammal, fish, bird (including any migratory, nonmigratory, or endangered bird for which protection is also afforded by treaty or other international agreement), amphibian, reptile, mollusk, crustacean, arthropod or other invertebrate, and includes any part, product, egg, or offspring thereof, or the dead body or parts thereof.

(9) The term "foreign commerce" includes, among other things, any transaction--

(A) between persons within one foreign country;

(B) between persons in two or more foreign countries;

(C) between a person within the United States and a person in a foreign country; or

(D) between persons within the United States, where the fish and wildlife in question are moving in any country or countries outside the United States.

(10) The term "import" means to land on, bring into, or introduce into, or attempt to land on, bring into, or introduce into, any place subject to the jurisdiction of the United States, whether or not such landing, bringing, or introduction constitutes an importation within the meaning of the customs laws of the United States.

(11) Repealed. Pub.L. 97-304, § 4(b), Oct. 13, 1982, 96 Stat. 1420.

(12) The term "permit or license applicant" means, when used with respect to an action of a Federal agency for which exemption is sought under section 1536 of this title, any person whose application to such agency for a permit or license has been denied primarily because of the application of section 1536(a) of this title to such agency action.

(13) The term "person" means an individual, corporation, partnership, trust, association, or any other private entity; or any officer, employee, agent, department, or instrumentality of the Federal Government, of any State, municipality, or political subdivision of a State, or of any foreign government; any State, municipality, or political subdivision of a State; or any other entity subject to the jurisdiction of the United States.

(14) The term "plant" means any member of the plant kingdom, including seeds, roots and other parts thereof.

(15) The term "Secretary" means, except as otherwise herein provided, the Secretary of the Interior or the Secretary of Commerce as program responsibilities are vested pursuant to the provisions of Reorganization Plan Numbered 4 of 1970; except that with respect to the enforcement of the provisions of this chapter and the Convention which pertain to the importation or exportation of terrestrial plants, the term also means the Secretary of Agriculture.

(16) The term "species" includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.

(17) The term "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Virgin Islands, Guam, and the Trust Territory of the Pacific Islands.

(18) The term "State agency" means any State agency, department, board, commission, or other governmental entity which is responsible for the management and conservation of fish, plant, or wildlife resources within a State.

(19) The term "take" means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.

(20) The term "threatened species" means any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

(21) The term "United States", when used in a geographical context, includes all States.

CREDIT(S)

(Pub.L. 93-205, § 3, Dec. 28, 1973, 87 Stat. 885; Pub.L. 94-359, § 5, July 12, 1976, 90 Stat. 913; Pub.L. 95-632, § 2, Nov. 10, 1978, 92 Stat. 3751; Pub.L. 96-159, § 2, Dec. 28, 1979, 93 Stat. 1225; Pub.L. 97-304, § 4(b), Oct. 13, 1982, 96 Stat. 1420; Pub.L. 100-478, Title I, § 1001, Oct. 7, 1988, 102 Stat. 2306.)

Notes of Decisions (94)

16 U.S.C.A. § 1532, 16 USCA § 1532
Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

End of Document

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedLimitation Recognized by Miccosukee Tribe of Indians of Florida v. U.S. Army Corps of Engineers, 11th Cir.(Fla.), Sep. 15, 2010

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

United States Code Annotated
Title 16. Conservation
Chapter 35. Endangered Species (Refs & Annos)

16 U.S.C.A. § 1533

§ 1533. Determination of endangered species and threatened species

Effective: November 24, 2003
Currentness

(a) Generally

(1) The Secretary shall by regulation promulgated in accordance with subsection (b) of this section determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) the present or threatened destruction, modification, or curtailment of its habitat or range;

(B) overutilization for commercial, recreational, scientific, or educational purposes;

(C) disease or predation;

(D) the inadequacy of existing regulatory mechanisms; or

(E) other natural or manmade factors affecting its continued existence.

(2) With respect to any species over which program responsibilities have been vested in the Secretary of Commerce pursuant to Reorganization Plan Numbered 4 of 1970--

(A) in any case in which the Secretary of Commerce determines that such species should--

(i) be listed as an endangered species or a threatened species, or

(ii) be changed in status from a threatened species to an endangered species,

he shall so inform the Secretary of the Interior, who shall list such species in accordance with this section;

(B) in any case in which the Secretary of Commerce determines that such species should--

(i) be removed from any list published pursuant to subsection (c) of this section, or

(ii) be changed in status from an endangered species to a threatened species,

he shall recommend such action to the Secretary of the Interior, and the Secretary of the Interior, if he concurs in the recommendation, shall implement such action; and

(C) the Secretary of the Interior may not list or remove from any list any such species, and may not change the status of any such species which are listed, without a prior favorable determination made pursuant to this section by the Secretary of Commerce.

(3)(A) The Secretary, by regulation promulgated in accordance with subsection (b) of this section and to the maximum extent prudent and determinable--

(i) shall, concurrently with making a determination under paragraph (1) that a species is an endangered species or a threatened species, designate any habitat of such species which is then considered to be critical habitat; and

(ii) may, from time-to-time thereafter as appropriate, revise such designation.

(B)(i) The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 670a of this title, if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

(ii) Nothing in this paragraph affects the requirement to consult under section 1536(a)(2) of this title with respect to an agency action (as that term is defined in that section).

(iii) Nothing in this paragraph affects the obligation of the Department of Defense to comply with section 1538 of this title, including the prohibition preventing extinction and taking of endangered species and threatened species.

(b) Basis for determinations

(1)(A) The Secretary shall make determinations required by subsection (a) (1) of this section solely on the basis of the best scientific and commercial data available to him after conducting a review of the status of the species and after taking into account those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction, or on the high seas.

(B) In carrying out this section, the Secretary shall give consideration to species which have been--

(i) designated as requiring protection from unrestricted commerce by any foreign nation, or pursuant to any international agreement; or

(ii) identified as in danger of extinction, or likely to become so within the foreseeable future, by any State agency or by any agency of a foreign nation that is responsible for the conservation of fish or wildlife or plants.

(2) The Secretary shall designate critical habitat, and make revisions thereto, under subsection (a) (3) of this section on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impact, of specifying any particular area as critical habitat. The Secretary may exclude any area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific and commercial data available, that the failure to designate such area as critical habitat will result in the extinction of the species concerned.

(3)(A) To the maximum extent practicable, within 90 days after receiving the petition of an interested person under section 553(e) of Title 5, to add a species to, or to remove a species from, either of the lists published under subsection (c) of this section, the Secretary shall make a finding as to whether the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. If such a petition is found to present such information, the Secretary shall promptly commence a review of the status of the species concerned. The Secretary shall promptly publish each finding made under this subparagraph in the Federal Register.

(B) Within 12 months after receiving a petition that is found under subparagraph (A) to present substantial information indicating that the petitioned action may be warranted, the Secretary shall make one of the following findings:

(i) The petitioned action is not warranted, in which case the Secretary shall promptly publish such finding in the Federal Register.

(ii) The petitioned action is warranted, in which case the Secretary shall promptly publish in the Federal Register a general notice and the complete text of a proposed regulation to implement such action in accordance with paragraph (5).

(iii) The petitioned action is warranted, but that--

(I) the immediate proposal and timely promulgation of a final regulation implementing the petitioned action in accordance with paragraphs (5) and (6) is precluded by pending proposals to determine whether any species is an endangered species or a threatened species, and

(II) expeditious progress is being made to add qualified species to either of the lists published under subsection (c) of this section and to remove from such lists species for which the protections of this chapter are no longer necessary,

in which case the Secretary shall promptly publish such finding in the Federal Register, together with a description and evaluation of the reasons and data on which the finding is based.

(C)(i) A petition with respect to which a finding is made under subparagraph (B)(iii) shall be treated as a petition that is resubmitted to the Secretary under subparagraph (A) on the date of such finding and that presents substantial scientific or commercial information that the petitioned action may be warranted.

(ii) Any negative finding described in subparagraph (A) and any finding described in subparagraph (B) (i) or (iii) shall be subject to judicial review.

(iii) The Secretary shall implement a system to monitor effectively the status of all species with respect to which a finding is made under subparagraph (B)(iii) and shall make prompt use of the authority under paragraph 7 [1] to prevent a significant risk to the well being of any such species.

(D)(i) To the maximum extent practicable, within 90 days after receiving the petition of an interested person under section 553(e) of Title 5, to revise a critical habitat designation, the Secretary shall make a finding as to whether the petition presents substantial scientific information indicating that the revision may be warranted. The Secretary shall promptly publish such finding in the Federal Register.

(ii) Within 12 months after receiving a petition that is found under clause (i) to present substantial information indicating that the requested revision may be warranted, the Secretary shall determine how he intends to proceed with the requested revision, and shall promptly publish notice of such intention in the Federal Register.

(4) Except as provided in paragraphs (5) and (6) of this subsection, the provisions of section 553 of Title 5 (relating to rulemaking procedures), shall apply to any regulation promulgated to carry out the purposes of this chapter.

(5) With respect to any regulation proposed by the Secretary to implement a determination, designation, or revision referred to in subsection (a)(1) or (3) of this section, the Secretary shall--

(A) not less than 90 days before the effective date of the regulation--

(i) publish a general notice and the complete text of the proposed regulation in the Federal Register, and

(ii) give actual notice of the proposed regulation (including the complete text of the regulation) to the State agency in each State in which the species is believed to occur, and to each county or equivalent jurisdiction in which the species is believed to occur, and invite the comment of such agency, and each such jurisdiction, thereon;

(B) insofar as practical, and in cooperation with the Secretary of State, give notice of the proposed regulation to each foreign nation in which the species is believed to occur or whose citizens harvest the species on the high seas, and invite the comment of such nation thereon;

(C) give notice of the proposed regulation to such professional scientific organizations as he deems appropriate;

(D) publish a summary of the proposed regulation in a newspaper of general circulation in each area of the United States in which the species is believed to occur; and

(E) promptly hold one public hearing on the proposed regulation if any person files a request for such a hearing within 45 days after the date of publication of general notice.

(6)(A) Within the one-year period beginning on the date on which general notice is published in accordance with paragraph (5)(A)(i) regarding a proposed regulation, the Secretary shall publish in the Federal Register--

(i) if a determination as to whether a species is an endangered species or a threatened species, or a revision of critical habitat, is involved, either--

(I) a final regulation to implement such determination,

(II) a final regulation to implement such revision or a finding that such revision should not be made,

(III) notice that such one-year period is being extended under subparagraph (B) (i), or

(IV) notice that the proposed regulation is being withdrawn under subparagraph (B) (ii), together with the finding on which such withdrawal is based; or

(ii) subject to subparagraph (C), if a designation of critical habitat is involved, either--

(I) a final regulation to implement such designation, or

(II) notice that such one-year period is being extended under such subparagraph.

(B)(i) If the Secretary finds with respect to a proposed regulation referred to in subparagraph (A)(i) that there is substantial disagreement regarding the sufficiency or accuracy of the available data relevant to the determination or revision concerned, the Secretary may extend the one-year period specified in subparagraph (A) for not more than six months for purposes of soliciting additional data.

(ii) If a proposed regulation referred to in subparagraph (A)(i) is not promulgated as a final regulation within such one-year period (or longer period if extension under clause (i) applies) because the Secretary finds that there is not sufficient evidence to justify the action proposed by the regulation, the Secretary shall immediately withdraw the regulation. The finding on which a withdrawal is based shall be subject to judicial review. The Secretary may not propose a regulation

that has previously been withdrawn under this clause unless he determines that sufficient new information is available to warrant such proposal.

(iii) If the one-year period specified in subparagraph (A) is extended under clause (i) with respect to a proposed regulation, then before the close of such extended period the Secretary shall publish in the Federal Register either a final regulation to implement the determination or revision concerned, a finding that the revision should not be made, or a notice of withdrawal of the regulation under clause (ii), together with the finding on which the withdrawal is based.

(C) A final regulation designating critical habitat of an endangered species or a threatened species shall be published concurrently with the final regulation implementing the determination that such species is endangered or threatened, unless the Secretary deems that--

(i) it is essential to the conservation of such species that the regulation implementing such determination be promptly published; or

(ii) critical habitat of such species is not then determinable, in which case the Secretary, with respect to the proposed regulation to designate such habitat, may extend the one-year period specified in subparagraph (A) by not more than one additional year, but not later than the close of such additional year the Secretary must publish a final regulation, based on such data as may be available at that time, designating, to the maximum extent prudent, such habitat.

(7) Neither paragraph (4), (5), or (6) of this subsection nor section 553 of Title 5 shall apply to any regulation issued by the Secretary in regard to any emergency posing a significant risk to the well-being of any species of fish or wildlife or plants, but only if--

(A) at the time of publication of the regulation in the Federal Register the Secretary publishes therein detailed reasons why such regulation is necessary; and

(B) in the case such regulation applies to resident species of fish or wildlife, or plants, the Secretary gives actual notice of such regulation to the State agency in each State in which such species is believed to occur.

Such regulation shall, at the discretion of the Secretary, take effect immediately upon the publication of the regulation in the Federal Register. Any regulation promulgated under the authority of this paragraph shall cease to have force and effect at the close of the 240-day period following the date of publication unless, during such 240-day period, the rulemaking procedures which would apply to such regulation without regard to this paragraph are complied with. If at any time after issuing an emergency regulation the Secretary determines, on the basis of the best appropriate data available to him, that substantial evidence does not exist to warrant such regulation, he shall withdraw it.

(8) The publication in the Federal Register of any proposed or final regulation which is necessary or appropriate to carry out the purposes of this chapter shall include a summary by the Secretary of the data on which such regulation is based and shall show the relationship of such data to such regulation; and if such regulation designates or revises critical habitat, such summary shall, to the maximum extent practicable, also include a brief description and evaluation of those activities (whether public or private) which, in the opinion of the Secretary, if undertaken may adversely modify such habitat, or may be affected by such designation.

(c) Lists

(1) The Secretary of the Interior shall publish in the Federal Register a list of all species determined by him or the Secretary of Commerce to be endangered species and a list of all species determined by him or the Secretary of Commerce to be threatened species. Each list shall refer to the species contained therein by scientific and common name or names, if any, specify with respect to each such species over what portion of its range it is endangered or threatened, and specify any critical habitat within such range. The Secretary shall from time to time revise each list published under the authority of this subsection to reflect recent determinations, designations, and revisions made in accordance with subsections (a) and (b) of this section.

(2) The Secretary shall--

(A) conduct, at least once every five years, a review of all species included in a list which is published pursuant to paragraph (1) and which is in effect at the time of such review; and

(B) determine on the basis of such review whether any such species should--

(i) be removed from such list;

(ii) be changed in status from an endangered species to a threatened species; or

(iii) be changed in status from a threatened species to an endangered species.

Each determination under subparagraph (B) shall be made in accordance with the provisions of subsections (a) and (b) of this section.

(d) Protective regulations

Whenever any species is listed as a threatened species pursuant to subsection (c) of this section, the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation of such species. The Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 1538(a)(1) of this title, in the case of fish or wildlife, or section 1538(a)(2) of this title, in the case of plants, with respect to endangered species; except that with respect to the taking of resident species of fish or wildlife, such regulations shall apply in any State which has entered into a cooperative agreement pursuant to section 1535(c) of this title only to the extent that such regulations have also been adopted by such State.

(e) Similarity of appearance cases

The Secretary may, by regulation of commerce or taking, and to the extent he deems advisable, treat any species as an endangered species or threatened species even though it is not listed pursuant to this section if he finds that--

(A) such species so closely resembles in appearance, at the point in question, a species which has been listed pursuant to such section that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species;

(B) the effect of this substantial difficulty is an additional threat to an endangered or threatened species; and

(C) such treatment of an unlisted species will substantially facilitate the enforcement and further the policy of this chapter.

(f) Recovery plans

(1) The Secretary shall develop and implement plans (hereinafter in this subsection referred to as "recovery plans") for the conservation and survival of endangered species and threatened species listed pursuant to this section, unless he finds that such a plan will not promote the conservation of the species. The Secretary, in developing and implementing recovery plans, shall, to the maximum extent practicable--

(A) give priority to those endangered species or threatened species, without regard to taxonomic classification, that are most likely to benefit from such plans, particularly those species that are, or may be, in conflict with construction or other development projects or other forms of economic activity;

(B) incorporate in each plan--

(i) a description of such site-specific management actions as may be necessary to achieve the plan's goal for the conservation and survival of the species;

(ii) objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of this section, that the species be removed from the list; and

(iii) estimates of the time required and the cost to carry out those measures needed to achieve the plan's goal and to achieve intermediate steps toward that goal.

(2) The Secretary, in developing and implementing recovery plans, may procure the services of appropriate public and private agencies and institutions, and other qualified persons. Recovery teams appointed pursuant to this subsection shall not be subject to the Federal Advisory Committee Act.

(3) The Secretary shall report every two years to the Committee on Environment and Public Works of the Senate and the Committee on Merchant Marine and Fisheries of the House of Representatives on the status of efforts to develop and implement recovery plans for all species listed pursuant to this section and on the status of all species for which such plans have been developed.

(4) The Secretary shall, prior to final approval of a new or revised recovery plan, provide public notice and an opportunity for public review and comment on such plan. The Secretary shall consider all information presented during the public comment period prior to approval of the plan.

(5) Each Federal agency shall, prior to implementation of a new or revised recovery plan, consider all information presented during the public comment period under paragraph (4).

(g) Monitoring

(1) The Secretary shall implement a system in cooperation with the States to monitor effectively for not less than five years the status of all species which have recovered to the point at which the measures provided pursuant to this chapter are no longer necessary and which, in accordance with the provisions of this section, have been removed from either of the lists published under subsection (c) of this section.

(2) The Secretary shall make prompt use of the authority under paragraph 7 [1] of subsection (b) of this section to prevent a significant risk to the well being of any such recovered species.

(h) Agency guidelines; publication in Federal Register; scope; proposals and amendments: notice and opportunity for comments

The Secretary shall establish, and publish in the Federal Register, agency guidelines to insure that the purposes of this section are achieved efficiently and effectively. Such guidelines shall include, but are not limited to--

(1) procedures for recording the receipt and the disposition of petitions submitted under subsection (b)(3) of this section;

(2) criteria for making the findings required under such subsection with respect to petitions;

(3) a ranking system to assist in the identification of species that should receive priority review under subsection (a)(1) of this section; and

(4) a system for developing and implementing, on a priority basis, recovery plans under subsection (f) of this section.

The Secretary shall provide to the public notice of, and opportunity to submit written comments on, any guideline (including any amendment thereto) proposed to be established under this subsection.

(i) Submission to State agency of justification for regulations inconsistent with State agency's comments or petition

If, in the case of any regulation proposed by the Secretary under the authority of this section, a State agency to which notice thereof was given in accordance with subsection (b)(5)(A)(ii) of this section files comments disagreeing with all or part of the proposed regulation, and the Secretary issues a final regulation which is in conflict with such comments,

or if the Secretary fails to adopt a regulation pursuant to an action petitioned by a State agency under subsection (b)(3) of this section, the Secretary shall submit to the State agency a written justification for his failure to adopt regulations consistent with the agency's comments or petition.

CREDIT(S)

(Pub.L. 93-205, § 4, Dec. 28, 1973, 87 Stat. 886; Pub.L. 94-359, § 1, July 12, 1976, 90 Stat. 911; Pub.L. 95-632, §§ 11, 13, Nov. 10, 1978, 92 Stat. 3764, 3766; Pub.L. 96-159, § 3, Dec. 28, 1979, 93 Stat. 1225; Pub.L. 97-304, § 2(a), Oct. 13, 1982, 96 Stat. 1411; Pub.L. 100-478, Title I, §§ 1002 to 1004, Oct. 7, 1988, 102 Stat. 2306; Pub.L. 108-136, Div. A, Title III, § 318, Nov. 24, 2003, 117 Stat. 1433.)

Notes of Decisions (403)

Footnotes

1 So in original. Probably should be “paragraph (7)”.

16 U.S.C.A. § 1533, 16 USCA § 1533

Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 16. Conservation
Chapter 35. Endangered Species (Refs & Annos)

16 U.S.C.A. § 1536

§ 1536. Interagency cooperation

Currentness

(a) Federal agency actions and consultations

(1) The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter. All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this chapter by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 1533 of this title.

(2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency 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 habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

(3) Subject to such guidelines as the Secretary may establish, a Federal agency shall consult with the Secretary on any prospective agency action at the request of, and in cooperation with, the prospective permit or license applicant if the applicant has reason to believe that an endangered species or a threatened species may be present in the area affected by his project and that implementation of such action will likely affect such species.

(4) Each Federal agency shall confer with the Secretary on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under section 1533 of this title or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. This paragraph does not require a limitation on the commitment of resources as described in subsection (d) of this section.

(b) Opinion of Secretary

(1)(A) Consultation under subsection (a) (2) of this section with respect to any agency action shall be concluded within the 90-day period beginning on the date on which initiated or, subject to subparagraph (B), within such other period of time as is mutually agreeable to the Secretary and the Federal agency.

(B) In the case of an agency action involving a permit or license applicant, the Secretary and the Federal agency may not mutually agree to conclude consultation within a period exceeding 90 days unless the Secretary, before the close of the 90th day referred to in subparagraph (A)--

(i) if the consultation period proposed to be agreed to will end before the 150th day after the date on which consultation was initiated, submits to the applicant a written statement setting forth--

(I) the reasons why a longer period is required,

(II) the information that is required to complete the consultation, and

(III) the estimated date on which consultation will be completed; or

(ii) if the consultation period proposed to be agreed to will end 150 or more days after the date on which consultation was initiated, obtains the consent of the applicant to such period.

The Secretary and the Federal agency may mutually agree to extend a consultation period established under the preceding sentence if the Secretary, before the close of such period, obtains the consent of the applicant to the extension.

(2) Consultation under subsection (a) (3) of this section shall be concluded within such period as is agreeable to the Secretary, the Federal agency, and the applicant concerned.

(3)(A) Promptly after conclusion of consultation under paragraph (2) or (3) of subsection (a) of this section, the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat. If jeopardy or adverse modification is found, the Secretary shall suggest those reasonable and prudent alternatives which he believes would not violate subsection (a) (2) of this section and can be taken by the Federal agency or applicant in implementing the agency action.

(B) Consultation under subsection (a) (3) of this section, and an opinion issued by the Secretary incident to such consultation, regarding an agency action shall be treated respectively as a consultation under subsection (a) (2) of this section, and as an opinion issued after consultation under such subsection, regarding that action if the Secretary reviews the action before it is commenced by the Federal agency and finds, and notifies such agency, that no significant changes have been made with respect to the action and that no significant change has occurred regarding the information used during the initial consultation.

(4) If after consultation under subsection (a)(2) of this section, the Secretary concludes that--

(A) the agency action will not violate such subsection, or offers reasonable and prudent alternatives which the Secretary believes would not violate such subsection;

(B) the taking of an endangered species or a threatened species incidental to the agency action will not violate such subsection; and

(C) if an endangered species or threatened species of a marine mammal is involved, the taking is authorized pursuant to section 1371(a)(5) of this title;

the Secretary shall provide the Federal agency and the applicant concerned, if any, with a written statement that--

(i) specifies the impact of such incidental taking on the species,

(ii) specifies those reasonable and prudent measures that the Secretary considers necessary or appropriate to minimize such impact,

(iii) in the case of marine mammals, specifies those measures that are necessary to comply with section 1371(a)(5) of this title with regard to such taking, and

(iv) sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or applicant (if any), or both, to implement the measures specified under clauses (ii) and (iii).

(c) Biological assessment

(1) To facilitate compliance with the requirements of subsection (a) (2) of this section, each Federal agency shall, with respect to any agency action of such agency for which no contract for construction has been entered into and for which no construction has begun on November 10, 1978, request of the Secretary information whether any species which is listed or proposed to be listed may be present in the area of such proposed action. If the Secretary advises, based on the best scientific and commercial data available, that such species may be present, such agency shall conduct a biological assessment for the purpose of identifying any endangered species or threatened species which is likely to be affected by such action. Such assessment shall be completed within 180 days after the date on which initiated (or within such other period as is mutually agreed to by the Secretary and such agency, except that if a permit or license applicant is involved, the 180-day period may not be extended unless such agency provides the applicant, before the close of such period, with a written statement setting forth the estimated length of the proposed extension and the reasons therefor) and, before any contract for construction is entered into and before construction is begun with respect to such action. Such assessment may be undertaken as part of a Federal agency's compliance with the requirements of section 102 of the National Environmental Policy Act of 1969 (42 U.S.C. 4332).

(2) Any person who may wish to apply for an exemption under subsection (g) of this section for that action may conduct a biological assessment to identify any endangered species or threatened species which is likely to be affected by such action. Any such biological assessment must, however, be conducted in cooperation with the Secretary and under the supervision of the appropriate Federal agency.

(d) Limitation on commitment of resources

After initiation of consultation required under subsection (a) (2) of this section, the Federal agency and the permit or license applicant shall not make any irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate subsection (a) (2) of this section.

(e) Endangered Species Committee

(1) There is established a committee to be known as the Endangered Species Committee (hereinafter in this section referred to as the "Committee").

(2) The Committee shall review any application submitted to it pursuant to this section and determine in accordance with subsection (h) of this section whether or not to grant an exemption from the requirements of subsection (a) (2) of this section for the action set forth in such application.

(3) The Committee shall be composed of seven members as follows:

(A) The Secretary of Agriculture.

(B) The Secretary of the Army.

(C) The Chairman of the Council of Economic Advisors.

(D) The Administrator of the Environmental Protection Agency.

(E) The Secretary of the Interior.

(F) The Administrator of the National Oceanic and Atmospheric Administration.

(G) The President, after consideration of any recommendations received pursuant to subsection (g) (2) (B) of this section shall appoint one individual from each affected State, as determined by the Secretary, to be a member of the Committee for the consideration of the application for exemption for an agency action with respect to which such recommendations are made, not later than 30 days after an application is submitted pursuant to this section.

(4)(A) Members of the Committee shall receive no additional pay on account of their service on the Committee.

(B) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of Title 5.

(5)(A) Five members of the Committee or their representatives shall constitute a quorum for the transaction of any function of the Committee, except that, in no case shall any representative be considered in determining the existence of a quorum for the transaction of any function of the Committee if that function involves a vote by the Committee on any matter before the Committee.

(B) The Secretary of the Interior shall be the Chairman of the Committee.

(C) The Committee shall meet at the call of the Chairman or five of its members.

(D) All meetings and records of the Committee shall be open to the public.

(6) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a nonreimbursable basis, any of the personnel of such agency to the Committee to assist it in carrying out its duties under this section.

(7)(A) The Committee may for the purpose of carrying out its duties under this section hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Committee deems advisable.

(B) When so authorized by the Committee, any member or agent of the Committee may take any action which the Committee is authorized to take by this paragraph.

(C) Subject to the Privacy Act [5 U.S.C.A. § 552a], the Committee may secure directly from any Federal agency information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Committee, the head of such Federal agency shall furnish such information to the Committee.

(D) The Committee may use the United States mails in the same manner and upon the same conditions as a Federal agency.

(E) The Administrator of General Services shall provide to the Committee on a reimbursable basis such administrative support services as the Committee may request.

(8) In carrying out its duties under this section, the Committee may promulgate and amend such rules, regulations, and procedures, and issue and amend such orders as it deems necessary.

(9) For the purpose of obtaining information necessary for the consideration of an application for an exemption under this section the Committee may issue subpenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents.

(10) In no case shall any representative, including a representative of a member designated pursuant to paragraph (3)(G) of this subsection, be eligible to cast a vote on behalf of any member.

(f) Promulgation of regulations; form and contents of exemption application

Not later than 90 days after November 10, 1978, the Secretary shall promulgate regulations which set forth the form and manner in which applications for exemption shall be submitted to the Secretary and the information to be contained in such applications. Such regulations shall require that information submitted in an application by the head of any Federal agency with respect to any agency action include, but not be limited to--

(1) a description of the consultation process carried out pursuant to subsection (a) (2) of this section between the head of the Federal agency and the Secretary; and

(2) a statement describing why such action cannot be altered or modified to conform with the requirements of subsection (a) (2) of this section.

(g) Application for exemption; report to Committee

(1) A Federal agency, the Governor of the State in which an agency action will occur, if any, or a permit or license applicant may apply to the Secretary for an exemption for an agency action of such agency if, after consultation under subsection (a) (2) of this section, the Secretary's opinion under subsection (b) of this section indicates that the agency action would violate subsection (a) (2) of this section. An application for an exemption shall be considered initially by the Secretary in the manner provided for in this subsection, and shall be considered by the Committee for a final determination under subsection (h) of this section after a report is made pursuant to paragraph (5). The applicant for an exemption shall be referred to as the "exemption applicant" in this section.

(2)(A) An exemption applicant shall submit a written application to the Secretary, in a form prescribed under subsection (f) of this section, not later than 90 days after the completion of the consultation process; except that, in the case of any agency action involving a permit or license applicant, such application shall be submitted not later than 90 days after the date on which the Federal agency concerned takes final agency action with respect to the issuance of the permit or license. For purposes of the preceding sentence, the term "final agency action" means (i) a disposition by an agency with respect to the issuance of a permit or license that is subject to administrative review, whether or not such disposition is subject to judicial review; or (ii) if administrative review is sought with respect to such disposition, the decision resulting after such review. Such application shall set forth the reasons why the exemption applicant considers that the agency action meets the requirements for an exemption under this subsection.

(B) Upon receipt of an application for exemption for an agency action under paragraph (1), the Secretary shall promptly (i) notify the Governor of each affected State, if any, as determined by the Secretary, and request the Governors so notified to recommend individuals to be appointed to the Endangered Species Committee for consideration of such application; and (ii) publish notice of receipt of the application in the Federal Register, including a summary of the information contained in the application and a description of the agency action with respect to which the application for exemption has been filed.

(3) The Secretary shall within 20 days after the receipt of an application for exemption, or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary--

(A) determine that the Federal agency concerned and the exemption applicant have--

(i) carried out the consultation responsibilities described in subsection (a) of this section in good faith and made a reasonable and responsible effort to develop and fairly consider modifications or reasonable and prudent alternatives to the proposed agency action which would not violate subsection (a) (2) of this section;

(ii) conducted any biological assessment required by subsection (c) of this section; and

(iii) to the extent determinable within the time provided herein, refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d) of this section; or

(B) deny the application for exemption because the Federal agency concerned or the exemption applicant have not met the requirements set forth in subparagraph (A) (i), (ii), and (iii).

The denial of an application under subparagraph (B) shall be considered final agency action for purposes of chapter 7 of Title 5.

(4) If the Secretary determines that the Federal agency concerned and the exemption applicant have met the requirements set forth in paragraph (3) (A) (i), (ii), and (iii) he shall, in consultation with the Members of the Committee, hold a hearing on the application for exemption in accordance with sections 554, 555, and 556 (other than subsection (b) (1) and (2) thereof) of Title 5 and prepare the report to be submitted pursuant to paragraph (5).

(5) Within 140 days after making the determinations under paragraph (3) or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary, the Secretary shall submit to the Committee a report discussing--

(A) the availability of reasonable and prudent alternatives to the agency action, and the nature and extent of the benefits of the agency action and of alternative courses of action consistent with conserving the species or the critical habitat;

(B) a summary of the evidence concerning whether or not the agency action is in the public interest and is of national or regional significance;

(C) appropriate reasonable mitigation and enhancement measures which should be considered by the Committee; and

(D) whether the Federal agency concerned and the exemption applicant refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d) of this section.

(6) To the extent practicable within the time required for action under subsection (g) of this section, and except to the extent inconsistent with the requirements of this section, the consideration of any application for an exemption under this section and the conduct of any hearing under this subsection shall be in accordance with sections 554, 555, and 556 (other than subsection (b) (3) of section 556) of Title 5.

(7) Upon request of the Secretary, the head of any Federal agency is authorized to detail, on a nonreimbursable basis, any of the personnel of such agency to the Secretary to assist him in carrying out his duties under this section.

(8) All meetings and records resulting from activities pursuant to this subsection shall be open to the public.

(h) Grant of exemption

(1) The Committee shall make a final determination whether or not to grant an exemption within 30 days after receiving the report of the Secretary pursuant to subsection (g) (5) of this section. The Committee shall grant an exemption from the requirements of subsection (a) (2) of this section for an agency action if, by a vote of not less than five of its members voting in person--

(A) it determines on the record, based on the report of the Secretary, the record of the hearing held under subsection (g) (4) of this section and on such other testimony or evidence as it may receive, that--

(i) there are no reasonable and prudent alternatives to the agency action;

(ii) the benefits of such action clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and such action is in the public interest;

(iii) the action is of regional or national significance; and

(iv) neither the Federal agency concerned nor the exemption applicant made any irreversible or irretrievable commitment of resources prohibited by subsection (d) of this section; and

(B) it establishes such reasonable mitigation and enhancement measures, including, but not limited to, live propagation, transplantation, and habitat acquisition and improvement, as are necessary and appropriate to minimize the adverse effects of the agency action upon the endangered species, threatened species, or critical habitat concerned.

Any final determination by the Committee under this subsection shall be considered final agency action for purposes of chapter 7 of Title 5.

(2)(A) Except as provided in subparagraph (B), an exemption for an agency action granted under paragraph (1) shall constitute a permanent exemption with respect to all endangered or threatened species for the purposes of completing such agency action--

(i) regardless whether the species was identified in the biological assessment; and

(ii) only if a biological assessment has been conducted under subsection (c) of this section with respect to such agency action.

(B) An exemption shall be permanent under subparagraph (A) unless--

(i) the Secretary finds, based on the best scientific and commercial data available, that such exemption would result in the extinction of a species that was not the subject of consultation under subsection (a) (2) of this section or was not identified in any biological assessment conducted under subsection (c) of this section, and

(ii) the Committee determines within 60 days after the date of the Secretary's finding that the exemption should not be permanent.

If the Secretary makes a finding described in clause (i), the Committee shall meet with respect to the matter within 30 days after the date of the finding.

(i) Review by Secretary of State; violation of international treaty or other international obligation of United States

Notwithstanding any other provision of this chapter, the Committee shall be prohibited from considering for exemption any application made to it, if the Secretary of State, after a review of the proposed agency action and its potential implications, and after hearing, certifies, in writing, to the Committee within 60 days of any application made under this section that the granting of any such exemption and the carrying out of such action would be in violation of an international treaty obligation or other international obligation of the United States. The Secretary of State shall, at the time of such certification, publish a copy thereof in the Federal Register.

(j) Exemption for national security reasons

Notwithstanding any other provision of this chapter, the Committee shall grant an exemption for any agency action if the Secretary of Defense finds that such exemption is necessary for reasons of national security.

(k) Exemption decision not considered major Federal action; environmental impact statement

An exemption decision by the Committee under this section shall not be a major Federal action for purposes of the National Environmental Policy Act of 1969 [42 U.S.C.A. § 4321 et seq.]: *Provided*, That an environmental impact statement which discusses the impacts upon endangered species or threatened species or their critical habitats shall have been previously prepared with respect to any agency action exempted by such order.

(l) Committee order granting exemption; cost of mitigation and enhancement measures; report by applicant to Council on Environmental Quality

(1) If the Committee determines under subsection (h) of this section that an exemption should be granted with respect to any agency action, the Committee shall issue an order granting the exemption and specifying the mitigation and enhancement measures established pursuant to subsection (h) of this section which shall be carried out and paid for by

the exemption applicant in implementing the agency action. All necessary mitigation and enhancement measures shall be authorized prior to the implementing of the agency action and funded concurrently with all other project features.

(2) The applicant receiving such exemption shall include the costs of such mitigation and enhancement measures within the overall costs of continuing the proposed action. Notwithstanding the preceding sentence the costs of such measures shall not be treated as project costs for the purpose of computing benefit-cost or other ratios for the proposed action. Any applicant may request the Secretary to carry out such mitigation and enhancement measures. The costs incurred by the Secretary in carrying out any such measures shall be paid by the applicant receiving the exemption. No later than one year after the granting of an exemption, the exemption applicant shall submit to the Council on Environmental Quality a report describing its compliance with the mitigation and enhancement measures prescribed by this section. Such a report shall be submitted annually until all such mitigation and enhancement measures have been completed. Notice of the public availability of such reports shall be published in the Federal Register by the Council on Environmental Quality.

(m) Notice requirement for citizen suits not applicable

The 60-day notice requirement of section 1540(g) of this title shall not apply with respect to review of any final determination of the Committee under subsection (h) of this section granting an exemption from the requirements of subsection (a) (2) of this section.

(n) Judicial review

Any person, as defined by section 1532(13) of this title, may obtain judicial review, under chapter 7 of Title 5, of any decision of the Endangered Species Committee under subsection (h) of this section in the United States Court of Appeals for (1) any circuit wherein the agency action concerned will be, or is being, carried out, or (2) in any case in which the agency action will be, or is being, carried out outside of any circuit, the District of Columbia, by filing in such court within 90 days after the date of issuance of the decision, a written petition for review. A copy of such petition shall be transmitted by the clerk of the court to the Committee and the Committee shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Attorneys designated by the Endangered Species Committee may appear for, and represent the Committee in any action for review under this subsection.

(o) Exemption as providing exception on taking of endangered species

Notwithstanding sections 1533(d) and 1538(a)(1)(B) and (C) of this title, sections 1371 and 1372 of this title, or any regulation promulgated to implement any such section--

(1) any action for which an exemption is granted under subsection (h) of this section shall not be considered to be a taking of any endangered species or threatened species with respect to any activity which is necessary to carry out such action; and

(2) any taking that is in compliance with the terms and conditions specified in a written statement provided under subsection (b)(4)(iv) of this section shall not be considered to be a prohibited taking of the species concerned.

(p) Exemptions in Presidentially declared disaster areas

In any area which has been declared by the President to be a major disaster area under the Disaster Relief and Emergency Assistance Act [42 U.S.C.A. § 5121 et seq.], the President is authorized to make the determinations required by subsections (g) and (h) of this section for any project for the repair or replacement of a public facility substantially as it existed prior to the disaster under section 405 or 406 of the Disaster Relief and Emergency Assistance Act [42 U.S.C.A. §§ 5171 or 5172], and which the President determines (1) is necessary to prevent the recurrence of such a natural disaster and to reduce the potential loss of human life, and (2) to involve an emergency situation which does not allow the ordinary procedures of this section to be followed. Notwithstanding any other provision of this section, the Committee shall accept the determinations of the President under this subsection.

CREDIT(S)

(Pub.L. 93-205, § 7, Dec. 28, 1973, 87 Stat. 892; Pub.L. 95-632, § 3, Nov. 10, 1978, 92 Stat. 3752; Pub.L. 96-159, § 4, Dec. 28, 1979, 93 Stat. 1226; Pub.L. 97-304, §§ 4(a), 8(b), Oct. 13, 1982, 96 Stat. 1417, 1426; Pub.L. 99-659, Title IV, § 411(b), (c), Nov. 14, 1986, 100 Stat. 3742; Pub.L. 100-707, Title I, § 109(g), Nov. 23, 1988, 102 Stat. 4709.)

Notes of Decisions (697)

16 U.S.C.A. § 1536, 16 USCA § 1536
Current through P.L. 115-90. Also includes P.L. 115-92 to 115-117, and 115-119. Title 26 current through 115-122.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 152. Pesticide Registration and Classification Procedures (Refs & Annos)
Subpart A. General Provisions (Refs & Annos)

40 C.F.R. § 152.3

§ 152.3 Definitions.

Effective: February 10, 2009
Currentness

Terms used in this part have the same meaning as in the Act. In addition, the following terms have the meanings set forth in this section.

Act or FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in § 174.3 of this chapter.

Acute dermal LD_{50} means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC_{50} means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD_{50} means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Administrator means the Administrator of the United States Environmental Protection Agency or his delegate.

Agency means the United States Environmental Protection Agency (EPA), unless otherwise specified.

Applicant means a person who applies for a registration or amended registration under FIFRA sec. 3.

Biological control agent means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

Distribute or sell and other grammatical variations of the term such as “distributed or sold” and “distribution or sale,” means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

End use product means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

Final printed labeling means the label or labeling of the product when distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by § 174.3 of this chapter.

Institutional use means any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

(1) Hospitals and nursing homes.

(2) Schools other than preschools and day care facilities.

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Manufacturing use product means any pesticide product that is not an end-use product.

New use, when used with respect to a product containing a particular active ingredient, means:

(1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation under section 408 of the Federal Food, Drug and Cosmetic Act;

(2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

(3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Operated by the same producer, when used with respect to two establishments, means that each such establishment is either owned by, or leased for operation by and under the control of, the same person. The term does not include establishments owned or operated by different persons, regardless of contractual agreement between such persons.

Package or packaging means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use, or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(1) Is a new animal drug under FFDCA sec. 201(w), or

(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or

(3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s)(1) or (2) of this section.

Pesticide product means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Released for shipment. A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where finished products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment unless subsequent activities, such as relabeling or repackaging, constitute production.

Residential use means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

Credits

[66 FR 37814, July 19, 2001; 73 FR 64224, Oct. 29, 2008; 73 FR 75594, Dec. 12, 2008]

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15975, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Notes of Decisions (4)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 152. Pesticide Registration and Classification Procedures (Refs & Annos)
Subpart F. Agency Review of Applications (Refs & Annos)

40 C.F.R. § 152.113

§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

Currentness

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15980, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Notes of Decisions (4)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 158.70

§ 158.70 Satisfying data requirements.

Effective: December 26, 2007
Currentness

(a) General policy. The Agency will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated, were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(1) The provisions in this part 158 should be read in conjunction with the provisions in § 152.85 to claim eligibility for the formulators' exemption.

(2) [Reserved]

(b) Good laboratory practices. Applicants must adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160 when conducting studies. Applicants must also adhere to GLP standards when conducting a study in support of a waiver request of any data requirement which is within the scope of the GLP requirements.

(c) Agency guidelines. EPA has published Test Guidelines that contain standards for conducting acceptable tests, guidance on the evaluation and reporting of data, definition of terms, and suggested study protocols. Copies of the Test Guidelines may be obtained by visiting the agency's website at www.epa.gov/pesticides.

(d) Study protocols—

(1) General. Any appropriate protocol may be used to generate the data required by this part, provided that it meets the purpose of the test standards specified in the pesticide assessment guidelines, and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure

which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(2) Organization for Economic Co–Operation and Development (OECD) protocols. Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Applicants should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(e) Combining studies. Certain toxicology studies may be combined to satisfy data requirements. For example, carcinogenicity studies in rats may be combined with the rat chronic toxicity study. Combining appropriate studies may be expected to reduce usage of test animals as well as reduce the cost of studies. EPA encourages this practice by including standards for acceptable combined tests in the Pesticide Assessment Guidelines. Registrants and applicants are encouraged to consider combining other tests when practical and likely to produce scientifically acceptable results. Registrants and applicants, however, must consult with the EPA before initiating combined studies.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Current through April 5, 2018; 83 FR 14604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart A. General

50 C.F.R. § 402.01

§ 402.01 Scope.

Currentness

(a) This part interprets and implements sections 7(a)–(d) [16 U.S.C. 1536(a)–(d)] of the Endangered Species Act of 1973, as amended ("Act"). Section 7(a) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical ("critical habitat"). Section 7(a)(1) of the Act directs Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or of Commerce, as appropriate, to utilize their authorities to further the purposes of the Act by carrying out conservation programs for listed species. Such affirmative conservation programs must comply with applicable permit requirements (50 CFR parts 17, 220, 222, and 227) for listed species and should be coordinated with the appropriate Secretary. Section 7(a)(2) of the Act requires every Federal agency, in consultation with and with the assistance of the Secretary, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat. Section 7(a)(3) of the Act authorizes a prospective permit or license applicant to request the issuing Federal agency to enter into early consultation with the Service on a proposed action to determine whether such action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Section 7(a)(4) of the Act requires Federal agencies to confer with the Secretary on any action that is likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat. Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat Biological assessments are required under section 7(c) of the Act if listed species or critical habitat may be present in the area affected by any major construction activity as defined in § 404.02. Section 7(d) of the Act prohibits Federal agencies and applicants from making any irreversible or irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternatives which would avoid jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Section 7(e)–(o)(1) of the Act provide procedures for granting exemptions from the requirements of section 7(a)(2). Regulations governing the submission of exemption applications are found at 50 CFR part 451, and regulations governing the exemption process are found at 50 CFR parts 450, 452, and 453.

(b) The U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) share responsibilities for administering the Act. The Lists of Endangered and Threatened Wildlife and Plants are found in 50 CFR 17.11 and 17.12 and the designated critical habitats are found in 50 CFR 17.95 and 17.96 and 50 CFR Part 226. Endangered or threatened species under the jurisdiction of the NMFS are located in 50 CFR 222.23(a) and 227.4. If the subject species is cited in 50 CFR 222.23(a) or 227.4, the Federal agency shall contact the NMFS. For all other listed species the Federal Agency shall contact the FWS.

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (305)

Current through February 1, 2018; 83 FR 4604.

End of Document

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedPrior Version Held Invalid Cape Hatteras Access Preservation Alliance v. U.S. Dept. of Interior, D.D.C., Nov. 01, 2004

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart A. General

50 C.F.R. § 402.02

§ 402.02 Definitions.

Effective: March 14, 2016
Currentness

Act means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 et seq.

Action means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

(a) actions intended to conserve listed species or their habitat;

(b) the promulgation of regulations;

(c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or

(d) actions directly or indirectly causing modifications to the land, water, or air.

Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

Applicant refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

Biological assessment refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

Biological opinion is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Conference is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

Conservation recommendations are suggestions of the Service 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.

Critical habitat refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

Cumulative effects are 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.

Designated non-Federal representative refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

Director refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

Early consultation is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

Effects of the action refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.

Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

Framework programmatic action means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

Jeopardize the continued existence of means to engage in an action that reasonably would be 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.

Listed species means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11–17.12.

Major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

Mixed programmatic action means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Preliminary biological opinion refers to an opinion issued as a result of early consultation.

Proposed critical habitat means habitat proposed in the Federal Register to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

Proposed species means any species of fish, wildlife, or plant that is proposed in the Federal Register to be listed under section 4 of the Act.

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director believes necessary or appropriate to minimize the impacts, i.e., amount or extent, of incidental take.

Recovery means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

Service means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

Credits

[73 FR 76286, Dec. 16, 2008; 74 FR 20422, May 4, 2009; 80 FR 26844, May 11, 2015; 81 FR 7225, Feb. 11, 2016]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (234)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.12

§ 402.12 Biological assessments.

Currentness

(a) Purpose. A biological assessment shall evaluate the potential effects of the action on listed and proposed species and designated and proposed critical habitat and determine whether any such species or habitat are likely to be adversely affected by the action and is used in determining whether formal consultation or a conference is necessary.

(b) Preparation requirement.

(1) The procedures of this section are required for Federal actions that are "major construction activities"; provided that a contract for construction was not entered into or actual construction was not begun on or before November 10, 1978. Any person, including those who may wish to apply for an exemption from section 7(a)(2) of the Act, may prepare a biological assessment under the supervision of the Federal agency and in cooperation with the Service consistent with the procedures and requirements of this section. An exemption from the requirements of section 7(a)(2) is not permanent unless a biological assessment has been prepared.

(2) The biological assessment shall be completed before any contract for construction is entered into and before construction is begun.

(c) Request for information. The Federal agency or the designated non-Federal representative shall convey to the Director either (1) a written request for a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area; or (2) a written notification of the species and critical habitat that are being included in the biological assessment.

(d) Director's response. Within 30 days of receipt of the notification of, or the request for, a species list, the Director shall either concur with or revise the list or, in those cases where no list has been provided, advise the Federal agency or the designated non-Federal representative in writing whether, based on the best scientific and commercial data available, any listed or proposed species or designated or proposed critical habitat may be present in the action area. In addition to listed and proposed species, the Director will provide a list of candidate species that may be present in the action area. Candidate species refers to any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule. Although candidate species have no legal status and are accorded no protection under the Act, their inclusion will alert the Federal agency of potential proposals or listings.

(1) If the Director advises that no listed species or critical habitat may be present, the Federal agency need not prepare a biological assessment and further consultation is not required. If only proposed species or proposed critical habitat may be present in the action area, then the Federal agency must confer with the Service if required under § 402.10, but preparation of a biological assessment is not required unless the proposed listing and/or designation becomes final.

(2) If a listed species or critical habitat may be present in the action area, the Director will provide a species list or concur with the species list provided. The Director also will provide available information (or references thereto) regarding these species and critical habitat, and may recommend discretionary studies or surveys that may provide a better information base for the preparation of an assessment. Any recommendation for studies or surveys is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

(e) Verification of current accuracy of species list. If the Federal agency or the designated non-Federal representative does not begin preparation of the biological assessment within 90 days of receipt of (or concurrence with) the species list, the Federal agency or the designated non-Federal representative must verify (formally or informally) with the Service the current accuracy of the species list at the time the preparation of the assessment is begun.

(f) Contents. The contents of a biological assessment are at the discretion of the Federal agency and will depend on the nature of the Federal action. The following may be considered for inclusion:

(1) The results of an on-site inspection of the area affected by the action to determine if listed or proposed species are present or occur seasonally.

(2) The views of recognized experts on the species at issue.

(3) A review of the literature and other information.

(4) An analysis of the effects of the action on the species and habitat, including consideration of cumulative effects, and the results of any related studies.

(5) An analysis of alternate actions considered by the Federal agency for the proposed action.

(g) Incorporation by reference. If a proposed action requiring the preparation of a biological assessment is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may fulfill the biological assessment requirement for the proposed action by incorporating by reference the earlier biological assessment, plus any supporting data from other documents that are pertinent to the consultation, into a written certification that:

(1) The proposed action involves similar impacts to the same species in the same geographic area;

(2) No new species have been listed or proposed or no new critical habitat designated or proposed for the action area; and

(3) The biological assessment has been supplemented with any relevant changes in information.

(h) Permit requirements. If conducting a biological assessment will involve the taking of a listed species, a permit under section 10 of the Act (16 U.S.C. 1539) and part 17 of this title (with respect to species under the jurisdiction of the FWS) or parts 220, 222, and 227 of this title (with respect to species under the jurisdiction of the NMFS) is required.

(i) Completion time. The Federal agency or the designated non- Federal representative shall complete the biological assessment within 180 days after its initiation (receipt of or concurrence with the species list) unless a different period of time is agreed to by the Director and the Federal agency. If a permit or license applicant is involved, the 180–day period may not be extended unless the agency provides the applicant, before the close of the 180–day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why such an extension is necessary.

(j) Submission of biological assessment. The Federal agency shall submit the completed biological assessment to the Director for review. The Director will respond in writing within 30 days as to whether or not he concurs with the findings of the biological assessment. At the option of the Federal agency, formal consultation may be initiated under § 402.14(c) concurrently with the submission of the assessment.

(k) Use of the biological assessment.

(1) The Federal agency shall use the biological assessment in determining whether formal consultation or a conference is required under § 402.14 or § 402.10, respectively. If the biological assessment indicates that there are no listed species or critical habitat present that are likely to be adversely affected by the action and the Director concurs as specified in paragraph (j) of this section, then formal consultation is not required. If the biological assessment indicates that the action is not likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (56)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.13

§ 402.13 Informal consultation.

Effective: May 4, 2009
Currentness

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non–Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required. If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

Credits
[73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (16)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.14

§ 402.14 Formal consultation.

Effective: June 10, 2015
Currentness

(a) Requirement for formal consultation. Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) Exceptions.

(1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) Initiation of formal consultation. A written request to initiate formal consultation shall be submitted to the Director and shall include:

(1) A description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statement, environmental assessment, or biological assessment prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat.

Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12. Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area or a segment of a comprehensive plan. This does not relieve the Federal agency of the requirements for considering the effects of the action as a whole.

(d) Responsibility to provide best scientific and commercial data available. The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) Duration and extension of formal consultation. Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

(2) The information that is required to complete the consultation, and

(3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) Additional data. When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's

request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) Service responsibilities. Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Formulate its biological opinion as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)–(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45–day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45–day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10–day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

(h) Biological opinions. The biological opinion shall include:

(1) A summary of the information on which the opinion is based;

(2) A detailed discussion of the effects of the action on listed species or critical habitat; and

(3) The Service's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy biological opinion"); or, the action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(i) Incidental take.

(1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, i.e., the amount or extent, of such incidental taking on the species (A surrogate (e.g., similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinitiate consultation immediately.

(5) Any taking which is subject to a statement as specified in paragraph (i)(1) of this section and which is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(6) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) Conservation recommendations. The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) Incremental steps. When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(l) Termination of consultation.

(1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

Credits

[54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (206)

Current through February 1, 2018; 83 FR 4604.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 424. Listing Endangered and Threatened Species and Designating Critical Habitat (Refs & Annos)
Subpart B. Revision of the Lists

50 C.F.R. § 424.12

§ 424.12 Criteria for designating critical habitat.

Effective: March 14, 2016
Currentness

(a) To the maximum extent prudent and determinable, we will propose and finalize critical habitat designations concurrent with issuing proposed and final listing rules, respectively. If designation of critical habitat is not prudent or if critical habitat is not determinable, the Secretary will state the reasons for not designating critical habitat in the publication of proposed and final rules listing a species. The Secretary will make a final designation of critical habitat on the basis of the best scientific data available, after taking into consideration the probable economic, national security, and other relevant impacts of making such a designation in accordance with § 424.19.

(1) A designation of critical habitat is not prudent when any of the following situations exist:

(i) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species; or

(ii) Such designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Services may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of "critical habitat."

(2) Designation of critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking; or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of "critical habitat."

(b) Where designation of critical habitat is prudent and determinable, the Secretary will identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat.

(1) The Secretary will identify, at a scale determined by the Secretary to be appropriate, specific areas within the geographical area occupied by the species for consideration as critical habitat. The Secretary will:

(i) Identify the geographical area occupied by the species at the time of listing.

(ii) Identify physical and biological features essential to the conservation of the species at an appropriate level of specificity using the best available scientific data. This analysis will vary between species and may include consideration of the appropriate quality, quantity, and spatial and temporal arrangements of such features in the context of the life history, status, and conservation needs of the species.

(iii) Determine the specific areas within the geographical area occupied by the species that contain the physical or biological features essential to the conservation of the species.

(iv) Determine which of these features may require special management considerations or protection.

(2) The Secretary will identify, at a scale determined by the Secretary to be appropriate, specific areas outside the geographical area occupied by the species that are essential for its conservation, considering the life history, status, and conservation needs of the species based on the best available scientific data.

(c) Each critical habitat area will be shown on a map, with more-detailed information discussed in the preamble of the rulemaking documents published in the Federal Register and made available from the lead field office of the Service responsible for such designation. Textual information may be included for purposes of clarifying or refining the location and boundaries of each area or to explain the exclusion of sites (e.g., paved roads, buildings) within the mapped area. Each area will be referenced to the State(s), county(ies), or other local government units within which all or part of the critical habitat is located. Unless otherwise indicated within the critical habitat descriptions, the names of the State(s) and county(ies) are provided for informational purposes only and do not constitute the boundaries of the area. Ephemeral reference points (e.g., trees, sand bars) shall not be used in any textual description used to clarify or refine the boundaries of critical habitat.

(d) When several habitats, each satisfying the requirements for designation as critical habitat, are located in proximity to one another, the Secretary may designate an inclusive area as critical habitat.

(e) The Secretary may designate critical habitat for those species listed as threatened or endangered but for which no critical habitat has been previously designated. For species listed prior to November 10, 1978, the designation of critical habitat is at the discretion of the Secretary.

(f) The Secretary may revise existing designations of critical habitat according to procedures in this section as new data become available.

(g) The Secretary will not designate critical habitat within foreign countries or in other areas outside of the jurisdiction of the United States.

(h) The Secretary will not designate as critical habitat land or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to a compliant or operational integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a) if the Secretary determines in writing that such plan provides a conservation benefit to the species for which critical habitat is being designated. In determining whether such a benefit is provided, the Secretary will consider:

(1) The extent of the area and features present;

(2) The type and frequency of use of the area by the species;

(3) The relevant elements of the INRMP in terms of management objectives, activities covered, and best management practices, and the certainty that the relevant elements will be implemented; and

(4) The degree to which the relevant elements of the INRMP will protect the habitat from the types of effects that would be addressed through a destruction-or-adverse-modification analysis.

Credits

[45 FR 13022, Feb. 27, 1980; 45 FR 64195, Sept. 29, 1980; 77 FR 25622, May 1, 2012; 81 FR 7439, Feb. 11, 2016]

SOURCE: 45 FR 13022, Feb. 27, 1980; 49 FR 38908, Oct. 1, 1984; 78 FR 53076, Aug. 28, 2013, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (43)

Current through February 1, 2018; 83 FR 4604.

ADDENDUM OF DECLARATIONS

TABLE OF CONTENTS

PAGE(S)

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF JOHN BUSE IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, JOHN BUSE, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the order granting a conditional registration of Enlist Duo Herbicide (Enlist Duo), containing the active ingredients 2,4-Dichlorophenoxyacetic acid (2,4-D) and glyphosate, for uses in thirty-four states on genetically engineered corn, soybean, and cotton that have been engineered to resist 2,4-D and glyphosate filed by Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, Pesticide Action Network North America.

2. I have been a member of the Center for Biological Diversity since 2005. I am also a Senior Attorney and the Legal Director for the Center for Biological Diversity (the "Center").

3. I live in Indianapolis, Indiana. Indiana is one of the states where the EPA registered Enlist Duo for use on genetically engineered corn and soybean that have been engineered to resist Enlist Duo. The states of Indiana and Illinois are among the largest producers of both corn and soybean, and the majority of agricultural land in and around Marion County, Indiana where I live is used for corn and soybean production. I am also familiar with the Chicago metropolitan area, which is also surrounded by lands used for intense corn and soybean production.

4. I am a 1985 graduate of the University of Chicago, with a degree in the History, Philosophy and Social Studies of Science and Medicine. I also have a master's degree in Biological Chemistry from the University of Illinois–Chicago Medical Center. I am a 1992 graduate of the University of California–Davis School of Law, where I focused on environmental law and related topics.

5. Thanks to my educational background and personal experience, I have a deep professional and personal interest in evolutionary biology and the diversity of life on earth.

6. As a member and staff member of the Center, I count on the Center to represent my interest in protecting biodiversity and conserving threatened and endangered species and their habitats through legal advocacy, public education, and other means.

7. Through my professional work and personal observation, I have become very concerned about the effect of conventional agriculture on threatened and endangered species. I have become aware of the enormous quantities of pesticides used to support conventional agricultural operations in Indiana, Illinois, and other Midwestern states, and have followed with interest the reports that agricultural chemicals disrupt endocrine activity in amphibians. I am concerned that the effects of commonly used pesticides and herbicides extend beyond impacts on amphibians, and may pose a significant threat to the wellbeing and recovery of

many other threatened and endangered species, as well as to water quality and human health.

8. I enjoy looking for rare native wildlife, fish, and plants in their natural habitats in and around where I live.

Indiana bat

9. I regularly observe bats at or near my home in Indianapolis on summer and fall evenings. I have specifically observed Indiana bats (*Myotis sodalis*) at a known colony south of Indianapolis International Airport as part of a bat count. I watched and counted the bats as they emerged from their tree colony at twilight.

10. I appreciate the Indiana bat and its continued existence in the wild for its quiet but persistent presence, for its stealthy hunting of insects, and for the valuable habitat it maintains in close proximity to urban centers. I also believe that all species, including the Indiana bat, have inherent value, and I have an interest in maintaining the diversity of life.

11. I have hiked and recreated near Indiana bat's habitat on numerous occasions while attempting to observe wildlife. I will continue to seek out and observe bats, including Indiana bats, as long as I live here.

12. I hope to again see an Indiana bat in the wild here in Indiana and elsewhere, and I look forward to the recovery of the Indiana bat throughout its

native range. I am concerned that Enlist Duo will be routinely applied in Indiana and elsewhere in and around Indiana bat habitat without regard to the species' conservation and recovery. Killing of non-target insects and plants by pesticides and herbicides is well-documented, and I fear that Indiana bats are being inadvertently killed and harmed by agricultural chemicals. If the remaining populations of Indiana bats in Indiana were extirpated or reduced, my appreciation of the area's unique natural environment would be diminished.

Hine's emerald dragonfly

13. As a Center staff attorney, I worked on a lawsuit involving the Hine's emerald dragonfly (*Somatochlora hineana*). The lawsuit resulted in a settlement in which the U.S. Fish and Wildlife Service revised its critical habitat designation for the dragonfly. This experience reinforced my personal interest in the Hine's emerald dragonfly, one of the few federally-listed species found in Chicago's urban environment.

14. I appreciate the Hine's emerald dragonfly for its resilience in persisting in an urban environment, for its beauty, and for its status as an indicator species for the health of the fens, bogs, and other wetlands that remain in Chicago and surrounding areas. I also believe that all species, including the Hine's emerald dragonfly, have inherent value, and I have an interest in maintaining the diversity of life.

15. On several occasions, I have attempted to observe Hine's emerald dragonflies in and around Chicago, but I have not experienced a confirmed Hine's emerald observation. I intend to return to Chicago in June 2018 to look for Hine's emerald dragonflies in their known habitat.

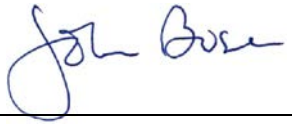
16. Even if I fail to observe a Hine's emerald dragonfly, I take comfort in the continued existence of the dragonfly in the wild. I look forward to the recovery of the Hine's emerald dragonfly throughout its native range. I am concerned that Enlist Duo will be applied in and around Illinois and elsewhere without regard to Hine's emerald dragonfly conservation and recovery. Killing of non-target insects and plants by pesticides and herbicides is well-documented, and I fear that Hine's emerald dragonflies are being inadvertently killed and harmed by agricultural chemicals. In addition, Hine's emerald dragonflies spend most of their lifecycle in water (eggs and larvae are aquatic). I am concerned that pesticide and herbicide runoff is harming the quality of the aquatic ecosystems that Hine's emerald dragonflies depend on, and is disrupting biochemical signals essential for the perpetuation of the species. If the remaining populations of Hine's emerald dragonflies in and around Chicago were extirpated or reduced, my appreciation of the area's unique natural environment would be markedly diminished.

17. In summary, I have professional, aesthetic, and recreational interests in the preservation of the Indiana bat and Hine's emerald dragonfly and their

habitats. These interests are being harmed by the Environmental Protection Agency's failure to consult with the U.S. Fish and Wildlife Service on impacts of its registration of Enlist Duo on these species. Specifically, I believe that the Environmental Protection Agency's failure to follow the law makes the species more likely to suffer further population declines. And if these species decline or become extinct, this loss would deprive me of the benefits I currently enjoy from their existence. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of this pesticide on these species, which is important to ensure that my interests in the species are preserved and remain free from injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 3, 2018, in Indianapolis, Indiana.



John Buse

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF MARTHA L. CROUCH IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, MARTHA L. CROUCH, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners) in their Petition for Review of the registration of new uses of the herbicide Enlist Duo.

2. I am a member of Center for Food Safety (CFS). I joined CFS because I am concerned about the environmental, health, and public safety impacts of food and agriculture. I support CFS's efforts to advocate for more stringent government oversight of food production and its work on reducing the amount of chemical inputs into U.S. agriculture.

3. I am a resident of Bloomington, Indiana which is located in Monroe County. The state of Indiana is one of the largest producers of both corn and soybean. The majority of agricultural land in and around Monroe County is used for corn and soybean production.

4. I earned a Bachelor of Science degree in botany from Oregon State University, and a Ph.D. in developmental biology from Yale University. I am a retired professor of biology at Indiana University, where for 20 years I conducted research on plant molecular biology and taught courses such as Introduction to

Biology, Biology for Elementary School Teachers, Plant Physiology, Plant Molecular Biology, and Biology of Food. I am currently a consultant on issues of agriculture and technology, focusing specifically on pesticide-related issues. I primarily consult for the Center for Food Safety regarding these issues.

5. Besides my professional work, I am an amateur naturalist and I consider myself a "Craniac," as those of us who follow the whooping crane (*Grus americana*) populations often refer to ourselves.

6. I first became interested in whooping cranes about fifty years ago, when my mother gave me the book "North With the Spring," by Edwin Way Teale. In the book, Teale visited a lone whooping crane in a zoo in New Orleans in 1947, where he thought he might be experiencing the same feeling as those who viewed the last passenger pigeon experienced. I have been fascinated by, and interested in, whooping cranes ever since, and I will continue to be for the foreseeable future.

7. I am aware that there are three populations of whooping cranes, two of which migrate, including a self-sustaining western population that overwinters in Texas, and migrates up through Oklahoma, Kansas, Nebraska, South Dakota, North Dakota, and northeastern Montana to northeastern Alberta and the southern Northwest Territories in Canada, where it summers and raises chicks before migrating back.

8. I am aware that crane conservationists, out of concern that having the entire whooping crane population overwintering in one location put the species at risk from a single adverse event, received permission to raise an experimental population to reduce the risk to the species. That experimental eastern population now summers in Wisconsin and winters in Florida, with the help of a dedicated whooping crane recovery team.

9. The western population does not migrate where I live, but I have some friends in Rockport, Texas, whose house is near to the Aransas National Wildlife Refuge where the western population winters. I purposefully time my visits to my friends who reside in Rockport, Texas to coincide with the "Whooping Crane Festival" in Port Aransas, Texas and nearby islands, so that I may see, watch, and observe the western flock of whooping cranes while they winter in Texas. On my last visit I saw two pairs of whooping cranes in the fields outside of the Aransas National Wildlife Refuge where they winter in Texas.

10. I plan to continue visiting my friends' residence in Rockport, Texas during the months when the whooping crane is wintering in the nearby wildlife refuge, so I can observe the western population. I am making plans to visit my friends and stay with them in the spring of 2019 so that I may attend the festival again and observe the western population of whooping cranes there.

11. In addition to my following, observing, and interest in the western population, I have experience with the eastern population, as well. This population migrates over Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida. The migration pattern of this population leads some to fly directly over my house, and on two occasions I have seen them going over in mixed flocks with sandhill cranes. I have visited the wildlife refuges here in Indiana where many whooping cranes spend quite a bit of time, such as the Goose Pond Fish and Wildlife Area in Greene County, near Linton, Indiana. I read news and blogs about both populations.

12. I am worried about how the EPA's new conditional registration of Enlist Duo, which will greatly expand its use not only in corn and soybean, but also in cotton, and across thirty-four states, may affect whooping cranes because they frequent agricultural fields. The flyway of the western population goes right through parts of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas, where Enlist Duo has been approved for use on 2,4-D-resistent corn, soybeans, and cotton. The eastern flock migrates through the states of Wisconsin, Illinois, Indiana, Kentucky, Tennessee, Alabama, Georgia, and Florida where Enlist Duo has been approved for use on 2,4-D-resistent corn, soybeans, and cotton. Many photos taken by birdwatchers of whooping cranes show them foraging in crop fields in the fall, including corn, soybean, and cotton fields, and I

am aware that they also stop over in crop fields in the spring, where they have the potential to be exposed to toxic agricultural chemicals. During the spring migration north, whooping cranes may stop over in corn, soybean, and cotton fields that have been prepared for planting or recently planted, and sprayed with herbicides, including Enlist Duo. Cranes, including whooping cranes, are known to uproot corn seedlings and eat them, and thus they could be exposed to high levels of Enlist Duo residues.

13. I am aware that, based on the instructions and guidelines for Enlist Duo use on 2,4-D-resistant corn, soybean, and cotton production, it is possible that food and water sources used by whooping cranes in these fields could or will have very high residues of 2,4-D on them, the exposure to which may have adverse effects on the whooping cranes. EPA's registration of Enlist Duo thus injures my aesthetic interest in both the eastern and western flocks.

14. I do not believe that the risks of registering Enlist Duo have been properly assessed in regards to the whooping crane populations that I care about so deeply. It concerns me that given the stresses the cranes already have to endure, allowing Enlist Duo to be used on Enlist corn, soybeans, and cotton in the agricultural fields which they migrate through and spend considerable time in, will be another serious stress that can and will severely harm their recovery.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 11, 2018 in Bloomington, Indiana.

MARTHA L. CROUCH, Ph.D.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF JAY FELDMAN IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, JAY FELDMAN, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am the Executive Director of Beyond Pesticides. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners) in their Petition of Review of the registration of new uses of the herbicide Enlist Duo.

2. Beyond Pesticides is a Washington, D.C.-based, nonprofit organization that works to protect public health and the environment with regard to pesticide use. I co-founded Beyond Pesticides in 1981 and have been its Executive Director since then. Beyond Pesticides has members in fifty states and the District of Columbia. Many of the members of Beyond Pesticides reside in Illinois, Indiana, Iowa, Kentucky, Michigan, Minnesota, Missouri, Ohio, Texas, and Wisconsin, where the U.S. Environmental Protection Agency (EPA) has approved the use of Enlist Duo on 2,4-D-resistant corn, soybean, and cotton—the challenged new uses at issue in the present petition for review.

3. Beyond Pesticides promotes safe air, water, land, and food and works to protect public health and the environment by encouraging a transition away from the use of toxic pesticides, including herbicides such as Enlist Duo that is at

issue in this lawsuit. With the resources of Beyond Pesticides made available to the public on a national scale, Beyond Pesticides contributes to a significant reduction in unnecessary pesticide use, thus improving protection of public health and the environment. The risks to public health and the environment from pesticides are large.

4. To achieve its goals, Beyond Pesticides provides the public with resources and information on the risks associated with pesticides, including 2,4-D, one of the two active ingredients in Enlist Duo.[1] Beyond Pesticides's *Gateway on Pesticide Hazards and Safe Pest Management* provides the public with easy access to current and historical information on pesticide hazards, and safe and organic pest management; drawing on and linking to numerous sources and organizations that include information related to pesticide science, policy, and action. The *Pesticide-Induced Disease Database* (PIDD), with over 1,011 studies, facilitates access to epidemiologic and laboratory studies based on real world exposure scenarios that link pesticides to public health effects, including asthma, autism and learning disabilities, birth defects and reproductive dysfunction, diabetes, Parkinson's and Alzheimer's diseases, and several types of cancer. Additionally, Beyond Pesticides's *Genetic Engineering* program publicizes the serious health

[1] *See Gateway on Pesticide Hazards and Safe Pest Management: 2,4-D*, Beyond Pesticides, https://beyondpesticides.org/resources/pesticide-gateway?pesticideid=1 (last visited Mar. 30, 2018).

and pest resistance problems related to genetically engineered (GE) crops as well as provides important links to activists working in the pesticide community.

5. Beyond Pesticides and its members are being, and will be, adversely affected by EPA's decision to register the Enlist Duo herbicide for new uses on 2,4-D-resistant corn, soybeans, and cotton.

6. When necessary, and as here, Beyond Pesticides also engages in public interest litigation to address the impacts of pesticides on the environment, its members, and the public interests. Beyond Pesticides submitted organizational comments in 2014 and 2016 on the proposed registration and expanded uses of Enlist Duo, the pesticide product at issue in this petition for review.

7. The interests of the members of Beyond Pesticides are harmed by EPA's decision to register new uses for the herbicide Enlist Duo, which contains as an active ingredient the drift-prone and volatile 2,4-D. Many members of Beyond Pesticides live, work, and recreate in and near agricultural areas and other outdoor settings where Enlist Duo is being, or will be, applied or where crops treated with this harmful pesticide are being, or will be, planted. The increase in the use of Enlist Duo in U.S. agriculture and outdoor landscapes injures the members of Beyond Pesticides by interfering with their aesthetic enjoyment of outdoor spaces and biodiversity. EPA's decision to approve the registration of Dow's Enlist Duo on Enlist corn, soybean, and cotton for use in 34 states injures the aesthetic and

recreational interests of the members of Beyond Pesticides.

8. Additionally, EPA's approval of new uses for Enlist Duo on GE corn, soybean, and cotton injures the personal health of Beyond Pesticides's members. One of the two active ingredients in Enlist Duo, 2,4-D, is highly toxic, as it is linked to numerous adverse health effects, including increased risk of birth defects, reduced sperm counts, increased risk of non-Hodgkin lymphoma, Parkinson's disease, and endocrine disruption. EPA has itself identified chronic endpoints, including developmental toxicity and neurotoxicity, where effects have been reported in laboratory organisms. As evidenced with other GE crops, the use of 2,4-D-tolerant crops will simultaneously increase 2,4-D use in the environment, leading to unreasonable adverse risks that will impact the personal health of Beyond Pesticides's members. Since 2,4-D is highly toxic, EPA's expansion of new uses for Enlist Duo is not appropriate, given weak label recommendations, and increased exposure to the public and the environment.

9. In sum, EPA's decision to register Enlist Duo for use on 2,4-D-resistant corn, soybean, and cotton adversely injures Beyond Pesticides's organizational interests, as well as the aesthetic, recreational, and personal health interests of our members.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 10, 2018, in Washington, D.C.

JAY FELDMAN
Executive Director, Beyond Pesticides

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF LISA GRIFFITH IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, LISA GRIFFITH, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am the Interim Executive Director of Petitioner National Family Farm Coalition (NFFC). I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners) in their Petition of Review of the registration of new uses of the herbicide Enlist Duo.

2. NFFC is a Washington, D.C.-based, nonprofit corporation that serves as a national link for a coalition of family farm and rural groups on the challenges facing family farms and rural communities. Founded in 1986, NFFC today represents farmers and ranchers from 25 grassroots member organizations in 32 states, including farmers and ranchers from Colorado, Georgia, Iowa, Kentucky, Mississippi, Missouri, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Texas, and Wisconsin, where the U.S. Environmental Protection Agency (EPA) has approved the use of Enlist Duo on 2,4-D-resistant corn, soybean, and cotton, the challenged new uses at issue in the present petition for review. The combination of our member groups' grassroots strength and NFFC's experience working at the national level enables us to play a unique role in securing a sustainable, economically just, healthy, safe, and secure

food and farm system.

3. NFFC chooses its projects based on the potential to empower family farmers by reducing the corporate control of agriculture and promoting a more socially just farm and food policy. NFFC's member organizations contribute to NFFC financially, participate in NFFC's executive decision-making, and help NFFC set its priorities. NFFC staff collaborate with NFFC members—family farmers and ranchers, community-based fishermen, and rural advocates—who comprise the Trade, Farm and Food Policy, and Credit committees that determine NFFC's campaigns. Working by committee enables farm groups of differing commodities and in various regions to develop national organizing strategies and directly participate in issue work.

4. NFFC and its members are being, and will be, adversely affected by EPA's decision to register the Enlist Duo herbicide for new uses on 2,4-D-resistant corn, soybeans, and cotton.

5. Since the mid-1990s, NFFC has devoted significant resources to addressing the harms stemming from the use of pesticides on genetically engineered, pesticide-resistant crops. NFFC's Farmer to Farmer Campaign on Genetic Engineering sought to build a nationwide campaign focused on the risks of genetic engineering to agriculture. As part of the campaign, NFFC published educational materials on the liabilities of genetic engineering, and conducted

trainings to develop farmer leaders on various genetically engineering issues, including the agronomic, human health, and environmental harms of pesticide use on such crops. In 2009, Farmer to Farmer also published the *Out of Hand Report*[1] to outline the problems farmers have faced through concentration in the seed industry, including diminished options, higher costs, and the increased use of toxic herbicides.

6. Between 2012 and 2017, NFFC participated in bi-weekly calls with allied organizations, farmers, and media to oppose the deregulation of new herbicide-resistant crops, including 2,4-D-resistant crops and the expected increase in the spraying of those herbicides.[2] On behalf of the farmers and ranchers NFFC represents, NFFC submitted organizational comments back in 2014, and in December 2016 , to EPA, regarding the agency's proposal to conditionally register new uses of Enlist Duo on 2,4-D-resistant corn, soybean, and cotton.

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[1] http://www.farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf.

[2] An April 2012 telepress call on Dow Chemical's proposed 2,4-D corn led to articles published online by Reuters, San Francisco Chronicle, and others. *See* Gary Gilliam, *Protesters Urge U.S. to Scuttle Dow's New GMO Corn*, Reuters, Apr. 26, 2012, https://www.reuters.com/article/usa-food-24-d/protesters-urge-u-s-to-scuttle-dows-new-gmo-corn-idUSL2E8FPILH20120426; Carolyn Lochhead, *Genetically Modified Crops' Results Raise Concern*, SFGate, Apr. 30, 2012, https://www.sfgate.com/science/article/Genetically-modified-crops-results-raise-concern-3520087.php; Ashley Portero, *Farmers, Scientists Protest USDA Approval of Dow's 'Agent Orange Corn'*, Int'l Bus. Times, Apr. 27, 2012, http://www.ibtimes.com/farmers-scientists-protest-usda-approval-dows-agent-orange-corn-693573.

7. The approved new uses of Enlist Duo injure NFFC members' farm productivity, livelihoods and environment, to the detriment of their economic and personal interests. NFFC's members live, farm, and recreate in many locations where Enlist Duo has been sprayed or will be sprayed. Many of NFFC's farmer members who grow vulnerable crops, such as tomatoes, grapes, and non 2,4-D resistant corn and soybeans, are at risk of 2,4-D damage. Because EPA's approval authorizes Enlist Duo use in corn, soybean, and cotton states for in-season use, NFFC's farmer members may have to adjust their planting season and choice of seed or crop, or impose costly measures such as buffer zones, in an attempt to avoid crop damage by Enlist Duo.

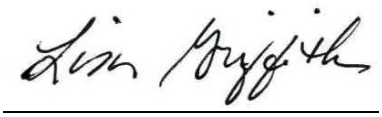
8. Many of NFFC's members are heavily involved with reducing the use of pesticides and preserving the use of non-patented seed crops. They see the use of conventional, non-genetically engineered seeds and the ability to save their seeds as vital components of rural life and their way of farming. Because EPA's approved new uses of Enlist Duo on 2,4-D-resistant corn, soybean, and cotton creates a longer period of time whereby farmers may suffer drift damage from Enlist Duo, many farmers in localities where NFFC farmers reside have no choice but to switch to planting 2,4-D-resistant corn, soybean, and cotton in order to avoid economic losses due to drift damage to their crops. This, in turn, reduces the local availability of non-genetically engineered seeds as local seed banks have no

incentive to sell such varieties due to reduced demand. Thus, the registration of Enlist Duo has, and will continue to, injure NFFC's members' interest and ability to obtain and plant non-genetically engineered seeds, costing them additional time and money in order to locate such seeds.

9. In sum, EPA's decision to register Enlist Duo for use on 2,4-D-resistant corn, soybean, and cotton adversely injures NFFC's organizational interests, as well as the economic and personal interests of our members.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 10, 2018, in Washington, D.C.



LISA GRIFFITH
Interim Executive Director

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF MARCIA ISHII-EITEMAN IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, MARCIA ISHII-EITEMAN, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am a Senior Scientist of Pesticide Action Network North America (PANNA). I submit this declaration in support of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners)'s opening brief.

2. PANNA is a Berkeley, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. PANNA has more than 125,000 members across the United States. Many of our members are farmers or residents of rural communities. PANNA also has offices in Minneapolis, Minnesota and Des Moines, Iowa; states directly affected by the U.S. Environmental Protection Agency (EPA)'s regulatory approval of the expanded uses of the herbicide Enlist Duo.

3. PANNA was founded in 1982 to combat the proliferation of chemical-intensive, mono-crop agriculture. PANNA's mission is to advance a post-industrial vision of agriculture that replaces the use of hazardous pesticides with healthier, ecologically-sound pest management. The costs of industrial food production and the increased use of pesticides now touch every aspect of our lives,

from residues on our produce, to increased chronic disease, to biodiversity loss. In order to meet its objectives, PANNA links local and international consumer, labor, health, environment, and agriculture groups into an international citizens' action network. Through this network, PANNA challenges the global expansion of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable food system.

4. To protect our health and restore our ecosystems, PANNA shares information and builds alliances with numerous partners and coalitions across the United States and globe. PANNA works together with these groups to reduce reliance on toxic chemicals, promote food democracy, and move toward a healthy, resilient system of food and farming for all. PANNA's partners include the California Climate and Agricultural Network, Californians for Pesticide Reform, National Coalition for Pesticide-Free Lawns, National Family Farm Coalition, National Pesticide Reform Coalition, Rural Coalition, and many more. We also work closely with food and farming groups to reduce the negative health and livelihood impacts of pesticide drift in the states where Enlist Duo has been approved for use, including the Iowa Farmers Union, Iowa Organic Association, and Practical Farmers of Iowa.

5. In addition to coalition building, we bring our strength in grassroots science and strategic communications to tackle a multitude of pesticide-related

problems. PANNA provides scientific expertise, public education, and access to pesticide data and analysis, policy development, and coalition support to more than 100 affiliated organizations in North America.

6. PANNA previously submitted organizational comments to EPA on the agency's initial proposal to register Enlist Duo for use on genetically engineered (GE) corn and soybean in 2012, and again in 2014 on EPA's subsequent decision to amend the registration to expand those uses of Enlist Duo to additional states.

7. PANNA submitted organizational comments in December 2016 to EPA regarding the agency's renewed proposal to register Enlist Duo for uses on GE soybean and corn in fifteen states, and its new proposals to expand Enlist Duo for those uses in nineteen additional states, as well as on GE cotton in all thirty-four states.

8. Dow's Enlist Duo was developed to be used with GE, 2,4-D-resistant corn, cotton, and soybeans. USDA estimates that use of 2,4-D, one of the two active ingredients in Enlist Duo, will increase by 200% to 600% in corn and soybean, generating significant public health risks and potential harm to non-target organisms.[1] Use levels will increase even higher, with deregistration for cotton.

[1] U.S. Dep't of Agric., Draft Environmental Impact Statement, Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties (2013).

Members of PANNA include farmers whose crops, and thus their livelihoods, are likely to be damaged by drift and vaporization of 2,4-D. EPA's conditional registration of new uses for Enlist Duo herbicide will harm the economic interests of PANNA's members because drift and vaporization of the pesticide may injure their traditional soybean crops, as well as other sensitive fruits and vegetables such as peaches, green beans, grapes, and tomatoes located close to cotton-growing areas. Additionally, PANNA's farmer members may have to adjust their planting season or impose costly measures such as buffer zones, in an attempt to avoid crop damage by Enlist Duo.

9. PANNA and its members are being, and will be, adversely affected by EPA's approval of Dow's petition to greatly expand uses of Enlist Duo not only in corn and soybean, but also in cotton, and across thirty-four states. PANNA's members live, work, and recreate in many locations where Enlist Duo is currently being sprayed or will be sprayed. PANNA's members are deeply concerned about the enormous implications EPA's registration of new uses for Enlist Duo will have for the integrity of both crop-based agroecosystems and surrounding natural ecosystems, on and off-farm biodiversity, the health of rural communities, and the economic success of farmers growing crops vulnerable to 2,4-D drift.

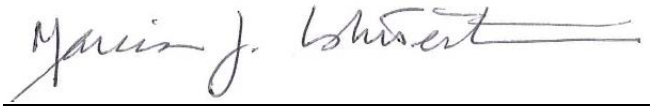
10. PANNA's members are heavily involved with reducing the use of pesticides to protect various species of plants and animals and enhance

biodiversity. Biodiversity is essential to a healthy and thriving ecosystem and successful agriculture. The conditional registration of new uses for Enlist Duo will harm sensitive, threatened and endangered species, which will injure PANNA's members' aesthetic interest in protecting natural ecosystems and wildlife and maintaining biodiversity.

11. EPA's decision to register Enlist Duo for use on Enlist corn, soybean, and cotton in thirty-four states adversely injures PANNA's organizational interests, as well as the aesthetic, recreational, economic, and personal health interests of our members.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 6, 2018, in Berkeley, California.



MARCIA ISHII-EITEMAN, Ph.D.
Senior Scientist, PANNA

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF GEORGE KIMBRELL IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, GEORGE KIMBRELL, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I am the Legal Director of the Center for Food Safety (CFS) and counsel in this case. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners) in their Petition of Review of the registration of new uses of the herbicide Enlist Duo.

2. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; and Washington, D.C. CFS represents more than 950,000 farmer and consumer members, in every state throughout the country, including over 400,000 in the 34 states covered by the Enlist Duo use approval challenged in this case. CFS and its members are being, and will be, adversely affected by EPA's decision to register the Enlist Duo herbicide for new uses on 2,4-D-resistant corn, soybeans, and cotton.

3. CFS was founded in 1997. Since its inception CFS's mission has been to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. Accordingly, CFS's program activities are focused in several areas, including the environmental, public health, and economic impacts of the development and commercialization of agriculture and food

processing technologies. A cornerstone of this mission is to advocate for thorough, science-based safety testing of new agricultural products and technologies. This includes major programs on both pesticides as well as genetically engineered crops.

4. CFS combines multiple tools and strategies in pursuing its mission, including public and policymaker education, outreach, and campaigning. For example, CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the effects of industrial food production, agricultural products, and pesticides, on human health and the environment. These educational and informational materials include, but are not limited to, news articles, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets. CFS often has provided expert testimony to policymakers on the potentially-harmful agrichemical impacts associated with industrial monoculture cropping systems, including the increased use of pesticides and chemical fertilizers.

5. Staff members regularly monitor the Federal Register and submit comments to the U.S. Environmental Protection Agency (EPA) and other regulatory agencies via the public notice-and-comment process. CFS also regularly sends out action alerts to its members, encouraging them to participate in the notice-and-comment process, or to submit letters to government officials related to

the oversight of industrial agriculture, pesticide use, genetically engineered crops, and other issues affecting CFS's mission to build a sustainable food system.

6. When necessary, and as here, CFS also engages in public interest litigation to address the impacts of industrial food production and pesticides on its members, the environment, and the public interest. CFS submitted organizational comments in 2012, 2014, and 2016 to the EPA dockets on the proposed registration of Enlist Duo, the pesticide product at issue in this petition for review. CFS also submitted more than 100,000 comments on behalf of its members.

7. As a party to this proceeding, CFS and its members are injured by the approved novel and increased use of Enlist Duo on herbicide-resistant corn, soybean, and cotton specifically engineered to withstand its application. CFS and its members are concerned by the detrimental impacts on farmers, the environment, including on endangered species and their habitat, and on the public health that will result from the approved use of Enlist Duo.

8. CFS and its members are being, and will be, adversely affected by the challenged EPA's decision to register Enlist Duo's new use on Dow's Enlist corn, soybean, and cotton genetically engineered to resist its application. Many members of CFS are heavily involved with maintaining a healthy environment for many species of animals for recreational, aesthetic, and personal reasons. The use of

Enlist Duo will negatively harm non-target organisms, injuring CFS members' recreational and aesthetic interests.

9. Many of CFS's members are farmers and/or live in rural areas where excessive amounts of pesticides are being applied to corn, soybean, and cotton crops genetically engineered with resistance 2,4-D. These members are especially susceptible to the environmental and health risks associated with EPA's approval of Enlist Duo for use on corn, soybean, and cotton fields in 34 states. Moreover, the intensive use of Enlist Duo on crops compromises our members' enjoyment of their local environment, and injures the aesthetic and recreational interests of our members in maintaining biodiversity and protecting sensitive species.

10. CFS members' interests are also injured by EPA's decision to approve Enlist Duo without consulting with the expert U.S. Fish and Wildlife Service (FWS) on the potential harm to federally endangered and threatened species and their critical habitats, as required under the Endangered Species Act. Many of CFS's members have significant recreational interests in observing these sensitive species, including the Indiana bat and whooping crane, and preserving their habitats. CFS's members' aesthetic interest in biodiversity and protection of these sensitive species are injured by EPA's decision to register Enlist Duo without consulting with FWS, as required under the Endangered Species Act.

11. Similarly, members of CFS include farmers and gardeners who live and grow crops that have already been damaged or are likely to be damaged by drift and vaporization of 2,4-D, one of the two active ingredients in Enlist Duo. Reports of injury from 2,4-D drift to non-target crops, including specialty crops and agriculture such as organic, are already common. Continued approval will lead to increased use and more frequent applications of Enlist Duo this year, making it more likely that CFS's farmers and gardeners members who cultivate crops near areas of Enlist Duo application will suffer crop or land use damage. Such members may have to adjust their planting season, or impose costly measures such as buffer strips, or forego the planting of certain crops, in order to try to reduce the negative impacts of Enlist Duo use near their crops. The livelihood and economic interests of CFS members who cultivate and farm such crops are injured by the EPA approval.

12. In sum, EPA's decision to register Enlist Duo for use on corn, soybean, and cotton injures CFS's organizational interests in protecting agriculture and the environment, as well as the aesthetic, recreational, economic, and personal health interest of CFS's hundreds of thousands of members. CFS and its members will be redressed if and when this Court vacates the registration.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 10, 2018, in Portland, OR.

George Kimbrell
Legal Director, CFS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF LESLIE LIMBERG IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

I, LESLIE LIMBERG, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity (collectively Petitioners) in their Petition of Review of the registration of new uses of the herbicide Enlist Duo.

2. I have been a member of Petitioner Center for Food Safety for roughly seven years. As a member of the Center for Food Safety, I rely on the Center for Food Safety to represent my interest in protecting biodiversity, including sensitive species and their habitats, from the adverse impacts of industrial agriculture and pesticide use through litigation, public education, and other means.

3. I previously submitted a declaration in support of Center for Food Safety's petition for review of EPA's prior approval of Enlist Duo.

4. I live in Wentzville, Missouri. Missouri is one of thirty-four states where the Environmental Protection Agency (EPA) has approved the conditional registration and use of Enlist Duo on genetically engineered (GE) corn and soybean. Wentzville is known as "the Crossroads of the Nation," and is within twenty miles of the Mississippi River and Missouri-Illinois border. Illinois is also one of the thirty-four states where EPA has approved the conditional registration

and use of Enlist Duo on GE corn and soybean. Additionally, I understand that Missouri is one of thirty-four states, which also includes Illinois, where EPA has approved the new use of Enlist Duo on GE cotton.

5. I earned a Bachelor of Science in Nutrition and Dietetics from Dominican University. Although I am retired in my professional life, in my heart I will never retire. In my personal and family life, I always aim to avoid toxins, stay on the lookout for chemicals, and try to find honest food with the least amount of artificial ingredients.

6. I am also always looking for worthwhile causes to which I can lend and raise my voice. One way in which I have done so is being involved in bat habitat improvement, rehabilitation, and public education, particularly for the endangered Indiana bat (*Myotis sodalis*) and the little brown bat.

7. I am a current board member, and past president, of the Missouri Master Naturalists, a volunteer arm of the Missouri Department of Conservation and the University of Missouri Extension. I have been a member since 2005.

8. I am concerned about the conservation of the Indiana bat's habitat and the species itself, because the bat is a keystone species. Indiana bats are indicators like the proverbial canary in the mine. They are hugely valuable pollinators and control vast swatches of millions of insects every night. They are exceptionally vulnerable to temperature change, microbial diseases, habitat change, and

environmental contamination. The bat immune system is already seriously compromised, and it is under threat from chemicals in the environment. Without the Indiana bat, we ourselves are at risk.

9. I know that contributions to the Indiana bat's decline include disturbance from humans during winter hibernation, commercialization of caves, loss of summer habitat, pesticides and other contaminants, and the disease commonly known as white-nose syndrome.

10. In Missouri, the bat habitat consists of hardwood forests with numerous caves interspersed among farmland and watersheds. Caves, sinkholes, and karst formations produce perfect hibernation temperatures for bats. Bat habitat is primarily porous dolomite-limestone caves carved out by underground water. These water sources are hugely important when conditions are hot and droughty, as well as in winter, with deep drops well below freezing temperatures. Groundwater with fertilizer, chemical, and pesticide run off can pollute these water sources that are so important for the bats.

11. Southern Illinois, where Enlist Duo has been approved for use on corn, soy, and cotton by EPA, is also extremely important for the Indiana bat's survival. Several major rivers converge and drain into the Mississippi River watershed in this area. This watershed consists of important cropland and swampland for bats. Bats living in the caves of Southern Illinois and Missouri can

fly fifty to one hundred miles in a night, and their primary feeding ground is wherever there are the most insects. The swamps of Southern Illinois are important feeding grounds for bats, as they are breeding grounds for the insects on which bats subsist. In turn, the chemicals that are being used in croplands in Illinois and other Midwestern states are also critical to ensure the bat's health, since the insects and larvae on which bats subsist feed on corn and soybean crops. Enlist Duo is more alarming than any other pesticides I have seen in the past with regard to the health hazards the pesticide poses to Indiana bat populations.

12. As a member of the Missouri Master Naturalists, I have taken part in multiple activities to help protect the Indiana bat, particularly to help research, reduce, and prevent occurrences of "white nose syndrome," an illness that has killed millions of bats since 2006, causing massive population declines for multiple hibernating bat species, including the Indiana bat.

13. One such activity is netting to help research occurrences of white nose syndrome. When bats come out of hibernation, we put up nets to capture the bats, and observe and record their weight, wingspan, occurrences of white nose syndrome, and their overall health.

14. Caves that serve as bat habitat must now be gated to reduce the vulnerability of fragile bats from park visitors and sports enthusiasts (spelunkers) who contribute to the spread of disease. With the Missouri Master Naturalists, I

have also gated off caves to prevent the public from entering and spreading disease or otherwise disturbing the bats.

15. I have participated, and plan to continue to participate, in these activities in various locations throughout Missouri, including the Ozark National Scenic Riverways, Missouri's largest national park, in Shannon County; Washington State Park, in Washington County; Johnson Shut-Ins State Park, in Reynolds County; and Elephant Rocks State Park, in Iron County.

16. The Missouri Master Naturalists also work to conserve Indiana bat populations in Illinois. As a volunteer with Missouri Master Naturalists, I have provided, and continue to provide, ongoing assistance on bat habitat conservation in Southern Illinois. For example, I have helped with research on the impacts of flooding on populations of roosting colonies in Green Ash, Sweet Gum, and Pin Oak trees in the Greater Mississippi River floodplain and adjacent farmland, including the Oakwood Bottoms floodplain, in Jackson County, Illinois, east of the Big Muddy River and Cedar Creek; as well as in the Bluff Lake Swamp area, near Millcreek, in Union County, Illinois. During June through August, I have been working together with Bat Conservation International in Texas, approximately five hours a week, taking part in the Friday night public education event for locals and tourists to view and learn about Austin's South Congress Bridge bats. I also have volunteered sixteen hours yearly with Bat Conservation International to build and

install bat houses in Texas. I will continue to volunteer my time and efforts to assist with bat conservation efforts in Missouri, Illinois, and Texas.

17. In addition to these activities, I help with outreach and public education so humans do not disturb the bats and their habitats. I plan to continue these activities and continue to volunteer with conservationists.

18. In light of my ongoing efforts to protect and conserve the habitat of Indiana bats in both Missouri and Illinois, I am injured by EPA's conditional registration of Enlist Duo for uses on GE corn, soybean, and cotton, and by its failure to consult with the U.S. Fish and Wildlife Service (FWS) regarding the impacts that this decision will have on the Indiana bat population.

19. I am worried about how the approval of conditional registration and new use of Enlist Duo may affect Indiana bats because they subsist on insects, moths, and larvae that frequent agricultural fields. Additionally, groundwater that may contain toxic chemicals or runoff from application of Enlist Duo may enter the caves that serve as habitat for the bats.

20. I do not believe that the risks of conditionally registering Enlist Duo for uses on GE corn, soybean, and cotton have been properly assessed in regards to the Indiana bat populations that I care about so deeply. It concerns me that allowing Enlist Duo to be used on Enlist corn, soybeans, and cotton in the agricultural fields surrounding the bat habitat, and that serve as the habitat for the

insects on which the bat subsists, will be another stress that will harm the recovery of the Indiana bat. I am injured by the threat to the continued existence of the Indiana bat from the use of Enlist Duo.

21. In summary, I have personal, aesthetic, and recreational interests in the preservation of Indiana bats and their habitat. These interests are being harmed by EPA's failure to consult with FWS on impacts of its conditional registration for new uses of Enlist Duo on the Indiana bat. Specifically, I believe EPA's failure to follow the law makes the species more likely to suffer further population declines. The decline of the Indiana bat injures my ongoing efforts to protect and conserve the species, and deprives me of the benefits I currently enjoy from their existence. Consultation with FWS could result in protective measures aimed at reducing impacts of this pesticide on the Indiana bat, which is important to ensure that my interests in the species are preserved and remain free from injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed April 10, 2018 in Wentzville, Missouri.

LESLIE LIMBERG

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF ERIC POOL IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

DECLARATION OF ERIC POOL

I, ERIC POOL, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the opening brief of Petitioners Center for Food Safety, National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Pesticide Action Network North, and Center for Biological Diversity in their Petition of Review of the registration of new uses of the herbicide Enlist Duo.

2. I am a resident of 300 N. Elm Street, Claremont, Illinois 62421.

3. I am currently a member of Center for Food Safety (CFS). I joined CFS in 2012 because CFS promotes sustainable agricultural practices and advocates on behalf of family farms and rural communities. I grew up near the small town of Berryville, Illinois. I was raised helping my father on his farm cultivating grain crops such as corn and beans.

4. I received a Bachelor's of Science in Business Administration with a concentration in Entrepreneurship from the University of Illinois in 1998. During the spring prior to my graduation, I decided to plant a vineyard. My father owned a parcel of land just three miles north of Berryville, Illinois, which was ideal for growing grapes. In 2001, I began harvesting trees around the vineyard to build a winery. After honing my winemaking skills in my basement with the first few

crops, the 2002 vintage was the first crop commercially crafted in my winery, Berryville Vineyards.[1]

5. I currently farm about 10 acres of wine grapes and small amounts of various fruits, including blackberries and strawberries. Berryville Vineyards is nestled amongst a mixture of land used for raising grain crops, as well as pasture and woods. The vineyard is comprised of over twenty varieties of wine grapes. Our main cultivars of grape are Vignoles, Vidal, Cynthiana, Chambourcin, and Diamond. During my first year of farming, in 1998, I planted two acres of wine grapes on land that belonged to my father at that time. I spent all the money I had planting those 2 acres, but was able to obtain loans from the U.S. Department of Agriculture to continue planting and purchasing land. At my peak acreage, I was farming 12.7 acres.

6. All wines at Berryville Vineyards are a hundred percent estate grown and bottled in my winery. I am proud of my winery's many sustainable farming methods. For example, in our effort not to contribute to erosion and the release of carbon dioxide, we do not till at Berryville Vineyards. We mainly use organic fertilizer and no synthetic herbicides. Our winery also uses a number of sustainable practices, including not using plastic; never tilling our vineyard; using only

[1] *About Us*, Berryville Vineyards, http://buunyd.wixsite.com/berryvillevineyards (last visited Mar. 30, 2018).

geothermal heating and cooling; and having a wood stove for heat.[2]

7. Farming and operating a sustainable winery is extremely challenging, especially since my vineyard is near farmlands growing grain crops like soybean, corn, and wheat, and using farming methods that rely heavily on herbicides. In fact, growing up and seeing the amount of chemical inputs in grain farming was a significant factor in my decision to grow grapes, instead of grain, because I did not see it as a sustainable way of farming. Throughout the years, I was able to negotiate and convince my father, who farms grain crops in some of the plots of land surrounding my vineyard, not to use herbicides that are particularly harmful to my grapes and fruits. However, I have no control over the use of such herbicides by my other neighbors.

8. I am aware that the U.S. Environmental Protection Agency (EPA) has recently approved the conditional registration for new uses of Enlist Duo, which contains the active ingredient 2,4-D, on 2,4-D-resistant, genetically engineered corn, soybean, and cotton in thirty-four states, including Illinois.

9. I am aware that 2,4-D is drift-prone and volatile, and can have damaging impacts on certain crops and plants, including sensitive fruits and vegetables such as grapes, tomatoes, strawberries, and blackberries. Because of

[2] *Going Green*, Berryville Vineyards, http://buunyd.wixsite.com/berryvillevineyards/going-green (last visited Mar. 30, 2018).

where my vineyard is located, even prior to the approval of Enlist Duo's new use on Dow's Enlist corn, soybean, and cotton, I had experienced damage to my grapevines from 2,4-D-use by neighboring farms. When I first began farming grapes, Roundup Ready predominated and I had little to no problems. As the weeds became glyphosate resistant, chemical representatives started telling farmers to "add 2,4-D at burndown," which is when I started to have problems with drift damaging my grapevines. While I have tried over the years to protect my grapevines against 2,4-D drift by placing buffer strips around my fields, no matter what I do, I always end up with some percentage of my grapevines damaged by drift. Prior to the EPA's approval of Enlist Duo, the damage to my grapevines from 2,4-D drift typically occurs in the spring, as neighboring farmers apply 2,4-D to kill weeds before planting their beans and corn. Over the years, I have filed multiple complaints with the Illinois Department of Agriculture to report such drift damage, but each time the Department's investigation comes back with an inconclusive finding of whether or not the damage was due to 2,4-D drift from surrounding farms. However, having grown up on a corn and bean farm, I have learned to recognize drift damage from 2,4-D.

10. EPA's approval of Enlist Duo for use on 2,4-D-resistant corn, soybean, and cotton injures me economically. Because EPA's approval of Enlist Duo allows 2,4-D to be sprayed for a longer period of time during the growing

season, and due to my past experience with unavoidable 2,4-D drift damaging my wine grapes, I have been forced to remove grapevines and decrease the amount of planted acreage. In light of my past experience with 2,4-D drift damage to my grapevines and likelihood of increased 2,4-D use over a longer period of time on 2,4-D-resistant corn and soybean, I have had to halt further grape production and removed acreage to avoid investment into grapevines that would just be damaged and lost. I have removed up to 2 acres in total, even though local stores and my customers continue to demand the products on my farm.

11. As a direct result of EPA's proposal to approve Enlist Duo, I will likely continue to scale back on the amount of my vineyards I farm, since I know that any additional investment to replant new fields would likely result in a significant yield loss from 2,4-D damage. As long as Enlist Duo remains on the market, I will not be able to maximize my acreage for wine grape production, and will continue to plant on reduced acreage, rather than investing in replanting or planting out new fields, to reduce the cost of planting and growing grapevines that will only be damaged by 2,4-D drift. I would estimate that the reduction in planting to avoid drift damage from Enlist Duo has cost my business at least $50,000 in lost wine grape production.

12. My ability to expand my vineyard and grow my business has been injured by EPA's decision to approve Enlist Duo. It is difficult to make "best

practice" decisions on where and how to plant my grapevines when I know they will be affected by volatile chemicals like 2,4-D. I am unable to invest further in my business's growth due to the realistic threat of Enlist Duo drift wiping out my vineyard.

13. EPA's approval of Enlist Duo also injures my vocation by limiting my ability to grow wine grapes and produce wine sustainably. I chose to farm wine grapes sustainably because I believe in a different way of life than being beholden to farming with pesticides. Yet as long as Enlist Duo remains approved for use on 2,4-D-resistant corn, soybeans and cotton, I am beholden to a future where I have to plan my farming practices and business around the risk of drift damage from pesticides like Enlist Duo.

14. The damage caused by 2,4-D drift from other farms in the surrounding area has also hurt my personal relationships with my neighbors. Many of my neighbors no longer want to connect with me because they see me as a troublemaker who might report them to the Illinois State Department of Agriculture. Neighboring farms see drift damage to my grapevines from spraying volatile chemicals, such as 2,4-D-resistant Enlist Duo, on their crops as my problem for planting a vineyard in that area because they were farming corn and soybean first. These farmers do not see it as their responsibility to keep their chemicals to themselves. To me, as the pesticide makers also now are often the

companies producing the herbicide-resistant seeds, farming around me seems to require more chemicals, not less. I have heard that more farmers in my town are going to switch over to planting 2,4-D resistant corn and soybeans in order to avoid damage from Enlist Duo. This is only going to increase the risk of drift damage to my grapevines from 2,4-D as the "if you can't beat em, join em" mentality takes hold.

15. Managing my business and protecting it from potential damage from pesticide use like Enlist Duo has become the biggest stressor in my life. I could have taken over my father's farm and farmed corn, soybean, and other grains using pesticides, but I chose not to do so because I did not see it as a sustainable way of farming. Although I chose to farm grapes, instead of grain, now, as a result of the availability of pesticides such as Enlist Duo and their companion genetically engineered corn and soybean, grain farming still continues to control and affect how I farm my vineyard.

16. In sum, EPA's approval of Enlist Duo for new uses on Enlist corn, soybean, and cotton has injured, and will continue to injure, my economic and social interests. Without a court finding that EPA violated its duties in registering Enlist Duo for use on 2,4-D-resistant corn and soybean, the growth of my winery and my relationships with my neighbors will continue to be adversely affected by the use of Enlist Duo.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 11, 2018, in Claremont, Illinois.

ERIC POOL

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, *et al*., *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70810
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. SCOTT PRUITT, *et al*., *Respondents*, and DOW AGROSCIENCES LLC, *Intervenor*.	No. 17-70817

DECLARATION OF KIERÁN SUCKLING IN SUPPORT OF PETITIONERS NATIONAL FAMILY FARM COALITION, ET AL.'S OPENING BRIEF

DECLARATION OF KIERÁN SUCKLING

I, KIERÁN SUCKLING, declare that if called as a witness in this action I would competently testify of my own personal knowledge as follows:

1. I submit this declaration in support of the Petition for Review of the order granting a conditional registration of Enlist Duo Herbicide, containing the active ingredients 2,4-Dichlorophenoxyacetic acid (2,4-D) and glyphosate, for uses in thirty-four states on genetically engineered corn, soybean, and cotton engineered to resist 2,4-D and glyphosate.

2. I have been a member of the Center for Biological Diversity since 1989. I am a co-founder and the Executive Director.

3. I live in Tucson, Arizona. Arizona is one of the states where the EPA registered Enlist Duo for use on genetically engineered cotton. Cotton is one of Arizona's major agricultural commodities. Along with cattle, copper and citrus, cotton makes up the "Four Cs" dominating Arizona's resource economy. Cotton is grown primarily in Graham, Maricopa, Pima, Pinal, Cochise, Greenlee, La Paz, Mohave and Yuma counties.

4. The Center for Biological Diversity (the "Center") is a tax-exempt, nonprofit membership organization headquartered in Arizona with offices in Florida, Indiana, and Minnesota, among other places. I helped found the Center (formerly the Southwest Center for Biological Diversity) in 1989 to fight the

growing number of threats to biodiversity. Our mission is to secure a future for all species, great and small, hovering on the brink of extinction through science, policy, education, and environmental law. As a result of groundbreaking petitions, lawsuits, policy advocacy and outreach to media, hundreds of species have gained protection. The Center has a full-time staff of scientists, lawyers and other professionals who work exclusively on campaigns to save species and their habitat. Our members rely on the Center to represent their interests in protecting biodiversity and conserving threatened and endangered species and their habitats.

5. I have dedicated my life to protecting rare and imperiled wildlife, fish, and plants. I believe all of nature's living organisms, from beetles to polar bears, are equal, have inherent value, and are necessary for a healthy environment, including for humans. I have long been concerned about the widespread toxic contamination in our environment and the impacts these chemicals are having on biodiversity and human health. We developed the Environmental Health Program within the Center to address the adverse effects of pesticides and other toxic substances.

6. I am very concerned about the effects of pesticides on species and their habitats—many that I enjoy viewing in the wild and that I have worked to protect. I regularly enjoy looking for species in their natural habitats wherever I am during my travels, and especially in my home state of Arizona. I have definite

plans to continue to look for and enjoy these species. In Arizona, I am specifically concerned about the potential effects of the use of Enlist Duo on the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog.

7. The Southwestern willow flycatcher (*Empidonax traillii extimus*) is a small migratory bird that was formerly common along desert rivers from Texas to California. It is now very rare, but maintains a few important stronghold populations in Arizona. I was one of the authors of the 1992 citizen petition to list it as a federally endangered species and to designate critical habitat for it. The Center had to file numerous lawsuits from 1995 through 2010 to protect the flycatcher: first, to get the U.S. Fish and Wildlife Service list it as endangered, then to designate critical habitat, including numerous lawsuits over the adequacy of the critical habitat. The Center also sued US Animal and Plant Health Inspection Service (APHIS) and the US Department of Agriculture (USDA) for violating the Endangered Species Act when it allowed the release of the tamarisk-defoliating leaf beetle within Southwestern willow flycatcher nesting areas and critical habitat.

8. I regularly hike and recreate along Arizona's rivers and have seen the Southwestern willow flycatcher on the San Pedro River, Santa Cruz River, Gila River, Bill Williams River and Colorado River. I have seen cotton fields in the uplands adjacent to each of these rivers. If Enlist Duo is applied on these or new fields and reaches the rivers through direct spraying, run off or drift, the flycatcher

could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the flycatcher in these and other places in southern Arizona.

9. The yellow-billed cuckoo (*Coccyzus americanus*) was formerly common along rivers from Arizona to Washington State. Today, the cuckoo is found in a mere handful of locations, including several critically important strongholds in southern and western Arizona. In 1998, the Center submitted a citizen petition, primarily written by myself, to list the yellow-billed cuckoo as a federally endangered species and to designate critical habitat for it. Again, the Center had to file lawsuits before the U.S. Fish and Wildlife Service listed the western populations as threatened in 2014. The Service has also proposed critical habitat, including in southern Arizona.

10. I regularly hike and recreate in southern Arizona and have seen the yellow-billed cuckoo on the San Pedro River, Bill Williams River, Colorado River, Gila River, Verde River, Sonoita Creek and Cienega Creek. If Enlist Duo is applied on these or new fields and reaches the rivers through direct spraying, run off or drift, the yellow-billed cuckoo could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the cuckoo in these and other places in southern and western Arizona.

11. The Chiricahua leopard frog (*Rana chiricahuensis*) was once found at more than 400 sites along rivers in Arizona and New Mexico, but it is now found at fewer than 80. In southeast Arizona, it has declined more than any other leopard frog. In 1998, the Center submitted a citizen petition, primarily written by myself, to list it as a federally endangered species and to designate critical habitat for it. Again, the Center had to file lawsuits before the U.S. Fish and Wildlife Service listed the frog as threatened in 2002. In 2007, the Center became part of the stakeholders' group that developed the federal plan to recover the frog.

12. I regularly hike and recreate in southeast Arizona and have seen the Chiricahua leopard frog at isolated ponds and watering holes in the San Pedro, Santa Cruz, Brawley and Cienega creek river basins. If Enlist Duo is sprayed on these or new fields and reaches the rivers through direct spraying, run off or drift, the Chiricahua leopard frog could be harmed, killed or even locally extirpated. This would dramatically harm my professional, recreational and aesthetic interests. I intend to continue to look for and hope to see the frog in these and other places in southern Arizona.

13. I am concerned that Enlist Duo will be routinely applied on cotton in Arizona in and around habitat for the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog and have negative impacts on them and their habitat. I am concerned and fear that these species will be harmed by use

of Enlist Duo and other agricultural chemicals. If these species are further impacted and their populations reduced or extirpated, my enjoyment Arizona's unique natural environment would be diminished.

14. I have professional, aesthetic, and recreational interests in the preservation of the Southwestern willow flycatcher, the yellow-billed cuckoo, and the Chiricahua leopard frog and their habitat. My interests are being harmed by the Environmental Protection Agency's failure to ensure that these species will not be put in jeopardy through consultation with the U.S. Fish and Wildlife Service on impacts of its registration of new uses of the herbicide Enlist Duo on this species. The EPA's failure makes it more likely these species will further decline or become extinct. If that should happen, I will be deprived of my enjoyment of these species in the wild. Consultation with the U.S. Fish and Wildlife Service could result in protective measures aimed at reducing impacts of this pesticide on this species, which is important to ensure that my interests in the species are preserved and remain free from injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 10, 2018, in Tucson, Arizona.

KIERÁN SUCKLING