**Case Nos. 14-73353, 14-73359, 15-71207, 15-71213**

**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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NATURAL RESOURCES DEFENSE COUNCIL, INC.,
*Petitioner*,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
*Respondent*,
DOW AGROSCIENCES LLC,
*Respondent-Intervenor*.

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CENTER FOR FOOD SAFETY, ET AL.,
*Petitioners*,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
*Respondents*,
DOW AGROSCIENCES LLC,
*Respondent-Intervenor*.

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On Petition for Review of Two Orders of the
United States Environmental Protection Agency

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# PETITIONERS' OPENING BRIEF

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Dated: October 23, 2015

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

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

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# INTRODUCTION

Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity (collectively, "CFS Petitioners") challenge Respondent U.S. Environmental Protection Agency ("EPA")'s unlawful registration of the pesticide Enlist Duo. EPA's approval violated both the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and the Endangered Species Act ("ESA") because the agency failed to comply with these laws in assessing Enlist Duo's impacts to the environment.

Enlist Duo is a new combination of two powerful pesticides, glyphosate and 2,4-D. EPA approved a new use of this pesticide combination: to be sprayed on a new type of genetically engineered corn and soybean, specifically engineered to be resistant to Enlist Duo. These products allow producers to douse growing fields with the pesticide and kill weeds without killing the engineered crop. The fifteen states EPA's approval covers include some 150 million acres of corn and soybean cropland. Consequently, government estimates conservatively conclude that 2,4-D's use in agriculture will rise 200-600 percent by 2020. Dow's 2,4-D, formerly one component of the Vietnam-era defoliant "Agent Orange," is toxic to a wide spectrum of terrestrial and aquatic plants, birds, and mammals, in addition to its effects on human health.

In its analyses, EPA repeatedly acknowledged Enlist Duo's significant environmental impacts, yet the agency moved ahead with its approval. In so doing the agency made several fundamental errors that require reversal. First, by ignoring its own prior findings of harm, EPA violated its FIFRA duty to ensure that Enlist Duo will not cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(D). This it cannot do, as this Court recently re-affirmed. *See, e.g.*, *Pollinator Stewardship Council v. U.S. Envt'l Prot. Agency*, 800 F.3d 1176 (9th Cir. 2015). EPA's assumptions that vulnerable plants' and animals' real-world exposures to Enlist Duo will be less than the agency's own calculations demonstrate are not supported by substantial evidence, and fail to show a rational connection between the facts found and the conclusion made.

Second, EPA violated the ESA by failing to enter into consultation with the expert wildlife agencies to insure Enlist Duo will not jeopardize ESA-protected species or destroy their designated critical habitats. EPA's own analyses showed that Enlist Duo's fifteen-state, 150-million-acre approval may affect 186 protected species. The ESA strictly requires an agency in this circumstance to consult the expert agencies. 50 C.F.R. § 402.14(a). This Court has repeatedly instructed this duty's trigger is a low bar: "any possible effect" on species or their habitat is sufficient. *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006 (9th Cir. 2012) (*en banc*). But EPA did not consult, instead guessing the impacts to protected

species would not be "of concern." Yet this is not the ESA standard or the agency's prerogative; EPA conflated its FIFRA procedures for the ESA's mandates and unlawfully attempted to redefine ESA consultation thresholds. EPA must consult unless its action will have "no effect," not "an effect of no concern to EPA."

For these reasons, EPA's registration must be vacated and remanded for EPA to further assess Enlist Duo's effects on the environment, and to consult the expert wildlife agencies on its impacts to ESA-protected species and their habitats, as the ESA requires.

## JURISDICTIONAL STATEMENT

This Court has jurisdiction under 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. Envt'l Prot. Agency*, 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 555-98, 59-72. CFS Petitioners may bring this challenge because they were "a party" to the EPA proceedings, having submitted substantive written comments, and are "adversely affected" by EPA's

orders registering Enlist Duo. 7 U.S.C. § 136n(b); ER76-203, ER212-441 (comments of CFS Petitioners).

CFS 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 Earth, Inc. v. Laidlaw Envt'l Serv. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). A public interest organization like CFS Petitioners, in turn, have representational standing "when its members would otherwise have standing to sue in their own right, the interests it seeks to protect are germane to the organization's purpose, and 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 CFS Petitioners' members' environmental, recreational, aesthetic, and economic interests. *See* Decl. of Marti Crouch, No. 14-73359, ECF No. 32-3, ¶¶ 5-13, and ECF No. 52-2 (attesting to effects of the action on her interests in whooping cranes); Decl. of John Buse, No. 14-73359, ECF No. 32-2, ¶¶ 19-24, and

Decl. of Leslie Limberg, No. 14-73359, ECF No. 32-5, ¶¶ 6-20 (attesting to effects of the action on their interests in Indiana bats).[1]

Finally, CFS Petitioners timely filed their petition for review within sixty days of entry of EPA's approval orders. *See* ER7-36; Pet. Review, No. 14-73359 (9th Cir. Oct. 30, 2014), ECF No. 1-2; ER1-6; Pet. Review, No. 15-71207 (9th Cir. Apr. 20, 2015), ECF No. 1-2.

## ISSUES PRESENTED

1. Given that EPA's own analysis demonstrates that Enlist Duo will cause unreasonable harm to non-target species, did EPA violate FIFRA?

2. Did EPA violate the ESA by failing to consult the expert wildlife agencies concerning the potential effects of Enlist Duo on threatened and endangered species and their critical habitats, despite ample record evidence that its registration of Enlist Duo "may affect" them?

[1] Venue is proper because CFS Petitioners include organizations that reside and/or have places of business within this Circuit. *See* Decl. of Lori Ann Burd ¶ 2; Decl. of Thomas Cluderay ¶ 2; Decl. of Marcia Ishii-Eiteman ¶ 2; Decl. of Andrew Kimbrell ¶ 2 (filed concurrently). For the Court's convenience, copies of all previously-filed and concurrently-filed declarations are filed together herewith in the attached supporting Addendum of Declarations.

# STATEMENT OF THE CASE AND FACTS

## I. EPA'S REGISTRATION OF ENLIST DUO

On October 15, 2014, EPA granted Intervenor Dow AgroSciences' ("Dow's") petition to register "Enlist Duo," a new pesticide product. ER7-36. The pesticide[2] contains the active ingredients 2,4-dichlorophenoxyacetic acid ("2,4-D") choline salt and glyphosate dimethylammonium salt ("glyphosate"). EPA's unconditional registration allowed its use in six states—Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin—on new genetically engineered corn and soybean varieties bearing the tradename Enlist, which Dow genetically engineered specifically to be immune to these two pesticides. CFS Petitioners petitioned for review of that decision on October 30, 2014. Pet. Review, No. 14-73359, ECF No. 1-2.

On March 31, 2015, EPA amended its registration to allow Enlist Duo's use in nine additional states: Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. ER1-6. CFS Petitioners petitioned for review of that decision on April 20, 2015. Pet. Review, No. 15-71207, ECF No. 1-2. The two petitions were consolidated on June 2, 2015. Order, ECF No. 66.

[2] 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.

Dow's 2,4-D is a synthetic plant hormone, or auxin, that causes uncontrolled cell growth leading to plant death. *See* ER1056. Glyphosate is a nonselective, systemic herbicide Monsanto developed and uses as the active ingredient in its "Roundup" brand herbicides. *See* ER1162-1163, ER1181-1183; ER685, ER689-690. The two are combined in Enlist Duo specifically for use with a new generation of genetically engineered ("GE") crops, to address an agronomic and environmental problem the previous generation of GE crops created: herbicide-resistant "superweeds." ER846-848, ER852-853. Glyphosate-resistant GE crops allow growers to douse fields with that chemical and kill weeds without killing the crop; agrichemical companies sell both the patented seed and the herbicide used on it as a "crop system." *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013) (describing Monsanto's "Roundup Ready" "crop system" of GE crop and associated pesticides); *Monsanto Co. v. David*, 516 F.3d 1009, 1011-12 (Fed. Cir. 2008) (explaining Monsanto's "Roundup Ready" biotechnology).

These crops' widespread adoption resulted in growers greatly increasing glyphosate use and repeatedly applying it to their fields. This had a predicted result: Just as overuse of antibiotics breeds antibiotic-resistant bacteria, constant application of glyphosate to GE crop fields bred an abundance of weeds immune to

glyphosate.[3] Dow genetically engineered "Enlist" corn and soy to resist both 2,4-D and glyphosate, ER2, and markets these seed varieties together with Enlist Duo to growers now faced with weeds resistant to glyphosate alone.

According to EPA, "2,4-D is an active ingredient that is currently registered in a variety of salt, amine, and ester formulations and is registered for a variety of food and feed uses, including corn and soybeans." ER2. However, EPA's Enlist Duo registration entailed a "new use pattern" for 2,4-D; since 2,4-D kills conventional corn and soy, it previously could be used on those crops only in limited circumstances, but the 2,4-D-resistant GE varieties allows use "over the top," *i.e.*, on growing crops. *Id.*; ER1051 (registration "allows for applications to [GE] corn and soybeans that are later in the growing season (later growth stages) than conventional varieties of these crops"). Consequently, the U.S. Department of Agriculture ("USDA") conservatively estimates that 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. ER75.

[3] Some individual weeds are naturally resistant to the particular herbicide used. These survive when all others are killed, and proliferate without competition until the field is infested with the herbicide-resistant weed. *See* USDA, *Final Environmental Impact Statement for 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, Appendix 6* (Aug. 2014) 6-3 to 6-5; *available at* http://www.aphis.usda.gov/brs/aphisdocs/24d_feis_appendices.pdf. The Court is asked to take judicial notice under Fed. Rule Ev. 201(b) of the facts in this and the other government documents cited herein.

EPA acknowledged 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 fifteen states with approximately 150 million acres of corn and soy farmland.[4] 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 registration. ER29, ER35-36 (admitting need to monitor weed resistance to 2,4-D); ER759-60. 2,4-D has also been associated with a wide range of human health harms, ranging from neurological injuries to impacts to kidney, thyroid, and reproductive organs. ER743-51; ER1017. The agency's ecological risk assessment recognized that 2,4-D is toxic to terrestrial and aquatic plants, birds, and mammals. ER1052. EPA's own database for tracking pesticide-associated accidental kills recorded hundreds of incidents. *See* ER1090.

Regarding glyphosate, EPA concluded that all proposed uses of Enlist Duo "are already registered on other glyphosate products and are currently in use on GE corn and soybeans for the same use pattern." *Id.* Despite glyphosate never having been mixed with 2,4-D for use on crops, EPA performed no new evaluation of

[4] *See* Nat'l Agric. Statistics Serv., USDA, *Crop Acreage* (June 30, 2015), http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2015.pdf

glyphosate, which, since EPA last assessed it in 1993, has been determined to be a probable carcinogen.[5] Also since then, glyphosate has been recognized as a major cause of the precipitous, ninety percent decline of the monarch butterfly in less than twenty years, prompting the U.S. Fish and Wildlife Service ("FWS") to determine that listing the butterfly as threatened or endangered under the Endangered Species Act may be warranted.[6]

A. EPA's Environmental Risk Assessment

On January 15, 2013, EPA released its environmental risk assessment for Enlist Duo. ER1043-145. Among other things, the assessment purported to characterize the risk that Enlist Duo's use presents to "non-target" organisms, *i.e.*, organisms other than the weeds it is intended to kill. The assessment ignored glyphosate entirely, focusing on 2,4-D's potential impact exclusively. ER1051. The EPA assessment also ignored any of the 2,4-D/glyphosate combination's synergistic effects, which it acknowledged "may be more toxic to plants than the single active ingredient products." ER1104.

[5] *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.

[6] 79 Fed. Reg. 78,77578,778 (December 31, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FWS-R3-ES-2014-0056-0001.

1. EPA's Methodology

EPA's risk assessment for non-target organisms involved several steps. First, EPA used computer modeling to estimate the extent to which different categories of organisms (*e.g.*, birds, mammals, terrestrial plants) will be exposed to 2,4-D. *See* ER1069-82. EPA refers to these modeled exposure levels as "estimated exposure concentrations," or "EECs."

Next, using laboratory toxicity studies, EPA attempted to estimate the level of 2,4-D exposure that will cause a certain threshold level of adverse effect on different categories of non-target organisms.[7] For example, to estimate toxicity to birds in general, EPA reviewed four laboratory studies conducted on Northern bobwhite quails and mallard ducks. ER1087.

Finally, for each category of non-target organism, EPA divided the EEC by the corresponding toxicity value, to calculate what EPA refers to as the "risk quotient," or "RQ." The resulting risk quotients were compared to EPA's predetermined "level of concern," or "LOC," for each species. *See* ER1093. If the

[7] Because EPA was unaware of any independently available 2,4-D choline toxicity studies, "only studies submitted by the registrant [*i.e.*, Dow] were evaluated to determine the effects of 2,4-D choline salt on non-target organisms." ER1083. Moreover, most of the studies submitted by Dow did not assess 2,4-D choline salt, but rather assessed other forms of 2,4-D. For example, none of the bird or mammal studies involved 2,4-D choline salt. *See* ER1087-88.

risk quotient exceeded the level of concern, EPA concluded the pesticide's proposed use presents an unacceptable risk to the subject non-target organism.

2. EPA's Conclusions

Following this process, EPA concluded that proposed 2,4-D choline salt uses:

- *may directly affect birds* on an acute basis.
- *may directly affect mammals* on an acute and chronic basis.
- *may directly affect terrestrial plants* (monocots and dicots).

ER1053 (emphases added).

Notably, EPA characterized these same conclusions differently with respect to species protected as threatened or endangered under the ESA, which requires EPA to consult FWS if the registration "may affect" any such species:

> The screening-level analysis for 2,4-D choline salt indicated that there was *insufficient information* to determine if there were direct effects to mammals (acute and chronic); birds, reptiles, and land-phase amphibians (acute); and terrestrial plants.

ER1053 (emphasis added).

Having reached these determinations, EPA concluded that "information such as biological distribution, species biology, spray drift properties specific to the 2,4-D choline formulations, and mitigation efforts in regions where the pesticide is used, could be used to *reduce the uncertainty* regarding potential direct and indirect effects." ER1044 (emphasis added). For example, EPA stated that

"*buffers of 202 feet* would reduce risk quotients for birds (acute), mammals (acute and chronic), and terrestrial plants below [EPA's] level of concern." *Id.* (emphasis added). EPA did not propose mitigation to address exposure within fields themselves sprayed with Enlist Duo.

3. Subsequent Addenda to the EPA Assessment

On June 13, 2013, EPA issued an addendum to its Environmental Risk Assessment slashing the spray drift buffers needed to keep risk quotients for non-target organisms below the agency's levels of concern, from 202 feet down to "from < 25 ft to 30 ft." ER1021. EPA claimed the dramatic reduction was justified by using drift data for 2,4-D *salt/amines* instead of regarding "2,4-D *ester* moieties." ER1021-22 (emphases added).

On February 12, 2014, EPA issued a second addendum purporting to "refine" the assessment of risk to endangered species. ER922-68. It begins by acknowledging that the analysis in the original assessment shows "[p]otential direct risk concerns *could not be excluded* for mammals (acute and chronic); birds, reptiles, and terrestrial-phase amphibians (acute); and terrestrial plants." ER922-23 (emphasis added).

Nevertheless, the addendum concludes Enlist Duo will have "no effect" on any listed species based on the following: First, EPA assumed 30-foot buffers will completely eliminate the effect of any drift outside the sprayed field. ER924. For

this reason, EPA claimed that Enlist Duo will have "no effect" on forty-nine ESA-listed species not expected to occur within crop fields themselves. ER922-24.

Second, while not disputing the remaining four listed species "reasonably expected to occur on treated corn and soybean fields" will be exposed, EPA relied on species-specific data regarding diet, metabolism, and other factors to conclude their actual 2,4-D exposure will not exceed EPA's level of concern, and therefore Enlist Duo will have "no effect" on them.[8]

B. Proposed Registration

On April 30, 2014, EPA proposed to register Enlist Duo. The proposed registration decision concedes risks to birds, reptiles, landphase amphibians, mammals, and plants:

> The screening-level analysis indicates that risks for acute exposures to birds, reptiles, and landphase amphibians do result in [risk quotients] that exceed the Agency's [level of concern] for acute exposures. Additionally, risks for mammals resulted in [risk quotients] that exceed the Agency's [level of concern] for both acute and chronic exposures. Risks for plants resulted in [risk quotients] that exceed the Agency's [level of concern] for both terrestrial monocots and terrestrial dicots.

[8] EPA's September 17, 2014 addendum reflects a revised toxicity value for the Indiana bat, but reaches the same "no effect" conclusion. ER682-683.

ER869. EPA dismissed these risks, however, based largely on assertions that the analysis in the assessment was "conservative" or "worst-case," and that actual exposures "may be lower." ER870-72.

C. Final Registration Decision

EPA issued its final decision to register Enlist Duo in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin on October 15, 2014, together with a response to the public comments it received. ER7-36. With respect to toxicity to **birds**, the final decision summarizes the findings in the Environmental Risk Assessment as follows:

> In order to make the most conservative risk estimation, acute toxicity risk quotients were based on the oral toxicity study for the northerner [*sic*] bobwhite quail. The risk quotients for birds of 0.01 to 4.18 were then compared to the Agency's screening level of concern for non-listed species (RQ>0.5).

ER23. However, the Final Decision dismisses EPA's findings that the risk quotients for birds exceed EPA's own level of concern *by over 800 percent*, based on the following line of reasoning:

> While concern levels are triggered, further consideration of all lines of evidence does suggest that risks under *more usually* encountered circumstances *may* be lower. For example, high end residues compared to toxicity study endpoints using chemicals actually incorporated in the animal's diet do not trigger non-listed species concerns, suggesting that 2,4-D choline consumed in the diet *may possibly be less* available than assumed using dose-based exposures. Further, *more frequently* expected residues levels, such as mean or median estimates of exposure would be lower by a factor of two or

> more, suggesting that residues are *often not likely* to trigger concerns for *many* food items.

*Id.* (emphases added). The Final Decision also concludes the 30-foot buffer will "further *reduce* off-site exposure for birds." *Id.* (emphasis added).

With respect to **mammals**, the Final Decision again concedes that "potential risks from the new 2,4-D choline salt uses result in [risk quotients] that exceed the Agency's [level of concern] for mammals in both acute and chronic scenarios." ER23. Again, the Final Decision dismisses acute risks to mammals on the grounds that its risk assessment is "designed to be conservative" and "EPA expects that actual risks to these mammals is lower." ER24. The Final Decision does not address acknowledged chronic risks to mammals, but concludes that the 30-foot buffer "is intended to *reduce* the areas where *such risks may occur*." *Id.* (emphases added).

With respect to **plants**, the Final Decision relies entirely on the 30-foot buffer, and restriction against spraying when "rain or irrigation is expected within 24 hours," to address the acknowledged risk. ER25-26.

Finally, with respect to **ESA-listed species** in particular, the Final Decision concedes that risks "could not be excluded" for birds, mammals, and terrestrial plants. ER26-27. EPA nonetheless concludes that the registration of Enlist Duo will have "no effect" on the four listed species likely to occur within treated fields (whooping crane, Canada lynx, Indiana bat, and American burrowing beetle).

ER27. It also declares none of the dozens of listed species found near, but not in, the fields will be affected based on the assumption that none of the pesticide that will drift or run off any of the fields will affect them. ER27.

D. Amended Registration Decision

On March 31, 2015, EPA issued its final decision amending the registration to also allow Enlist Duo use in Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. ER1-6. It performed no new risk assessments except for ESA-listed species. ER1-2. Since additional ESA-listed species are found in fields in these additional states (gray wolf, Ozark bat, Louisiana black bear, Mississippi sandhill crane, and gopher tortoise), along with all of the listed species found in fields in the original six states, EPA performed a "refined endangered species assessment," ER603-81, purporting to assess risk to the additional endangered species. Using the same methodology, EPA again found "no effect" on any listed species. *Id.* EPA also applied the same rationale as in its previous decision, that spray drift and runoff will not affect any of the well over a hundred listed species found near, but not in, the sprayed fields. ER605.

## STANDARDS OF REVIEW

The Court may sustain EPA's Enlist Duo registrations 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).

Further, "the substantial evidence standard affords an agency less deference than the arbitrary and capricious standard." *Pollinator Stewardship Council*, 800 F.3d at 1118 (N.R. Smith, J., concurring) (*citing Universal Camera Corp.*, 340 U.S. at 477 and *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). 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.

EPA violated the Endangered Species Act 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. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). This duty is triggered by "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe*, 681 F.3d at 1027.

## SUMMARY OF ARGUMENT

EPA's approval of Enlist Duo violated the agency's distinct statutory duties to protect the environment, one governed by FIFRA, the other by the ESA. EPA violated the ESA by failing to consult with FWS on Enlist Duo's potential impacts on protected species and their designated critical habitats. The ESA's consultation process—the "heart" of the ESA—strictly requires action agencies like EPA to consult with the expert wildlife agencies on any action that "may affect" protected species or habitat. The standard for such a finding is very low: "*Any possible effect*, whether beneficial, benign, adverse or of an undetermined character" triggers the requirement. *Karuk Tribe*, 681 F.3d at 1027. The only time consultation is not required is when there is absolutely "no effect."

EPA's own assessments plainly show its approval of the pesticide "may affect" numerous endangered species and critical habitats. EPA approved a novel combination of pesticides known to be toxic to a wide array of animals and plants. The approval will dramatically increase use of, and exposure to, 2,4-D, potentially seven-fold.[9] The approval spans fifteen states that currently have a combined 150 million corn and soy acres.[10] It beggars belief that such an approval will have no possible effect on any of the nearly 200 endangered species that live in these areas, or any of their dozens of habitats designated as critical to their survival and recovery, and EPA's own assessments show plainly that approval of Enlist Duo will.

To avoid a "may affect" finding and the consultation it mandates, EPA ratcheted up the ESA threshold to consult, attempting to redefine it as requiring consultation only if Enlist Duo's impacts meet EPA's own FIFRA policy metric, its "level of concern." This the ESA does not countenance: Once EPA found there would be any effect, it had to consult, and its failure to do so here violated the ESA.

Non-endangered wildlife may not be protected by the ESA, but FIFRA still requires that EPA ensure Enlist Duo "does not cause any unreasonable adverse

[9] *See* USDA, Final Environmental Impact Statement, *supra* note 3, at 134.

[10] *See* Nat'l Agric. Statistics Serv., *supra* note 4.

effects on the environment." Here again, the agency made a fundamental error requiring reversal. EPA's modeling showed risks to wildlife from Enlist Duo exceeding the agency's own risk thresholds. Yet, EPA unlawfully ignored its own metrics by speculating, without record support, that real world exposures would be less than the impacts its own calculations revealed. EPA's suppositions are a far cry from the substantial evidence required, and its decision requires reversal.

## ARGUMENT

### II. EPA VIOLATED FIFRA

FIFRA, as amended in 1972, governs EPA's duty to assess registration of Enlist Duo's effects on human health and the environment generally, and reflects "mounting public concern about the safety of pesticides and their effect on the environment." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). The statute "sets forth a comprehensive regulatory scheme for controlling the use, sale, and labeling of pesticides." *Wash. Toxics Coal. v. Envt'l Prot. Agency*, 413 F.3d 1024, 1030 (9th Cir. 2005).

Prior to registering a pesticide, EPA has a duty to ensure it "will not generally cause unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(D), "taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." *Id.*, § 136(bb). Thus, "FIFRA's objective is to protect human health and prevent environmental harm from

pesticides through a cost-benefit analysis." *Wash. Toxics Coal.*, 413 F.3d at 1032. "Once [EPA] has found that a risk inheres in the use of a pesticide, [the agency] has an obligation to explain how the benefits of … use outweigh that risk." *Envt'l Defense Fund v. Envt'l Prot. Agency*, 548 F.2d 998, 1012 (D.C. Cir. 1976); *see also* S. Rep. 970, 92d Cong. 2d Sess., *reprinted in* 1972 U.S.C.C.A.N. 4092, 4095 ("[A]ny adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide.").

### A. EPA's Conclusion that Use of Enlist Duo Will Not Present an Unreasonable Risk to Non-Target Species Is Unsupported by Substantial Evidence, in Violation of FIFRA.

As explained above in the Statement of the Facts, EPA's Environmental Risk Assessment concluded that Enlist Duo would result in risk quotients exceeding EPA's levels of concern for birds, mammals, and terrestrial plants. ER24, 26. EPA offered no rationale that these risks are outweighed by any benefits, as required. *See Envt'l Defense Fund*, 548 F.2d at 1012. Having applied its risk assessment methodology and reached this determination, EPA may not then simply dismiss the results, as it did here.

In *Natural Resource Defense Council v. Environmental Protection Agency*, 735 F.3d 873 (9th Cir. 2013), this Court considered EPA's decision to register a new "nano-silver" antimicrobial pesticide (referred to as "AGS-20"). To assess the potential risk to children, EPA calculated what it calls the "margin of exposure" or

"MOE," a human health risk assessment concept akin to the risk quotient used in the Environmental Risk Assessment for Enlist Duo. *Id.* at 881. EPA concluded "there is a risk concern if the aggregate dermal and oral exposure to AGS-20 is less than *or equal to* [a MOE of] 1,000." *Id.* In its subsequent analysis, EPA calculated a MOE of greater than 1,000 (meaning no risk of concern) in every instance, save one. "In one instance, EPA calculated an aggregate exposure of 1,000, which is obviously equal to 1,000." *Id*. Because all but one of the calculated MOEs exceeded 1,000, and because the outlier was exactly equal to 1,000, EPA concluded AGS-20 did not pose a risk concern. *Id.*

The Court rejected EPA's conclusion, holding it unreasonable and unsupported by substantial evidence:

> EPA articulated the assumptions that led it to set the target MOE at 1,000. And it stated the rule that there is a risk concern if the MOE is less than or equal to 1,000…. Having established a rule of decision of less than or equal to 1,000, EPA cannot unmake it because its actual MOE is in the neighborhood. Nor can we revise EPA's assumptions, alter its rule of decision, or perform our own risk assessment.

735 F.3d at 884 (internal citations and emphasis omitted). The Court concluded: "EPA may wish to revisit its standards in the future, but it cannot ignore them." *Id.*

Here, EPA's risk quotients exceeded EPA's own levels of concern for multiple non-target organisms. *See supra* pp. 13-18. Having set those standards, EPA cannot now "ignore them." EPA's subsequent conclusion that Enlist Duo "will not generally cause unreasonable adverse effects on the environment," 7

U.S.C. § 136a(c)(5)(D), thus is unsupported by substantial record evidence. *Natural Res. Def. Council*, 735 F.3d at 884.

No substantial evidence supports EPA's assumption that actual exposure for mammals and birds "may" be less than the exposure EPA calculated. *See, e.g.*, ER23 (asserting actual risk to birds "*may* be lower" than those calculated in the Environmental Risk Assessment) (emphasis added). While EPA asserted that, because the risk assessment is "designed to be conservative," the agency "expects that actual risks to … mammals is lower," *id*., this Court has repeatedly rejected EPA's efforts to avoid the consequences of its actual measurements triggering risk concerns, according to its own protocols. The Court recently reaffirmed this basic principle in *Pollinator Stewardship Council*, explaining: "The EPA chose to set its level of concern at a measurement it now feels is overly conservative, but a court cannot alter the agency's own rule." 800 F.3d at 1186. " '[C]lose enough' … just does not fly" for a FIFRA registration risk assessment. *Id.*, *see also Wang v. Immigration & Naturalization Serv*., 352 F.3d 1250, 1258 (9th Cir. 2003) ("Speculation and conjecture may not substitute for substantial evidence.").

Moreover, EPA's supposition that actual exposure might be lower than the exposure it calculated—which is not only unsupported, but at odds with the undisputed massive increase in 2,4-D's projected use in absolute and per-acre terms—is not entitled to deference, because courts "may not defer to an agency

decision that is without substantial basis in fact." *Tucson Herpetological Soc'y v. Salazar*, 566 F.3d 870, 878 (9th Cir. 2009); *see also Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 377 (1989) (courts defer only to "the informed discretion of the responsible federal agencies"); *Jurewicz v. Dept. of Agric.*, 741 F.3d 1326, 1331 (D.C. Cir. 2014) ("The Court does not defer to conclusory or unsupported suppositions."). This failing is analogous to the arbitrary and capricious standard's requirement that agencies show a "rational connection between the facts found and the conclusions made." *Native Ecosystems Council v. U.S. Forest Serv.*, 418 F.3d 953, 960 (9th Cir. 2005); *see also, id*. at 965 ("In an administrative appeal, we cannot divine the grounds for government decisions that are not explained or apparent."). EPA unlawfully failed to do so here.

The Enlist Duo registration violated FIFRA, and must be vacated and remanded for EPA to obtain further studies and data regarding the effects of 2,4-D on non-target species. *Pollinator Stewardship Council*, 800 F.3d at 1187.

## III. EPA'S FAILURE TO CONSULT THE EXPERT WILDLIFE AGENCIES TO INSURE THAT ENLIST DUO DOES NOT JEOPARDIZE LISTED SPECIES VIOLATED THE ENDANGERED SPECIES ACT

The ESA governs EPA's actions relating to species listed under that statute as threatened or endangered, such as registering Enlist Duo. Under the ESA, "[e]ach federal agency" must "insure" its actions will not "jeopardize" any species, 16 U.S.C. § 1536(a)(2), defined as engaging 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…." 50 C.F.R. § 402.02. It also must "insure" its action will not adversely modify any habitat designated as "critical." 16 U.S.C. § 1536(a)(2). Critical habitat consists of "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).

A. The ESA's Consultation Process and Standards

Section 7(a)(2) is a critical component of Congress's plan to conserve threatened and endangered species. *See Cal. ex rel. Lockyer v. U.S. Dep't of Agric*., 575 F.3d 999, 1018 (9th Cir. 2009) (Section 7(a)(2) is "the heart of" the ESA). The duty to insure against jeopardy or adverse modification is "rigorous." *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987). To comply with this duty, Congress required the agency to evaluate its action'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 the National Marine Fisheries Service

("NMFS") (for marine species).[11] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). Identifying the likely effects of the action through the consultation process is a distinct procedural duty, but it is integral to compliance with the ESA's substantive protections. *See Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("If anything, the 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.").

Every federal agency, using the "best scientific and commercial information available," 16 U.S.C. § 1536 (a)(2), must first determine whether its actions—here, EPA's Enlist Duo registration—"may affect" any listed species or designated critical habitat. 50 C.F.R. § 402.14(a). Of central importance to this case, the standard for whether EPA's action "may affect" a species or critical habitat, triggering consultation, is 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 (emphasis added). "*Any possible effect*, whether beneficial, benign, adverse or of an undetermined character" triggers the requirement. *Id.*

[11] For simplicity, CFS Petitioners refer to FWS as the consulting expert agency, but EPA's consultation duties include NMFS if any marine species may be affected by EPA's action.

(quoting *Lockyer*, 575 F.3d at1018–19 (quoting 51 Fed. Reg. 19,926, 19,949 (June 3, 1986)) (emphasis in *Lockyer*). This consultation trigger is a " 'low' threshold." *Karuk Tribe*, 681 F.3d at 1027 (quoting *Lockyer*, 575 F.3d at 1018); *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2010) (same).

If the action "may affect" any listed species or critical habitat, the agency *must* consult FWS prior to taking final action. 50 C.F.R. § 402.14(a). Consultation initially may be "informal." 50 C.F.R. §§ 402.14(a), (b); 402.13(a). If, after informal consultation, FWS *concurs in writing* that EPA's action is "not likely to adversely affect" any listed species or critical habitat, the process ends. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *see 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…."). Otherwise, EPA must enter formal consultation. *Id.*; 50 C.F.R. § 402.14(a).

At the completion of formal consultation, FWS issues a Biological Opinion, providing FWS's expert opinion on whether the action agency's action is likely to jeopardize the continued existence of any species or adversely modify any designated critical habitat, and authorizes any incidental "take." 50 C.F.R. § 402.14(h)(3), (i). In all of these analyses, all agencies are required to "give the benefit of the doubt to the species." *Conner*, 848 F.2d at 1454 (*quoting* H. R.

Conf. Rep. No. 96-697, 96th Cong., 1st Sess. 12 (1979), *reprinted in* 1979 U.S.C.C.A.N. 2572, 2576).

### B. EPA's Duties Under FIFRA and ESA Are Very Different, and EPA Conflated Them.

FIFRA and the ESA thus address different issues, reflect different policies, and apply different standards; EPA's role under each regime is very different. Whereas FIFRA subjects pesticide registrations to a cost-benefit balancing, "[t]he plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, whatever the cost." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 184 (1978); *see also 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.") (quoting *Nat'l Assoc. of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 671 (2007)). While pesticide regulation is among EPA's 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.

Further, while Congress specifically tasked EPA with registering pesticides under FIFRA, EPA has no special charge or expertise regarding effects on endangered species' survival and recovery or the ESA's standards, and Congress did not merely suggest, but expressly required, that EPA seek FWS's expertise to

"insure" against jeopardizing species or modifying habitat. 16 U.S.C § 1536(a)(2). As the court explained in *City of Tacoma, Washington v. F.E.R.C.*, 460 F.3d 53 (D.C. Cir. 2006): "This interagency consultation process reflects Congress's awareness that expert agencies (such as the Fisheries Service and the Fish and Wildlife Service) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species." *Id.* at 75.

EPA's fundamental error in this case is that, through various internal procedures, it unlawfully sought to raise the consultation threshold above "no effect" and failed to consult the expert wildlife agencies when it was required to do so. EPA's efforts to redefine that threshold are contrary to the ESA's fundamental standards and longstanding precedent. A legitimate "no effect" finding allowing an agency to forego consultation with the expert agencies means just that: *no effect*. Consultation is required not only when an action "will harm" a listed species or critical habitat, or even "will affect" it, or "meet or exceed levels of toxicological concern for reproduction and development." Instead, "actions 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).

FWS and NMFS's *Endangered Species Consultation Handbook* ("*Consultation Handbook*")[12] further elucidates the distinction between "no effect" and "not likely to adversely affect":

> **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* at *xv-xvi*.

As will be shown, all of EPA's "no effect" determinations in this case at best meet the legal definition of "not likely to adversely affect," subject to FWS concurrence. By conflating the standards, EPA unlawfully failed to engage in any form of consultation with FWS. This was reversible error. *See* 5 U.S.C. § 706(2)(A).

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[12] FWS & NMFS, *Endangered Species Consultation Handbook, available at* 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).

### C. EPA's Assessment Showed the Registration "May Affect" Endangered Species.

As explained, the ESA regime governing EPA's obligations regarding endangered species adds independent and substantial requirements for EPA to register Enlist Duo, very different from those imposed by FIFRA. Yet EPA's approach to evaluating Enlist Duo reveals it failed to respect the critical distinctions between its FIFRA and ESA roles and duties. The ESA strictly prohibits proceeding with an action unilaterally unless it has "no effect" on any listed species or habitat. EPA's entire FIFRA level-of-concern-based risk assessment framework is premised on the assumption that some level of adverse effects to non-target organisms are acceptable in reaching an overall decision to register a pesticide. But even if effects do not rise above EPA's level of concern, they are occurring, and for ESA-listed species, as a matter of law as well as practical fact, only the expert wildlife agencies are in a position to determine whether the effects are of concern. EPA assumed that if its process persuaded itself that Enlist Duo would *not likely adversely affect* listed species or their habitat—did not exceed EPA's level of concern—it complied with the ESA and its work was done. It was wrong.

EPA's January 15, 2013 risk assessment, ER1043-1145, admitted Enlist Duo will harm many non-target plant and animal species. *Supra* at 12-19. It specifically found that risk quotients far exceeded EPA's levels of concern for both

birds and mammals. *See* ER1097 (birds); ER1102-03 (mammals). EPA then performed additional analyses. In its February 12, 2014 addendum, ER922-68, EPA admitted its additional screening analysis found: "53 [threatened or endangered] species in the 6 states [initially] proposed for registration (Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin) were identified as within the action area … associated with the new herbicide-tolerant corn and soybean uses." ER923. EPA acknowledged that "risk concerns for all taxa were possible for any species that have dependencies (e.g., food, shelter, habitat) on mammals, birds, reptiles, terrestrial-phase amphibians, or terrestrial plants," ER922-23, ranging from the iconic whooping crane, the piping plover, and pallid sturgeon to indicator species such as the Indiana bat, the gray bat, and Hine's emerald dragonfly to vital pollinators including Karner blue butterfly and Mitchell's Satyr butterfly, and numerous other endangered and threatened terrestrial and aquatic species. ER936.

EPA followed the same approach in assessing the risks of amending its registration to include nine additional states. *See* ER604 (168 listed species located within the action area). Its own screening analysis shows the amended approval puts at risk even more federally protected sensitive species, including the Louisiana black bear, the Ozark big-ear bat, gray wolf, and Mississippi sandhill crane. *See* ER617-22.

### D. EPA's Restriction of the "Action Area" to Avoid "May Affect" Findings for Dozens of Protected Species Near Enlist Duo Fields Violates the ESA.

After making what under the ESA should have been determinations that the registrations "may affect" nearly 200 federally protected species, EPA did not consult FWS, as Section 7(a)(2) requires. Instead, EPA went through a series of contortions seeking to shoehorn its findings into its distorted view of ESA compliance. First, it redefined the registration's "action area," shrinking it drastically. When assessing the impacts of its registration, EPA must look at all effects within the "action area." *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 901 (9th Cir.2002); 50 C.F.R. §§ 402.02, 402.12. The "action area" includes "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 (emphasis added).

The registration's action areas therefore includes not only the 150 million acres of corn and soybean fields where EPA approved Enlist Duo for use, but also the areas nearby, where there might be *any* direct or indirect effect—as EPA initially acknowledged. But EPA then assumed mitigation, such as spray nozzle specifications and small buffers, would reduce the effect of the admitted transport of the pesticide beyond the sprayed fields—by spray drift, volatilization, and pesticide runoff—below "loadings that will trigger concerns." ER924; ER599. EPA employed this assumption to conclude that there would be "no effect" on

forty-nine of the fifty-three at-risk listed species it originally had identified as being in the action area in the initial six states, ER924, or on 157 of 168 species in the original action area of the amended registration, ER599.

EPA is well aware, and the record clearly demonstrates, that pesticides routinely travel and affect public health and wildlife well beyond the fields in which they are sprayed, and has often acknowledged this. *See, e.g.*, ER18 ("Spray drift is *always* a potential source of exposure to residents nearby to spraying operations. Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact.") (emphasis added). As one comment on the registration pointed out, the 2,100 annual complaints of pesticide drift, most involving crop damage from herbicide drift, are likely a small proportion of the actual instances. ER753. Indeed, 2,4-D is one of the most frequent subjects of drift complaints. ER755. Pesticide label restrictions have long existed and have failed to prevent many documented instances of 2,4-D drift damage. ER757-58. Damage is not confined to adjacent fields; tens and even hundreds of thousands of acres have been damaged at one time by 2,4-D drift and volatilization. *Id*.

Although EPA attempted to *reduce* off-site transport through mitigation measures and label restrictions, it admitted it will still occur. *See, e.g.*, ER61 ("The

Agency makes no claim that drift and runoff do not occur," but that exposures "high enough to cause acute or chronic effects are not reasonably expected to occur.") The standard for consultation under Section 7(a)(2) is not whether an action causes "acute or chronic effects," but whether it may cause "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe*, 681 F.3d at 1027.

Accordingly, EPA's redefinition of the "action area," and categorical finding that the millions of pounds of Enlist Duo to be sprayed in the coming years will have "no affect" on any species or critical habitat outside the treated fields, such that the expert wildlife agencies need not be consulted, is arbitrary and capricious, not in accordance with the definition of "action area;" and violates EPA's consultation obligations. *See Wilderness Soc. 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). This also fails to give the benefit of the doubt to the endangered species, as EPA is required to do in making determinations under the ESA. *Conner*, 848 F.2d at 1454.

### E. EPA's Conclusion That Enlist Duo Will Have "No Effect" Even on Protected Species Within Sprayed Fields Is Not in Accordance With Law.

EPA also made unlawful "no effect" determinations as to the protected species it acknowledged are found within sprayed fields. EPA admitted in both its original and amended registrations that no drift mitigation will prevent listed species, including the whooping crane, Indiana bat, Louisiana black bear, and Mississippi sandhill crane, from ingesting Enlist Duo because the animals are "reasonably expected to occur on treated corn and soybean fields." ER924; ER605-06. At this point the agency was required to stop and consult FWS, the expert agency. Instead, after what should have been a clear "may affect" finding, EPA consulted only itself, and continued to assess the potential for harm to these species according to how EPA supposed that ought to be done: applying FIFRA protocols and guessing whether the impacts to listed species were bad enough to trigger consultation. This violated the ESA.

In the FIFRA pesticide registration context, EPA uses a risk assessment protocol that "integrates the results of exposure and toxicity data to evaluate the likelihood of adverse ecological effects on non-target species." ER1263. The basic analysis is a 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, OPP 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 the Agency's [levels of concern]. These [levels of concern] 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.

*Id*. (emphasis added).

EPA uses the same procedure to assess effects on endangered species, and assumes endangered species "may be potentially affected" when acute risk quotient >0.1, *id*., and chronic risk quotient >1. ER1264. This process has never been found to be sufficiently protective of endangered species. In *Washington Toxics Coalition v. U.S. Department of Interior*, 457 F. Supp. 2d 1158, 1179-80 (W.D. Wash. 2006), the court noted the difference between EPA's risk assessment process and the ESA's requirements:

> *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 (emphasis added) (quoting a NMFS scientist). *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'").

Despite using an underprotective and legally inadequate approach, EPA marched forward. EPA's screening-level assessment found risk quotients far exceeding the levels triggering a risk finding, with acute risk quotients for birds up to 4.18, ER870, acute risk quotients for mammals up to 0.57, ER871, and chronic risk quotients for mammals up to 5.78, *id*.

1. EPA's Failure to Consult Violated Its Own Policies.

EPA's action is contrary not only to the ESA but also to its own policy guidelines for determining when consultation is required in pesticide assessments. *See, e.g.*, *INS v. Yueh–Shaio Yang*, 519 U.S. 26, 32 (1996) (unexplained departure from existing agency policy evinces arbitrary and capricious action). EPA's policy provides that when a screening assessment shows the risk threshold is exceeded for one or more listed species, as EPA's January 15, 2013 risk assessment did here, ER1043-1145, EPA may refine its assessments, but *not to determine whether there will be "no effect"* and consultation may be avoided entirely. Instead, refined assessments may only determine whether the species is "likely to be adversely affected," which would allow EPA to forego formal consultation *only if* FWS

concurs in writing with this finding after informal consultation (*see Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8):

> In cases where screening-level acute [risk quotients] for a given animal group equal or exceed the endangered species acute [level of concern] … additional analysis … may be performed using Services-provided "species profiles" as well as evaluations of the geographical and temporal nature of the exposure to ascertain *if a not likely to adversely affect determination can be made*….

ER1265 (emphasis added). EPA professes to take the same approach on its website; consistent with the ESA, it does not offer the option to convert a "may affect" determination to a "no effect" determination using more refined assessments:

> The result of an assessment to determine potential effects of a pesticide's registration to a listed species will result in one of two determinations:
>
> - The pesticide's registered use will have "no effect" on the species or designated critical habitat,
> - The pesticide's registered use "may affect" the species or designated critical habitat.
>
> If EPA determines the pesticide "may affect" the species it refines its assessment to determine whether the pesticide's use:
>
> - "may affect, but is not likely to adversely affect" the species or designated critical habitat; or
> - "may affect and is likely to adversely affect" the species or designated critical habitat.
>
> …

> … If EPA determines that a pesticide's use "may affect, but is not likely to adversely affect" a listed species, EPA *will engage the Services in a process called informal consultation*.[13]

EPA's guidance in a context legally indistinguishable from this one—EPA's pesticide registration review program—similarly requires that "any species or critical habitat that overlaps with the action area *will be considered a 'May Affect.'*"[14] The guidance confirms unequivocally: "For species and critical habitats that do overlap with the action area, the call *will be 'May Affect,'* and the analysis *will proceed* with [informal consultation with FWS]."[15]

But that is not what EPA did here. Instead, EPA referred the matter to its Field and External Affairs Division ("FEAD"), which persisted in seeking a *de facto* unilateral "not likely to adversely affect" determination, and disguise it as a "no effect" finding.

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[13] EPA, *Assessing Pesticides under the Endangered Species Act*, http://www2.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act (emphasis added) (last visited October 8, 2015).

[14] EPA, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*, at 4, *available at* http://www2.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

[15] *Id.* at 7 (emphases added).

### F. EPA's Further Species-Specific Analyses and "No Effect" Determinations Violated the ESA.

Instead of following the ESA's mandates and its own policies and consulting FWS, EPA resorted to more and more tenuous and speculative contortions of whether the acknowledged impacts would exceed EPA's own "level of concern"—a concept alien to the ESA and which EPA has no business using in Section 7(a)(2) determinations—and applied them to critically endangered species.

#### 1. Whooping Crane (*Grus Americana*)

The whooping crane is one of the most endangered animals on earth, pushed to the brink of extinction by unregulated hunting and loss of habitat. There were fewer than fifty whooping cranes in North America prior to 1968, with as few as twenty-one in 1954.[16] Conservation efforts over the past seventy years have led to only a limited recovery; as of 2006, there were only an estimated 338 whooping cranes in the wild.[17] 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."[18]

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

[17] *Id*. at 1.

[18] *Id.*

EPA admitted that during migration, whooping cranes "will stop to eat and may consume arthropod prey" sprayed with 2,4-D. ER925. A clear "may affect" situation. But rather than consult FWS, EPA guessed the cranes' metabolic rate, guessed the amount of 2,4-D in the prey a hypothetical crane might consume, guessed the amount of such prey it was likely to consume, and compared this collection of guesses with EPA's internal level of concern. ER925-926. Legally, this was the equivalent of a determination that the exposure was "not likely to adversely affect" the crane, which is not EPA's decision to make, without at least informal consultation and FWS's written concurrence. *See supra* at pp. 28-31.

a. EPA Failed to Use the Best Scientific and Commercial Information Available.

Further, although EPA's policy identifies FWS's Recovery Plans as a source of "best available and current information" for performing species-specific assessments, ER1267 and although the ESA expressly requires EPA to use the "best scientific and commercial information available" for these assessments, 16 U.S. C. § 1536(a)(2), EPA never reviewed FWS's Whooping Crane Recovery Plan, which is absent from EPA's administrative record. (Despite the likelihood that FWS has amassed hundreds, if not thousands, of documents on the whooping crane, the most recent FWS document in the record concerning whooping cranes, record identifier ("AR") 5932, dates from 1978.) Instead, EPA cited only two sources for the data it used for its whooping crane species-specific assessment. It

cited "Dunning 1984," AR376, for the bird's weight[19], and EPA's Wildlife Exposure Factors Handbook ("Handbook"), AR484 (excerpts at ER1276-81), for all other data. *See* ER925 (citing the Handbook as "USEPA 1993").

EPA's reliance on the Handbook violates the ESA's mandate that it use the "best scientific and commercial information available," 16 U.S.C. § 1536 (a)(2). The Handbook nowhere mentions the whooping crane, the ESA, or any endangered species. The Handbook is not intended to be used to assess effects on any endangered species, or for more intensive inquiries following screening assessments showing any species may be affected. On the contrary, its stated "scope and purpose" is "to provide a convenient source of information and an analytic framework for *screening-level risk assessments* for *common* wildlife species." ER1277 (emphases added). Indeed, the Handbook itself cautions against relying on it for other levels of assessment, as EPA improperly did here:

> Although the data presented in the Handbook can be used for *screening analyses*, we recommend that anyone establishing a cleanup goal or criterion on the basis of values contained herein obtain the original literature on which the values are based to confirm that the study quality is sufficient to support the criterion.

*Id*. (emphasis added).

[19] Even this source is obsolete, having been superseded twice. The current edition, published in 2007, covers 8,700 species. *See* W. Bird Banding Org., Publications, http://www.westernbirdbanding.org/publications.html (last viewed Oct. 19, 2015).

Moreover, the Handbook notes the importance of obtaining data for the particular species being addressed, while here, the Handbook contains no data about any type of crane:

> Exposure varies between different species and even between different populations of the same species; behavioral attributes and diet and habitat preferences influence this variation.

ER1278.

The Handbook emphasizes that the screening-level assessments for which it is intended are merely a starting point, requiring other sources of data to refine an analysis if, as in this case, the screening-level assessment suggests risk of harm. ER1279 ("When a screening-level exposure assessment indicates that adverse effects are likely, additional confirmatory data may be needed in the decision-making process."). Where the agency must make a more refined, site-specific analysis, the Handbook instructs:

> For site-specific ecological risk assessments, it is important to note that the values for exposure factors presented in this Handbook *may not accurately represent specific local populations*. The species included in the Handbook have broad geographic ranges, and they may exhibit different values for many of the exposure factors in different portions of their range. Some species exhibit geographic variation in body size, survival, and reproduction. Breeding and migration also influence exposure. *Site-specific values for these parameters can be determined more accurately using published studies of local populations and assistance from the U.S. Fish and Wildlife Service*….

ER1280-1281 (emphases added).

EPA, of course, never sought any such expert assistance, as it is legally required to do. Instead, relying on this patently inappropriate source of critical data and its own guesses in contravention of the ESA, EPA concluded that because the total load of 2,4-D it estimated a crane would consume was less than its own level of concern—the toxicity level EPA, not FWS, considered acceptable—the registration would have "no effect" on any whooping cranes. ER925-26. EPA gave FWS no opportunity to provide guidance or input, let alone disagree. Yet EPA's "level of concern" about an effect is not the ESA threshold for consultation—*any possible effect is*. EPA improperly transposed its FIFRA standard into its ESA duties and in so doing violated the statute's mandates.

For its amended registration, which EPA admitted will cause 2,4-D spraying on fields in additional states where whooping cranes feed, ER605, EPA repeatedly claimed it relied on a risk assessment bearing the internal identifier DP Barcode 411614. ER603, ER611, ER614. Nothing in that cited document, ER1020-1021, bears any relation to assessing effects of Enlist Duo on animals. But whatever document it relied on, EPA falsely claimed its "effects determination relied on effects endpoints and ingestion rates specifically tailored to the whooping crane…." ER611. As discussed above, *see supra* at pp. 44-48, EPA did *not* rely on data "specifically tailored to the whooping crane" (other than perhaps the crane's body weight), but instead relied on a manual that contains no information

about that or any other crane, and which was not to be used for refined, species-specific assessments or endangered species.

2. Indiana Bat (*Myotis sodalis*)

EPA went even further in its effort to evade consultation on the endangered Indiana bat, protected since 1967. ER1253. 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. *Id.* Their population has continued to decline despite conservation and recovery efforts; as of 2009, less than half of those that existed when the species was listed as endangered remained.[20] FWS's Indiana bat recovery team specifically identified pesticide contamination of the bats' food supply as a reason for their continued decline. ER1254 *et seq*.

EPA's species-specific assessment revealed that 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

[20] FWS, *Endangered Species: Indiana Bat (Myotis sodalis)*, http://www.fws.gov/Midwest/Endangered/mammals/inba/index.html (last updated Nov. 20, 2014).

> lines of evidence found in the screening level risk assessment screening level risk methods.

ER927 (emphases added).

Once 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 v. Thomas*, 30 F.3d at 1054 n.8, or entering formal consultation so that FWS could determine whether the registration is likely to jeopardize the species' continued existence, EPA unlawfully arrogated all determinations to itself. It first declared the assumptions that underlay its prior analysis "conservative," and then "explored 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." ER927.

Without the necessary expertise in wildlife biology, EPA guessed at how often the bats were likely to visit sprayed fields, how much of their diet would likely come from those fields, and how much 2,4-D residue their prey likely would carry, all without a word to or from FWS. ER930. EPA's "modeling" predicted the bats would be exposed to 2,4-D at levels laboratory tests showed "produced reduced pregnancies, and skeletal malformations and well as a reduction in the survival of pups." ER931. 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.*

Yet, after finding, once again, that the registration "may affect" the endangered bats, EPA unlawfully failed to turn to FWS to help resolve the "uncertainty," but instead continued its quest for a unilateral "no effect" finding.[21] EPA delved deeper into studies performed on *rats*, a distantly-related taxonomic group, to try to determine the "toxicologically significant" dose of 2,4-D on the Indiana bat. As bat experts have pointed out, 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. ER1541-42 ("There are important

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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 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.)

differences between rat and bats, and bats may be harmed at lower levels of a contaminant like 2,4-D than rats, so relying on rat data is inappropriate. … Lab rats are much bigger (body mass) than Indiana bats and do not share the same physiology or locomotion, so conclusions drawn from any of these studies are speculation at best."); ER1554 ("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.").

Yet EPA again relied for key assumptions about the Indiana bat's physiology and metabolism on its Handbook—which contains no data about the Indiana bat or any other bat species, and was not intended for this purpose. *See* ER927, ER933 (citing "EPA 1993").

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 (and on which EPA had previously relied, AR471), 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 only found support in unpublished studies performed by the applicant, Intervenor Dow. ER931-32. On this basis, EPA substituted a toxicity threshold (55 mg/kg/day) for the significantly lower levels EPA had previously used in both its screening assessment and its

previous full-scale assessments, *see*, *e.g.*, AR471—levels that EPA and other agencies had concluded would likely cause harm to small insect-eating mammals such as bats.[22] ER932.

EPA then fudged more estimates 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. ER928-33. 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 rejected the data FWS provided in the Indiana Bat Recovery Plan, AR445—a standard source of "best available and current information" for species-specific assessments per EPA's policy, ER1262—and assumed the bats use such habitat *only half as often*, and therefore that 2,4-D-tainted prey would comprise only half as much of their diet—all of this without any input from FWS. ER933. Applying these and other assumptions, EPA concluded Indiana bats would be unlikely to consume enough 2,4-D to "meet

[22] *See* Forest Serv., USDA, 2,4-D *Human Health and Ecological Risk Assessment Final Report* (September 30, 2006) *xxi*, 3-15, 4-36 ("*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), AR471), *available at* http://www.fs.fed.us/foresthealth/pesticide/pdfs/093006_24d.pdf

or exceed levels of toxicological concern for reproduction and development." ER934.[23]

Once again, in addition to EPA's inappropriate data sources and manipulations, exceeding EPA's "level of toxicological concern" is simply not the ESA standard for triggering consultation. In ESA terms, the determinations EPA made here—that an exposure will not "meet or exceed levels of toxicological concern for reproduction and development"—is a determination that 2,4-D is "not likely to adversely affect" Indiana bats, not a proper "no effect" finding. EPA's fundamental error is that a "not likely to adversely affect" finding is FWS's prerogative alone to make, and FWS must concur with it in writing for EPA to avoid formal consultation. 50 C.F.R. § 402.14(a), (b). In taking all of these actions, EPA ignored the ESA's mandate to stop and consult the expert agencies.

3. EPA's Errors Affect a Wide Range of Imperiled Species.

EPA's failure to consult FWS to insure it does not jeopardize the whooping crane and Indiana bat are merely illustrative; EPA's ESA violations but are by no means limited to those endangered species. As mentioned, EPA's improper and unfounded assumptions affect all of the 186 listed species EPA admitted will be

[23] For its amended registration determination that Enlist Duo's use in the additional nine states will have "no effect" on the endangered Indiana bat, EPA used the calculations from its previous assessment. *See* ER607-08.

found in areas near Enlist Duo-sprayed fields, and most obviously, those found within the fields themselves. Just one other example is the Mississippi sandhill crane (*Grus canadensis pulla*).

EPA also admits that Mississippi sandhill cranes (another animal not found in the Handbook) are "reasonably expected to occur on treated soybean and corn fields." ER611. They are "well known to feed on farms," on "adult and larval insects, earthworms, crayfish, small reptiles, amphibians, roots, tubers, seeds, nuts, fruits and leaves," *id*., all of which may be sprayed with 2,4-D. Yet EPA concluded its amended registration would have "no effect" because—according to its own guesstimates of the cranes' metabolic rate, how much the cranes will eat, how much 2,4-D will be in the food they consume, and how much 2,4-D must be consumed to exceed EPA's own "level of concern"—the amount of toxic chemical the endangered cranes will eat will not exceed EPA's FIFRA-based "level of concern." ER611-12. This is not a legally permissible "no effect" determination, but an unlawful, unilateral "not likely to adversely affect" determination lacking FWS's required written concurrence. 50 C.F.R. § 402.14(b); *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

## IV. EPA UNLAWFULLY FAILED TO CONSULT THE EXPERT AGENCIES CONCERNING EFFECTS TO DESIGNATED CRITICAL HABITAT

As mentioned above, ESA § 7(a)(2) also requires that action agencies "insure" their actions will not destroy or adversely modify any habitat designated as "critical" pursuant to ESA § 4(a)(3)(A). The legal standard for triggering EPA's duty to consult where its registration "may affect" a listed species' designated critical habitat is identical to the requirement to consult where the action "may affect" the species itself. *Karuk Tribe,* 681 F.3d at 1027 ("[A]ctions that have *any chance of affecting* listed species *or critical habitat*—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA.") (emphases added); *id*. ("*Any possible effect*, whether beneficial, benign, adverse or of an undetermined character" triggers the requirement) (citations omitted).

In *Karuk Tribe*, the plaintiff challenged the U.S. Forest Service's failure to consult when issuing notices of intent to conduct mining activities in threatened coho salmon critical habitat within national forest. This Court sitting *en banc* reversed and entered judgment for the plaintiff. Intervenor mining interests had 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. The Court pointed out that whether an

action harms a species is distinct from whether the authorizing agency has a procedural duty to consult the expert agencies, and that "[i]t is not the responsibility of the plaintiffs to prove, nor the function of the courts to judge, the effect of a proposed action on an endangered species when proper procedures have not been followed." *Id.* (quoting *Thomas v. Peterson*, 753 F.2d 754, 765 (9th Cir.1985)).

Second, the miners argued that mitigation measures the Forest Service imposed "assured" that there would be "no impact whatsoever on listed species." *Id.* The Court observed that the argument "cuts against, rather than in favor of" no duty to consult, since the perceived need to reduce possible effects underscored that effects were possible, compelling consultation. *Id*. Finally, the Court noted that only mining activities that "might cause" disturbance of surface resources require a notice of intent, virtually assuring consultation was required. *Id*. at 1027, 1029.

The EPA's cursory dismissal here of its duty to consult concerning critical habitat fell far short of the ESA's requirements. Having overlooked the issue entirely in its original registration, ER442, EPA prepared a belated assessment purporting to assess possible effects to critical habitat caused by both the original and amended registrations. In it, EPA noted that critical habitat has been designated for 59 of the 186 listed species found in the combined states where EPA

authorized use of Enlist Duo. ER443. EPA then categorically eliminated any possibility that 52 of these 59 critical habitats triggered consultation with the following blanket assumption:

> Fifty-two species with critical habitat were judged to not use corn or soybean fields and so the critical habitat determination for these was no modification.

ER443.

This "assessment" is a legal *non sequitur*. First, as discussed *supra* at pp.34-38, EPA's assumption that if the impacts of off-site transport of Enlist Duo will not be "high enough to cause acute or chronic effects," ER61, this proves the pesticide will have "no effect," is legally unfounded, as it applies the wrong standard. But even if it were true, EPA's analysis is still flawed. These corn and soybean fields are within designated critical habitats, or there would be no reason for EPA to mention them in this assessment. Whether the endangered species are known to physically use the fields that are part of their critical habitats has little to do with whether spraying toxic chemicals on those fields "may affect" the habitat, triggering consultation.

Critical habitat is designated to preserve specific features known as "primary constituent elements" ("PCEs"). PCEs are the "physical or biological features" that are "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). An area may be designated because it provides shelter, or prey, or many other features. If an action impairs any PCE, this "may affect" the critical habitat, triggering consultation. *See* ER443 (acknowledging need to address PCEs); *see Consultation Handbook* at 4-24 (assessing effects of an action should consider "primary constituent elements of the critical habitat, including direct and indirect effects.").

The species' physical presence in a particular section of critical habitat is incidental; the value of the habitat to the species may be impaired if one or more PCE in any part of the designated habitat is affected. For example, if habitat has been designated in part because it contains the species' prey, any reduction in that prey, or even in the prey's prey or the vegetation cover it uses in the agricultural fields may reduce the prey's availability elsewhere in the habitat, and affect the habitat's overall ability to support the endangered species' survival and recovery, regardless of whether the listed species seeks that prey within the fields themselves. Whether EPA's registration will *adversely affect* any of the dozens of critical habitats is not before the Court; that determination requires FWS's written concurrence after informal consultation, in which EPA never engaged. 50 C.F.R. § 402.14(b)(1). EPA did not even meaningfully consider whether spraying the fields "may affect" the habitats, and its unfounded, summary "no effect" findings for all 52 critical habitats were contrary to law.

Eschewing consultation, EPA went on to summarily dismiss any possibility that spraying the fields with a toxic chemical "may affect" the critical habitats for species known to use the fields themselves, declaring that "the PCE's are not relatable to agricultural fields." ER443. While EPA at least mentions PCEs here, it offers no supporting analysis or explanation for its declaration that none will be affected. The PCEs for some of these species' critical habitats are quite varied and extensive, such as those for the Louisiana black bear, ER448-449. A blanket assertion without any meaningful record support does not comply with EPA's duty to "insure" against adverse modification of critical habitat in consultation with FWS. 16 U.S.C. § 1536(a)(2).

## V. CONCLUSION

The bottom line is that EPA applied an unlawful approach to determining whether registration of Enlist Duo "may affect" listed species or critical habitat. It substituted a FIFRA-based standard under which EPA made unilateral *de facto* "not likely to adversely affect" determinations, which require FWS's written concurrence after consultation, in the guise of "no effect" findings.

As discussed, EPA's critical habitat "assessment" is utterly ungrounded in record support, rational explanation, or apparent understanding of the ESA's requirements. EPA's "no effect" determinations regarding the endangered species themselves were based on studies exposing animals to 2,4-D, noting the point at

which harm was observed, calculating an internally-generated "level of concern," and then rejiggering all of the inputs, over and over, until it could satisfy itself that the level of concern would not likely be exceeded. But "level of concern" is a "policy" tool EPA uses in *FIFRA* determinations, to "analyze potential risk to non-target organisms and the need to consider regulatory action." ER1263. EPA here decided that endangered animals consuming toxic chemicals at doses below its unilaterally-determined "level of concern" equated to "no effect" under the ESA, but EPA has no authority to make policy regarding ESA compliance. Nor do the agency's interpretations of ESA standards and compliance get any deference. *See Karuk Tribe*, 681 F.3d at 1017 ("an agency's interpretation of a statute outside its administration is reviewed *de novo*.") Under the ESA, neither EPA nor any other action agency may unilaterally decide that its action may proceed because it is not likely to *adversely affect* a listed plant or animal or its critical habitat; this requires FWS's written concurrence. *Pac. Rivers Council v. Thomas*, 30 F.3d at 1054 n.8.

EPA has a history of trying to apply its FIFRA approach to ESA determinations, underestimating pesticide effects on endangered species, and seeking to avoid consultation. In 2004, FWS, NMFS, and EPA promulgated counterpart regulations obviating the need for FWS's concurrence in EPA's "not likely to adversely affect" determinations in pesticide registrations.

Notwithstanding FWS's and NMFS's cooperation in this effort, the court rejected it as inconsistent with the ESA's explicit consultation requirement. *Wash. Toxics Coal.*, 457 F. Supp. 2d at 1179-80. EPA has attempted to accomplish exactly the same result the *Washington Toxics* court rejected, by improperly characterizing an exposure it considers "not likely to adversely affect" the species or habitat as "no effect," to obviate the need for ESA consultation. Because the threshold for "may affect" is so low, neither this Court nor, to CFS Petitioners' knowledge, any other court has ever upheld an action agency's "no effect" determination where, as here, endangered species will even be found in the action area. Not only is it undisputed that whooping cranes, Indiana bats, Louisiana black bears, Mississippi sandhill cranes, and other ESA-protected species will be found in the action area even as EPA narrowly redefined it to include only the sprayed fields themselves, but it also is undisputed that the action will cause these endangered animals to consume a toxic chemical.

ESA § 7(a)(2)'s consultation requirement applies to "[e]ach federal agency." As an action agency under this law, EPA enjoys no special status. Congress did not intend that every (or any) federal agency develop its own consultation standard, based on its own "level of concern," decide for itself whether its action's effects are "of concern," and consult the expert agencies only if it decides they are. Rather, consultation is required where there is "[a]ny possible effect, whether

beneficial, benign, adverse, or of an undetermined character…." *Karuk Tribe*, 681 F.3d at 1027.

## RELIEF REQUESTED

The Court should vacate EPA's registrations of Enlist Duo and order EPA to conduct a new FIFRA process that properly analyzes and weighs the impacts on non-target organisms in and around Enlist crop fields.

EPA's failure to consult FWS or NMFS with respect to its registration decisions' effects on species listed as threatened or endangered, or their critical habitats, violates ESA's Section 7 and its decisions must be vacated for that reason as well. In conjunction with the new FIFRA process, the Court should order EPA to consult with the expert wildlife agencies under ESA Section 7 on the potential effects of its action on protected species and their habitat.

Respectfully submitted this 23rd day of October, 2015.

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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 13,743 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: October 23, 2015.

/s/ Paul H. Achitoff
Paul H. Achitoff

# STATUTORY AND REGULATORY ADDENDUM

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United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
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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 (3572)

5 U.S.C.A. § 706, 5 USCA § 706

Current through P.L. 114-51 approved 9-24-2015

End of Document

United States Code Annotated
Title 7. Agriculture
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) of this section, 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 [16 U.S.C.A. § 1531 et seq.].

(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) of this section; 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) of this section), 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 Oct. 21, 1972, Pub.L. 92-516, § 2, 86 Stat. 975; amended Dec. 28, 1973, Pub.L. 93-205, § 13(f), 87 Stat. 903; Nov. 28, 1975, Pub.L. 94-140, § 9, 89 Stat. 754; Sept. 30, 1978, Pub.L. 95-396, § 1, 92 Stat. 819; Oct. 25, 1988, Pub.L. 100-532, Title I, § 101, Title VI, § 601(a), Title VIII, § 801(a), 102 Stat. 2655, 2677, 2679; Dec. 13, 1991, Pub.L. 102-237, Title X, § 1006(a)(1), (2), (b)(3)(A), (B), 105 Stat. 1894, 1895; Aug. 3, 1996, Pub.L. 104-170, Title I, §§ 105(a), 120, Title II, §§ 210(a), 221, 230, Title III, § 304, 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. 114-51 approved 9-24-2015

**End of Document**

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 7. Agriculture
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) of this section--

**(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) of this section 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) of this section 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) of this section.

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

Notes of Decisions (92)

7 U.S.C.A. § 136a, 7 USCA § 136a
Current through P.L. 114-51 approved 9-24-2015

**End of Document**

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

Notes of Decisions (65)

7 U.S.C.A. § 136n, 7 USCA § 136n
Current through P.L. 114-51 approved 9-24-2015

**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. § 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 (67)

16 U.S.C.A. § 1532, 16 USCA § 1532
Current through P.L. 114-51 approved 9-24-2015

**End of Document**

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted **Limitation 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 Treatment Proposed 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 (334)

Footnotes

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

16 U.S.C.A. § 1533, 16 USCA § 1533

Current through P.L. 114-51 approved 9-24-2015

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 (630)

16 U.S.C.A. § 1536, 16 USCA § 1536
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**End of Document**

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted **Limitation 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 Treatment Proposed Legislation

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

16 U.S.C.A. § 1538

# § 1538. Prohibited acts

Currentness

(a) Generally

**(1)** Except as provided in sections 1535(g)(2) and 1539 of this title, with respect to any endangered species of fish or wildlife listed pursuant to section 1533 of this title it is unlawful for any person subject to the jurisdiction of the United States to--

**(A)** import any such species into, or export any such species from the United States;

**(B)** take any such species within the United States or the territorial sea of the United States;

**(C)** take any such species upon the high seas;

**(D)** possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such species taken in violation of subparagraphs (B) and (C);

**(E)** deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, any such species;

**(F)** sell or offer for sale in interstate or foreign commerce any such species; or

**(G)** violate any regulation pertaining to such species or to any threatened species of fish or wildlife listed pursuant to section 1533 of this title and promulgated by the Secretary pursuant to authority provided by this chapter.

**(2)** Except as provided in sections 1535(g)(2) and 1539 of this title, with respect to any endangered species of plants listed pursuant to section 1533 of this title, it is unlawful for any person subject to the jurisdiction of the United States to--

**(A)** import any such species into, or export any such species from, the United States;

**(B)** remove and reduce to possession any such species from areas under Federal jurisdiction; maliciously damage or destroy any such species on any such area; or remove, cut, dig up, or damage or destroy any such species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law;

**(C)** deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, any such species;

**(D)** sell or offer for sale in interstate or foreign commerce any such species; or

**(E)** violate any regulation pertaining to such species or to any threatened species of plants listed pursuant to section 1533 of this title and promulgated by the Secretary pursuant to authority provided by this chapter.

(b) Species held in captivity or controlled environment

**(1)** The provisions of subsections (a)(1)(A) and (a)(1)(G) of this section shall not apply to any fish or wildlife which was held in captivity or in a controlled environment on (A) December 28, 1973, or (B) the date of the publication in the Federal Register of a final regulation adding such fish or wildlife species to any list published pursuant to subsection (c) of section 1533 of this title: *Provided*, That such holding and any subsequent holding or use of the fish or wildlife was not in the course of a commercial activity. With respect to any act prohibited by subsections (a)(1)(A) and (a)(1)(G) of this section which occurs after a period of 180 days from (i) December 28, 1973, or (ii) the date of publication in the Federal Register of a final regulation adding such fish or wildlife species to any list published pursuant to subsection (c) of section 1533 of this title, there shall be a rebuttable presumption that the fish or wildlife involved in such act is not entitled to the exemption contained in this subsection.

**(2)(A)** The provisions of subsection (a) (1) of this section shall not apply to--

**(i)** any raptor legally held in captivity or in a controlled environment on November 10, 1978; or

**(ii)** any progeny of any raptor described in clause (i);

until such time as any such raptor or progeny is intentionally returned to a wild state.

**(B)** Any person holding any raptor or progeny described in subparagraph (A) must be able to demonstrate that the raptor or progeny does, in fact, qualify under the provisions of this paragraph, and shall maintain and submit to the Secretary, on request, such inventories, documentation, and records as the Secretary may by regulation require as being reasonably appropriate to carry out the purposes of this paragraph. Such requirements shall not unnecessarily duplicate the requirements of other rules and regulations promulgated by the Secretary.

(c) Violation of Convention

**(1)** It is unlawful for any person subject to the jurisdiction of the United States to engage in any trade in any specimens contrary to the provisions of the Convention, or to possess any specimens traded contrary to the provisions of the Convention, including the definitions of terms in article I thereof.

**(2)** Any importation into the United States of fish or wildlife shall, if--

**(A)** such fish or wildlife is not an endangered species listed pursuant to section 1533 of this title but is listed in Appendix II to the Convention,

**(B)** the taking and exportation of such fish or wildlife is not contrary to the provisions of the Convention and all other applicable requirements of the Convention have been satisfied,

**(C)** the applicable requirements of subsections (d), (e), and (f) of this section have been satisfied, and

**(D)** such importation is not made in the course of a commercial activity,

be presumed to be an importation not in violation of any provision of this chapter or any regulation issued pursuant to this chapter.

(d) Imports and exports

(1) In general

It is unlawful for any person, without first having obtained permission from the Secretary, to engage in business--

**(A)** as an importer or exporter of fish or wildlife (other than shellfish and fishery products which (i) are not listed pursuant to section 1533 of this title as endangered species or threatened species, and (ii) are imported for purposes of human or animal consumption or taken in waters under the jurisdiction of the United States or on the high seas for recreational purposes) or plants; or

**(B)** as an importer or exporter of any amount of raw or worked African elephant ivory.

(2) Requirements

Any person required to obtain permission under paragraph (1) of this subsection shall--

**(A)** keep such records as will fully and correctly disclose each importation or exportation of fish, wildlife, plants, or African elephant ivory made by him and the subsequent disposition made by him with respect to such fish, wildlife, plants, or ivory;

**(B)** at all reasonable times upon notice by a duly authorized representative of the Secretary, afford such representative access to his place of business, an opportunity to examine his inventory of imported fish, wildlife, plants, or African elephant ivory and the records required to be kept under subparagraph (A) of this paragraph, and to copy such records; and

**(C)** file such reports as the Secretary may require.

(3) Regulations

The Secretary shall prescribe such regulations as are necessary and appropriate to carry out the purposes of this subsection.

(4) Restriction on consideration of value or amount of African elephant ivory imported or exported

In granting permission under this subsection for importation or exportation of African elephant ivory, the Secretary shall not vary the requirements for obtaining such permission on the basis of the value or amount of ivory imported or exported under such permission.

(e) Reports

It is unlawful for any person importing or exporting fish or wildlife (other than shellfish and fishery products which (1) are not listed pursuant to section 1533 of this title as endangered or threatened species, and (2) are imported for purposes of human or animal consumption or taken in waters under the jurisdiction of the United States or on the high seas for recreational purposes) or plants to fail to file any declaration or report as the Secretary deems necessary to facilitate enforcement of this chapter or to meet the obligations of the Convention.

(f) Designation of ports

**(1)** It is unlawful for any person subject to the jurisdiction of the United States to import into or export from the United States any fish or wildlife (other than shellfish and fishery products which (A) are not listed pursuant to section 1533 of this title as endangered species or threatened species, and (B) are imported for purposes of human or animal consumption or taken in waters under the jurisdiction of the United States or on the high seas for recreational purposes) or plants, except at a port or ports designated by the Secretary of the Interior. For the purpose of facilitating enforcement of this chapter and reducing the costs thereof, the Secretary of the Interior, with approval of the Secretary of the Treasury and after notice and opportunity for public hearing, may, by regulation, designate ports and change such designations. The Secretary of the Interior, under such terms and conditions as he may prescribe, may permit the importation or exportation at nondesignated ports in the interest of the health or safety of the fish or wildlife or plants, or for other reasons if, in his discretion, he deems it appropriate and consistent with the purpose of this subsection.

**(2)** Any port designated by the Secretary of the Interior under the authority of section 668cc-4(d) of this title, shall, if such designation is in effect on December 27, 1973, be deemed to be a port designated by the Secretary under paragraph (1) of this subsection until such time as the Secretary otherwise provides.

(g) Violations

It is unlawful for any person subject to the jurisdiction of the United States to attempt to commit, solicit another to commit, or cause to be committed, any offense defined in this section.

**CREDIT(S)**

(Pub.L. 93-205, § 9, Dec. 28, 1973, 87 Stat. 893; Pub.L. 95-632, § 4, Nov. 10, 1978, 92 Stat. 3760; Pub.L. 97-304, § 9(b), Oct. 13, 1982, 96 Stat. 1426; Pub.L. 100-478, Title I, § 1006, Title II, § 2301, Oct. 7, 1988, 102 Stat. 2308, 2321; Pub.L. 100-653, Title IX, § 905, Nov. 14, 1988, 102 Stat. 3835.)

Notes of Decisions (158)

16 U.S.C.A. § 1538, 16 USCA § 1538
Current through P.L. 114-51 approved 9-24-2015

**End of Document**

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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 Oct. 15, 2015; 80 FR 62427.

**End of Document**

50 C.F.R. § 402.02

§ 402.02 Definitions.

Effective: June 10, 2015
Currentness

<For statute(s) affecting validity, see: 5 U.S.C.A. § 551 et seq.; 16 U.S.C.A. §§ 1531(b), 1533(a)(3)(A), 1536, 1538, 1539.>

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 both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.

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]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (219)

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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 (15)

Current through Oct. 15, 2015; 80 FR 62427.

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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 (183)

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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: May 31, 2012
Currentness

(a) Critical habitat shall be specified to the maximum extent prudent and determinable at the time a species is proposed for listing. If designation of critical habitat is not prudent or if critical habitat is not determinable, the reasons for not designating critical habitat will be stated in the publication of proposed and final rules listing a species. A final designation of critical habitat shall be made on the basis of the best scientific data available, after taking into consideration the probable economic and other impacts of making such a designation in accordance with § 424.19.

(1) A designation of critical habitat is not prudent when one or both 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.

(2) Critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

(b) In determining what areas are critical habitat, the Secretary shall consider those physical and biological features that are essential to the conservation of a given species and that may require special management considerations or protection. Such requirements include, but are not limited to the following:

(1) Space for individual and population growth, and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and generally;

(5) Habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

When considering the designation of critical habitat, the Secretary shall focus on the principal biological or physical constituent elements within the defined area that are essential to the conservation of the species. Known primary constituent elements shall be listed with the critical habitat description. Primary constituent elements may include, but are not limited to, the following: roost sites, nesting grounds, spawning sites, feeding sites, seasonal wetland or dryland, water quality or quantity, host species or plant pollinator, geological formation, vegetation type, tide, and specific soil types.

(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, an inclusive area may be designated as critical habitat.

Example: Several dozen or more small ponds, lakes, and springs are found in a small local area. The entire area could be designated critical habitat if it were concluded that the upland areas were essential to the conservation of an aquatic species located in the ponds and lakes.

(e) The Secretary shall designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species.

(f) Critical habitat may be designated for those species listed as threatened or endangered but for which no critical habitat has been previously designated.

(g) Existing critical habitat may be revised according to procedures in this section as new data become available to the Secretary.

(h) Critical habitat shall not be designated within foreign countries or in other areas outside of United States jurisdiction.

**Credits**

[45 FR 13022, Feb. 27, 1980; 45 FR 64195, Sept. 29, 1980; 77 FR 25622, May 1, 2012]

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.

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| NATURAL RESOURCES DEFENSE COUNSEL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |

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| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71207 |
| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71213 |

**DECLARATION OF LORI ANN BURD IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S OPENING BRIEF**

I, Lori Ann Burd, 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 Director of the Environmental Health Program for the Center for Biological Diversity.

2. The Center for Biological Diversity is a tax-exempt, nonprofit membership organization with offices in Tucson, Arizona; Flagstaff, Arizona; Anchorage, Alaska; Oakland, California; Los Angeles, California; Joshua Tree, California; Petaluma, California; St Petersburg, Florida; Honolulu, Hawaii; La Paz, Mexico; Minneapolis, Minnesota; Duluth, Minnesota; Pomona, New York; Portland, Oregon; Richmond, Vermont; and Washington, D.C.

3. The Center for Biological Diversity (the Center) represents more than 900,000 members throughout the country including members in California, Oregon, Washington, Idaho, Montana, Nevada, Alaska, and Arizona.

4. The Center for Biological Diversity (formerly the Southwest Center for Biological Diversity) was founded in 1989 to fight the growing number of national and worldwide threats to biodiversity. Our mission is to secure a future for all species, great and small, hovering on the brink of extinction. We believe that the welfare of human beings is deeply linked to nature—to the existence in our world of a vast diversity of wild animals and plants.

5. To achieve its mission, the Center for Biological Diversity uses biological data, legal expertise, and citizen petitions to obtain sweeping, legally binding protections for animals, plants, and their habitat. As a result of groundbreaking petitions, lawsuits, policy advocacy and outreach to media, hundreds of species have gained protection. The Center for Biological Diversity has a full-time staff of environmental lawyers and scientists who work exclusively on campaigns to save species and their habitat.

6. 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.

7. We frequently pursue public interest litigation to protect threatened and endangered species from numerous harms, such as pesticide use. For example, the Center for Biological Diverity is a named plaintiff and serves as counsel in *Center for Biological Diversity v. U.S. Environmental Protection Agency*, No. 15-1054 (D.C. Cir. filed Apr. 13, 2015), a case challenging EPA's decision to register the insecticide flupyradifurone without consulting with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) to ensure that the pesticide would not jeopardize any listed species or destroy or adversely

modify critical habitat in violation of the Endangered Species Act. This is just one of many pieces of litigation intended to advance our mission.

8. The Center for Biological Diversity submitted organizational comments to Respondent Environmental Protection Agency (EPA) regarding the impacts posed by EPA's proposed registration of Enlist Duo herbicide, the pesticide product at issue in the present consolidated petitions for review.

9. Members rely on the Center to protect biodiversity and conserve threatened and endangered species and their habitats through legal advocacy, public education and other means. Some members have become very concerned about the effect of conventional agriculture on threatened and endangered species. Enormous quantities of pesticides, such as Enlist Duo, are used to support agriculture operations throughout the country. These pesticides contain chemicals that disrupt endocrine activity in amphibians, and our members are 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.

10. As a party to this proceeding, the Center for Biological Diversity and its members are concerned that new and increased uses of Enlist Duo herbicide on herbicide-tolerant corn and soybean will have detrimental impacts on human

health, the environment, and federally listed sensitive species and their critical habitats.

11. The Center for Biological Diversity and its members are being, and will be, adversely affected by EPA's decision to register Enlist Duo herbicide for new uses. Our members live, work, and recreate in many locations where Enlist Duo is currently being sprayed and will be sprayed. Many of our members are involved with ensuring a healthy environment for threatened and endangered species for recreational, aesthetic, professional, and personal reasons. The Center for Biological Diversity's members' interests are injured by the use of Enlist Duo and its harm to federally endangered and threatened species, including Hine's emerald dragonfly, Mitchell's satyr butterfly, the Indiana bat, and their habitats.

12. Many of the Center's members live near areas where excessive amounts of pesticides are being applied to herbicide resistant crops. These members are especially susceptible to the environmental and health risks associated with the application of particular pesticides and the potential for the pesticides to drift. Moreover, intensive pesticide use compromises our members' enjoyment of their local environment because it poses risks to wildlife and injures the aesthetic and recreational interests of those who seek to maintain biodiversity.

13. In sum, the Center for Biological Diversity's organizational interests and the aesthetic, recreational, economic, professional and personal interests of our

members are injured by EPA's decision to register Enlist Duo herbicide for use on Enlist corn and soybean.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 22, 2015 in Portland, Oregon.

Lori Ann Burd
Director, Environmental Health Program
Center for Biological Diversity

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |
| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73359 |

**DECLARATION OF JOHN BUSE IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S MOTION FOR STAY PENDING REVIEW**

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 Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity (collectively CFS or Petitioners)'s motion for stay pending review of Respondent U.S. Environmental Protection Agency (EPA)'s decision to register the pesticide Enlist Duo.

2. I am a recent resident of Indianapolis, Indiana. Between February 2005 and September 2011, I resided in Chicago, Illinois.

3. The state of Indiana is one of the largest producers of both corn and soybean, and the majority of agricultural land in and around Marion County where I live is used for corn and soybean production. Enlist Duo has been approved for use on Enlist corn and soybeans in Indiana and Illinois, as well as other states.

4. I am a Senior Attorney and the Legal Director for the Center for Biological Diversity (the "Center"). I am also a member of the Center, and have been a member continuously since 2005.

5. 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.

6. 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.

7. 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.

8. 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 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.

**Hine's emerald dragonfly**

9. 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.

10. 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.

11. 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 or July 2015 to look for Hine's emerald dragonflies in their known habitat.

12. 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.

**Mitchell's satyr butterfly**

13. I am a frequent visitor to Michigan's Lake Michigan shore. In particular, I frequently visit, stay near, and recreate near Van Buren State Park in Van Buren County, Michigan. I hike, boat, swim, and observe wildlife during my visits to this area.

14. When I visit an area, I am interested to find what rare wildlife, fish, and plants are endemic to the area. I enjoy looking for these species in their natural habitats. In reviewing the U.S. Fish and Wildlife Service's website, I found that the Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*), a

federally-listed endangered species, is native to Van Buren County, Michigan.

15. I appreciate the Mitchell's satyr butterfly and its continued existence in the wild for its role as a native pollinator, for its beauty, and for its status as an indicator species for the health of the fens, bogs, and other wetlands. I also believe that all species, including the Mitchell's satyr butterfly, have inherent value, and I have an interest in maintaining the diversity of life.

16. I have hiked and recreated near this species' habitat on numerous occasions while attempting to observe wildlife. To my knowledge, I have not seen a Mitchell's satyr butterfly during my visits to Michigan, but I intend to return to Van Buren County, Michigan during July of 2015 and beyond to look for Mitchell's satyr butterflies.

17. In addition, the Mitchell's satyr butterfly is native to Lagrange and La Porte counties in northern Indiana, where Enlist Duo has been registered for use. Use of Enlist Duo in northern Indiana may impact recovery of Mitchell's satyr butterflies in Indiana and harm the viability of the species as whole, which would diminish my chances of seeing the butterfly during my next trip to Michigan.

18. I hope to see a Mitchell's satyr butterfly in the wild, but even if I fail to observe the species, I am happy knowing that the species persists in the wild. I would be happier if the species can recover, and I look forward to the recovery of the Mitchell's satyr butterfly throughout its native range. I am concerned that

Enlist Duo will be applied in and around Mitchell's satyr butterfly 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 Mitchell's satyr butterflies are being inadvertently killed and harmed by agricultural chemicals. If the remaining populations of Mitchell's satyr butterflies in Michigan were extirpated or reduced, my appreciation of the area's unique natural environment would be diminished.

**Indiana bat**

19. I enjoy looking for rare native wildlife, fish, and plants in their natural habitats in and around where I live.

20. 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.

21. 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.

22. 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.

23. 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.

24. In summary, I have professional, aesthetic, and recreational interests in the preservation of the Hine's emerald dragonfly, Mitchell's satyr butterfly, Indiana bat, 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 January 30, 2015 at Indianapolis, Indiana.

/s/ John Buse
John Buse

**I, George A. Kimbrell, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/s/) within this e-filed document.**

DATED: February 6, 2015, in San Francisco, CA.

/s/ George A. Kimbrell
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*Attorney for Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity*

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71213 |

**DECLARATION OF THOMAS CLUDERAY IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S OPENING BRIEF**

I, Thomas Cluderay, 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 General Counsel of the Environmental Working Group (EWG).

2. EWG is a non-profit, non-partisan organization dedicated to protecting human health and the environment. EWG has offices in Oakland, California; Sacramento, California; Los Angeles, California; Ames, Iowa; and Washington, D.C.

3. EWG represents more than 1.27 million consumers throughout the country including more than 281,524 in California, Oregon, Washington, Idaho, Montana, Nevada, Alaska, and Arizona.

4. EWG was founded more than two decades ago to answer questions regarding human health and the environment, such as what pesticides are on your food. EWG's mission is to empower people to live healthier lives in a healthier environment. EWG's work focuses on six major program areas: toxics, food, agriculture, children's health, energy, and water. Informing consumers of the health impacts of pesticides is essential to EWG's toxics, food, agriculture, and children's health programs. By using breakthrough research and education, EWG drives consumer choice and civic action.

5. To achieve its mission, EWG's team of scientists, policy experts, lawyers, communication experts, and programmers work tirelessly to stand up for public health when government or industry fails to do so. Through reports, online databases, mobile apps and communications campaigns, EWG is educating and empowering consumers to make safer and more informed decisions about the products they buy and the companies they support. In response to consumer pressure, companies give up potentially dangerous chemical ingredients in their products and improve their practices.

6. In 2014, EWG combined forces with Healthy Child Healthy World to empower parents to protect their children against harmful chemicals, including pesticides like Enlist Duo. EWG—through its Healthy Child Healthy World program—inspires parents, promotes solutions, and influences policy to create a cleaner, greener, healthier world.

7. EWG's reports educate and inform consumers on a variety of issues, including increased pesticide use. While the proposed registration of Enlist Duo was pending, EWG created an interactive map showing potential exposure to 2,4-D from applications on corn and soybean fields near elementary schools in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin—the six states where Enlist

Duo was initially approved.[1] EWG created a similar interactive map concerning the use of glyphosate on corn and soybean fields near schools.[2] EWG also analyzed, and made publicly available, the organization's analysis of valuable fruits and vegetables that may be damaged by 2,4-D drift.[3] Furthermore, EWG also did a six-state survey of athletic fields and parks in small town America that showed more than ninety percent of these types of recreational areas are within 1,000 feet of a corn or soybean field where the toxic weed killers could be sprayed; fifty-six percent were within 200 feet.

8. Consumers rely on EWG's research and guides to protect themselves from harm to their health and the environment. Consumers are becoming increasingly aware and concerned of the explosion in the use of herbicides such as Enlist Duo. Many parents are becoming aware that schools and recreational areas

[1] EWG, Potential 2,4-D Exposure, https://api.tiles.mapbox.com/v4/ewg.j49ac68j/page.html?access_token=pk.eyJ1IjoiZXdnIiwiYSI6IlYxUUpUTlUifQ.87Ean7pyT-H6eapPSES_pA#5/39.249/-95.889 (last visited Oct. 20, 2015).

[2] M. E. Kustin and S. Rundqulst, EWG, Monsanto's Glyphosate Blankets GMO Crops Near Schools (May 8, 2015), http://www.ewg.org/agmag/2015/05/monsanto-s-glyphosate-blankets-gmo-crops-near-schools (last visited Oct. 20, 2015).

[3] M. E. Kustin and S. Rundqulst, EWG, New GE Crops/Weed Killer Combo Puts Foods At Risk (Oct. 23, 2014), http://www.ewg.org/agmag/2014/10/new-ge-cropsweed-killer-combo-puts-foods-risk (last visited Oct. 20, 2015).

are being regularly doused with escalating amounts of toxic weed killers and are worried about the health impacts to their children.

9. EWG submitted organizational comments to the U.S. Environmental Protection Agency (EPA) regarding the impacts posed by EPA's Proposed Registration of Enlist Duo herbicide, the pesticide product at issue in the present consolidated petitions for review.

10. As a party to this proceeding, EWG is concerned that new and increased uses of Enlist Duo herbicide on herbicide-tolerant corn and soybean will have detrimental impacts on human health, the environment, and threatened and endangered species.

11. EWG and consumers who rely on EWG are being, and will be, adversely affected by EPA's decision to register Enlist Duo herbicide for new uses. Consumers who rely on EWG live, work, and recreate in many locations where Enlist Duo is currently being sprayed and will be sprayed. Additionally, EWG and consumers who rely on EWG are likely to be damaged by drift and vaporization of 2,4-D, one of the two active ingredients in Enlist Duo. 2,4-D has been linked to cancer, decreased sperm count, liver disease, and Parkinson's disease. Thus, EPA's registration of Enlist Duo herbicide will harm EWG and consumers because it is a dangerous herbicide that is prone to drift off target, threatening the health of nearby communities.

12. Consumers who rely on EWG include women and children, who are particularly susceptible to the environmental and health risks associated with the application of particular pesticides. Since Enlist Duo is a dangerous pesticide that is prone to drift off target, EPA's approval of its registration poses an increased risk of adverse human health impacts to vulnerable populations.

13. Many consumers who rely on EWG have children who go to school or play in parks and fields that are within 1,000 feet of corn or soybean fields. The increased use of Enlist Duo will likely expose these consumers and their children to the herbicide. Moreover, parents may limit their children's use of fields near these corn and soybean fields for fear of exposure to Enlist Duo, negatively injuring their aesthetic and recreational interests.

14. In sum, EWG's organizational interests and the aesthetic, recreational, agricultural, and personal health interests of consumers who rely on EWG are injured by EPA's decision to register Enlist Duo herbicide for use on Enlist corn and soybean.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 20, 2015 in Washington, D.C.

Thomas Cluderay
General Counsel, EWG

UNITED STATES COURT OF APPEALS
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**DECLARATION OF MARTHA L. CROUCH, PhD, IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S MOTION FOR STAY PENDING REVIEW**

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 Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity (collectively Petitioners)'s Motion for Stay Pending Review of Respondent U.S. Environmental Protection Agency (EPA)'s decision to register the pesticide Enlist Duo.

1. 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.

2. 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.

3. 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 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.

4. 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*) population often refer to ourselves.

5. 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.

6. I am aware that there are three populations of whooping cranes, two of which migrate, including a self-sustaining western flock that overwinters in Texas, and migrates up through Arkansas, Kansas, South Dakota, and North Dakota to Northern Canada where it summers and raises chicks, before migrating back.

7. 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 flock now summers in Wisconsin and winters in Florida, with the help of a dedicated whooping crane recovery team.

8. The western flock does not migrate where I live, but I have some friends in Rockport, Texas, who live right next to the Aransas National Wildlife Refuge where the western population winters. I purposefully time my visits to my friends so I can see, watch, and observe the whooping cranes while they winter, and have attended the "Whooping Crane Festival" in Port Aransas, Texas and nearby islands. On my last visit five years ago I saw two pairs of whooping cranes in the fields outside of the Aransas National Wildlife Refuge where they winter in Texas.

9. I plan to continue visiting my friends in Texas during the months when the whooping crane is wintering in the nearby wildlife refuge, so I can observe the western population.

10. In addition to my following, observing, and interest in the western flock, I have experience with the eastern flock, 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 those 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, and watch the online-live "crane cam," which I sometimes place in the corner of my computer monitor and follow along as they are migrating. I donate to Operation Migration, the organization that leads some juveniles of the eastern whooping cranes on their first migration with ultralight planes, and will be attending a talk by their staff at the "Marsh Madness" birding event at Goose Pond on March 6, 2015.

11. I am worried about how the registration of Enlist Duo may affect whooping cranes because they frequent agricultural fields. The flyway of the western flock goes right through part of the western Corn Belt, including through South Dakota, where Enlist Duo has been approved for use on Enlist corn and soybeans. The eastern flock migrates through the Corn Belt states of Indiana, Illinois, and Wisconsin where Enlist Duo has been approved for use on Enlist corn and soybeans. Many of the "crane cam" views are of whooping cranes show them foraging in corn and soybean fields in the fall, and I am aware that they also stopover in corn and soybean 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 and soybean fields that have been recently planted and sprayed with herbicides. 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.

12. I am aware that, based on the instructions and guidelines for Enlist Duo use on Enlist corn, it is possible that these corn seedlings, which the whooping cranes are so efficient at accessing, could or will have very high residues of Enlist Duo on them, the exposure to which may have adverse effects on the whooping cranes.

13. I do not believe that the risks of registering Enlist 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 and soybeans 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 this 2nd day of February, 2015 in Bloomington, Indiana.

/s/ Martha L. Crouch
Martha L. Crouch, Ph.D.

**I, George A. Kimbrell, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/s/) within this e-filed document.**

DATED: February 6, 2015, in San Francisco, CA.

/s/ George A. Kimbrell
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*Attorney for Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity*

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |
| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73359 |

**SECOND DECLARATION OF MARTHA L. CROUCH, PhD, IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S MOTION FOR STAY PENDING REVIEW**

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 supplemental declaration in support of Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity (collectively CFS Petitioners)'s Motion for Stay Pending Review of Respondent U.S. Environmental Protection Agency (EPA)'s decision to register the pesticide Enlist Duo, ECF No. 32-1

2. I am a member of Petitioner Center for Food Safety (CFS). I previously submitted a declaration in support of Petitioners' Motion for Stay Pending Review with the filing of Petitioners' Motion , ECF No. 32-1, on February 6, 2015. *See* Crouch Decl., ECF No. 32-3.

3. My prior declaration details my professional background and my interest in the whooping crane (*Grus americana*). I submit this supplemental declaration to further clarify my interest in the western whooping crane population.

1. As I stated in my previous declaration, I time my visits to my friends who reside in Rockport, Texas to coincide with the "Whooping Crane Festival" in Port Aransas, Texas, so that I may see, watch, and observe the western flock of whooping cranes while they winter in Texas. *See* Crouch Decl. ¶ 8, ECF No. 32-3.

2. My friends' residence in Rockport, Texas, is along the Gulf of Mexico that is very near the Aransas National Wildlife Refuge, where the western population of whooping cranes winters. I have made plans to visit my friends and stay at their residence in February 2016, during the time of the Whooping Crane Festival, so that I may observe the western population of whooping cranes there.

3. In addition to making plans to observe the wintering western whooping cranes, as I stated in my prior declaration, I continue to follow and study the western flock by reading news and blogs about the western population. *See* Crouch Decl. ¶ 10, ECF No. 32-3.

4. EPA's registration of Enlist Duo thus injures my aesthetic interests in whooping cranes, including the western flock. As I previously stated, the flyway of the western flock goes right through part of the western Corn Belt, including through South Dakota, where Enlist Duo has been approved for use on Enlist corn and soybeans. *See* Crouch Decl. ¶ 10, ECF No. 32-3.

5. As I stated in my prior declaration, I do not believe that the risks of registering Enlist 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 in Enlist corn and soybean fields which they migrate through and spend considerable time in, and in

which they feed, will be another serious stress that can and will severely harm their recovery. *See* Crouch Decl. ¶¶ 11-13, ECF No. 32-3.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18th day of March, 2015 in Bloomington, Indiana.

Martha L. Crouch, Ph.D.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73359 |
| NATURAL RESOURCES DEFENSE COUNSEL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |

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| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71207 |
| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71213 |

**DECLARATION OF MARCIA ISHII-EITEMAN IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY 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).

2. PANNA is an Oakland, 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, where the U.S. Environmental Protection Agency (EPA) has approved the use of 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 Pesticide Reform Coalition, and many more. We also work closely with food and farming groups in the states where Enlist Duo has been approved for use, including the Iowa Farmers Union and Practical Farmers of Iowa, in order to reduce the negative impacts of pesticide drift.

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 submitted organizational comments to EPA on the agency's initial proposal to register Enlist Duo, the pesticide product at issue in the present

consolidated petitions for review. PANNA also submitted organizational comments on EPA's subsequent decision to amend the registration to expand its use in nine additional states.

7. PANNA and its members are being, and will be, adversely affected by EPA's decision to register Enlist Duo herbicide for new uses. 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 that Dow's Enlist Corn system will contaminate their environment, to the detriment of their personal health and recreational interests.

8. Additionally, members of PANNA include farmers whose crops, and thus their livelihoods, are likely to be damaged by drift and vaporization of 2,4-D, one of the two active ingredients in Enlist Duo. EPA's registration of 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 grapes and tomatoes. 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.

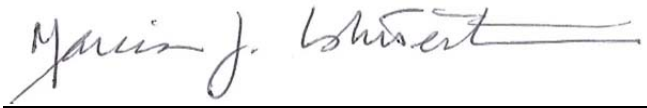
9. PANNA's members are heavily involved with reducing the use of pesticides to protect various species of animals and enhance biodiversity. Biodiversity is essential to a healthy and thriving ecosystem and successful

agriculture. The registration of Enlist Duo will harm threatened and endangered species, which will injure PANNA's members' aesthetic interest in protecting these animals and maintaining biodiversity.

11. EPA's decision to register Enlist Duo for use on Enlist corn and soybean in fifteen 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 October 21st, 2015 in Oakland, California



Marcia Ishii-Eiteman
Senior Scientist, PANNA

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| CENTER FOR FOOD SAFETY, *et al.*,<br>*Petitioners*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,<br>*Respondents*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73359 |
| NATURAL RESOURCES DEFENSE COUNSEL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 15-71213 |

**DECLARATION OF ANDREW KIMBRELL IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S OPENING BRIEF**

I, Andrew 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 Executive Director and Founder of the Center for Food Safety (CFS).

2. CFS is a tax-exempt, nonprofit membership organization with offices in San Francisco, California; Portland, Oregon; Honolulu, Hawai‘i; and Washington, D.C. CFS represents more than 700,000 farmer and consumer members in every state throughout the country, including 157, 000 members in Arizona, Nevada, California, Oregon, Washington, Idaho, Montana, and Alaska.

3. I founded CFS in 1997. Since its inception, I have served as a member of the CFS Board of Directors and helped create its organizational purpose and goals. In creating CFS, I sought to establish a nonprofit organization that protects public health and the environment from the harms of industrial agriculture. Chief among my concerns were pollution from pesticides, water and air contamination from factory farming, and biological and ecosystem contamination from genetically engineered organisms. 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. Principal among these activities are analyses and actions to mitigate the impact of genetically engineered (GE)

agricultural products on public health and the environment, and opposition to the use of toxic chemicals and pesticides in agriculture.

4. It is CFS's mission to ameliorate the adverse impacts that industrial food production has on human and animal health and the environment. A cornerstone of this mission is to advocate for thorough, science-based safety testing of new agricultural products and technologies.

5. CFS combines multiple tools and strategies in pursuing its mission, including public and policymaker education, outreach, and campaigning. For instance, CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the effects of industrial food production, GE 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. On several occasions, CFS has provided expert testimony to policymakers on the potentially-harmful agrichemical impacts associated with GE crops, including the increased use of pesticides and chemical fertilizers.

6. In addition, CFS 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 genetic engineering, pesticide use, animal factories, and other issues affecting CFS's mission to build a sustainable food system.

7. When necessary, 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. For example, CFS is a named plaintiff and serves as counsel in *Ellis v. Bradbury*, No.: 3:13-cv-01266-MMC (N.D. Cal. filed March 27, 2013), a case challenging EPA's decisions to register and continue to register certain pesticides that have been found to harm honey bees, other pollinator species, and birds; including numerous federally-listed threatened and endangered species. CFS is also a named plaintiff and serves as counsel in *Center for Biological Diversity v. U.S. Environmental Protection Agency*, No. 15-1054 (D.C. Cir. filed Apr. 13, 2015), a case challenging EPA's decision to register the insecticide flupyradifurone without consulting with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) to ensure that the pesticide would not jeopardize any listed species or destroy or adversely modify critical habitat in violation of the Endangered Species Act. In addition, CFS filed in amicus brief in *Pollinators Stewardship Counsel v. EPA*, No. 13-72346 (9th Cir. filed Dec. 6, 2013), a case challenging EPA's approval of a new insecticide

sulfaloxaflor in violation of the Federal Insecticide, Fungicide, and Rodenticide Act for failing to take into account the high toxicity and unreasonable adverse effects against honey bees.

8. CFS submitted organizational comments in 2012 and 2014 to the EPA docket on the proposed registration of Enlist Duo, the pesticide product at issue in the present consolidated petitions for review. CFS also submitted more than 100,000 comments on behalf of its members.

9. As a party to this proceeding, CFS and its members are injured by the increased uses of Enlist Duo on herbicide-resistant corn and soybean specifically engineered to withstand its application. CFS and its members are concerned by the detrimental impacts on human health and the environment, including impacts on federally listed sensitive species and their critical habitats that will result from the approved use of Enlist Duo.

10. CFS and its members are being, and will be, adversely affected by EPA's decision to register Enlist Duo for use on Dow's Enlist corn and soybean 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.

11. Many of CFS's members live in rural areas where excessive amounts of pesticides are being applied to herbicide resistant crops. These members are especially susceptible to the environmental and health risks associated with EPA's approval of Enlist Duo for use on Enlist corn and soybean fields. 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.

12. CFS members' interests are also injured by EPA's decision to approve Enlist Duo without consulting with the expert 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.

13. Similarly, members of CFS include farmers and gardeners who grow crops that are likely to be damaged by drift and vaporization of 2,4-D, one of the two active ingredients in Enlist Duo. EPA's registration of Enlist Duo will lead to increased use and more frequent applications of 2,4-D, making it more likely that

CFS's farmers and gardeners members who cultivate crops near areas of Enlist Duo application will suffer crop 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 EPA's approval of the use of Enlist Duo.

14. In sum, EPA's decision to register Enlist Duo for use on Enlist corn and soybean 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 thousands of members.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 20, 2015 in San Francisco, CA.

Andrew Kimbrell
Executive Director, CFS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br>*Petitioner*,<br>v.<br>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,<br>*Respondent*,<br>and<br>DOW AGROSCIENCES LLC,<br>*Intervenor-Respondent*. | No. 14-73353 |
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**DECLARATION OF LESLIE LIMBERG IN SUPPORT OF PETITIONERS CENTER FOR FOOD SAFETY ET AL.'S MOTION FOR STAY PENDING REVIEW**

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 Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity (collectively Petitioners)'s motion for stay pending review of Respondent U.S. Environmental Protection Agency (EPA)'s decision to register the pesticide Enlist Duo.

2. I have been a member of Petitioner Center for Food Safety for roughly four 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 live in Wentzville, Missouri. Missouri is one of ten states where the EPA has proposed to register Enlist Duo. Wentzville is known as "the Crossroads of the Nation," and is within twenty miles of the Mississippi River and Missouri-Illinois border. Illinois is one of the six states where EPA has approved the registration and use of Enlist Duo. I understand that EPA has also proposed the use of Enlist Duo in Missouri.

4. 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.

5. 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.

6. I am a current member, and past president, of the Missouri Master Naturalists, a volunteer arm of the Missouri Department of Conservation and the University of Missouri Extension.

7. 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 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.

8. 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.

9. In Missouri, the bat habitat consist 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.

10. Southern Illinois, where Enlist Duo has been approved for use by EPA, is also extremely important for the Indiana bat's survival. Several major rivers that 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 is also critical to ensure the bat's health, since the insects and larvae on which bats subsist feed on corn and soybean crops.

11. As a member of the Missouri Master Naturalists, I take 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 at least a million bats since 2006.

12. 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.

13. 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.

14. I have participated 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.

15. The Missouri Master Naturalists also work to conserve Indiana bat populations in Illinois. As a volunteer of 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. I will continue to volunteer my time and efforts to assist with bat conservation efforts in both Missouri and Illinois.

16. 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 the Missouri Master Naturalists.

17. 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 registration of Enlist Duo 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.

18. I am worried about how the approval 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.

19. I do not believe that the risks of registering Enlist 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 and soybeans 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.

20. 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 registration 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 this 5th day of February, 2015 in Wentzville, Missouri.

/s/ Leslie Limberg
Leslie Limberg

**I, George A. Kimbrell, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/s/) within this e-filed document.**

DATED: February 6, 2015, in San Francisco, CA.

/s/ George A. Kimbrell
George A. Kimbrell
Center for Food Safety
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: (415) 826-2770 / F: (415) 826-0507
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*Attorney for Petitioners Center for Food Safety, National Family Farm Coalition, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity*